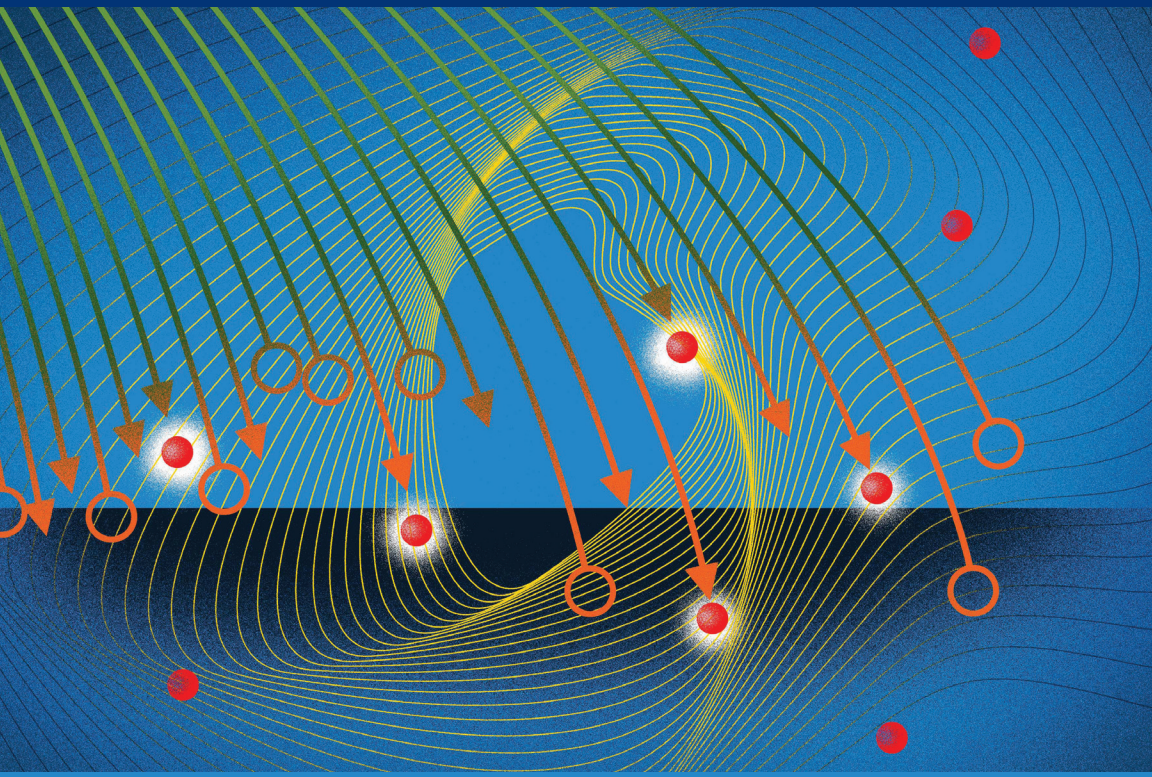
BIODEFENSE IN CRISIS

IMMEDIATE ACTION NEEDED TO ADDRESS NATIONAL VULNERABILITIES

A REPORT BY THE
BIPARTISAN COMMISSION ON BIODEFENSE

March 2021



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The Bipartisan Commission on Biodefense thanks the many subject matter experts and government officials who provided valuable information and insights as we evaluated the implementation of our recommendations from the Commission's first report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts* (2015) and how those recommendations would have impacted the initial 2019 novel coronavirus response. The Commission thanks Lisa O. Monaco for her valuable contribution and insight. We thank Dr. Ellen Carlin for her research perspicacity and assistance with developing the findings in this report. We are grateful for the perspectives of our ex officio members on public and private sector capacity and capability, as well as the national and global environments in which biodefense occurs. We thank Hudson Institute for serving as our fiscal sponsor. The Commission also expresses its gratitude for the financial support our donors provide.

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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.

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.[1]

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.*[2]

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[3] along with National Security Presidential Memorandum 14 to direct its implementation.[4] 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.

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[5] and a vaccine has yet to be approved. The Ebola outbreaks in Africa were never fully eradicated and defy control to this day.[6] The 2018–2019 influenza season resulted in nearly 57,000 deaths in the United States because the vaccine was only 29 percent effective.[7] 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.[8]

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.[9] 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.[10]

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.[11] 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.[12] 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.[13] The Department of Defense (DOD) also commissioned the National Academy of Sciences to report on synthetic biology and the new vulnerabilities it creates.[14]

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).[15] 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[16] comprised of state, local, tribal, 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*.[17] 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.[18] 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.[19]

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.[20] 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

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.[21] 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.[22] 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.[23] 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.[24]

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.[25] 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.

Implementer:	Status:
White House	**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,

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.

Implementer:	Status:
White House, OMB	**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.[26]

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[27] established the Biodefense Steering Committee to oversee the implementation of the National Biodefense Strategy.[28] 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.

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.

Implementer:	Status:
White House	**Crisis Action**

COVID-19

In response to the COVID-19 pandemic, President Trump convened the Coronavirus Task Force on January 27, 2020.[29] 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.[30]

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.[31]

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.[32] 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.[33] 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.

Implementer:	Status:
White House	**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.[34] 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.[35]

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[36] to receive verbal input regarding implementation of the National Biodefense Strategy and issued a call for written public comments thereafter.[37] 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.

Implementer:	Status:
White House	**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.[38]

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

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.

Implementer:	Status:
White House	**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.

Implementer:	Status:
White House	**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.

Implementer:	Status:
White House, OMB	**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 that 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

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.[39] 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.[40] 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.

Implementer:	Status:
White House	**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.[41] 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.[42] 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.

Implementer:	Status:
Congress	**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.

Implementer:	Status:
White House, Congress	◯ **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.[43]

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 catalog 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

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.

Implementer:	Status:
White House, Congress, OMB	**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).[44] Congress again included such a requirement in the conference report for the Consolidated Appropriations Act of 2020 (P.L. 116-93).[45] 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.[46]

Implementer:	Status:
White House, OMB	**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.

Implementer:	Status:
White House, OMB	**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.

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.[47] 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.[48]

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.

Implementer:	Status:
White House, OMB, Federal Government	◯ **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.[49]

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 115th Congress, and 50 biodefense-related hearings—the vast majority of which addressed the response to COVID-19—in the 116th 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.[50] Through this forum, representatives from all relevant committees with authorization and appropriation

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 116th 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.[51]

Implementer:	Status:
Congress	**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.[52]

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

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.[53] 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.

Implementer:	Status:
Director of National Intelligence	**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.

Implementer:	Status:
Director of National Intelligence	**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.

Implementer:	Status:
Director of National Intelligence	**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.

Implementer:	Status:
Director of National Intelligence	**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.[54]

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.

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.[55] 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.[56] 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.[57]

Implementer:	Status:
White House	**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.[58] After the end of that initial comment period, USDA again invited public comments for the proposed rule in August 2020.[59] USDA has not yet finalized the rule.

Implementer:	Status:
APHIS	**Partial Action**

Action Item c.

Prioritize emerging and reemerging infectious diseases.

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.

Implementer:	Status:
DOD, HHS, USDA	**Inaction**

RECOMMENDATION 8

Prioritize and align investments in medical countermeasures among all federal stakeholders. The success of the 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.[60]

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,

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.

Implementer:	Status:
White House	**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

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.

Implementer:	Status:
White House	◯ **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 21st 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.

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.

Implementer:	Status:
White House, Congress, NIAID	◯ **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.[61]

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.[62] 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.

Implementer:	Status:
White House	**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.

Implementer:	Status:
Congress	**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.[63]

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.[64] However, leadership and policy with regard to remediation activities has not been clearly established.

Implementer:	Status:
White House	**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)[65] 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.[66] 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).[67] 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.

Implementer:	Status:
Congress	◯ **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).

Implementer:	Status:
White House, Congress	**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.[68]

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.[69] 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-

141).[70] 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.

Implementer:	Status:
White House	**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.[71]

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.[72] 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.[73] 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.

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.[74] 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.

Implementer:	Status:
DHS	**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.[75]

ACTION ITEMS	IMPLEMENTER	STATUS
a. Assess the viability of the National Biosurveillance Integration System as the prime integrator of biosurveillance information.	White House	◯ Inaction
b. Incentivize data sharing.	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.[76] 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."[77] 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.

