U.S. Department of Health and Human Services

Public Health Emergency Medical Countermeasures Enterprise

Multiyear Budget

Fiscal Years 2018-2022

December 2019

Saving Lives. Protecting Americans.

ASPR

U.S. Department of Health and Human Services

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Executive Summary

Section 2811(b)(7) of the Public Health Service (PHS) Act requires the Assistant Secretary for Preparedness and Response (ASPR) to lead the development of a coordinated five-year budget plan for medical countermeasure (MCM) development and to update the plan annually. This Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget Report (MYB) is the fifth submission in response to that requirement. This report includes the multiyear budgets for the following Department of Health and Human Services (HHS) entities involved in MCM development and stockpiling: the National Institutes of Health (NIH), ASPR's Biomedical Advanced Research and Development Authority (BARDA) and Strategic National Stockpile (SNS), and the Food and Drug Administration (FDA)[1] for fiscal years (FY) 2018–2022.

This report revises and updates the estimated funding data in the FY 2017–2021 PHEMCE Multiyear Report submitted to Congress in February 2019. The House Appropriations Committee stated in its FY 2020 Labor-HHS-Education appropriations committee report:

> "The Committee appreciates the release of the Public Health Emergency Medical Countermeasures Enterprise multiyear budget in February 2019. The Committee expects more timely future submissions, as the updates are due annually."

This abbreviated report seeks to meet this expectation. The Department anticipates submitting a full report for FYs 2019–2023 in March 2020.

For the five-year period of fiscal years (FYs) 2018–2022, this report provides estimates for HHS total spending which would be $28.8 billion, a $4.0 billion, or 14 percent, increase compared with the projection for FYs 2017–2021, which was $24.8 billion. The five-year funding total aggregates MCM-related spending estimates for NIH, BARDA, SNS, and FDA (**Table 1**).

This year's report updates the previous report and provides an amended analysis. The report maintains the methodology from last year's report by including an estimate of funding needed to replenish products held in the SNS that were originally purchased by Project BioShield (PBS) but are anticipated to be approved or licensed by the FDA prior to FY 2022. This report includes estimates of the replenishment costs that would be incurred by the SNS beginning in FY 2020 through FY 2022 and this amount totals $1.1 billion. Replenishment costs arise from products purchased previously by BARDA or SNS that expire and need to be restocked.

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

Division	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	Total	Change Over FYs 2017-2021
NIH	$2,170	$2,329	$2,011	$2,065	$2,121	$10,695	$392
ASPR BARDA	$1,514	$1,653	$1,698	$4,217	$3,671	$12,753	$2,778
ASPR SNS	$610	$610	$620	$1,081	$1,657	$4,578	$803
FDA	$142	$141	$154	$173	$178	$787	$12
Total	**$4,436**	**$4,733**	**$4,483**	**$7,535**	**$7,626**	**$28,813**	**$3,985**

This report developed the spending estimates in the report as follows: for FYs 2018 and 2019, the report includes the enacted annual appropriation levels; for FY 2020, the report includes the FY 2020 President's Budget request. In addition, for FYs 2018, 2019, and 2020, estimated spending also includes the use of funds from pandemic influenza no-year supplemental appropriations balances. The out-year funding levels (FYs 2021 and 2022) were developed without regard to the competing priorities considered in the annual budget formulation process. As the Administration formulates Congressional budget requests for FYs 2021 and 2022, these estimates may be subject to change.

The following summary describes estimated spending by threat for the cumulative five-year period and the change relative to the last year's report for FYs 2017–2021:

[1]Section 2811-1 of the PHS Act (as amended by P.L. 116-22) establishes the members of the PHEMCE to include the following HHS members or their designees: the ASPR, the Director of the Centers for Disease Control and Prevention (CDC), the Director of the NIH, and the Commissioner of FDA. Representatives from other federal agencies may also be part of PHEMCE as determined appropriate by the Secretary, including: the Director of BARDA, the Director of the SNS, the Director of the National Institute of Allergy and Infectious Diseases (NIAID), and the Director of the Office of Public Health Preparedness and Response.

Pandemic and Seasonal Influenza: $5.7 billion, an increase of $1.4 billion (+33 percent), to fully support necessary efforts to address identified gaps in pandemic influenza preparedness and response capabilities, develop a universal influenza vaccine, and maintain current capabilities. BARDA would begin a robust development program for more effective, non-egg based vaccines that can be domestically manufactured, delivered faster, and last on shelves longer. Development of novel influenza antivirals and therapeutics, including repurposing of currently approved products, would start. Efforts to push diagnostics to home use to allow more rapid detection and treatment would be increased. Currently existing domestic manufacturing facility capacity, critical to the Nation's response capabilities, will be maintained. A portion of this increase also supports replenishment of expiring material in the SNS.

Broad Spectrum Antimicrobials: $3.7 billion, an increase of $193 million (+6 percent), for the development and approval of one current and one new product to address gaps for threats caused by Gram-negative bacteria (broad-spectrum antimicrobials). This includes the transition of two products from advanced research and development (ARD) to PBS. These investments are consistent with objectives in the National Strategy for Combating Antibiotic-Resistant Bacteria (2015–2020).

Cross-Cutting Science Portfolio: $2.9 billion, a decrease of $90 million (-3 percent), for NIAID and BARDA research activities that cannot be assigned to a specific threat, but augment preparedness and response as overarching capabilities. These investments support such necessary areas as animal model development, diagnostics, sequencing facilities, reagent manufacturing, clinical training programs, epitope mapping, biosafety lab support, and computational biology. Investments in this area also support the development of vaccine platform technologies that could be used to generate candidate vaccines against multiple different established or emerging pathogens. These platforms include gene-based vaccination systems such as viral vectors, plasmid DNA, and mRNA, and stabilization technologies (e.g., dry versus liquid formulations).

Other Threats Portfolio: $2.8 billion, an increase of $186 million (+7 percent), for investments to support activities against threats such as arboviruses (including Zika virus), MERS-CoV, waterborne and foodborne pathogens, tuberculosis, adjuvant discovery/development, and activities investigating fundamental aspects of the human immune system. This portfolio includes investments supporting advanced development of MCMs against other emerging infectious disease threats. The funding estimate reflects the multitude of infectious diseases that have emerged over the last decades and pose a serious threat to health security, the need to have licensed MCMs available to detect, treat, and prevent these diseases, and the numerous countermeasures that have completed early development and are situated for advanced product development. Funding will also support development and testing of platform technologies to streamline vaccine discovery and development and facilitate a rapid response to emerging infectious diseases. Specifically, development of MCMs against the Zika virus are captured in this portfolio as well. Part of the estimated increase reflects successful advancement of the current vaccine candidates toward licensure, and a need for BARDA to fund pivotal clinical trials and manufacturing work in order to achieve FDA approval.

Anthrax: $2.3 billion, an increase of $302 million (+15 percent).This portfolio supports the development, procurement, and support for preparation of an application for licensure of the next-generation anthrax vaccine, AV7909, as well as anthrax therapeutics. The increase in estimated spending supports the replenishment of anthrax therapeutics in the SNS.

Radiological and Nuclear Threats: $2.0 billion, an increase of $191 million (+10 percent) for basic and advanced clinical research and development of products to address acute radiation syndrome (ARS) and the delayed effects of acute radiation exposure (DEARE), and procurements of anti-neutropenic cytokines, biodosimetry devices, and multiple candidate products for the treatment of thermal burns.

Filoviruses (including the Ebola virus): $1.9 billion, an increase of $282 million (+18 percent), to support a variety of activities related to the development of Ebola vaccines and therapeutics, including: 1) manufacturing of clinical investigational lots, 2) conducting clinical trials in the U.S. and West Africa that are essential to assess whether the products are safe and effective, 3) attaining the ability to manufacture these MCMs at commercial scale, and 4) ultimately procuring vaccine and therapeutic MCMs. The funding estimate would support the transition of one Sudan ebolavirus therapeutic from ARD to PBS.

Smallpox: $1.8 billion, an increase of $563 million (+47 percent), for the procurement of a next-generation vaccine against smallpox, potentially providing a longer shelf-life and, therefore, lower replenishment costs. This increase in estimated spending also includes replenishment of current vaccinia and immune globulin stockpiles in the SNS.

Chemical Threats: $1.6 billion, an increase of $448 million (+39 percent), to support the development of safer and more effective therapeutics to treat exposure to nerve agents, vesicating chemicals, pulmonary agents, and toxic industrial chemicals. This amount includes a substantial investment in countermeasures against pharmaceutical-based agents, such as fentanyl.

Botulinum: $132 million, a decrease of $250 million (-65 percent), for continued support for the hBAT (botulinum antitoxin, heptavalent) program that includes processing additional hyperimmune plasma into finished product. This decrease reflects the removal of a placeholder expense for regenerating the hyperimmune horse herd that provides the antibodies for the hBAT product. The existing supply and production capacity for the hBAT product is sufficient to meet the current PHEMCE requirement for the next 10 years.

Centers for Innovation in Advanced Development and Manufacturing (CIADM): $125 million, an increase of $125 million, for maintaining and increasing the capabilities of the CIADMs. This increase reflects the transition to a capability-based approach, which takes advantage of previous investments to address existing public health threats by having access to rapid domestic manufacturing capabilities for a broad array of countermeasures.

Other Portfolios: The remaining funds ($3.5 billion) for the five-year period are allocated to: SNS Non-Procurement Costs and federal medical stations, FDA Regulatory Science, NIH's Multiplex Diagnostics, BARDA's Management and Administration, BARDA's Medical Countermeasure Innovator Program, MCM for plague and tularemia, MCM for glanders and melioidosis, ancillary products, and biodiagnostics.

This FYs 2018–2022 PHEMCE MYB highlights the PHEMCE pipeline from bench research to FDA approval and procurement. This pipeline has resulted in more than 200 products in advanced research and development, 15 countermeasures that are, or have been, stockpiled in the SNS that are available during a public health emergency, and 48 products achieving FDA approval since 2007.

Background

The PHEMCE is an interdepartmental governance structure overseen by HHS for the research, advanced development, procurement, stockpiling, and development of plans for effective use of MCMs needed to respond to infrequent, but high-consequence, public health and medical emergencies. These events may result from intentional, accidental, or natural occurrences. The PHEMCE is led by ASPR and includes multiple HHS divisions. Several interagency partners have been active within the PHEMCE, including the U.S. Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), the U.S. Department of Homeland Security (DHS), and the U.S. Department of Agriculture (USDA). The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (P.L. 116-22) added the Director of National Intelligence to the membership of PHEMCE.

