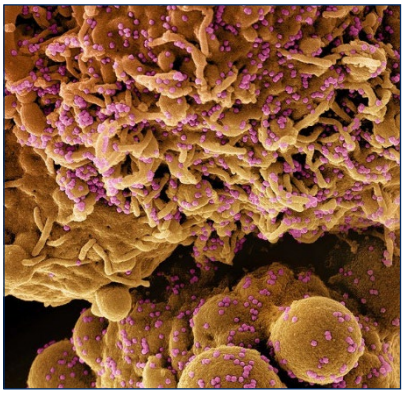
U.S. Department of Health & Human Services

Administration for Strategic Preparedness & Response

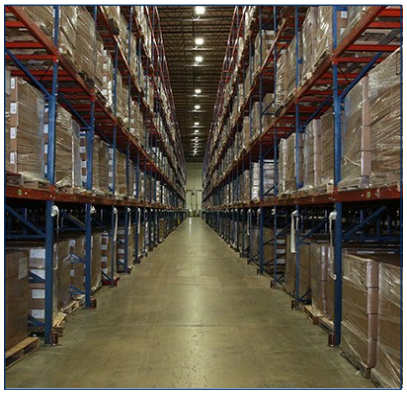
Public Health Emergency Medical Countermeasures Enterprise

Multiyear Budget: Fiscal Years 2025-2029

July 2026



ASPR



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Dear Colleague,

Please find here the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multi-Year Budget (MYB) as required by Section 2811(b)(7) of the Public Health Service Act. The last MYB covered 2023-2027 and was delivered in March 2024. I am pleased to provide this update to the last report.

The 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.

John Knox
Principal Deputy Assistant Secretary
Administration for Strategic Preparedness and Response

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Executive Summary

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget (MYB) provides a five-year view of the funding required to conduct basic research, advanced research and development, regulatory related activities, procurement, stockpiling, and replenishment of the USG's civilian medical countermeasure (MCM) products needed to respond to threats that could affect national security. In recent years, understanding of the threat landscape has evolved to include, not only known terrorist-driven chemical, biological, radiological and nuclear (CBRN) threats, but also accidental and deliberate threats and a wider range of potential naturally occurring novel pathogens that could affect national security. The need to account for known threats, however, is not eliminated.

For fiscal years (FY) 2025 through 2029, the PHEMCE projects an estimated overall funding need of $66.9 billion. This need is determined without regard to competing priorities and aligns with the corrective actions recommended by the PHEMCE as part of the 2024 Medical Countermeasure Preparedness Review (MCMPR) and emerging threat preparedness goals. If funding continues at the proposed FY 2026 levels over the projected five-year period, an estimated $33.5 billion funding gap from the total projected need is expected.

The forecasted budget needs are primarily driven by costs associated with maintaining capabilities against traditional CBRN threats while addressing novel, emerging threats. Where possible, PHEMCE agencies prioritize investments that enable development of flexible, multi-threat, or threat agnostic technologies. This includes research and development (R&D) into platforms or technologies that can be leveraged at times of need for a wide variety of threats. As such, multi-threat/threat agnostic and emerging infectious disease investments account for about sixty-five percent (65%) of the total estimated five-year need in this report. Pandemic influenza accounts for the largest single threat investment, addressing improvement to pre-exposure prophylaxis MCMs and improved manufacturing capabilities. This is followed by the broad-spectrum antimicrobials portfolio to address antimicrobial resistant (AMR) pathogens. These investments align with PHEMCE analyses, which identify emerging respiratory diseases and AMR as the highest priorities.

Additionally, ASPR Strategic National Stockpile (SNS) is supporting the transition of up to thirteen developed products into the stockpile, by FY 2029. The ASPR SNS budget has not kept pace with the cost of stockpiling the full PHEMCE requirements for MCMs, including Biomedical Advanced Research and Development Authority (BARDA)-supported products with stockpiling requirements. In addition to transition of new products, the SNS must also maintain its current preparedness posture through replenishment of deployed or expired supplies, including chemical antidotes, radiological/nuclear treatments, and antimicrobials necessary for post-exposure prophylaxis as part of the anthrax portfolio and antivirals for the treatment of pandemic influenza. Along with MCM development, sustainment of domestic, commercial manufacturing capability and stockpiled products remain the primary challenges to ensuring appropriate preparedness.

Introduction

The PHEMCE MYB Report addresses Section 2811(b)(7) of the Public Health Service Act. Section 2811(b)(7) requires ASPR to lead the development of a coordinated five-year budget plan for 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.*

Emergency preparedness requires concerted investment of resources and expertise across the USG, including human and animal disease surveillance, threat assessments, research and development, regulation, manufacturing, procurement, distribution, and administration. This report is limited to actual and projected budgets (FY2025-2029) for 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) specific programs responsible for research, development, stockpiling and appropriate use of MCMs for civilian use during a public health emergency affecting national security. Appendix B provides descriptions of agency roles and responsibilities related to MCMs. Although other funded programs are not included in this analysis, such as Department of War's (DOW) MCM programs, ASPR's Industrial Base Management and Supply Chain (IBMSC), or Veterans Affairs' biosurveillance programs, they are integral to the MCM enterprise and in many cases leveraged to enable R&D, reduce costs, and respond when emergencies arise. As the PHEMCE regularly assesses methods and improves fidelity of the budget formulation, future iterations of the MYB may include additional functions also critical to ensuring effective availability and use of MCMs in emergencies, such as ensuring nationwide readiness to receive and use deployed MCMs by the U.S. population.

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 through late clinical research, as well as dissemination/implementation research to better understand the biological effects of and to develop MCMs for CBRN and certain existing and emerging infectious disease threats. Once NIH has advanced an MCM through the early development stage, ASPR's Biomedical Advanced Research and Development Authority (BARDA) may continue development of NIH's most promising MCM candidates and technologies against PHEMCE's highest priority threats. Occasionally, NIH may take MCMs directly forward for regulatory consideration. Once a countermeasure progresses through late-stage clinical trials, ASPR BARDA or NIH supports the industry partner to file for FDA approval and may also assist with the scale-up manufacturing of the new countermeasures from clinical- to population scale-manufacturing. As of March 2026, ASPR BARDA investments resulted in 110 FDA approvals, licenses, and clearances for MCMs up from 86 in January 2024.[1]

FDA serves as the regulatory authority responsible for determining whether MCMs meet the standards required for approval, licensure, clearance, or emergency authorization. FDA provides formal feedback on regulatory submissions, relevant technical advice, regulatory science perspectives, and expertise to support developers in navigating regulatory pathways across the MCM development lifecycle. FDA reviews MCM marketing applications and approves those that meet standards for safety, effectiveness, and quality — a prerequisite for procurement into the SNS. FDA also works proactively with PHEMCE partners and industry to facilitate access to MCMs through appropriate regulatory mechanisms.

Upon achieving FDA approval, licensure, or clearance, certain products may 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. Procurement may be intended for centralized stockpiling or through vendor managed inventory (VMI). However, sustainment remains a challenge due to budget constraints and competing priorities. Note, not all products may be appropriate for procurement and those determinations would be driven by the product type, indicated use against PHEMCE priority threats, available funds, and any supply chain constraints.

CDC supports and complements efforts across NIH, ASPR, and FDA by leading the USG's approach to infectious disease surveillance, including monitoring and tracking disease incidence, disease characterization, and informing selection and targeting MCMs. Through the Public Health Emergency Preparedness (PHEP) cooperative agreement, CDC administers the critical funding that enables state, local, tribal, and territorial (SLTT) public health agencies and supports access to and administration of MCMs, in addition to building and sustaining response capacity. CDC also plays an important role in the development and evaluation of MCMs for viral hemorrhagic fevers (VHFs), poxviruses, and other high-consequence viral pathogens, often using its high-containment laboratories in Atlanta. These efforts are strengthened through international collaborations, especially sample sharing with global partners enabling CDC to obtain viral isolates, characterize them, and assess the effectiveness of candidate MCMs. CDC performs domestic diagnostic and surveillance testing and is the primary organization that characterizes domestic isolates of relevant pathogens. CDC's epidemiologic, laboratory, and clinical expertise and surveillance infrastructure ensure timely decision making on topics including who MCMs are for, how much is needed, and where MCMs may need to be deployed. Additionally, CDC collaborates with other agencies, including ASPR and FDA, to develop and maintain regulatory mechanisms that facilitate access to stockpiled MCMs and ensure their safe and effective use for all populations for CBRN threats, including emerging infectious diseases, and provide subject matter expert support and technical assistance for chemical and radiation threats. CDC performs laboratory-based studies (e.g. resistance monitoring) and case-based surveillance (e.g. monitoring vaccine breakthrough infections) to inform decision making around SNS assets for preparedness purposes.

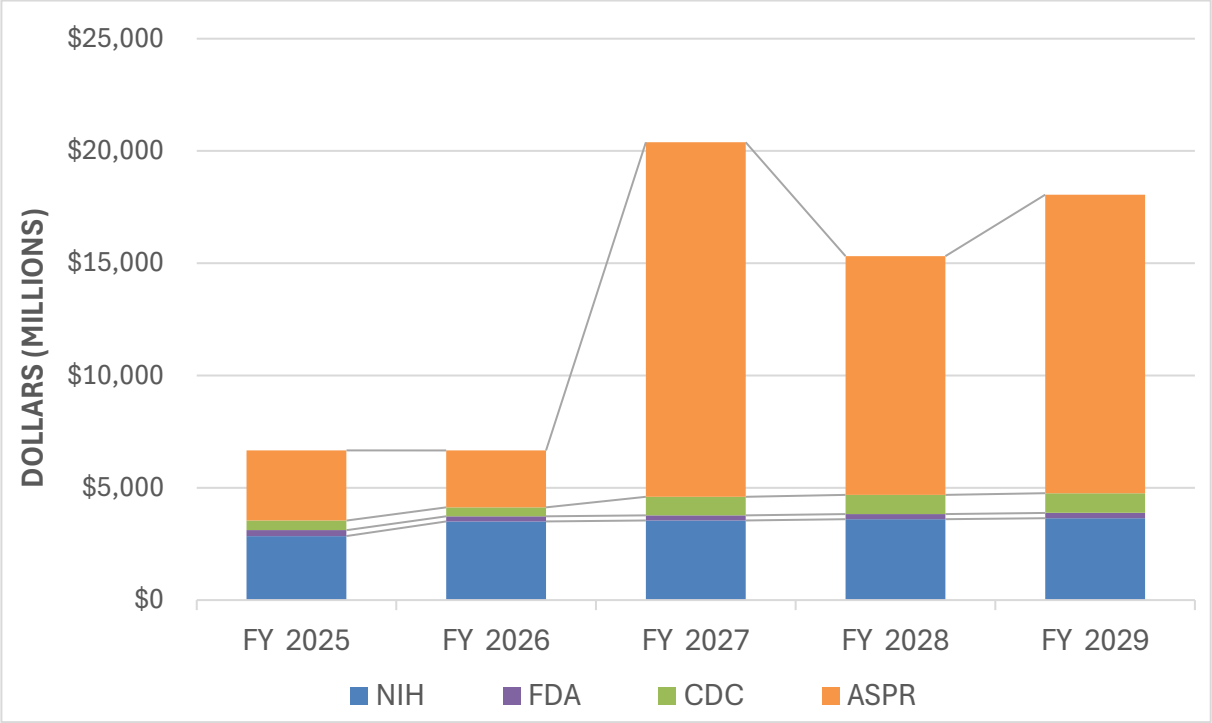
Importantly, the MYB projects gaps based on annual discretionary funding. Supplemental and mandatory funds are not considered in this document to keep year-over-year funding estimates comparable. This report includes professional judgement estimates and does not consider competing priorities or budget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

[1] FDA Approvals, Licensures & Clearances for BARDA Supported Products.

Funding Landscape

The PHEMCE estimates an overall funding need of $66.9 billion over the five-year period across four HHS agencies (Figure 1), a decrease of $4 billion from the 2023 report. As in previous years, this MYB reflects enacted FY 2025 funding levels and is consistent with the FY 2026 President's budget. FY 2027-2029 estimates are projected using the methodology described in this report (termed professional judgement). Agency methodologies are described in appendix A. If, however, future funding (FY27 through FY29) aligns to the FY 2026 President's budget levels, an estimated gap of $33.5 billion from the total projected need is expected.

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



Note: FY 2025 reflects enacted levels, FY 2026 reflects the President's budget levels, and FY 2027-2029 reflects agency professional judgement levels.

In total, HHS was appropriated $6.7 billion in FY 2025 to support MCMs and related activities in the PHEMCE portfolio. The same was requested to support these efforts in FY 2026. Beginning in FY 2027, increased investments align with the corrective actions recommended by the PHEMCE as part of the 2024 Medical Countermeasure Preparedness Review (MCMPR) and to address critical development or stockpiling gaps that exist within USG preparedness, including product transitions from BARDA to SNS. The estimated five-year spending across the HHS enterprise is delineated in Table 1 with portfolio-specific spending provided in appendix D.

The difference by agency, also presented in Table 1, highlights the funding gap assuming FY 2026 levels remain consistent through FY 2029. These shortfalls necessitate consideration of tradeoffs and may impact overall levels of preparedness.

Table 1: Estimated PHEMCE Spending by HHS Division and Fiscal Year (Dollars in Millions). FY 2025 reflects enacted levels, FY 2026 reflects the President's budget levels, and FY 2027-2029 reflect agency professional judgement levels.

HHS Division	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	Total
ASPR-BARDA Professional Judgement	$2,148	$1,783	$13,735	$8,514	$10,964	$37,144
ASPR-BARDA FY 2026 - Flat	$2,148	$1,783	$1,783	$1,783	$1,783	$9,282
					Difference	**$27,862**
ASPR-SNS Professional Judgement	$980	$750	$2,052	$2,120	$2,322	$8,224
ASPR-SNS FY 2026 - Flat	$980	$750	$750	$750	$750	$3,979
					Difference	**$4,244**
NIH Professional Judgement	$2,852	$3,497	$3,546	$3,596	$3,647	$17,137
NIH FY 2026 - Flat	$2,852	$3,497	$3,497	$3,497	$3,497	$16,840
					Difference	**$297**
CDC Professional Judgement	$440	$410	$742	$779	$814	$3,185
CDC FY 2026 - Flat	$429	$410	$410	$410	$410	$2,069
					Difference	**$1, 116**
FDA Professional Judgement	$261	$234	$234	$234	$234	$1,198
FDA FY 2026 - Flat	$261	$234	$234	$234	$234	$1,198
					Difference	**$0**

Note: Values in the table are rounded to the nearest million, after calculations to ensure more precise total values. Therefore, in some instances the sum of the value in the rows will not equal the summed total presented.

Sustainment of domestic, commercial manufacturing capability and stockpiled products remain the primary challenges to ensuring appropriate preparedness. Successful advanced development and procurement of an MCM requires ASPR (BARDA and SNS) to consider lifecycle funding for storage, sustainment, maintenance as necessary, replenishment upon expiry, appropriate training ahead of a response, and deployment. Similarly, maintaining a sustainable portfolio relies on continuously updating and maintaining capabilities at all stages of development to ensure a robust pipeline and the continued availability of products for future responses. 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.

Bridging the Preparedness Gap

To address the broad landscape of threats that can impact national security, the anticipated budget needs beyond the enacted FY 2025 levels are largely attributed to maintaining capabilities against traditional CBRN threats and addressing emerging threats. To maximize investments, the PHEMCE prioritizes threat agnostic technologies and platforms and associated capabilities. PHEMCE agencies prioritized funds for activities to address existing preparedness gaps.

