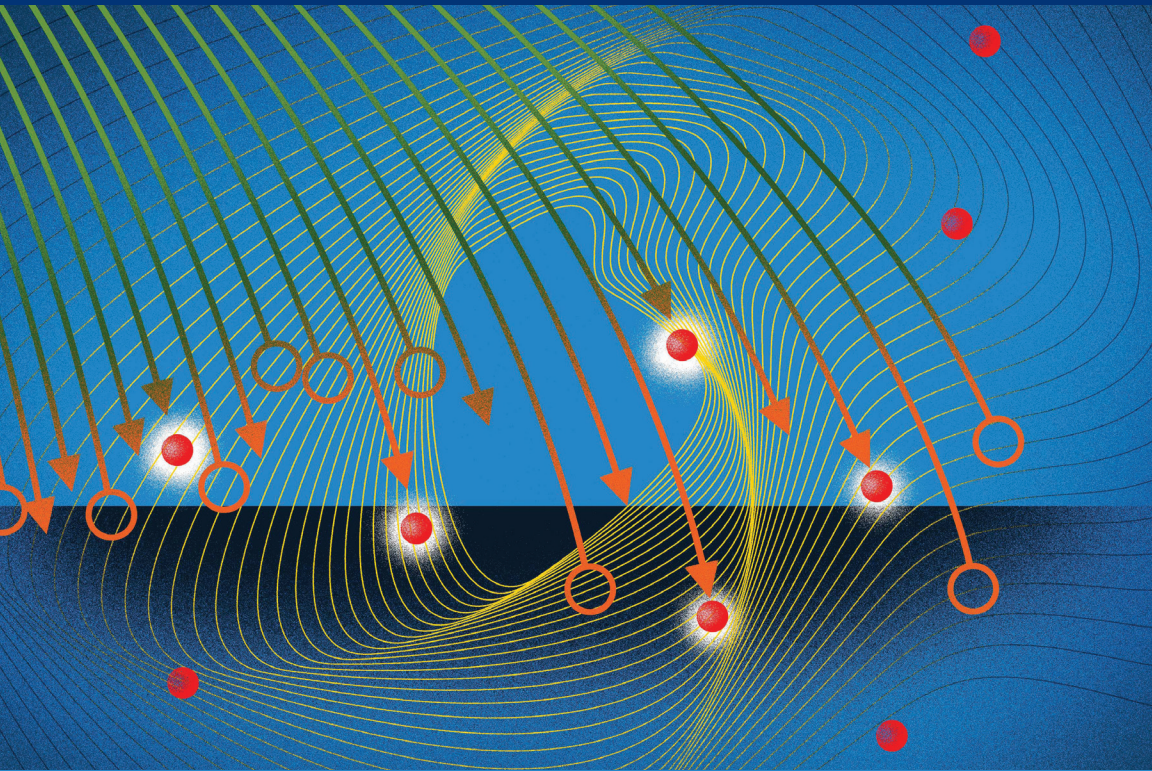


# BIODEFENSE IN CRISIS

IMMEDIATE ACTION NEEDED TO  
ADDRESS NATIONAL VULNERABILITIES

A REPORT BY THE  
BIPARTISAN COMMISSION ON BIODEFENSE

*March 2021*



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# PREFACE

March 30, 2021

To the President, Congress, and the American People:

We convened the Bipartisan Commission on Biodefense more than six years ago in recognition of the severity of the biological threat and the lack of cohesive national preparedness for a large-scale event. In the hopes of preventing calamity, we produced our foundational report in 2015, *A National Blueprint for Biodefense*, in which we noted that the Nation was dangerously vulnerable to biological threats—including an infectious disease pandemic or a terrorist attack with biological weapons. Addressing the totality of federal biodefense policies and programs, the report offered improvements for how the government could prevent, deter, prepare for, detect, respond to, attribute, recover from, and mitigate a biological event. However, little was done in response to warnings and recommendations from our Commission and others.

Unfortunately, the Coronavirus Disease 2019 (COVID-19) pandemic has proven us correct. The disease has inflicted great human and economic losses upon our country. We thank, applaud, and support the tireless work of researchers, public health professionals, healthcare deliverers, and frontline responders to bring the pandemic to an end.

COVID-19 continues to threaten the Nation and will remain a constant presence in our lives even with a successful vaccination campaign. Unfortunately, this pandemic will not be the last. Strong federal leadership is critical to enable the Nation to better defend against biological threats. Lessons can and should be learned from what went right during the various stages of response to COVID-19, as well as what went wrong.

The Executive and Legislative Branches did act on several of our recommendations. Most notably, the government developed and released a National Biodefense Strategy in 2018 in accordance with the third recommendation in *A National Blueprint for Biodefense*. Some Members of Congress and officials within the Obama, Trump, and Biden Administrations have also recognized the dire threat that pathogens pose and acted accordingly.

Regrettably, most of the Commission's recommendations were unaddressed or only partially addressed before the COVID-19 pandemic began. **Had the government fully implemented *A National Blueprint for Biodefense* or responded to warnings from experts, the Nation would have been much better prepared for COVID-19.** Our recommendations would not have prevented infectious disease, but their adoption would have greatly assisted the federal government and its state, local, tribal, territorial, and non-governmental partners in preventing COVID-19 from becoming a pandemic.

## PREFACE

We urge the public and private sectors to identify and act upon the difficult lessons learned from the current pandemic and place a high priority on combating the continuing biological threat to America and the world. We must do this now. Countless lives can be saved in the future by federal leadership; many lives will be lost without it.





# INTRODUCTION

The Bipartisan Commission on Biodefense was established in 2014 to examine the Nation's ability to defend against biological threats—including infectious diseases and bioterrorist attacks. In October 2015, the Commission released its foundational report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*. This report contained 33 recommendations and 87 corresponding action items to strengthen the federal government's biodefense policies and programs.<sup>1</sup>

At a May 2017 public meeting of the Commission, Ron Klain, former White House Ebola Response Coordinator and current White House Chief-of-Staff, spoke presciently about the magnitude of the biological threat to the United States:

*I believe that, sadly, sometime during this President's tenure, his national security team is going to be summoned to the Oval Office and have to discuss a catastrophe of historic proportions with the President. Hundreds of thousands of deaths in a remote corner of the world...the President may well be told that the United States could be the next place that sees such death and destruction. Now a lot of things could cause that death and destruction...but the single most likely cause is an epidemic.<sup>2</sup>*

Three years later, COVID-19 disrupted the global economy and every society in the world. The disease has taken hundreds of thousands of lives in the United States, many that might have been spared had our country taken more preventative action to strengthen national biodefense. Despite warnings from public health professionals and our Commission, the country was caught unprepared by the pandemic. Today, America is better prepared than before the current COVID-19 crisis, but still remains dangerously vulnerable to biological threats.

In September 2018, the White House implemented one of the key recommendations in *A National Blueprint for Biodefense*—the creation of the National Biodefense Strategy<sup>3</sup> along with National Security Presidential Memorandum 14 to direct its implementation.<sup>4</sup> Issuing the National Biodefense Strategy was a critical step toward strengthening U.S. biodefense. National Security Presidential Memorandum 14 provided direction to execute the Strategy and included mechanisms to review and revise its goals and objectives. Unfortunately, the federal government did not make significant progress in implementing the Strategy before the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus emerged in 2019 and caused the COVID-19 pandemic.

## INTRODUCTION

This report provides: (1) assessment of governmental efforts to implement our recommendations to prevent, deter, prepare for, detect, respond to, attribute, recover from, and mitigate biological threats; and (2) preliminary findings regarding our recommendations and COVID-19. Information in this report is current as of January 2021.

We concluded in our 2015 report that all of the recommendations in *A National Blueprint for Biodefense* could be implemented by the Executive and Legislative Branches within five years. From 2015–2020, out of the 87 action items we recommended, the government completed 3, took some action to address 56, took no action on 22, and took emergency or crisis actions on 6 to address the COVID-19 pandemic. **More than five years after we released *A National Blueprint for Biodefense*, the United States remains at catastrophic biological risk.**



# INDICATORS OF PROGRESS

Every year since the Commission began its efforts in 2014, the biological threat has increased. All federal departments and agencies agree that the threat has increased, but the country's efforts to defend against the biological threat have not kept up with the threat.

Despite its novelty, the COVID-19 pandemic was predictable. The global crisis resulted from a foreseeable, easily anticipated combination of mutations, lack of immunity, poor preparedness, limited surveillance, and failure to learn from past pandemics.

The threat of a pandemic caused by influenza or any number of other highly contagious diseases, whether naturally occurring or human generated, loomed clearly over the world well before SARS-CoV-2 emerged. Zika resulted in more than 3700 cases of congenital birth defects in the Americas<sup>5</sup> and a vaccine has yet to be approved. The Ebola outbreaks in Africa were never fully eradicated and defy control to this day.<sup>6</sup> The 2018–2019 influenza season resulted in nearly 57,000 deaths in the United States because the vaccine was only 29 percent effective.<sup>7</sup> It was only two years ago that the United Nations issued a global influenza strategy after the World Health Organization (WHO) insisted that pandemic influenza could result in devastating consequences across the globe.<sup>8</sup>

The current spotlight on COVID-19 is necessary and urgent. However, we cannot focus solely on this pandemic to the exclusion of all other biological threats. Nation states such as China, Iran, North Korea, and Russia have invested and continue to invest heavily in advancing biotechnology, much of which is dual-use, could generate large quantities of biological agents and weapons, and result in unintended consequences.<sup>9</sup> Terrorist organizations also remain interested in the asymmetric advantages that bioterrorism affords them and they continue to place materials online to show their members how to conduct attacks with anthrax, botulism, and other biological agents.<sup>10</sup>

Federal and private sector facilities that work in the United States with select agents also remain unacceptably insecure and troubling safety and security lapses still occur.<sup>11</sup> These institutions provide much needed research to support the biodefense enterprise. However, such work requires stronger management, funding, and oversight to prevent accidental or intentional releases of pathogens from high containment laboratories.

The Director of National Intelligence annually addresses the biological threat in testimony before Congress about the Intelligence Community's worldwide threat assessment. In 2019, then Director of National Intelligence Dan Coats expressed

the Community's apprehension about the increasing diversity of, and ability to develop, traditional and novel biological agents; the ways in which they can be used in attacks; the ease with which biological weapons can be developed; and the threats they pose to economies, militaries, public health, and agriculture.<sup>12</sup> The National Intelligence Council made similar statements in their 2017 *Global Trends* report, addressing the risk associated with synthetic biology and genome editing, and noting that advanced biotechnology is making it easier to develop and use biological weapons of mass destruction.<sup>13</sup> The Department of Defense (DOD) also commissioned the National Academy of Sciences to report on synthetic biology and the new vulnerabilities it creates.<sup>14</sup>

The U.S. contribution to rapid vaccine development for COVID-19 yielded results outstripping even the most optimistic of assessments, but nearly every other aspect of our response to the pandemic falls short of our peer countries and that of many low-to-middle income countries in the developing world. COVID-19 has devastated American lives, the economy, and our national confidence, and yet the next biological event could be even worse and happen at any time.

**Action items for the following recommendations from *A National Blueprint for Biodefense* require immediate action to eliminate weaknesses in the Nation's biodefense.**

## Leadership

National biodefense must begin and end with strong national leadership. The scope of the biodefense enterprise encompasses a wide swath of programs and policies which cannot be delegated to the states, localities, tribes, or territories. All federal departments and agencies with responsibilities for biodefense need to be coordinated and held accountable.

### White House Leadership

National Security Presidential Memorandum 14 charged the Secretary of Health and Human Services with leading implementation of the National Biodefense Strategy, in coordination with the Assistant to the President for National Security Affairs (also known as the National Security Advisor).<sup>15</sup> National Security Presidential Memorandum 14 made the Secretary of Health and Human Services responsible for overseeing the Biodefense Steering Committee which coordinates implementation of the Strategy by the federal government. Additionally, National Security Presidential Memorandum 14 directed the Secretary—who delegated responsibility to the Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health and Human Services (HHS)—to identify all existing federal biodefense programs and related spending by collecting information from other federal departments and agencies.

**Our Commission strongly believes that one federal department cannot tell other departments and agencies what to do, especially in a critical area of responsibility like biodefense.** The stalled execution of the National Biodefense Strategy demonstrates what we believed to be true: only the White House can direct all parts of the federal government to work together to defend the Nation against biological threats. Direction must come from someone occupying a position with the imprimatur of the President and the authority to act on the President's behalf.

The White House has historically prioritized biodefense only in response to immediate crises, letting a leadership vacuum develop when the threats pass. For example, after the H1N1 influenza pandemic faded away, the Obama Administration eliminated the position of the Special Assistant to the President for Health and Biodefense when it reorganized the White House staff and eliminated dedicated staff for the Homeland Security Council. When Ebola reached the United States, the Obama Administration had to create a temporary dedicated position to coordinate the government's response to the crisis. The Obama Administration considered the Commission's recommendation to put the Vice President of the United States in charge of the biodefense enterprise, but decided instead to reinstate a directorate, this time in the National Security Council (NSC), to deal with global health security and biodefense. The Trump Administration subsequently eliminated this directorate as part of another White House reorganization, again diminishing the priority placed on biodefense policy. In response to the COVID-19 crisis, the Trump Administration, like its predecessor, again had to appoint a coordinator to address the response. The Biden Administration has now reinstated a global health security and biodefense directorate in the NSC.

This experience is not at all unusual. Biological crisis after biological crisis, dating back to the Wilson Administration, reveal the same cycle with our leaders assuming, or hoping, that the latest biological crisis will be the only such crisis to occur during their terms. However, the escalating frequency of infectious disease events since the turn of the century, along with the increasing global mobility of people and goods, means that the White House must constantly remain focused on the probability of the next biological threat.

When the Commission first took up the question of federal leadership in 2015, we looked for a structure that would be able to: (1) guarantee that departments and agencies with biodefense responsibilities work with each other; and (2) provide the constant high-level focus on the biological threat needed in order to ensure our national security. After examining approaches taken by previous Administrations, we recommended that the Vice President take the lead. While we continue to believe that the structure provides an ideal nexus of leadership, authority, and physical presence within the White House, we recognize that putting the Vice President

permanently in charge did not appeal to either the Obama or Trump Administrations, and that the NSC may be the second best choice for national leadership of America's biodefense.

### ■ NEW ACTION ITEM

In support of Recommendation 1 of *A National Blueprint for Biodefense*, the President should establish a dedicated Deputy National Security Advisor for Biodefense, overseen by the Vice President of the United States and supported by NSC staff in a Directorate for Global Public Health Security and Biodefense and a Directorate for Domestic Public Health Security and Biodefense.

## Coordination

Despite National Security Presidential Memorandum 14, the federal government still lacks a mechanism to coordinate biodefense efforts effectively. Previous Administrations used different structures to coordinate biodefense activities across all federal departments and agencies before, during, and following a biological event—with the Trump Administration's Coronavirus Task Force as the most recent example. All were flawed.

### Interagency Coordination

The COVID-19 crisis clearly illustrates the perils of uncoordinated response efforts. Despite the existence of the Trump Administration's Coronavirus Task Force, the federal government's response has often been disorganized and contradictory, abdicating key national responsibilities to state, local, tribal, and territorial governments that required strong, continuing federal leadership. Wildly different approaches, as well as costly and inefficient competition among state, local, tribal, and territorial governments for personal protective equipment, testing supplies, and other critical materials, resulted in chaos across the country.

National Security Presidential Memorandum 14 established the interagency Biodefense Steering Committee to oversee implementation of the National Biodefense Strategy, and a Biodefense Coordination Team at the Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response to assist the Biodefense Steering Committee in executing its duties. As one department of the federal government is limited in its ability to tell another department or agency what to do, neither the Biodefense Steering Committee nor the Biodefense Coordination Team can exercise sufficient authority over other federal departments and agencies. They cannot compel them to participate in meetings, provide information, or take any other action.

Though the Biodefense Steering Committee includes many federal departments and agencies, it does not include all federal entities with biodefense responsibilities. The membership of the Biodefense Steering Committee is also limited only to federal officials, but considering the especially prominent roles and responsibilities that state, local, tribal, and territorial governments and the private sector have in addressing the COVID-19 pandemic, the Biden White House should include, and seek input from, non-federal stakeholders in the implementation of the National Biodefense Strategy, while retaining control.

### ■ NEW ACTION ITEM

The White House should establish a federal advisory committee<sup>16</sup> comprised of state, local, tribal, and territorial, and private sector representatives charged with advising the Biodefense Steering Committee. The Biodefense Steering Committee, prior to finalizing the second annual Biodefense Assessment, should also invite public comment on the Assessment after taking appropriate measures to protect sensitive and classified information.

## National Biodefense Strategy

Before the establishment of the National Biodefense Strategy, the federal government relied upon a panoply of disparate, uncoordinated policies and strategies to address biological threats. The creation of the National Biodefense Strategy offered an opportunity to finally combine and align federal policy to support comprehensive biodefense.

The COVID-19 pandemic demonstrates the extent to which gaps remain in federal policies to defend the Nation against the biological threat. COVID-19 and its variants may remain a pervasive threat, continuously revealing our national vulnerabilities to the biological threat well into the future. We will never know what impact full implementation of the National Biodefense Strategy might have had on the response to COVID-19 in 2020, but such a process would certainly have brought to light many of the problems that arose during the early days of the pandemic before the crisis occurred. While we appreciate the development and delivery of the first Biodefense Assessment (the wide-ranging description of biodefense programs and spending required by National Security Presidential Memorandum 14), its delivery to the White House in late 2020 came too late to inform federal policy and spending decisions as the Nation continued to struggle with COVID-19.

The modest implementation plan incorporated into the National Biodefense Strategy does not sufficiently answer the most important question of how the federal government will achieve the mission, goals, and objectives set forth in that document. Though some sub-objectives are detailed, there is no assignment of responsibilities other than the presence of, and coordination among, the members of the Biodefense Steering Committee itself. The plan also lacks tasks and timelines for each objective.

### ■ NEW ACTION ITEM

The NSC, in coordination with the Biodefense Steering Committee, should develop and issue a comprehensive implementation plan for the National Biodefense Strategy. This plan should address all federal departments and agencies with responsibilities for biodefense, and clearly articulate their requirements with a federal lead assigned for each goal and objective detailed in the National Biodefense Strategy. The Biodefense Steering Committee should also delineate activities, milestones, and timelines for completion for each goal and objective. These roles, responsibilities, and taskings should inform the development of the next iterations of the National Biodefense Strategy until its goals and objectives are addressed and its mission accomplished.

## Congressional Agenda

Congressional biodefense activities are still grossly uncoordinated. Just as the responsibility for biodefense cuts across multiple federal departments and agencies, numerous Congressional committees have jurisdiction over various aspects of the federal government's efforts to defend the Nation against biological threats. Fragmented and stovepiped oversight prevents effective legislative responses to persistent problems and encourages short-term emergency legislating rather than sustainable solutions.

In 2015, we recommended that Congress establish a clear oversight agenda for biodefense and provided additional detail about that recommendation in our 2018 report, *Budget Reform for Biodefense: Integrated Budget Needed to Increase Return on Investment*.<sup>17</sup> We recommended that congressional leaders convene the Chairs and Ranking Members of relevant authorization, appropriations, and budget committees in the House of Representatives and the Senate to establish structures and processes for comprehensive oversight of the federal biodefense enterprise. Congress has yet to act on these recommendations and organize its activities to better protect our country from biological threats.



**The pandemic has drawn the public’s attention to the biological threat in a way we have not seen in modern times.** Congress should leverage this political will to rationalize oversight of the federal biodefense efforts for COVID-19 as well as future biological events.

**NEW ACTION ITEM**

House and Senate leadership should establish a bipartisan, bicameral Congressional Working Group on Biodefense. This entity should be comprised of the Chairs and Ranking Members of each Committee with biodefense jurisdiction (see Table 1). This group should meet regularly to: (1) develop recommendations for congressional leaders to ensure national biodefense; (2) develop budgetary figures for overall biodefense spending; (3) more closely align biodefense appropriations to authorization; and (4) develop an annual Biodefense Authorization Act to give Congress a vehicle to regularly review the effectiveness of biodefense programs and policies.

**Table 1. Congressional Committees with Biodefense Oversight Authority**

U.S. House of Representatives	U.S. Senate
Agriculture	Agriculture, Nutrition and Forestry
Appropriations	Appropriations
Armed Services	Armed Services
Budget	Budget
Energy and Commerce	Health, Education, Labor and Pensions
Financial Services	Finance
Foreign Affairs	Foreign Relations
Homeland Security	Homeland Security and Governmental Affairs
Judiciary	Judiciary
Natural Resources	Energy and Natural Resources
Science, Space and Technology	Commerce, Science and Transportation
Transportation and Infrastructure	Environment and Public Works
Veterans’ Affairs	Veterans’ Affairs
Ways and Means	Banking, Housing and Urban Affairs
Permanent Select Committee on Intelligence	Select Committee on Intelligence
Oversight and Reform	

## Biological Intelligence

Although we recommended in *A National Blueprint for Biodefense* that the Director of National Intelligence establish a National Intelligence Manager for biological threats, the Director has not done so. Instead, in 2019, the Director tasked the Director for the National Counterproliferation Center with coordinating biodefense intelligence matters throughout the Intelligence Community, even though the collection activities of the Community's agencies largely fall outside of the Center's purview. This arrangement did little to clarify and coordinate responsibilities for biological intelligence among the various intelligence agencies and national intelligence managers and failed to raise the priority placed on biological threats.

### ■ NEW ACTION ITEM

Congress should mandate in the Intelligence Authorization Act for Fiscal Year 2022 an annual, comprehensive report on biodefense activities of all Intelligence Community agencies and national intelligence managers. This report should include descriptions of how these agencies and national intelligence managers interact, with whom in the White House they work, and how funds are used for biological intelligence activities. This entire report should be classified.

## Biological Attribution

Despite the important roles of several Cabinet departments, including the Department of State (DOS), DOD, and the Department of Justice, there is no structure in place to direct and coordinate activities to determine the cause of a particular biological event, and to provide that information in a usable form to the White House decision-making apparatus.

Attribution of COVID-19 was inefficient at best. Had it been determined that COVID-19 was not naturally occurring (i.e., that it had been intentionally introduced or accidentally released from a laboratory), there would have been no clearly defined mechanism in place to provide leaders in the White House and throughout the federal government with the information they needed to make far reaching, globally significant decisions about how to respond. The implications of imposing sanctions and embargoes, cutting off diplomatic relations, and declaring war are too important to leave to a loose set of occasional federal players and policies.

**■ NEW ACTION ITEM**

Congress should, in the National Defense Authorization Act, direct the Secretary of State, the Secretary of Defense, the Secretary of Homeland Security, the Attorney General, and the Director of National Intelligence to jointly develop, plan for, and establish a national biological attribution apparatus to inform decision-making. The plan should articulate department and agency roles, responsibilities, and requirements, as well as milestones for adjudicating attribution information and informing decisions following any biological event with national security implications.

**Collaboration**

Active collaboration with non-federal stakeholders remains a key component of effective biodefense. Early and frequent federal outreach remains necessary to ensure that these partners have the support they need to deal with biological threats when they occur.