Implementer:	Status:
White House	**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.

Implementer:	Status:
White House	**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.[78]

ACTION ITEMS	IMPLEMENTER	STATUS
a. 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.	Congress, DHS	Partial Action
b. Fund the National Animal Health Laboratory Network at a level that allows it to achieve success.	White House, Congress	Completed
c. Develop guidance for the serious implications of companion animal and wildlife zoonoses.	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.[79] 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.[80] 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.[81]

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.[82] 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.[83]

Implementer:	Status:
Congress, DHS	**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.[84]

Implementer:	Status:
White House, Congress	**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.

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,[85] 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).

Implementer:	Status:
Congress, CDC, FEMA, APHIS	**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.[86]

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.[87] 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.

Implementer:	Status:
DHS	**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.[88] 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.

Implementer:	Status:
CDC, FDA, ASPR	**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.[89]

Implementer:	Status:
HHS	**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.[90]

ACTION ITEMS	IMPLEMENTER	STATUS
a. Strengthen the Joint Counterterrorism Assessment Team (JCAT).	Director of National Intelligence	◯ Inaction
b. Strengthen the ability of local police intelligence units to address the biological threat.	Department of Justice, Director of National Intelligence	◒ Partial Action
c. Enable fusion centers to address the biological threat.	FEMA, DHS Office of Intelligence & Analysis (I&A)	◯ 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.[91] Prior to dissemination, the National Counterterrorism Center, DHS, and FBI review the intelligence.

Implementer:	Status:
Director of National Intelligence	**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.

Implementer:	Status:
Department of Justice, Director of National Intelligence	**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

(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.[92]

Implementer:	Status:
FEMA, DHS I&A	**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.[93]

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

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.[94] 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.[95] Congress ultimately appropriated $695 million for Public Health Emergency Preparedness cooperative agreements as part of the FY 2021 omnibus funding package, $20 million more than FY 2020 appropriations, and $10 million more than authorized levels.[96] We applaud

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.

Implementer:	Status:
White House, Congress	**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.[97]

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.

Implementer:	Status:
Congress, HHS, DOL	**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.[98] 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.[99] 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.

Implementer:	Status:
White House, HHS, DOL	**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.[100] 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.[101]

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.[102] 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.[103]

Implementer:	Status:
HHS, DOL	**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.[104]

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.

Implementer:
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.[105] 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.[106] 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.

Implementer:	Status:
ASPR	**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.[107]

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),[108] 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.

Implementer:	Status:
CMS, ASPR	**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.[109] However, CMS did eventually issue clear guidance regarding reimbursement for COVID-19 treatment.[110]

Implementer:	Status:
Congress	**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.[111] CMS took a number of steps in response to the crisis, including rules relaxing the allowable use of telehealth for patients,[112] a rule that would make any COVID-19 vaccine authorized by the FDA reimbursable under Medicare and Medicaid,[113] 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.[114]

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."[115] 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.[116]

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.[117]

Implementer:	Status:
HHS	**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.[118] 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.[119]

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.

Implementer:	Status:
CMS	**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.

Implementer:	Status:
CMS	**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.[120]

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,

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;[121] (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.[122]

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.

Implementer:	Status:
ASPR, CDC, FEMA	**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.[123]

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.[124]

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.[125] 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.

Implementer:	Status:
ASPR	**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.

Implementer:	Status:
White House, ASPR	**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.[126]

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.[127] 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

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.[128]

Implementer:	Status:
White House	**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.[129] 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.

Implementer:	Status:
HHS, USDA	**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 Immigration and Customs Enforcement 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.

Implementer:	Status:
White House, DHS, ICE	**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.[130]

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.[131] 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.

Implementer:	Status:
DOS	**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.

Implementer:	Status:
White House, DOS	**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.

Implementer:	Status:
White House, DOS	**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).[132] 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.

Implementer:	Status:
Congress	**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.[133]

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.

Implementer:	Status:
DOD	**Partial Action**

Action Item b.

Establish military-civilian biodefense collaboration.

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.

Implementer:	Status:
DOD	**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.[134] 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.[135] 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.

Implementer:	Status:
White House, DOD	**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[136] and the National Strategy for Countering Weapons of Mass Destruction Terrorism[137] 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.[138]

Implementer:	Status:
DOD	**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.[139]

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

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 21st 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.[140] 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.[141]

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,"[142] 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 21st Century Cures Act authorized multi-year funding for an NIH Innovation Fund, expenditures were restricted to areas unrelated to medical countermeasure development.

Implementer:	Status:
BARDA	**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.[143] 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.[144] 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.

Implementer:	Status:
NIAID, BARDA, DOD ASD NCB	**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.

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.[145]

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.

Implementer:	Status:
NIAID, BARDA, DOD ASD NCB, APHIS, DHS Science & Technology Directorate	**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.

Implementer:	Status:
NIAID, BARDA, DOD ASD NCB, APHIS, DHS Science & Technology Directorate	◯ **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.[146]

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

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.[147] 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.[148] 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.

Implementer:	Status:
Congress, BARDA	**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.[149] 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.[150]

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.[151] 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.

Implementer:	Status:
White House, Congress	◯ **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

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.[152] 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.[153] 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.

Implementer:	Status:
Congress, ASPR	◯ **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.

Implementer:	Status:
ASPR, DOD ASD NCB	◒ **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.[154]

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 21st Century Cures Act (P.L. 114-255) to restore independent contracting authority to BARDA.[155] 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.

Implementer:	Status:
ASPR	**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.[156] 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.

Implementer:	Status:
BARDA	**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 21st Century Cures Act (P.L. 114-255) eliminated OMB review of Project BioShield procurements.[157] 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.

Implementer:	Status:
OMB	**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.[158]

ACTION ITEM	IMPLEMENTER	STATUS
a. Develop requirements for rapid point-of-care diagnostics for all material biological threats and emerging infectious diseases.	**BARDA**	◯ **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

leadership in overcoming this market failure.[159] 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.

Implementer:	Status:
BARDA	◯ **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 21st 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.[160]

ACTION ITEMS	IMPLEMENTER	STATUS
a. Fund the development of advanced environmental detection systems to replace BioWatch.	**White House, Congress, DHS, DOD**	◯ **Inaction**
b. Replace BioWatch Generation 1 and 2 detectors.	**Congress, DHS**	◯ **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 21st Century Acquisition Program.[161] 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.[162] 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,[163] 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 21st 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 21st 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.

Implementer:	Status:
White House, Congress, DHS, DOD	◯ **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

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.[164] 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.

Implementer:	Status:
Congress, DHS	◯ **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.[165]

ACTION ITEMS	IMPLEMENTER	STATUS
a. Undertake a major reassessment of the Select Agent Program. Congress should direct the National Science Advisory Board for Biosecurity (NSABB), 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.	Congress, NSABB	◯ Inaction
b. Overhaul the Select Agent Program.	HHS, USDA, Congress	◯ Inaction

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 NSABB 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 NSABB 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.[166] 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.[167] 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 NSABB 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.[168] Congress should direct the NSABB to undertake a systematic, evidence-based assessment of the Select Agent Program, including extensive consultation with all stakeholders.

Implementer:	Status:
Congress, NSABB	◯ **Inaction**

Action Item b.

Overhaul the Select Agent Program.

Based on the recommendations of the NSABB 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.

Implementer:	Status:
HHS, USDA, Congress	◯ **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.[169]

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.

Implementer:	Status:
DOS	**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.[170] 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.