- NIH will support activities to advance a robust pipeline of candidate MCMs for the development of safe and effective products, systems and services against existing and emerging biological, radiation exposure, and chemical threats. Further, NIH strongly emphasizes basic research to determine mechanisms of infectious threat agents (including modes of infection, virulence, and drug resistance) and understand the human response. NIH implements innovative methods toward developing effective diagnostics and MCMs for disease, prevention, and treatment.
- ASPR BARDA will support the advanced development, manufacturing, FDA approval, and initial procurement of MCMs. Pandemic Influenza MCM development efforts will include novel and pre-exposure prophylaxis (PrEP), novel diagnostics, and improved seasonal influenza vaccine platforms that

could provide some protection against novel influenza viruses, as well as maintaining and improving vaccine response capabilities with currently licensed technologies/platforms. Across the threat space, BARDA will continue to support development of technologies and other capabilities that will enable improved responses to current and future health security threats. These include MCMs effective against a broad range of threats, such as broad-spectrum antivirals, syndrome-based therapeutics, sequence-based diagnostics, blood products, burn treatments, and next-generation vaccine platforms. Finally, funding will address key requirements in domestic manufacturing, sustaining existing MCM manufacturing capability, and investing in manufacturing capabilities that can rapidly be brought to bear to support response efforts.

- ASPR SNS supported the transition of two MCM candidates from ASPR BARDA's Project BioShield (PBS) to the stockpile and will support the transition of up to eleven (11) others by the ASPR SNS by FY 2029. SNS will prioritize procurement of MCMs that lack a commercial market while working to provide jurisdictions with the tools necessary to build stockpiles tailored to their needs. The ASPR SNS budget has not kept pace with the cost of stockpiling the full PHEMCE requirements for MCMs, including BARDA-supported products with stockpiling requirements. In the absence of additional funding to move these products into the 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 developed by BARDA, the 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 in coordination with CDC.

- FDA will maintain and, as needed, establish clear, scientifically supported regulatory pathways for MCMs; review MCM marketing applications and approve those that meet standards for safety, effectiveness, and quality; and support efforts to fill critical scientific gaps to inform regulatory decision-making and support efforts to establish regulatory policies and mechanisms to facilitate availability of MCMs.

- CDC supports both new and ongoing programs related to research and development activities and provide support functions including developing data-driven guidance for appropriate selection and use of MCMs and monitoring of safety and real-world effectiveness during emergencies. Implementing these activities will strengthen the PHEMCE's ability to ensure MCMs, including vaccines and, antibiotics against bacterial strains that are resistant, and therapeutics, are available in such situations.

Product Transitions

In FY 2025, ASPR BARDA transitioned two (2) products from Project BioShield to ASPR SNS and anticipates up to eleven (11) others from FY2026-2029. Transitioning these products will increase the funding need 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 $854 million is estimated to support the transition and replenishment of MCMs by ASPR SNS. 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, in consultation with the PHEMCE, establishes requirements for the capabilities and product types and quantities necessary to prepare for and respond to domestic public health threats. These requirements, informed by risk assessments, guide MCM development, acquisition, and the capabilities that are needed to effectively utilize these MCMs to respond to national security threats.

While prior reports estimated the cost to fully meet PHEMCE requirements for transitioning products, these

estimates did not align with historical appropriation levels or existing manufacturing levels. This report scales back previous estimates for CYFENDUS (Anthrax), JYNNEOS (Smallpox), EBANGA (Ebola), and INMAZEB (Ebola).

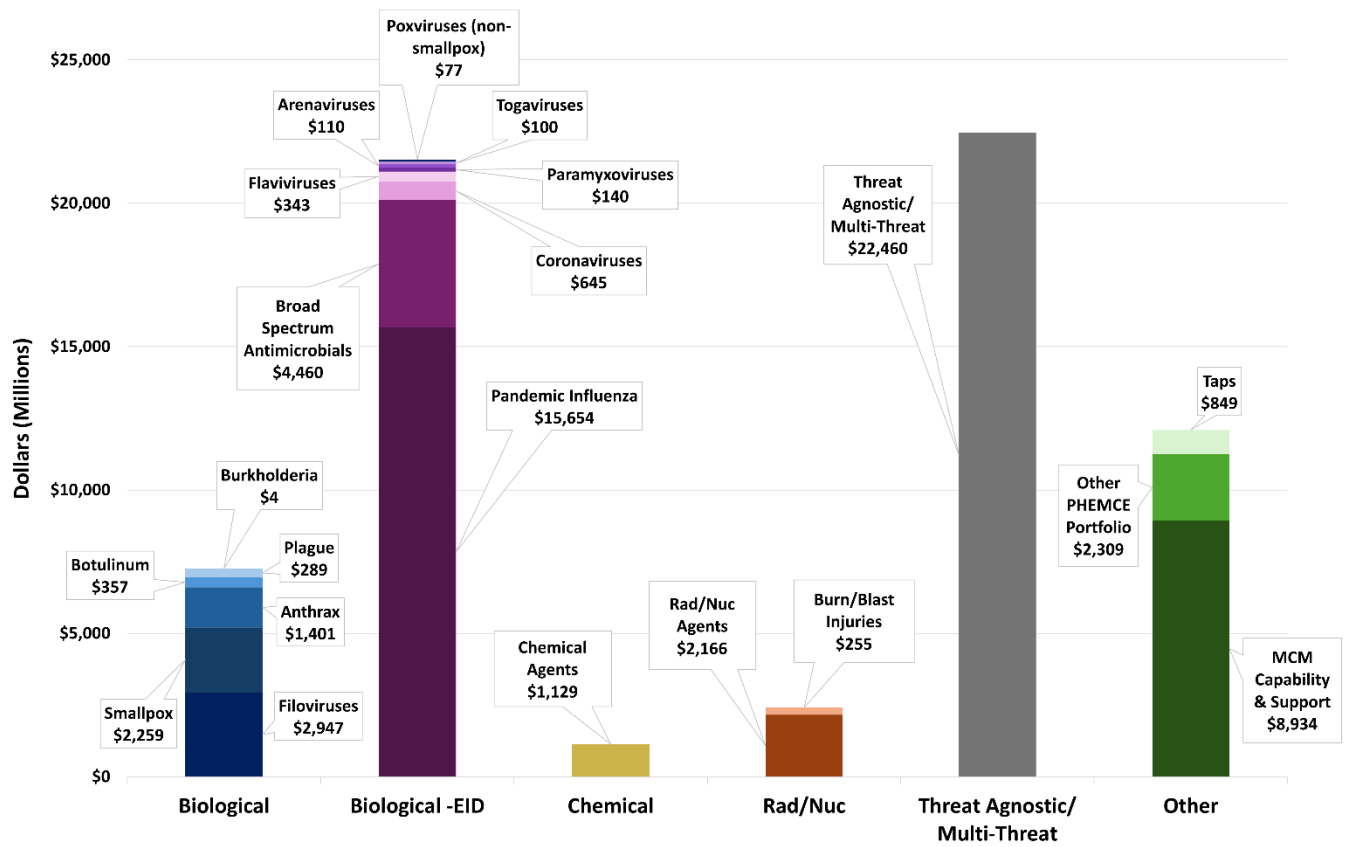
Table 2: Estimated ASPR SNS Spending Needed for MCM Product Replenishment of Products Previously Procured under Project BioShield, FY 2025–2029 (Dollars in Millions).

Estimated Transition	Portfolio	Description	FY25	FY26	FY27	FY28	FY29	FY25 - 29 Total
Transitioned in FY25	Anthrax	ANTHIM	$0.0	$30.0	$112.5	$112.5	$112.5	$367.5
	Botulism	HBAT	$62.4	$9.8	$66.8	$68.8	$68.8	$276.6
In Process	Rad/Nuc	LEUKINE	$0.0	$30.0	$191.5	$191.5	$191.5	$604.5
		NEULASTA	$0.0	$7.7	$36.8	$36.8	$36.8	$118.1
		Silverlon Wound Contact Burn Dressing	$4.0	$4.0	$4.0	$4.0	$4.0	$20.0
	Smallpox	TPOXX Capsules	$30.0	$30.0	$72.3	$72.3	$72.3	$276.9
FY26	Anthrax	CYFENDUS	$30.0	$30.0	$30.0	$30.0	$30.0	$150.0
FY27	Ebola	EBANGA	$0.0	$0.0	$0.0	$0.0	$100.0	$100.0
		ERVEBO	$0.0	$0.0	$49.7	$49.7	$49.7	$149.1
		INMAZEB	$0.0	$0.0	$100.0	$100.0	$100.0	$300.0
	Smallpox	JYNNEOS	$0.0	$0.0	$120.0	$120.0	$120.0	$360.0
FY28	Smallpox	TPOXX IV	$0.0	$0.0	$0.0	$24.0	$24.0	$48.0
FY29	Anthrax	NUZYRA	$0.0	$0.0	$0.0	$0.0	$37.5	$37.5
Grand Total			**$126.4**	**$141.5**	**$783.6**	**$809.6**	**$947.1**	**$2,808.2**

Funding by Portfolio

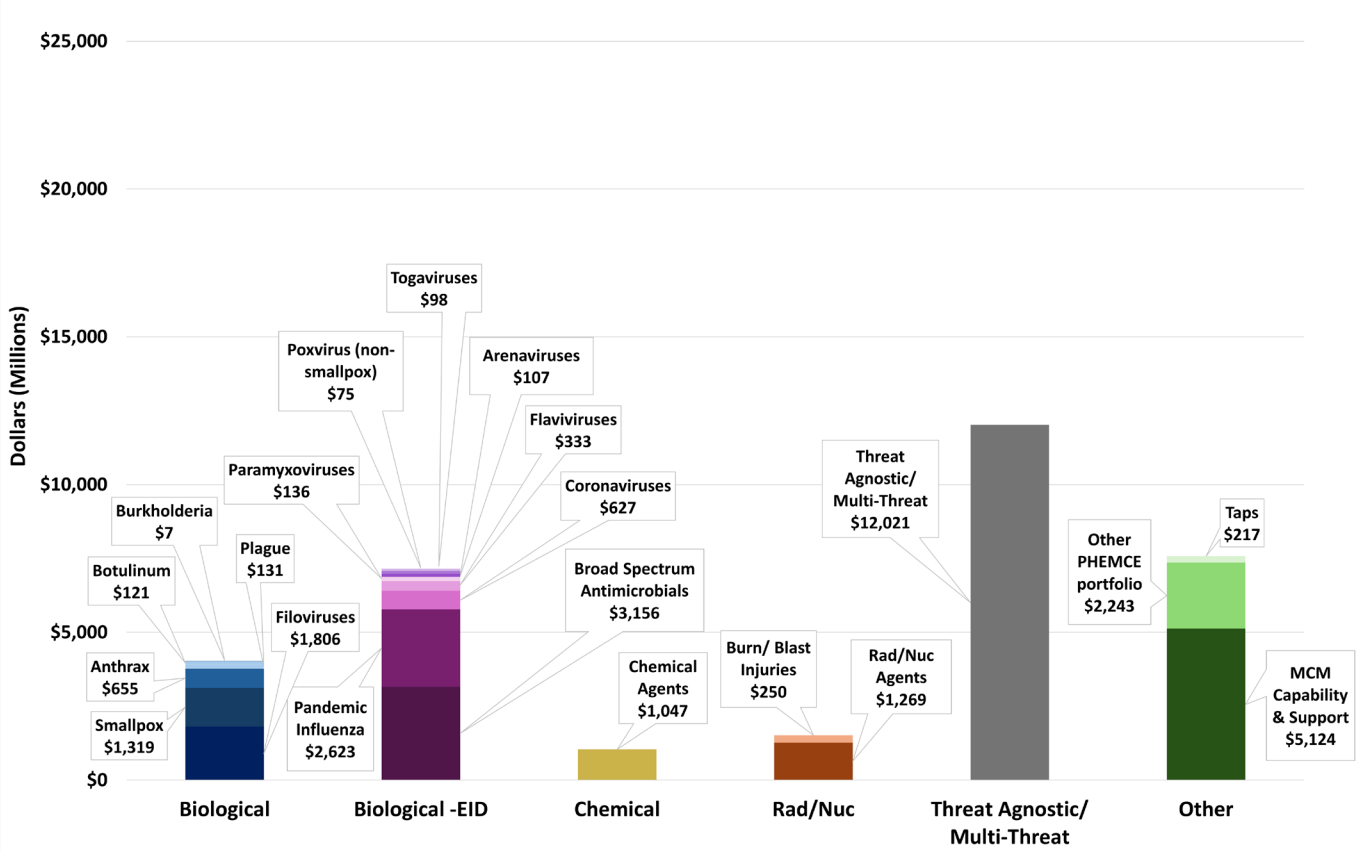
Multi-threat/threat agnostic and emerging infectious disease investments account for about sixty-five percent (65%) of the total estimated five-year need. Pandemic influenza accounts for the largest single threat investment followed by broad-spectrum antimicrobials (figure 2a, appendix C). These investments align with PHEMCE analyses, which identify emerging respiratory diseases and AMR as the highest priority.

Figure 2a: Estimated Spending Needs by Portfolio FY 2025-2029 (Dollars in Millions).



Note: Where portfolios span multiple categories, such as those relevant to both deliberate and emerging threat portfolios, they were consolidated in one category. For example, filovirus investments are included with deliberate biological agents because investment is largely driven by Material Threat Determinations (MTDs) for Ebola and Marburg viruses. While broad-spectrum antimicrobials are included with Emerging Infectious Diseases (EIDs) to best align with novel AMR pathogens. Taps comprise of non-discretionary funding for HHS activities that extend beyond the PHEMCE scope (listed as PHS Evaluation in appendix D).

Figure 2b: Estimated Spending Need by Portfolio FY 2025-2029 (Dollars in Millions) based on Flat FY26 Funding.



Note: Five-year flat funding estimates are calculated applying the President's budget for FY26 for fiscal years 2026-2029. Taps comprise of non-discretionary funding for HHS activities that extend beyond the PHEMCE scope (listed as PHS Evaluation in appendix D).

Detailed PHEMCE Portfolio Activities

Biological

Threats in the biological portfolio include DHS-identified threats with MTDs. These include *Bacillus anthracis* (anthrax), *Clostridium botulinum* toxin (botulism), Ebolavirus (Ebola hemorrhagic fever), Marburgvirus (Marburg hemorrhagic fever), variola virus (smallpox), *Francisella tularensis* (tularemia), *Burkholderia mallei* (glanders) and *Burkholderia pseudomallei* (melioidosis), *Rickettsia prowazekii* (typhus) and *Yersinia pestis* (plague).