**National Biosurveillance**

As originally envisioned, the Department of Homeland Security (DHS) National Biosurveillance Integration System was supposed to aggregate, analyze, and disseminate biosurveillance information, from inside and outside of the federal government. However, too few federal departments and agencies provide data to the System, and federal officials often question the value of the products issued.<sup>18</sup> Without direct access to biosurveillance data from other federal departments and agencies, the National Biosurveillance Integration System cannot fulfill its mandate. It will never serve as an effective mechanism for aggregating and analyzing federal biosurveillance data unless other departments and agencies provide the necessary data to the System. If they do not do so—either on their own or by Congressional mandate—Congress should put the System’s funding to better use.

**■ NEW ACTION ITEM**

Congress should amend the Homeland Security Act of 2002 to direct the Secretary of Homeland Security to conduct a comprehensive assessment of the National Biosurveillance Integration System. This review should detail the extent to which the System fulfills its statutory responsibilities and identify any additional authorities needed to fulfill those requirements. Congress should amend the Homeland Security Act of 2002; National Defense Authorization Act; Public Health Service Act; Veterans Benefits, Health Care, and Information Technology Act of 2006; and Agriculture Improvement Act to provide those authorities.<sup>19</sup>

## Stratified Biodefense Hospital System

The Nation lacks a stratified biodefense hospital system. The federal government has neither established, nor sufficiently incentivized hospitals to create, such a system. As a result, hospitals respond to biological events individually, spontaneously, and in an uncoordinated fashion, as seen during the COVID-19 pandemic. Hospitals also lacked standardized clinical infection control guidance specific to COVID-19 for many months.

The Regional Disaster Health Response System, a pilot run by HHS, showed some promise. The Regional Disaster Health Response System is operational in three metropolitan jurisdictions on a trial basis and could help inform a broader, nationwide organization. Should the program deliver desired results, implementation of a nationwide system will require robust funding to enable hospitals to participate. This application will require more than just additional funding for the Hospital Preparedness Program that is overseen by the Department of Health and Human Services Assistant Secretary for Preparedness and Response. The Centers for Medicare and Medicaid Services (CMS) must also allow for reimbursement of related costs before biological events occur.

### ■ NEW ACTION ITEM

Congress should amend the Public Health Service Act to authorize the HHS Regional Disaster Health Response System.<sup>20</sup> Congress should direct the Secretary of Health and Human Services and the Administrator of the Centers for Medicare and Medicaid Systems to produce a plan to regionalize biodefense preparedness and response through the Regional Disaster Health Response System with criteria and benchmarks to guide implementation. As with other stratified hospital systems, CMS must reimburse costs associated with providing different levels of care during biological events. Congress should also allocate additional funding on a multiyear basis to commit resources and enable program participants to plan confidently.

## Innovation

Although the federal government has made some progress in developing innovative solutions to prevent, detect, prepare for, respond to, attribute, recover from, and mitigate biologic threats, serious gaps and shortfalls remain.

### Medical Countermeasure Enterprise

Federal programs have successfully developed and stockpiled some critical medical countermeasures to address multiple threats. However, as demonstrated by COVID-19, the federal government needs to provide additional funding and prioritization to develop medical countermeasures. Although a number of COVID-19 drug candidates

## INDICATORS OF PROGRESS

made rapid progress thanks to the efforts of federal agencies (including the HHS Biomedical Advanced Research and Development Authority (BARDA)), the lack of long-term funding and investments in medical countermeasure development continue to threaten our Nation's ability to defend against biological threats.

Despite modest funding increases in recent years, federal investment lags far behind the biological threat. Congress must provide robust appropriations for Project BioShield and other medical countermeasure development programs on a multi-year basis to provide certainty to federal agencies and their private sector partners.

COVID-19 also reveals fragmentation in the distribution of medical countermeasures. Without strong federal leadership, state, local, tribal, and territorial governments were inadequately prepared to distribute millions of vaccine doses after receiving them from the federal government. Some federal vaccination prioritization recommendations have also been ignored in an attempt to inoculate the local population faster.<sup>21</sup> State vaccination policies lacked guidance for distributing expiring doses, resulting in some officials scrambling to quickly administer the doses to members of the community, regardless of their age or health condition.<sup>22</sup> A Medical Countermeasure Response Framework, as recommended previously in *A National Blueprint for Biodefense*, would help non-federal partners better plan for distribution.

### ■ NEW ACTION ITEMS

Congress should amend the Public Health Service Act to direct the Secretary of Health and Human Services to conduct a comprehensive review of existing medical countermeasure programs, policies, and assets, including the Centers for Innovation in Advanced Development and Manufacturing. Findings should inform the FY 2023 budget request.

Based on this review, Congress should amend the Public Health Service Act to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense and the Secretary of Agriculture, to develop an interagency product transition plan to speed up advanced development of promising medical countermeasures before the next infectious disease pandemic.

## Environmental Biodetection

Current BioWatch technology performs poorly and is far from the deterrence mechanism it was originally intended to be. BioWatch detectors, when they work, only provide useful data hours or days after an event. While we appreciate that DHS heard our concerns and is looking into replacing outdated non-functional BioWatch technology, Biodetection 2021, the DHS acquisition program to identify and acquire new biodetection technology, has its own difficulties. Clear requirements for replacement technology have not been

established for this acquisition program and concerns abound regarding the methods utilized by DHS to field and test these new technologies. In the meantime, BioWatch continues to use limited, decades-old collection equipment paired with more advanced laboratory testing capability, limping along until the Biodetection 2021 program acquires usable new technology and DHS can procure it.

### ■ NEW ACTION ITEM

Considering the continued inability of DHS to identify, test, acquire, procure, and deploy replacement biodetection technology, the Office of Management and Budget (OMB), in coordination with the NSC, should eliminate the BioWatch program from all future Presidential Budget Requests. Instead, OMB should increase the budget for a directed funding request for research and development to be conducted by the National Laboratories and academia to produce biodetection technology that can be used in national biodetection systems. Congressional appropriators should deny further funding for BioWatch activities until proven replacement technology is identified and confirmed to meet the needs of the program.

## Global Health

All nations are affected by the COVID-19 pandemic, no matter what their current case counts may be. As long as COVID-19 and its variants exist anywhere in the world, they will continue to threaten all lives and economies.

Our Nation cannot afford to ignore global health concerns. An emerging infectious disease in one location can pose an existential threat to the entire world. We must proactively engage with other countries and international bodies to strengthen our collective biosurveillance and response capabilities, so that we can swiftly identify and stamp out the next biological event before it becomes a pandemic. The federal government's Global Health Security Agenda, still only an Executive Branch initiative, provides a good foundation upon which to base these activities.

### ■ NEW ACTION ITEM

Congress should amend the Foreign Assistance Act of 1961 to authorize the Global Health Security Agenda and provide increased, consistent appropriations to support the Agenda's activities.<sup>23</sup> Congress should prioritize funding and programmatic support for early warning biosurveillance activities, including within the United States. The White House should involve all countries in the Agenda.

# CONCLUSION

The emergence of the SARS-COV-2 virus and the resulting COVID-19 pandemic reveals the numerous gaps remaining in U.S. biodefense.

We acknowledge and appreciate the work of the past two presidential Administrations and three Congresses in addressing some of our recommendations, including the development and release of the National Biodefense Strategy in 2018. However, while a few of our other recommendations were recently addressed as a direct result of the COVID-19 pandemic, many of our recommendations remain only partially or incompletely realized.

We call upon the Biden Administration and Congress to remedy this situation and fully implement the recommendations we made in *A National Blueprint for Biodefense* and our subsequent reports. The federal government has had five years and more than enough evidence regarding the severity of the biological threat to warrant immediate action.

**The Commission urges policymakers to learn from the COVID-19 pandemic and address critical gaps in the Nation's biodefense, without waiting for COVID-19 to disappear, and before we find ourselves facing the next infectious disease pandemic or biological attack.**

# IMPLEMENTATION STATUS

The implementation status of all 33 recommendations from the 2015 *A National Blueprint for Biodefense* follows below. Of the 87 associated action items, the federal government:



## Completed

Completed 3 action items



## Partial Action

Took partial action to address 56 action items



## Inaction

Took no action on 22 action items



## Crisis Action

Took 6 emergency actions in response to the COVID-19 pandemic. These are actions that may not reflect permanent policy, resource or coordination gains for future threats, and may be abandoned when the pandemic is no longer viewed as a priority by the federal government.

Recommendations are organized in accordance with the following categories from *A National Blueprint for Biodefense*:

**LEADERSHIP  
RECOMMENDATIONS**

**COORDINATION  
RECOMMENDATIONS**



**COLLABORATION  
RECOMMENDATIONS**

**INNOVATION  
RECOMMENDATIONS**



# RECOMMENDATION 1

**Institutionalize biodefense in the Office of the Vice President of the United States.** Institutionalizing this responsibility in the Office of the Vice President will ensure that biodefense will be addressed by every Administration, at the highest levels, and with adequate access to the President.<sup>24</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Empower the Vice President with jurisdiction and authority.	White House	 Crisis Action
b. Empower the Vice President with budget authority.	White House, OMB	 Crisis Action


## *Action Item a.*

### **Empower the Vice President with jurisdiction and authority.**

The President should place the Vice President in charge of national biodefense. The Vice President should take necessary action to ensure adequate biodefense for the United States, address relevant international issues and requirements, and coordinate the U.S. biodefense enterprise. The President should also provide the Vice President with jurisdiction within, and authority to coordinate among, the various relevant councils in the White House.

Prior to the spread of COVID-19 to the United States, neither President Obama nor President Trump made the Vice President responsible for federal biodefense as recommended by the Commission. When confronted with the 2014 Ebola crisis, President Obama appointed Ron Klain to serve as the coordinator within the White House to address this biological threat.<sup>25</sup> Through National Security Presidential Memorandum 14, President Trump assigned primary responsibility for implementation of the National Biodefense Strategy to the National Security Advisor. While President Trump eventually put Vice President Pence in charge of the COVID-19 response, this authority did not extend to biodefense more broadly. President Biden has also chosen to locate the biodefense portfolio within the NSC, instead of with Vice President Harris.

Implementor:  
**White House**

Status:  
 **Crisis Action**

# COVID-19

**On February 26, 2020, President Trump directed Vice President Pence to assume control of the U.S. response to COVID-19.** President Trump empowered Vice President Pence to take necessary action to combat, respond to, and coordinate the efforts of the U.S. biodefense enterprise to address COVID-19. President Trump did not provide Vice President Pence with any additional authorities to coordinate among the various councils in the White House that address COVID-19, including the Domestic Policy Council, National Economic Council, and NSC.

The Commission acknowledges that the Trump Administration elevated biodefense policy to the level of the National Security Advisor and put the Vice President in charge of COVID-19 response. However, national biodefense requires a permanent centralized authority who can effectively act on behalf of the President to manage and make budgetary decisions about the fifteen departments, eight independent agencies, and one independent institution that comprise the national biodefense enterprise.

President Trump assigned implementation of the National Biodefense Strategy to the National Security Advisor. While helpful to elevate biodefense to this level, the National Security Advisor has too much on their plate and cannot provide sustained focus. COVID-19 made this abundantly clear when neither the National Security Advisor nor the Secretary of Health and Human Services effectively managed COVID-19 and the federal response to it, resulting in the appointment of Vice President Pence to lead the effort.

## *Action Item b.*

### **Empower the Vice President with budget authority.**

**The President must give the Vice President authority to review and advise on all agency biodefense budgets to achieve national security goals for biodefense at any point during the budget development and submission process. This authority should extend to directing the budget submissions of departments and agencies in collaboration with the Director of the Office of Management and Budget**

As recommended in *A National Blueprint for Biodefense*, neither President Obama nor President Trump directed their Vice Presidents to review and advise on federal biodefense budget submissions, work with OMB to direct these submissions,

## RECOMMENDATION 1

or make decisions about the biodefense budget. Instead, as usual, the NSC coordinated with OMB to set biodefense priorities in the President's Budget Request. Empowering the Vice President or another individual within the White House with budget authority over biodefense is critical to ensuring adequate federal funding of the Nation's biodefense.

Implementor:

**White House, OMB**




Status:

 **Crisis Action**



# RECOMMENDATION 2

**Establish a Biodefense Coordination Council at the White House, led by the Vice President.** A coalition approach is needed to create cohesion among departments, agencies, states, localities, tribes, territories, and industry. Such an approach can help smooth the competing priorities and demands that drive organizations to operate independently.<sup>26</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Require broad federal participation.	White House	 Crisis Action
b. Structure the Council for consensus and accountability.	White House	 Partial Action
c. Invite broad non-federal stakeholder participation.	White House	 Partial Action

### *Action Item a.*

#### **Require broad federal participation.**

The Vice President should direct all departments and agencies that address biodefense (in keeping with the National Biodefense Strategy of the United States of America per Recommendation 3) to hold a seat on the Biodefense Coordination Council. The designees should be at the Deputy Secretary level.

Instead of a Biodefense Coordination Council, National Security Presidential Memorandum 14<sup>27</sup> established the Biodefense Steering Committee to oversee the implementation of the National Biodefense Strategy.<sup>28</sup> The Biodefense Steering Committee is a policy-focused principals committee which must seek assistance from other federal departments and agencies as needed to carry out its duties. Chaired by the Secretary of Health and Human Services, the Biodefense Steering Committee is composed of the Secretary of State, Secretary of Agriculture, Secretary of Defense, Secretary of Homeland Security, Secretary of Veterans Affairs, Attorney General, and Administrator of the Environmental Protection Agency. The Secretary of Energy, Secretary of the Treasury, Administrator of the United States Agency for International Development, and Director of the Federal Bureau of Investigation are listed as Covered Officials in National Security Presidential Memorandum 14 and are Biodefense Steering Committee members by invitation of the Secretary of Health and Human Services.

## RECOMMENDATION 2

Although the Biodefense Steering Committee includes many key federal agencies, not all federal departments, agencies, and institutions with biodefense responsibilities are required to participate, and National Security Presidential Memorandum 14 does not ensure that their interests are represented by other members. Additionally, the White House decision to place the Secretary of Health and Human Services in charge of the Biodefense Steering Committee, rather than the National Security Advisor or another official within the White House itself—means the Biodefense Steering Committee must reach decisions by consensus, with the White House resolving problems as needed.

Implementor:

White House

Status:

 Crisis Action

# COVID-19

**In response to the COVID-19 pandemic, President Trump convened the Coronavirus Task Force on January 27, 2020.**<sup>29</sup> The President charged this entity with leading the U.S. response to COVID-19. Initially, the Task Force was chaired by the Secretary of Health and Human Services and included only representatives from the White House, HHS, DHS, Department of Transportation, and DOS. Vice President Pence became more involved with the Task Force's activities after President Trump asked him to lead the federal government's COVID-19 response efforts. Vice President Pence expanded the membership of the Task Force to include the Secretary of Agriculture, Secretary of Labor, Secretary of Housing and Urban Development, Secretary of the Treasury, Commissioner of the Food and Drug Administration, Director of the National Institutes of Health, Administrator of the Centers for Medicare and Medicaid Services, Food and Drug Administration Director of the Center for Biologics Evaluation and Research, Administrator of the Health Resources and Services Administration, Surgeon General, Director of the White House Office of Science and Technology Policy, and Director of the National Economic Council.<sup>30</sup>

While the Task Force brought together various federal departments and agencies to coordinate action in the early stage of the pandemic, the organization became less visible and active as the initial wave of infections subsided. Without leadership and effective communications from the White House, the federal government responded ineffectively to the disease as the Nation entered the fall and winter months of late 2020 and early 2021.

*Action Item b.***Structure the Council for consensus and accountability.**

**The Vice President should lead the primary designees and the members as a coalition that will prioritize needed activities, designate responsibilities, and ensure accountability. Each federal department and agency with a seat on the Council should be charged, through the National Biodefense Strategy, with deliverables that the Council will develop and periodically evaluate.**

National Security Presidential Memorandum 14 describes tasks and responsibilities for both the Biodefense Steering Committee and the Biodefense Coordination Team. It requires those federal departments and agencies addressed by the National Security Presidential Memorandum to compile and submit biodefense programmatic and spending data to the Committee and OMB. This information is meant to be assessed by the NSC and OMB and factored into the President's Budget Request.<sup>31</sup>

National Security Presidential Memorandum 14 requires the Biodefense Steering Committee to submit an annual Biodefense Assessment to the National Security Advisor and the Director of Office of Management and Budget that identifies shortfalls and redundancies, describes challenges to implementation of the National Biodefense Strategy, and recommends updates to the National Biodefense Strategy. National Security Presidential Memorandum 14 required the initial Biodefense Assessment to be completed and submitted to the NSC and OMB within 180 days after the establishment of the Biodefense Coordination Team. The Team completed and finalized the FY 2019 Biodefense Assessment well after the required deadline of June 15, 2019. The 2019 Biodefense Assessment was ultimately submitted to the National Security Advisor and the Director of Office of Management and Budget in December 2020. The Fiscal Year 2020 Biodefense Assessment is currently under development.

A publicly available summary of the 2019 Biodefense Assessment—required by National Security Presidential Memorandum 14—was released in September 2020 by the Biodefense Steering Committee.<sup>32</sup> The report discussed the biological threat environment and steps taken to address the five goals of the National Biodefense Strategy, but the document failed to specify the roles and responsibilities federal departments and agencies have in addressing those goals, with one exception.<sup>33</sup> Though not required by National Security Presidential Memorandum 14, roles, responsibilities, and other requirements are essential to developing successful accountability structures for implementing the National Biodefense Strategy.

Implementor:

**White House**

Status:

 **Partial Action**

*Action Item c.***Invite broad non-federal stakeholder participation.**

**In addition to the primary designees, the Vice President should include a state governor, a mayor, a territorial governor/administrator, a tribal leader, and private sector leaders representing critical infrastructure sectors that are vital to the success and continuity of biodefense.**

The Biodefense Steering Committee does not include non-federal stakeholders.<sup>34</sup>

While the Biodefense Steering Committee is empowered to “establish appropriate consultative or advisory mechanisms” to obtain input from non-federal partners, it is not obligated to do so.<sup>35</sup>

As the chair of the Biodefense Coordination Team, the Department of Health and Human Services Assistant Secretary for Preparedness and Response hosted a summit with non-federal stakeholders in April 2019<sup>36</sup> to receive verbal input regarding implementation of the National Biodefense Strategy and issued a call for written public comments thereafter.<sup>37</sup> While this was helpful, it fell far short of incorporating state, local, tribal, and territorial government, and private sector perspectives into the Biodefense Steering Committee.

Implementor:







**White House**

Status:

 **Partial Action**

# RECOMMENDATION 3

**Develop, implement, and update a comprehensive national biodefense strategy.** The Vice President should direct the development of the National Biodefense Strategy of the United States of America. This strategy should be comprehensive and harmonized and should define all Executive Branch organizational structures and requirements, modernization and realignment plans, and resource requirements necessary for implementation.<sup>38</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Collate the whole of biodefense policy.	White House	 Partial Action
b. Identify requirements within all extant policies.	White House	 Partial Action
c. Assess spending history and value.	White House, OMB	 Partial Action
d. Produce the National Biodefense Strategy of the United States of America and its Implementation Plan.	White House	 Partial Action
e. Develop a gap analysis based on this comprehensive strategy.	Congress	 Partial Action
f. Institute a major quadrennial biodefense review.	White House, Congress	 Inaction

## *Action Item a.*

### **Collate the whole of biodefense policy.**

The NSC should collate all extant biodefense policies, laws, and treaties that promulgate defense responsibilities against intentionally introduced, accidentally released, and naturally occurring biological threats.

The National Defense Authorization Act of Fiscal Year 2017 (P.L. 114-328) required DOD, HHS, DHS, the Department of Agriculture (USDA), and other departments and agencies with biodefense responsibilities to develop the National Biodefense



### RECOMMENDATION 3

Strategy. The law mandated that this Strategy include a review and assessment of biodefense policies, practices, programs, and initiatives. Accordingly, as part of the Strategy's development, the NSC obtained input from 17 federal departments and agencies that implement biodefense policies and programs. Having not obtained input from all governmental agencies with biodefense responsibilities, it is unlikely that the Trump NSC collated all biodefense policy, but it came much further in doing so than previous Administrations.

Implementor:  
**White House**

Status:  
 **Partial Action**

#### *Action Item b.*

#### **Identify requirements within all extant policies.**

**Based on the body of policy documents identified in action item 3a, the NSC and other relevant offices in the White House should catalog responsibilities and delineated requirements in all biodefense-related laws, directives, and other policy documents. Other relevant White House offices and councils beyond the NSC should further examine requirements in keeping with their areas of expertise and responsibility.**

The NSC's work developing the National Biodefense Strategy included the identification of biodefense requirements across several federal policies. However, the White House has not yet described and assigned specific roles, responsibilities, and requirements to each goal in the Strategy. Some of these details should be captured by the implementation and periodic update process required by National Security Presidential Memorandum 14.

Additionally, National Security Presidential Memorandum 14 establishes an annual process to collect data across federal agencies to develop a Biodefense Assessment. This Assessment must identify any gaps, shortfalls, and redundancies; describe any challenges to the implementation and execution of the Strategy; and recommend any necessary updates or changes to the National Biodefense Strategy. To gather this data, the Secretary of Health and Human Services issued an initial request for information to numerous federal agencies to determine how programs and activities governed by their agencies contribute to the objectives of the National Biodefense Strategy.

Implementor:  
**White House**

Status:  
 **Partial Action**

*Action Item c.***Assess spending history and value.**

The Director of the Office of Management and Budget should identify how much funding has been budgeted and appropriated for each requirement identified in action item 3b. OMB should audit performance and determine if requirements are still appropriate, and if not, provide options for refining, moving, or eliminating them.

Prior to the release of the National Biodefense Strategy, OMB started an analysis of biodefense program spending. This appears to be a function of the order in which the Trump Administration initiated the development of the National Biodefense Strategy. Policy identification and alignment occurred first. If the federal government executes National Security Presidential Memorandum 14 as directed, the implementation process should capture budgetary analysis and alignment, and the annual Biodefense Assessment should also include an analysis of the extent to which allocated resources support the Strategy's goals and objectives.

Implementor:

**White House, OMB**

Status:

 **Partial Action***Action Item d.***Produce the National Biodefense Strategy of the United States of America and its Implementation Plan.**

The Vice President (using the information collected from action items 3a, 3b, and 3c) should develop a comprehensive national biodefense strategy and implementation plan. Departments and agencies must be held accountable for the elements of the plan for which they have been made responsible. A progress report should be provided to Congress annually.

The Trump Administration released the National Biodefense Strategy in September 2018. The Strategy provided vision and mission statements, as well as specific goals and broad objectives. President Trump concurrently signed National Security Presidential Memorandum 14, which described some of the structures and processes needed for implementation of the Strategy. The National Biodefense Strategy also included an implementation plan, but it lacked sufficient detail. The implementation plan described the goals of the Strategy, but it did not assign responsibilities, roles, timelines, or milestones—key elements of any effective implementation plan.