This report, the *FYs 2018–2022 Public Health Emergency Medical Countermeasures Enterprise Multiyear Budget*, describes the five-year interagency budget plan for the basic research, advanced research and development, regulatory review, procurement, stockpiling, and replenishment of the U.S. government's civilian medical countermeasure enterprise.[2] The report consolidates PHEMCE budget forecasting into one document providing an update for FYs 2018–2022 of PHEMCE budget priorities across chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza, and other emerging, or re-emerging, infectious diseases for ASPR (including BARDA and the SNS), FDA, and NIH.

Background on Medical Countermeasure Development

The development of MCMs is a time-intensive, risky, and expensive endeavor, requiring substantial coordination among federal departments and agencies, and the concerted efforts of commercial partners. It is also a critical component of the Nation's health preparedness and response capability. Prioritizing federal funding across portfolios and the stages of MCM development is fundamental to achieving the PHEMCE's goals. Successful coordination requires strategic planning that incorporates discrete funding streams into a coherent plan spanning many years.

The PHEMCE's success is demonstrated by the products that evolved across programs, achieved regulatory approval, and were stockpiled in the SNS. Currently, HHS's advanced research and development pipeline contains more than 200 products. The PHEMCE stockpiled 15 countermeasures in the SNS that are available for use during a public health emergency. Since 2007, the FDA has approved 48 products for CBRN threats and pandemic influenza supported by HHS's PHEMCE agencies, including BARDA.

This report forecasts that seven MCM candidates will transition from procurement under BARDA's Project BioShield to stockpiling by the SNS by 2022. Although these MCMs may not have FDA approval at the time of initial delivery to the SNS, they may potentially be used under investigational drug protocols, such as clinical trials or may potentially be used under the FDA provisions for Emergency Use Authorization (EUA), as needed, and authorized under the Federal Food, Drug and Cosmetic (FD&C) Act.[3] SNS will be responsible for the replenishment costs of those MCMs procured by BARDA under PBS once these products achieve FDA approval. The SNS also procures commercially available, FDA-approved or licensed materials that meet identified PHEMCE MCM requirements.

Background on the Multiyear Budget

The multiyear budget report (MYB) fulfills the requirement to "develop, and update on an annual basis, a coordinated five-year budget plan based on the medical countermeasure priorities," in section 2811(b)(7) of the PHS Act. This report provides cost estimates for the three HHS PHEMCE agencies within the scope of this report and involved in MCM development and stockpiling. These cost estimates are based on enacted appropriations in FYs 2018 and 2019, and the FY 2020 President's Budget request. In addition, for FYs 2018, 2019, and 2020, estimated spending also includes the use of funds from pandemic influenza no-year supplemental appropriations balances. For FYs 2021 and 2022, funding estimates are to support MCM-related activities, including research, development, or procurement of MCMs.

[2]For purposes of this document, "approval" refers to "FDA approval, licensure, or clearance" under sections 505, 510(k), or 515 of the FD&C Act, or under section 351 of the PHS Act.

[3]The Project BioShield Act of 2004, [PL 108-276], amended the Federal Food Drug and Cosmetic Act, which was further amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 [PL 113-5], to give authority to the Secretary of HHS to declare that circumstances exist that justify the emergency use authorization, and for FDA to grant emergency use authorization, of certain MCMs that are not approved, or for uses for which the MCMs are not approved, in emergencies under certain terms and conditions [21 USCS § 360bbb-3]. An emergency use authorization does not require the declaration of a public health emergency under section 319 of the PHS Act.

Each office and program developed its own methodology for providing estimates for this report. The estimates for procurement costs are point-in-time estimates and could change in future reports to reflect current market prices.

- NIH assumed an inflationary increase in FYs 2021 and 2022, indexed to the Biomedical Research and Development Price Index.
  BARDA assumed funding levels to address all DHS-identified threats with Material Threat Determinations and to meet the goals of the HHS 2017 Pandemic Influenza Plan Update.
- The SNS assumed funding levels necessary to maintain the current inventory, including replenishment of all FDA approved MCMs, including those originally acquired by PBS. Also, SNS includes an estimate of the funding that will be needed in out-years to replenish products originally purchased by PBS that are not yet FDA approved, but which are forecasted to become so and require replacement in those years.
- FDA assumed a three percent increase for each of FYs 2021 and 2022.
- The out-year funding levels (FYs 2021 and 2022) for NIH, BARDA, SNS, and FDA, were developed without regard to the competing priorities considered in the annual President's Budget formulation process. These estimates are subject to change in the future.

PHEMCE-Wide Findings

In coordination with its interagency partners, the PHEMCE's investments and accomplishments are the result of the actions of all member agencies. This section provides an overview of spending across NIH, ASPR, and FDA, and describes accomplishments and projections over the course of the five-year period. Congress does not appropriate funding directly to the PHEMCE, but the PHEMCE, led by ASPR, helps to coordinate those appropriations to achieve the PHEMCE's goals and objectives.

Overview

In total, the four HHS Divisions spent $4.4 billion on MCMs and MCM-related activities in FY 2018. Estimated spending across the HHS enterprise is delineated in Table 2. The Appendix A – Spend Plan Tables provide additional detail. PHEMCE investments for the five-year period total $28.8 billion, a $4.0 billion or 14 percent increase compared with the projections in the FYs 2017–2021 report.

Table 2. Estimated Total PHEMCE Spending by HHS Division and Fiscal Year (dollars in millions)

Division	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	Total	Change Over FYs 2017-2021
NIH	$2,170	$2,329	$2,011	$2,065	$2,121	$10,695	$392
ASPR BARDA	$1,514	$1,653	$1,698	$4,217	$3,671	$12,753	$2,778
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FDA	$142	$141	$154	$173	$178	$787	$12
Total	**$4,436**	**$4,733**	**$4,483**	**$7,535**	**$7,626**	**$28,813**	**$3,985**

Threat-Based Approaches

PHEMCE recognizes the need to address high-priority threats. While PHEMCE is evolving toward a capability-based approach across threats, it proposes to maintain key threat-based approaches to address national health security.

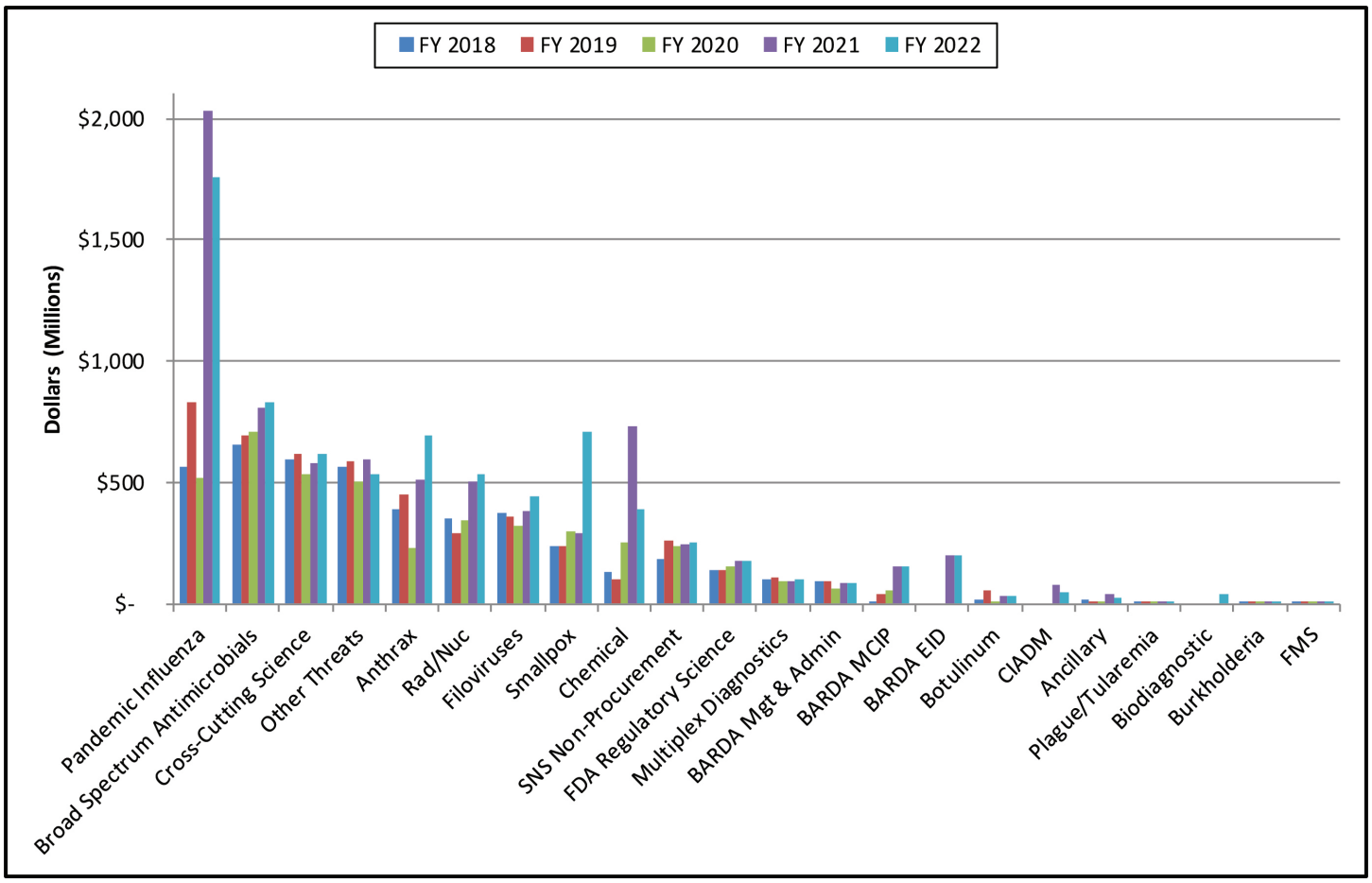
Figure 1 depicts estimated PHEMCE spending by portfolio for FYs 2018-2022. As ranked by cumulative estimated spending, PHEMCE's investments reflect the priorities established in the 2017-2018 PHEMCE SIP (increases and decreases are changes from the estimates contained in the FYs 2017–2021 report).

Across NIH, BARDA, SNS, and FDA, estimated spending on pandemic and seasonal influenza is $5.7 billion over the five-year period, which represents an increase of $1.4 billion (+33 percent). This increase is critical to support pandemic preparedness objectives as outlined in the *2017 Pandemic Influenza Plan Update.* This update includes HHS's establishment of one of its key actions to "support innovation in influenza vaccine production for improved efficiencies to enable the production and distribution of final presentation vaccines for pandemic response within 12 weeks from the declaration of an influenza pandemic."[4] Other requirements objectives include the need for improvements in diagnostics and treatment options. The increased spending estimate supports BARDA to begin a robust development program for more effective vaccines that can be made and delivered faster than currently available vaccines. NIH would continue to support discovery of innovative new pandemic influenza vaccine prototypes, while advancing the clinical development of current universal influenza vaccine candidates. Efforts to push diagnostics to home use to allow more rapid detection and treatment would be increased. Existing manufacturing facility capacity, critical to the nation's response capabilities, will be maintained.

