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**EXECUTIVE OFFICE OF THE PRESIDENT**

**OFFICE OF MANAGEMENT AND BUDGET**

Report to Congress on Biodefense Activities

January 2023

## Report Summary

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This report provides analysis on the fiscal year (FY) 2023 President's Budget for biodefense activities pursuant to the request in section 363 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116-283). This report was developed prior to the enactment of the Consolidate Appropriations Act, 2022 on December 29, 2022. All information included in this report is unclassified.

The FY 2023 President's Budget requested an estimated \$11 billion in discretionary funding for biodefense activities across 16 departments and agencies. This figure does not include supplemental funding for COVID-19 response. Within this total, the highest contributing departments were the Department of Health and Human Services (59 percent of total funding) and the Department of Defense (15 percent of total funding).

The FY 2023 President's Budget also included \$88.2 billion in mandatory funding, available over five years, across the Department of Health and Human Services (HHS), the Department of State, and the U.S. Agency for International Development (USAID) to prepare for future biological threats to support national and global biodefense and pandemic preparedness strategies and plans. Within this request, \$81.7 billion was for HHS across the Administration for Strategic Preparedness and Response, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health, and \$6.5 billion is for the Department of State and USAID. Please refer to the [White House Fact Sheet: The Biden Administration's Historic Investment in Pandemic Preparedness and Biodefense in the FY 2023 President's Budget](#) for a detailed summary of the request. This report focuses on discretionary resources that broadly support biodefense activities, including pandemic preparedness. Thus, the report is broader in scope than the Administration's mandatory proposal for pandemic preparedness going forward.

About 90 percent of funds requested for biodefense activities in the FY 2023 President's Budget support one of three Biodefense Capabilities: Preparedness, Response, or Surveillance & Detection. The FY 2023 President's Budget also supported other Biodefense Capabilities, including: Prevention (6 percent of total requested funding); Recovery (2 percent of total requested funding); Threat Awareness (2 percent of total requested funding); and Mitigation (less than 1 percent of total requested funding).

Funding for biodefense activities in the FY 2023 President's Budget also advances all five goals of the National Biodefense Strategy (NBS):

1. Enable risk awareness to inform decision-making across the biodefense enterprise
2. Ensure biodefense enterprise capabilities to prevent bioincidents
3. Ensure biodefense enterprise preparedness to reduce the impacts of bioincidents
4. Rapidly respond to limit the impacts of bioincidents
5. Facilitate recovery to restore the community, the economy, and the environment after a bioincident

## **Purpose of Report**

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This report was prepared by the Office of Management and Budget (OMB) pursuant to section 363 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116-283):

### **SEC. 363. BIODEFENSE ANALYSIS AND BUDGET SUBMISSION.**

(a) Annual Analysis.--For each fiscal year, beginning in fiscal year 2023, the Director of the Office of Management and Budget, in consultation with the Secretary of Health and Human Services shall--

- (1) conduct a detailed and comprehensive analysis of Federal biodefense programs; and
- (2) develop an integrated biodefense budget submission.

(b) Definition of Biodefense.--In accordance with the National Biodefense Strategy, the Director shall develop and disseminate to all Federal departments and agencies a unified definition of the term "biodefense" to identify which programs and activities are included in the annual budget submission required under subsection (a).

(c) Requirements for Analysis.--The analysis required under subsection (a) shall include--

- (1) the display of all funds requested for biodefense activities, both mandatory and discretionary, by agency and categorized by biodefense enterprise element, such as threat awareness, prevention, deterrence, preparedness, surveillance and detection, response, attribution (including bioforensic capabilities), recovery, and mitigation; and
- (2) detailed explanations of how each program and activity included aligns with biodefense goals and objectives as part of the National Biodefense Strategy required under section 1086 of the National Defense Authorization Act for Fiscal Year 2017 (6 U.S.C. 104).

(d) Submittal to Congress.--The Director, in consultation with the Secretary of Health and Human Services, shall submit to Congress the analysis required under subsection (a) for a fiscal year concurrently with the President's annual budget request for that fiscal year.

## **Background on the National Biodefense Strategy**

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Section 104 of title 6, United States Code directs the Secretaries of Defense, Health and Human Services, Homeland Security, and Agriculture to jointly develop a national biodefense strategy and associated implementation plan.

The National Biodefense Strategy (NBS), issued in September 2018, brought together and put in place for the first time, a single coordinated effort to orchestrate the full range of activity that is carried out across the United States Government to protect the American people from biological threats. The NBS describes the goals and objectives that will guide the United States in assessing, preventing, detecting, preparing for, responding to, and recovering from a biological

incident, consistent with its international obligations, including those identified in the World Health Organization's International Health Regulations (2005). The five goals of the NBS are:

1. Enable risk awareness to inform decision-making across the biodefense enterprise
2. Ensure biodefense enterprise capabilities to prevent bioincidents
3. Ensure biodefense enterprise preparedness to reduce the impacts of bioincidents
4. Rapidly respond to limit the impacts of bioincidents
5. Facilitate recovery to restore the community, the economy, and the environment after a bioincident

On October 18, 2022, the Biden-Harris Administration released an updated strategy and vision for biodefense and pandemic preparedness that builds upon the 2018 NBS and incorporates lessons learned from the COVID-19 pandemic and other recent biological incidents. Data for this report was collected before release of the 2022 NBS and therefore aligns with the 2018 NBS. Subsequent reports will reflect the updated strategy and implementation plan.