Implementer:	Status:
White House, DOS	◯ **Inaction**

ACRONYMS

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

ENDNOTES

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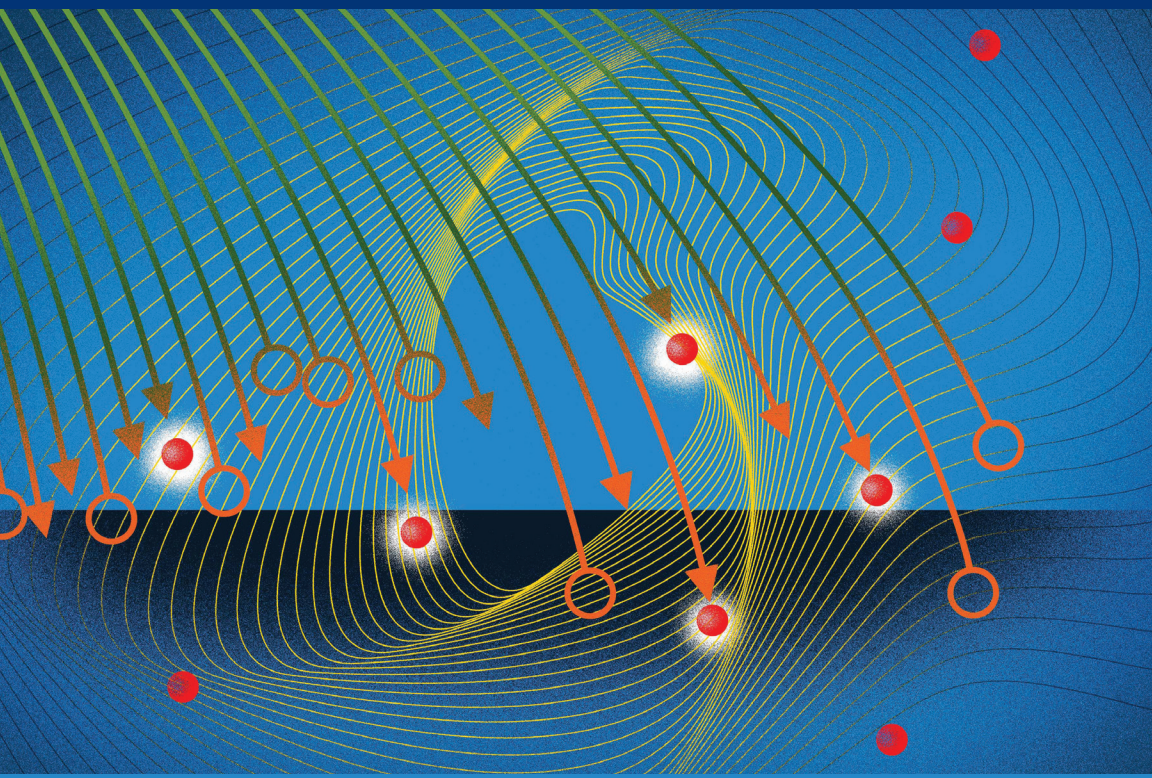

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THE APOLLO PROGRAM FOR BIODEFENSE

WINNING THE RACE AGAINST BIOLOGICAL THREATS

A RECOMMENDATION BY THE
BIPARTISAN COMMISSION ON BIODEFENSE

January 2021

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EXECUTIVE SUMMARY

The COVID-19 pandemic is a stark wake-up call for the United States to take biological threats seriously. The virus has taken the lives of more than 400,000 Americans and cost our economy trillions of dollars in just a year. The risks of future pandemics are increasing as technological progress eases barriers to modifying pathogens, raising the specter of novel biological agents causing diseases much worse than humanity has ever faced. Meanwhile, U.S. vulnerabilities to biological attacks have never been clearer to our adversaries.

However, there is a path forward. *The Apollo Program for Biodefense* would provide the United States the opportunity to mobilize the nation and lead the world to meet these challenges: a world where we detect and continually trace any new pathogen from the source; where we can distribute rapid point-of-person tests to every household in the country within days of that detection; where effective treatments are already in-hand; where vaccine development and rollout occur in weeks rather than years; and where pandemics will never again threaten the lives and livelihoods of Americans and people around the world.

With clarity of purpose, this world is possible within the next decade. While ambitious, consider that in 1960, it was hard to imagine landing a person on the moon. Yet in 1961, President John F. Kennedy committed the United States to achieve that goal "before the decade is out." Nine years later, with 161 days to spare, the United States accomplished the Apollo 11 mission and made human history. The United States can, and must, similarly put an end to pandemics before this decade is out.

The existential threat that the United States faces today from pandemics is one of the most pressing challenges of our time; and ending pandemics is more achievable today than landing on the moon was in 1961. Advances in the life sciences, accelerated by the pandemic, have brought technology to an inflection point where ending pandemics is within our grasp, but only if we commit ourselves.

Even the most ambitious program (about $10 billion annually) would be a small fraction of the current cost of the COVID-19 pandemic and an investment in our health, economy, and national security. Along with the needed structural, policy, and leadership changes detailed in the Commission's 2015 *National Blueprint for Biodefense, The Apollo Program for Biodefense* would effectively end the era of pandemic threats by 2030.

RECOMMENDATIONS

To achieve *The Apollo Program for Biodefense*:

- **Implement the National Blueprint for Biodefense –** The Administration and Congress should fully implement the recommendations in the Commission's 2015 report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*, to enable the Nation to defend against intentionally introduced, accidentally released, and naturally occurring biological events.
- **Produce a National Biodefense Science and Technology Strategy –** The Administration should produce and implement a National Biodefense Science and Technology annex to the National Biodefense Strategy to achieve *The Apollo Program for Biodefense* before the decade is out.
- **Produce a Cross-Cutting Budget –** The Administration should include funds for *The Apollo Program for Biodefense* as part of a unified biodefense budget and in the President's Budget Request.
- **Appropriate Multi-Year Funding –** Congress should appropriate long-term multi-year funding to implement *The Apollo Program for Biodefense*.

The Apollo Program for Biodefense is an ambitious goal-directed program to develop and deploy the technologies needed to defend against all biological threats, empower public health, and prevent pandemics, no matter what the source.

TECHNOLOGY PRIORITIES

With input from over 125 experts, the Bipartisan Commission on Biodefense has identified the following core technology priorities for *The Apollo Program for Biodefense*:

- Vaccine Candidates for Prototype Pathogens
- Multi-Pathogen Therapeutic Drugs in Advance of Outbreaks
- Flexible and Scalable Manufacturing of Pharmaceuticals
- Needle-Free Methods of Drug and Vaccine Administration
- Ubiquitous Sequencing
- Minimally- and Non-Invasive Infection Detection
- Massively Multiplexed Detection Capabilities
- Point-of-Person Diagnostics
- Digital Pathogen Surveillance
- A National Public Health Data System
- An Integrated National Pathogen Surveillance and Forecasting Center
- Next-Generation Personal Protective Equipment
- Pathogen Transmission Suppression in the Built Environment
- Comprehensive Laboratory Biosafety
- Technologies to Deter and Prevent Bad Actors

INTRODUCTION

COVID-19: YET ANOTHER WAKE-UP CALL

The COVID-19 pandemic has killed over two million people around the world to date,[1] ravaged health systems,[2] and destroyed economies.[3] It has also exposed destabilizing divisions within[4] and among countries[5] and revealed domestic and global weaknesses in biodefense. For these reasons and more, we must do everything in our power to ensure that the devastation caused by a pandemic never happens again.

Catastrophic infectious disease outbreaks have occurred regularly throughout history[6] and experts agree that they will occur with even greater frequency in the future.[7] The COVID-19 pandemic has resulted in more American deaths than World War I, the Korean War, the Vietnam War, the Gulf War, the War in Afghanistan, and the Iraq War altogether.[8] COVID-19 will likely cost the United States over $16 trillion.[9] We spend billions preparing for other threats to American lives, which may or may not occur. Spending on biological risk reduction would be far less than the significant cost of continuing to let future pandemics devastate the United States again.

The Commission's baseline 2015 report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*, warned that the United States was inadequately prepared for biological threats.[10] Five years later, the U.S. experience with COVID-19 continues to validate our original findings. In addition to revealing U.S. vulnerability to naturally occurring diseases, the effects of the pandemic exposed national vulnerabilities and weaknesses in the Nation's ability to respond to biological events.

We acknowledge that technology is only one part of an ambitious program to end pandemics. We described other crucial elements in the *Blueprint for Biodefense*, including strengthened public health systems; integrated and cooperative federal, state, local, tribal, and territorial relationships; effective public-private partnerships; multi-year funding; agency responsibilities clarified in advance of crises; and reduced regulatory bottlenecks.

Yet technology holds great promise. Within weeks of recognizing the existence of a novel coronavirus, scientists mapped its entire genome and developed and produced vaccines

faster than ever before. We accomplished these previously unimaginable feats because of forward-looking programs, ranging from the Human Genome Project to the advanced research programs that led to many of the vaccines currently in clinical trials.

We must stop fighting the last war. We need new strategies and defenses. Through *The Apollo Program for Biodefense*, we can make invisible biological enemies visible and take pandemic threats off the table by the end of the decade.