Consistent with the *National Strategy for Combating Antibiotic-Resistant Bacteria (2015-2020)*, one of the largest spending estimates is for new products to address gaps in the broad-spectrum antimicrobial portfolio for threats caused by bacteria and other Gram-negative bacteria (broad-spectrum antimicrobials) that complicate the ability to respond to any public health emergency. This estimated spending totals $3.7 billion over five years, which represents an increase of $193 million (+6 percent). This total includes the transition of two products from BARDA ARD to PBS. Significant investment is also planned for development of diagnostics that quickly identify which antibiotics are effective to treat a patient and inform antibiotic stewardship.

[4]https://www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf

Figure 1. Estimated PHEMCE Spending by Portfolio and Fiscal Year



The cross-cutting science portfolio includes the NIAID research activities that cannot be assigned to a specific threat. These investments support capabilities such as animal models, diagnostics, sequencing facilities, reagent manufacturing, clinical training programs, epitope mapping, biosafety lab support, computational biology, and development of vaccine platform technologies. The five-year budget plan estimate for this portfolio is $2.9 billion, which represents a decrease of $90 million (-3 percent).

The Other Threats portfolio is the next largest area of estimated spending and includes investments at NIAID that support activities against threats such as arboviruses, waterborne and foodborne pathogens, tuberculosis, adjuvant discovery/development, and activities investigating fundamental aspects of the human immune system. Total five-year spending on these investments is estimated to be $2.8 billion, which represents an increase of $186 million (+7 percent).

The next largest threat-specific investment is the anthrax portfolio, with total estimated spending of $2.3 billion over the five-year period, an increase of $302 million (+15 percent). This portfolio supports the development, preparation of an application for approval, and procurement of the next-generation anthrax vaccine, AV7909, as well as anthrax therapeutics and diagnostics. AV7909 will potentially lower future stockpiling and replenishment costs by reducing the number of doses of vaccine needed to treat patients. The increased spending estimate also supports the replenishment of anthrax therapeutics, including antibiotics, by the SNS.

Spending by BARDA and NIAID on MCMs against radiological and nuclear threats, the next largest investment for this five-year period, totals $2.0 billion, which represents an increase of $191 million (+10 percent). This investment includes spending for basic and advanced clinical research and development of products to address ARS and DEARE, as well as procurements for anti-neutropenic cytokines, biodosimetry devices, and artificial skin for the treatment of thermal burns.

In the filovirus portfolio, the PHEMCE estimates five-year spending to be $1.9 billion, which represents an increase of $282 million (+18 percent). This increase supports the late-stage development and procurement of MCMs against the Ebola virus. At this funding level, the PHEMCE would continue to support activities associated with the transition of MCM candidates from early development supported by the NIH and the DoD to advanced development at BARDA and toward FDA approval if safety and efficacy are demonstrated. These activities include the following: 1) manufacture of clinical investigational lots, 2) clinical trials to be conducted in the U.S. and West Africa, 3) development of the capacity to manufacture these MCMs at commercial scale, and, 4) ultimately, the procurement of MCMs. This portfolio includes the expected transition of one Sudan ebolavirus therapeutic from ARD to PBS.

Investment in MCMs to mitigate smallpox is forecasted to have a five-year total of $1.8 billion, which represents an increase of $563 million (+47 percent). This increase reflects the investment in a lyophilized formulation of IMVAMUNE, a non-replicating smallpox vaccine being developed for individuals at risk for adverse events from replicating smallpox virus, which is a mandate under the PHS Act. Future investments are expected to decrease over this period due to the availability of a next-generation vaccine against smallpox, potentially providing greater shelf-life and, therefore, lower replenishment costs.

Spending on MCMs to mitigate chemical threats is forecasted to have a five-year total of $1.6 billion, which represents an increase of $448 million (+39 percent). The chemical threats portfolio includes research at NIAID, the National Institute of Neurological Disorders and Stroke, other NIH institutes, and BARDA on the development of safe and more effective therapeutics for exposures to nerve agents, vesicating chemicals, pulmonary agents, and toxic industrial chemicals. This increase also includes additional estimated funding for countermeasures against pharmaceutical-based agents, such as fentanyl.

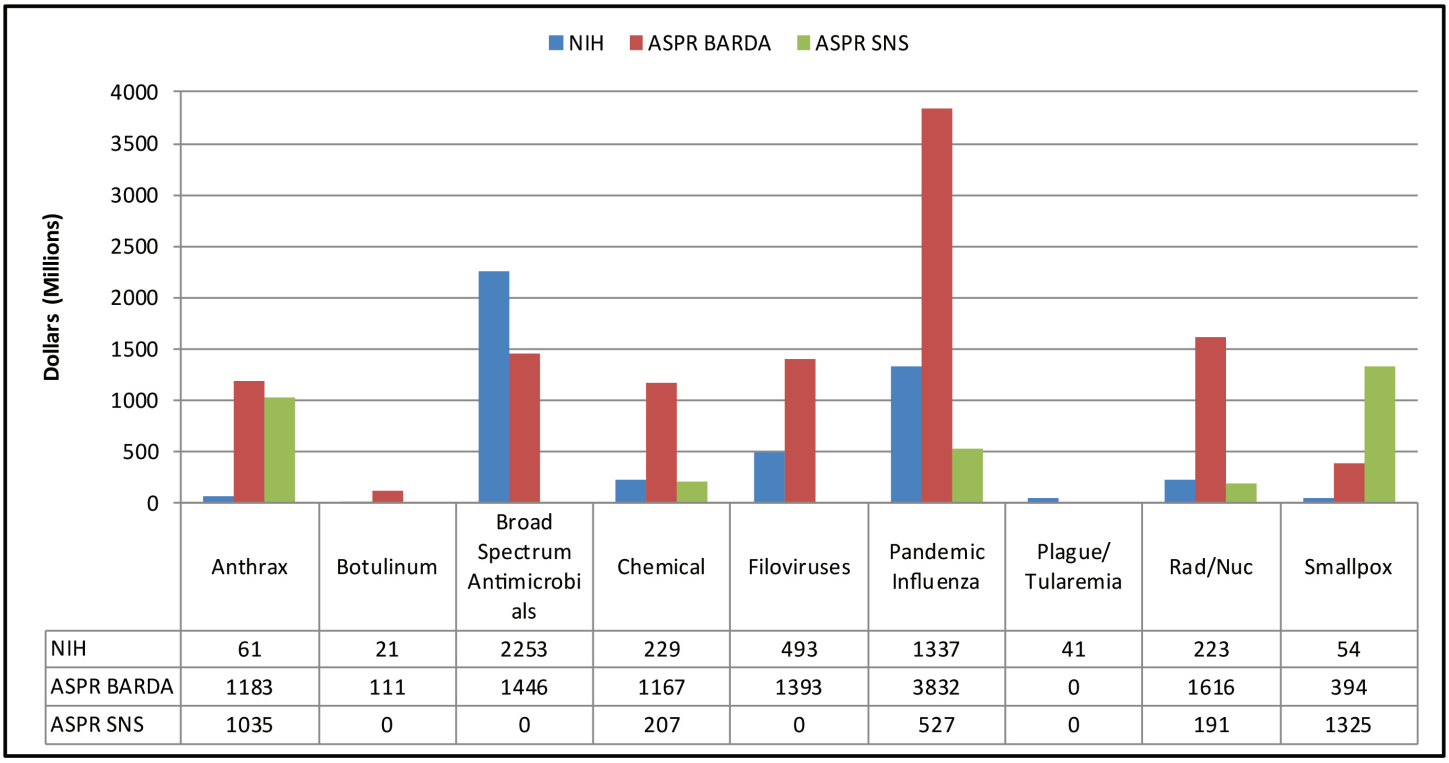
This report also includes estimated spending in BARDA for two new areas related to addressing advanced development of MCMs against emerging biological threats, for a five-year total of $525 million. Advanced development of MCMs against emerging infectious disease threats is estimated at a total of $400 million. Funds would be used to advance candidates developed by PHEMCE partners and others through late-stage advanced development and eventual application for approval if safety and efficacy are demonstrated. The funding estimate reflects the multitude of infectious diseases that have emerged over the last decades and that pose a serious threat to national health security, the need to have licensed MCMs available to detect, treat, and prevent these diseases, and the numerous countermeasures that have completed early development and are situated for advanced product development. Finally, spending to further develop the CIADMs to provide a rapid, flexible, capability (rather than specific threat-based) is forecast at $125 million over the five-year period.

Portfolio Investments across NIH, ASPR, and FDA

Funding for MCM development varies depending on the stage of development with greater investment per product being needed as development proceeds. Furthermore, to ensure success of at least one MCM to address a threat, it is necessary to fund more than one candidate product at earlier stages of development. In addition, a product that has been procured, FDA approved, and stored in the SNS will eventually expire, and the SNS, or in rare instances BARDA, would need to fund replenishment of the product.

Figure 2 shows total five-year spending by HHS division for high-priority threats. No single factor drives spending within any one portfolio, and each portfolio may contain several types of MCMs (e.g., vaccine, therapeutic, and diagnostic, etc.). Relatively more mature portfolios require sustained investment by SNS in replenishment costs (e.g., anthrax, pandemic influenza, chemical, nerve agent, and smallpox). Relatively less mature portfolios will show an absence of SNS spending (e.g., broad-spectrum antimicrobials, filoviruses, and radiological or nuclear threats). A significant investment by BARDA may lead to a novel MCM that could be procured and stockpiled by the SNS during this report's timeframe. Estimated spending for antibiotics to prevent and treat plague and tularemia to meet PHEMCE requirements are largely supported by the anthrax portfolio as the antibiotic requirement for the former is much lower (fewer doses) than the latter.

Figure 2. MCM Estimated Spending by High-Priority Portfolio and HHS Division for FYs 2018–2022



	Anthrax	Botulinum	Broad Spectrum Antimicrobials	Chemical	Filoviruses	Pandemic Influenza	Plague/ Tularemia	Rad/Nuc	Smallpox
NIH	61	21	2253	229	493	1337	41	223	54
ASPR BARDA	1183	111	1446	1167	1393	3832	0	1616	394
ASPR SNS	1035	0	0	207	0	527	0	191	1325

Product Transitions

The transition of candidate or approved products across the PHEMCE partners is a key indicator of success of the PHEMCE. Coordination among the partners is central to efficient use of funding for this purpose. The MYB provides a long-range forecast of when products may be available for transition to the next stage (i.e., to the next PHEMCE partner or the next source of funding) for development or procurement. It may also inform decision-making concerning PHEMCE activities such as the SNS Annual Review.