National Security Presidential Memorandum 14 also describes the way in which the Strategy is to be implemented, beginning with the establishment of the Biodefense Steering Committee. This Committee is responsible for monitoring and coordinating

### RECOMMENDATION 3

the implementation of the Strategy and is supported by the Biodefense Coordination Team as led by a designated senior official in, or detailed to, HHS. Presently, this official is the Department of Health and Human Services Assistant Secretary for Preparedness and Response. National Security Presidential Memorandum 14 also requires the Biodefense Coordination Team to develop a proposal that would address the accountability structures and action items needed for implementation of the National Biodefense Strategy.<sup>39</sup> Though originally scheduled for finalization and release in late 2019, the proposal was never released by the Trump Administration.

The National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283) requires the Secretary of Health and Human Services, the Secretary of Defense, the Secretary of Agriculture, the Secretary of Homeland Security, the Secretary of State, and other federal departments and agencies with biodefense responsibilities, to update the implementation plan for the National Biodefense Strategy.<sup>40</sup> These updates include adding processes, roles, and responsibilities for executing the Strategy, as well as short, medium, and long term goals. The law instructs these departments and agencies to work with the National Security Advisor and the Director of the Office of Management and Budget to update the implementation plan.

Implementor:

**White House**

Status:

 **Partial Action**

## COVID-19

**Although the National Biodefense Strategy was released in September 2018, the Executive Branch did not implement the Strategy—or produce a comprehensive implementation plan—before COVID-19 emerged in the United States.** In fact, the United States responded to COVID-19 without a comprehensive national strategy, leaving individual states, localities, tribes, and territories to respond with wildly different approaches and public health outcomes across the country, and to compete in a costly and inefficient fashion for personal protective equipment, testing supplies, and other critical materials.

*Action Item e.***Develop a gap analysis based on this comprehensive strategy.**

Congress should direct the Government Accountability Office (GAO) to analyze gaps in resources mapped against the requirements of the National Biodefense Strategy and estimate resource requirements for small-, medium-, and large-scale events.

In 2019, the Secretary of Health and Human Services issued a request for information to federal departments and agencies to assess how their programs align with the National Biodefense Strategy. The deadline for responding to the request for information was May 2019. The Biodefense Coordination Team collected the information from federal departments and agencies with biodefense responsibilities to inform the Biodefense Assessment and the following budget cycle. The Biodefense Steering Committee transmitted the Fiscal Year 2019 Biodefense Assessment to the National Security Advisor and the Director of the Office of Management and Budget in December 2020. The Department of Health and Human Services Assistant Secretary for Preparedness and Response released a public-facing 2019 Biodefense Public Report in September 2020, based on the 2019 Biodefense Assessment.<sup>41</sup> Future assessments should assist with periodically refreshing the National Biodefense Strategy.

Additionally, the National Defense Authorization Act of Fiscal Year 2017 (P.L. 114-328) required the GAO to analyze gaps in resources mapped against the requirements of the National Biodefense Strategy and other existing biodefense policies. GAO released this report on February 19, 2020.<sup>42</sup> This report concluded that the structure of the National Biodefense Strategy and National Security Presidential Memorandum 14 showed promise but identified several obstacles to implementation, including a lack of centralized authority to influence policy and make budget decisions for federal departments and agencies with biodefense responsibilities. Although the statute required GAO to assess resource gaps regarding the goals set forth in the National Biodefense Strategy, GAO did not address this matter in its final report.

Implementor:

**Congress**

Status:

 **Partial Action**

*Action Item f.***Institute a major quadrennial biodefense review.**

At the direction of Congress and under the management of the Vice President, the NSC should conduct a major quadrennial biodefense review of all relevant departments and agencies, with a report and updated National Biodefense Strategy submitted on behalf of the Executive Branch to Congress by the Vice President.

Congress has not passed legislation requiring a quadrennial biodefense review, and the Executive Branch has not indicated interest in such an effort. A long-range review of federal departments and agencies with biodefense responsibilities should follow implementation of the National Biodefense Strategy and corresponding review and unification of existing federal biodefense spending. In turn, the review should inform the next iteration of the Strategy.

Implementor:





**White House, Congress**

Status:

**Inaction**

# RECOMMENDATION 4

**Unify biodefense budgeting.** Congress should mandate the development of a unified budget that allows Congress and the Administration to understand how the entire biodefense enterprise is funded.<sup>43</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Develop and execute a mandatory annual biodefense call for data.	White House, Congress, OMB	 Completed
b. Conduct a cross-cutting biodefense budget analysis.	White House, OMB	 Partial Action
c. Align budget items to the National Biodefense Strategy of the United States of America.	White House, OMB	 Partial Action
d. Provide predictable and multi-year funding for all biodefense programs.	White House, OMB, Federal Government	 Inaction

*Action Item a.*

**Develop and execute a mandatory annual biodefense call for data.**

The President and congressional appropriators should require the Director of the Office of Management and Budget to conduct this data call, coordinated by the Vice President. Each department and agency should catalogue all of their biodefense programs and indicate which support specific biodefense requirements in the National Biodefense Strategy, and which do not. The submissions should include historical annual expenditures for each program and predicted future needs.

National Security Presidential Memorandum 14 tasks the Secretary of Health and Human Services with issuing an annual request for information to identify federal programs and activities that contribute to the objectives of the National Biodefense Strategy. Each federal department and agency develops an annual Biodefense Memorandum in response to the request for information that the Biodefense Coordination Team uses to prepare an annual Biodefense Assessment to identify gaps, shortfalls, and redundancies; describe challenges to the implementation and execution


## RECOMMENDATION 4

of the Strategy; and recommend any necessary updates or changes to the Strategy. Based on the Biodefense Assessment, the NSC and OMB are tasked with working together to align biodefense policy priorities with program budgets. OMB and agency budget personnel should help formulate the reporting criteria to enable this assessment.

Implementor:

**White House, Congress, OMB**

Status:

 **Completed**

### *Action Item b.*

#### **Conduct a cross-cutting biodefense budget analysis.**

**Using the information collected in the data call, the Vice President and the Director of the Office of Management and Budget should identify gaps and overlaps in and among federal programs. This analysis should be used to inform OMB budgetary guidance sent to departments and agencies for the coming fiscal year.**

In February 2019, Congress included a requirement that OMB conduct a cross-cutting biodefense budget analysis in the conference report for the Consolidated Appropriations Act of 2019 (P.L. 116-6).<sup>44</sup> Congress again included such a requirement in the conference report for the Consolidated Appropriations Act of 2020 (P.L. 116-93).<sup>45</sup> Congress further emphasized their interest in oversight of federal biodefense by including in the National Defense Authorization Act of 2021 (P.L. 116-283) a permanent standing requirement to conduct a biodefense budget analysis and submit an annual biodefense budget to Congress. However, OMB has yet to finalize and release the analysis required by the two previous conference reports. As Congress and the federal government continue COVID-19 response activities and begin work to reassess the funding and organization of the Nation's biodefense efforts, a cross-cutting analysis would serve as a useful tool for the development of future policy recommendations.<sup>46</sup>

Implementor:

**White House, OMB**

Status:

 **Partial Action**

### *Action Item c.*

#### **Align budget items to the National Biodefense Strategy of the United States of America.**

**The Director of the Office of Management and Budget should require that all annual budget request submissions pertaining to biodefense adhere to the guidance from OMB, based on the National Biodefense Strategy and the budget crosscut.**

National Security Presidential Memorandum 14 requires departments and agencies to describe to the Secretary of Health and Human Services how existing programs and resources could be better utilized or allocated to align with the National Biodefense Strategy and how additional resources could be applied to support the goals of the Strategy. National Security Presidential Memorandum 14 further requires departments and agencies to submit budgets for biodefense-related programs that are based on policy guidance derived from the National Biodefense Strategy and informed by the annual Biodefense Assessment. Departments and agencies are required to justify spending relative to the goals of the National Biodefense Strategy. National Security Presidential Memorandum 14 also requires submission of annual budget requests to conform with budget guidance issued by OMB and detail how they align with the National Biodefense Strategy.

The results of the process required by National Security Presidential Memorandum 14 were partially reflected in the FY 2021 budget, most explicitly in the budget for the Office of the Department of Health and Human Services Assistant Secretary for Preparedness and Response. However, other legacy biodefense programs saw little budgetary change from one fiscal year to the next and lacked references to the National Biodefense Strategy.

Implementor:

**White House, OMB**

Status:

 **Partial Action**

#### *Action Item d.*

### **Provide predictable and multi-year funding for all biodefense programs.**

**The President should request funding for all biodefense activities in the annual budget request, including multi-year requests for those programs that the Vice President and Director of the Office of Management and Budget determine would benefit from such forward funding. Additionally, departments and agencies should provide multi-year grants, contracts, and/or cooperative agreements wherever possible.**

With limited exceptions, the White House has not requested, and Congress has not appropriated, multi-year funding for biodefense programs. Instead, biodefense programs have received funding through the annual appropriations process. In recent years, Congress has struggled to finalize government funding prior to the start of each fiscal year, leaving key biodefense programs subject to continuing resolutions and government shutdowns. This presents challenges to federal departments and agencies seeking to make long-term investments in biodefense.



## RECOMMENDATION 4

Lack of predictable multi-year funding also makes it more difficult for federal departments and agencies to incentivize private sector entities to develop medical countermeasures, where the federal government is the only purchaser.<sup>47</sup> The medical countermeasure development process is long and risky and relies on continued governmental engagement with industry. Multi-year funding would allow for more efficient utilization of available resources and provide market certainty to private sector partners who may be hesitant to invest in the biodefense enterprise.

Notably, some discrete activities do have multi-year budgets. The Public Health Emergency Medical Countermeasures Enterprise annually issues a five-year budget covering HHS entities involved in medical countermeasure development and procurement: the Food and Drug Administration (FDA), the National Institutes of Health (NIH), BARDA, and Strategic National Stockpile. This multi-year budgeting approach should be mirrored across the biodefense enterprise. Moreover, OMB and Congress should consider these multi-year budgets as part of the budgeting and appropriations processes, respectively.

Compounding the challenges of dependency on the annual appropriations process, chronic federal underfunding of biodefense programs has necessitated significant emergency spending when crises occur. Responses to all recent infectious disease public health emergencies (i.e., H1N1 influenza, Ebola, Zika, COVID-19) were funded through emergency supplemental appropriations, an approach that dramatically reduces certainty and consistency in preventing, deterring, preparing for, detecting, responding to, attributing, recovering from, and mitigating biological events.<sup>48</sup>

The nature of supplemental funding can also have significant implications for the success of the programs it is designed to support. The uncertain nature of emergency funding prevents non-federal partners from conducting long-term biodefense planning. State, local, tribal, and territorial governments that depend on federal assistance to support their biodefense programs can better apply resources over a multi-year timeframe. Moreover, because this emergency funding is provided outside the normal appropriations process, it usually disappears after the immediate crisis has abated. In many cases, this means that valuable response capacity and capability are lost when funding dwindles, leaving the public and private sectors to start afresh with each new crisis.

Implementor:

**White House, OMB, Federal Government**

Status:


 **Inaction**

# COVID-19

**Annual appropriations for emergency readiness fall short of providing recipients with the resources they need to enhance preparedness and build capacity for the future.** Supplemental funding at higher levels is only provided when a disaster occurs and is often earmarked by Congress for a singular event. For recipients of federal readiness funds to be proactive (as opposed to reactive) and build upon prior work, funding needs to be sustained. For example, the Department of Health and Human Services Assistant Secretary for Preparedness and Response used COVID-19 emergency supplemental funding to create the National Special Pathogen System. Unless the National Special Pathogen System is included in annual requests to Congress in the future, the program will receive no new funding in upcoming fiscal years. This system is designed to solve the critical challenges the Healthcare and Public Health Sector faced in confronting COVID-19 by creating a nationwide network to address special pathogen outbreaks. However, if sustained funding is not provided for the National Special Pathogen System, the Sector will yet again face similar challenges during the next pandemic.

# RECOMMENDATION 5

**Determine and establish a clear congressional agenda to ensure national biodefense.** Congress must ensure that the Nation is protected by an efficient, effective biodefense enterprise through augmented and coordinated congressional oversight.<sup>49</sup>

ACTION ITEM	IMPLEMENTER	STATUS
a. Develop joint congressional oversight agendas.	Congress	 Crisis Action

## *Action Item a.*

### **Develop joint congressional oversight agendas.**

At the start of each congressional session, Senate and House leadership should direct each committee with biodefense jurisdiction, in accordance with House and Senate rules, to convene for an in-depth classified biological threat briefing. Leadership should ensure that all identified committees include pressing biodefense topics in their oversight agendas. These agendas should include joint committee and joint chamber hearings, and other oversight activities.

Thirty-one Congressional committees have jurisdiction over aspects of the Nation's biodefense enterprise. Despite this overlapping jurisdiction and the importance of adequate oversight, Congressional leadership has yet to develop joint congressional oversight agendas, and Congress has not held joint committee and joint chamber hearings. House and Senate committees did hold 17 biodefense-related oversight hearings in the 115<sup>th</sup> Congress, and 50 biodefense-related hearings—the vast majority of which addressed the response to COVID-19—in the 116<sup>th</sup> Congress. These hearings varied substantially in scope and aim. Additionally, in April 2020, Speaker of the House Nancy Pelosi created the Select Subcommittee on the Coronavirus Crisis within the House Committee on Oversight and Reform to investigate the federal response to the crisis and monitor the spending of federal emergency appropriations to address the pandemic. Though the Committee's focus is on the immediate threat posed by COVID-19, its oversight activities could address overall federal biodefense capabilities.


In 2018, we recommended that House and Senate leadership establish a bicameral, bipartisan Congressional Biodefense Working Group.<sup>50</sup> Through this forum, representatives from all relevant committees with authorization and appropriation

## RECOMMENDATION 5

responsibilities for biodefense would convene regularly. Discussion would address oversight objectives for Congressional authorization and appropriations, and potential government reform.


In addition to oversight hearings, COVID-19 drove substantial congressional activity. Numerous pieces of legislation were introduced in the 116<sup>th</sup> Congress, addressing various aspects of the Nation's ability to prevent, deter, prepare for, detect, respond to, attribute, recover from, and mitigate biological events, although few made it past committee consideration. Additionally, Congress passed several large emergency legislative packages to fund public and private sector response efforts.<sup>51</sup>

Implementor:  
**Congress**

Status:  
 **Crisis Action**

# RECOMMENDATION 6

**Improve management of the biological intelligence enterprise.** The Director of National Intelligence should address the biological threat in the same way that other issues have been handled that cut across multiple intelligence agencies.<sup>52</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Create a National Intelligence Manager for Biological Threats.	Director of National Intelligence	 Partial Action
b. Make biological weapons programs and related activities a discrete intelligence topic.	Director of National Intelligence	 Partial Action
c. Address bystanders.	Director of National Intelligence	 Partial Action
d. Distribute assessments.	Director of National Intelligence	 Partial Action

## *Action Item a.*

### **Create a National Intelligence Manager for Biological Threats.**

The Director of National Intelligence should create a National Intelligence Manager for Biological Threats and ensure that this National Intelligence Manager interacts appropriately with other National Intelligence Managers who address some aspect of the biological threat. The Director of National Intelligence should make this new National Intelligence Manager the executive agent for distributing certain funds for biological intelligence activities, transferring responsibility from the Central Intelligence Agency.

Former Director of National Intelligence Coats chose not to establish a separate National Intelligence Manager for Biological Threats. Instead, he assigned primary responsibility for biological threats to the National Intelligence Manager for Weapons of Mass Destruction, who is also the Director of the National Counterproliferation Center. The National Intelligence Manager for Weapons of Mass Destruction already

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had a portfolio that included biological weapons of mass destruction and the Director of National Intelligence believed that a separate National Intelligence Manager was, therefore, unnecessary.

In January 2021, President Biden issued a National Security Memorandum to address federal COVID-19 response efforts and biological preparedness, including biological intelligence.<sup>53</sup> The Memorandum instructs the Director of National Intelligence to review Intelligence Community activities related to pandemics and high consequence-biological threats, and develop a plan to strengthen biodefense intelligence capabilities. The Memorandum suggests the creation of National Intelligence Manager and National Intelligence Officer positions focused on biological threats as solutions for further prioritizing the biological threat.

Meanwhile, the National Counterterrorism Center and other National Intelligence Managers continue their own activities addressing the biological threat. Military intelligence efforts—especially those supporting and resulting from U.S. Special Operations Command (that assumed responsibilities for addressing weapons of mass destruction from U.S. Strategic Command)—have continued as well.

Implementor:

**Director of National Intelligence**

Status:

 **Partial Action**

### *Action Item b.*

#### **Make biological weapons programs and related activities a discrete intelligence topic.**

**The Director of National Intelligence should ensure that the Intelligence Community assigns priorities to countries and non-state actors as they relate to biological weapons programs and activities. The Intelligence Community should broaden focus to address classes of biological agents, as opposed to individual diseases. The Intelligence Community should also collaborate with the private sector when conducting this analysis and ensure that scientific and other expertise resident within the Community is sufficient to develop biological threat futures.**

The Intelligence Community continues to determine how best to assign priorities to the biological weapons programs and activities of countries and non-state actors, as well as to classes of biological agents.

Implementor:

**Director of National Intelligence**

Status:

 **Partial Action**

*Action Item c.***Address Bystanders.**

**The Director of National Intelligence should ensure that the Intelligence Community develops intelligence collection strategies that address bystanders, who may be able to provide useful information.**

In 2019, the Director of National Intelligence released the National Intelligence Strategy that aligns intelligence objectives with national strategies and communicates these objectives to the Intelligence Community workforce, partners, oversight, customers, and citizens. Bystanders are not addressed by the Strategy. However, the Intelligence Community addresses bystanders as part of regular intelligence activities.

Implementor:

**Director of National Intelligence**

Status:

 **Partial Action***Action Item d.***Distribute assessments.**

**The Director of National Intelligence should ensure that the Intelligence Community dedicates sufficient intelligence and scientific resources to collection and analysis to produce and distribute comprehensive biological threat assessments to all members of the biodefense enterprise.**

According to the 2019 National Intelligence Strategy, the Intelligence Community will provide in-depth assessments, context, and expertise about the strategic environment, including capabilities, activities, and intentions of key state and non-state entities to inform U.S. national security policy and strategy development. While the Intelligence Community does develop some biological threat-related products, it does not produce and distribute comprehensive biological threat assessments to the entire biodefense enterprise.

Implementor:




**Director of National Intelligence**

Status:

 **Partial Action**

# RECOMMENDATION 7

**Integrate animal health and One Health approaches into biodefense strategies.** Effective solutions for defense against emerging infectious disease and bioterrorist threats lie at the interface of human, animal, and environmental health.<sup>54</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Institutionalize One Health.	White House	 Partial Action
b. Develop a nationally notifiable animal disease system.	USDA Animal and Plant Health Inspection Service (APHIS)	 Partial Action
c. Prioritize emerging and reemerging infectious diseases.	DOD, HHS, USDA	 Inaction

## *Action Item a.*

### **Institutionalize One Health.**

The White House should lead all relevant agencies to a new level of understanding, planning, and operating with respect to biodefense that includes an animal health and, more broadly, a One Health mindset. The Vice President should direct the NSC to review all strategic biodefense documents to ensure that animal health and environmental health agencies are identified and assigned responsibility, and that their activities are fully aligned and coordinated with other biodefense activities and are current with respect to new science and evidence.

The federal approach to biodefense is still largely geared toward human health, instead of an approach that also factors in animal and environmental health. COVID-19 demonstrates this disparity. Though SARS-CoV-2 is the third zoonotic coronavirus in recent years, related federal animal health and human health programs and policies are not integrated. Two of these three viruses originated in wildlife, also indicating the need for expertise from agencies such as the Department of the Interior (DOI). The federal government continues to prioritize human health above that of animal or environmental health, with little coordination across responsible federal agencies.



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Limited steps have been taken to embed the One Health approach in federal biodefense strategies and activities. One recent development is the One Health Federal Interagency Network.<sup>55</sup> Run by the Centers for Disease Control and Prevention (CDC) One Health Office, the Network is developing a five-year strategic plan built on multisectoral collaboration for One Health. CDC, DOI, and USDA co-lead this effort, working to find multisectoral ways to desegregate public health security-related activity while taking human, animal, and environmental health into consideration. The onset of the COVID-19 pandemic delayed development of this plan.

Complete response and recovery plans for zoonotic diseases do not yet exist. However, the January 2017 update of the *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* took the human-animal interface into account.<sup>56</sup> The Annex reinforced the need for animal surveillance and infection control, medical countermeasure development, and other activities in the event of a zoonotic outbreak. It contains some elements of a zoonotic disease emergency response plan. The 2019 Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22), also required the National Health Security Strategy to specifically address zoonoses.<sup>57</sup>

Implementor:

**White House**

Status:

 **Partial Action**

### *Action Item b.*

#### **Develop a nationally notifiable animal disease system.**

**The Administrator of the Department of Agriculture’s Animal and Plant Health Inspection Service, working with the Director of the Department of the Interior’s U.S. Fish and Wildlife Service and other partners as appropriate, should develop a nationally notifiable animal disease list and implement a reporting system for states, localities, tribes, territories, and other owners of disease information. USDA should afford DHS, HHS, and other agencies engaged in biodefense access to the data in this system.**

In an important step toward a national animal disease system, USDA published a draft framework for public comment in 2016 that would make reporting of notifiable diseases mandatory by veterinary practitioners, producers, diagnostic laboratory personnel, and others with knowledge of confirmed or suspected occurrences. For the first time, private laboratories and entities would be required to report both notifiable and monitored diseases. The framework would rely on collaboration among federal, state, tribal, and territorial officials, and the private

sector to determine the specific data needs for each disease on the monitored list. The framework underwent a prolonged review period and a proposed rule for the National List of Animal Diseases was issued on April 2, 2020 for public comment.<sup>58</sup> After the end of that initial comment period, USDA again invited public comments for the proposed rule in August 2020.<sup>59</sup> USDA has not yet finalized the rule.

Implementor:

**APHIS**

Status:

 **Partial Action**

### *Action Item c.*

#### **Prioritize emerging and reemerging infectious diseases: Inaction.**

The Secretary of Health and Human Services, in coordination with the Secretary of Agriculture and Secretary of Defense, should prioritize emerging infectious disease threats. They should consider using a multi-criteria decision analysis tool and transparent methodology to develop these determinations. They should address pathogens and pathogen families with the potential to cause a catastrophic public health emergency sufficient to affect national security, including agents known to infect wildlife and domestic animals. The list should drive funding in surveillance, response planning, medical countermeasure development, and any activities revealed as gaps per action item 3e.

HHS and USDA leadership have not convened to systematically determine the most pressing emerging infectious disease threats and inform funding decisions. Before we issued our recommendation in *A National Blueprint for Biodefense*, the CDC developed a zoonotic disease prioritization tool and began utilizing it in several countries. In December 2017, the CDC applied this tool to the United States partially addressing this recommendation.

Cabinet-level leadership must drive any threat identification and prioritization process. Absent this effort, it will remain difficult to determine how best to budget finite resources for defense against emerging and reemerging infectious diseases.