THE FUTURE LANDSCAPE OF BIOLOGICAL THREATS

COVID-19 will not be the last biological threat we face. The world can no longer consider a devastating biological event like the COVID-19 pandemic to be a rare, once-in-a-century, occurrence. Future naturally occurring biological threats will likely be more deadly and transmissible than SARS-CoV-2. Interconnected air travel networks, food production methods, climate and land-use changes, and increasing urbanization and human-wildlife interfaces contribute to the increasing risk and frequency of naturally occurring infectious diseases with pandemic potential.[11,12] Animal diseases that spill over to humans are increasing in frequency and represent approximately 75% of the world's emerging infectious diseases.[13]

The world can no longer consider a devastating biological event like the COVID-19 pandemic to be a rare, once-in-a-century, occurrence.

The 1918 influenza pandemic may have killed over 50 million people.[14] The next biological threat could be far more devastating. Other diseases like smallpox are more contagious than COVID-19[15] and 30–100 times more lethal.[16] Advances in biotechnology have also made it easier to obtain or modify these pathogens,[17] creating the possibility of pandemics emerging from deliberate attacks or laboratory accidents. COVID-19 will also not be the worst biological threat we will face.

Biological threats jeopardize national security. COVID-19 put a U.S. aircraft carrier out of commission for two months,[18] sent the Joint Chiefs of Staff into quarantine,[19] breached the White House, and hospitalized the Commander-in-Chief.[20] The pandemic brightly illuminates how our national security vulnerabilities increase and our deterrence capabilities falter during biological events. Rogue states wishing to challenge American primacy could take advantage of the Nation's disease-stricken state to test our country's ability and willingness to maintain global order.

The visibility of our vulnerabilities increases the likelihood of biological attacks in the future,[21] as do the continued breakthroughs in biotechnology that lower the technical barriers to producing biological weapons. The likelihood of an accidental release of pathogens from laboratories may also increase as nations build more high containment laboratories and conduct more biomedical research.[22,23]

We must bolster our defenses against these threats. The cost, while considerable, is manageable.

THE PATH FORWARD: THE APOLLO PROGRAM FOR BIODEFENSE

The path forward must include solutions rooted in public policy, science, technology, and innovation. Operation Warp Speed (a public-private partnership created to facilitate and accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics)[24] demonstrates that we can achieve ambitious technological goals with unprecedented speed during a pandemic. However, the Nation needs a broader, preemptive, and sustained effort to better protect against future biological threats. To succeed, we need to think big, on the scale of the lunar Apollo Program that brought humanity to the moon.[25]

The Nation has a history of taking on grand technological challenges in times of need, such as the Manhattan Project (to split the atom), the Interstate Highway System (to create a network of highways to connect the entire nation),[26] and the Global Positioning System (to enable geolocation anywhere on or near the earth).[27] Those efforts share similarities in scale, ambition, necessity, and difficulty of execution, and demonstrate our ability to engage in systematic, large-scale execution and funding of a goal-oriented and coordinated effort to achieve the technological capabilities the Nation needs.

These projects also resulted in critical ancillary products. The lunar Apollo Program, for example, produced a variety of revolutionary spinoff technologies, including solar panels and pacemakers.[28] *The Apollo Program for Biodefense* could produce breakthroughs in areas as varied as precision medicine, sustainable food production, manufacturing at scale, and even space travel (just as space travel led to innovations in health and medicine). These advances could also accelerate the growth, and improve the strength, of the U.S. bioeconomy,[29] which is already larger than the U.S. semiconductor industry.[30] Such a significant propellant to the bioeconomy could create additional jobs and economic growth for the United States while simultaneously helping to stave off foreign economic competitors. It is no coincidence that Russia called its new COVID-19 vaccine Sputnik V after the Soviet era satellite that triggered the space race in 1957.[31]

Only sustained bipartisan support and U.S. leadership will enable the Nation to develop the new technologies needed to prevent biological events. Only the public sector can provide the strategic direction, coordination, and funding needed to make the Apollo

> Only sustained bipartisan support and U.S. leadership will enable the Nation to develop the new technologies needed to prevent biological events.

Program happen. But only the private sector can produce the tools and innovations at the scale needed. Thus, the public and private sectors must work together, with the private sector providing research, insight, manufacturing, and efficiency, and the government allowing accelerated approvals and liability protection when appropriate.

International engagement in grand challenges can be an effective diplomatic tool. The United States has found this to be the case with grand challenges, such as the Human Genome Project.[32] Other countries, notably China and Russia, have used technological innovation during the COVID-19 pandemic to increase their international influence.[33,34,35] Involving other countries in a U.S.-led *Apollo Program for Biodefense*, with the goal of making the world safe from pandemics, will also strengthen our international relationships.

CALL TO ACTION

The expanding biological threat landscape includes the potential for catastrophe. We are at a turning point. If we harness the American know-how and can-do attitude, we can achieve resilience to biological threats. Alternatively, if we fail to move forward, we could remain permanently vulnerable to biological threats.

Previous national grand challenges focused on singular goals, such as landing on the moon or harnessing the power of the atom. *The Apollo Program for Biodefense* would not be limited to a singular goal (e.g., a moonshot), but would achieve multiple groundbreaking technological advances with a single, overarching goal—to gain technological superiority over biological threats. We envision a time when people will look back and wonder how we ever let infectious diseases wreak havoc on society and how we tolerated seasonal influenza, let alone COVID-19 and biological weapons.

Now is the time to advance technological solutions to the problems COVID-19 has revealed with horrific clarity. Operation Warp Speed took some first steps, making the most of new technologies, converging fields of study, and introducing multiple promising innovations on the cusp of realization. When the original Apollo Project began, the know-how needed to get to the moon did not exist. **Today we possess the scientific capabilities to achieve the mission of *The Apollo Program for Biodefense*.** Now we must bring them together to make this promise real.

RECOMMENDATIONS

The need to control COVID-19 created momentum to produce many technologies that we previously lacked the will and resources to pursue before the pandemic began. We need to build on that progress and push for technological advances to protect us from the next biological threat. These can come to fruition by the end of this decade, but only with leadership, resources, and interest that go beyond technical constraints and the usual crisis-neglect cycle timelines.

As with the effort to eradicate smallpox, we have the opportunity to do what once may have seemed impossible. We should not accept biological threats as inevitable when *The Apollo Program for Biodefense* can prevent outbreaks from spreading worldwide or occurring in the first place. While outbreaks may be inevitable, pandemics are not. The following ambitious recommendations have the potential to reshape our world if adopted and implemented fully.

The Administration and Congress should fully implement the recommendations in the Commission's 2015 *National Blueprint for Biodefense*. Recommendations 27–33 from the *Blueprint* are of relevance to *The Apollo Program for Biodefense*. These recommendations address the need to prioritize innovation over incrementalism (Rec. 27), incentivize the medical countermeasures enterprise (Rec. 28), incentivize the development of rapid point-of-care diagnostics (Rec. 30), and develop a modern environmental detection system (Rec. 31). The implementation of the *Blueprint*, in concert with *The Apollo Program for Biodefense*, would enable the Nation to defend against intentionally introduced, accidentally released, and naturally occurring biological threats.

The Administration should develop and implement a National Biodefense Science and Technology Strategy. The Administration should commence with *The Apollo Program for Biodefense* immediately to create the capabilities needed to defend against all biological threats and prevent pandemics before the decade is

out. Developing a National Biodefense Science and Technology Strategy is a crucial first step. White House leadership of this strategy will be necessary to coordinate interagency efforts across the federal government and harmonize contributions from academia and the private sector. To achieve this whole-of-America approach, the Administration should produce a National Biodefense Science and Technology Strategy with a focus on the technology priorities of *The Apollo Program for Biodefense* (see Appendix A). The Administration should provide this strategy in an annex to the National Biodefense Strategy.

A dedicated Deputy Assistant to the President within the National Security Council should lead the implementation of *The Apollo Program for Biodefense*, and the Director of the Office of Science and Technology Policy should have an integral role in the prioritization and development of the required technology capabilities.

In accordance with Recommendation 4 of *A National Blueprint for Biodefense* to unify biodefense budgeting, **Congress should require the Office of Management and Budget to provide a cross-cutting budget for *The Apollo Program for Biodefense* as a component of a unified biodefense budget.** A unified approach to budgeting is a vital part of any strategic interagency effort and would ensure that activities across the government are coordinated, complementary, and effective.