Anthrax

Five Year Need	Funding Activities
$1.40 billion to support the continued development and procurement of MCMs necessary to respond to Anthrax	NIH will: Continue providing preliminary safety and immunogenicity data needed to transition the product to BARDA following the completion of the Phase 1 trial comparing liquid versus lyophilized AV7909 (CYFENDUS) and a Phase II dose ranging study of (liquid) AV7909. Generate data needed to support FDA approval for new label indications of SNS drugs amoxicillin and Augmentin for the treatment of inhalational anthrax and to enhance treatment options for children and pregnant women. Support the development of a small molecule inhibitor of anthrax lethal factor (anti-LF) toxin and demonstrated protection of rabbits from lethal anthrax spore challenge, as well as cleared bacteremia within 72 hours when used in combination with a suboptimal

Five Year Need	Funding Activities
	dose of antibiotics.
	ASPR BARDA will: Support fulfillment of post-marketing commitments and operational clinical trials to inform potential dose-sparing or pre-exposure prophylaxis potential. Working towards a CYFENDUS anthrax vaccine pre-exposure prophylaxis indication would also have the potential to positively impact DOW by increasing force health protection vaccination options for its Anthrax Vaccine Immunization Program. Work to expand regulatory approvals for simplified use of portable Anthrax tests in near-patient settings.
	ASPR SNS will: Support the transition of CYFENDUS, ANTHIM, and NUZYRA to the stockpile (the timing and funds needed to support this transition are outlined in Table 2). SNS will also support procurement of antimicrobials necessary to respond to anthrax.
	CDC will: Maintain and perform specialized laboratory testing to detect anthrax toxin and biomarkers of exposure, supporting rapid confirmation of suspected cases, informing timely MCM use, and providing data for clinical case management. Provide 24/7 consultation services for clinicians and health departments to assess and inform treatment of suspected cases of anthrax, monitor for potential outbreaks, and develop and disseminate risk communication and clinical guidance materials in the event of an anthrax event.

Botulinum

Five Year Need	Funding Activities
$357 million to support development of next-generation interventions and procure antitoxin to treat botulinum neurotoxin (BoNT)	NIH will: Support the discovery and development of MCMs that can prevent or reverse BoNT neuronal intoxication. These MCMs will be developed based on antibody (natural or engineered multivalent antibodies) or non-antibody-therapeutics capable of reversing BoNT intoxication and restoring neuronal function. MCMs should cover all BoNT serotypes of concern (BoNT A-G). Support the discovery and development of monoclonal antibody-based antitoxins against BoNT including BoNT/F subtypes and BoNT/G.
	ASPR BARDA will: Support the test and evaluation of candidate botulism products to support down selection for advanced development work, with a focus on investigational products that have demonstrated the ability to reverse the symptoms of BoNT intoxication caused by any serotype. Support development of a polyclonal antibody cocktail with anticipated improved safety and manufacturability compared to the current licensed product.

Five Year Need	Funding Activities
	ASPR SNS will: Support the continued procurement of botulinum anti-toxin (BAT).
	CDC will: Provide 24/7 consultation services for clinicians and health departments to assess suspected cases of botulism and monitor for potential outbreaks or bioterrorism events; authorize release of botulinum antitoxin from the SNS and then facilitate distribution of anti-toxin from pre-positioned CDC port health stations to hospitals and sites of care. Maintain and evaluate the only source of national surveillance data for botulism to identify emerging trends and ensure continued effectiveness of current MCMs. Maintain compliance with CLIA and Tier 1 Select Agent and Toxins regulations: successfully complete competency assessments and proficiency testing; maintain personnel's security clearance; successfully pass internal and external assessments; maintain toxins inventory and strains; complete 510(k) application to obtain clearance for the BoNT Endopep-MS assay, to be used by public health laboratories. Establish a whole genome multi-locus sequence typing (wgMLST) database for C. botulinum in PulseNet 2.0. Validate a new BoNT gene real-time PCR assay, to be deployed to the LRN. Provide subject matter expertise on the clinical presentation and effective treatment of botulism in USG workgroups and response planning to ensure emergency preparedness plans are sufficient to address intentional botulism exposures. Maintain and perform specialized laboratory testing to detect botulinum toxin and biomarkers of exposure, supporting rapid confirmation of suspected cases, informing timely MCM use, and providing data for clinical case management. Provide consultation and surge support to state and local health departments to help manage potential outbreaks, including providing risk communications materials and developing and distributing clinical guidance regarding use of MCMs for local clinicians.

Smallpox

Five Year Need	Funding Activities
$2.26 billion to advance the development and availability of MCMs against smallpox	NIH will: Continue to support a robust portfolio of basic and translational research on poxvirus biology and countermeasures. This includes supporting production of a Monkeypox Plaque Reduction Neutralization Test (PRNT) and an Enzyme-Linked Immuno-Sorbent Assay (ELISA) for use in clinical trial testing; evaluating monoclonal antibodies and small molecules with broad protection against several human poxviruses, including monkeypox, to identify optimal antibody cocktails as possible next generation therapeutic and prophylactic treatments; and supporting the development of novel vaccines that are broadly protective against poxviruses. Establish and refine a monkeypox non-human primate model focused upon emerging circulating clades that enable rigorous efficacy testing that will support regulatory approval and use of established and novel MCMs. Support development of small molecule MCMs, with target mechanisms distinct from FDA approved products, for broad-spectrum poxviruses, including cowpox virus (CPXV),

Five Year Need	Funding Activities
	monkeypox virus (MPXV), and variola virus (VARV), the etiological cause of smallpox, as well as vaccinia virus (VACV), the prototypical poxvirus, and rabbitpox (RPXV) virus. Support the development of monoclonal antibody products for prevention and/or treatment of diseases caused by poxviruses (e.g., smallpox, mpox). Support development of diagnostic platform technologies for monkeypox and other poxvirus detection and identification.
	ASPR BARDA will: Support investment and procurement in the more stable, FDA-licensed lyophilized formulation of JYNNEOS, ahead of transition to ASPR SNS, to both bolster smallpox preparedness and replace doses used during the monkeypox outbreak. Support late stage and post-marketing activities for TPOXX and TEMBEXA, therapeutics licensed for smallpox; support sustained domestic cGMP manufacturing and procurements of these and the development of a pediatric formulation for TPOXX. If available to transition from an early development partners, support advanced development (pivotal clinical trials and preclinical studies, and validated manufacturing) of a next generation therapeutic for smallpox to mitigate against the risk of resistance and provide a MCM appropriate for special populations.
	ASPR SNS will: Support the transition of smallpox vaccine and therapeutic products previously supported by ASPR BARDA. The timing and funds needed are outlined in Table 2. Support acquisition of ACAM2000 smallpox vaccine, and Vaccinia Immunoglobulin (VIG) to treat severe complications associated with vaccines.
	CDC will: Continue as the USG lead for the smallpox research agenda performing critical work as part of this agenda including housing one of only two laboratories in the world approved to work with live variola virus (i.e., smallpox); develop and refine MCMs to increase the diagnostic capacity of state and local public health laboratories within the Laboratory Response Network (LRN); and evaluate the effectiveness of smallpox MCMs in the event of a smallpox outbreak. Continue to focus on smallpox MCM research and development where live variola virus is needed. This includes testing products in development by USG agencies and commercial entities. CDC has the largest poxvirus inventory in the world and will use this inventory for smallpox preparedness including to screen novel therapeutic compounds (prior to testing against smallpox) and to develop accurate next-generation diagnostic tests. Support labs within the LRN to assess and support utilization of the clinical and diagnostic testing algorithms and diagnostic assays used to identify poxviruses (e.g., smallpox and monkeypox) within the LRN laboratories. Focus diagnostic development on a new PCR test to help laboratories more efficiently differentiate monkeypox clades and a serological based test that differentiates infection from vaccination (funding captured in the “other PHEMCE portfolios” below). CDC will continue to assess smallpox/monkeypox MCMs (JYNNEOS, TPOXX, TEMBEXA, and existing diagnostics), used to detect, prevent and treat, poxvirus disease, to increase

Five Year Need	Funding Activities
	understanding of the effectiveness of these MCMs in the event of a smallpox outbreak. Continue evaluation of the third-generation smallpox vaccine, JYNNEOS, using existing clinical study platforms, domestic case-based surveillance, and serological studies that began prior to and during the 2022 monkeypox outbreak. Continue to coordinate with FDA and other agencies to monitor the safety and/or efficacy, and/or accuracy of diagnostics, vaccines, and treatments. Continue sequencing of monkeypox specimens to determine if viral mutations may impact therapeutics (e.g., TPOXX resistance) or poxvirus diagnostics). CDC is the primary USG agency that performs domestic surveillance and diagnostic testing and thus has a large repository of domestic viral specimens in addition to targeted international surveillance projects in areas where viruses of concern are spreading. Additionally, CDC has developed bioinformatics tools that screen publicly deposited sequences for viral mutations that could impact US assets in the SNS.

Filoviruses

Despite the significant threats posed by filoviruses, including but not limited to Ebola virus species[2] (e.g., Zaire, Sudan, Marburg, Bundibugyo), FDA-licensed MCMs are currently limited for this viral family with licensed and approved MCMs only for Ebola Zaire virus. At the current funding level, investments would continue to support activities associated with the transition of MCM candidates from early development supported by the NIH and DOW 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
$2.95 billion to advance the development and availability of MCMs against filoviruses	NIH will: Support discovery of transmission dynamics to understand and prevent emergence and transmission, including the finding that Jamaican fruit bats' competence for Ebola but not Marburg virus is driven by intrinsic differences not environment. Develop 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). Develop small molecule therapeutics, including Antiviral Drug Discovery Centers (AViDDs) discovery of novel candidate drugs and nonhuman primate efficacy studies with broad-spectrum antiviral candidates. Develop small molecule therapeutics for the treatment of filoviruses (Ebola Zaire, Sudan, and Marburg) with the goal of advancing the most promising candidates to Phase 1 clinical trials. These efforts include the possible development of a pan-ebolavirus small molecule MCM. Develop pre- and post- exposure bispecific antibodies (Ebola BiSp107LS, Zaire) and vaccines against MARV and SUDV. Develop improved single dose vaccine platforms, such as pre/post-exposure VSV-EBOV vaccine, including their characterization in preclinical models and the potential for low-

[2] *Orthoebolavirus zairense/* Ebola virus (EBOV), *Orthoebolavirus Sudanese*/Sudan ebolavirus (SUDV)*, Orthomarburgvirus marburgenese* Marburg virus (MARV), Orthoebolavirus bundibugyo/ Bundibugyo virus (BDBV)

Five Year Need	Funding Activities
	dose protection efficacy of the VSV-Marburg virus (MARV), and VSV-Ebola virus (ERVEBO) vaccine in the preclinical nonhuman primate model. Develop and manufacture of adenovirus-vectored vaccines against Sudan (ChAd3- SUDV) and Marburg (ChAd3-MARV) viruses in preclinical models and Phase 1 human trials. Develop MARV and SUDV international antibody standards for clinical sample testing. Produce, characterize and distribute WCCM stocks for filovirus strains (including. EBOV, SUDV and MARV) to be used in regulatory approval studies. Develop point-of care diagnostics for the detection and differentiation of filoviruses to improve control of filovirus outbreaks.
	ASPR BARDA will: Support maintaining vaccine manufacturing capacity and national preparedness by procurement of the only FDA-licensed Zaire ebolavirus vaccine, ERVEBO. Continue support for advanced development and onshoring of vaccines against Marburg virus and Sudan ebolavirus, including clinical data and supply of clinical trial material that could be used in large ring vaccination clinical studies for two candidates for each virus. Continue to support scale-up and 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; work to identify small molecule antivirals that can address multiple or all filovirus threats; and potential evaluation of syndrome-directed therapeutics to reduce morbidity and mortality associated with infection. Support continued diagnostics development for detecting and differentiating Filoviruses, including portable testing devices to better inform disease containment in remote locations during outbreaks. Initiate development of candidate Bundibugyo ebolavirus MCMs as needed during responses to the ongoing outbreak. As available and as directed by the HHS Secretary, BARDA will continue to support filovirus outbreak response efforts, working with development partners to provide licensed and investigational MCMs to support national health security by halting the outbreak at its point of origin.
	ASPR SNS will: Support the transition of three products previously supported by ASPR BARDA (the timing and funds needed to support this transition are outlined in Table 2).
	CDC will: Develop and evaluate effective MCMs to diagnose, prevent, and treat viral hemorrhagic fevers (VHFs). Specifically, CDC will use its expertise in reverse genetics methods to identify and characterize potential therapeutic candidates. CDC will characterize these compounds to understand their mechanism of action, test analogues to identify more potent candidates, and test for efficacy in appropriate non-clinical models. In collaboration with academic and industry partners, CDC will test additional compound

Five Year Need	Funding Activities
	libraries to identify new compounds that show promise in treating VHFs. Support the development of prototype vaccines by using non-clinical models to test the safety and efficacy of vaccines and the protective immune responses to vaccination. CDC will coordinate with FDA and other agencies to monitor the safety of vaccines and treatments once available. Develop and validate novel technologies for the diagnostic detection of Ebola, Marburg, and other high consequence viral threats, which will inform efficient deployment and clinical use of MCMs. CDC will pursue innovative techniques, technologies, and partnerships to develop rapid, deployable, multi-pathogenic assays and devices that can readily be deployed to screen for potential threats. Work closely with SNS to provide guidance to PHEMCE, clinicians, health care providers and state and local partners to ensure the effective, efficient, and safe utilization of MCMs against VHFs. Improve non-clinical models used to test MCMs against PHEMCE priority pathogens. Support international cooperative agreements that enable surveillance in regions where these pathogens occur in enzootic or endemic settings. These systems facilitate early detection of outbreaks and provide platforms for evaluating and implementing investigational MCMs and diagnostics through clinical trials and, when appropriate, as part of routine surveillance activities. These partnerships also allow for sample sharing back to CDC headquarters for viral isolation, characterization, and evaluation of MCMs and diagnostics.

Biological – Emerging Infectious Diseases

For emerging infectious disease threats, the PHEMCE prioritizes novel high consequence pathogens that have the potential to be introduced into the U.S. and result in a domestic public health emergency requiring mobilization of Federal resources. Pathogens are genetically grouped (by viral family or novel resistance mechanisms).[3] Priority groups include the following: Orthomyxoviridae (pandemic influenza), Coronaviridae, Paramyxoviridae, Poxviridae, Flaviviridae, Filoviridae, Togaviridae, Arenaviridae, Antimicrobial Resistant Pathogens. Detailed spending for novel filoviruses is captured in the preceding biological section, as most activities are focused on Ebola and Marburg viruses, which have MTDs. Similarly, antimicrobial resistance, which may have natural or engineered origins are included in EIDs because the mechanism of resistance will be novel, and MCM solutions will be similar regardless of introduction pathway. Support for AMR Pathogens is captured under the broad-spectrum antimicrobials portfolio.

Broad-Spectrum Antimicrobials

Five Year Need	Funding Activities
$4.46 billion to support the continued development of antimicrobials	NIH will: Enhance research efforts to tackle AMR by investigating resistance mechanisms, developing rapid diagnostics, and creating more effective vaccines and treatments for drug-resistant microbes. Strengthen the pipeline for antimicrobial candidates by advancing multiple Gram-negative small molecule therapeutics to clinical trials. This includes supporting multi-

[3] *PHEMCE Priority Threats*.