During FYs 2018–2022, BARDA anticipates seven MCM product transitions from Project BioShield to SNS. Transitioning these products will increase the need for funding in the SNS budget to support replenishment of expiring MCMs. Replenishment costs arise from products purchased previously by BARDA or SNS that expire and need to be restocked. A total of $1.1 billion is estimated to support replenishment of MCMs by SNS. This report also removes the transition of the botulinum countermeasure, hBAT, from **Table 3**. The previous report included the best available estimate for regenerating the hyperimmune horse herd that provides the antibodies for the hBAT product. The existing supply and production capacity for the hBAT product is sufficient to meet the current PHEMCE requirement for the next 10 years. Progress toward regulatory approval for two additional products has accelerated their planned transition and they are added to the table under Radiological or Nuclear (Rad/Nuc) MCMs. Table 3 details the products expected to transition from PBS to SNS and the associated two-year replenishment costs.

Future Challenges

The primary challenge faced by the PHEMCE is the sustainability of the MCM response capabilities and capacities of the SNS built through PBS. Successful procurement of an MCM obligates SNS to expend additional funding for sustainment. First, SNS faces replenishment requirements upon expiration for products added to the SNS by BARDA through PBS contracts. PBS funding used for initial MCM procurement rarely supports ongoing maintenance and replacement of the products after it is approved by FDA. In the past, the PHEMCE SNS Annual Review recommended tradeoffs when available SNS funds were insufficient to both maintain current capabilities and absorb additional products. These tradeoffs translated to increasing levels of risk across the threat portfolios potentially jeopardizing the nation's ability to realize the full benefits of prior research and development investments. For example, prior SNS Annual Reviews proposed reducing anthrax vaccine holdings and in 2015 proposed reducing both anthrax vaccine

Table 3. Estimated SNS Spending Needed for MCM Product Replenishment of Products Anticipated to Achieve FDA Approval Previously Procured by BARDA under Project Bioshield, FYs 2018–2022

Medical Countermeasure	Estimated Transition Timeframe (FY)	Estimated Cost FY 2020–2021 (dollars in millions)
Anthrax Therapeutic	2021	$287.0
Anthrax Therapeutic	2021	$153.9
Anthrax Therapeutic	2020	TBD [5]
Chemical Anticonvulsant	2021	$41.6
Rad/Nuc Thermal Burn	2020	$12.0
Rad/Nuc Antineutropenic	2021	$134.0
Smallpox Vaccine	2022	$196.0
Smallpox Antiviral	2020	$253.1

and antibiotics to meet budget constraints. The 2016 SNS Annual Review reported that the SNS inventory was below the established stockpiling goals for several types of MCMs.

Preparing the nation against the threat of pandemic influenza remains a prominent challenge. The *2017 Pandemic Influenza Plan Update* establishes as one of the key actions that HHS will "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."[6] To achieve this, BARDA supports the advanced development of cell- and egg-based vaccine domestic manufacturing and infrastructure capacity. Infrastructure capacity is critical to maintaining domestic vaccine manufacturing capability, and includes ongoing vaccine and adjuvant stockpiling programs, including storage, stability, and testing. The estimated funding projected in the out-years (FY 2021 and FY 2022) will also provide continued support for advanced development of therapeutics and novel antiviral drugs for severely ill and hospitalized patients, universal influenza vaccines, home-use diagnostics, as well as reusable respirators, and universal portable ventilators.

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

[5] Cost estimate pending policy review of anthrax antitoxin stockpiling requirements.

[6] https://www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf

Conclusion

This report represents HHS's current estimates for the basic research, advanced research and development, regulatory review, procurement, stockpiling, and replenishment of the U.S. government's civilian medical countermeasure enterprise. ASPR developed this budget forecast without regard to the competing priorities that the Secretary, other HHS officials, and the President must consider when developing the annual President's Budget request.

The PHEMCE continues to successfully deliver MCM products to the SNS that mitigate the risk presented by the most important threats to the nation. It does so with a continuous focus on being effective stewards of the resources that Congress appropriated toward these efforts. Since its inception, the PHEMCE targeted resources to high-priority threats and as a result has a ready stockpile of MCMs against anthrax, smallpox, botulinum, and pandemic influenza. In recent years, the PHEMCE expanded its capabilities by developing, licensing, and procuring MCMs against chemical, radiological, and nuclear threats. Additionally, PHEMCE prioritizes the needs of special or vulnerable populations, such as children, pregnant women, and immunocompromised individuals, in the development of products and technologies.

The PHEMCE also maintains its commitment to progress by improving MCM response capabilities and identifying the need for a 14 percent increase in total forecasted funding relative to the FYs 2017–2021 Report. For several years, the PHEMCE has faced difficult decisions regarding prioritizing research and development efforts, and sustaining domestic manufacturing and other capacity, as well as the SNS formulary. This effort has become more challenging over time due to the number of existing MCM requirements, Project BioShield and other products successfully achieving approval, and the emergence of new threats, while the purchasing power has not increased correspondingly. Plans for completing the 2017 SNS Annual Review (FY 2020 Plan) are under review.

The PHEMCE faces the challenge of maintaining a stockpile of MCMs against a plethora of low-probability, high-consequence threats, while continuing to develop important countermeasures against other threats, and maintaining the capacity to rapidly respond to novel threats like emerging or re-emerging infectious diseases. To stretch the taxpayer dollar further, the PHEMCE is examining new mechanisms for reducing development and stockpiling costs. These include new public-private partnerships to reduce development costs, vendor-managed inventory of commercially available drugs to reduce replenishment costs, and the development of next-generation MCMs.

Appendix A – Spend Plan Tables

(dollars in millions)

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 - FY 2022 Total
ASPR BARDA	Project BioShield SRF, No-Year	Anthrax	Therapeutics	$8.8	$0.0	$0.0	$0.0	$0.0	$8.8
ASPR BARDA	Project BioShield SRF, No-Year	Anthrax	Vaccine	$113.9	$254.1	$170.0	$250.0	$250.0	$1,038.0
ASPR BARDA	Project BioShield SRF, No-Year	Biodiagnostic		$0.0	$0.0	$0.0	$0.0	$40.0	$40.0
ASPR BARDA	Project BioShield SRF, No-Year	Botulinum	Botulinum Antitoxin	$11.3	$50.0	$0.0	$0.0	$0.0	$61.3
ASPR BARDA	Project BioShield SRF, No-Year	Broad Spectrum Antimicrobials		$0.0	$60.0	$100.0	$140.0	$150.0	$450.0
ASPR BARDA	Project BioShield SRF, No-Year	Chemical	Chemical Countermeasures	$0.6	$0.0	$40.0	$200.0	$200.0	$440.6
ASPR BARDA	Project BioShield SRF, No-Year	Filoviruses	Ebola	$254.6	$194.0	$200.0	$250.0	$270.0	$1,168.6
ASPR BARDA	Project BioShield SRF, No-Year	Rad/Nuc	ARS - Skin/Lung/GI	$154.9	$80.0	$80.0	$100.0	$100.0	$514.9
ASPR BARDA	Project BioShield SRF, No-Year	Rad/Nuc	Biodosimetry	$1.8	$3.2	$45.0	$25.0	$25.0	$100.0
ASPR BARDA	Project BioShield SRF, No-Year	Rad/Nuc	Thermal Burns	$25.2	$20.7	$30.0	$75.0	$75.0	$225.9
ASPR BARDA	Project BioShield SRF, No-Year	Smallpox	Antivirals	$101.9	$25.0	$20.0	$0.0	$0.0	$146.9
ASPR BARDA	Project BioShield SRF, No-Year	Smallpox	Vaccine	$37.0	$48.0	$50.0	$0.0	$0.0	$135.0
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual Appropriations	Pandemic Influenza	International MCM and Sample Testing Initiative	$0.0	$0.0	$0.0	$10.0	$10.0	$20.0
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual Appropriations	Pandemic Influenza	Vaccine Stockpile, Storage, Stability, and Testing	$2.1	$28.0	$28.0	$117.0	$117.0	$292.1

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 - FY 2022 Total
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual Appropriations	Pandemic Influenza	Vx AD (Universal, Cell and Recomb)	$25.9	$0.0	$0.0	$0.0	$0.0	$25.9
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Ventilators/Respirators / Diagnostics AD	$0.0	$20.0	$20.0	$220.7	$220.7	$481.4
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Facilities, Infrastructure Readiness, and Sustainability	$12.0	$130.0	$90.0	$264.2	$172.2	$668.4
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Fill/Finish Network	$2.7	$0.0	$0.0	$0.0	$0.0	$2.7
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Infrastructure	$83.2	$0.0	$0.0	$0.0	$0.0	$83.2
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Therapeutics Advanced Development	$49.3	$42.0	$55.0	$233.9	$203.8	$584.0
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Vx AD (Improved vaccines including cell and recombinant technologies)	$48.7	$33.0	$60.0	$661.4	$525.1	$1,328.2
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Vaccine Stockpile, Storage, Stability, and Testing	$9.1	$0.0	$0.0	$29.3	$12.0	$50.4
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	MCM Innovation	$10.0	$0.0	$0.0	$5.0	$5.0	$20.0
ASPR BARDA	Pandemic Influenza - PHSSEF, Sup Bal No-Year	Pandemic Influenza	Diagnostics AD	$24.0	$0.0	$0.0	$0.0	$0.0	$24.0
ASPR BARDA	Pandemic Influenza - PHSSEF, Sup Bal No-Year	Pandemic Influenza	Vx AD (Improved vaccines including cell and recombinant technologies)	$0.0	$9.6	$0.0	$0.0	$0.0	$9.6
ASPR BARDA	Pandemic Influenza - PHSSEF, Sup Bal No-Year	Pandemic Influenza	Vaccine Stockpile, Storage, Stability, and Testing	$0.0	$38.0	$0.0	$0.0	$0.0	$38.0