Congress should require the Office of Management and Budget to provide a cross-cutting budget for *The Apollo Program for Biodefense* as a component of a unified biodefense budget.

Congress should provide multi-year appropriations to implement *The Apollo Program for Biodefense*. This funding should be commensurate with the goals of the program and aligned with the magnitude of the threat, as opposed to historical appropriations. Funding should also include multi-year budget authority to allow agencies to procure systems and medical countermeasures that take years to develop and produce. Multi-year funding breaks the cycle of panic and neglect by providing a predictable and more stable time horizon for planning and investment in research, development, and production. This helps the government attract the best talent and private sector capital.

CONCLUSION

The Apollo Program for Biodefense **is relatively expensive, but the cost of inaction is remarkably higher. COVID-19 demonstrates all too painfully the cost of a pandemic to our economy, our standing in the world, and most importantly, the lives and livelihoods of our citizens. A realistic, achievable effort to ensure that such a biological crisis never happens again is clearly worth the investment.**

APPENDIX A: TECHNOLOGY PRIORITIES

The following technologies and capabilities should be top priorities for *The Apollo Program for Biodefense*. This list does not include all technologies that could have a substantial impact but contains those deemed especially promising.

- Vaccine Candidates for Prototype Pathogens
- Multi-Pathogen Therapeutic Drugs in Advance of Outbreaks
- Flexible and Scalable Manufacturing of Pharmaceuticals
- Needle-Free Methods of Drug and Vaccine Administration
- Ubiquitous Sequencing
- Minimally- and Non-Invasive Infection Detection
- Massively Multiplexed Detection Capabilities
- Point-of-Person Diagnostics
- Digital Pathogen Surveillance
- A National Public Health Data System
- An Integrated National Pathogen Surveillance and Forecasting Center
- Next-Generation Personal Protective Equipment
- Pathogen Transmission Suppression in the Built Environment
- Comprehensive Laboratory Biosafety
- Technologies to Deter and Prevent Bad Actors

These priorities vary widely. In many cases, the technology already exists or experienced incredible innovation and momentum from the ongoing pandemic, and the challenge remains in effectively integrating it with existing systems or scaling it to more ambitious levels. In other cases, exciting capabilities exist only as promising demonstrations or prototypes, and investments would need to target bringing technology to full maturity and wide deployment.

The priorities listed here also only address state-of-the-art technologies. Long-term success will require a continual assessment of changing capabilities over time. Trends in telehealth, automation, and robotics, to name a few, will continue and provide additional resilience to biological threats. In all instances, Congress and the Administration must fund, support, and coordinate the efforts needed to bring these capabilities to fruition.

Success will also require a whole-of-government approach. Relevant agencies and departments span the federal government, and all must be stakeholders in the success of *The Apollo Program for Biodefense*. The removal of institutional and bureaucratic barriers and the advancement of innovative incentive mechanisms will be necessary to bring some of the technologies to fruition. Such changes could include prize competitions, advanced market commitments, and regulatory awards. The National Security Council (NSC), the Office of Science and Technology Policy (OSTP), and the National Science and Technology Council (NSTC) should provide leadership through established or joint committees. They should bring together the relevant departments, agencies, and Executive Office of the President components to ensure engagement and coordination of science and technology efforts.[36]

VACCINE CANDIDATES FOR PROTOTYPE PATHOGENS

Vaccine development is a time-consuming endeavor that has traditionally taken several decades per pathogen. Advances in many fields have enabled new approaches to vaccine development with much shorter timelines.[37] However, even with these innovations, vaccine development is a multi-step process that takes precious time.

Fortunately, vaccine development for one pathogen is often translatable to other pathogens in the same viral family.[38] Thus, the extent to which we have previously invested in vaccine development against the same or related pathogens determines our capacity to rapidly develop a vaccine against a new pathogen.[39]

Although scientists frequently discover new viral species that infect humans, the number of viral families that these species belong to has plateaued. Therefore, by investing in vaccines for at least one prototype pathogen in each of the 25 viral families known to infect humans, we could reduce the global burden of infectious disease while simultaneously preparing for the next unknown biological threat. These efforts would also help develop a strong and diverse research community, better prepare us to address new threats rapidly as they emerge, and prevent the need for difficult and blunt interventions.

By investing in research and development at home and providing resources to international public-private partnerships, the United States could provide leadership and coordination globally, while also enabling the Nation's talent to lead scientifically.

Operation Warp Speed has generated significant momentum for vaccine development capability that should continue beyond the COVID-19 pandemic to prevent the next.

We should continue research to validate generalizability. When we need to use the same vaccine approach in the future, rapid entry into Phase 1 clinical trials will be possible by leveraging data from previous clinical trials. For pathogens that are currently endemic and that frequently cause outbreaks, clinical trials should progress through Phase 2 and 3, to serve affected populations and provide a stronger basis for efficacy for a given vaccine design.

MULTI-PATHOGEN THERAPEUTIC DRUGS IN ADVANCE OF OUTBREAKS

At the very beginning of an outbreak of a novel pathogen, our best pharmaceutical line of defense will be those drugs that have either already been approved by the Food and Drug Administration (FDA), or those that have advanced far into clinical trials and can be rapidly deployed. For example, Remdesivir—a drug with a validated safety profile in Phase 1 clinical trials against Ebola, and that had preclinical data showing activity against multiple viruses— including coronaviruses—was able to rapidly proceed into Phase 3 clinical trials and was the first drug to receive an Emergency Use Authorization (EUA) from the FDA. While Remdesivir was not panacea for patients admitted to the hospital, previous trials made the rapid pace at which Phase 3 trials started possible. Unfortunately, drugs like Remdesivir are rare due to systematic underinvestment by the pharmaceutical industry in the development of treatments for acute viral diseases.

To ensure that we have a multitude of drugs ready at the beginning of the next pandemic, we need to make investments in the development of multi-pathogen therapeutics—those that can be effective against multiple phylogenies of viruses.[40,41,42] Previous efforts to develop multi-pathogen therapeutics have largely targeted direct-acting small molecule antivirals. However, new modalities are emerging that may result in increased breadth and potency and which warrant extra investment, including host-directed antivirals and monoclonal antibodies targeting regions conserved across multiple viral species.[43,44] Funding the development of a diverse repertoire of multi-pathogen therapeutics through Phase 1 clinical trials—and, for endemic pathogens that currently affect populations throughout the world, Phase 2 and 3 clinical trials—would ensure that we could treat patients as early as possible in an outbreak, no matter the pathogen. Also, we can gain valuable information about the process of drug development that would inform efforts to develop even more effective therapeutics after an outbreak has occurred and the specific viral pathogen identified.

FLEXIBLE AND SCALABLE MANUFACTURING OF PHARMACEUTICALS

Following the successful development of therapeutics and vaccines against a novel pathogen, they must be rapidly manufactured at scale, both initially for clinical trials and later for distribution to the public. Currently, many of the drug and vaccine modalities that we rely on are not readily amenable to both flexible and scalable manufacturing. Small molecule drugs often require multiple steps to synthesize, and each requires its own set of reaction conditions that may vary by temperature, pressure, and reagents, as well as different isolation and purification steps. As a result, manufacturing processes for small molecules are often specific to each drug, making it difficult to repurpose existing facilities to scale manufacturing of a new drug.

Recombinant proteins form the basis of the plurality of vaccine and therapeutic candidates developed specifically against COVID-19. While existing manufacturing infrastructure supports large-scale recombinant protein production, the need to use cell culture for their production increases the time required to produce each batch of vaccine. Also, each protein may require its own expression, isolation, purification, and formulation conditions, making it difficult to repurpose existing facilities for the development and manufacturing of a new recombinant protein. Recombinant protein-based vaccines were, therefore, months behind leading vaccine candidates in entering COVID-19 clinical trials.