Five Year Need	Funding Activities
	disciplinary translational research centers dedicated to MCMs for preventing, diagnosing, and treating resistant bacterial and urgent fungal threats. Support the Chemistry Center for Combating Antibiotic Resistant Bacteria to innovate novel chemotypes for treating Gram-negative and other drug-resistant pathogens, has already generated 4,000 new compounds and partnered with over 50 researchers. Focus on developing a new class of small molecule inhibitors targeting penicillin-binding proteins in Gram-negative bacteria, resistant to beta-lactamase inactivation, making them highly effective against pathogens like drug-resistant *Acinetobacter baumannii*. Advance next-generation aminoglycosides for treating infections caused by Gram-negative bacteria resistant to current aminoglycosides, with clinical trials expected next year for a newly identified agent. Develop first-in-class inhaled and oral antibacterial agents for treating certain biothreat pathogens as well as bronchiectasis-related Pseudomonas infections among others, with clinical trials projected in the coming year. Continue to evaluate adjunctive agents to current clinical antibacterial therapy for MDR *Pseudomonas aeruginosa* infections (hospital-acquired and ventilator-associated bacterial pneumonia) using unique mechanisms to inhibit dissemination and establishment of infection to other host organs. Advance the small molecule antibiotic product epetraborole (EBO) for treating acute melioidosis and other biothreat agents like plague, anthrax, and tularemia. Finalize evaluations for new FDA-approved antibiotic indications for anthrax, plague, and tularemia, while advancing model qualifications for plague and tularemia. Develop tuberculosis drug regimens and new anti-TB drugs targeting drug-sensitive and resistant tuberculosis in adults and children. Continue industry collaboration to develop a novel tuberculosis-specific oxazolidinone, currently in Phase 1 clinical trials. Utilize BEI Resources Repository to collect, characterize, and distribute clinical isolates of AMR pathogens with defined resistance phenotypes for countermeasure and diagnostic screenings. Provide in-kind services to CARB-X awardees to accelerate broad-spectrum antimicrobial and diagnostic technology development. Support vaccine development against AMR threats, including Shigella/ETEC, *Neisseria gonorrhea, Klebsiella pneumonia,* and *Staphylococcus aureus.*
	ASPR BARDA will: Accelerate the preclinical research and clinical development of promising antimicrobial candidates targeting multidrug-resistant pathogens through mechanisms including the Combatting Antibiotic Resistant Bacteria Accelerator (CARB-X). Support over 10 clinical stage assets, including 5 that are in Phase 3 clinical development for antimicrobial-resistant bacterial and fungal threats that can complicate the ability to respond to and recover from a public health emergency. Support post-marketing commitments, the development of antimicrobials for pediatric patients, domestic production of starting materials and finished drug products, and the development of antibiotics to treat biothreat pathogens, including the pathogens that cause plague, melioidosis, and tularemia. Advance development of diagnostics that quickly identify effective antimicrobials to treat a patient and inform antibiotic stewardship, including tests to distinguish bacterial

Five Year Need	Funding Activities
	from non-bacterial infections to minimize inappropriate antibiotic use.
	CDC will: Through the CDC and FDA Antimicrobial Resistance Isolate Bank, provide curated isolate panels of antimicrobial-resistant bacterial and fungal pathogens to support development and testing of new drugs, diagnostics, and therapeutics. CDC will provide these isolate panels at no cost (other than shipping) to industry, academia, and other appropriate stakeholders. The Isolate Bank will also support implementation of new antimicrobials in healthcare delivery through appropriate clinical test validation. CDC will also continue to support partners in the Prevention Epicenters network to develop and evaluate MCMs and other interventions for drug-resistant infections. Continue to provide updated estimates of the burden of antimicrobial-resistant threats in the U.S. through the Antimicrobial Resistance Threats Report. PHEMCE member agencies, including HHS ASPR BARDA, use the list of urgent, serious, and concerning AMR threats to guide antimicrobial development funding priorities. Programs such as the CDC Antimicrobial Resistance Laboratory Network and the Emerging Infections program support testing and tracking of AMR trends in the U.S. to inform identification of the most urgent threats. CDC will also continue to track antimicrobial utilization and work to ensure that antimicrobials are used appropriately through implementation of antibiotic stewardship to optimize benefits and minimize harms. Support departmental and agency priorities to develop innovative microbiome-based solutions to improve overall health by preventing colonization and infection with antimicrobial-resistant pathogens and reducing transmission of antimicrobial-resistant pathogens. This may include development and implementation interventions to improve the appropriate use of existing and new antibiotics and antifungals and support for development of microbiome-based diagnostics, pathogen reduction products, and alternatives to antibiotics.

Pandemic Influenza

Funding will support pandemic preparedness objectives as outlined in the HHS Pandemic Influenza Plan 2017 Update[4], and Executive Order 13887[5] Modernizing Influenza Vaccines in the U.S. to Promote National Security and Public Health. 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
$15.65 billion to advance pandemic influenza preparedness	NIH will: Support transmission dynamics studies of emerging influenza strains of pandemic potential such as bovine highly pathogenic avian influenza virus (HPAIV) H5N1. Support studies of viral evolution of highly pathogenic avian influenza A (H5N1) including the recent use of human lung organoids to compare replication and host response in historic and current viral strains. Support the development of new or repurposed diagnostics for detection of emerging

[4] *Pandemic Influenza Plan, 2017 Update*.
[5] *Executive Order 13887-Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health.*

Five Year Need	Funding Activities
	influenza threats including the recent evaluation of Rapid Influenza Diagnostic Tests (RIDTs) for the detection of H5N1. Support the development of novel therapeutics with demonstrated activity against pandemic and seasonal influenza strains as well as the discovery of innovative new monoclonal antibodies for treatment and/or prevention of influenza strains of pandemic potential, such as H5N1. Support the development of innovative new pandemic influenza vaccine prototypes while advancing the clinical development of current universal influenza vaccine candidates; 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 or H5N1). Support preclinical and translational development of a diverse portfolio of improved seasonal, pre-pandemic, and broadly protective universal influenza vaccines. Support clinical trials of broadly protective universal influenza A virus vaccine candidates, work to develop vaccine and antiviral countermeasures for H5N1. Pursue advanced testing of a whole virus universal influenza vaccine candidate, BPL-1357, that provided near universal protection against a wide range of influenza viruses in non-clinical models. With the Phase 1 study complete, intranasal and intramuscular formulations of BPL-1357 are poised to be tested in Phase 2 trials in early 2026 while further Phase 1b trials evaluating additional dosing strategies are being developed. Pursue advanced nanoparticle-based vaccine candidates for both pandemic and seasonal strains of influenza by evaluating in phase 1 clinical trials. Support development of diagnostic technologies for detection and distinguishing seasonal, non-seasonal, and highly pathogenic avian influenza virus.
	ASPR BARDA will: Increase support for development of more effective influenza vaccine platforms; development of pandemic vaccines with higher efficacy, broad and durable protection, and potential for self-administration; and development of better seasonal vaccines with some pandemic benefit and finally establishing US-based manufacturing platforms that can rapidly pivot to pandemic response. Improve and sustain pandemic influenza vaccine domestic manufacturing capabilities; maintaining domestic manufacturing and pandemic capacity commitments; continue domestic pandemic readiness by supporting creation of reagents, storage of pre-pandemic vaccines and adjuvants, and manufacturing improvements. Support 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. Support development of therapeutics to treat acute respiratory distress syndrome (ARDS) including ARDS caused by influenza infection. Support development of technologies that move testing closer to the patient at home, doctor's office and remote settings. Support development of low-cost and high-sensitivity portable/home-use capable

Five Year Need	Funding Activities
	platforms and syndromic test panels at a market sustainable price point. Make FDA-cleared next-generation sequencing-based testing for influenza and other respiratory viruses a reality and continue to support influenza pathogen family tests for pandemic preparedness.
	ASPR SNS will: Support sustainment of current level of preparedness through replacement of expiring antivirals, including baloxavir.
	CDC will: Monitor and detect novel influenza viruses in collaboration with SLTT health departments, through comprehensive and robust public health surveillance systems. With its public health partners collect and analyze influenza viruses to inform seasonal and pandemic influenza vaccine strain selection. Study vaccine effectiveness, especially for new vaccines that may be part of a pandemic response. Continue to coordinate with FDA and other agencies to monitor the safety of vaccines and treatments. Develop and assess influenza virus diagnostics. Continue to improve selection, development, and evaluation of candidate vaccine viruses (CVVs) in support of vaccine strategies and technologies. This work directly supports the USG goal of having a pandemic vaccine in 12 weeks as CVVs are the first step in the vaccine development pipeline.

Viral Families

Five Year Need	Funding Activities
$1.42 billion to support discovery and development of products that address PHEMCE prioritized emerging infectious diseases pathogen groups	NIH will: Multiple Viral Families: Support the continued development of models that accurately recapitulate human disease, including innovative organoid models as well as innovative models such as organoids; the repurposing of and/or development of new and improved diagnostic, therapeutic, and preventive MCMs. Support the ReVAMPP Network, which aims to develop MCMs and generalizable knowledge for nine virus families: *Paramyxoviridae, Flaviviridae, Togaviridae, Arenaviridae, Picornaviridae, Nairoviridae, Hantaviridae, Phenuiviridae, and Peribunyaviridae*. ReVAMPP Centers apply the prototype pathogen approach to develop platforms and approaches that can be applied across a virus family. Develop a multiplex point-of-care diagnostic for the detection and differentiation of Flaviviruses and Togaviruses for patient management and monitoring virus transmission. Support preclinical services (in vitro anti-viral testing, medicinal chemistry, pharmacokinetic and toxicity assessment) to derisk early-stage drug candidates for emerging and reemerging infectious diseases.

Five Year Need	Funding Activities
	Support studies to determine the antiviral inhibitory effect (EC_{50}/EC_{90}) and cytotoxicity (CC_{50}) of experimental compounds against high-consequence and emerging viruses. Establish reproducible small and large non-clinical models for testing MCMs against BSL-4-high consequence pathogens, including Nipah (*Paramyxoviridae*) and Lassa (*Arenaviridae*) viruses. Models will be used in the development of drugs and other products, particularly under FDA's Animal Rule. Test and evaluate candidate therapies against emerging viral pathogens in relevant models to provide an initial demonstration of therapeutic efficacy against challenge with live viruses. These models will provide early testing data required to support FDA approval and will be used to prioritize compounds for further *in vivo* testing and/or further investigations. Candidate therapies against the following viral pathogens have been or will be tested: SARS-CoV-2, MERS, Enteroviruses, Coxsackie, Polio, Oropouche, Usutu, Dengue, Rift Valley, Venezuelan/Eastern/Western Equine Encephalitis, West Nile, Yellow Fever, Zika, Chikungunya, Japanese Encephalitis, Tacaribe, and Mayaro. Support multiple translational research centers, Antiviral Drug Discovery (AViDD), for the discovery and development of direct-acting antivirals for the treatment of various clinically relevant viruses including but not limiting to filoviruses, flaviviruses, coronaviruses, enteroviruses, alphaviruses, and paramyxoviruses. *Coronaviridae*: Support preclinical and translational development of a diverse portfolio of pre-pandemic and broadly protective coronavirus vaccines. Support the development of novel therapeutics and monoclonal antibodies for treatment and/or prevention of coronaviruses, such as SARS-CoV-2 and MERS. Continue to support the development and clinical evaluation of novel pan-sarbecovirus vaccine candidates, and multivalent, mucosally administered SARS-CoV-2 vaccine candidates capable of conferring broad protection against future variants of concern. *Arenaviridae*: Continue to support the development of a small molecule therapeutic targeting Lassa Fever virus, including the manufacturing of Phase 3 material and New Drug Application Registration Path activities. Support the development of a combination of three antibodies for the treatment of Lassa virus infection. Support the development of a point-of care diagnostic for Lassa virus to improve case detection and outbreak response. Support the development and clinical evaluation of an inactivated rabies virus vectored Lassa Fever vaccine candidate, LASSARAB. *Flaviviridae*: Support monoclonal antibody development against Zika virus infection. Support a clinical trial of a candidate West Nile Virus vaccine. *Paramyxoviridae*:

Five Year Need	Funding Activities
	Refine the established measles NHP model for defining treatment endpoints and evaluating efficacy of novel therapeutics. Support development of MCMs against Nipah virus, including highly potent monoclonal antibodies and a vaccine (VSV-NiVG) that has shown promise in preclinical trials.
	ASPR BARDA's current funding does not enable support for EID procurement and other late stage and post approval efforts. BARDA's EID support efforts are all done in the context of threats with an MTD, pandemic influenza, or threat-agnostic capabilities, to better enable a sustainable response. Many of these investments will equally enhance future EID response.
	CDC will: Develop clinical guidance to inform MCM use in U.S. healthcare settings. In collaboration with FDA, CDC will support the development and management of appropriate regulatory mechanisms, including Investigational New Drug applications (INDs), Emergency Use Authorization requests (EUAs) and/or Emergency Use Instructions (EUI) against multiple high-risk pathogens. Develop 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 improve preparedness for future respiratory pandemics and CBRN events. Work with health departments, health systems, and other public health partners to improve use of PPE in healthcare settings. This includes training appropriate use, as part of guideline development and implementation, providing updated science-based guidelines for infection prevention in healthcare settings, infection prevention training for all healthcare workers, and coordinating with health departments and health systems to assess and improve infection prevention programs in healthcare facilities. This work also improves the resilience of healthcare facilities and the healthcare workforce, leading to improved protection of healthcare workers and patients. In collaboration with FDA, monitor medications for adverse events and the safety of licensed and authorized vaccines and the blood supply and transparently communicate information on immunization safety to policymakers, the public, healthcare providers, manufacturers, and jurisdictional health departments. CDC will also continue to assess changes to the burden of antimicrobial-resistant threats in the U.S. Provide expertise, protocols, guidance and test methods to increase national and international laboratory capacity to detect and characterize emerging infectious disease pathogens. Prioritize the development and evaluation of effective MCMs for high consequence viral pathogens such as for Lassa and Nipah virus, two highly pathogenic viruses that cause severe lethal outbreaks and have the potential for human-to-human transmission. These MCMs will be used to diagnose, prevent, and treat Lassa fever and Nipah virus disease. CDC will apply its expertise in reverse-genetics approaches to identify and characterize promising therapeutic candidates. These compounds will be evaluated to determine their mechanisms of action, screened for more potent analogues, and assessed for efficacy in appropriate non-clinical models. CDC will collaborate with academic and industry partners to screen additional compound libraries and identify novel candidates with potential to treat Lassa fever and Nipah virus infections. CDC supports the

Five Year Need	Funding Activities
	development of prototype vaccines by using non-clinical models to evaluate vaccine safety, efficacy, and immune responses. Specifically, with sufficient funding, CDC could advance virus replicon particle (VRP) vaccine platforms for Nipah and Lassa. Monitor and detect novel and emerging coronaviruses in collaboration with the STLT health departments and other public health partners through comprehensive and robust public health surveillance systems. Study vaccine effectiveness, especially for new vaccines that may be used in response to pandemics involving emerging coronaviruses.

