



Testimony

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NATIONAL BIODEFENSE STRATEGY

Opportunities and Challenges with Early Implementation

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Chairwoman Maloney, Ranking Member Jordan, and Members of the Committee:

We are pleased to be here today to discuss our recently issued work on the National Biodefense Strategy.¹ Catastrophic biological threats highlight the inextricable link between security and public health concerns. These threats—whether naturally-occurring, intentional, or accidental—have the potential to cause loss of life and sustained damage to the economy, societal stability, and global security. The vast and evolving biological threat landscape includes threats of naturally-occurring infectious diseases, bioterrorism, and safety and security lapses at facilities that house biological threat agents. For example, the unpredictable nature of naturally-occurring disease, such as the novel coronavirus (COVID-19), poses a threat to humans. As of March 5, 2020, COVID-19 has spread from China to nearly 80 countries, including the United States, which has over 150 cases and nearly a dozen deaths associated with the virus. This novel virus poses a public health and economic threat, and may eventually be declared a pandemic, as seen with severe acute respiratory syndrome (SARS) in 2003. Infectious diseases, such as coronaviruses, can be transmissible from animals to humans, demonstrating how our relationships with animals may increase the risk of disease transmission among people, pets, livestock, and wildlife.

Since March 2011, we have called for a more strategic approach to guiding the systematic identification of risks, assessing resources needed to address those risks, and prioritizing and allocating investments across the biodefense enterprise.² At that time, we said the biodefense enterprise would benefit from institutionalized leadership with sufficient time, responsibility, authority, and resources needed to promote efficiency and accountability. Similarly, so that leadership can help to ensure that federal programs are well coordinated, and that gaps and duplication in capabilities are avoided, we called for a strategy that would help ensure

¹GAO, *National Biodefense Strategy: Additional Efforts Would Enhance Likelihood of Effective Implementation*, [GAO-20-273](#) (Washington, D.C.: Feb. 19, 2020).

²The nation's biodefense capabilities consist of all efforts to counter biological threats, reduce risks, and prepare for, respond to, and recover from biological incidents that could have catastrophic consequences. GAO, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue*, [GAO-11-318SP](#) (Washington, D.C.: Mar. 1, 2011).

that plans and actions across various biodefense functions are cohesive, compatible, and mutually reinforcing.

Signed into law in December 2016, the National Defense Authorization Act for Fiscal Year 2017 (NDAA) required the departments of Defense (DOD), Health and Human Services (HHS), Homeland Security (DHS), and Agriculture (USDA) to jointly develop a national biodefense strategy and associated implementation plan.³ In September 2018, the White House issued the National Biodefense Strategy (Strategy) and characterized it as a new direction to protect the nation against biological threats, stating that its implementation would promote a more efficient, coordinated, and accountable biodefense enterprise. At the same time, the President issued the Presidential Memorandum on the Support for National Biodefense/National Security Presidential Memorandum-14 (NSPM-14), which details a governance structure and implementation process to achieve the Strategy's goals. For example, it established two governing bodies: the Biodefense Steering Committee—chaired by the Secretary of HHS—and the Biodefense Coordination Team to support the efforts of the Steering Committee.⁴

Our testimony today highlights key findings from our February 2020 report, which analyzed the extent to which the Strategy and related implementation efforts are designed to allow an enterprise-wide approach.⁵ We made four recommendations to HHS in our report, aimed at improving the Strategy's implementation. HHS concurred with our recommendations.

For our February 2020 report, we evaluated the early Strategy implementation efforts of HHS, DOD, USDA, and DHS; the departments of State, Justice (specifically the FBI), and Veterans Affairs (VA); and the

³ See Pub. L. No. 114-328, § 1086, 130 Stat. 2000, 2423 (2016) (codified at 6 U.S.C. § 104).

⁴The Biodefense Steering Committee is chaired by the Secretary of HHS and consists of the Secretaries of DOD, USDA, DHS, and the Departments of State and Veterans Affairs (VA); the Attorney General; and the Administrator of the Environmental Protection Agency (EPA). The Biodefense Coordination Team members include representatives from: HHS (including the Office of the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention, the National Institutes of Health, and the Food and Drug Administration), DOD, DHS, EPA, USDA, Department of Justice (including the FBI), Department of State, VA, the Office of the Director of National Intelligence, the U.S. Agency for International Development, and the Departments of Commerce, Energy, Treasury, Interior, Transportation, and Labor.