These leading vaccine candidates largely rely on platform technologies (i.e., technologies that use the same processes for manufacturing, formulation, and delivery of a drug or vaccine against multiple different pathogens). Such platform technologies typically involve genetically encoding the therapeutic or vaccine candidate in mRNA, DNA, or a viral vector, enabling the production of different therapeutic or vaccine candidates simply by changing a genetic sequence.[45] As a result, a facility designed to manufacture a therapeutic or vaccine candidate using a platform technology against one pathogen could be quickly repurposed against a new pathogen without much need to make changes to physical infrastructure or established production processes.[46]

The U.S. government should broadly invest in the advancement of platform technologies to ensure that therapeutic and vaccine candidates against the next pandemic pathogen can be rapidly manufactured at scale. Certain technical challenges that stand in the way of platform technologies becoming more broadly utilized could be overcome with further research. For example, unstable viral vectored and mRNA vaccines require constant refrigeration, complicating the logistics of their distribution to the public. Research into formulations that would reduce the dependence on a cold chain for distribution could significantly increase the utility of these vaccines. Also, mRNA and DNA vaccines have thus far lacked significant validation in human clinical trials. Further clinical experience with these nucleic acid-based vaccines would allow us to iteratively improve their

safety and efficacy profiles. Finally, while much research effort has gone towards the development of vaccine candidates that leverage platform technologies, the same cannot be said for therapeutic candidates that leverage the same technologies. Monoclonal antibodies are drugs that are currently produced as recombinant proteins, making them expensive and time-consuming to manufacture. If we develop and produce them using platform technologies instead, they might be significantly more scalable in a pandemic. We need further preclinical and clinical research to validate the applicability of platform technologies to the delivery of therapeutics.

With enough investment in their maturation, platform technologies might eventually become well-established as a means of producing pharmaceutical products during and between pandemics, ensuring that we would always have a large, manufacturing base that could be rapidly redirected to produce medical countermeasures at the beginning of a pandemic. Also, if we can build up a strong track record of safety and efficacy for a given platform in the clinic, we can benefit from more flexible regulatory standards for products developed using that platform subsequently. Streamlining manufacturing and regulatory approval processes that platform technologies might enable could allow us to develop, manufacture, test, and distribute medical countermeasures in months, not years, ultimately saving countless lives and livelihoods in the next pandemic.

NEEDLE-FREE METHODS OF DRUG AND VACCINE ADMINISTRATION

Once discovered, developed, and manufactured, we still need to distribute drugs and vaccines to the public. Today, most drugs and vaccines that would be useful during a pandemic require intravenous or intramuscular delivery—and thus, a healthcare provider to administer them. During a global pandemic, there may not be enough healthcare workers available to help treat or vaccinate the world's population, especially in countries with less-developed healthcare systems. Also, the widespread fear of needles may reduce the population uptake of a new vaccine. Thus, we need new methods of drug and vaccine delivery that would enable self-administration so that these medical countermeasures reach the most individuals possible.

Several different technologies exist that could facilitate the self-administration of drugs and vaccines. Microneedle patches—which are bandage-like patches that enable the simple delivery of a drug or vaccine through the skin—have been extensively investigated for influenza vaccine delivery, and have the advantage of reduced reliance on a cold chain for storage and transportation, and pain-free administration.[47] Intranasal or inhalable drugs or vaccines may also enable self-administration and would deliver the medical countermeasure to the respiratory tract, which would be of particular medical benefit against a respiratory pathogen.[48] Finally, while oral delivery is common for small molecule drugs, it has seen limited use with biologic drugs and vaccines. If technical barriers in

oral delivery could be overcome, this method of administration could be the most readily adopted by patients. We could deliver self-administrable drugs and vaccines through the mail or patients could pick them up at their local pharmacy, greatly reducing the logistical challenges of delivering these pharmaceuticals to potentially billions of people.

The U.S. government should invest in the advancement of the aforementioned technologies which enable transdermal (microarray patches), intranasal, inhalable, and oral delivery of drugs and vaccines. We can deliver pharmaceuticals that use these methods by developing them for infectious diseases for which needle-based delivery is currently predominant (e.g., influenza, measles), which can serve as proving grounds for these technologies. We should advance these pharmaceuticals through at least Phase 1 clinical trials to enable timely evaluation of initial pharmacokinetics (for drugs) or immunogenicity (for vaccines). However, we should take care to ensure that any devices required for delivery are easy to use and manufactured on a large scale. With further advancement of self-administered vaccines, we could dramatically streamline the process by which we get life-saving treatments and vaccines to the public.

UBIQUITOUS SEQUENCING

Nucleic acid sequencing (i.e., the reading of genetic material) is now widespread and has seen orders of magnitude decreases in cost, while simultaneously achieving increases in throughput. Sequencing provided the critical information to identify SARS-CoV-2 as a novel threat and enabled that information to travel around the world *faster* than the virus, enabling the design and manufacture of medical countermeasures. While impressive, it has substantially more to offer.

Metagenomic sequencing, the reading of all genetic material from a sample, offers advantages that many other capabilities struggle to rival.[49] All pathogens have genetic material and produce tell-tale signs in an infected individual, known as host-responses. Sequencing allows us to read these signals, and is crucial for early detection, characterization of pathogens, epidemiological tracking, attribution, and development of other biotechnologies generally. Crucially, sequencing offers the ability to detect pathogens without looking for a specific threat, which is essential to identifying novel pathogens, whether natural or engineered.

Despite continued advances, often outpacing Moore's law, sequencing technology has critical bottlenecks to achieving the ubiquity, simplicity, and affordability needed.[50] If realized, sequencing could become routine in the clinical setting, as well as in high-risk low-resource areas of the world, expanding access to the most capable diagnostic tool. Sequencing could serve as the diagnostic for diseases generally and permit novel pathogen detection early and beyond our borders. All this, while also being robust against genetic changes in pathogens and offering the details needed to track, and ultimately reduce pathogen transmission.

To advance sequencing, we must increase investments in novel sequencing modalities, prioritizing methods enabling miniaturization and decreases in reagents or even reagent-free sequencing. Coupled with research and development focused on microfluidics and on-chip sample preparation, we can realize the vision of truly hand-held, affordable, easily operated sequencers. Decreasing the cost and applying advances in bioinformatics to the output would enable sequencing to become ubiquitous and permit the incorporation of sequencers into several products and settings that are currently prohibitive.[51] Sequencing broadly and frequently would provide a baseline understanding of the genetic material around us, permitting the early detection of new threats, while providing the critical diagnostic capacity needed to reduce the global infectious disease burden.

MINIMALLY- AND NON-INVASIVE INFECTION DETECTION

The detection of an infection is most commonly pathogen-specific and initiated after the onset of symptoms or suspected exposure. Detection at this point is often too late and can miss both asymptomatic and pre-symptomatic infections where unsuspecting individuals may spread the disease further. In response to an outbreak, it should be possible to deploy simple point-of-person tests to detect infections and guide resources for interventions, but these types of tests will not be available immediately. Even once they are available, tests will not be continuously conducted and must be done at some interval. New sensing capabilities, though, such as non-invasive volatolomics (the detection of volatile compounds emitted by an individual) and wearables could permit constant passive monitoring of markers of infection without interfering with or inconveniencing our daily lives. Furthermore, non-invasive and minimally-invasive detection techniques could provide avenues to monitor high-risk, high-concern, and sentinel populations for infections, without disrupting daily life.

We are on the verge of the ability to detect whether the body is currently infected with any pathogen, known or unknown, through the interrogation of host biomarkers. Increasingly, we can also detect infection indicators non-invasively through advances in wearables[52] and volatolomics.[53] These techniques can accurately measure digital biomarkers (e.g., physiological, biometric, biophysical, biochemical, mobility, and circadian rhythm changes) constantly and longitudinally, and detect subtle changes from an established baseline indicative of the onset of infection. This allows the device to prompt the user to change behavior or seek a clinical diagnosis.

Minimally invasive technologies (i.e., those that permit sample acquisition without pain, discomfort, inconvenience, or risk) would also facilitate molecular diagnostics for the identification of pathogens. This capability would allow for the detection of pre-symptomatic exposure, and asymptomatic infection and spread without the need for individuals to present in a clinical setting, allowing for early detection and substantially improved monitoring of novel biological threats.

Sensors are already shrinking in size, becoming more affordable, and increasingly capable. Yet, there is a need for more work on the integration and analytic systems that would permit drawing rapid inferences from them. We should make investments in the development of sensing and sampling capabilities, as well as testing of technologies to fully understand their potential and challenges. Additionally, particular attention should be given to the privacy of users of any device undertaking constant monitoring to prevent exploitation by malicious actors. If achieved, we could build the ability to detect novel and seasonal infections into our environment, while also facilitating advances in telemedicine and pushing capabilities into more austere areas.