Chemical

Five Year Need	Funding Activities
$1.13 billion to support discovery and development of improved therapeutics to treat injuries caused by exposure to chemical agents	The NIH chemical portfolio currently includes 60 basic research projects and 28 translational research efforts with candidate MCMs under evaluation against PHEMCE's high priority chemical threats. NIH will: Support basic research developing models of toxic chemical exposure to better understand the health effects of almost 200 compounds designated by the Department of Homeland Security as Chemicals of Concern; Support translational research to inform discovery and early development of MCMs to rapidly treat or prevent serious immediate and long-term injuries following exposure to these highly toxic chemicals.
	ASPR BARDA will: Continue to explore the pathophysiology of chemicals of concern through both non-clinical and microphysiological models to identify targets for drug repurposing and threat agnostic therapeutics. Support the development of effective rescue medications for respiratory depression caused by pharmaceutical-based agents, expanding efforts from synthetic opioids to emerging threat classes. Develop through approval or clearance and procurement of next-generation drug delivery systems, including needleless autoinjectors, that contain rapid treatments to reverse the effects of nerve agents and other organophosphates as well as synthetic opioids and improve and ease the emergency delivery of MCMs.
	ASPR SNS will: Support sustainment of the CHEMPACK program. CHEMPACKs are containers of nerve agent antidotes placed in secure locations around the country that allow rapid response to chemical incidents. More than 90 percent of the US population is within 1 hour of a CHEMPACK location.
	CDC will: Provide technical assistance and subject matter expertise for the National Response Framework Emergency Support Functions (ESF) ESF #8 Public Health and Medical Services and ESF #10 Oil and Hazardous Materials Response. Maintain and perform specialized laboratory testing for chemical and toxin exposures,

Five Year Need	Funding Activities
	including CBRN threats, toxic industrial chemicals, and related biomarkers. Provide 24/7 medical toxicology subject matter expert consultation to assist state and local health departments, clinicians, and poison centers with activities such as managing patients exposed to chemicals or toxins, CBRN threats or exposures, MCM use, provide data for clinical case management, risk communication, clinical guidance materials, facilitate access to SNS assets, and monitor for potential bioterrorism events. Work with SNS to provide guidance to PHEMCE, clinicians, health care providers and state and local partners to ensure the effective, efficient, and safe utilization of MCM during CBRN incidents. Provide 24/7 toxicology subject matter expert consultation concerning non-clinical hazardous substances and oil incidents. Review National Response Center reports, provide urgent environmental data reviews to assist with interpretation of risk levels and potential exposures, provide health recommendations, develop and disseminate messaging for health departments, clinicians, and poison centers. Works alongside and support the US National Response Team (NRT) that provides technical assistance, resources, and coordination on preparedness, planning, response and recovery activities for emergencies involving hazardous substances, pollutants and contaminants, oil, and CBRN weapons in natural and technological disasters and other environmental incidents of national significance. Work with interagency, health departments, public health partners, health systems to improve use of PPE in occupational and healthcare settings, including training on appropriate use, as part of guideline development and implementation. This includes providing updated science-based guidelines for destruction, transport, testing for chemical warfare agents (e.g., sulfur mustard containing munitions), exposure precautions, decontamination, and interagency coordination (e.g., FDA) as well as coordination with health departments, public health partners, health systems, and poison centers to assess and improve prevention, recognition, mitigation, and management of exposure chemical warfare agents. Develop and support development of medical management guidelines (MMG), CBRN guidance documents and educational materials. Develop clinical guidance to inform MCM use in U.S. healthcare settings. In collaboration with FDA, CDC will support the development and management of appropriate regulatory mechanisms, including INDs, EUAs and/or EUI against CBRN threats. Assist and support interagency priorities in their MCM development programs, FDA and other agencies to monitor adverse events and safety of MCM used in CBRN incidents, interagency with improving selection, development, and evaluation of MCM candidates for chemical and toxin threats, and maintain personnel's security clearance.

Radiological and Nuclear

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

Five Year Need	Funding Activities
$2.42 billion to	NIH will: Continue to support basic research on model development and conduct radiation injury

Five Year Need	Funding Activities
advance the development and availability of MCMs to address injuries from radiation exposure, trauma, and thermal burns that would occur after a nuclear detonation	studies to determine potential targets for MCM development. Advance products to address radiation-induced damage to the gastrointestinal tract, skin, lung, kidneys, nervous system, and cardiovascular system. Develop diagnostic platforms to enable rapid triage of large numbers of radiation-exposed people to guide medical management and scarce resource allocation. Support advanced development of at least one approach for each organ system injury under FDA regulatory consideration. Seek FDA approval for a repurposed anti-hypertensive drug as a treatment for radiation-induced lung injury. Continue to support a clinical trial to study the safety and pharmacokinetics of a novel oral product that can remove a broad range of radioactive particles from the body.
	ASPR BARDA will: Invest in advanced research and development to treat injuries resulting from radiation exposure, trauma, and thermal burns following a nuclear detonation, with a priority on developing threat agnostic therapeutics with potential commercial sustainability. Support the procurement of dried plasma products as well as the advanced development of next-generation, multipurpose blood products with submission of an application for marketing approval of spray dried plasma anticipated in FY 2027. Support development of MCMs to address vascular injury, endotheliopathy, gastrointestinal injury, exposure to heavy metals and radioactive isotopes, and next generation blood products as platforms to improve the safety of blood supplies. Support the development of a range of MCMs for rapid detection and treatment of traumatic brain injuries (TBI) and blunt musculoskeletal injuries. Support advancement of novel technologies used to detect and facilitate the timely care of internal injuries, such as 3D ultrasound probes, portable X-ray, and clinical validation of biomarkers seen in 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. Continue procuring several products previously supported by ASPR BARDA, including two antineutropenic drugs and a burn/blast bandage. The timing and funds needed to support this transition are outlined in Table 2.
	CDC will: Provide technical assistance and subject matter expertise for the National Response Framework Emergency Support Functions (ESF), including ESF #8: Public Health and Medical Services and ESF #10: Oil and Hazardous Materials Response). Provide 24/7 medical toxicology subject matter expert consultation to assist state and local health departments, clinicians, and poison centers with activities such as managing patients exposed to radiological isotopes, CBRN threats or exposures, MCM use, provide data for clinical case management, risk communication, clinical guidance materials, facilitate access to SNS assets, and monitor for potential bioterrorism events.

Five Year Need	Funding Activities
	Work with Strategic National Stockpile (SNS) to provide guidance to PHEMCE, clinicians, health care providers and state and local partners to support the effective, efficient, and safe use of medical countermeasures during CBRN incidents. Provide 24/7 radiation health and safety subject matter expert consultation concerning interpretation of risk levels and potential exposures, provide health recommendations, develop and disseminate messaging for health departments, clinicians, and poison centers. Works alongside and support the US National Response Team (NRT) that provides technical assistance, resources and coordination on preparedness, planning, response and recovery activities for emergencies involving radiation, CBRN weapons, and related incidents of national significance. Work with interagency, health departments, public health partners, health systems to improve use of PPE in occupational and healthcare settings, including training on appropriate use, as part of guideline development and implementation. This includes providing updated science-based guidelines for destruction, transport, testing for radiological agents precautions, decontamination, and interagency coordination, including with FDA. It also includes coordination with health departments, public health partners, health systems, and poison centers to assess and improve prevention, recognition, mitigation, and management of exposure to radiological warfare agents. Maintain specialized radiobioassay testing to detect and quantify internal radionuclide contamination, provide rapid dose assessment to guide clinical management, and deliver 24/7 medical toxicology consultation to support timely MCM use during radiological and nuclear emergencies. Maintain capacity as the only laboratory in the country capable of providing results on over 100 samples within eight hours of sample receipt. Develop CBRN guidance documents and educational materials. Develop clinical guidance to inform MCM use in U.S. healthcare settings. In collaboration with FDA, CDC will support the development and management of appropriate regulatory mechanisms, including INDs, EUAs and/or EUI against CBRN threats. Assist and support interagency priorities in their MCM development programs, FDA and other agencies to monitor adverse events and safety of MCM used in CBRN incidents, interagency with improving selection, development, and evaluation of MCM candidates for radiological threats, and maintain personnel security clearance.

Threat-Agnostic/Multi-Threat

Maintaining multi-hazard capabilities, including platform technologies, chemical and radiological detection, drug screening and diagnostic readiness, and clinical and toxicological guidance needed during response incidents, ensures readiness to respond to these events that may occur alongside or independently of emerging infectious disease threats. The threat-agnostic/multi-threat portfolio captures efforts to advance research and development of vaccines, diagnostics, and therapeutics that have broad applications to multiple threats.

Five Year Need	Funding Activities
$22.46 billion to advance the development of multi-threat MCMs and capabilities	NIH will: Support a cross-cutting science portfolio to support threat agnostic MCM approaches to include establishing capabilities such as model optimization and development, including non-animal/alternative models (e.g., complex *in vitro* models, organoids, microphysical systems); sequencing facilities; reagent manufacturing; well-characterized pathogen stocks for diagnostics and pre-clinical studies; clinical training programs; epitope mapping;

Five Year Need	Funding Activities
	biosafety lab support; computational biology; and development of vaccine platform technologies. Support development of 'threat agnostic' diagnostic platforms that can detect and identify any known or unknown bacterial, fungal, viral (planned) pathogen in a biological specimen. Activities include development of state-of-the-art sample preparation methods from intractable biospecimens; faster metagenomic sequencing methods; and broader, highly curated sequence databases for accurate identification and resistance prediction. These systems in development have the flexibility to be sustainable commercial systems in routine clinical care, facilitate identification and characterization of novel infectious pathogens, as well as enhance diagnostic capacity during surge events. Support the development of a dual acting small molecule antiviral targeting a key host protein that is hijacked for viral replication by RNA viruses such as enteroviruses and coronaviruses. The antiviral activities of the molecules have been demonstrated in multiple murine viral infection models. In addition, the molecules protected mice from sepsis by inhibiting the host inflammation. Due to its host targeting nature the molecules have high barrier to resistance by viral mutations. A clinical candidate is at the IND-enabling stage of drug development.
	BARDA's threat-agnostic and rapid response efforts include the Congressionally mandated Disease X MCM program to combat infectious disease outbreaks of pandemic potential. This effort consists of supporting advanced research and development in three pillars, a) threat-agnostic and multi-threat MCMs that can address more than one pathogen; b) platforms and other technologies that can be quickly pivoted to address new threats; and c) domestic manufacturing capabilities to sustain access to licensed MCMs, and pivot production as new threats emerge. Underpinning these efforts are unique, flexible contracting and partnership approaches that enable a nimble response. BARDA will: Continue to invest in advanced development of a variety of threat-agnostic diagnostics, including next-generation sequencing, as well as emerging technologies such as wearables and AI-enabled digital tools. Improved broad-spectrum antivirals and syndrome-based therapeutics are currently under-represented in the pipeline and will be supported, as well as next-generation vaccine and therapeutic platforms that address current limitations. Additional investments will focus on enabling technologies, including precision medicine tools, artificial intelligence (AI) approaches to accelerate MCM development, manufacturing and formulation enhancements, novel immunoassays, and sample-sparing technologies. Finally, BARDA will continue to support domestic manufacturing to ensure readiness and long-term access to licensed MCMs. This effort will include support of annual production campaigns to test rapid response platform capabilities and increase the amount of stockpiled product immediately available; provide surge capacity during public health emergencies; and enhance capabilities to rapidly develop and manufacture new MCMs against emerging threats.
	CDC will: Invest in the development, validation, assessment, deployment, and training for use of diagnostic tests, including rapid diagnostic and multiplex tests and reagents for the rapid identification of high-risk threats that are utilized to inform MCM deployment decisions. Activities include the development of new tests for detecting multidrug resistance in

Five Year Need	Funding Activities
	Bacillus anthracis and *Burkholderia pseudomallei*. CDC will also invest in development of pathogen non-specific genome sequencing methods for diagnosis and development of expanded pathogen capability for wastewater surveillance for early identification and monitoring of infectious disease threats. Expand diagnostic testing methods for rapid detection of chemical, toxin, and radiological exposures; strengthen radio-bioassay laboratory capacity needed to support clinical management and MCM decision-making during radiological or nuclear incidents; and maintain the regulatory mechanisms required for the safe and effective emergency use of stockpiled MCMs across diverse populations. Provide clinical guidance, surge capacity, and associated regulatory support for appropriate MCM use during CBRN mass-casualty incidents, ensuring that critical laboratory, epidemiologic, toxicological, and response capabilities remain functional when multiple hazards demand attention at the same time. Collaborate with local and regional poison centers in response to CBRN incidents and outbreaks. Coordinate with FDA and other agencies to monitor the safety of the blood supply and any potential vaccines and treatments.

Other Portfolios

These funds will be allocated across agencies and divisions that support activities against threats such as plague, Burkholderia species, arboviruses, waterborne and foodborne illnesses (from pathogens, radioactive particles, and chemical contaminants), tuberculosis (TB), toxins, adjuvant discovery/development, and activities investigating fundamental aspects of the human immune systems.

Five Year Need	Funding Activities
$2.60 billion to support additional activities	NIH will: Support the Adjuvant Development Program, whose goal is to establish and expand the availability of novel vaccine adjuvants that researchers can use for preclinical vaccine development in both infectious and immune-mediated diseases. Advance immune systems modeling through the NIAID-funded national Center of Excellence (CoE) for Multiscale Immune Systems Modeling (MISM). The CoE will coordinate modeling research activities across NIAID funded projects in the extramural community with a focus on computational modeling, data sharing, and reproducibility. Support the development of novel TB treatments through the Facilitating Accelerated Science and Translation for TB Regiment Development (FAST-TB) program (a platform promoting global collaboration and resource sharing between organizations and researchers whose purpose is to streamline the development of novel treatments for TB). In addition, support for digital adherence technologies (DATs), which offer promising solutions for monitoring and supporting adherence to complex treatment regimens, including tuberculosis (TB) treatment. Ensuring that interventions are adaptable, user-friendly, and capable of addressing diverse patient needs.
	ASPR BARDA will: BARDA will invest in developing diagnostic tests that detect biothreats with an MTD (e.g. plague, tularemia, Burkholderia species) that allow results to be obtained closer to the patient at home, doctor's office and remote settings.

Five Year Need	Funding Activities
	CDC will: Maintain capacity for specialized laboratory testing at CDC's National Center for Environmental Health Division of Laboratory Sciences to detect chemical agents, toxins, and radiological exposures. Continue to develop additional methods to detect exposures to emerging threats, as well as continue to build capacity at state and local public health laboratories to detect these threats through the LRN for Chemical Threats (LRN-C). Maintaining and increasing capacity to identify and confirm exposures to these agents will inform timely medical countermeasure use and provide data for clinical management of cases. Maintain public health infrastructure to rapidly detect exposures to waterborne and foodborne health threats so that medical countermeasures can be rapidly deployed. For example, CDC's Safe Water program will continue to support testing private wells for CBRN contamination and continue to provide technical assistance to states as they address drinking water, recreational water, and wastewater contamination issues.

MCM Capability and Support

An essential and costly component of MCM development is funding to support workforce, core services, stockpile operations and logistics management, which address storage, sustainment, deployment and other capabilities.