⁵[GAO-20-273](#).

Environmental Protection Agency (EPA). We analyzed the Strategy and associated plans, reviewed agency products created in response to requirements set forth in NSPM-14, and solicited perspectives from key officials in the eight agencies named above. More information on our scope and methodology can be found in the report. The work on which this statement is based was performed from October 2018 to February 2020 in accordance with generally accepted government auditing standards.

The Biodefense Strategy Provides Opportunity to Create an Enterprise-Wide Approach, but Implementation Challenges Remain

We found that the National Biodefense Strategy and associated plans bring together all the key elements of federal biodefense capabilities, which presents an opportunity to identify gaps and consider enterprise-wide risk and resources for investment trade-off decisions.⁶ However, challenges with planning to manage change; limited guidance and methods for analyzing capabilities; and lack of clarity about decision-making processes, roles, and responsibilities while adapting to a new enterprise-wide approach could limit the success of the Strategy's implementation.

Framework Created to Assess Enterprise-Wide National Biodefense Capabilities

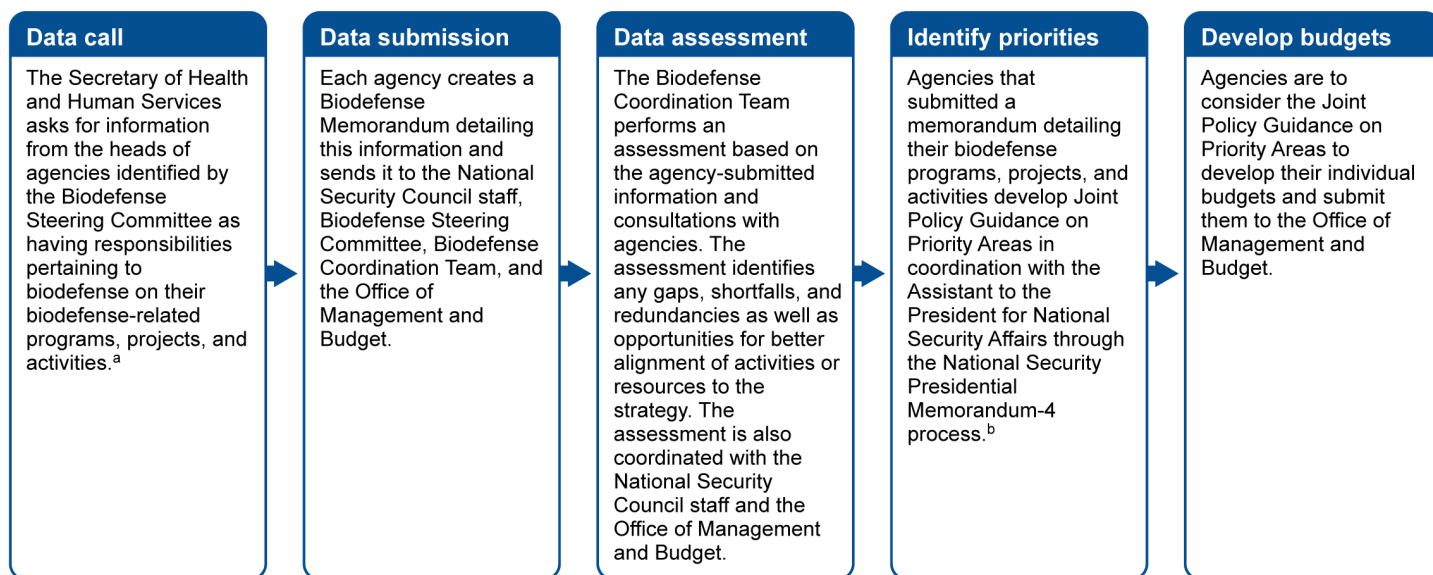
The National Biodefense Strategy and its associated plans bring together the efforts of federal agencies with significant biodefense roles, responsibilities, and resources to address naturally-occurring, accidental, and intentional threats. The Strategy and plans also provide processes for collecting and analyzing comprehensive information across the enterprise, an important step toward the kind of enterprise-wide strategic decision-making we have called for. The Strategy defines the term "biothreat" broadly to include all sources of major catastrophic risk, including naturally-occurring biological threats, the accidental release of pathogens, and the deliberate use of biological weapons. Officials we interviewed noted that this is the first time that the federal government has identified activities across the whole biodefense enterprise and assessed resources and gaps to address multiple sources of threat regardless of source.