Implementor:




**DOD, HHS, USDA**

Status:

 **Inaction**

# RECOMMENDATION 8

**Prioritize and align investments in medical countermeasures among all federal stakeholders.** The success of all medical countermeasure enterprise will be predicated on a highly coordinated approach among the Public Health Emergency Medical Countermeasures Enterprise partners to prioritize and budget for the right countermeasures.<sup>60</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Ensure NIH research supports civilian medical countermeasure priorities.	White House	 Partial Action
b. Ensure funding allocations are appropriate to meet the need.	White House	 Inaction
c. Require a biodefense spend plan from the National Institute of Allergy and Infectious Diseases (NIAID).	White House, Congress, NIAID	 Inaction

## *Action Item a.*

### **Ensure NIH research supports civilian medical countermeasure priorities.**

The Vice President should ensure that Public Health Emergency Medical Countermeasures Enterprise priorities, as well as those agents that have been determined to be material threats, guide NIH biodefense research investments and ensure delivery of medical countermeasure candidates that address Public Health Emergency Medical Countermeasures Enterprise medical countermeasure priorities.

The NIH, through NIAID, is heavily involved in the basic research needed to support the development of effective medical countermeasure candidates for subsequent advanced development. NIAID grants also support the early development of promising medical countermeasure candidates before transitioning products to BARDA for continued development assistance. The relationship between NIH and BARDA has matured, and there are now stronger connections between BARDA requirements and NIH basic research to support those requirements. Additionally,

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NIAID is a member of the Public Health Emergency Medical Countermeasures Enterprise. Recent reorganization of the Public Health Emergency Medical Countermeasures Enterprise by the Department of Health and Human Services Assistant Secretary for Preparedness and Response and the codification of Public Health Emergency Medical Countermeasures Enterprise structures and requirements in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) should also help drive further progress.

Despite these positive developments, systematic prioritization of emerging infectious diseases remains necessary to provide NIH with additional information in support of medical countermeasures for emerging infectious diseases. A NIAID spend plan is also still needed.

Implementor:

**White House**

Status:

 **Partial Action**

### *Action Item b.*

#### **Ensure funding allocations are appropriate to meet the need.**

**The Vice President should assess whether the level of funding allocated for biological agents that have received a material threat determination, and the proportion of funding allocated for early research and development of medical countermeasure candidates versus advanced research and development, is appropriate for maximizing opportunity to achieve overall success. The unified budget per Recommendation 4 provides a mechanism to achieve this harmonization. If the funding level for BARDA needs to be increased, that must be requested.**

Neither the White House nor the federal departments and agencies that develop medical countermeasures has issued a publicly available assessment of the funding levels that would address national medical countermeasure requirements based on material threat determinations and ascertain whether the balance of basic and advanced research is yielding needed results. Historically, the nation's medical countermeasure enterprise has lacked the necessary funding to develop and stockpile medical countermeasures for all material biological threats, let alone for emerging and reemerging infectious diseases.

DHS determined that Ebola virus was a material threat a decade prior to the West Africa Ebola outbreak seven years ago, but medical countermeasures were nonexistent when the need arose in 2014 because early basic research candidates had long since been abandoned. Whereas the Defense Advanced Research and

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Projects Agency is permitted to take risks (it is effectively their mandate to do so), BARDA is not. BARDA is expected to succeed with every contract it awards, and to do so at a much lower price than the regular drug development process entails. The Public Health Emergency Medical Countermeasures Enterprise Multiyear Budget includes two projected out-years of funding, but when the time comes to request the funding for those out-years, the agencies involved provide different justification for the requested resources than the explanation given in the original multiyear budget.

Implementor:

**White House**

Status:

 **Inaction**

### *Action Item c.*

#### **Require a biodefense spend plan from NIAID.**

**Pursuant to action items 8a and 8b, and concurrent with the annual President's Budget Request, the Director of the National Institute of Allergy and Infectious Diseases should annually submit a plan to Congress that describes in detail the goals for NIAID medical countermeasure research investments, including transition to advanced research, development, and procurement planning at BARDA. The Director of the National Institute of Allergy and Infectious Diseases should base this plan on the development of medical countermeasure candidates targeted against agents that have received a material threat determination, as well as to priorities identified on the emerging infectious disease list developed per action item 7c. The Director of the National Institute of Allergy and Infectious Diseases should include ways to strengthen the bridge between NIAID and BARDA so that products can more easily transition from early-stage development to advanced research and development.**

NIAID does not submit an annual plan to Congress that describes its goals for research investments to meet BARDA requirements. The Public Health Emergency Medical Countermeasures Enterprise does submit a five-year budget plan, and the 21<sup>st</sup> Century Cures Act (P.L. 114-255) requires submission of this plan no later than March 1st of each year. Although the submission does break down the multi-year budget by agency, including for NIAID, this plan does not capture the NIAID spending plan in detail. The plan also frequently differs dramatically from the President's Budget Request and is subject to change when the Administration requests funding from Congress for the out-years of the five-year budget plan. The plan consists primarily of a high-level, three-page narrative that explains NIAID's past accomplishments. It does not describe how NIAID intends to map its funding to a specific list of BARDA requirements for medical countermeasures.

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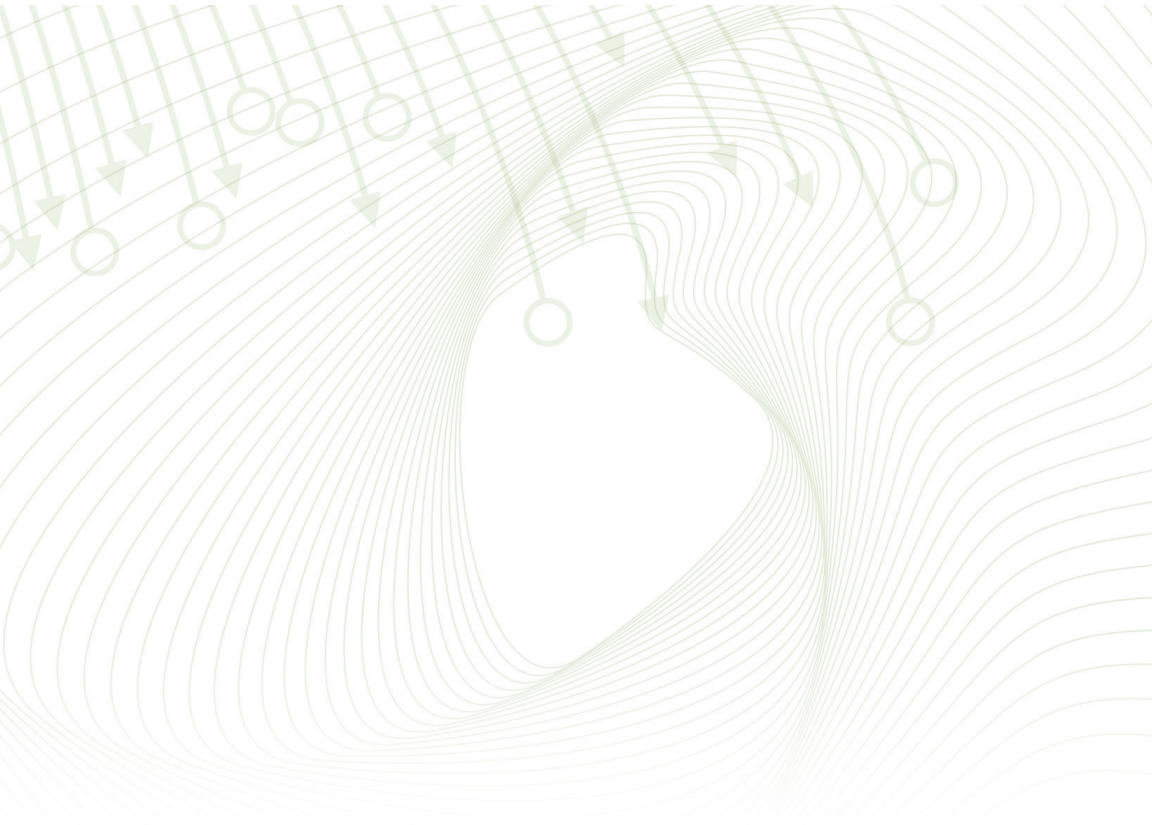
The major disconnect between NIAID and BARDA regarding the development of Ebola medical countermeasures became problematic when the disease reemerged in 2014 and no product candidates were available. Congress and BARDA must understand the ways that NIAID investments specifically address BARDA medical countermeasure requirements. The existing five-year Public Health Emergency Medical Countermeasures Enterprise plan does not fulfill this requirement.

Implementor:

**White House, Congress, NIAID**


Status:

**Inaction**



# RECOMMENDATION 9

**Establish better support to inform decisions based on biological attribution.** The United States has yet to fully establish biological attribution capability due to the inherent challenges associated with microbial forensic techniques and related analyses. There is no formal apparatus that uses attribution information to inform decisions.<sup>61</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Establish a national biological attribution decision-making apparatus.	White House	 Inaction
b. Place the Federal Bureau of Investigation (FBI) in charge of the National Bioforensics Analysis Center.	Congress	 Partial Action


## *Action item a.*

### **Establish a national biological attribution decision-making apparatus.**

The Vice President should direct the Secretary of State, Secretary of Defense, Secretary of Homeland Security, the Attorney General, and the Director of National Intelligence to establish and formalize this apparatus. They should inform this apparatus with 1) standards/burdens of proof in the U.S. criminal justice system; 2) evidence, information, and intelligence regarding the source; 3) accuracy, reliability, timeliness, credibility and defensibility of that evidence, information, and intelligence; and 4) national security considerations. This apparatus should be exercised to inform decisions and to ensure that these decisions are defensible.

There is currently no framework in place for the White House, departments, and agencies to inform decisions in the aftermath of a biological event. Various federal departments and agencies contributed to attribution efforts related to COVID-19 and found no evidence that the SARS-CoV-2 strain that caused the disease was genetically engineered.<sup>62</sup> The federal government should assess the attribution process undertaken to reach that conclusion and use it as a foundation to develop a national apparatus for future biological threats requiring attribution activities.

Implementor:  
**White House**

Status:  
 **Inaction**

*Action item b.*

### **Place the FBI in charge of the National Bioforensics Analysis Center.**

The FBI is the primary customer of the National Bioforensics Analysis Center and has the needed credibility and influence to allow the Center to fulfill its role in biological forensics and attribution. Congress should amend The Act to Enact Title 5 of the U.S. Code, “Government Organization and Employees,” and make the FBI responsible for the National Bioforensics Analysis Center, its administration, and its activities, including interagency support and coordination. Congress should reallocate appropriations accordingly. Congress should also increase its oversight over National Bioforensics Analysis Center activities.

The National Bioforensics Analysis Center provides dedicated biological attribution capability. The federal government, foremost the FBI, uses the facility to help determine the origin and characteristics of biological specimens. The President’s Budget Request for FY 2018 sought to close the National Biodefense Analysis and Countermeasures Center, the home of the National Bioforensics Analysis Center. Thankfully, Congress did not agree. Language contained in the National Defense Authorization Act for Fiscal Year 2018 (P.L. 115-91) required the Secretary of Homeland Security and the Secretary of Defense to submit a report to Congress on the functions, mission, and end users of the National Biodefense Analysis and Countermeasures Center, as well as a transition plan in the event of the facility’s closure.


At the direction of OMB, and as reflected in the President’s Budget Request for FY 2019, DHS and the FBI entered into a Memorandum of Agreement in September 2018 about National Bioforensics Analysis Center funding and operational responsibilities. Under the Memorandum of Agreement, the FBI and DHS share the costs of operating the National Bioforensics Analysis Center. The FBI is responsible for daily operations of the National Bioforensics Analysis Center while DHS operates and maintains the building. The President’s Budget Requests for FY 2020 and FY 2021 reflect this new *status quo*.

Congress should transfer responsibility for the National Bioforensics Analysis Center to the FBI. Additionally, Congress should provide additional funding to the FBI to support the agency’s new responsibilities with regard to the National Bioforensics Analysis Center.

Implementor:

**Congress**

Status:




 **Partial Action**



# RECOMMENDATION 10

## Establish a national environmental decontamination and remediation capacity.

The Nation must be able to decontaminate and remediate affected environments in a coordinated, predictable fashion. This national capacity must be sufficient to address accidents, bioterrorism, and emerging infectious diseases.<sup>63</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Include the Federal Emergency Management Agency (FEMA) in efforts to address remediation.	White House	 Partial Action
b. Assign responsibility to the Environmental Protection Agency (EPA) for environmental decontamination and remediation.	Congress	 Inaction
c. Conduct studies of those exposed to disease-causing agents.	White House, Congress	 Partial Action

### Action Item a.

#### Include FEMA in efforts to address remediation.

The Vice President should ensure that FEMA is included in interagency efforts led by the Office of Science and Technology Policy (OSTP) and other federal efforts to study and determine policy regarding remediation after biological attacks.

There is no indication that FEMA has been included in any federal effort to study and develop policy for environmental remediation following a biological event. Under the 2017 *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans*, FEMA is primarily responsible for managing coordinating centers, funding sources, and non-medical supply resourcing, and supporting the Emergency Support Functions and Recovery Support Functions for biological incidents.<sup>64</sup> However, leadership and policy with regard to remediation activities has not been clearly established.

Implementor:

White House

Status:

 Partial Action

*Action Item b.***Assign responsibility to the EPA for environmental decontamination and remediation**

**Congress should amend the National Environmental Policy Act of 1969 to place the Administrator of the Environmental Protection Agency in charge of environmental decontamination and remediation after accidental releases and biological attacks. The EPA should assume operational responsibility and coordinate with other agencies, non-federal governments, academia, and private sector organizations for environmental decontamination and remediation after accidental releases and biological attacks.**

Congress has not amended the National Environmental Policy Act of 1969 (P.L. 91-190)<sup>65</sup> to place the Administrator of the Environmental Protection Agency in charge of environmental decontamination and remediation after accidental releases and biological attacks. However, under the 2017 *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans*, EPA is the lead agency for environmental cleanup and remediation in the inland zone.<sup>66</sup> In the event of environmental contamination due to a biological incident, HHS is supposed to collaborate with EPA to develop and implement strategies for sampling and sharing testing results. Additionally, EPA conducts response activities under the Comprehensive Environmental Response Compensation and Liability Act (42 U.S.C. §9601 et seq.), or an Emergency Support Function 10 mission assignment in the event of a declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Public Law 93-288, as amended, 42 U.S.C. 5121 et seq.).<sup>67</sup> The National Biodefense Strategy superseded HSPD-10 but did not make the EPA the lead agency responsible for decontamination.

Real world events have not tested these plans and responsibilities. FEMA should work with EPA and HHS to exercise the *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* regarding environmental remediation and include DOI to address issues related to preventing or controlling the establishment of new wildlife reservoirs of disease agents introduced into the United States.

Implementor:

**Congress**

Status:

 **Inaction**

*Action Item c.***Conduct studies of those exposed to disease-causing agents.**

The Vice President and Congress should require the Secretary of Defense, Secretary of Agriculture, Secretary of Health and Human Services, Secretary of Homeland Security, Secretary of the Interior, Secretary of Veterans Affairs, and the Attorney General to monitor those that come under their purview when they have or could have been exposed during or as a result of accidental releases, natural occurrences, and biological attacks. The Vice President and Congress should require the Secretary of Health and Human Services to conduct cross-sectional studies of those exposed to anthrax on Capitol Hill and elsewhere during the events of 2001.

The Vice President and Congress have not required the Secretary of Agriculture, Secretary of Defense, Secretary of Health and Human Services, Secretary of the Interior, and Secretary of Veteran's Affairs to monitor those under their purview for ill effects from exposure to naturally occurring, accidentally released, or intentionally introduced diseases (including those due to biological terrorism and warfare).

Implementor:


**White House, Congress**

Status:

 **Partial Action**

# RECOMMENDATION 11

**Implement an integrated national biosurveillance capability.** The White House must finalize and release the implementation plan for the National Strategy for Biosurveillance.<sup>68</sup>

ACTION ITEM	IMPLEMENTER	STATUS
a. Implement the National Strategy for Biosurveillance.	White House	 Partial Action

## Action Item a.

### Implement the National Strategy for Biosurveillance.

Under the direction of the Vice President, NSC staff should finalize and release the implementation plan for this strategy. The plan must describe roles and responsibilities for specific departments and agencies and provide metrics and goals for the individuals responsible. The plan must identify information required by decision makers (federal, state, local, tribal, territorial, and private sector) to manage a biological event. These requirements should then be used to determine needed data sources, technology, and operational processes to achieve situational awareness and response capabilities. The plan should encourage and incentivize private sector input.

The federal government implemented some of the elements of the 2012 National Strategy for Biosurveillance. However, the release of the National Biodefense Strategy effectively supplanted the National Strategy for Biosurveillance.

The National Biodefense Strategy includes objectives related to national biosurveillance. Goal 1.2 of the National Biodefense Strategy emphasized the importance of coordinated domestic and international information-sharing systems that are capable of timely prevention, detection, assessment, response, and recovery from biological incidents, and specified the need to enhance integration of biosurveillance systems and improve information-sharing and reporting.<sup>69</sup> Goal 4.1 calls for the sharing of biological threat and incident information with appropriate stakeholders to support multi-sectoral decision-making.

In July 2019, DHS completed a Strategy for Integrated Biosurveillance to govern the Department's biosurveillance activities, as required by the Joint Explanatory Statement accompanying the Consolidated Appropriations Act of 2018 (P.L. 115-

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141).<sup>70</sup> A corresponding implementation plan is in development but has not yet been released. The federal government continues to face problems in assisting state, local, tribal, territorial, and private sector biosurveillance efforts. The lack of integrated COVID-19 biosurveillance data at the federal level illustrates this capability gap.

Implementor:  
**White House**


Status:  
 **Partial Action**



# RECOMMENDATION 12

## Empower non-federal entities to become equal biosurveillance partners.

A timely response to a biological event cannot occur without increased collaboration among federal, state, local, tribal, and territorial jurisdictions, as well as non-governmental stakeholders.<sup>71</sup>

ACTION ITEM	IMPLEMENTER	STATUS
a. Create an interagency biosurveillance planning committee.	DHS	 Partial Action

### Action item a.

#### Create an interagency biosurveillance planning committee.

The Secretary of Homeland Security should make this committee the nexus for active collaboration with non-federal government and non-governmental organizations. This group will clarify and coordinate the response and recovery goals, objectives, and activities of federal, state, local, tribal, and territorial agencies, and non-governmental organizations following the determination that a biological event has occurred.

An interagency biosurveillance planning committee as envisioned by *A National Blueprint for Biodefense* does not currently exist, and current organizational structures fall short of what is needed to ensure timely collaboration among federal and non-federal stakeholders.

The National Biodefense Strategy requires the Biodefense Steering Committee to “establish appropriate consultative or advisory mechanisms” to obtain input from non-federal partners.<sup>72</sup> However, the Biodefense Steering Committee is not obligated to do so, and existing mechanisms for stakeholder input have been limited.

Additionally, there is no standing advisory board on which state, local, tribal, and territorial officials can support the National Biosurveillance Integration System. According to the DHS Countering Weapons of Mass Destruction Office, resource limitations have impacted its ability to stand up an advisory board.<sup>73</sup> This is especially troubling because stakeholder input is critical for the successful execution of the National Biosurveillance Integration System’s activities, particularly considering the DHS Strategy for Integrated Biosurveillance.

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The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) also included provisions related to biosurveillance. The statute requires the Secretary of Health and Human Services to establish technical and reporting standards for biosurveillance, and to convene a public meeting to gather input from federal departments and agencies with biosurveillance responsibilities; state, local, tribal, and territorial representatives; and non-governmental experts.<sup>74</sup> The Pandemic and All-Hazards Preparedness and Advancing Innovation Act mandates that this public meeting inform a strategy and implementation plan that include a review and assessment of existing capabilities and measures of progress. The law required the strategy and implementation plan to be submitted no later than December 2020.

Implementor:

**DHS**

Status:

 **Partial Action**



# RECOMMENDATION 13

**Optimize the National Biosurveillance Integration System.** The System must be optimized to meet its potential as both an early warning and a situational awareness system capable of working across the federal government.<sup>75</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
<b>a. Assess the viability of the National Biosurveillance Integration System as the prime integrator of biosurveillance information.</b>	White House	 Inaction
<b>b. Incentivize data sharing.</b>	White House	 Partial Action

## *Action Item a.*

### **Assess the viability of the National Biosurveillance Integration System as the prime integrator of biosurveillance information.**

As directed by the Vice President, the NSC should immediately examine the System to determine whether expenditures have yielded sufficient amounts of useful information to decision makers beyond DHS. A serious effort at planning and prioritization on the part of the White House is the only means to achieve success in this complicated interagency endeavor. If it cannot be achieved, the current effort should be discontinued.

A 2016 independent appraisal of the Nation's readiness to prevent, detect, and respond to biological threats concluded that different purposes and funding streams resulted in parallel biosurveillance systems with poor interoperability and electronic linkages.<sup>76</sup> The National Biosurveillance Integration System would have solved many of these problems through integrated analysis of human and animal data.

The response of the Department of Health and Human Services Assistant Secretary for Preparedness and Response to this independent appraisal contained several action items targeted for calendar years 2018 and 2019, including the development of "a plan for increasing interagency liaison activity between the National Biosurveillance Integration System and 14 federal departments and agencies" and provision of "an information technology system designed to integrate and exchange surveillance information between departments and agencies as part of a national targeting capability."<sup>77</sup> Additionally, DOD is working with the National Biosurveillance Integration System on a joint venture to further collaboration and data analysis. This system, the Biosurveillance Ecosystem, is



a technological platform that will allow for controlled and secure collaboration across users, customized data analytics, and advanced machine learning.

Neither the White House nor DHS has assessed the viability of the National Biosurveillance Integration System as the primary hub for federal biosurveillance information aggregation, analysis, and dissemination. The White House and DHS also have not offered corrective actions or alternative approaches to Congress for how to resolve existing challenges for the National Biosurveillance Integration System to fulfill its statutory requirements.

Implementor:

**White House**

Status:

 **Inaction**

### *Action Item b.*

#### **Incentivize data sharing.**

**The NSC should convene data owners and other stakeholders to evaluate incentive options and determine which are most viable for data and information sharing. These incentives should then be built into the National Biosurveillance Integration System, or a different construct as determined by the NSC and Congress.**

A lack of data and information-sharing—not technology platforms—is the primary barrier to effective biosurveillance. Incentives for interagency and non-federal entities to share biosurveillance data and information would help resolve these issues. The NSC can play a vital role by convening data owners and other stakeholders to evaluate and implement options that could incentivize data and information-sharing.

In the absence of this national coordination, some organizations are finding ways to facilitate information-sharing on their own. For instance, the Biosurveillance Ecosystem platform includes organization-specific spaces that are firewalled and controlled by the tenant of that space, allowing the tenant to control who sees their data and the extent to which their data may be integrated with that of others. As another example, a joint effort by the National Biosurveillance Integration System and the National Wildlife Health Center to enable federal, state, tribal, and territorial partners to rapidly report wildlife mortality events is working to enable export to, and interoperability with, other systems. The National Biosurveillance Integration System has also worked with interagency platforms and emergency medical service providers to develop an early warning and situational awareness tool using state and local data. The program accomplishes this by providing a no-cost platform that allows biosurveillance and analysis of events in users' own and surrounding communities.