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 - FY 2022 Total
ASPR BARDA	Pandemic Influenza - PHSSEF, Sup Bal No-Year	Pandemic Influenza	Therapeutics Advanced Development	$0.0	$56.0	$0.0	$0.0	$0.0	$56.0
ASPR BARDA	Pandemic Influenza - PHSSEF, Sup Bal No-Year	Pandemic Influenza	Facilities, Infrastructure Readiness, and Sustainability	$0.0	$0.0	$148.4	$0.0	$0.0	$148.4
ASPR BARDA	Direct Appropriation, Multiyear	Anthrax	Therapeutics	$1.2	$4.0	$0.0	$0.0	$0.0	$5.2
ASPR BARDA	Direct Appropriation, Multiyear	Anthrax	Vaccine	$14.2	$21.7	$10.0	$35.0	$50.0	$130.9
ASPR BARDA	Direct Appropriation, Multiyear	Botulinum	Next generation candidates	$0.0	$0.0	$0.0	$25.0	$25.0	$50.0
ASPR BARDA	Direct Appropriation, Multiyear	BARDA EID		$0.0	$0.0	$0.0	$200.0	$200.0	$400.0
ASPR BARDA	Direct Appropriation, Multiyear	BARDA MCIP	Medical Countermeasures Innovation	$7.0	$39.0	$55.0	$150.0	$150.0	$401.0
ASPR BARDA	Direct Appropriation, Multiyear	BARDA Mgt & Admin		$92.0	$93.6	$60.0	$85.0	$85.0	$415.6
ASPR BARDA	Direct Appropriation, Multiyear	Broad Spectrum Antimicrobials	BARDA CARB	$107.0	$107.0	$107.0	$107.0	$107.0	$535.0
ASPR BARDA	Direct Appropriation, Multiyear	Broad Spectrum Antimicrobials		$109.3	$33.0	$73.0	$123.0	$123.0	$461.3
ASPR BARDA	Direct Appropriation, Multiyear	Chemical		$50.5	$35.7	$60.0	$115.0	$115.0	$376.2
ASPR BARDA	Direct Appropriation, Multiyear	Chemical	Pharmaceutical-Based Agents	$0.0	$0.0	$0.0	$350.0	$0.0	$350.0
ASPR BARDA	Direct Appropriation, Multiyear	CIADM	Operations	$0.0	$0.0	$0.0	$75.0	$50.0	$125.0
ASPR BARDA	Direct Appropriation, Multiyear	Cross-Cutting Science	Animal Models	$14.0	$15.1	$0.0	$40.0	$45.0	$114.1
ASPR BARDA	Direct Appropriation, Multiyear	Cross-Cutting Science	Clinical Services Network	$1.0	$1.1	$12.0	$5.0	$20.0	$39.1
ASPR BARDA	Direct Appropriation, Multiyear	Filoviruses		$19.0	$58.3	$32.0	$40.0	$75.0	$224.3

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 - FY 2022 Total
ASPR BARDA	Direct Appropriation, Multiyear	Other Threats	Vaccine Development	$0.0	$0.0	$0.0	$75.0	$0.0	$75.0
ASPR BARDA	Direct Appropriation, Multiyear	Rad/Nuc	ARS - Neutropenia/ Skin/Lung/GI	$75.2	$66.4	$60.0	$100.0	$120.0	$421.6
ASPR BARDA	Direct Appropriation, Multiyear	Rad/Nuc	Biodosimetry and Biodiagnostics	$23.9	$40.0	$48.0	$30.0	$40.0	$181.9
ASPR BARDA	Direct Appropriation, Multiyear	Rad/Nuc	Thermal Burn Products	$13.4	$28.7	$30.0	$50.0	$50.0	$172.1
ASPR BARDA	Direct Appropriation, Multiyear	Smallpox	Vaccine/Antivirals	$9.0	$18.0	$15.0	$30.0	$40.0	$112.0
			Subtotal (non-add)	**$1,514**	**$1,653**	**$1,698**	**$4,217**	**$3,671**	**$12,753**
NIH	Direct Appropriation, Annual	Anthrax	Basic/Other Research	$7.2	$7.5	$6.5	$6.6	$6.8	$34.6
NIH	Direct Appropriation, Annual	Anthrax	Vaccines	$5.5	$5.7	$4.9	$5.0	$5.1	$26.2
NIH	Direct Appropriation, Annual	Botulinum	Basic/Other Research	$0.9	$0.9	$0.8	$0.8	$0.8	$4.1
NIH	Direct Appropriation, Annual	Botulinum	Vaccines	$0.6	$0.7	$0.6	$0.6	$0.6	$3.1
NIH	Direct Appropriation, Annual	Botulinum	Antitoxins	$2.8	$2.9	$2.5	$2.6	$2.7	$13.5
NIH	Direct Appropriation, Annual	Broad Spectrum Antimicrobials	Antibiotics	$362.1	$413.6	$356.1	$365.7	$375.6	$1,873.0
NIH	Direct Appropriation, Annual	Broad Spectrum Antimicrobials	Antivirals	$77.7	$80.8	$69.6	$71.4	$73.4	$372.8
NIH	Direct Appropriation, Annual	Cross-Cutting Science	Basic/Other Research	$285.7	$296.1	$255.0	$261.9	$268.9	$1,367.5
NIH	Direct Appropriation, Annual	Cross-Cutting Science	Product Development	$142.8	$148.6	$133.8	$137.4	$141.1	$703.7
NIH	Direct Appropriation, Annual	Cross-Cutting Science	Translational	$128.2	$133.3	$114.8	$117.9	$121.0	$615.1
NIH	Direct Appropriation, Annual	Cross-Cutting Science	Animal Model	$22.2	$23.1	$19.9	$20.4	$21.0	$106.5

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 - FY 2022 Total
NIH	Direct Appropriation, Annual	Filoviruses	Basic/Other Research	$58.0	$60.3	$51.9	$53.4	$54.8	$278.4
NIH	Direct Appropriation, Annual	Filoviruses	Vaccines	$44.8	$46.6	$40.1	$41.2	$42.3	$214.9
NIH	Direct Appropriation, Annual	Pandemic Influenza	Basic/Other Research	$98.4	$102.3	$88.1	$90.4	$92.9	$472.0
NIH	Direct Appropriation, Annual	Pandemic Influenza	Vaccines	$149.7	$195.7	$168.5	$173.0	$177.7	$864.7
NIH	Direct Appropriation, Annual	Multiplex Diagnostics	Diagnostics	$101.9	$106.0	$91.3	$93.7	$96.3	$489.1
NIH	Direct Appropriation, Annual	Other Threats	Basic/Other Research	$433.5	$450.9	$388.2	$398.7	$409.4	$2,080.7
NIH	Direct Appropriation, Annual	Other Threats	Vaccines	$104.8	$109.0	$93.9	$96.4	$99.0	$503.1
NIH	Direct Appropriation, Annual	Smallpox	Basic/Other Research	$10.2	$10.6	$9.1	$9.4	$9.6	$48.9
NIH	Direct Appropriation, Annual	Smallpox	Vaccines	$1.0	$1.0	$0.9	$0.9	$0.9	$4.6
NIH	Direct Appropriation, Annual	Plague/Tularemia	Basic/Other Research	$5.9	$6.2	$5.3	$5.4	$5.6	$28.4
NIH	Direct Appropriation, Annual	Plague/Tularemia	Vaccines	$2.7	$2.8	$2.4	$2.5	$2.5	$12.9
NIH	Direct Appropriation, Annual	Broad Spectrum Antimicrobials	Antibiotics	$1.5	$1.5	$1.3	$1.3	$1.4	$7.0
NIH	Direct Appropriation, Annual	Multiplex Diagnostics	Diagnostics	$1.4	$1.4	$1.2	$1.3	$1.3	$6.5
NIH	Direct Appropriation, Annual	Other Threats	Basic/Other Research	$21.6	$22.8	$18.7	$19.2	$19.8	$102.1
NIH	Direct Appropriation, Annual	Other Threats	Vaccines	$2.0	$2.1	$1.8	$1.9	$1.9	$9.8
NIH	Direct Appropriation, Annual	Chemical	Chemical Countermeasures Research	$49.2	$49.2	$42.4	$43.5	$44.7	$228.9

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 - FY 2022 Total
NIH	Direct Appropriation, Annual	Rad/Nuc	Nuclear/Radiological Countermeasures	$47.9	$47.9	$41.3	$42.4	$43.5	$223.1
			Subtotal (non-add)	**$2,170**	**$2,329**	**$2,011**	**$2,065**	**$2,121**	**$10,695**
FDA	Direct Appropriation, Annual	FDA Regulatory Science	Antimicrobial Resistance MCM	$22.6	$22.2	$22.0	$22.6	$23.3	$112.7
FDA	Direct Appropriation, Annual	FDA Regulatory Science	CBRN MCM Base Funding (pre-MCMi)	$48.4	$48.6	$57.2	$58.9	$60.7	$273.8
FDA	Direct Appropriation, Annual	FDA Regulatory Science	MCMi Annual	$24.6	$24.6	$31.6	$46.1	$47.5	$174.3
FDA	Direct Appropriation, Annual	FDA Regulatory Science	Pandemic Influenza MCM	$40.5	$41.1	$43.7	$45.0	$46.3	$216.6
FDA	Ebola Emergency Funding, Multiyear, Direct	FDA Regulatory Science	Ebola Emergency	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
FDA	Transfer from No-Year PI Funding	FDA Regulatory Science	Transfer from No-Year Pandemic Influenza	$1.7	$0.0	$0.0	$0.0	$0.0	$1.7
FDA	Direct Appropriation, Multiyear	FDA Regulatory Science	MCMi Multiyear	$4.1	$4.1	$0.0	$0.0	$0.0	$8.2
			Subtotal (non-add)	**$142**	**$141**	**$154**	**$173**	**$178**	**$787**
ASPR SNS	Direct Appropriation, No-Year	Ancillary	Other supportive (incl. antimicrobials)	$17.0	$0.0	$10.9	$36.5	$27.6	$92.1
ASPR SNS	Direct Appropriation, No-Year	Ancillary	Therapeutic	$0.0	$5.0	$0.0	$0.0	$0.0	$5.0
ASPR SNS	Direct Appropriation, No-Year	Anthrax	Antibiotic	$126.2	$11.0	$37.7	$79.0	$79.2	$333.0
ASPR SNS	Direct Appropriation, No-Year	Anthrax	Therapeutic	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
ASPR SNS	Direct Appropriation, No-Year	Anthrax	Vaccine	$115.8	$145.0	$0.0	$0.0	$0.0	$260.8
ASPR SNS	Direct Appropriation, No-Year	Burkholderia	Antibiotic	$0.7	$0.7	$2.3	$2.3	$2.3	$8.4

