

Clear Lines of Responsibility Would Facilitate Implementation of the National Biodefense Strategy

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KEY TAKEAWAYS

There has been little discussion of the current National Biodefense Strategy, the foundation for the federal government's pandemic preparedness and response.

The biodefense enterprise is currently extremely fragmented and requires a herculean level of coordination at the higher levels of the federal government.

Now is the time for the Administration and Congress to create better budgetary visibility and better lines of authority over the federal biodefense enterprise.

Amidst a global pandemic that has seen tens of thousands of Americans lose their lives and tens of millions lose their jobs, there is little discussion of the current National Biodefense Strategy (NBS), which should be serving as the foundation for the federal government's preparedness and response to the pandemic. That may be because its implementation is frustrated by the lack of clear lines of accountability and responsibility.

Further complicating efforts, it is challenging to get a complete picture of how much the federal government actually allocates to health security, which includes pandemic preparedness, biosecurity, and multiple hazard preparedness. The federal government itself does not have a clear answer for it. In the year for which credible, non-governmental data exists, approximately \$13.6 billion was applied at the federal level for health security.¹

This paper, in its entirety, can be found at <http://report.heritage.org/ib5079>

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Is that too little? Too much? Only by establishing a tighter correlation between necessary tasks and required funding can Congress and officials in the executive branch even hope to make such an assessment. Now is the time to create better budgetary visibility and better lines of authority over the federal biodefense enterprise.

National Biodefense Strategy

The National Defense Authorization Act (NDAA) for Fiscal Year 2017 required the development of a National Biodefense Strategy and an associated implementation plan.² It further required the Government Accountability Office (GAO) to review the strategy and identify gaps in implementation.³ The NBS was released to the public on September 18, 2018.⁴ Accompanying the strategy, the White House also released a Presidential Memorandum to support the implementation.⁵

The NBS outlines a vision in which it “prevents, prepares for, responds to, recovers from, and mitigates risk from natural, accidental, or deliberate biological threats.”⁶ In this strategy, the term biodefense encompasses both preparations for a biological attack and for a naturally occurring outbreak.

Since the 2001 anthrax attacks brought biological weapons to the forefront of the American imagination, the federal government has worked on strategies to prepare the government and the country to better handle biological challenges. The current National Biodefense Strategy is the fourth since 2004. On April 28, 2004, the Bush Administration released a Homeland Security Presidential Memorandum titled “Biodefense for the 21st Century.”⁷ It identified four pillars for biodefense: threat awareness, prevention and protection, surveillance and detection, and response and recovery. All the pillars require the coordination and integration of multiple federal agencies. On November 1, 2005, the Administration also released a “National Strategy for Pandemic Influenza.”⁸

The Obama Administration released two documents related to biodefense: the 2009 National Strategy for Countering Biological Threats and the 2012 National Strategy for Biosurveillance.⁹ The strategies are valuable in the sense that they highlight the continuing importance of the issue and provide a framework to think about federal action in the area.

The Trump Administration’s National Biodefense Strategy follows in those footsteps and goes one beyond by issuing a presidential memorandum identifying relevant actors and creating a structure to move the strategy forward.¹⁰ The strategy establishes five goals for the biodefense enterprise:

1. Risk awareness, such as determining biological risks;
2. Prevention capabilities, such as minimizing the chances of laboratory accidents and strengthening biosecurity;
3. Preparedness, such as ensuring a strong public health infrastructure;
4. Rapid response, such as information-sharing networks and public communications; and
5. Enabling recovery, such as recovery support and impact mitigation.¹¹

The presidential memorandum created a Biosecurity Steering Committee, a Biodefense Coordination Team to support the committee, and issued a data call for budgetary data from the federal agencies involved. However, looking at the situation later, “GAO found there are no clear, detailed processes, roles, and responsibilities for joint decision-making, including how agencies will identify opportunities to leverage resources or who will make and enforce those decisions.”¹²

Because of those challenges, the GAO pointed out that the fiscal year 2022 budget, set to be released in February 2021, would be the first one in which impact of the NBS implementation might be observable.¹³ Along these lines, the GAO also found that “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.”¹⁴

Further, the GAO added that “[a]gency officials we interviewed noted that the process for the identification of biodefense resources and activities across the federal government outlined by NSPM-14 could be ‘transformational’ for the biodefense enterprise and approached the data collection process in good faith, but said that it will take time to get right.”¹⁵ Changing practices within a federal bureaucracy takes time under the best of circumstances—let alone changing the practices and budgets of over 20 agencies.

Extreme Fragmentation Has Inherent Challenges

Many different parts of the federal government have a program or activity that should be considered part of the biodefense enterprise, from the development of public health policy and the certification process for new drugs to international nonproliferation treaties. The GAO stated that “the

intersection of human, animal, plant, and environmental health, as well as the nexus to the national security and economic sectors, represent challenges that no single agency can address alone.”¹⁶

Further, any truly comprehensive coordination of biodefense in the United States would have to involve governmental authorities at federal, state, and local levels, as well as private-sector entities such as hospitals, pharmaceutical companies, and nonprofit organizations. This increases exponentially the coordination challenges. However, even just assessing the federal government actors is like untangling a Gordian knot.