Five Year Need	Funding Activities
$8.93 billion to support workforce, core services, logistics management, and other capabilities	NIH will: Establish structure-function studies, models, and immunological assays, to enable a rapid pivot and application to different pathogens within the same viral family in the future. Expand application of new approach methods to screening and demonstrating efficacy of MCMs to existing and emerging pathogens and work with regulatory agencies to establish benchmark and evaluable data packages. Support development of vaccines, adjuvants, monoclonal antibodies, diagnostics, and therapeutics (both pathogen specific and agnostic). Advance promising MCM candidates through Phase 1/2 clinical trials, shortening development timelines in future public health emergencies of known and unknown threats.
	ASPR BARDA's mission requires a world class workforce to support industry partners, which is supported through management and administration funding. Funding will be used to bolster scientific personnel and other key staff, including contracting officers and contracting specialists, as the overall number and complexity of contracts increase. BARDA also supports MCM development with nonclinical and clinical core services. Nonclinical core services include supporting BARDA's Nonclinical Network of CBRN-capable contract research laboratories, providing subject matter expertise in MCM nonclinical development and nonclinical project management, and providing a suite of nonclinical data management services. Clinical core services include providing specialized medical, advanced biostatistics, and multidisciplinary clinical operations expertise to our partners, as well as stand-alone clinical trial capabilities and infrastructure to support advanced development.
	FDA will:

Five Year Need	Funding Activities
	Support its workforce including hundreds of subject matter experts across the various MCM types (e.g., drugs, vaccines, monoclonal antibodies, and devices, including diagnostic tests and personal protective equipment) with scientific expertise in each of the highest priority disease threats. FDA's experts will continue to engage with each of our PHEMCE partners through the variety of activities that support public health preparedness and response throughout the MCM lifecycle as described throughout this report and in more detail in appendix B, including: Provide technical support for development of new technologies and advance regulatory science for MCM development and advanced manufacturing. Work directly with regulated-industry and funding partners to provide technical assistance and guidance on evidentiary requirements and clear regulatory pathways for approval, licensure and clearance. Determine appropriate pathways to provide for emergency use, including review and feedback on proposals for clinical trials, expanded access protocols under investigational applications, EUAs, and section 564A emergency use authorities, such as extensions of expiration dating. Monitor information regarding the safety and efficacy of approved or authorized MCMs to continue to inform regulatory and clinical use decisions.
	ASPR SNS will continue to support sustainment and operating costs; and procurement of ancillary supplies.
	CDC will: Develop non-clinical models critical for research and evaluation of novel compounds to support the next generation of MCMs. CDC will screen antiviral candidates against viral hemorrhagic fevers and leveraging CDC's laboratories to identify potential targets for candidate therapeutic development against multiple high consequence pathogens. Develop clinical guidance to inform use of MCMs, including treatment of tularemia and continual updates for anthrax, melioidosis, 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, including INDs, EUAs, and/or EUI against multiple high-risk pathogens. Develop 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. Work with health departments, health systems, and other public health partners to improve the use of PPE in healthcare settings, including training on appropriate use, as part of guideline development and implementation. This includes providing updated science-based guidelines for infection prevention in healthcare settings, infection prevention training for all healthcare workers, and coordinating with health departments and health systems to assess and improve infection prevention programs in healthcare facilities. This work also improves the resilience of healthcare facilities and the healthcare workforce, leading to improved protection of healthcare workers and patients. In collaboration with FDA, monitor medications for adverse events and safety of licensed and authorized vaccines and transparently communicate information on immunization

Five Year Need	Funding Activities
	safety to policymakers, the public, healthcare providers, manufacturers, and jurisdictional health departments. Provide 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. Strengthen collaboration with the nation's clinical and public health laboratories to ensure high-quality laboratory science at CDC, reliable laboratory diagnostics for outbreaks, infectious diseases, chronic conditions, harmful exposures such as chemicals, toxins, and radiation, and extensive engagement with public and private-sector partners.

Impact of Preparedness

Throughout 2024 and 2025, PHEMCE member agencies were involved in numerous efforts to respond to domestic and international outbreaks related to PHEMCE priorities. These included Highly Pathogenic Avian Influenza (HPAI) A(H5N1), multiple filovirus outbreaks (including Ebola, Marburg, and Sudan), Oropouche, Dengue, and monkeypox, among others. Notable response efforts are highlighted below. Response efforts are enabled and built on years of interagency collaboration and dedicated investment in early and late R&D, highlighting the need to ensure existing capabilities have long-term sustainment while investing in new technologies to combat emerging health security threats.

For certain high-consequence pathogens, particularly viral hemorrhagic fevers (VHFs) with significant national security implications, the USG is often the only—or one of very few—sources of investigational products due to the absence of a viable commercial market. Additionally, international outbreaks, in some instances, provide the only opportunity to conduct clinical trials as the diseases do not occur in the U.S. Outbreak-related clinical trials help protect the American people as they may generate the clinical evidence needed to advance USG-supported MCMs toward FDA authorization and licensure, while also containing dangerous pathogens at their international source. International MCM deployments decisions are made in accordance with Administration policy and consistent with authorities regarding use of appropriations.

HPAI A(H5N1) in the United States

In March 2024, the U.S. Department of Agriculture (USDA) reported the first detection of HPAI A(H5N1) in a dairy cattle herd in the U.S. By September 2025, more than 1,000 dairy cattle herds in 17 states reported positive samples. Between April 2024 and February 2025, 71 confirmed human cases of influenza A(H5) were reported in the U.S. including two fatalities in people exposed to infected backyard poultry. No new cases and no human-to-human transmission was identified in this outbreak and CDC continues to assess that the risk to human health in the general population is low. The USG worked collaboratively to monitor and respond to highly pathogenic avian influenza (HPAI) H5 viruses and share information rapidly and transparently across PHEMCE partners.

In collaboration with HHS and state and local partners, USDA supported surveillance and epidemiologic investigations, assisting in diagnosis and symptomatic treatment of impacted herds, enhancing bulk milk testing, and enabling the rapid development of two bovine vaccine candidates to protect dairy cows from A(H5N1).

CDC's comprehensive and layered influenza surveillance systems were essential to monitor novel influenza cases in people and provide an early warning for an avian influenza outbreak. CDC analyzed influenza viruses to look for changes that would indicate an increased threat to human health. Between April 2024 and March 2026, CDC and state and local public health departments monitored more than 23,300 people following exposure to infected animals, tested more than 1,030 exposed people in affected states who showed symptoms of respiratory disease, and tested more than 288,426 virus specimens nationally through routine influenza surveillance. This was in parallel to continuous virus specimen analysis to detect markers of reduced susceptibility to antivirals and potential influenza (H5) vaccines, as well for adaptations in the virus that could be associated with the potential

for human-to-human transmission or severe outcomes in people. As a part of pandemic preparedness activities, CDC develops CVV for influenza A (H5) and other avian influenza A viruses, which are used to produce influenza vaccines. Having a CVV that protects against H5 bird flu in humans is an important step for being prepared for an H5 vaccination program, if needed.

The NIH National Institute of Allergy and Infectious Diseases (NIAID) mobilized infrastructure to provide scientific support to USDA and state and federal partners, including assisting with surveillance and virus characterization activities. The NIAID research agenda highlighted objectives for H5N1 influenza basic and translational research[6] that support understanding of H5N1 viral spread and evolution allowing for monitoring changes in pathogenesis, mammalian adaptation, and impacts on the effectiveness countermeasures for pre-exposure prophylaxis and H5N1 virus infection treatment. The NIH National Institute of Biomedical Imaging and Bioengineering (NIBIB) performed independent validation of all 12 commercially available rapid influenza diagnostic MCMs for HPAI A(H5N1) inclusivity.[7]

ASPR BARDA leveraged the U.S. National Pre-pandemic Influenza Vaccine Stockpile (NPIVS) program, which produces millions of doses of H5 vaccines from a well matched CVV, if vaccine is needed. They conducted three different clinical trials of these vaccines to support regulatory and policy decisions on potential use of the vaccines and invested hundreds of millions of dollars to increase adjuvant VMI, and technologies to improve both near- and long-term pandemic influenza response capabilities.

FDA worked to ensure the safety of the milk, dairy product, and animal feed supply, and supported the development and/or availability of human MCMs, including drugs, vaccines, and diagnostics. FDA supported the development of the Amended Determination of a Significant Potential for a Public Health Emergency for pandemic influenza A viruses and influenza A viruses with pandemic potential pursuant to Section 564(b) of the FD&C Act. FDA maintained active communication with drug manufacturers to monitor U.S. supply of influenza antivirals and, in preparation for the potential need for human vaccines, engaged with federal partners and industry in assessing approved pandemic influenza vaccines and potential novel vaccine candidates. FDA worked with the CDC to assess use of their H5N1 diagnostic assay for alternative sample types (e.g., conjunctival swabs) and conducted outreach to industry regarding interest in developing additional H5-specific tests. The agency also worked with the NIH Rapid Acceleration of Diagnostics (RADx®) initiative and FDA's Independent Test Assessment Program (ITAP) for their assessment of flu in vitro diagnostics reactivity with 2024 HPAI H5N1, and posted on its website a list of cleared, de novo, and authorized influenza A tests that may detect H5.

Ebola Outbreak in the Democratic Republic of the Congo (DRC)

On September 4, 2025, the DRC Ministry of Public Health (MOH) officially declared an Ebola outbreak in the Bulape health zone in Kasai Province. On September 5, 2025, CDC established an incident management structure to support the DRC's MOH response pillars, including providing support from the CDC Country Office in Kinshasa, deployments to the outbreak area, and funding key implementing partners. Following a formal request from the DRC, and approval by the HHS Secretary, Ebola diagnostic tests, procured by ASPR BARDA and stored in the SNS, were transferred and hand-carried by CDC personnel to DRC. These tests provided a stop gap measure enabling continuous testing and helping to halt disease spread. The last reported case was discharged October 19, 2025.

PHEMCE partners closely collaborated to rapidly share information and mobilize MCM deployment from ASPR's inventory. This included facilitating a request from the DRC MOH to HHS through CDC headquarters and CDC's country office to release doses of INMAZEB, a monoclonal antibody treatment developed by ASPR BARDA, and to Department of State to support U.S. personnel responding to the outbreak and treat Congolese patients. The deployment of investigational products, including INMAZEB, was conducted under appropriate regulatory frameworks facilitated by FDA, including expanded access authorities, ensuring that investigational MCMs could be made available to patients while maintaining appropriate oversight.

[6] *NIAID Research Agenda for 2024 H5N1 Influenza.*

[7] Bassit L et al. 2025. Toward diagnostic preparedness: detection of highly pathogenic avian influenza A(H5N1) in contrived nasal swab specimens using rapid antigen and point-of-care molecular tests. J Clin Microbiol 63:e00548-25.

At the conclusion of the outbreak, declared over December 1, 2025, the DRC MOH reported 64 cases (53 confirmed and 11 probable), 45 deaths (34 confirmed and 11 probable) among the cases (case fatality rate 70%). Nineteen cases were discharged from Ebola treatment centers.

Marburg Outbreak in Ethiopia

As the DRC Ebola outbreak was ending, the Ethiopian MOH confirmed its first reported Marburg outbreak, with three cases confirmed on November 14, 2025, in the South Ethiopia Regional State. By December 29, 2025, Ethiopia reported 14 confirmed cases and 9 deaths. CDC incorporated this outbreak into the existing incident management structure of the ending DRC Ebola response and deployed Marburg experts into the field. CDC's country office in Ethiopia worked closely with the Ethiopian MOH and Ethiopia Public Health Institute to support response activities, offering technical expertise in case investigation and contact tracing, surveillance and laboratory testing, infection prevention and control, point-of-entry and exit screening, and MCM strategy and use.

On November 21st, 2025, the Ethiopian MOH requested up to 5,000 doses of Sabin's investigational Marburg vaccine and up to 25 treatment courses of Mapp Bio's investigational Marburg virus therapeutic for use under regulatorily appropriate clinical trials and/or expanded access authority. Both products are funded for advanced development by ASPR BARDA. The HHS Secretary notified the Ethiopian MOH the transfer of up to 25 treatment courses of Mapp Bio's investigational therapeutic and up to 2,500 doses of Sabin's investigational vaccine was approved. The first tranches of product were received by the first week of December, and the vaccine clinical trial using the investigational vaccine, funded by CEPI, was initiated by the MOH as the trial sponsor on December 8, 2025. The trial vaccinated a total of 527 individuals, with 217 in the open label cohort and 310 in the randomized control trial cohort. Due to lack of additional cases, the trial ended and the collected safety and immunogenicity data will support the BARDA-funded development program. FDA supported the deployment of these investigational products by facilitating the appropriate regulatory mechanisms necessary for their use under clinical trial and expanded access frameworks, consistent with FDA's authorities under the FD&C Act.

Anthrax in the United States

In 2024, CDC leveraged investments in diagnostic laboratory capacity to aid selection of the correct MCMs for a patient with welder's anthrax. Using a newly developed laboratory method, CDC rapidly identified, in hours instead of days, the anthrax toxin-producing bacteria affecting a patient in Louisiana. Rapid recognition, the informed decision to rapidly deploy antibody treatment from the SNS for this patient, and use of antimicrobials along with patient and other clinical factors contributed to the patient's positive clinical outcome. CDC's monitoring of the patient's anthrax toxin blood levels during treatment informed assessment of whether additional antibody doses beyond the standard single dose was indicated to maximize survival. CDC is currently the only laboratory in the U.S. able to make these rapid, critical measurements for this toxin in human blood samples, and remains prepared to rapidly identify future biological, chemical, and radiological agents to guide response actions and treatment for those exposed to these agents.

ASPR, through the SNS, also deployed anthrax vaccine as part of post-exposure prophylaxis to people potentially exposed to anthrax from post-mortem examinations of cattle in 2024 (Wyoming) and 2026 (Utah).

Conclusion

This report includes the multiyear budgets for FY 2025-2029 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 related activities, procurement, stockpiling and replenishment, and deployment of the USG's civilian MCM enterprise. A robust and sustainable MCM enterprise relies on diverse investments to continuously update and maintain capabilities at all stages of development and procurement to ensure the continued availability of the best available products for future responses. PHEMCE agencies continue working closely together to maximize the use of existing resources to best prepare the nation for the next public health emergency or disaster.

Appendix A: Multiyear Budget Methodology

Each agency and program developed its methodology for providing estimates for the PHEMCE MYB. Out-year funding levels (FY 2027, 2028, and 2029) for NIH, ASPR, FDA, and CDC were developed without regard for competing priorities or budget totals considered in the annual President's Budget formulation process. These estimates are subject to change in the future. Procurement cost estimates are point-in-time estimates and could change in future reports to reflect current market prices.

- NIH utilized the actuals from the official Research, Condition, and Disease Categorization (RCDC) Biodefense and Related Countermeasures category for FY 2024 to derive the preliminary estimates for FY 2025 figures. NIH then applied the guidance outlined in the President's Budget while incorporating an inflationary increase for FY 2026 through 2029 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. The $1.69 billion increase in FY 2026, 2027, 2028 and 2029 for Rapid Response Capabilities is a professional judgement for funding to implement the prototype pathogen approach, characterize pathogens of pandemic potential, and develop vaccines, monoclonal antibodies, and therapeutic strategies. Use of the Biodefense and Related Countermeasures RCDC category for developing NIH's input to the MYB predates a recent transition in NIAID's mission and research priorities from its historic triad of HIV, Biodefense/Pandemic Preparedness, and Other Infectious and Immunologic Diseases programmatic areas to two integrated pillars: the Infectious Disease Research Program and the Immunology, Allergy, and Autoimmune Disease Research Program which better aligns NIAID's research priorities with the most pressing health challenges and chronic diseases facing Americans. NIH will continue to support a robust research portfolio related to emerging infectious disease agents, and other infectious disease threats to public health that will contribute to PHEMCE-related activities. However, specific research activities and mechanisms for budget estimates will change to align with NIH's new vision, and the numbers in this Budget represent an overestimate of relevant activities.
- ASPR BARDA assumed funding levels to address all DHS-identified threats with MTDs and to meet the goals of the HHS Pandemic Influenza Plan 2017 Update and Executive Order 13887. This funding is also in alignment with several Executive Orders, including EO 14001 - 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), Project BioShield (PBS), and Pandemic Influenza (PI) funding. These sources have different authorities and periods of availability. For example, ASPR BARDA's Project BioShield funding can only be utilized to support threats with an MTD and cannot be used with an OTA procurement mechanism.
- FDA assumed a three percent increase for each of FY 2027-2029. Reductions in FY 2026 are primarily a result of efficiencies rather than changes to scope of work.
- ASPR SNS's projection methodology applies funding for lower-cost items at the level necessary to achieve requirements in FY 2026. For higher-cost products, projections use level funding sufficient to reach the requirement level by FY 2029, the final year of the current MYB. Vaccine projections reflect the full funding amount for the given option year. 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.
- CDC's budget estimates for FY 2026- FY 2028 are professional judgments of the resources needed to support research and evaluation of new MCMs, diagnostic development, MCM clinical guidance and regulatory support, and monitoring of MCM safety and real-world effectiveness in support of comprehensive PHEMCE MCM readiness and planning for use of stockpiled MCMs in response to a public health emergency, including CBRN events, and natural disasters.