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 - FY 2022 Total
ASPR SNS	Direct Appropriation, No-Year	Chemical	Anticonvulsant	$0.2	$2.2	$10.4	$0.2	$1.9	$14.9
ASPR SNS	Direct Appropriation, No-Year	Chemical	Nerve agent antidote	$29.3	$14.7	$97.1	$3.5	$6.4	$150.8
ASPR SNS	Direct Appropriation, No-Year	FMS	Antibiotic	$0.1	$0.1	$0.2	$0.2	$0.2	$0.7
ASPR SNS	Direct Appropriation, No-Year	Pandemic Influenza	Antiviral	$47.5	$25.5	$9.0	$222.7	$222.7	$527.3
ASPR SNS	Direct Appropriation, No-Year	Rad/Nuc	Antibiotic	$0.0	$0.0	$0.0	$0.3	$0.0	$0.3
ASPR SNS	Direct Appropriation, No-Year	Rad/Nuc	Antiviral	$1.5	$0.0	$0.0	$0.8	$0.8	$3.0
ASPR SNS	Direct Appropriation, No-Year	Rad/Nuc	Decorporation	$6.4	$0.0	$3.2	$3.2	$3.2	$16.1
ASPR SNS	Direct Appropriation, No-Year	Rad/Nuc	Other supportive (incl. antimicrobials)	$2.1	$5.0	$4.1	$7.1	$7.4	$25.6
ASPR SNS	Direct Appropriation, No-Year	Smallpox	Antiviral	$1.6	$1.6	$1.1	$0.8	$1.1	$6.2
ASPR SNS	Direct Appropriation, No-Year	Smallpox	Uricosuric	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1
ASPR SNS	Direct Appropriation, No-Year	Smallpox	Vaccine	$78.4	$136.4	$143.7	$248.2	$263.4	$870.1
ASPR SNS	Direct Appropriation, No-Year	SNS Non-Procurement	Operating	$15.0	$28.1	$28.9	$29.8	$30.7	$132.5
ASPR SNS	Direct Appropriation, No-Year	SNS Non-Procurement	Sustainment	$91.0	$148.9	$122.5	$126.2	$130.0	$618.6
ASPR SNS	Direct Appropriation, No-Year	SNS Non-Procurement	Program Support	$77.6	$85.5	$87.8	$90.5	$93.2	$434.6
ASPR SNS	Direct Appropriation, No-Year	Smallpox	Vaccine	$0.0	$0.0	$0.0	$0.0	$196.0	$196.0
ASPR SNS	Direct Appropriation, No-Year	Chemical	Nerve agent antidote	$0.0	$0.0	$0.0	$22.4	$19.2	$41.6
ASPR SNS	Direct Appropriation, No-Year	Rad/Nuc	Antineutropenic	$0.0	$0.0	$0.0	$67.0	$67.0	$134.0

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 - FY 2022 Total
ASPR SNS	Direct Appropriation, No-Year	Anthrax	Vaccine	$0.0	$0.0	$0.0	$0.0	$287.0	$287.0
ASPR SNS	Direct Appropriation, No-Year	Anthrax	Therapeutic	$0.0	$0.0	$0.0	$136.0	$17.9	$153.9
ASPR SNS	Direct Appropriation, No-Year	Rad/Nuc	Thermal Burn Products	$0.0	$0.0	$4.0	$4.0	$4.0	$12.0
ASPR SNS	Direct Appropriation, No-Year	Smallpox	Antiviral	$0.0	$0.0	$57.1	$0.0	$196.0	$253.1
Subtotal (non-add)				**$610**	**$610**	**$620**	**$1,081**	**$1,657**	**$4,578**

Appendix B – Agency or Office Figures and Tables

Figure 3. Estimated NIH MCM Spending by Portfolio, FYs 2018–2022 (dollars in millions)

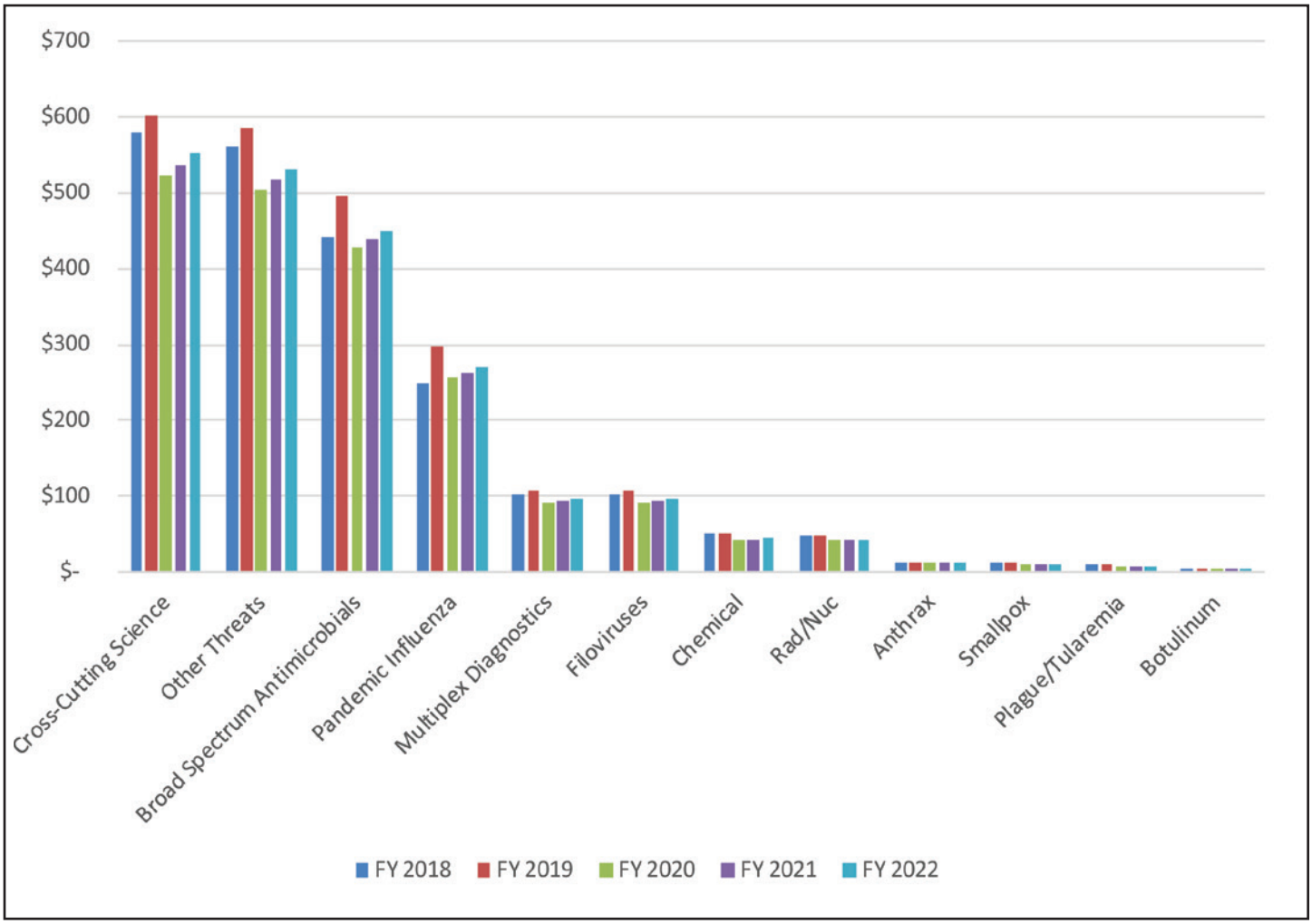


Figure 4. Estimated BARDA MCM Spending by Portfolio, FYs 2018–2022 (dollars in millions)

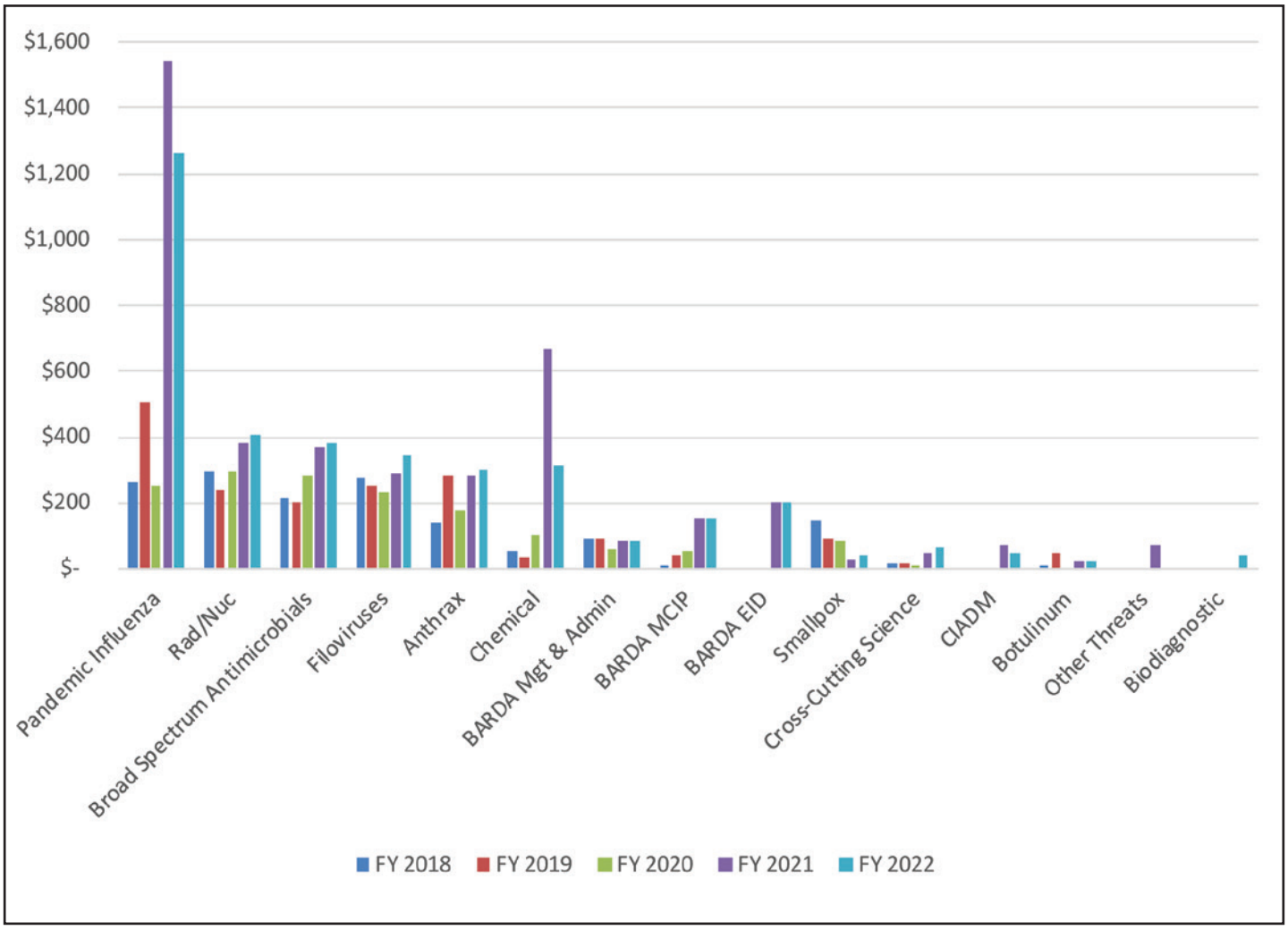


Table 4. Estimated BARDA MCM Spending by Funding Source, FYs 2018–2022 (dollars in millions)