The Strategy also outlines high-level goals and objectives to help define priorities. NSPM-14, which was issued to support the strategy,

⁶"Associated plans" refers to the implementation plan, which was included as Annex I in the National Biodefense Strategy, and NSPM-14, which accompanied the release of the Strategy and provides a governance structure to guide the Strategy's implementation.

established a structure and process by which federal agencies can assess enterprise-wide biodefense capabilities and needs, and subsequently develop guidance to help inform agency budget submissions. NSPM-14 lays out, in broad strokes, a process to identify biodefense efforts and assess how current resources support the Strategy, how existing programs and resources could better align with the Strategy, and how additional resources, if available, could be applied to support the goals of the Strategy. As shown in figure 1, this process begins through a data call with participating agencies documenting all biodefense programs, projects, and activities within their purview in a biodefense memorandum.

Figure 1: Process to Identify and Assess Biodefense Activities to Inform Budget Submissions



Source: GAO analysis of National Security Presidential Memorandum-14 and agency information. | GAO-20-483T

^aNational Security Presidential Memorandum-14 identifies the heads of these agencies as “Covered Officials.”

^bNational Security Presidential Memorandum-4, issued in 2017, describes the National Security Council’s organization. It assigns the role of managing the development and implementation of national security policies by multiple executive departments and agencies to policy coordination committees. These committees are designed to provide policy analysis for consideration by the more senior committees of the national security system and ensure timely responses to the President’s decisions.

In interviews, officials from participating agencies stated that the NSPM-14 processes constitute a new approach to identifying gaps and setting budget priorities for biodefense, and that they viewed the approach as generally well designed. Additionally, agency officials said that the

assessment and joint policy guidance development process outlined in NSPM-14 offered some promise for helping agencies identify the resources necessary to achieve the Strategy's goals. Nevertheless, officials from all of the agencies we interviewed, even those with the most optimistic views on the leadership and governance structure design, tempered their responses with the caveat that implementation is in such early stages that it remains to be seen how effective these structures will actually be once tested.

Implementation Challenges Remain

In our February 2020 report, we also identified challenges that if not addressed could hinder enterprise-wide biodefense efforts. Specifically, although the Strategy and associated plans establish the foundation for enterprise risk management, we and biodefense agency officials identified multiple challenges that could affect the Strategy's implementation.⁷ These include challenges individual agencies faced during the initial data collection process as well as a lack of planning and guidance to support an enterprise-wide approach. In our analyses and interviews, we found that parts of the process in the first year were underdeveloped, raising questions about (1) the plans to support change management practices and ensure that early-implementation limitations do not become institutionalized in future years' efforts; (2) guidance and methods for meaningfully analyzing the data; and (3) the clarity of decision-making processes, roles, and responsibilities.

Challenges adapting to new procedures. During our interviews, agency officials reported challenges they faced in the first-year's data collection effort. These challenges may have led to incomplete data collection, but are not wholly unexpected given they occurred in the context of the individual agencies and officials adapting to new procedures and a broader cultural shift from how they have approached their biodefense missions in the past. Officials told us that because of the learning involved the first time through the process, agencies may not have submitted complete or detailed information about their biodefense programs. Some officials we interviewed voiced concern that this first-year effort could set a poor precedent for these activities in future years if the challenges are

⁷Enterprise risk management is a strategy for helping policymakers make decisions about assessing risks, allocating resources, and taking actions under conditions of uncertainty. For some areas, like biodefense, where activities cut across multiple federal and nonfederal entities, applying enterprise risk management principles becomes more challenging, but equally important to help ensure the responsible parties can make decisions that help to ensure effectiveness and maximize opportunities to better manage risk.

not acknowledged and addressed. For example, an official noted that committing to the first-year's results as the "baseline" for future years of the Strategy's implementation could compound or institutionalize the issues encountered in the first year. Officials from HHS and Office of Management and Budget staff stressed that this process will be iterative, with the first year being primarily about outlining the existing biodefense landscape.