MASSIVELY MULTIPLEXED DETECTION CAPABILITIES

Historically, diagnostic capabilities were specific to the pathogen, slow, and expensive. Single-pathogen diagnostics require clinical suspicion and are not readily available, or available at all, for some pathogens. If we suspect multiple pathogens, then we would need to run several assays, thereby increasing the cost and time to a diagnosis. Multiplexed detection capabilities address these challenges and bring new benefits by simultaneously testing for multiple pathogens, resistance genes, biomarkers, and analytes in a single simple assay.[54] Massively multiplexed detection capabilities in the form of pan-viral and pan-microbial assays have also been demonstrated, ushering in a new paradigm for diagnostics.[55]

Syndromic panels via multiplexed PCR assays (e.g., those used to test for approximately 25 of the pathogens most associated with respiratory infections) are currently available in many parts of the world, but do not include most known pathogens. While adequate for most presentations of infectious disease, crucially, these panels do not cover less common and novel pathogens. Massively multiplexed panels can address these limitations by including virtually all known human pathogens and even detect novel pathogens based on conserved sequence homology[56] (i.e., the ability to detect similar regions in a pathogen's genetic tree). While the ability to detect almost any known pathogen is a tremendous advantage, for wide deployment, these arrays will need to become cheaper, more robust, simpler to operate, and faster. They must also achieve high sensitivity and specificity and ultimately be interpretable to clinicians.

To bring about these capabilities, the United States should make massively multiplexed assays a priority and provide funding for their research, development, and prototyping. New CRISPR-based massively multiplexed panels are particularly promising.[57] Other methods beyond these techniques have also been demonstrated previously, and new methods may also be possible. We should prioritize techniques enabling the tests to move out of centralized laboratories, and especially those that can operate in resource-constrained settings. The detection of viral pathogens for any host, including agricultural plants and animals, rapidly and with confidence would provide a capability to complement metagenomic sequencing and pathogen-specific point-of-person diagnostics.

RAPID POINT-OF-PERSON DIAGNOSTICS

Rapid point-of-person diagnostics, also known as point-of-need diagnostics, are tests that can rapidly identify an infection wherever the individual is located. Point-of-person diagnostics stand in contrast to clinically administered diagnostics, which often require transportation to centralized laboratories, and days or weeks before rendering results.

In accordance with Recommendation 30 of the *National Blueprint for Biodefense*[58] and the recommendations made in *Diagnostics for Biodefense: Flying Blind with No Plan to Land*,[59] the Commission urges the U.S. federal government to pursue rapid point-of-need diagnostics and the FDA to develop pathways for diagnostics to be approved for their public health potential to reduce community transmission.[60] Rapid testing can enable detection. Tests that take more than three days to produce a result are essentially useless in the context of outbreak control since beyond that point contract tracing becomes increasingly difficult.

Point-of-person diagnostics should be considered public health instruments, as opposed to simply clinical tools. Rapid tests should be readily available, minimally-invasive, portable, and user-friendly (i.e., easy to conduct and interpret). The end goal is to integrate point-of-person diagnostics with public health data systems. These tests can also extend testing to communities and populations that cannot readily access care.[61] Smartphone apps and other digital tools can aid in both the use and interpretation of results, as well as make results available to public health authorities. Rapid low-cost tests also allow for repeated use, which can be essential for novel pathogens with unknown incubation time, and for essential and frontline workers with multiple potential exposures. In the absence of such diagnostics, testing through a centralized laboratory will only increase the risk of spread by requiring individuals to present themselves publicly (especially in the case of extremely contagious pathogens). Additionally, a longer wait time places too much faith in a person's ability to quarantine for the appropriate duration.

DIGITAL PATHOGEN SURVEILLANCE

Digital pathogen surveillance systems, which use internet-based and other electronically available data (e.g., medical bulletins, search queries, social media), have shown some improvement in recent years, including the provision of early warning signs for COVID-19. These systems, which have the potential for near real-time warning ability, international detection, and automated operation, could complement more traditional public health surveillance systems. With access to international airline routes, known disease networks, and anonymized mobility data, to name a few, we can predict the spread of infection and focus on resources and interventions in advance of outbreaks.

Limited access to information, poor integration of public and private data, and failure to bring the best talent and latest innovations to solve the problem of real-time digital surveillance have limited the capability of extant systems to detect biological events early enough to respond effectively and contain the threat. By leveraging advances in machine learning, and in particular natural language processing,[62] we can continuously track vast amounts of data and filter the noise to provide relevant information to public health experts. This information is useful to prompt further investigation, allocate resources, and inform clinicians and public health authorities about potential pathogens to consider in their routine work.

The federal government should implement a system that monitors biological threats within and outside of U.S. borders. We should leverage data sources (e.g., medical bulletins, livestock reports, satellite data, social media, online forums), in concert with the National Pathogen Surveillance and Forecasting Center ensuring data interoperability. The government should clear obstacles to access necessary data, incentivize innovation in the field through inducement prizes, and fund long-term efforts to continuously update the system with new data and capabilities as they become available.

A NATIONAL PUBLIC HEALTH DATA SYSTEM

As past outbreaks and the current pandemic have demonstrated, reliable, accurate, and comprehensive data is necessary for effective decision making during a crisis. Without timely and relevant information, it is not possible to prioritize resources and interventions, coordinate efforts, and respond in a manner the American people deserve. Although it is an enormous undertaking, a National Public Health Data System would provide the capabilities needed to effectively address the spectrum of biological threats.[63] To be successful, the system must be able to efficiently integrate, curate, and analyze data in a timely manner from federal, state, local, tribal, and territorial public health agencies.[64]

The Coronavirus Aid, Relief, and Economic Security (CARES) Act provided the Centers for Disease Control and Prevention (CDC) with $500 million for public health data modernization and to support system-to-system interoperability and cloud-based centralized repositories. These efforts, while ongoing, will hopefully provide a strong foundation for future efforts to further ensure that data are simple to gather and deposit (while preserving privacy), available in real-time, and secured against cyberattacks. We should design continuous and timely integration of emerging technologies and data streams into the system from the start, with aims of reducing the burden of reporting and keeping outputs from the system simple to interpret and act on.

Our priority should be to establish and sustain a national and integrated public health data capability. With this foundation, we could integrate additional capabilities as they become available or advanced (e.g., digital pathogen surveillance, new streams of clinical and laboratory data, access to electronic health records, anonymized human movement,

new visualization capabilities, improved analytics). The government should continue to prioritize public health data and sustain investments in both the maintenance and advancement of the system.

A NATIONAL PATHOGEN SURVEILLANCE AND FORECASTING CENTER

An integrated real-time national pathogen surveillance and forecasting center with advanced capabilities to detect and model naturally occurring, accidentally released, and intentionally introduced biological threats does not currently exist. The abilities to identify and forecast threats rapidly is critical at the beginning of an outbreak and the understanding of infectious disease prevalence, including seasonal pathogens, are essential components of public health planning and response.[65] Aggregating diverse data sources in real-time and forecasting infectious disease outbreaks are necessary to prevent or rein in the spread of biological threats. Improved forecasting through modeling also allows for better projection of the pandemic potential that a threat poses and aids in the prioritization of resources, mobilization of a response, and initiation of countermeasure development and deployment.[66]

Current infectious disease forecasting capabilities rely on data that are sometimes unavailable for weeks. An assortment of academic groups usually coordinates to create a forecast, but they must be able to gather and analyze data quickly for it to be accurate and useful. The United States should be ahead of the curve, take these threats more seriously, and establish a permanent National Pathogen Surveillance Forecasting Center. This center would maintain forecasting capacity, improve science, and invest resources in the building and maintenance of the best models, pipeline, and community of researchers. Furthermore, the Center should integrate the National Public Health Data System and aggregate information from clinical molecular diagnostics, distributed sentinel surveillance, digital pathogen surveillance, laboratory biosafety monitoring, and animal and environmental pathogen surveillance. This would allow for improved detection of novel biological threats and a better understanding of rapidly evolving outbreaks and attacks.