Funding Source	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	Total
Advanced Research and Development	$537	$562	$562	$1,635	$1,295	$4,590
PI - PHSSEF, Annual Appropriations	$28	$28	$28	$127	$127	$338
PI - PHSSEF, Annual No-Year	$215	$225	$225	$1,415	$1,139	$3,218
PI - PHSSEF, Sup Bal No-Year	$24	$104	$148	$-	$-	$276
Project BioShield SRF, No-Year	$710	$735	$735	$1,040	$1,110	$4,330
Total	**$1,514**	**$1,653**	**$1,698**	**$4,217**	**$3,671**	**$12,753**

Figure 5. Estimated BARDA ARD MCM Spending by Portfolio, FYs 2018–2022 (dollars in millions)

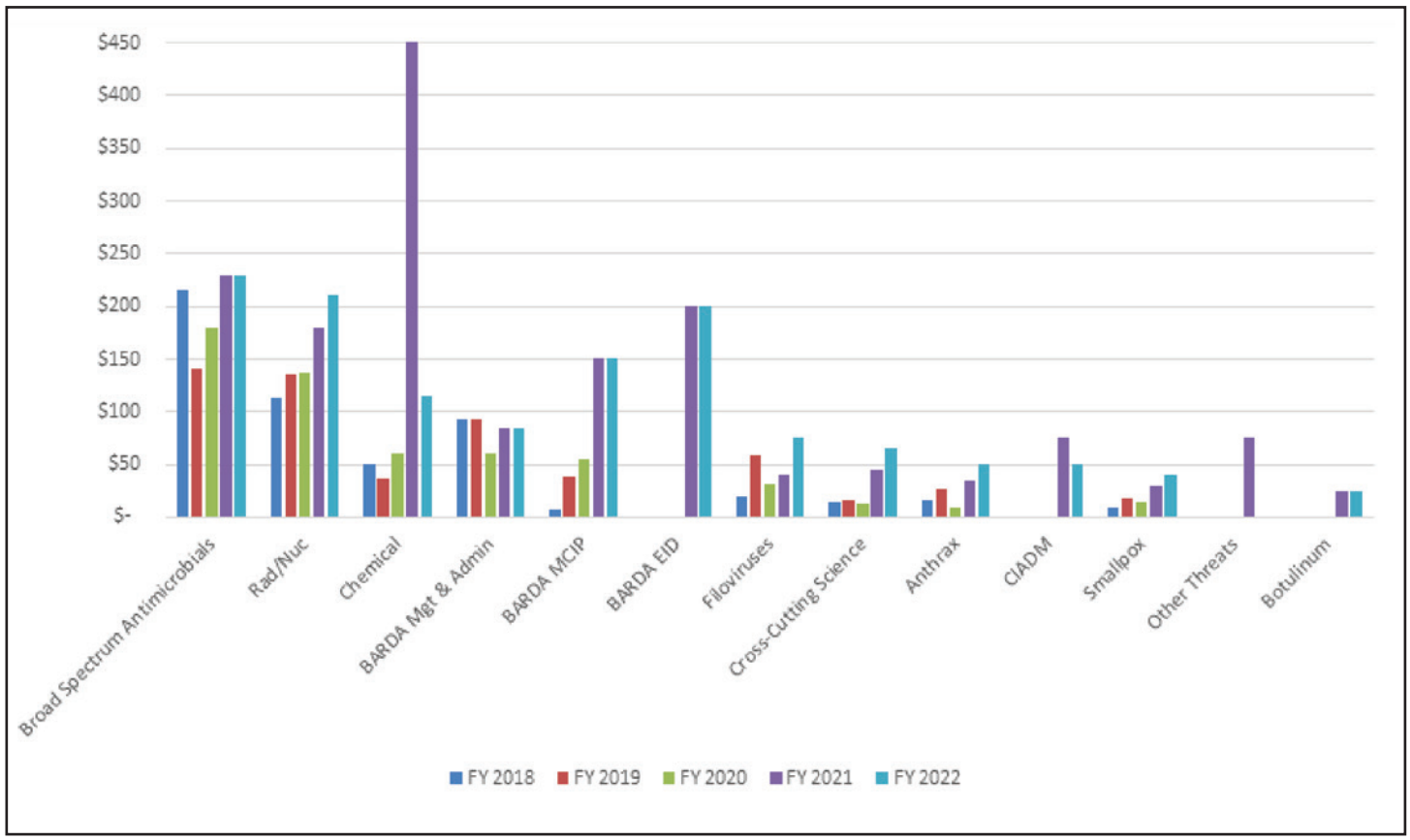


Figure 6. Estimated BARDA PBS MCM Spending by Portfolio, FYs 2018–2022 (dollars in millions)

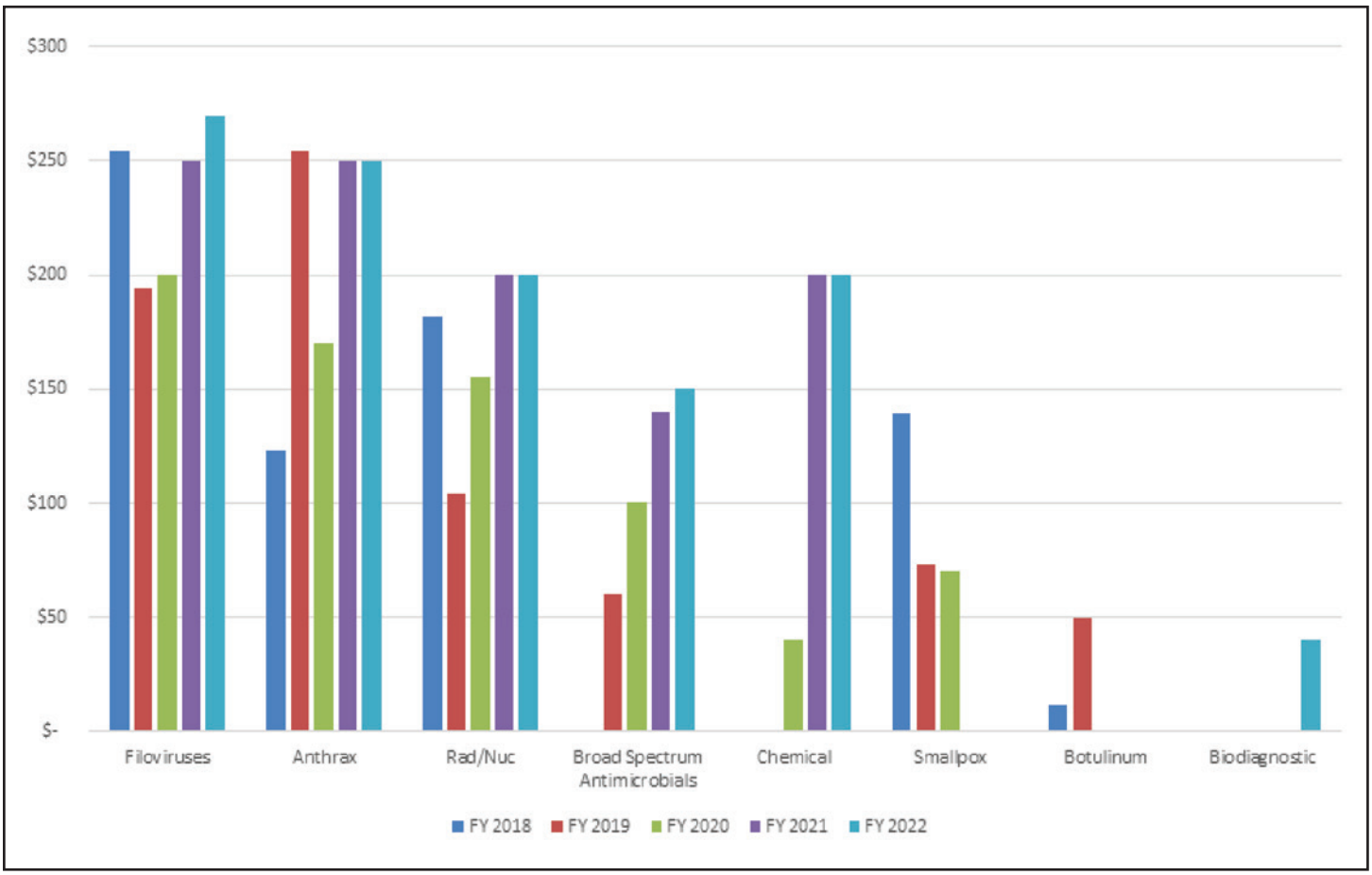


Figure 7. Estimated BARDA Pandemic Influenza MCM Spending by Portfolio, FYs 2018–2022 (dollars in millions)