Implementor:




**White House**

Status:

 **Partial Action**

# RECOMMENDATION 14

**Improve surveillance of, and planning for, animal and zoonotic outbreaks.** Government agencies must prioritize the collection of animal pathogen data and support new means of integrating them into analysis of human data. Agencies must also plan for major impacts of companion animal and wildlife zoonoses.<sup>78</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
<p><b>a.</b> Increase opportunities for animal health data collection. Congress should fund and facilitate enhanced opportunities for data collection at the livestock and wildlife levels via USDA, DHS, and DOI.</p>	Congress, DHS	 Partial Action
<p><b>b.</b> Fund the National Animal Health Laboratory Network at a level that allows it to achieve success.</p>	White House, Congress	 Completed
<p><b>c.</b> Develop guidance for the serious implications of companion animal and wildlife zoonoses.</p>	Congress, CDC, FEMA, APHIS	 Partial Action

## *Action Item a.*

### **Increase opportunities for animal health data collection.**

The Secretary of Homeland Security, via the National Biosurveillance Integration System, should further DHS collaborations with federal, state, local, tribal, territorial, and private sector entities that collect animal health data. Establishing partnerships with these stakeholders for data and information sharing will require incentives.

The 2018 Farm Bill (P.L. 115-334) required USDA to establish a National Animal Disease Preparedness and Response Program that would address the risk of the introduction and spread of animal pests and diseases that affect livestock and related industries.<sup>79</sup> Congress authorized this program to work through cooperative or other legal agreements with state departments of agriculture, academic institutions, producers, veterinary organizations, and others to enhance animal disease analysis and

surveillance, and electronic sharing of health data and risk analysis.<sup>80</sup> The authorities and funding mechanisms are discretionary, so USDA leadership and the White House must still prioritize animal health data collection. In FY 2019, USDA awarded \$5.2 million in funding for the program to support animal disease preparedness projects in 29 states.

USDA has continued its data collection activities in two primary populations: wild birds (with regard to avian influenza) and feral swine (with regard to pseudorabies and brucellosis). The USDA National Institute for Food and Agriculture (NIFA) has instituted a competitive program, the Food and Agriculture Cyberinformatics and Tools Initiative, designed to catalyze innovative ideas for harnessing big data and to synthesize new knowledge in agriculture.<sup>81</sup>

At DHS, the National Biosurveillance Integration System disseminates animal disease outbreak information through various channels to its federal and other partners. The National Biosurveillance Integration System has a long-standing liaison with USDA APHIS and more recently with the DOI National Wildlife Health Center. The National Biosurveillance Integration System has also partnered with the National Wildlife Health Center to modernize the latter's wildlife mortality reporting system, such that state, local, tribal, and territorial officials can digitally transmit mortality data to DHS in real time.

The national response to the COVID-19 pandemic demonstrated the value of a One Health approach to disease tracking. For example, the Bronx Zoo in New York City diagnosed COVID-19 in several of its tigers.<sup>82</sup> Previously, the Zoo also discovered West Nile Virus in wild birds and several of its captive birds before the disease was found in New York's human population.<sup>83</sup>

Implementor:

**Congress, DHS**

Status:

 **Partial Action**

### *Action Item b.*

## **Fund the National Animal Health Laboratory Network at a level that allows it to achieve success.**

**The Administration should request, and Congress should fund, the National Animal Health Laboratory Network at its authorized levels.**

In FY 2019, the National Animal Health Laboratory Network received approximately \$16.8 million in discretionary funding through APHIS and NIFA. The 2018 Farm Bill (P.L. 115-334) increased the Network's authorized funding level to \$30 million and made available \$40 million a year from the Commodity

Credit Corporation through FY 2022 for agricultural security programs, including the National Animal Health Laboratory Network. This funding is separate from annual discretionary appropriations for the Network. APHIS veterinary diagnostics programs, including the National Animal Health Laboratory Network, received only \$7 million in additional discretionary funding in FY 2020 relative to FY 2019 appropriations. Additionally, the President's Budget Request for FY 2021 included a \$5.1 million cut in funding to the Network for infrastructure needs. If enacted, these cuts would impact the Network's ability to provide real-time animal health surveillance.<sup>84</sup>

Implementor:

**White House, Congress**

Status:

 **Completed**

### *Action Item c.*

#### **Develop guidance for the serious implications of companion animal and wildlife zoonoses.**

**The Director of the Centers for Disease Control and Prevention, Administrator of the Federal Emergency and Management Agency and Administrator of the Animal and Plant Health Inspection Service, in collaboration with non-federal stakeholders, should develop guidance for states, localities, tribes, and territories to handle companion animal infections in the event of a major zoonotic disease outbreak. States, localities, tribes, and territories can then base their own planning requirements on this guidance. Congress should amend the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Public Law 93-288, as amended, 42 U.S.C. 5121 et seq) to require the Administrator of the Federal Emergency Management Agency to ensure that state, local, tribal, and territorial emergency preparedness and response plans address the handling of zoonoses in companion animals and wildlife.**

Specific guidance for state, local, tribal, and territorial partners, and the private sector on how to handle high consequence emergent zoonotic diseases in companion animals and wildlife has not yet been developed. A comprehensive One Health approach has not materialized.

In December 2017, DOI, USDA, and CDC convened a One Health workshop with the goal of prioritizing endemic, existing, and zoonotic diseases of greatest national concern. The One Health Federal Interagency Network has been developing a national One Health five-year strategic plan aimed at enabling multisectoral collaboration (e.g., linking surveillance systems across sectors). However, the COVID-19 pandemic has impeded their ability to finalize the Network's strategic plan.

## RECOMMENDATION 14

The zoonotic nature of COVID-19, as well as its spillback from humans into animals, including both farmed and wild mink in the United States,<sup>85</sup> underscores the dire need for this strategy.

CDC is also working with the National Association of State Public Health Veterinarians to develop recommendations to prevent diseases related to animals in public settings. A variety of programs already exist that can foster needed progress. DOI, USDA, and CDC, for example, collaborate on several programs for the surveillance and control of diseases like rabies, brucellosis, bovine tuberculosis, and swine and avian influenza. The USDA also detailed a liaison to the CDC who could become part of zoonotic emergency response and incident command there. Additionally, CDC holds monthly webinars on zoonotic threats.

FEMA published an updated *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* in 2017. This policy document falls under the National Response Framework and governs federal response activities to biological threats. The Annex points out that the primary Emergency Support Function for animal issues during a biological incident is ESF #8, Public Health and Medical Services (coordinated by HHS).

Implementor:




**Congress, CDC, FEMA, APHIS**

Status:

 **Partial Action**

# RECOMMENDATION 15

**Provide emergency service providers with the resources they need to keep themselves and their families safe.** Fulfill the Nation's commitment to these professionals while helping to ensure their participation in the event of a biological emergency.<sup>86</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Provide vaccines to responders who request them.	DHS	 Partial Action
b. Provide medkits to emergency service providers and their families.	CDC, FDA, ASPR	 Inaction
c. Establish reasonable personal protective equipment guidelines and requirements in advance of a biological event.	HHS	 Partial Action

## *Action Item a.*

### **Provide vaccines to responders who request them.**

The Secretary of Homeland Security must ensure that the DHS pilot program to provide emergency service providers with anthrax vaccines is implemented. The Secretary should make doing so an immediate priority. If successful, the Secretary should formalize the program and extend it to meet other threats.

In 2016, the First Responder Anthrax Preparedness Act (P.L. 114-268) authorized DHS, in coordination with CDC, to distribute and administer anthrax vaccine stored in the Strategic National Stockpile that is nearing its labeled usage date for administration to emergency response providers who choose to participate.

The legislation required participation of two to five cities. Implementation was delayed in 2017 and 2018, due in part to the reorganization that produced the DHS Countering Weapons of Mass Destruction Office. DHS began implementing the two-year First Responder Vaccine Initiative Pilot Program in 2019, with Mississippi

and Missouri participating through a cooperative agreement. As of September 2020, the program has trained nearly 2,000 emergency responders, and has administered 2,300 doses of anthrax vaccine from the Strategic National Stockpile to more than 1,000 first responder volunteers.<sup>87</sup> The COVID-19 pandemic has limited the total number of volunteers participating in the pilot, but the Countering Weapons of Mass Destruction Office anticipates completion of the trial by the end of FY 2021. Furthermore, the Countering Weapons of Mass Destruction Office is assessing both the impact of the pandemic on the program, as well as opportunities for the program to enhance COVID-19 vaccine distribution efforts. Congress and federal agencies should build on this initiative to ensure first responders have access to other vaccines in the Strategic National Stockpile for material threats, such as smallpox.

Implementor:

DHS

Status:

 Partial Action
*Action Item b.***Provide medkits to emergency service providers and their families.**

**The Director of the Centers for Disease Control and Prevention, Commissioner of the Food and Drug Administration, and Department of Health and Human Services Assistant Secretary for Preparedness and Response should finalize plans for prepositioning medkits with emergency service providers and their families, and request annual funding to implement the program.**

CDC has not prepositioned medkits with emergency services providers and their families and has no plans to do so. The agency evaluated the idea but declined to pursue it, citing issues such as program sustainability, the potential for antimicrobial resistance, and the lack of measures to prevent access by children and pets.<sup>88</sup> Instead, CDC personnel engaged in discussions with federal and other stakeholders to address the last mile question of getting supplies and medicines to first responders. Proposals under discussion include pre-positioning medkit components at pharmacies and residential delivery by the private sector.

Implementor:

CDC, FDA, ASPR

Status:

 Inaction

*Action Item c.***Establish reasonable personal protective equipment guidelines and requirements in advance of a biological event.**

The Secretary of Health and Human Services should commission the Institute of Medicine to examine current personal protective equipment research and requirements in light of potential biological threats. The Institute of Medicine should conduct this assessment in conjunction with the National Institute for Occupational Safety and Health, Occupational Safety and Health Administration (OSHA), and representatives from all of the major emergency service associations.

Not later than June 2021, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) requires HHS to establish guidelines addressing the safety and personal protection of healthcare workers. Additionally, the Department of Health and Human Services Assistant Secretary for Preparedness and Response has taken steps since 2015 to increase personal protective equipment training through the development of the Regional Ebola Treatment Network (now the National Special Pathogen System), which seeks to improve infection control practices at participating healthcare institutions.<sup>89</sup>

Implementor:

**HHS**

Status:

 **Partial Action**



# RECOMMENDATION 16

**Redouble efforts to share information with state, local, tribal, and territorial partners.** Emergency services providers are valid customers of threat-related information. The Intelligence Community must recognize this, work to eliminate barriers, and share more information with the emergency services critical infrastructure sector about the biological threat.<sup>90</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Strengthen the Joint Counterterrorism Assessment Team (JCAT).	Director of National Intelligence	<input type="radio"/> Inaction
b. Strengthen the ability of local police intelligence units to address the biological threat.	Department of Justice, Director of National Intelligence	<input checked="" type="radio"/> Partial Action
c. Enable fusion centers to address the biological threat.	FEMA, DHS Office of Intelligence & Analysis (I&A)	<input type="radio"/> Inaction

## *Action Item a.*


### **Strengthen the JCAT.**

The Director of National Intelligence should improve upon the partnerships (with first responders and other non-federal personnel) that are critical to the effective performance of the Director of National Intelligence-hosted JCAT. The Director of National Intelligence should solicit their feedback on how the JCAT can function in a way that allows these stakeholders to participate more fully and provides more value to them. The Director of National Intelligence should use this feedback to improve the program.

The JCAT is housed within the National Counterterrorism Center and staffed by employees from the National Counterterrorism Center, DHS, and FBI, as well as non-federal public safety officers (including law enforcement, fire service, emergency medical services, and emergency management). The JCAT identifies, produces, and disseminates counterterrorism intelligence to state, local, tribal, and territorial consumers. For example, in response to the COVID-19 pandemic, JCAT developed and issued guidance to state, local, tribal, and territorial agencies

regarding the potential for terrorists to take advantage of the national crisis.<sup>91</sup> Prior to dissemination, the National Counterterrorism Center, DHS, and FBI review the intelligence.

Implementor:  
**Director of National Intelligence**

Status:  
 **Inaction**

#### *Action Item b.*

### **Strengthen the ability of local police intelligence units to address the biological threat.**

**The Attorney General and Director of National Intelligence should share analytic methods relevant to these units to assist in the development of more robust and effective biological threat analysis.**

Limited progress has been made to strengthen this capability locally. In September 2017, the Director of National Intelligence created the First Responder Toolbox, an *ad hoc*, unclassified, For Official Use Only reference to promote coordination among federal and state, local, tribal, and territorial government authorities (including law enforcement) in deterring, preventing, disrupting, and responding to terrorist attacks. However, while progress has been made in increasing the number of information sharing platforms, the Attorney General and Director of National Intelligence have not shared analytic methods with local police intelligence units regarding the biological threat.

Implementor:  
**Department of Justice, Director of National Intelligence**

Status:  
 **Partial Action**

#### *Action Item c.*

### **Enable fusion centers to address the biological threat.**

**The Administrator of the Federal Emergency Management Agency and the Department of Homeland Security Under Secretary for Intelligence and Analysis should provide technical assistance to fusion centers to enable them to obtain needed biological information and intelligence from all relevant federal, non-federal governmental, and private sector sources.**

FEMA and DHS I&A provide technical assistance to fusion centers. DHS manages the Fusion Center Performance Program and conducts a regular assessment to measure the performance of individual fusion centers and those in the national network. The 2017 assessment found that the number of major events or incidents

## RECOMMENDATION 16

(e.g., special security events, disasters, active shooters) supported by fusion centers was increasing. The report recommended that FEMA identify opportunities to further information sharing, intelligence, and prevention-focused use of grant funds, with specific emphasis on fusions centers' ability to address current and emerging threats associated with terrorism, drugs, gangs, active shooters, transnational organized crime, and cybersecurity. Congress has also expressed interest in increased dissemination of biological risk information to federal and state, local, tribal, and territorial agencies.<sup>92</sup>


Implementor:  
**FEMA, DHS I&A**

Status:  
 **Inaction**



# RECOMMENDATION 17

**Fund the Public Health Emergency Preparedness cooperative agreement at no less than authorized levels.** The Administration and Congress must recognize that gains in public health preparedness locally benefit all jurisdictions nationally. They must also recognize that states, localities, tribes, and territories do not have the financial capacity to maintain past gains achieved by the Public Health Emergency Preparedness cooperative agreement through their own budgets.<sup>93</sup>

ACTION ITEM	IMPLEMENTER	STATUS
<p><b>a. Appropriate Public Health Emergency Preparedness funding to authorized levels or the President’s Budget Request, whichever is higher.</b></p>	<p>White House, Congress</p>	<p> Partial Action</p>

## *Action Item a.*

### **Appropriate Public Health Emergency Preparedness funding to authorized levels or the President’s Budget Request, whichever is higher.**

Congress authorized \$685 million per year from FY 2019–2023 for this program. Congress should at a minimum meet the President’s Budget Request for FY 2021, which at \$675 million is level funding relative to the amounts appropriated in FY 2019 and FY 2020.<sup>94</sup> More importantly, the Administration and Congress should increase funding for this vital program to support the activities of public health departments, benefiting their own populations and the entire country.

The President’s Budget Request for FY 2021 would have maintained Public Health Emergency Preparedness cooperative agreement program funding at \$675 million. Such an amount would have kept the funding at the same level as that of FY 2020. The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) authorized the program at \$685 million for FY 2019 to FY 2023, or \$10 million above FY 2020 funding levels and the FY 2021 request.<sup>95</sup> Congress ultimately appropriated \$695 million for Public Health Emergency Preparedness cooperative agreements as part in the FY 2021 omnibus funding package, \$20 million more than FY 2020 appropriations, and \$10 million more than authorized levels.<sup>96</sup> We applaud

## RECOMMENDATION 17

Congress for establishing a multi-year budget for the Public Health Emergency Preparedness cooperative agreement, and we urge Congress to continue to appropriate funding to at least authorized levels to help strengthen state, local, tribal, and territorial preparedness and response capabilities.

Implementor:

**White House, Congress**




Status:

 **Partial Action**



# RECOMMENDATION 18

**Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.** The time to change the way in which federal agencies issue guidelines is not in the middle of a crisis. Both the CDC and OSHA have important contributions to make and must work together and with private sector experts to develop and issue hospital guidelines now, in advance of the next outbreak.<sup>97</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Standardize the development of clinical infection control guidelines before biological events occur.	Congress, HHS, Department of Labor (DOL)	 Partial Action
b. Institute a process for obtaining and incorporating feedback regarding clinical infection control guidelines during biological events.	White House, HHS, DOL	 Partial Action
c. Require training based on these guidelines.	HHS, DOL	 Partial Action

## *Action Item a.*

### **Standardize the development of clinical infection control guidelines before biological events occur.**

Congress should direct the Secretary of Health and Human Services and the Secretary of Labor to implement a process (involving experts throughout the federal government and the private sector) to develop clinical guidelines for treatment, infection control, use of personal protective equipment, waste management, and other activities needed in the hospital setting. The Secretary of Health and Human Services and the Secretary of Labor should direct the CDC and OSHA, respectively, to identify specific steps within this process and make the description of that process readily and publicly available in advance of a biological event.

Contrary to the recommendation in *A National Blueprint for Biodefense*, Congress and the federal government have not taken action to standardize the development of clinical infection control guidelines. Rather, HHS and DOL continue to address individual outbreaks (e.g., Ebola, Zika, COVID-19) as they occur.

The National Biodefense Strategy placed further emphasis on the need to address clinical infection control. Goal 3 concentrates on developing plans that implement or support surge capabilities and should include clinical guidance to assist with appropriate triage and medical management of illnesses. The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) also requires the creation of guidelines for disease containment as part of a larger regional healthcare emergency response system.

Implementor:

**Congress, HHS, DOL**

Status:

 **Partial Action**

## COVID-19

**As with previous infectious disease events, CDC and DOL developed separate infection control guidelines in response to the COVID-19 pandemic.**<sup>98</sup> There is no standardized, established process for developing these guidelines. Instead, infection control guidelines are developed *ad hoc* in response to, rather than in advance of, biological events. Though OSHA rules refer to CDC guidelines and vice versa, healthcare workers must still consult both the CDC and OSHA guidelines to determine how to properly protect themselves and their patients.

### *Action Item b.*

**Institute a process for obtaining and incorporating feedback regarding clinical infection control guidelines during biological events.**

**During events occurring in the United States, the Vice President should direct the Secretary of Health and Human Services and the Secretary of Labor to convene a standing group of experts (including those from outside of the federal government) that reviews feedback from federal, state, local, tribal, territorial, and private healthcare facilities, and meets at least weekly to evaluate, update, and reissue clinical guidance.**

During the U.S. response to Zika, OSHA and the National Institute for Occupational Health and Safety solicited input from private sector experts and state, local, tribal, and territorial officials on Zika guidelines. HHS established the Healthcare Infection Control Practices Advisory Committee in 1991 to provide external perspective to CDC and the Secretary of Health and Human Services.<sup>99</sup> CDC has leveraged this entity to obtain and incorporate feedback during the response to the COVID-19 pandemic

from healthcare providers, advocacy organizations, health departments, and other stakeholders. However, outside of Healthcare Infection Control Practices Advisory Committee, it is unclear what formalized processes exist to facilitate discussion and sharing of infection control practices with the DOL or with HHS.

Implementor:

**White House, HHS, DOL**

Status:

 **Partial Action**

### *Action Item c.*

#### **Require training based on these guidelines.**

**The Secretary of Health and Human Services and the Secretary of Labor should regularly provide training for end users in the implementation of the guidelines.**

Limited steps have been taken to make infection control training available. CDC has developed training and educational resources to help healthcare providers understand the principles of infection control and how to produce risk assessments.<sup>100</sup> CDC has also developed training for Ebola and Zika. In response to COVID-19, CDC developed Project Firstline, a national training collaborative for infection control practices, and is working with state health departments to develop infection control training courses.<sup>101</sup>

Additionally, the Department of Health and Human Services Assistant Secretary for Preparedness and Response funded the National Emerging Special Pathogen Training and Education Center that provides education and training for public health and healthcare providers to manage individuals with suspected and confirmed highly infectious diseases.<sup>102</sup> The National Emerging Special Pathogen Training and Education Center is now one of four components of the National Special Pathogen System which builds on the Regional Ebola Treatment Network. The System was originally created to support the preparedness and response needs of hospitals, health systems, and healthcare providers to help prepare them to identify, isolate, assess, transport, and treat patients with COVID-19 or other special pathogens, or persons under investigation for such illnesses. As of December 2020, the National Emerging Special Pathogen Training and Education Center had conducted 119 virtual consultations, created 430 COVID-19 related resources, and established 1 phone line for emergency consultation with federal partners and healthcare facilities requiring assistance with patients suspected of or proven to be infected by special pathogens.<sup>103</sup>

Implementor:

**HHS, DOL**



Status:

 **Partial Action**



# RECOMMENDATION 19

**Minimize redirection of Hospital Preparedness Program funds.** The vast majority of the funding appropriated for the Hospital Preparedness Program must reach grant recipients. Program managers must base the application of these funds on a thorough review of successes and challenges within the program to date.<sup>104</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Cap Hospital Preparedness Program management and administration costs at three percent.	Congress	 Partial Action
b. Assess the impact of the Hospital Preparedness Program. Congress should task GAO to evaluate the impact of Hospital Preparedness Program grants on hospital preparedness.	ASPR	 Partial Action

## *Action Item a.*

### **Cap Hospital Preparedness Program management and administration costs at three percent.**

Congress should amend the Public Health Service Act to require that no less than 97 percent of appropriated Hospital Preparedness Program funds go directly to grantees.

The FY 2021 HHS Budget Justification requested \$257,555 million, a decrease of \$18 million from FY 2020. Of the \$257,555 million, \$26.1 million (10.1 percent) was set aside for Hospital Preparedness Program administration, performance evaluation, and oversight. This left slightly under 90 percent of funding for grants. In FY 2020, slightly above 84 percent of Hospital Preparedness Program funding went to the awardees, though the actual dollar amount for grants was the same in FY 2020 appropriations and the President's Budget Request for FY 2021.

Implementor:

**Congress**

Status:

 **Partial Action**

*Action Item b.***Assess the impact of the Hospital Preparedness Program.**

This evaluation should address, at a minimum: (1) the extent to which the goals of the Hospital Preparedness Program are being met; (2) how Hospital Preparedness Program funds should be allocated (e.g., based on risk); and (3) whether funding for the Hospital Preparedness Program is sufficient. The Department of Health and Human Services Assistant Secretary for Preparedness and Response and Congress should then use the results of the evaluation to determine reforms and funding needed to optimize the program.