Our prior work on organizational transformations states that incorporating change management practices improves the likelihood of successful reforms and notes that it is important to recognize agency cultural factors that can either help or inhibit reform efforts.⁸ However, the agencies involved in implementing the Strategy do not have a plan that includes change management practices that can help prevent these challenges from being carried forward into future efforts, and help reinforce enterprise-wide approaches, among other things. To address this issue, we recommended the Secretary of HHS direct the Biodefense Coordination Team to establish a plan that includes change management practices—such as strategies for feedback, communication, and education—to reinforce collaborative behaviors and enterprise-wide approaches and to help prevent early implementation challenges from becoming institutionalized. HHS concurred with this recommendation.

Guidance and methods for analyzing data. We found a lack of clear procedures and planning to help ensure that the Biodefense Coordination Team is prepared to analyze the data, once it has been collected, in a way that leads to recognition of meaningful opportunities to leverage resources in efforts to maintain and advance national biodefense capabilities. In particular, HHS (1) has not documented guidance and methods for analyzing the data, including but not limited to methods and guidance for how to account for the contribution of nonfederal capabilities; and (2) does not have a resource plan for staffing and sustaining ongoing efforts. Specifically, we found that the processes for the Biodefense Coordination Team to analyze the results of all the individual agency data submissions and identify priorities to guide resource allocation were not agreed upon or documented prior to the agency efforts and continue to lack specificity and transparency. In our interviews, officials from four agencies said they were uncertain about fundamental elements of the

⁸GAO, *Government Reorganization: Key Questions to Assess Agency Reform Efforts*, [GAO-18-427](#) (Washington, D.C.: June 13, 2018) and *Results-Oriented Cultures: Implementation Steps to Assist Mergers and Organizational Transformations*, [GAO-03-669](#) (Washington, D.C.: Jul. 2, 2003).

implementation process, including how information gathered will be used to identify gaps and set priorities. Additionally, the initial effort to collect information on all programs, projects, and activities focused on existing federal activities and did not include a complete assessment of biodefense capabilities at the nonfederal level—capabilities needed to achieve the goals and objectives outlined in the Strategy.

Officials we interviewed also expressed concern about the resources that the Biodefense Coordination Team had available to it, both in the first year and on an ongoing basis. The officials told us that not all agencies were able to provide a full-time detailee to help support the team. We have previously reported that agencies need to identify how interagency groups will be funded and staffed.⁹ However, officials from multiple agencies told us that the initial planning for the staffing and responsibilities for the Biodefense Coordination Team had not been finalized. Without a plan to help ensure sufficient resources and mitigate resource challenges for ongoing efforts, the Biodefense Coordination Team risks not having the capacity it needs to conduct meaningful analysis, which would undermine the vision created by the Strategy and NSPM-14. To address these issues, we recommended the Secretary of HHS direct the Biodefense Coordination Team to (1) clearly document guidance and methods for analyzing the data collected from the agencies, including ensuring that nonfederal resources and capabilities are accounted for in the analysis, and (2) establish a resource plan to staff, support, and sustain its ongoing efforts. HHS concurred with both recommendations.

Roles and responsibilities for joint decision-making. The governing bodies overseeing the National Biodefense Strategy’s implementation—the Biodefense Steering Committee and Biodefense Coordination Team—did not clearly document key components of the assessment process and roles and responsibilities for joint decision-making in the first year of NSPM-14 implementation. This raises questions about how these bodies will move from an effort to catalog all existing activities to decision-making that accounts for enterprise-wide needs and opportunities. For example, officials from multiple agencies were not certain how the governing bodies would make joint decisions regarding priority-setting and the allocation of resources, how they would assign new biodefense

⁹GAO, *Managing for Results: Implementation Approaches Used to Enhance Collaboration in Interagency Groups*, [GAO-14-220](#) (Washington, D.C.: Feb. 14, 2014) and *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

responsibilities if gaps were identified, and to what extent the Biodefense Steering Committee could enforce budgetary priorities, if at all.