Appendix B: PHEMCE MYB Agency Roles

National Institutes of Health (NIH)

NIH conducts and supports basic, translational, and clinical research to better understand the biological effects of, and to develop MCMs for CBRN 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 and applied and clinical research to evaluate candidate MCMs including diagnostics, therapeutics, and vaccines. This includes pathogen characterization advancing approaches that could be used to develop MCMs against multiple threats or pathogens, such as the development of vaccine platforms, 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. MCM development is also supported by other parts of NIH including the National Institute of Biomedical Imaging and Bioengineering (NIBIB) through the Rapid Acceleration of Diagnostics Technology (RADx® Tech) program.

NIH works with partners in industry, academia, and the PHEMCE to ensure that promising MCMs for biological, chemical, and radiological and nuclear 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 pursuing a prototype pathogen research strategy to further bolster preparedness for novel infectious disease threats by supporting the development of MCMs 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. In addition, given current concerns in radiological and nuclear preparedness due to global political actions, work being done by NIH to advance products to remove harmful radioactive particles from the body, as well as studies to advance accelerate approvals for MCMs and clearances for diagnostic devices for radiation-induced injuries will help to ensure a successful government medical response, should one be required.

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 appropriate for public health medical emergency response across a continuum of healthcare settings. MCMs for response to CBRN accidents, incidents, and attacks; pandemic influenza; and EIDs are developed. Through public/private partnerships, ASPR BARDA promotes the advanced development, manufacturing, procurement and long-term sustainment of manufacturing capability of MCMs against health security threats as well as engagement in enabling technologies to support the successful development of our MCMs, especially for preparedness against future PHEs.

Beyond assuming responsibility for and working with developers to take individual MCMs through FDA licensure, BARDA often continues to support additional development post-FDA approval. This includes supporting expanded label indications, such as pediatric indications, and procurements to sustain manufacturing efforts and increase stockpile readiness. In addition to supporting individual MCMs, BARDA supports infrastructure, technologies, platforms, and other capabilities that cut across multiple threats—MCMs that can detect, treat, or prevent more than one threat, technologies that can improve MCM performance, and manufacturing capabilities that can be used to sustain current capability as well as pivot to address near term threats. Finally, BARDA plays a significant

role in response, especially when approved products are not available. BARDA supports product development, potential use of investigational product under clinical trials or other regulatory oversight process, scaling up production, and potential procurement of MCMs through supplemental funding.

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. In response to the March 18, 2025, Executive Order "Achieving Efficiency Through State and Local Preparedness",[8] ASPR has strengthened its efforts to lead the nation in establishing jurisdictional stockpile programs. These programs will enable states, local, tribal and territorial jurisdictions to develop sustainable reserves that build their capacity to deploy MCM and critical supplies and enhance regional collaboration to reduce reliance on federal resources during emergency responses.

Centers for Disease Control and Prevention (CDC)

As the Nation's public health agency, CDC leads the federal government's efforts for detecting and responding to diseases, including EID, acts of bioterrorism, and chemical and radiological public health threats. In addition to its robust case-based and laboratory-based surveillance systems, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats across the CBRN domains. CDC provides global scientific leadership to address these threats across a range of public health issues, many for decades, including threats within the PHEMCE mission. 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, and monitor use and safety of 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 Cooperative Agreement, ORR supports SLTT operational capacity to execute large-scale distribution, dispensing, and administration of critical MCMs, capabilities essential to translating federal investments into public health action.

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) leads global collaboration and has global reference laboratories for Smallpox and other poxviruses and is the USG lead for MCM research requiring live Variola virus, in addition to leading efforts for VHF for the Americas. NCEZID is also responsible for the prevention, control, and management of more than 800 pathogens, including especially dangerous pathogens such as *B. anthracis* (the cause of anthrax) and Ebola virus disease, new, emerging, and re-emerging diseases like Oropouche and monkeypox, and efforts to improve infection prevention, and appropriate use of antimicrobials, in healthcare settings for both novel and emerging diseases and the prevention of more infections caused by antimicrobial-resistant pathogens. This includes providing updated science-based guidelines for infection prevention in healthcare settings, infection prevention training for all healthcare workers, and coordinating with health departments and health systems to assess and improve infection prevention programs in healthcare facilities. This work also seeks to improve the resilience of healthcare facilities and the healthcare workforce, leading to improved protection of healthcare workers and patients. NCEZID provides technical, scientific, and clinical 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 help ensure the integrity and safety of the blood supply, to monitor medications for adverse events as well as the safety of licensed and authorized vaccines, and to transparently communicate information on immunization safety to policymakers, the public, healthcare providers, manufacturers, and

[8] Achieving Efficiency Through State and Local Preparedness – The White House.

jurisdictional health departments. NCEZID develops, validates, and deploys diagnostic assays and reagents for timely, accurate detection of and response to public health threats, including determining a pathogen's susceptibility to available antimicrobial, and drug resistance to better inform MCM development and deployment. NCEZID coordinates CDC's agency-wide portfolio of work to combat AMR, including implementation of domestic and global laboratory networks, surveillance for AMR, containment of and response to AMR threats, and support for innovation of new infection prevention approaches and products.

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 plays a major role in year-round surveillance for early detection and identification of viral and bacterial pathogens, antigenically drifted seasonal influenza viruses, and novel influenza A viruses that may have pandemic potential. CDC collects and analyzes viruses and bacterium 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 SARS-CoV-2, arises with outbreak or pandemic potential, NCIRD ensures the availability of the genomic sequence and population-based surveillance data needed to determine the effectiveness of existing MCMs or to develop novel ones.

The National Center for Environmental Health and Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) seek to prevent death and illness from non-infectious hazards, including those stemming from toxic substances and chemical or radiological emergencies. NCEH/ATSDR evaluations of environmental exposures during emergencies, including exposures to chemical and radiological agents, inform public health actions, such as the use of MCMs. NCEH/ATSDR develops toxin detection, protein assays, and radio bioassay capability needed to support diagnosis, treatment, and prevention of toxin-mediated diseases such as botulism, anthrax, ricin, and abrin poisoning, chemical agents, and address internal radionuclide contamination. NCEH/ATSDR provides 24/7 medical toxicology, laboratory consultation, risk communication, and emergency management expertise on the use, limitations, and alternatives to MCMs to public health and medical professionals domestically and worldwide for chemical and radiological preparedness and response activities.

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 advances PPE innovation by driving science, performance standards, testing, and evaluations that ensure respirators and other protective technologies perform reliably in real-world conditions. Through the Respirator Approval Program, NIOSH verifies that respirators meet rigorous quality and performance requirements before and after entering the marketplace and maintains oversight to ensure continued compliance. NIOSH also provides technical guidance and scientific expertise to inform federal PPE procurement, stockpiling, and replenishment decisions, helping ensure that products acquired for the SNS, state, and local stockpiles are appropriate for the hazard, and ready for rapid deployment. During public health emergencies, NIOSH expands approval capacity and provides timely, science-based guidance on the selection and use of PPE to sustain the availability of protective equipment and protect the workforce that underpins healthcare delivery, emergency response, and critical infrastructure operations.

CDC's Office of Laboratory Systems and Response (OLSR) provides laboratory operations and systems support (across the fundamental elements of quality, safety, informatics, and response readiness) to the agency's laboratories and strengthens collaboration with the nation's clinical and public health laboratories to ensure high-quality laboratory science at CDC, reliable laboratory diagnostics for outbreaks, infectious diseases, chronic conditions, and harmful exposures, and extensive engagement with public and private-sector partners.

The Global Health Center (GHC) is America's first line of defense against health threats that originate overseas. These global efforts such as data analytics, disease and vector surveillance, diagnostics, laboratory systems, workforce development, emergency preparedness, and outbreak response systems provide critical epidemiological intelligence and preparedness for the U.S., ensuring early detection of potential health threats and enabling faster, more effective responses. The decades-long partnerships with other countries' ministries of health means CDC is often the "first call" when an event occurs, providing early intelligence about emerging global health threats to prevent and contain these health threats before they spread to the U.S.

Food and Drug Administration (FDA)

FDA plays a critical role in protecting the U.S. from CBRN and emerging/re-emerging infectious disease threats, such as Ebola, and monkeypox. 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 including working closely with the DOW to facilitate the development and availability of MCMs to support the unique needs of American military personnel. FDA supports PHEMCE agencies by providing subject-matter expertise in MCM development and by providing scientific and regulatory input that can help inform MCM development, procurement, expiration dating, and stockpiling decisions. FDA facilitates access to available MCMs to respond to public health and military emergencies, even when products are not yet approved for any use or are FDA-approved but not yet approved for the particular use, provided certain criteria are met.

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

- Providing regulatory advice, guidance, and technical assistance to developers, manufacturers, and others developing investigational MCMs for CBRN or emerging infectious disease threat indications;
- Clarifying standards and 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;
- Enabling access to MCMs that are not yet approved for use—when necessary—through appropriate regulatory mechanisms, such as clinical trials, expanded access protocols, or EUA;
- Responding to emerging and re-emerging public health threats;
- Establishing and sustaining action teams to identify and catalyze the resolution of regulatory and scientific challenges associated with MCMs that address high priority threats;
- Developing capabilities to monitor and assess MCMs used during public health emergencies and beyond, including providing technical advice to application holders on scientifically rigorous methods of assessing MCM effectiveness based on clinical trials and, if and when appropriate, 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 MCM 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 FDA regulatory and policy framework[11] adequately supports MCM development, enables preparedness and response activities, and sustains the MCM professional development program[12] to ensure FDA meets regulatory challenges posed by new scientific and technological developments to support MCMs.
- Protecting the safety of the food supply — including milk, dairy products, and animal feed — during public health emergencies where contamination or pathogen transmission through the food supply is a concern.

[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)).

[10] *Advanced Manufacturing*. U.S. Food and Drug Administration.

[11] *MCM Legal, Regulatory and Policy Framework*. U.S. Food and Drug Administration.

[12] *Professional Development Program*. U.S. Food and Drug Administration.

Appendix C: PHEMCE MYB Spending by Portfolio

Table 3 outlines spending by portfolio, aligned to "Detailed PHEMCE Portfolio Activities" in the body of the report. The projected funding needs over a five-year period, emphasize spending needs to ensure that capabilities against legacy threats are maintained while prioritizing multi-threat technologies that may address emerging threats and MCM capabilities that ensure MCMs can be safely and effectively distributed and utilized.

Table 3: Estimated Threat Portfolio Spending FY 2025-2029 (Dollars in Millions).

Portfolio	Total Five-Year Need (Millions)
Biological	**$7,257**
Anthrax	$1,401
Botulinum	$357
Burkholderia*	$4
Filoviruses	$2,947
Plague*	$289
Smallpox	$2,259
Biological – EIDs	**$21,530**
Arenaviruses	$110
Broad-spectrum Antimicrobials	$4,460
Coronaviruses	$645
Flaviviruses	$343
Pandemic Influenza	$15,654
Paramyxoviruses	$140
Togaviruses	$100
Poxviruses (non-smallpox)	$77
Chemical	**$1,129**
Chemical Agents	$1,129
Radiological and Nuclear	**$2,421**
Rad/Nuc Agents	$2,166
Burn Blast Injuries	$255
Threat Agnostic/ Multi-Threat	**$22,460**
Threat Agnostic/ Multi-Threat	$22,460
Other Costs	**$12,092**
MCM Capability & Support	$8,934
Taps*	$849
Other PHEMCE Portfolio*	$2,309
Total Estimated 5-Year Need	**$66,888**

** Values differ from the detailed PHEMCE activities section. Other portfolios in the "Detailed PHEMCE Portfolio Activities" section aggregates expenditures for Burkholderia, plague and other PHEMCE portfolios for a total of $2.6 Billion. Taps are not included in the details section, as these comprise of non-discretionary funding for HHS activities that extend beyond the PHEMCE scope. SNS taps are included in Program Support costs included in MCM Capability & Support.*

Appendix D: PHEMCE MYB Spend Plan Tables

Table 4: PHEMCE MYB Spend Plan Table (Dollars in Millions) for NIH.[13],[14]

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	FY 2025-29 Total
NIH	NIAID	Direct Appropriation, Annual	Anthrax	Basic/Other Research	$2	$1	$1	$1	$1	$8
NIH	NIAID	Direct Appropriation, Annual	Anthrax	Therapeutics	$1	$1	$1	$1	$1	$3
NIH	NIAID	Direct Appropriation, Annual	Anthrax	Vaccines	$1	$1	$1	$1	$1	$3
NIH	NIAID	Direct Appropriation, Annual	Botulinum	Antitoxin	$3	$2	$2	$2	$2	$11
NIH	NIAID	Direct Appropriation, Annual	Botulinum	Basic/Other Research	$1	$0	$0	$1	$1	$3
NIH	NIAID	Direct Appropriation, Annual	Botulinum	Vaccines	$1	$0	$0	$0	$0	$2
NIH	NIAID	Direct Appropriation, Annual	Broad-spectrum Antimicrobials/AMR	Therapeutics	$682	$430	$441	$453	$466	$2,473
NIH	NIAID	Direct Appropriation, Annual	Filoviruses (incl. Ebola/Marburg)	Basic/Other Research	$15	$9	$10	$10	$10	$53
NIH	NIAID	Direct Appropriation, Annual	Filoviruses (incl. Ebola/Marburg)	Diagnostics	$2	$2	$2	$2	$2	$9
NIH	NIAID	Direct Appropriation, Annual	Filoviruses (incl. Ebola/Marburg)	Therapeutics	$6	$4	$4	$4	$4	$23
NIH	NIAID	Direct Appropriation, Annual	Filoviruses (incl. Ebola/Marburg)	Vaccines	$12	$8	$8	$8	$8	$45
NIH	NIAID	Direct Appropriation, Annual	Pandemic Influenza	Basic/Other Research	$55	$35	$36	$36	$37	$199
NIH	NIAID	Direct Appropriation, Annual	Pandemic Influenza	Diagnostics	$2	$1	$1	$1	$1	$7
NIH	NIAID	Direct Appropriation, Annual	Pandemic Influenza	Therapeutics	$14	$9	$9	$9	$9	$49
NIH	NIAID	Direct Appropriation, Annual	Pandemic Influenza	Vaccines	$242	$152	$156	$161	$165	$875
NIH	NIAID	Direct Appropriation, Annual	Smallpox	Therapeutics	$0	$0	$0	$0	$0	$1
NIH	NIAID	Direct Appropriation, Annual	Arenaviruses	Antivirals	$9	$6	$6	$6	$6	$33
NIH	NIAID	Direct Appropriation, Annual	Arenaviruses	Basic/Other Research	$12	$8	$8	$8	$8	$45
NIH	NIAID	Direct Appropriation, Annual	Arenaviruses	Diagnostics	$1	$1	$1	$1	$1	$4
NIH	NIAID	Direct Appropriation, Annual	Arenaviruses	Vaccines	$8	$5	$5	$5	$5	$29
NIH	NIAID	Direct Appropriation, Annual	Coronaviruses	Antivirals	$31	$20	$20	$21	$21	$113
NIH	NIAID	Direct Appropriation, Annual	Coronaviruses	Basic/Other Research	$86	$54	$56	$57	$59	$313
NIH	NIAID	Direct Appropriation, Annual	Coronaviruses	Diagnostics	$5	$3	$3	$4	$4	$19
NIH	NIAID	Direct Appropriation, Annual	Coronaviruses	Vaccines	$55	$35	$36	$37	$38	$200
NIH	NIAID	Direct Appropriation, Annual	Flaviviruses	Antivirals	$17	$11	$11	$11	$12	$62

[13] The FY 2024 official Research, Condition, and Disease Categorization (RCDC) Biodefense and Related Countermeasures category was used as a baseline for preliminary estimates. Preliminary estimates are prepared and submitted prior to the final approval of RCDC categories and may differ from official final data that will be published on the NIH RePORT categorical spending webpage. RCDC categories represent the full portfolio and are not sub-categorized (e.g., into vaccines or basic/other research); therefore, the sub-portfolio dollars listed in this table may not match the reported categorical spending. Please note that preliminary estimates may also result in *portfolio* deviations from reported categories.