In 2017, Congress tasked GAO with conducting an analysis of the Hospital Preparedness Program and other key preparedness and capacity-building programs. GAO found that funding for the Hospital Preparedness Program decreased by about 54 percent from FY 2002 to FY 2017.<sup>105</sup> Additionally, GAO reviewed Hospital Preparedness Program performance measures for personal protection, focusing on Hospital Preparedness Program Ebola awards from supplemental appropriations. For each of the five measures in the area of protection, the majority (ranging from 61–97 percent) of Hospital Preparedness Program awardees met each target.

Additionally, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) contains a requirement for the Secretary of Health and Human Services to conduct a study examining healthcare preparedness and response capabilities and medical surge capacities of hospitals, long-term care facilities, and other healthcare facilities with respect to public health emergencies.<sup>106</sup> The study should capture, at least in part, the impact Hospital Preparedness Program has had on hospital preparedness. HHS is developing this assessment.

Public health departments administer Hospital Preparedness Program funding, even though the recipients are healthcare institutions. The Department of Health and Human Services Assistant Secretary for Preparedness and Response found that Hospital Preparedness Program awardees are spending approximately 21 percent of Hospital Preparedness Program funds on administrative costs, with roughly 40 percent going to healthcare institutions. In 2019, the Assistant Secretary for Preparedness and Response included a clause in Hospital Preparedness Program cooperative agreements prohibiting awardees from utilizing more than 18 percent of the award amount for administrative costs. In 2020, allowable administrative costs decreased to 15 percent.

Implementor:


**ASPR**

Status:

 **Partial Action**

# RECOMMENDATION 20

**Provide the financial incentives hospitals need to prepare for biological events.** Preparedness must be included within the health delivery reform efforts of CMS and private sector payers. Bioterrorism and highly infectious disease preparedness should be required for accreditation and the CMS funding that comes with it. Any financing strategy must be realistic, but must also account for all contingencies and associated hospital planning requirements.<sup>107</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Adopt a disaster preparedness portfolio.	CMS, ASPR	 Partial Action
b. Link CMS incentives and reimbursement to new accreditation standards.	Congress	 Partial Action

## Action Item a.

### Adopt a disaster preparedness portfolio.

The Administrator of the Centers for Medicare and Medicaid Services, in conjunction with the Department of Health and Human Services Assistant Secretary for Preparedness and Response, should seek the endorsement of the National Quality Forum and adopt, as part of its health delivery reform efforts, a disaster preparedness portfolio that includes: Conditions of Participation, Interpretive Guidance, measures of development for inclusion within value-based purchasing, and innovation projects. Preparedness measures should be included in the evolving Merit-Based Incentive Payment System program and link community, supplier, and provider resilience efforts to reimbursement and incentives.

In 2016, CMS issued *Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers* (commonly referred to as the Emergency Preparedness Rule),<sup>108</sup> to ensure adequate planning for naturally occurring

and human-generated disasters, and to promote coordination among federal and state, local, tribal, and territorial emergency preparedness programs. The rule ties reimbursement to certain preparedness activities.

Implementor:

**CMS, ASPR**

Status:

 **Partial Action**

*Action Item b.*

### **Link CMS incentives and reimbursement to new accreditation standards.**

**Congress should authorize CMS to provide funding to those hospitals that meet these new accreditation standards for bioterrorism preparedness and preparedness for other highly infectious disease events.**

While there is reimbursement for infection control, there is currently nothing in place that links reimbursement to an officially or unofficially stratified hospital system to which new accreditation standards would be associated.<sup>109</sup> However, CMS did eventually issue clear guidance regarding reimbursement for COVID-19 treatment.<sup>110</sup>

Implementor:

**Congress**

Status:

 **Partial Action**




## COVID-19

**Prior to the COVID-19 pandemic, CMS had not established incentives to encourage hospitals to adopt biodefense preparedness measures.**

Accordingly, many hospitals lacked procedures and equipment. They were overwhelmed by the initial and subsequent waves of infections, with many resorting to reusing equipment and developing new policies haphazardly.<sup>111</sup> CMS took a number of steps in response to the crisis, including rules relaxing the allowable use of telehealth for patients,<sup>112</sup> a rule that would make any COVID-19 vaccine authorized by the FDA reimbursable under Medicare and Medicaid,<sup>113</sup> and increasing hospital reimbursement under Medicare and Medicaid for COVID-19 treatments.

# RECOMMENDATION 21

**Establish a biodefense hospital system.** Hospitals are already stratified according to their abilities to treat patients according to various specialties. Applying this same approach to biodefense will result in better patient treatment, improved occupational health and safety, and more realistic expectations of hospitals.<sup>114</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Stratify hospitals.	HHS	 Partial Action
b. Develop accreditation standards for each stratum.	CMS	 Partial Action
c. Associate CMS funding.	CMS	 Inaction

## *Action Item a.*

### **Stratify hospitals.**

The Secretary of Health and Human Services should establish a stratified system of hospitals with increasing levels of capability to treat patients affected by bioterrorism and other events involving highly pathogenic infectious diseases. A categorical rather than disease-specific approach should be used. Where possible, the Secretary should add biodefense responsibilities to Accountable Care Organizations, trauma centers, and hospital coalitions to expand their capabilities.

In 2018, the Department of Health and Human Services Assistant Secretary for Preparedness and Response announced his intent to develop a Regional Disaster Health Response System, leveraging the Hospital Preparedness Program, the National Disaster Medical System, and the Regional Treatment Network for Ebola and Other Special Pathogens. The Regional Disaster Health Response System “aims to establish a network of state-level clinical response assets as well as regional assets to create a more coherent, comprehensive, and capable healthcare disaster response system.”<sup>115</sup> The Regional Disaster Health Response System is not intended to impact day-to-day patient referral patterns, but instead to define care delivery during catastrophic events.<sup>116</sup>

In 2019, the Assistant Secretary for Preparedness and Response awarded two grants for Regional Disaster Health Response System pilot projects to Massachusetts General Hospital and Nebraska Medicine to address healthcare preparedness, improve disaster readiness for healthcare delivery, and demonstrate the effectiveness and viability of a Regional Disaster Health Response System. The Assistant Secretary for Preparedness and Response established a third pilot project at Denver Health and Hospital Authority in late 2020 and tasked all three pilot participants to assist in developing guidelines for an eventual stratified hospital system.<sup>117</sup>

Implementor:

**HHS**

Status:



**Partial Action**

## COVID-19

**The federal government did not develop a stratified biodefense hospital system before the beginning of the COVID-19 pandemic in 2020.** As the pandemic progressed south and west from New York and New Jersey, smaller hospitals were caught without the resources and personnel to handle the sudden surges in cases. Rural areas in Missouri, North Dakota, Oklahoma, Wisconsin, and other states saw drastic increases in cases, taxing already limited capacity.<sup>118</sup> No centralized system was in place to identify and move patients to better-equipped hospitals in the immediate vicinity or region. Further, resources were not shared or allocated between hospitals based on need, except through *ad hoc* agreements between systems.

In March of 2020, the Assistant Secretary for Preparedness and Response expanded the Regional Ebola Treatment Network to become the National Special Pathogen System through COVID-19 emergency supplemental funding. Though the Assistant Secretary for Preparedness and Response initially created the System to prepare healthcare systems for the COVID-19 outbreak, the intent is for the System to develop a nationwide, systems-based network for all current and future special pathogens.<sup>119</sup>

*Action Item b.***Develop accreditation standards for each stratum**

**The Administrator of the Centers for Medicare and Medicaid Services should develop accreditation standards with the Joint Commission, Det Norske Veritas, Health Facilities Accreditation Program, and Center for Improvement in Healthcare Quality, as well as certification and licensure associated with each level.**

CMS is responsible for the certification of hospitals after they meet established standards to receive reimbursement from Medicare or Medicaid. Deeming entities (i.e., Joint Commission, Det Norske Veritas, Health Facilities Accreditation Program, Center for Improvement in Healthcare Quality) establish elements of performance based on CMS standards and use survey processes to ensure hospitals meet or exceed federal requirements. With the adoption of the Emergency Preparedness Rule, the Joint Commission updated its emergency management standards to include the following: continuity of operations and succession plans; documented collaboration with federal, state, local, tribal, and territorial emergency management officials; contact information of volunteers and tribal groups; annual training of all new and existing staff, contractors, and volunteers; and integrated healthcare systems. There is an additional emergency and standby power system requirement for hospitals (including critical access hospitals). Hospitals also have a requirement for transplant services. However, stratified biodefense hospital certification does not currently exist.

Implementor:

**CMS**

Status:

 **Partial Action***Action Item c.***Associate CMS funding.**

**The Administrator of the Centers for Medicare and Medicaid Services should associate hospital funding with the ability to meet these accreditation standards for each stratum.**

CMS has not associated hospital funding with meeting biodefense accreditation standards. In 2019, CMS, in partnership with the National Academies of Science, conducted a workshop with private sector stakeholders to create a matrixed incentive structure that could help CMS develop a system to provide funding to hospitals as a condition of participation. Considering CMS actions taken to reimburse telehealth and COVID-19 specific treatments during the response to the COVID-19 pandemic, the agency should offer financial incentives to hospitals.

Implementor:

**CMS**


Status:

 **Inaction**

# RECOMMENDATION 22

## Develop and implement a Medical Countermeasures Response

**Framework.** A stakeholder driven framework for solving continued challenges in operational medical countermeasure response will provide greater assurance that distribution and dispensing can be achieved quickly, efficiently, and safely.<sup>120</sup>

ACTION ITEM	IMPLEMENTER	STATUS
a. Produce a comprehensive framework to guide medical countermeasures distribution and dispensing planning.	ASPR, CDC, FEMA	 Partial Action

### *Action Item a.*

#### **Produce a comprehensive framework to guide medical countermeasure distribution and dispensing planning.**

Together with non-federal partners, the Department of Health and Human Services Assistant Secretary for Preparedness and Response, the Director of the Centers for Disease Control and Prevention, and the Administrator of the Federal Emergency Management Agency should identify requirements and capacities needed to achieve successful distribution and dispensing of medical countermeasures from the Strategic National Stockpile, as well as from local caches. The framework they develop must address unresolved issues. It should be a progressive and innovative approach that pushes the envelope beyond what a given agency might devise and the bureaucratic impediments associated with a federal-only distribution system. If implementation would exceed funding available through current grant allocations, additional funding must be requested.

Federal agencies have not yet produced a comprehensive medical countermeasure response framework. Oversight of the Strategic National Stockpile was transferred from CDC to the Assistant Secretary for Preparedness and Response in October 2018 and the Assistant Secretary for Preparedness and Response has made organizational changes to enable a more strategic end-to-end process from development through stockpiling of medical countermeasures. The Assistant Secretary for Preparedness and Response has identified the terminal distribution and dispensing of medical countermeasures (“The Last Mile”) as a key priority,



## RECOMMENDATION 22

and developed the following: (1) pilots in seven jurisdictions (Los Angeles, San Francisco, Chicago, Denver, Kansas City, MO, New York City, and Washington, D.C.) that could support federal points of distribution and alleviate pressure on local distribution resources;<sup>121</sup> (2) a pilot with mail-order pharmacy groups to augment national delivery in an emergency; (3) public-private partnerships with groups like hoteliers, retailers, and pharmacies that can reach large segments of a population experiencing crisis; (4) a projection of the cost of purchase, deployment, maintenance, and replacement of prepositioned medical countermeasures with states and localities; and (5) creating agreements with federal departments and agencies to support emergencies, such as by leveraging federally qualified health centers to staff points of distribution. The Assistant Secretary for Preparedness and Response developed a Medical Countermeasure Operations Program to support the implementation of these courses of action.<sup>122</sup>

Additionally, the Assistant Secretary for Preparedness and Response is evaluating coordination between the Strategic National Stockpile and the National Disaster Medical System, including cost efficiencies and ways to make response more effective.

Implementor:

**ASPR, CDC, FEMA**

Status:

 **Partial Action**



# COVID-19

**The COVID-19 pandemic revealed significant challenges with Strategic National Stockpile inventory management and deployment, strengthening the case for a comprehensive response framework.** During the course of the pandemic, the federal government assumed responsibility for stockpiling and distributing the limited supplies of therapeutics that received FDA emergency use authorizations. Additionally, through Operation Warp Speed, federal officials assumed responsibility for distributing COVID-19 vaccine doses after FDA began granting emergency use authorization to vaccine candidates in December 2020. However, as of January 2021, a national distribution strategy has not materialized.<sup>123</sup>

# RECOMMENDATION 23

## Allow for forward deployment of Strategic National Stockpile assets.

Pre-deployment of Strategic National Stockpile caches to those jurisdictions that have demonstrated the capability to appropriately handle Strategic National Stockpile contents will vastly improve preparedness.<sup>124</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Determine logistics and funding needs.	ASPR	 Partial Action
b. Implement forward deployments.	White House, ASPR	 Partial Action

### *Action Item a.*

#### **Determine logistics and funding needs.**

The Department of Health and Human Services Assistant Secretary for Preparedness and Response should determine the necessary assessment, logistical, and funding requirements to forward deploy Strategic National Stockpile assets.

As part of its effort to address challenges related to terminal distribution and dispensing of medical countermeasures, the Assistant Secretary for Preparedness and Response has developed The Last Mile Project.<sup>125</sup> The Last Mile Project tests various distribution and delivery efforts in seven major U.S. cities (Los Angeles, San Francisco, Chicago, Denver, Kansas City, MO, New York City, and Washington, D.C.), with a focus on oral antibiotics. One potential course of action under review is the limited prepositioning of medical countermeasures at the state and local (not tribal or territorial) levels. The Office of the Assistant Secretary for Preparedness and Response is reviewing the cost of this pre-positioning, including medical countermeasure purchase and replacement costs related to deployment.

Implementor:

**ASPR**

Status:

 **Partial Action**

*Action Item b.***Implement forward deployments.**

Once the requirements are established, the President should request funding in the next budget cycle to support forward deployments to cities that have demonstrated readiness. Deployments of reasonable quantities should go toward to high-threat, high-density urban areas that have demonstrated an ability to stand up points of distribution faster than Strategic National Stockpile medications can be delivered to these jurisdictions and subsequently distributed to points of distribution. The Assistant Secretary for Preparedness and Response should actively encourage leaders of other major urban areas to plan for, and demonstrate ability to, stand up points of distribution faster than Strategic National Stockpile contents can currently be delivered.

When oversight of the Strategic National Stockpile was held by CDC, the Strategic National Stockpile program worked with one city to forward deploy small quantities of Stockpile assets. However, that jurisdiction only received antibiotics as part of that agreement, which are of no use against viral threats like COVID-19. Control of the Strategic National Stockpile transitioned from CDC to the Office of the Assistant Secretary for Preparedness and Response in 2019. Through The Last Mile Project, the Assistant Secretary for Preparedness and Response is addressing pre-positioning and identifying additional options for rapid deployment of medical countermeasures at the state and local levels.

Implementor:

**White House, ASPR**

Status:

 **Partial Action**




# COVID-19

**State, local, tribal, and territorial governments had insufficient supplies of personal protective equipment, medical devices, and medications on hand to treat the initial wave of COVID-19 infections in the spring of 2020.**

Available Strategic National Stockpile resources took time to deploy to non-federal recipients and quickly depleted available federal supplies. Allowing state, local, tribal, and territorial jurisdictions to maintain pre-deployed assets from the Strategic National Stockpile could not only reduce the deployment times, but could also allow jurisdictions to better assess shortfalls in the early stages of an outbreak and more closely manage expiration of the assets in their control.

# RECOMMENDATION 24

**Harden pathogen and advanced biotechnology information from cyber-attacks.** The U.S. government, in partnership with the private sector, must innovate quickly to address the growing cyberbiological threat.<sup>126</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Develop and implement a security strategy for stored pathogen data.	White House	 Inaction
b. Provide the research community with tools and incentives to secure its data.	HHS, USDA	 Partial Action
c. Develop cyber-threat information-sharing mechanisms for the pathogen and advanced biotechnology communities.	White House, DHS, Immigration and Customs Enforcement (ICE)	 Partial Action

*Action Item a.*

**Develop and implement a security strategy for stored pathogen data.**

The Vice President must ensure that the security of pathogen information is addressed by national U.S. cybersecurity strategy and policy, incorporating such deterrent and enforcement measures as oversight and inspection.

Any policies promulgated pursuant to the strategy should set forth clear consequences for individuals or countries that undertake such actions. The measures developed should not imperil the legitimate sharing of scientific data and information.

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) requires HHS to develop a national strategy for public health preparedness and response to address cybersecurity threats that present a threat to national public health security. This strategy must also address the cyber threat to, and vulnerabilities of, unprotected sensitive pathogen data. Additionally, the Trump Administration took some steps to address the broad threat posed by cyberattacks, including the release of the National Cyber Strategy in September 2018.<sup>127</sup> The Strategy notes that the United States will seek to build a cyber deterrence initiative. However, the Strategy does not directly address the need to better secure pathogen data and does not

## RECOMMENDATION 24

articulate consequences for cyberattacks. Warnings from DHS and the FBI regarding hacking activities targeting research organizations focused on COVID-19 reinforce the need to develop a national pathogen data security strategy immediately.<sup>128</sup>

Implementor:

**White House**

Status:

 **Inaction**

*Action Item b.*

### **Provide the research community with tools and incentives to secure its data.**

**Federal departments and agencies should include federally supported pathogen research projects in the revised procurement model under development. They should develop and establish voluntary standards in partnership with the members of the research community. The Secretary of Agriculture and the Secretary of Health and Human Services should incorporate these standards into any new Select Agent Program regulations promulgated per Recommendation 32.**

HHS has not yet developed voluntary cybersecurity standards for the research community.<sup>129</sup> A Healthcare Cybersecurity Coordination Center located in the HHS Office of the Chief Information Officer helps prepare some outside partners for potential cyber events, but it primarily supports the Department's agencies and offices. The Department plans to incorporate and address the role of academia when it refreshes its critical infrastructure plan. Additionally, recent regulatory changes to the Federal Select Agent Program failed to address cybersecurity.

Implementor:

**HHS, USDA**

Status:

 **Partial Action**

*Action Item c.*

### **Develop cyber-threat information-sharing mechanisms for the pathogen and advanced biotechnology communities.**

**The Vice President should elevate the priority of addressing cyber threats to these communities, including both virtual and physical infrastructure. The Secretary of Homeland Security, working with existing privately led Information Sharing and Analysis Centers, should also address cyber threats to these communities. The Director of Immigration and Customs Enforcement should direct the Intellectual Property Rights Center and the ICE Cyber Crimes Center to specifically address cyber threats to, and vulnerabilities of, the data possessed by these communities**

and prevent intellectual property loss in this regard. The Vice President should also direct the Secretary of Health and Human Services to establish a formal pathogen and biotechnology subsector within the Healthcare and Public Health Critical Infrastructure Sector.

In December 2015, President Obama signed into law the Cybersecurity Act of 2015 as part of omnibus spending legislation (P.L. 114-113). This statute aimed to foster the sharing of cybersecurity information between the federal government and the private sector by providing liability protections and clarifying the process by which information can be transferred through privately led Information Sharing and Analysis Centers. However, it is unclear to what extent the owners of pathogen data have been made aware of, and are leveraging, this mechanism.

The Director of ICE did not direct the Intellectual Property Rights Center or the ICE Cyber Crimes Center to take action. The Secretary of Health and Human Services did not establish a formal pathogen and biotechnology subsector.

Implementor:

**White House, DHS, ICE**

Status:

 **Partial Action**

# RECOMMENDATION 25

## Renew U.S. leadership of the Biological and Toxin Weapons Convention.

Because the threat is real and growing, the United States must continue to engage in a biodefense program. However, the United States must not allow challenges associated with verification of, compliance with, and enforcement of the Biological and Toxin Weapons Convention to prevent it from exerting leadership in an arena that requires more than diplomatic support of the treaty.<sup>130</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Continue to strengthen implementation of the Biological and Toxin Weapons Convention where U.S. support is unequivocal.	DOS	 Partial Action
b. Set U.S. goals for the Biological and Toxin Weapons Convention.	White House, DOS	 Partial Action
c. Develop three actionable recommendations for Biological and Toxin Weapons Convention verification.	White House, DOS	 Partial Action
d. Establish better biological weapons sentencing guidelines in statute.	Congress	 Partial Action

### *Action Item a.*

#### **Continue to strengthen implementation of the Biological and Toxin Weapons Convention where U.S. support is unequivocal.**

The Secretary of State should lead U.S. efforts to revitalize the Biological and Toxin Weapons Convention by addressing topics such as universalization of the Convention; calls for national laws and regulations concerning use, storage, and transport; and submission of complete annual reports by all member State Parties. All U.S. federal agencies should press these issues in meetings with foreign counterparts.

The United States has continued to financially support and participate in the Biological and Toxin Weapons Convention but has not revitalized the Convention as recommended by the Commission. In general, the meetings of State Parties have been less productive than the technical meetings of experts.

The United States partnered with Parliamentarians for Global Action, a non-governmental organization that works to drive agreements to international treaties, including the Biological and Toxin Weapons Convention.<sup>131</sup> Overall, the United States has elected to use the Biological and Toxin Weapons Convention platform in ways that differ from the original intent. The United States has focused on routine country inspection, worked to promote public health security in developing countries, and garnered commitments from member states to provide voluntary response assistance in the event of a deliberate biological attack. Additionally, the United States continues to press for new national initiatives and ways to measure implementation, and worked to build relationships among implementers.

Implementor:

DOS

Status:



Partial Action

*Action Item b.*

**Set U.S. goals for the Biological and Toxin Weapons Convention and determine the conditions necessary to achieve them.**

**The Vice President should direct the NSC to use the period leading up to the December 2016 Biological and Toxin Weapons Convention Review Conference to determine desired outcomes. The Secretary of State should employ a high-level emissary to press these issues with other parties to the treaty in advance of the next review conference.**

The DOS entered the Eighth Biological and Toxin Weapons Convention Review Conference with some clear goals, including support to create a more transparent process. The U.S. has worked between sessions to help promote common understanding of the Biological and Toxin Weapons Convention and verification actions. The process enabled progress on some specific issues, such as laboratory pathogen security.

Unfortunately, the Conference was not able to agree upon the five-year work-plan that the United States and some other parties to the treaty supported. In the absence of a work-plan, the United States continued to strengthen the international nonproliferation regime.

The next Review Conference should occur in 2021. The United States should reexamine its stance with regard to the Convention and reinvigorate efforts to ensure the viability and practicability of the Convention.

Implementor:

White House, DOS

Status:



Partial Action



*Action Item c.***Develop three actionable recommendations for Biological and Toxin Weapons Convention verification.**

Prior to the next Biological and Toxin Weapons Convention Review Conference, the Vice President and the Secretary of State should convene a series of meetings with representatives from all Cabinet and independent agencies with responsibilities for biological defense, as well as industry and academia, to discuss verification and compliance with the Biological and Toxin Weapons Convention. The result of this meeting should be the development of three recommendations for a verification protocol that would meet U.S. national security needs as well as state-level compliance.

The DOS Biological Policy Office most recently held a Biological and Toxin Weapons Convention Engagement Workshop in November 2020 with 70 non-governmental entities. Participants from academia, industry, think tanks, laboratories, and other non-governmental organizations gathered to consider the major challenges facing the Biological and Toxin Weapons Convention and to discuss their role in the upcoming Ninth Review Conference and issues to consider at the meeting. A series of follow up roundtables to further discuss the matter are planned for 2021. The DOS has not convened meetings with all departments and agencies with biodefense responsibilities to further discuss verification of, and compliance with, the Biological and Toxin Weapons Convention, and to develop recommendations.