We also found a lack of shared understanding and agreement about how the interagency process would work to align resources toward any identified gaps and reconfigure resources for any identified redundancies or inefficiencies. Additionally, we found that Presidential memorandums guiding the process did not detail specific decision-making principles or steps for reaching consensus or even for raising decision points about how to best leverage or direct resources across the enterprise in response to any gaps or inefficiencies. Similarly, agency officials we interviewed were not clear how this process would work, how decisions would be made, or how agencies would agree to take on new responsibilities to bridge gaps to achieve the Strategy's goals.

Further, the governing bodies have not fully defined the roles and responsibilities for making enterprise-wide decisions that affect individual agency budgets and for enforcing enterprise-wide budget priorities. As with other parts of the NSPM-14 implementation process, the details regarding specific roles and responsibilities for directing and enforcing budget decisions lack detail and specificity. Additionally, officials from four agencies stated that the charter for the Biodefense Coordination Team has not been finalized, further delaying the articulation of roles and responsibilities and the ability to establish a shared agenda and common operating picture. As a result, some officials remain skeptical of the effectiveness of any decisions made.

We previously reported that effective national strategies should help clarify implementing organizations' relationships in terms of leading, supporting, and partnering.¹⁰ In the context of the Strategy, that includes how enterprise-wide decisions about leveraging or directing resources to fill gaps and reduce inefficiency will be made and by whom. Similarly, our previous work has found that articulating and agreeing to a process for making and enforcing decisions and clarifying roles and responsibilities can improve the clarity surrounding a shared outcome, and that articulating these agreements in formal documents can strengthen agency commitment to working collaboratively and provide the overall framework for accountability and oversight.¹¹ Uncertainty around the

¹⁰GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, [GAO-04-408T](#) (Washington, D.C.: Feb. 3, 2004).

¹¹[GAO-12-1022](#).

mechanisms to identify enterprise-wide priorities along with the lack of clearly documented and agreed upon processes, roles, and responsibilities for joint decision-making jeopardize the Strategy's ability to enhance efficiency and effectiveness of the nation's biodefense capabilities. To address this issue, we recommended that the Secretary of HHS direct the Biodefense Coordination Team to clearly document agreed upon processes, roles, and responsibilities for making and enforcing enterprise-wide decisions. HHS concurred.

In conclusion, the current COVID-19 outbreak demonstrates that responding to the ever-changing nature and broad array of biological threats is challenging. The National Biodefense Strategy calls for the need to improve state, local, tribal, territorial, private sector, federal, regional, and international surveillance systems and networks to contain, control and respond to biological incidents. As the current coronavirus outbreak continues to cross regional and international borders, the federal government must take necessary steps to protect the American public.

At the same time, we must not lose sight of the next threat. The National Biodefense Strategy and NSPM-14 put in place a framework to be able to assess threats and make difficult decisions about how to apply limited resources to achieve the best benefit. However, the Strategy is only as good as its implementation. Taking the necessary steps to address the recommendations we have made regarding managing this cultural change, analyzing data, ensuring sufficient resources to maintain implementation efforts, and clearly articulating roles and responsibilities for joint decision-making will better position our nation for the threats we face today and in the future.

Chairwoman Maloney, Ranking Member Jordan, and Members of the Committee, this concludes our prepared statement. We would be happy to respond to any questions you may have at this time.

GAO Contact and Staff Acknowledgments

If you or your staff has any questions concerning this testimony, please contact Christopher P. Currie at (404) 679-1875, CurrieC@gao.gov or Mary Denigan-Macauley at (202) 512-7114, DeniganMacauleyM@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Individuals making key contributions to this statement include Kathryn Godfrey (Assistant Director), Susanna Kuebler (Analyst-In-Charge), Michele Fejfar, Eric Hauswirth, Tracey King, and Jan Montgomery. Key contributors for the previous work that this testimony is based on are listed in each product.

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