For the development of the NBS, the NDAA mandated the collective leadership of four different departments: Defense, Health and Human Services (HHS), Homeland Security, and Agriculture. When the NBS created the Bio-defense Steering Committee, tasked with overseeing the implementation of the NBS, it included members from eight federal organizations—adding the Environmental Protection Agency and Departments of State, Veterans Affairs, and Justice to the group charged to develop the strategy.

The fragmentation is such that the Pacific Northwest National Laboratory, a Department of Energy national laboratory, in an effort to help portray the disparate responsibilities for biodefense tasks in law, developed a tool called the Biodefense Policy Landscape Analysis Tool.¹⁷ The tool identified 414 discreet responsibilities assigned to 22 entities in the government, including state and local authorities. These responsibilities range from the Central Intelligence Agency collecting and analyzing intelligence on agriculture, food, and water to the Department of Homeland Security coordinating a response to biological attacks.

This level of fragmentation creates a situation in which each of the responsible entities only have access to a small sliver of the problem—and a corresponding sliver of the resources. These diffused responsibilities and extreme fragmentation have plagued previous efforts to develop capabilities on biodefense and health security.¹⁸ With the current level of fragmentation, only the Executive Office of the Presidency has a chance of assembling a full picture of the federal government’s biodefense enterprise.

Hard-to-Assess Federal Funding

Because of the fragmentation, it is very challenging to get a complete sense of how much the federal government spends every year in biodefense. The Bipartisan Commission on Biodefense, an organization of former government officials from both sides of the aisle and from the executive and legislative branches, when assessing the budget stated: “The Executive Branch and Congress do not comprehensively assess how the government

currently spends its biodefense dollars.”¹⁹ The best estimates currently available are from a group of academics who, since 2001, have put together their own assessment, since the federal government does not.²⁰

The latest estimate available analyzed fiscal year 2019, which stated that \$13.6 billion were allocated to health security, which incorporates biodefense.²¹ In the past three fiscal years, the federal government is estimated to have allocated \$41.8 billion. This totals slightly less than the whole budget for the Department of Labor for fiscal year 2019.²² It is not an insignificant amount of money; however, it is distributed to 12 federal government agencies.²³

These 12 agencies alone manage over \$2 trillion in federal programs, so the biodefense budget is not a large portion of their budgets.²⁴ Further, these agencies’ main mission is not biodefense and, as one would expect, the GAO found that “[o]fficials from four agencies expressed reluctance to redirect resources away from their core missions to better support any enterprise-wide identified needs.”²⁵

Recommendations

The biodefense enterprise is currently extremely fragmented and requires a herculean level of coordination at the higher levels of the federal government in order to guarantee coherent efforts and avoid duplication. Further, there is little visibility on how much the federal government spends on biodefense. These are the main two problems that need to be tackled first.

To achieve these goals:

- **The White House needs to create clear responsibility lines for implementing the NBS.** Right now, only the Executive Office of the President is capable of amassing a full picture of the federal biodefense enterprise—and thus is the only possible focal point. Despite the promises of the NBS, there is no clear implementing agent or a clear decision-making process. The strategy did place HHS as leader of the Biodefense Steering Committee, but it did not go beyond that. Among Cabinet Secretaries, the Secretary of HHS has no authority to compel any other department to take any action. The GAO stated: “[C]hallenges 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.”²⁶ The White House needs to make those lines of responsibility clear and thus create accountability for implementing the strategy.

- **The Office of Management and Budget (OMB) should develop a system capable of tracking program funding by their functions in addition to their executing organization.** In order to implement the NBS in any meaningful manner, the strategy needs to explicitly link tasks and resources. This assessment would develop a clear connection between dollars and strategy. Right now, the best estimate of federal spending on health security is done by the private sector. The OMB needs to be able to have a better fiscal picture of the federal biodefense enterprise and how it has evolved through time.
- **The White House needs to assess the current distribution of missions and tasks within the federal biodefense enterprise.** The executive should evaluate if the agencies are located in the best department to achieve their missions. In order to increase the relative importance of the mission of biodefense in a given department, consolidation should be considered.
- **Congress needs to ask for program-based budgets and clear lines of responsibilities.** Congress cannot rely on the executive alone to execute the changes necessary to implement the NBS; it needs to utilize its oversight capabilities to push them. The executive reports the budget in terms largely dictated by Congress—and thus has a lot of leverage to change how the budget is organized.

Conclusion

Based on GAO assessment, the NBS is largely evaluated in a positive light, but is in its infancy.²⁷ In this regard, the GAO also states that “these efforts represent a start to a process and a cultural shift that may take years to fully develop.”²⁸

The framework developed by the NBS is solid; however, it needs to be fully executed and have the proper tools to be implemented. Implementing the NBS will put the federal government in a better position to respond to any future pandemic.

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