Implementor:

White House, DOS

Status:

 Partial Action
*Action Item d.***Establish better biological weapons sentencing guidelines in statute.**

Congress should amend the Biological Weapons Anti-Terrorism Act of 1989 (Public Law 101-298) and the USA PATRIOT Act (Public Law 107-56) to include more specific sentencing guidelines and consideration for the real and growing possibility that biological weapons will be used in the United States.

In July 2019, President Trump signed into law the Effective Prosecution of Possession of Biological Toxins and Agents Act (P.L. 116-31).<sup>132</sup> This law clearly made it illegal for any individual to knowingly obtain select agents without proper registration, strengthening penalties for the procurement of these deadly pathogens.

Implementor:





Congress

Status:

 Partial Action

# RECOMMENDATION 26

**Implement military-civilian collaboration for biodefense.** Civilian governmental and nongovernmental agencies would benefit from the experience, expertise, and technology resident in the U.S. military. Collaborative efforts should be institutionalized.<sup>133</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Conduct a review of military-civilian collaborative efforts.	DOD	 Partial Action
b. Establish military-civilian biodefense collaboration.	DOD	 Partial Action
c. Clarify parameters for military support to civilian authorities in response to a domestic biological attack.	White House, DOD	 Partial Action
d. Update and implement military biodefense doctrine.	DOD	 Partial Action

## *Action Item a.*

### **Conduct a review of military-civilian collaborative efforts.**

The Secretary of Defense should conduct a review of previous and current efforts to collaborate with civilian counterparts and partners, including on biodefense. The Secretary of Defense should identify best practices from other efforts that could be applied to collaboration on biodefense, constraints that could prevent collaboration, potential solutions for removing these constraints, and recommendations for creating, implementing, and institutionalizing a formal program for ongoing military-civilian interaction and collaboration for biodefense. DOD should report the results of this review to the Vice President and the House and Senate Committees on the Armed Services.

DOD has not conducted a comprehensive review of existing efforts to collaborate with civilian counterparts on biodefense. The National Biodefense Strategy and National Security Presidential Memorandum 14 require federal departments and agencies to conduct internal assessments of current biodefense activities and provide

this information to the Biodefense Coordination Team for its annual Biodefense Assessment. Ideally, the Assessment will identify areas in which DOD can further collaborate with its civilian counterparts. DOD has indicated that in the interim it is evaluating areas of overlap with other departments and agencies, such as with medical countermeasure development, where military resources could be used more efficiently to accomplish joint goals.

Implementor:

DOD

Status:



Partial Action

### *Action Item b.*

#### **Establish military-civilian biodefense collaboration: Partial action.**

**Congress should mandate military-civilian collaboration on biodefense, including research regarding force protection. Congress should include this requirement for ongoing collaboration in the National Defense Authorization Act and add it to the oversight agendas of the House and Senate Committees on the Armed Services.**

As directed by the National Defense Authorization Act of Fiscal Year 2017 (P.L. 114-328), DOD participated in the development process for the National Biodefense Strategy. The Strategy and National Security Presidential Memorandum 14 require relevant departments and agencies, including DOD, to participate in the Biodefense Steering Committee that will coordinate implementation of the Strategy.

Implementor:

DOD

Status:



Partial Action

### *Action Item c.*

#### **Clarify parameters for military support to civilian authorities in response to a domestic biological attack.**

**The Secretary of Defense should clarify existing military doctrine to provide this support. The Vice President should develop clear policies addressing the integration of military assets when called upon to respond to a domestic biological attack. The Vice President should also direct the NSC to determine in what specific circumstances decision-making may need to be delegated to DOD leaders and the National Command Authority in the event of a biological attack.**

Since the publication of *A National Blueprint for Biodefense*, DOD updated some of its policies for Defense Support to Civil Authorities, including Joint Public 3-11, Operations in Chemical, Biological, Radiological, and Nuclear Environments, and Joint

Publication 3-28, Defense Support of Civil Authorities.<sup>134</sup> Additionally, the development and release of the *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* further details the role of DOD in an interagency response to a large-scale biological event.<sup>135</sup> During the federal response to COVID-19, the military assumed many logistical duties traditionally associated with their civilian counterparts. It is unclear how much of this activity was governed by existing policies and procedures.

Implementor:

**White House, DOD**

Status:

 **Partial Action**

#### *Action Item d.*

#### **Update and implement military biodefense doctrine.**

**DOD must produce technically feasible and politically acceptable doctrine for biodefense activities if it is to fulfill its primary responsibilities for force protection and projection. The Secretary of Defense should be held accountable by the Vice President and Congress for ensuring that this doctrine has been developed and/or refreshed with the input and full concurrence of the Joint Chiefs of Staff. DOD should base scientific research and development, training, and other activities necessary for biodefense on this doctrine.**

DOD did update some military biodefense doctrine. The White House updated the National Defense Strategy<sup>136</sup> and the National Strategy for Countering Weapons of Mass Destruction Terrorism<sup>137</sup> in 2018. Further, the DOD functional contingency plan for Pandemic Influenza and Infectious Disease is currently under review. Additionally, DOD updated several other policies and programs addressing biological threats.<sup>138</sup>

Implementor:





**DOD**

Status:

 **Partial Action**

# RECOMMENDATION 27

**Prioritize innovation over incrementalism in medical countermeasure development.** Leaders must not only prioritize funding for distinctly innovative programs, but must also decide that innovation is the bold solution to meeting the biological threat.<sup>139</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
<p>a. Prioritize innovation in medical countermeasures at agencies with biodefense responsibilities.</p>	<p>BARDA</p>	<p> Partial Action</p>
<p>b. Exploit existing innovation.</p>	<p>HHS NIAID, BARDA, DOD Assistant Secretary for Nuclear, Chemical, and Biological Defense Programs (ASD NCB)</p>	<p> Crisis Action</p>
<p>c. Revolutionize development of medical countermeasures for emerging infectious diseases with pandemic potential.</p>	<p>HHS NIAID, BARDA, DOD ASD NCB, APHIS, DHS Science &amp; Technology Directorate</p>	<p> Crisis Action</p>
<p>d. Establish an antigen bank.</p>	<p>NIAID, BARDA, DOD ASD NCB, APHIS, DHS Science &amp; Technology Directorate</p>	<p> Inaction</p>

*Action Item a.*

**Prioritize innovation in medical countermeasures at agencies with biodefense responsibilities.**

Congress has proposed establishing an NIH Innovation Fund at \$2 billion annually. Ten percent of this fund, if appropriated, should be dedicated to innovation at NIH in biodefense and emerging infectious disease medical countermeasures tied to BARDA requirements. The Director of the Biomedical

**Advanced Research and Development Authority should devote no less than ten percent of BARDA’s annual budget to funding innovative technologies that can achieve progress across a broad spectrum of biological threats. Working groups should be established at all these agencies to secondarily review proposals rejected as being too risky.**

Limited steps have been taken to further innovation in medical countermeasure development. The 21<sup>st</sup> Century Cures Act (P.L. 114-255) authorized BARDA to establish a Division of Research, Innovation, and Ventures to accelerate transformative technological solutions for, and approaches to, public health security. Initial Division of Research, Innovation, and Ventures programs have focused on detecting, prognosticating outcomes, and enabling early interventions; solving the problem of sepsis; developing alternative vaccine technologies to make immunizations easier to administer and more widely available; repurposing therapeutics as medical countermeasures in the event of a chemical emergency; and deploying technologies to fight COVID-19.<sup>140</sup> However, BARDA continues to utilize inflexible contracting processes that are not aligned with private sector business models. Established by BARDA in 2018, the Division of Research, Innovation, and Ventures could solve some of these contracting problems with (1) an accelerator network of scouts seeking innovative solutions across the country; (2) a quicker and less cumbersome contracts and grants process (known as an easy Broad Agency Agreement); and (3) venture capital. BARDA issued a solicitation for non-profit third-party partner to bring new ideas and private equity funding to the table, which could help address existing gaps.

Innovation in advanced development and manufacturing is as important as innovation in novel biotechnology discoveries. Unfortunately, the Centers for Innovation and Advanced Development and Manufacturing, established by the Department of Health and Human Services Assistant Secretary for Preparedness and Response during the Obama Administration, failed to provide rapid, U.S.-based manufacturing capability as intended and were not prepared for the COVID-19 pandemic.<sup>141</sup>

BARDA has reviewed the Centers for Innovation and Advanced Development and Manufacturing program and intends to make major adjustments, provided funding is available. BARDA officials have expressed interest in identifying other solutions for domestic development and manufacturing, including ways to reduce the number of animals and humans needed for clinical trials, modernizing drug production, and simplifying emergency response drug formulations to decrease dependency on international ingredients. Congress encouraged the use of contractual vehicles to promote “platform technologies, technologies to administer countermeasures, and technologies to improve storage, transportation, and distribution of countermeasures,”<sup>142</sup> but has not appropriated funding to this end.

The Commission also recommended the use of an NIH Innovation Fund as a tool to dedicate funding to innovation at NIH in biodefense and emerging infectious disease medical countermeasures tied to BARDA requirements. While the 21<sup>st</sup> Century Cures Act authorized multi-year funding for an NIH Innovation Fund, expenditures were restricted to areas unrelated to medical countermeasure development.

Implementor:

**BARDA**

Status:

 **Partial Action**

## COVID-19

**The COVID-19 pandemic demonstrated both the importance of prioritizing medical countermeasure innovation and what is possible given sufficient resources.** Some of the most promising COVID-19 countermeasures in the development pipeline are also the most innovative and novel approaches to addressing biological threats. For example, one company leveraged a novel RNA platform for a vaccine that allowed them to enter clinical trials in less than two months after obtaining the genetic sequence.<sup>143</sup> Had the federal government previously pursued innovative platforms aggressively to counter pathogens with pandemic potential, a coronavirus vaccine or broad-spectrum therapeutic that could have been quickly adapted to address COVID-19 may have come to market much earlier.

### *Action Item b.*

#### **Exploit existing innovation.**

The Director of the National Institute of Allergy and Infectious Diseases, the Director of the Biomedical Advanced Research and Development Authority, and the Deputy Assistant Secretary of Defense for Chemical and Biological Defense should coordinate to identify at least five promising novel technologies (including platform technologies) that could ultimately be applied to medical countermeasure development for material threats. The most promising candidates (with sufficient safety and efficacy data to meet FDA standards) that enable use of multiple antigens on an existing platform should be developed. If needed, FDA should develop a new approval pathway for these technologies.

Despite broad support from policymakers and external stakeholders, platform technology did not advance substantially until the COVID-19 pandemic. The pandemic drove the government and industry to leverage existing scientific

advancements in new and rapid ways, but this effort has been the exception to the rule. In 2018, the Commission stressed in a letter to Congress that the acceleration of platform technology development must be a priority.<sup>144</sup> With targeted investment, these technologies (especially for vaccines and diagnostics) could come to fruition within three to four years.

While DOD, NIAID and BARDA have invested in novel technologies (including platforms) to various extents, the contracting reforms required to accommodate these innovations have not materialized. BARDA should also consider the role of the agricultural sector in providing needed technological advancements.

Implementor:

**NIAID, BARDA, DOD ASD NCB**

Status:

 **Crisis Action**

### *Action Item c.*

#### **Revolutionize development of medical countermeasures for emerging infectious diseases with pandemic potential.**

The Director of the Biomedical Advanced Research and Development Authority, in coordination with the Director of the National Institute of Allergy and Infectious Diseases, and the Deputy Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense Programs, should establish a program to rapidly develop medical countermeasures for emerging infectious diseases with pandemic potential. They should develop a strategy to identify those candidates that would be most suitable for the program (while continuing to invest in more traditional pathways for other targets) and make their efforts as transparent as possible to academic and industry partners during this process. The Administrator of the Animal and Plant Health Inspection Service, in coordination with the Department of Homeland Security Under Secretary for Science and Technology, and the Director of the National Institute of Allergy and Infectious Diseases should do the same for animal vaccine candidates.

DOD, NIAID, and BARDA did not revolutionize rapid medical countermeasure development for emerging infectious diseases with pandemic potential. Neither did APHIS lead such an initiative for animal medical countermeasure in coordination with the NIAID and DHS. However, the onset of the COVID-19 pandemic drove an unprecedented public-private partnership that developed safe, efficacious vaccine candidates within a year of the disease's emergence. It will be useful to build on this experience to facilitate rapid development of medical countermeasures to address threats effectively in the future.



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DHS, DOD, USDA, and other federal entities are members of the Public Health Emergency Medical Countermeasures Enterprise. The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) established the Public Health Emergency Medical Countermeasures Enterprise in statute, including membership from across the federal government, with the Director of National Intelligence as a new addition. All must bring the weight of their expertise, mission requirements, and budgets to bear on the Public Health Emergency Medical Countermeasures Enterprise process and outcomes.

The Department of Health and Human Services Assistant Secretary for Preparedness and Response is best positioned to drive medical countermeasure development transformation. The Office of the Assistant Secretary for Preparedness and Response has made strides toward transforming its portfolio, and programs like the Division of Research, Innovation, and Ventures may assist with that transformation. If DOD, USDA, and HHS do not establish programs for emerging and reemerging infectious diseases posing the greatest risk to the United States, there will be no foundation to build on when the next crisis occurs. APHIS also finds itself without the necessary funding needed to rapidly develop medical countermeasures for emerging threats.<sup>145</sup>

The drive to develop medical countermeasures for COVID-19 followed federal efforts in recent years to rapidly develop medical countermeasures for Ebola, Zika, and other diseases. Congress appropriated billions in emergency funding in March 2020 to speed the creation of COVID-19 vaccines and therapeutics. The White House was able to accelerate the previous medical countermeasure development timeframe by conducting different phases of development concurrently rather than consecutively through Operation Warp Speed. This approach resulted in the FDA issuing an Emergency Use Authorization for the first COVID-19 vaccine candidates in December 2020. However, such progress was only possible due to an unprecedented, coordinated, and focused investment of time, resources, and leadership from the public and private sectors.

Implementor:

**NIAID, BARDA, DOD ASD NCB, APHIS, DHS Science & Technology Directorate**

Status:

 **Crisis Action**

*Action Item d.***Establish an antigen bank.**

The Director of the National Institute of Allergy and Infectious Diseases, the Director of the Biomedical Advanced Research and Development and Authority, the Deputy Assistant Secretary of Defense for Chemical and Biological Defense, the Administrator of the Animal and Plant Health Inspection Service, and the Department of Homeland Security Under Secretary for Science and Technology should identify and establish a bank of antigen payloads with supporting characterization data and standards to operationalize a plug-and-play strategy using proven platform technologies for use in an emergency for both human and animal pathogens.

DOD, DHS, and HHS have not established an antigen bank, and they have not taken the necessary steps to create such a repository in the near future. Although it is a substantial investment of resources, such a stockpile would accelerate the Nation's ability to develop and deploy medical countermeasures, particularly in conjunction with platform technologies.

Implementor:





**NIAID, BARDA, DOD ASD NCB, APHIS, DHS Science & Technology Directorate**

Status:

 **Inaction**

# RECOMMENDATION 28

**Fully prioritize, fund, and incentivize the medical countermeasure enterprise.** Only through a firm and long-lasting commitment to medical countermeasure development can we successfully address the full spectrum of biological threats.<sup>146</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Fund the medical countermeasure enterprise to no less than authorized levels.	Congress, BARDA	 Partial Action
b. Reestablish multi-year biodefense funding medical countermeasure procurement.	White House, Congress	 Inaction
c. Address prioritization and funding for influenza preparedness.	Congress, ASPR	 Inaction
d. Improve the plan for incentivizing the private sector and academia.	ASPR, DOD ASD NCB	 Partial Action

*Action Item a.*

**Fund the medical countermeasure enterprise to no less than authorized levels.**

Congress should immediately fund medical countermeasure initiatives through BARDA, the Special Reserve Fund, and the Strategic National Stockpile consistent with the bipartisan authorized levels for these programs. Longer-term appropriations should be reflective of needs identified in the National Strategy for Biodefense and associated budgeting and prioritization initiatives in *A National Blueprint for Biodefense*.

Congress increased funding levels for major elements of the medical countermeasure enterprise in recent years, in an acknowledgement by the President and Congress of the need for investment in countermeasures against

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biological threats. For example, in FY 2018, the Project BioShield Special Reserve Fund was funded at \$710 million, a \$200 million increase over FY 2017; BARDA was funded at \$536.7 million, a \$25 million increase over FY 2017; the Strategic National Stockpile was funded at \$610 million, a \$35 million increase over FY 2017; and pandemic influenza was funded at \$250 million, a \$193 million increase over FY 2017.<sup>147</sup> In FY 2020, the Special Reserve Fund, Strategic National Stockpile, and pandemic influenza were all funded at or above the levels authorized in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22), while BARDA was funded slightly below authorized levels (\$561.7 million versus \$611.7 million authorized). While the Commission applauds the Administration and Congress for making these critical investments, federal funding still lags far behind the need.

The Public Health Emergency Medical Countermeasures Enterprise Multiyear Budget Report covers the year preceding the year of publication, the current request year, and two subsequent years.<sup>148</sup> The gap between the Enterprise's projected needs and what programs actually receive is high. For example, the shortfall for BARDA was about \$250 million in FY 2020 or more than 40 percent. Similarly, HHS believes Project BioShield should be funded at about \$900 million per year, well above the \$735 million it received in FY 2020. Strategic National Stockpile funding was \$705 million in FY 2020, well behind the projected needs of more than \$1 billion, and pandemic influenza investment levels are at best one-third of what they should be.

Implementor:

**Congress, BARDA**

Status:

 **Partial Action**

# COVID-19

**The lack of adequate funding for the U.S. medical countermeasures enterprise necessitates emergency funding each time the Nation faces a large-scale disease event.** Congress appropriated emergency supplemental funding to assist in the development of medical countermeasures for COVID-19, as it did when faced with the H1N1, Zika, and Ebola crises. However, funding came after nearly two months of disagreement between Congress and the White House regarding the precise need and funding levels. The delay pushed back the timeline for federal COVID-19 medical countermeasure efforts, though BARDA did make investments in vaccines and therapeutics before Congress acted. Moreover, the federal government's failure to follow through on the responses to Severe Acute Respiratory Syndrome (SARS) in 2003 and Middle East Respiratory Syndrome (MERS) in 2012 proved tragically shortsighted. Following those outbreaks, federal funding was initially allocated to develop coronavirus vaccines and therapeutics, but funding was eliminated before the work was completed because of the false perception that the threat had dissipated.<sup>149</sup> Had SARS and MERS vaccines and therapeutics been funded through to approval, the United States would have had a head-start in the development of products to combat COVID-19.

## *Action Item b.*

### **Reestablish multi-year biodefense funding for medical countermeasure procurement.**

**The President and Congress should reestablish multi-year funding for Project BioShield, thus reestablishing the marketplace while building and maintaining capabilities. A ten-year advance appropriation for the Special Reserve Fund is entirely appropriate.**

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) authorized \$7.1 billion for Project Bioshield from FY 2019–2028, a ten-year authorization that would allow the funds to remain available until expended. This would have been a positive step, but subsequent congressional appropriations for FY 2020 maintained an annual approach to funding the Project.

The Project BioShield Act of 2004 (P.L. 108-276) authorized appropriations for the Special Reserve Fund. Initial funding was provided by the DHS Appropriations Act of 2004 (P.L. 108-90), which advance appropriated \$5.593 billion for multi-year use from FY 2004–2013. This advance appropriation was especially critical because most medical countermeasures for biodefense lack a commercial marketplace. As such, private sector partners entering this risky and capital-intensive field of medical


countermeasure development are dependent on the federal government for funding for research and development as well as eventual procurement. The advance appropriation provided an important degree of certainty to industry, and in its first 10 years, Project BioShield resulted in 8 medical countermeasures entering the federal stockpile with another 80 in development.<sup>150</sup>

Although both the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5) and the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) reauthorized Project BioShield with no-year appropriations, Congress has repeatedly elected to fund the program through annual appropriations rather than another advance appropriation. The Assistant Secretary for Preparedness and Response and BARDA leadership have warned that BARDA is now a less reliable partner to industry, especially given Congress' recent reliance on short-term continuing resolutions to fund the government. Additionally, under annual appropriations, award sizes have been much smaller and rely on options rather than funding all late-stage development activities.<sup>151</sup> While BARDA has managed to shepherd products into the Strategic National Stockpile and toward licensure, the perennial uncertainty of appropriations and the many options on contracts not exercised disincentivize industry engagement, which in turn hurts the enterprise in the long term.

Implementor:

**White House, Congress**

Status:

 **Inaction**

### *Action Item c.*

#### **Address prioritization and funding for influenza preparedness.**

**At least every five years, the Department of Health and Human Services Assistant Secretary for Preparedness and Response, in coordination with all governmental and non-governmental stakeholders, should review existing pandemic influenza assets, assess their ability to fulfill goals, and inform near- and long-term budget requests. The Assistant Secretary for Preparedness and Response must more effectively engage and communicate with pandemic influenza industry stakeholders. Congress should consider providing complementary legislative authorization as appropriate to define and guide pandemic influenza programs.**

Because influenza infects humans and animals, and because it mutates, developing medical countermeasures to combat the disease is a challenge. BARDA maintains an influenza division that has stockpiled pre-pandemic influenza vaccines (using a best guess at the most problematic strains) and obtained licensure of an H5N1 influenza prototype vaccine that could be used as a platform to address other strains as needed. However, the annual \$300 million appropriated for the program is insufficient

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to support its mission. Outstanding needs include vaccines for other strains (notably H7N9), many more effective antivirals, and patient-side diagnostics.

Congressional authorizers have tangentially addressed the issue. For example, language in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) included pandemic influenza as a target for innovative medical countermeasure candidates.<sup>152</sup> Legislation was also introduced in the 116th Congress, but not passed, that would have provided additional funding for the development of a universal influenza vaccine.<sup>153</sup> Congressional appropriators, meanwhile, have provided HHS with funding for pandemic influenza preparedness and response, used by the department for the development of antivirals, diagnostic assays, and vaccines. In FY 2020, Congress appropriated \$260 million for pandemic influenza. While this is an increase from prior years, it falls far short of levels needed to develop the broad and innovative set of medical countermeasure tools required by an influenza pandemic.

Implementor:

**Congress, ASPR**

Status:

 **Inaction**

### *Action Item d.*

#### **Improve the plan for incentivizing the private sector and academia.**

**The Assistant Secretary for Preparedness and Response and Deputy Assistant Secretary of Defense for Chemical and Biological Defense should convene non-governmental stakeholders to identify meaningful incentives that are independent of congressional appropriations for medical countermeasure developers and manufacturers. They should report findings and recommendations to Congress within six months, identifying those incentives that would improve industry and academic participation in medical countermeasure development, and requesting congressional authorization for those that would require it.**

FDA, in consultation with DOD, BARDA, and other Public Health Emergency Medical Countermeasures Enterprise partners, should establish a medical countermeasure platform certification process. This regulatory construct, which would allow for the consideration of a company's novel platform as a basis for future medical countermeasure products, should effectively reduce the risk of future product development using a certified platform. FDA should also commit to the accelerated approval times associated with Priority Review for certified platforms.