[14] Use of the Biodefense RCDC category for developing NIH's input to the Spend Plan Table predates a recent transition in NIAID's mission and research priorities. The NIH numbers in this MYB represent an overestimate.

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	FY 2025-29 Total
NIH	NIAID	Direct Appropriation, Annual	Flaviviruses	Basic/Other Research	$46	$29	$30	$31	$31	$167
NIH	NIAID	Direct Appropriation, Annual	Flaviviruses	Diagnostics	$3	$2	$2	$2	$2	$11
NIH	NIAID	Direct Appropriation, Annual	Flaviviruses	Vaccines	$29	$18	$19	$19	$20	$104
NIH	NIAID	Direct Appropriation, Annual	Paramyxoviruses	Antivirals	$12	$8	$8	$8	$8	$43
NIH	NIAID	Direct Appropriation, Annual	Paramyxoviruses	Basic/Other Research	$12	$7	$8	$8	$8	$43
NIH	NIAID	Direct Appropriation, Annual	Paramyxoviruses	Diagnostics	$0	$0	$0	$0	$0	$0
NIH	NIAID	Direct Appropriation, Annual	Paramyxoviruses	Vaccines	$15	$9	$10	$10	$10	$54
NIH	NIAID	Direct Appropriation, Annual	Poxviruses (Other than Smallpox)	Antivirals	$6	$4	$4	$4	$4	$21
NIH	NIAID	Direct Appropriation, Annual	Poxviruses (Other than Smallpox)	Basic/Other Research	$9	$6	$6	$6	$6	$33
NIH	NIAID	Direct Appropriation, Annual	Poxviruses (Other than Smallpox)	Diagnostics	$1	$1	$1	$1	$1	$5
NIH	NIAID	Direct Appropriation, Annual	Poxviruses (Other than Smallpox)	Vaccines	$5	$3	$3	$3	$3	$19
NIH	NIAID	Direct Appropriation, Annual	Togaviruses	Antivirals	$5	$3	$3	$3	$3	$17
NIH	NIAID	Direct Appropriation, Annual	Togaviruses	Basic/Other Research	$12	$7	$7	$8	$8	$42
NIH	NIAID	Direct Appropriation, Annual	Togaviruses	Diagnostics	$1	$1	$1	$1	$1	$4
NIH	NIAID	Direct Appropriation, Annual	Togaviruses	Vaccines	$10	$6	$7	$7	$7	$37
NIH	NIAID	Direct Appropriation, Annual	Threat-Agnostic/Multi-Threat	Animal Models	$74	$46	$48	$49	$50	$267
NIH	NIAID	Direct Appropriation, Annual	Threat-Agnostic/Multi-Threat	Basic/Other Research	$190	$120	$123	$126	$130	$689
NIH	NIAID	Direct Appropriation, Annual	Threat-Agnostic/Multi-Threat	Diagnostics	$5	$3	$3	$3	$3	$18
NIH	NIAID	Direct Appropriation, Annual	Threat-Agnostic/Multi-Threat	Pandemic Preparedness	$0	$1,695	$1,695	$1,695	$1,695	$6,779
NIH	NIAID	Direct Appropriation, Annual	Threat-Agnostic/Multi-Threat	Product Development	$65	$41	$42	$43	$44	$236
NIH	NIAID	Direct Appropriation, Annual	Threat-Agnostic/Multi-Threat	Translational	$223	$140	$144	$148	$152	$808
NIH	NIAID	Direct Appropriation, Annual	Other Portfolios	Non-Interventional	$115	$72	$74	$76	$78	$415
NIH	NIAID	Direct Appropriation, Annual	Other Portfolios	Therapeutics	$43	$27	$28	$28	$29	$155
NIH	NIAID	Direct Appropriation, Annual	Other Portfolios	Vaccines	$69	$44	$45	$46	$47	$252
NIH	Non-NIAID	Direct Appropriation, Annual	Rad/Nuc	Nuclear/Radiological	$53	$36	$37	$38	$39	$202
NIH	Non-NIAID	Direct Appropriation, Annual	Chemical	Chemical Research	$52	$35	$36	$37	$38	$198
NIH	Non-NIAID	Direct Appropriation, Annual	Broad-spectrum Antimicrobials	Antibiotics/Antiviral	$92	$58	$60	$61	$63	$334
NIH	Non-NIAID	Direct Appropriation, Annual	Threat-Agnostic/Multi-Threat	Diagnostics	$33	$21	$21	$22	$22	$119
NIH	Non-NIAID	Direct Appropriation, Annual	Other Portfolios	Basic/Other Research	$384	$242	$249	$255	$262	$1,392
NIH	Non-NIAID	Direct Appropriation, Annual	Other Portfolios	Vaccines	$26	$16	$17	$17	$18	$94
				NIH Total	**$2,852**	**$3,497**	**$3,546**	**$3,596**	**$3,647**	**$17,137**

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

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	FY 2025-29 Total
ASPR	BARDA	ARD	BARDA Mgt & Admin	MCM Capability and Support	$218	$218	$708	$708	$708	$2,559

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	FY 2025-29 Total
ASPR	BARDA	ARD	Other Portfolios	PHS Evaluation	$20	$16	$158	$61	$111	$367
ASPR	BARDA	PBS	Other Portfolios	PHS Evaluation	$21	$18	$39	$26	$29	$133
ASPR	BARDA	PI Annual	Other Portfolios	PHS Evaluation	$8	$8	$120	$104	$110	$349
ASPR	BARDA	ARD	Anthrax	Anthrax Vaccines	$1	$0	$20	$0	$0	$21
ASPR	BARDA	ARD	Broad-spectrum Antimicrobials	Broad-spectrum Antimicrobials/Combating Antibiotic-Resistant Bacteria	$154	$0	$207	$200	$124	$686
ASPR	BARDA	ARD	Chemical	Chemical	$84	$60	$83	$96	$87	$409
ASPR	BARDA	ARD	MCM Capability and Support	Multidisciplinary	$138	$129	$753	$658	$689	$2,366
ASPR	BARDA	ARD	Rad/Nuc	Burn and Blast MCMs	$65	$50	$65	$40	$35	$255
ASPR	BARDA	ARD	Rad/Nuc	Radiological and Nuclear MCMs	$51	$50	$152	$151	$167	$571
ASPR	BARDA	ARD	Smallpox	Smallpox Vaccines and Therapeutics	$3	$0	$20	$10	$60	$93
ASPR	BARDA	ARD	Threat-Agnostic/Multi-Threat	Threat Agnostic MCMs	$87	$43	$4,861	$1,048	$2,867	$8,905
ASPR	BARDA	ARD	Botulinum	Botulism	$4	$0	$20	$20	$20	$64
ASPR	BARDA	ARD	Biodosimetry and Biothreat Diagnostics	Biodosimetry and Biothreat Diagnostics	$71	$50	$62	$99	$248	$530
ASPR	BARDA	ARD	Filoviruses	Viral Hemorrhagic Fever	$118	$134	$92	$103	$162	$610
ASPR	BARDA	PBS	Anthrax	Anthrax Vaccines	$50	$0	$0	$0	$0	$50
ASPR	BARDA	PBS	Broad-spectrum Antimicrobials	Broad-spectrum Antimicrobials	$143	$33	$278	$232	$281	$967
ASPR	BARDA	PBS	Chemical	Chemical MCM for nerve agent exposure and opioid overdoses	$24	$82	$59	$97	$9	$270
ASPR	BARDA	PBS	Filoviruses	Filovirus Therapeutics	$26	$80	$185	$85	$290	$666
ASPR	BARDA	PBS	Filoviruses	Filovirus Vaccines	$152	$132	$572	$68	$68	$992
ASPR	BARDA	PBS	Rad/Nuc	Rad/Nuc MCMs	$90	$60	$60	$60	$60	$330
ASPR	BARDA	PBS	Rad/Nuc	Burn and Blast Countermeasures	$80	$50	$20	$70	$20	$240
ASPR	BARDA	PBS	Rapid Response Capabilities	Rapid Response Capabilities	$75	$75	$75	$75	$75	$375
ASPR	BARDA	PBS	Smallpox	Smallpox Antivirals	$82	$50	$3	$45	$63	$243
ASPR	BARDA	PBS	Smallpox	Smallpox Vaccines	$80	$100	$140	$140	$140	$600
ASPR	BARDA	PBS	Biodosimetry/Biodiagnostics	Biodosimetry/Biodiagnostics	$2	$45	$171	$172	$159	$549
ASPR	BARDA	PI Annual	Pandemic Influenza	Facilities/Infrastructure Readiness and Sustainment	$20	$20	$20	$20	$20	$102
ASPR	BARDA	PI No-Year	Pandemic Influenza	Influenza Diagnostics Advanced Development	$25	$25	$91	$91	$89	$321
ASPR	BARDA	PI No-Year	Pandemic Influenza	Facilities/Infrastructure Readiness and Sustainment	$86	$97	$1,502	$1,458	$1,440	$4,584
ASPR	BARDA	PI No-Year	Pandemic Influenza	Vaccine Stockpiling, Clinical Assessment, and Storage and Analytical Testing	$30	$27	$492	$334	$337	$1,220
ASPR	BARDA	PI No-Year	Pandemic Influenza	Improved Influenza Vaccine Advanced Development	$74	$81	$1,770	$1,545	$1,395	$4,865
ASPR	BARDA	PI No-Year	Pandemic Influenza	Influenza Therapeutics Advanced Development	$65	$50	$935	$700	$1,100	$2,850
				BARDA Total	**$2,148**	**$1,783**	**$13,735**	**$8,514**	**$10,964**	**$37,144**

Table 6: PHEMCE MYB Spend Plan Table (Dollars in Millions) for CDC.

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	FY 2025-29 Total
CDC	NCEZID	Direct Appropriation Annual	Threat-Agnostic/Multi-Threat	Multidisciplinary	$143	$112	$225	$225	$225	$930
CDC	NCIRD	Direct Appropriation Annual	Threat-Agnostic/Multi-Threat	Multidisciplinary	$240	$235	$244	$254	$264	$1,237
CDC	NCEH	Direct Appropriation Annual	Threat-Agnostic/Multi-Threat	Multidisciplinary	$7	$7	$70	$70	$70	$224
CDC	ATSDR	Direct Appropriation Annual	Threat-Agnostic/Multi-Threat	Multidisciplinary	$3	$3	$30	$30	$30	$96
CDC	ORR	Direct Appropriation Annual	Threat-Agnostic/Multi-Threat	Multidisciplinary	$1	$2	$2	$2	$2	$9
CDC	NIOSH	Direct Appropriation Annual	Threat-Agnostic/Multi-Threat	Multidisciplinary	$23	$23	$23	$30	$35	$134
CDC	OLSR	Direct Appropriation Annual	Threat-Agnostic/Multi-Threat	Multidisciplinary	$23	$28	$148	$168	$188	$555
				CDC Total	**$440**	**$410**	**$742**	**$779**	**$814**	**$3,185**

Table 7: PHEMCE MYB Spend Plan Table (Dollars in Millions) for FDA.

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	FY 2025-29 Total
FDA	FDA	Direct Appropriation, Annual	MCM Capability and Support	Advanced Manufacturing	$44	$39	$39	$39	$39	$201
FDA	FDA	Direct Appropriation, Annual	MCM Capability and Support	Antimicrobial Resistance MCM Funding	$33	$33	$33	$33	$33	$166
FDA	FDA	Direct Appropriation, Annual	MCM Capability and Support	CBRN MCM Funding	$141	$123	$123	$123	$123	$633
FDA	FDA	Direct Appropriation, Annual	MCM Capability and Support	Pandemic Influenza Funding	$43	$39	$39	$39	$39	$198
				FDA Total	**$261**	**$234**	**$234**	**$234**	**$234**	**$1,198**

Table 8: PHEMCE MYB Spend Plan Table (Dollars in Millions) for ASPR SNS.

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	FY 2025-29 Total
ASPR	SNS	Direct Appropriation, Annual	MCM Capability and Support	Ancillary	$8	$17	$50	$55	$58	$188
ASPR	SNS	Direct Appropriation, Annual	Anthrax	Antibiotic	$134	$47	$186	$202	$230	$798
ASPR	SNS	Direct Appropriation, Annual	Anthrax	Therapeutic	-	$30	$113	$113	$113	$368
ASPR	SNS	Direct Appropriation, Annual	Anthrax	Vaccine	$30	$30	$30	$30	$30	$150
ASPR	SNS	Direct Appropriation, Annual	Botulinum	Antitoxin	$62	$10	$67	$69	$69	$276
ASPR	SNS	Direct Appropriation, Annual	Other Portfolios	Antibiotic	-	$2	$1	$1	$1	$4
ASPR	SNS	Direct Appropriation, Annual	Chemical	Anticonvulsant	$7	$9	$2	$3	$2	$23
ASPR	SNS	Direct Appropriation, Annual	Chemical	Nerve agent antidote	$51	$21	$37	$64	$54	$227
ASPR	SNS	Direct Appropriation, Annual	Chemical	Other supportive	$1	$0	$0	$0	$0	$2
ASPR	SNS	Direct Appropriation, Annual	Filoviruses (Ebola)	Therapeutic (Antiviral)	-	-	$100	$100	$100	$300
ASPR	SNS	Direct Appropriation, Annual	Filoviruses (Ebola)	Vaccine	-	-	$50	$50	$150	$249
ASPR	SNS	Direct Appropriation, Annual	MCM Capability and Support	FMS	$1	-	-	-	-	$1
ASPR	SNS	Direct Appropriation, Annual	Pandemic Influenza	Antiviral	$24	-	$186	$186	$186	$582
ASPR	SNS	Direct Appropriation, Annual	Other Portfolios	Antibiotic	$31	$25	$78	$78	$78	$290

Agency	Division	Funding Source	Portfolio	Sub Portfolio	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	FY 2025-29 Total
ASPR	SNS	Direct Appropriation, Annual	Rad/Nuc	Antibiotic	-	-	-	-	-	$0
ASPR	SNS	Direct Appropriation, Annual	Rad/Nuc	Antineutropenic	-	$38	$228	$228	$228	$723
ASPR	SNS	Direct Appropriation, Annual	Rad/Nuc	Antiviral	-	-	-	-	-	$0
ASPR	SNS	Direct Appropriation, Annual	Rad/Nuc	Decorporation	$4	$4	$17	$17	$17	$60
ASPR	SNS	Direct Appropriation, Annual	Rad/Nuc	Other supportive	$4	$9	$9	$9	$9	$40
ASPR	SNS	Direct Appropriation, Annual	Smallpox	Antiviral	$30	$30	$72	$72	$96	$301
ASPR	SNS	Direct Appropriation, Annual	Smallpox	Vaccine	$88	$79	$276	$278	$278	$998
ASPR	SNS	Direct Appropriation, Annual	MCM Capability and Support	Operating and Program Support	$152	$108	$94	$96	$98	$548
ASPR	SNS	Direct Appropriation, Annual	MCM Capability and Support	Sustainment	$352	$292	$456	$445	$526	$2,073
				SNS Total	**$980**	**$750**	**$2,052**	**$2,120**	**$2,322**	**$8,224**