## **Analytical Methods**

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This report is based on a government-wide data collection effort to identify all programs, projects, and activities (PPAs) that support biodefense activities. These data include funding requested for biodefense in the FY 2023 President's Budget and enacted in FY 2022. Of note, this report does not include supplemental funding appropriated in FY 2020 and FY 2021 to respond to the COVID-19 pandemic. In general, the supplemental funds were a one-time appropriation designated as an emergency requirement pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985, and thus, are not built into base annual funding of biodefense activities. FY 2022 Enacted served as the best estimate of baseline biodefense funding with which to compare the FY 2023 Budget request at the time the report was written.

To ensure all entities involved in this data collection effort used congruent definitions of the categories of biodefense funding, an interagency group of subject matter experts defined the terms included in Senate Report 116-111 and Public Law 116-283, that is: the biodefense enterprise elements (threat awareness, prevention, deterrence, preparedness, surveillance and detection, response, attribution, recovery, and mitigation) and bioforensic capabilities. The consensus of this group was that the terms "attribution" and "bioforensic capabilities" could best be understood by combining them into a new term "Bioforensics & Attribution," and that removing "deterrence" from the categories of biodefense funding helped to reduce overlap in definitions. The categories of biodefense funding used by OMB, herein referred to collectively as "Biodefense Capabilities" are: Threat Awareness, Prevention, Preparedness, Surveillance & Detection, Response, Recovery, Bioforensics & Attribution, and Mitigation. The subject matter experts defined the Biodefense Capabilities by cross-walking them to the sub-objectives of the NBS, as specified in Annex 1 of the 2018 *National Biodefense Strategy Implementation Plan*. In some cases, the sub-objectives of the NBS could be cross-walked to more than one Biodefense Capability, and thus, there is a small degree of overlap in the definitions of some of the Biodefense Capabilities. See Appendix A of this report for details on how the Biodefense Capabilities are defined in terms of the sub-objectives of the NBS.

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Departments and agencies identified PPAs that advance or could be expected to advance the goals of the NBS, and quantified, to the extent feasible, resources allocated to biodefense PPAs. In some cases, PPAs included biodefense-related work, but may not have had biodefense as a sole focus or explicit mission or goal. In such situations, for the purposes of quantifying biodefense investments, estimates were made to attribute a percentage of funding of the PPA to biodefense work. When biodefense funding within a given PPA was characterized as supporting more than one Biodefense Capability, for the purposes of quantifying investments by Biodefense Capability, total biodefense funding within the PPA was divided by the number of supported Biodefense Capabilities, and funding was attributed equally to each Biodefense Capability.

OMB will continue to work with the interagency working group to refine funding estimates attributable to biodefense. The aforementioned process was an initial approach to address the request in section 363 of Public Law 116-283. However, these capabilities are dated, overlap, and do not accurately reflect how agencies develop and execute biodefense budgets. In subsequent reports, OMB will use definitions from the updated 2022 National Biodefense Strategy and Implementation Plan to ensure a common government-wide understanding of biodefense capabilities and to reduce agency burden in development of this report. This approach will also track more closely to agency operations and budget execution, thereby providing a more practical assessment of biodefense investments.

## Analysis

### Biodefense Funding by Department/Agency

The FY 2023 President's Budget requests approximately \$11 billion for discretionary biodefense activities across 16 departments and agencies. Within this total, the highest contributing departments are the Department of Health and Human Services (59 percent of total funding) and the Department of Defense (15 percent of total funding). Table 1 below summarizes funding for biodefense activities by department and agency.

Department/Agency	Biodefense Funding (\$M)***	
	FY 2022 Enacted	FY 2023 Budget**
Department of Health and Human Services	8,237	6,689
Department of Defense	1,315	1,720
Department of Homeland Security	429	355
United States Agency for International Development	1,156	1,217
Department of Agriculture	527	593
Department of Labor	22	22
Department of State	61	314
Department of Energy	51	100
Federal Bureau of Investigation	84	79
Department of Veterans Affairs	71	72
Environmental Protection Agency	38	39
Department of Transportation	5	6
Department of Commerce	4	4
Department of the Treasury	4	4
Department of Justice	0.2	0.2
National Aeronautics and Space Administration	50	59
<b>TOTAL*</b>	<b>12,055</b>	<b>11,273</b>

\* Components may not sum to total due to rounding.

\*\* Table does not include \$88.2 billion in mandatory funding requested across HHS, USAID, and the Department of State to prepare for future biological threats.

\*\*\*The following Departments also reported mandatory funding in support of biodefense: \$20 million at HHS and \$129 million at USDA in both FY 2022 and FY 2023.