Implementor:

**ASPR, DOD ASD NCB**

Status:

 **Partial Action**

# RECOMMENDATION 29

**Reform BARDA contracting.** A variety of statutory and organizational issues impede efficient contracting by BARDA, leading to delays in the availability of medical countermeasures.<sup>154</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Return contracting authority to BARDA.	ASPR	✓ Completed
b. Leverage previously provided authorities.	BARDA	○ Partial Action
c. Eliminate OMB review of BioShield procurements.	OMB	○ Partial Action

## *Action Item a:*

### **Return contracting authority to BARDA.**

Contracting authority should be the exclusive responsibility of BARDA. The Department of Health and Human Services Assistant Secretary for Preparedness and Response should administratively reinstate BARDA as the sole authority to negotiate, award, and administer its own advanced research, development, and procurement contracts. If the Assistant Secretary for Preparedness and Response fails to do so, Congress should mandate this.

Congress used the 21<sup>st</sup> Century Cures Act (P.L. 114-255) to restore independent contracting authority to BARDA.<sup>155</sup> The Office of the Assistant Secretary for Preparedness and Response is also developing a strategic plan that ties together the activities of BARDA (development and initial procurement) and the Strategic National Stockpile (sustained procurement). At present, the two entities utilize separate contracting mechanisms. The Assistant Secretary for Preparedness and Response intends to release a plan for a single contracting process, which should increase efficiency.

Implementor:

**ASPR**

Status:

✓ **Completed**



*Action Item b.***Leverage previously provided authorities.**

**BARDA should prioritize the use of Other Transactional Authority and consider any other appropriate flexible contracting authorities for BioShield and advanced development contracts.**

Since the publication of *A National Blueprint for Biodefense*, BARDA has expanded the use of Other Transactional Authority for its contracts. The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) further encouraged use of BARDA Other Transactional Authority.<sup>156</sup> BARDA is now using these authorities more flexibly than previously, such as by administering multiple candidates or products through a single Other Transaction. BARDA is also utilizing its Other Transactional Authority for contracts addressing COVID-19.

Implementor:

**BARDA**

Status:

 **Partial Action**
*Action Item c.***Eliminate OMB review of BioShield procurements.**

**Congress should amend the Public Health Service Act to eliminate OMB review of BioShield procurement contracts.**

The 21<sup>st</sup> Century Cures Act (P.L. 114-255) eliminated OMB review of Project BioShield procurements.<sup>157</sup> However, even with statutory relief, BARDA still must provide justification to OMB for budget variances greater than 10 percent. BARDA also must seek approval from OMB and wait a minimum of 10 days before executing procurement decisions.

Implementor:

**OMB**

Status:

 **Partial Action**

# RECOMMENDATION 30

**Incentivize development of rapid point-of-care diagnostics.** Advanced diagnostics are clearly needed, and BARDA must incentivize their development. Without these tools, the Nation remains vulnerable.<sup>153</sup>

ACTION ITEM	IMPLEMENTER	STATUS
a. Develop requirements for rapid point-of-care diagnostics for all material biological threats and emerging infectious diseases.	BARDA	<input type="radio"/> Inaction

### *Action Item a.*

#### **Develop requirements for rapid point-of-care diagnostics for all material biological threats and emerging infectious diseases.**

The Director of the Biomedical Advanced Research and Development Authority should determine the suite of rapid diagnostics that is needed for biological agents determined to be material threats and emerging infectious diseases.

**BARDA must prioritize their development and acquisition, and implement a plan to work with industry and academia to achieve success in this arena. The medical countermeasure incentive discussion per action item 28d applies, and strong efforts should be made to provide companies with participation incentives.**

BARDA and other federal agencies have failed to prioritize rapid point-of-care diagnostics, instead focusing primarily on vaccines and therapeutics. As demonstrated by COVID-19, the availability of these diagnostics can mean the difference between uncontrolled spread of a disease and the ability to help control a pandemic through testing, contact tracing, and isolation.

Academia and others in the private sector have long struggled to develop rapid point-of-care diagnostics due to a lack of sustained federal support. BARDA has failed to provide requirements and CMS has not issued sufficient reimbursements to make investment worthwhile. In February 2019, the CDC, CMS, and FDA established a Tri-Agency Task Force for Emergency Diagnostics, but it is unclear what actions they have taken (if any). Further, even with adequate support for research and development, a product can still fail due to the lack of a viable commercial market. The Commission's 2020 report, *Diagnostics for Biodefense: Flying Blind with No Plan to Land*, explored the federal government's lack of

## RECOMMENDATION 30

leadership in overcoming this market failure.<sup>159</sup> Without further innovation and federal commitment, the Nation will struggle to track the spread of the next biological attack, naturally occurring disease, or accidental laboratory release of a pathogen.

Implementor:

**BARDA**

Status:

**Inaction**

# COVID-19

**The arrival of COVID-19 in the United States illustrates the vast gulf between expectations and reality when it comes to the Nation's ability to detect the spread of disease.** Rapid point-of-care and point-of-need diagnostic tests could have drastically altered the trajectory of the COVID-19 pandemic in the United States. The public now understands more than ever how important rapid diagnostics are in determining who has contracted an infectious disease. Given the scarce availability of rapid diagnostic tests and concerns regarding their effectiveness for asymptomatic individuals, COVID-19 screening for travel and commercial purposes has greatly relied on temperature checks and self-identification of symptoms—largely ineffective mechanisms in the face of a disease that is often spread by asymptomatic individuals. Even now, widespread availability of rapid point-of-care tests could significantly improve our ability to combat COVID-19.

Had the federal government continued previous research into SARS and MERS, this could have led to a rapid point-of-care test capable of detecting all known coronaviruses. In turn, this technology could have been easily adapted to detect COVID-19 when it appeared.

The private sector has engaged with the federal government during the COVID-19 pandemic to develop diagnostic tests and protocols that can be quickly mass produced and distributed throughout the Nation. The pandemic has made the business case for the need to develop new and innovative diagnostic tests.

# RECOMMENDATION 31

## Develop a 21<sup>st</sup> Century-worthy environmental detection system.

The Nation continues to lack a rapid and reliable environmental detection system for known and unknown biological threats, a situation that must be rectified.<sup>160</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Fund the development of advanced environmental detection systems to replace BioWatch.	White House, Congress, DHS, DOD	<input type="radio"/> Inaction
b. Replace BioWatch Generation 1 and 2 detectors.	Congress, DHS	<input type="radio"/> Inaction

### *Action Item a.*

#### **Fund the development of advanced environmental detection systems to replace BioWatch.**

Congress, through its appropriations to DHS and DOD, should fund an advanced environmental detection system capable of rapid agent characterization and confirmation. The system should be capable of recovering live agents from collection devices, determining geographical distribution, determining environmental persistence, and providing advanced molecular diagnostics at the laboratories that will support operational activities. The Vice President should call for a formal process between DHS, DOD, and all other federal agencies utilizing or developing biodetectors to share information regarding their biodetection successes and failures up to and including a mandate to procure another agency's technology if it fits requirements. For domestic biodetection, DHS must work with end users in state, local, tribal, and territories at the earliest stages of requirement development. DHS must also develop a standardized integration strategy and training requirements based on these discussions.

As part of an effort to eventually replace existing BioWatch detectors, DHS in 2018 used existing BioWatch funding to begin testing new biodetection technologies as part of the Biological Detection for the 21<sup>st</sup> Century Acquisition Program.<sup>161</sup> The DHS Countering Weapons of Mass Destruction Office tested technology candidates at 12 sites nationwide, intending to fully deploy by 2025, nearly 10 years after the release

of the Commission's recommendation in *A National Blueprint for Biodefense*. DOD shared some of its previously developed technologies with DHS for testing at these sites. However, this technology was older government-off-the-shelf equipment that had failed to meet DOD warfighter needs and requirements.

Compounding these issues, DHS did not initially consult with external stakeholders on this effort before beginning technology testing and deployment.<sup>162</sup> Given the new goal of the system to alert first responders—all of whom are state, local, tribal, or territorial—the failure to consult those stakeholders left the Countering Weapons of Mass Destruction Office blind to their needs. Considering previous concerns raised about the BioWatch program,<sup>163</sup> DHS must consult non-federal governmental and private sector experts and end-users of the data. DHS has since begun engaging with state, local, tribal, and territorial governments, industry, academia, and other partners.


DHS officials have stated that the goal for the Biological Detection for the 21<sup>st</sup> Century acquisition program is to identify a system that can rapidly alert first responders to potential threats, well before laboratory confirmation. Congress did not authorize this new goal for the system but also has not formally disagreed with it. Achieving this goal will require high-functioning biodetection systems that produce reliable and valid data, features that the current BioWatch system failed to demonstrate.

Leadership changes at the Countering Weapons of Mass Destruction Office stalled further movement of the Biological Detection for the 21<sup>st</sup> Century effort in late 2019 and early 2020. The effort appears to have stalled again. Technology identification, testing, and deployment should follow development of system requirements. Any further technology testing should be informed by stakeholder input and comprehensive system requirements.

Implementor:

**White House, Congress, DHS, DOD**

Status:

 **Inaction**

### *Action Item b.*

#### **Replace BioWatch Generation 1 and 2 detectors.**

**The Secretary of Homeland Security must replace these detectors within five years with the systems developed per action item 31a. If they cannot be replaced within that timeframe, the Secretary of Homeland Security should remove them from service.**

DHS has not yet identified or developed technology to replace the existing system of BioWatch detectors. The Pandemic and All-Hazards Preparedness and Advancing


## RECOMMENDATION 21

Innovation Act (P.L. 116-22) requires HHS to work with DOD and DHS to identify, exchange, and make recommendations regarding biodetection technology

Meanwhile, Congress has inexplicably continued annual appropriations of upwards of \$80 million per year for the program, demonstrating a commitment to legacy technology that has long outlived its utility.<sup>164</sup> Since the system's original deployment, detection technology has advanced, and mission needs have changed. Even assuming BioWatch is replaced with an effective substitute system by 2025—a prospect that appears increasingly unlikely—taxpayers will have spent nearly \$2 billion to develop and maintain a 22-year-old system that never met its original mission objectives. Only two arguments remain for the system: (1) its presence (not functionality) deters the use of biological weapons against the United States; and (2) the program (not the technology) strengthens partnerships with those public health departments that support the BioWatch system. The former argument is wholly unquantifiable and highly unlikely given the very public criticisms and failures of the technology. The latter argument would be much better advanced by either an effective substitute BioWatch system or an alternate partnership program focused on strengthening public health departments' preparedness and response capabilities.

The Commission recommended in *A National Blueprint for Biodefense* that DHS eliminate or replace the existing technology by 2020. The five years of savings from no longer supporting the program through 2025 would amount to roughly \$400 million in BioWatch funds that could instead be put toward developing new technology and strengthening public health surveillance systems or other biosurveillance and biodetection programs that would fill state, local, tribal, and territorial capability gaps revealed by the National Biodefense Strategy. Notably, not all BioWatch jurisdictions benefit fiscally from hosting the technology—some find it costly to their own budgets. This creates risks for future partnerships and must be addressed by any forthcoming joint endeavors.

Implementor:  
**Congress, DHS**

Status:  
 **Inaction**

# RECOMMENDATION 32

**Review and overhaul the Select Agent Program.** A comprehensive program assessment and overhaul is long overdue. Congress should ensure that these are initiated in the near term.<sup>165</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
<p>a. Undertake a major reassessment of the Select Agent Program. Congress should direct the National Science Advisory Board for Biosecurity, a federal advisory committee authorized in the Public Health Service Act (P.L. 78-410) to undertake a systematic, evidence-based assessment of the Select Agent Program.</p>	<p>Congress, National Science Advisory Board for Biosecurity (NSABB)</p>	<p><input type="radio"/> Inaction</p>
<p>b. Overhaul the Select Agent Program.</p>	<p>HHS, USDA, Congress</p>	<p><input type="radio"/> Inaction</p>

*Action Item a.*

**Undertake a major reassessment of the Select Agent Program.**

This assessment should include extensive consultation with all stakeholders, including the regulated community and the law enforcement and intelligence communities. The National Science Advisory Board for Biosecurity should evaluate all pertinent strategies, laws, and guidance related to the Select Agent Program; identify key drivers of safety and security lapses; and identify regulatory burdens in the Select Agent Program that stifle research and innovation. The report should include specific and actionable recommendations for revising Select Agent Program regulations and their implementation in order to improve security and safety and to incentivize laboratory certification under the program. The National Science Advisory Board for Biosecurity should provide the assessment and recommendations for program overhaul to the Secretary of Health and Human Services, Secretary of Agriculture, and Vice President within six months. The report should also be made public and provided to Congress shortly thereafter.

In November 2015, the National Science and Technology Council issued its own set of recommendations on the Select Agent Program, complementing those issued in December 2014 by the Federal Experts Security Advisory Panel (a federal interagency panel chaired by HHS and USDA) and the Fast Track Action Committee on Select Agent Regulations.<sup>166</sup> The National Science and Technology Council recommendations called for greater transparency with the public, sharing of best practices among the regulated community, and improving the inspections process and route of appeals. The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) requires the Secretary of Health and Human Services to report to Congress on the implementation of the Federal Experts Security Advisory Panel's and Fast Track Action Committee's recommendations annually, until they are fully implemented.

CDC and USDA have made limited improvements to the program since the publication of *A National Blueprint for Biodefense*. They jointly conducted an external review to assess the Program's current organizational structure, and subsequently developed a joint strategic plan in 2017.<sup>167</sup> Ongoing changes include a transition from a paper-based reporting system to a real-time electronic reporting system, harmonization of CDC and USDA activities, specific requirements for the inactivation of select agents, and the participation of NSC and OSTP staff in the Program's biannual review process.

While these changes may be useful upgrades, the larger question is whether the Select Agent Program is the correct governance structure to begin with. The fact that the Federal Experts Security Advisory Panel and Fast Track Action Committee reports were produced by the federal government runs counter to the need for independent perspective and oversight. The National Science Advisory Board for Biosecurity is a more appropriate choice to conduct such a review. While it ultimately reports to HHS, it is composed of up to 25 voting, non-federal experts.<sup>168</sup> Congress should direct the National Science Advisory Board for Biosecurity to undertake a systematic, evidence-based assessment of the Select Agent Program, including extensive consultation with all stakeholders.

Implementor:

**Congress, NSABB**

Status:

 **Inaction**



*Action Item b.***Overhaul the Select Agent Program.**

Based on the recommendations of the National Science Advisory Board for Biosecurity and input from other sources as appropriate, the Secretary of Agriculture and Secretary of Health and Human Services should undertake a comprehensive overhaul of the program to include development of a revised program strategy, notice of proposed rulemaking and public comment periods, and promulgation of new rules. Any new rulemaking must be undertaken to achieve optimal laboratory safety and security while minimizing bureaucratic burdens on the regulated community. Congress should provide oversight of all proposed rules for the Program.

In the absence of an external reassessment of how the Select Agent Program is structured, there is currently no clear path forward for comprehensive reform. The Secretary of Agriculture and the Secretary of Health and Human Services should continue to revise program strategies that address existing weaknesses identified by the Federal Experts Security Advisory Panel and Fast Track Action Committee recommendations. Though CDC and USDA developed a new strategy in the years since the release of *A National Blueprint for Biodefense*, any subsequent changes have been made within the existing structure of the Select Agent Program. More extensive reassessment and overhaul is necessary.

Implementor:



**HHS, USDA, Congress**

Status:

 **Inaction**

# RECOMMENDATION 33

**Lead the way toward establishing a functional and agile global public health response apparatus.** The United States should harness its considerable diplomatic influence to forge development of a response system with partner nations that can meet the need for rapid public health and animal outbreak response.<sup>169</sup>

ACTION ITEMS	IMPLEMENTER	STATUS
a. Convene human and animal health leaders.	DOS	 Partial Action
b. Establish the response apparatus.	White House, DOS	 Inaction

## *Action Item a.*

### **Convene human and animal health leaders.**

The Secretary of State should convene human and animal health leaders from throughout the world to evaluate current mechanisms and develop a strategy and implementation plan for global public health response. This cooperation should be multilateral and could be achieved through the Global Health Security Agenda and bilateral and multilateral agreements.

Much of the U.S. effort to build global health response capacity has gone toward building capacity at the country-level, rather than the global level. While functional country-level systems are clearly important, a major high-consequence event will rapidly overwhelm the capacity of countries to deal with it, necessitating a strategic, practiced, and supported global construct for response.

U.S. financial commitment to the Global Health Security Agenda has remained steady, even as federal agencies spent down supplemental appropriations related to the 2014 Ebola epidemic in West Africa. The President's Budget Request for FY 2021 requested \$225 million for Global Health Security Agenda activities, an amount higher than congressional appropriations in each of the previous three fiscal years. The Global Health Security Agenda does consider zoonotic diseases but remains predominantly oriented toward the human health.

Implementor:  
**DOS**

Status:  
 **Partial Action**

*Action Item b.***Establish a response apparatus.**

**Through the multilateral efforts described above, the United States should implement the plan and lead the establishment of a functional public health response system based on public-private partnerships. The President should request any required new funding via the unified biodefense budget.**

Though U.S. support for the Global Health Security Agenda assisted in building public health capacity in 30 countries, a coordinated international response apparatus has not been developed. The perils of this failure are evident in the COVID-19 response: Global public health response has been haphazard, dysfunctional, and less agile than the disease itself, and accordingly, countries have responded largely on an individual basis. Vaccine access also poses a problem necessitating an international response. WHO established the COVID-19 Vaccines Global Access Facility in September 2020 to facilitate purchase and equitable distribution of COVID-19 vaccine to countries who join the effort.<sup>170</sup> The Trump Administration previously chose not to join this endeavor, but the Biden Administration has reversed that decision and determined that the United States will participate along with more than 150 other countries.

Implementor:

**White House, DOS**

Status:

 **Inaction**

# ACRONYMS

<b>APHIS</b>	Animal and Plant Health Inspection Service
<b>ASD NCB</b>	DOD Assistant Secretary for Nuclear, Chemical, and Biological Defense Programs
<b>ASPR</b>	HHS Assistant Secretary for Preparedness and Response
<b>BARDA</b>	Biomedical Advanced Research and Development Authority
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CMS</b>	Centers for Medicare and Medicaid Services
<b>COVID-19</b>	Coronavirus Disease 2019
<b>DHS</b>	U.S. Department of Homeland Security
<b>DOD</b>	U.S. Department of Defense
<b>DOI</b>	U.S. Department of the Interior
<b>DOL</b>	U.S. Department of Labor
<b>DOS</b>	U.S. Department of State
<b>EPA</b>	Environmental Protection Agency
<b>FBI</b>	Federal Bureau of Investigation
<b>FDA</b>	Food and Drug Administration
<b>FEMA</b>	Federal Emergency Management Agency
<b>GAO</b>	Government Accountability Office
<b>HHS</b>	U.S. Department of Health and Human Services
<b>I&amp;A</b>	Office of Intelligence and Analysis
<b>ICE</b>	Immigration and Customs Enforcement
<b>JCAT</b>	Joint Counterterrorism Assessment Team
<b>MERS</b>	Middle East Respiratory Syndrome
<b>NIAID</b>	National Institute of Allergy and Infectious Diseases
<b>NIFA</b>	National Institute for Food and Agriculture
<b>NIH</b>	National Institutes of Health
<b>NSABB</b>	National Science Advisory Board for Biosecurity
<b>NSC</b>	National Security Council
<b>OMB</b>	Office of Management and Budget
<b>OSHA</b>	Occupational Safety and Health Administration
<b>OSTP</b>	Office of Science and Technology Policy
<b>SARS</b>	Severe Acute Respiratory Syndrome
<b>SARS-CoV-2</b>	Severe Acute Respiratory Syndrome Coronavirus 2
<b>USDA</b>	U.S. Department of Agriculture
<b>WHO</b>	World Health Organization

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- <sup>45</sup> Bill report language included in the final conference report of the Consolidated Appropriations Act of 2020 (Public Law 116-93).
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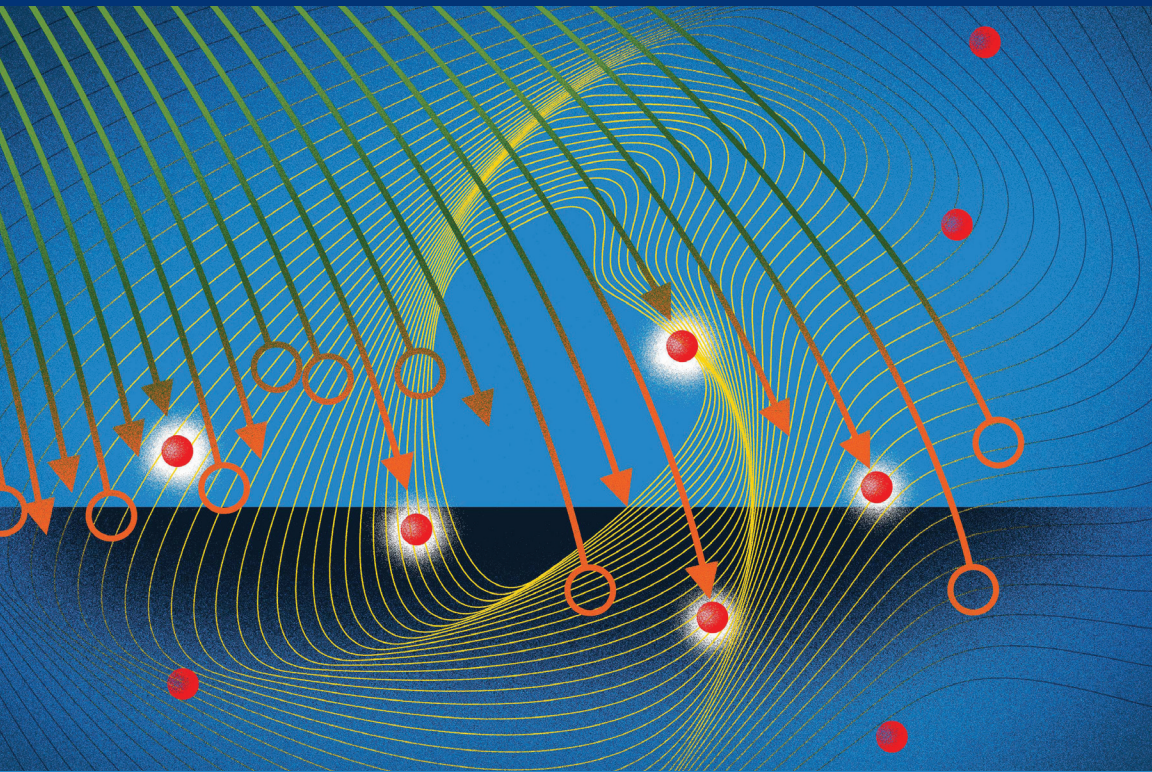
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