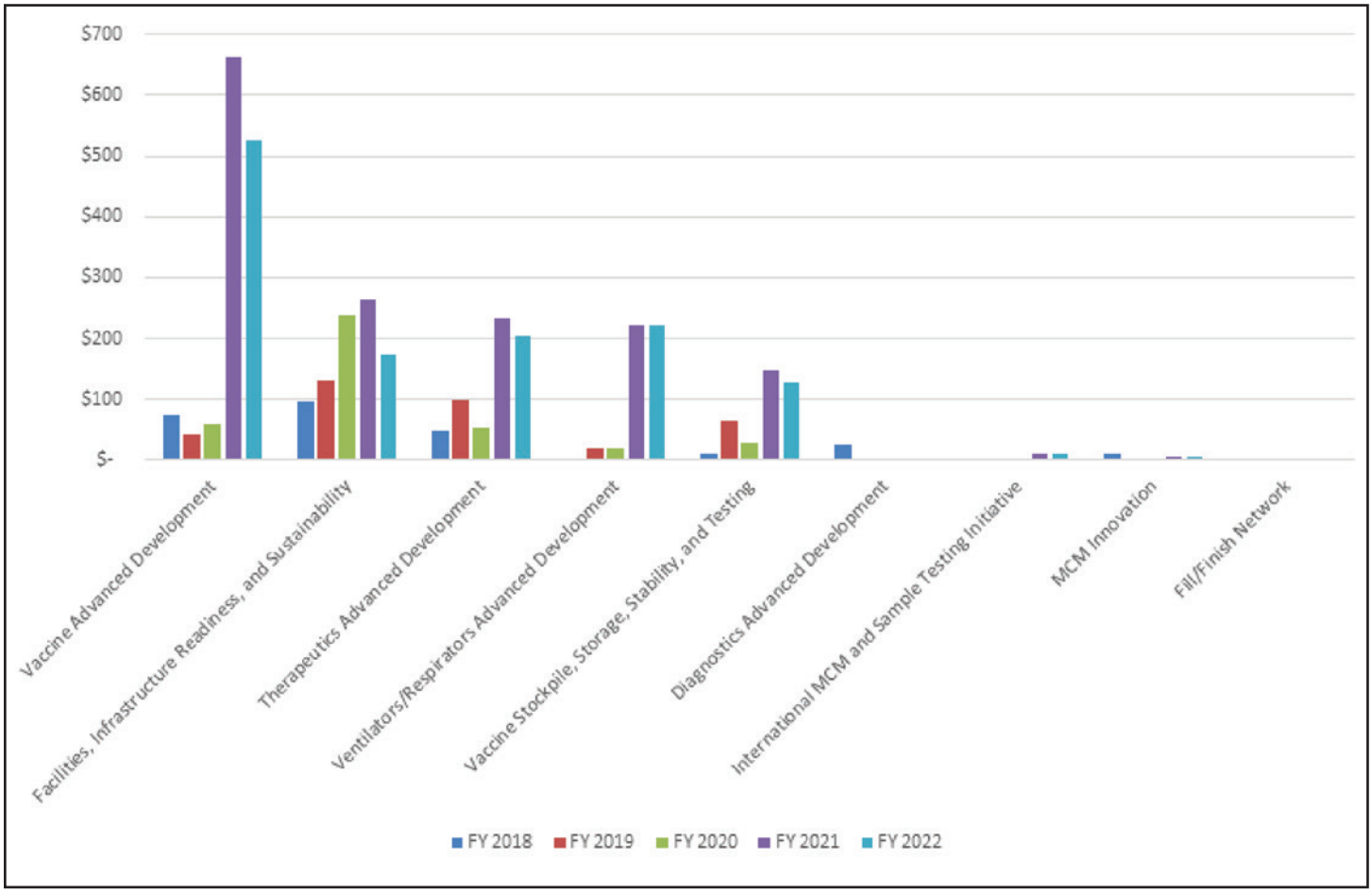


Figure 8. Estimated SNS MCM Spending by Portfolio, FYs 2018–2022 (dollars in millions)

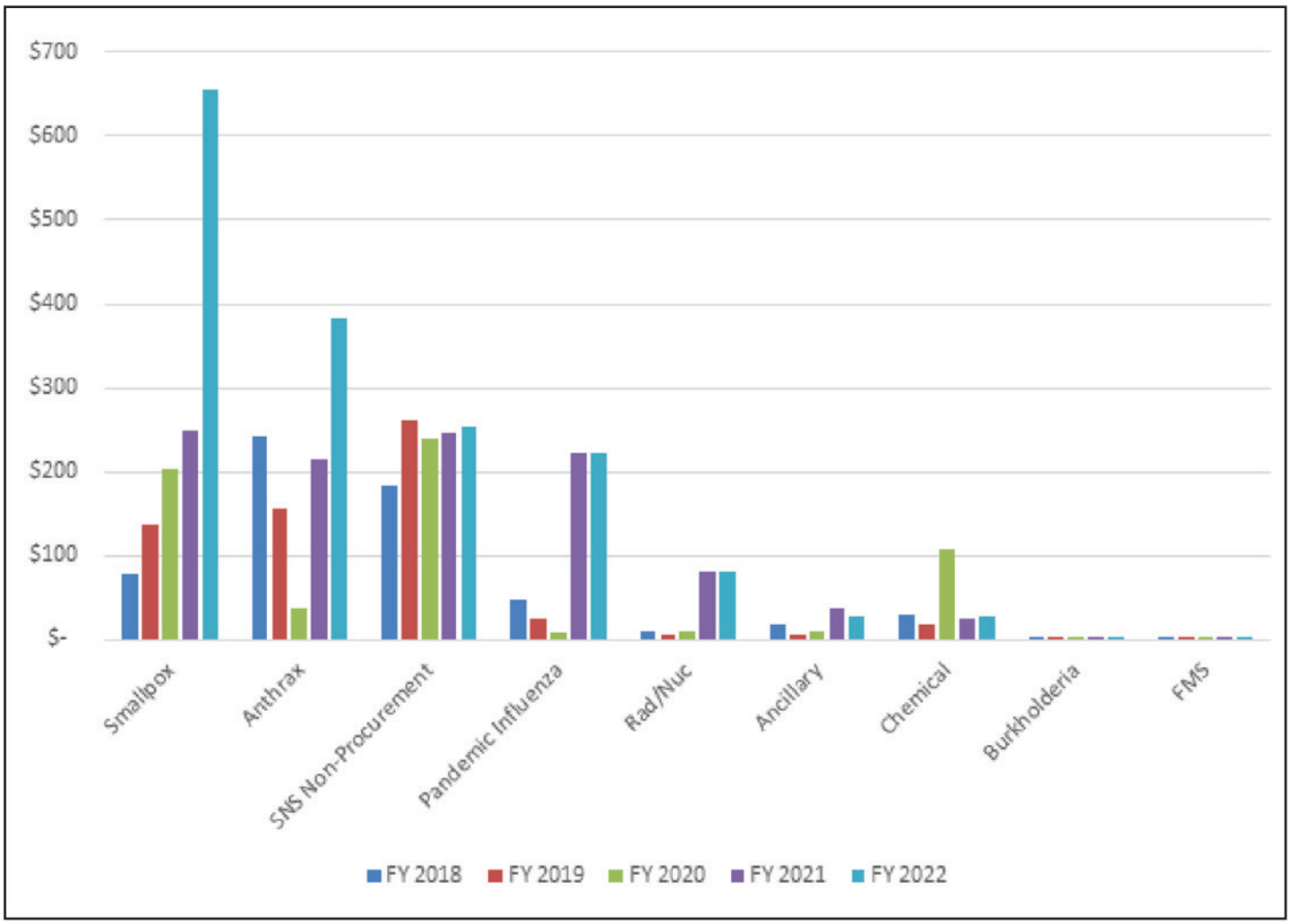
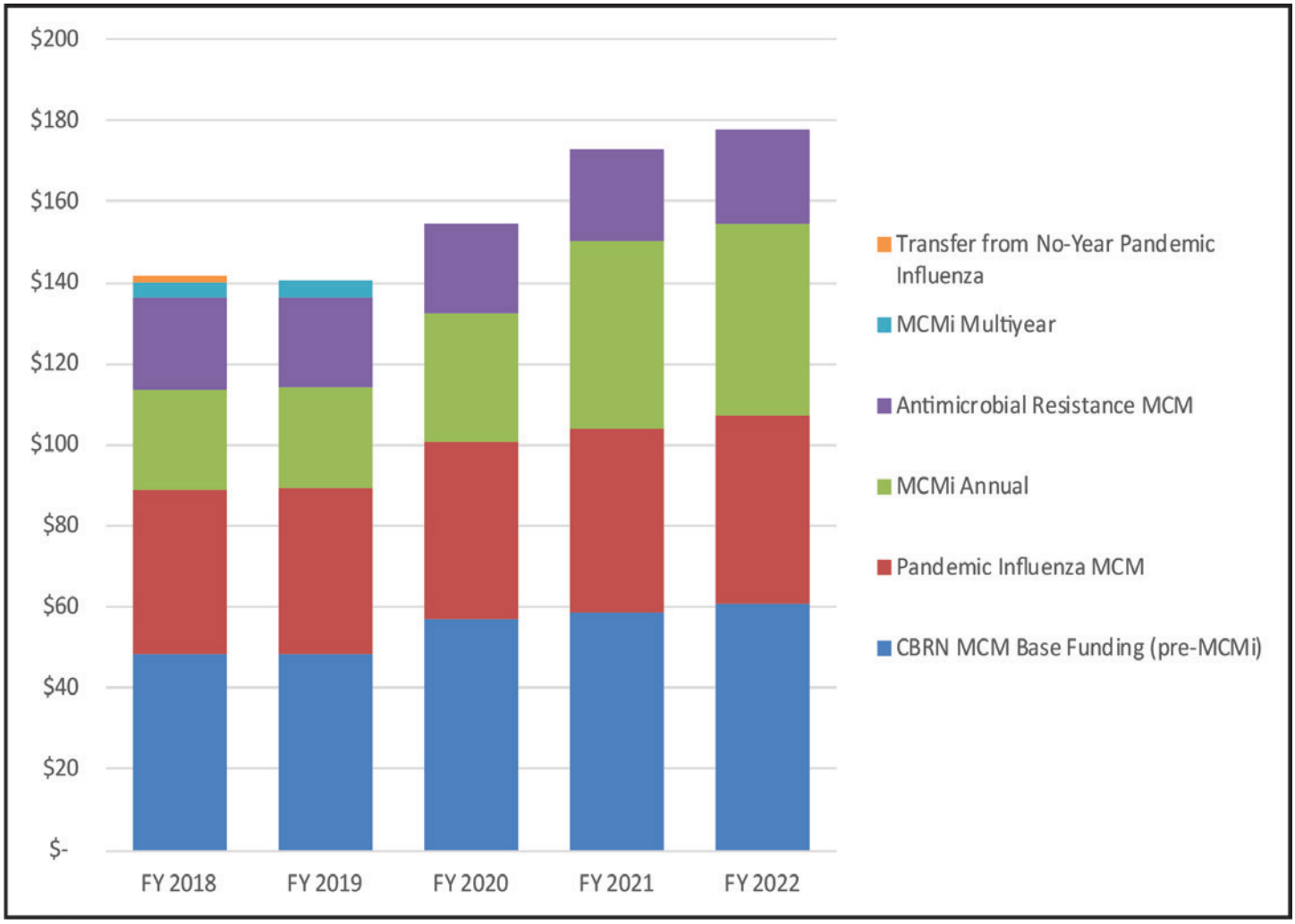


Figure 9. Estimated FDA MCM Spending by Portfolio, FYs 2018–2022 (dollars in millions)



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