\*\*\*\*This table does not include classified information.

There is a \$782 million decrease in biodefense funding proposed for FY 2023 compared to FY 2022 due to programmatic and budget execution factors. For example, the FY 2022 levels reflect a heightened level of COVID-19 related services and activities at HHS to respond to the Omicron surge in cases and hospitalizations, which is not assumed in FY 2023 due to the

availability of effective vaccines and oral antiviral treatments and continued strategic investments of supplemental resources provided in FY 2020 and FY 2021. In addition, funding levels reflect multi-year efforts that were obligated upfront in FY 2022 but were not repeated in FY 2023, as well as timing of stockpiling contracts, which are mostly driven by replenishment needs and availability of relevant medical countermeasures.

### Support for the Goals of the National Biodefense Strategy

Table 2 reflects FY 2023 discretionary funding for biodefense activities in the FY 2023 President’s Budget totaling \$11 billion. The Budget supports the eight Biodefense Capabilities and aligns with the goals of the National Biodefense Strategy as outlined in Table 2.

When biodefense funding within a given PPA was characterized as supporting more than one Biodefense Capability, total biodefense funding within the PPA was divided by the number of supported Biodefense Capabilities, and funding was attributed equally to each Biodefense Capability. Biodefense funding that could not be categorized is included in the Not Categorized line in Table 2.

The majority of biodefense funding is allocated to support Goals 1, 2, 3 and 4 of the National Biodefense Strategy (Enable risk awareness to inform decision-making across the biodefense enterprise, Ensure biodefense enterprise capabilities to prevent bioincidents, Ensure biodefense enterprise preparedness to reduce the impacts of bioincidents, and Rapidly respond to limit the impacts of bioincidents) than for Goal 5 (Facilitate recovery to restore the community, the economy, and the environment after a bioincident).

<b>Table 2: Discretionary Biodefense Funding by Biodefense Capability &amp; Alignment with NBS Goals</b>		
<b>Biodefense Capability (\$M)</b>	<b>FY 2023 President’s Budget</b>	<b>NBS Goal(s) Supported</b>
Preparedness	5,861	Goals 2 & 3
Response	1,209	Goals 3 & 4
Surveillance & Detection	635	Goals 1 & 2
Prevention	264	Goal 2
Threat Awareness	200	Goals 1 & 4
Recovery	204	Goals 3 & 5
Bioforensics & Attribution	-	Goal 4
Mitigation	1	Goals 3 & 5
Not Categorized	2,898	-
<b>TOTAL*</b>	<b>11,273</b>	<b>All Goals</b>

\* Components may not sum to total due to rounding.

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In subsequent reports, OMB will use definitions from the 2022 National Biodefense Strategy and Implementation Plan to ensure a common government-wide understanding of biodefense capabilities and to reduce agency burden in development of this report. This approach will also track more closely to agency operations and budget execution, thereby providing a more practical assessment of biodefense investments.



## Appendix A

Cross-walk of Biodefense Capabilities to sub-objectives of the 2018 National Biodefense Strategy (NBS). Sub-objectives of the NBS are defined in Annex 1 of the 2018 *National Biodefense Strategy Implementation Plan*. Each sub-objective supports one of the five goals of the NBS.

Biodefense Capability	Supported NBS Sub-Objectives by NBS Goal				
	Goal 1 Sub-Objectives	Goal 2 Sub-Objectives	Goal 3 Sub-Objectives	Goal 4 Sub-Objectives	Goal 5 Sub-Objectives
Threat Awareness	1.1.1 1.1.2 1.1.3 1.2.2			4.1.1 4.1.3	
Prevention		2.1.1 2.1.2 2.1.3 2.1.4 2.1.5 2.1.6 2.2.1 2.3.1 2.3.2 2.3.3 2.4.1 2.4.2			
Preparedness		2.2.2 2.3.4	3.1.1 3.1.2 3.2.1 3.2.2 3.3.1 3.3.2 3.3.4 3.3.5 3.4.2 3.5.1 3.5.2 3.7.1 3.7.2 3.8.1 3.9.1 3.9.2 3.9.3 3.9.4		
Surveillance & Detection	1.2.1 1.2.2 1.2.3 1.2.4 1.2.5	2.1.4 2.1.5 2.1.6 2.1.7			
Response			3.3.3 3.3.4 3.4.1	4.1.2 4.2.1 4.2.2	

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Biodefense Capability	Supported NBS Sub-Objectives by NBS Goal				
	Goal 1 Sub-Objectives	Goal 2 Sub-Objectives	Goal 3 Sub-Objectives	Goal 4 Sub-Objectives	Goal 5 Sub-Objectives
			3.4.3	4.2.3 4.2.4 4.2.5 4.4.1	
Bioforensics & Attribution				4.3.1 4.3.2 4.3.3	
Recovery			3.3.6 3.9.4		5.1.1 5.2.1 5.3.1
Mitigation			3.6.1		5.3.1 5.4.1