Effective modeling also requires reliable data and a thorough understanding of pathogen transmission and available public health interventions. Additionally, it is also necessary to have data on historical trends of transmission, population mobility, and individual decisions in response to public health threats.[67] Forecasting success will also depend on the ability to communicate and relay relevant information in an effective manner (e.g., through visualizations or other dashboards) to decision makers. As some have noted, weather forecasting through the National Weather Service successfully takes advantage of, and integrates data from automated weather stations, radar sites, and satellites; maintains archival data; and progressively improves forecasts.

The ability to forecast the trajectory of a pathogen rapidly and reliably is crucial for the United States to address seasonal infectious diseases, and to prepare for and respond to emerging and engineered threats. By establishing a National Pathogen Surveillance and Forecasting Center as a permanent federal institution, the United States could advance these capabilities and ensure future preparedness.

NEXT-GENERATION PERSONAL PROTECTIVE EQUIPMENT

Personal protective equipment (PPE) can be used to protect against a broad-spectrum of biological threats. However, the current state of PPE burdens its users, requires experience in proper usage, is seldomly reusable, is not widely available to all populations, and does not properly fit everyone (e.g., children).[68] Additionally, since the primary goal of PPE is to prevent the wearer from becoming infected, not enough emphasis has been placed on preventing the wearer from infecting others. Shortages of PPE leave frontline and essential workers at risk, threatening their health and reducing their capacity to respond.

The COVID-19 pandemic has highlighted limitations in our knowledge of PPE and exposed an inadequate ability to rapidly scale up production. However, the pandemic has also catalyzed efforts to make PPE reusable, spurred new ideas about respirator designs, seen the advent of personalized PPE, and eventually brought new production capacity to fruition. While these efforts mark advancements, focused research efforts and innovative approaches could achieve much more.

To develop the next generation of PPE, we should make innovations in the following areas: 1) reusable, sterilizable, and self-disinfecting equipment; 2) modular designs responsive to a wide range of threats, including those which go beyond biological threats; 3) personalization to ensure adequate protection, comfort, and attractiveness; 4) rapid production from widely available materials without supply vulnerabilities; 5) the ability to neutralize pathogens; 6) sensing capabilities to detect potential exposures; and 7) protection beyond traditional masks, respirators, gloves, gowns, etc., that safeguard the wearer without burden. The government should invest in and incentivize the development of these PPE innovations through inducement prize challenges, intramural and extramural research and development efforts, advance purchase commitments and consistent acquisition, and use-inspired basic research programs, such as the Defense Advanced Research Projects Agency (DARPA) Personalized Protective Biosystem effort. Establishing distributed capacity will ensure PPE is available in advance, and maintaining capability will ensure increased production and surge in response to a threat. Additionally, the government should develop standards and metrics for the evaluation of all forms of PPE to quantify capabilities, standardize comparisons, and assess progress.

PATHOGEN TRANSMISSION SUPPRESSION IN THE BUILT ENVIRONMENT

Transmission of most known pathogens occurs in human-built environments (e.g., offices, healthcare facilities, schools, public transportation, planes) via air, droplets, and fomites.[69] While we have exerted significant effort to engineer and make the built environment robust against fires, earthquakes, and other threats, we have put little effort into engineering and making our world robust against pathogens. Suppressing pathogen transmission, especially in high-risk and high-traffic spaces, would reduce the spread of infectious diseases, extinguish some outbreaks, and buy critical time to combat more aggressive pathogens. With permanent incorporation into the environment, we could continuously defend against threats, even prior to detection, and without the dramatic changes in human behavior needed to reduce pathogen transmission.[70]

To reduce the effective transmissibility of most airborne, droplet, vector-borne, and fomite-transmitted pathogens, we should make investments in:

- affordable air filtration and sterilization systems
- deliberate design of airflows
- self-sterilizing surfaces
- easily sterilized materials, robust against harsh sterilization
- robotic and autonomous integrated sterilization
- fomite neutralizing technologies
- integrated real-time pathogen sensing capabilities

Conducting pilot studies in select high-risk environments would help to achieve a deeper understanding of how to re-engineer the built environment to reduce pathogen transmission before eventually expanding implementation throughout all population dense environments in the Nation. We should fund research and development efforts to foster a field of study and discover innovative technologies to further advance capabilities. As part of a modernization effort, the federal government should invest in technologies to retrofit current infrastructure, such as HVAC systems and public transport, and incentivize the incorporation of suppression technologies into new production through tax credits and grants, before ultimately incorporating proven aspects into regulation.

COMPREHENSIVE LABORATORY BIOSAFETY

While high-containment laboratories already have an impressive number of safeguards in place, they could benefit from continuously updated research given the high risks involved. Recent biosafety lapses have included smallpox, anthrax, and contagious strains of influenza.[71,72] Indeed, some believe the 1977 H1N1 pandemic arose from a lab accident or botched vaccination experiment.[73]

Our risk tolerance in laboratories worldwide[74] working with biological threats should be comparable to that of air travel, where safety is engineered into the airlines and airports, and monitoring occurs constantly to detect and prevent human-generated and technology-based accidents. A constant focus on and prioritization of safety ensures that the complex and previously risky nature of flight can be undertaken safely.

We continuously innovate automobile safety technologies (e.g., lane departure warnings, blind spot monitoring, pedestrian detection). We should apply a similar approach to laboratory biosafety. This includes the refinement of current capabilities, analogous to advances in airbags for automobiles, to the introduction and rigorous testing of new technologies. Ultimately, we may realize the benefits of high-containment laboratory work while minimizing the risks to the greatest extent possible by developing pathogen monitoring capabilities, improved engineering controls, and risk assessment and analysis tools.[75] While training personnel is essential and the core of biosafety,[76] insider threats should also be more seriously considered, and safeguards put in place to deter and prevent any malicious behavior.

Additional funding is necessary for the study of laboratory accidents and the development and testing of new capabilities and tools to achieve comprehensive laboratory biosafety systems. These should be tested in safe environments, continuously incorporated into current high-containment labs, and ultimately integrated into all biosafety labs.

TECHNOLOGIES TO DETER AND PREVENT BAD ACTORS

The ability to investigate, analyze evidence, and attribute deliberate biological events is essential for both deterrence and response to a deliberate or accidental threat.[77] As tools are developed and the barriers to engineering pathogens continue to decrease, the number of possible actors may increase. Technologies are required to ensure safety is built in and capabilities developed in advance to prevent and deter action.

Unfortunately, biological attribution, genetic engineering detection, and microbial forensic techniques have only made small strides since the anthrax attacks of 2001. In the two decades since, there have been advancements in machine learning and physical characterization techniques, and artificial intelligence evolved from an “AI winter” to “AI summer.” However, we have yet to see these technologies extensively applied,

despite recent academic studies and government programs hinting at their impressive capabilities.[78,79] In particular, it should be possible to harness advances in machine learning techniques from several disciplines and apply them to distinguish natural and engineered DNA and to inform attribution. Training these machine learning tools will require access to relevant datasets which we must establish in advance.

Once developed, these capabilities could be broadly deployed and integrated into routine laboratory, clinical, and environmental settings as sentinels monitoring for engineered pathogens, in addition to being available for forensics applications. To advance these techniques, the federal government should make use of its investment capability and inducement prizes, as this would encourage the application of their capabilities developed for other applications to these problems. With additional dedicated funding to research, develop, acquire, and operate such technologies, as well as maintain the relevant repositories, we could establish a robust and known capability to detect, analyze, and attribute biological threats.

APPENDIX B: METHODOLOGY

The Bipartisan Commission on Biodefense was established in 2014 to inform U.S. biodefense and provide recommendations for change. The Commission, supported by academia, foundations, and industry, determines where the United States falls short in addressing bioterrorism, biological warfare, and emerging and reemerging infectious diseases.

RESEARCH QUESTIONS

To examine an Apollo Program for Biodefense, we developed the following research questions:

- What should be the top priorities for an Apollo Program for Biodefense?
- Are investments in the development of technologies commensurate with the challenge of biodefense?
- Is new funding required?
- What should we be doing that we are not already doing to address biological threats more adequately with technology?
- How will the biological threat landscape evolve over the next decade and what technologies are needed to ensure preparedness?
- How can the public and private sectors contribute to an Apollo Program for Biodefense?
- How can we be sure that new technologies for biodefense have limited dual-use potential?
- How will technological convergence shape the biological threat landscape moving forward? What should be taken into consideration?
- What sorts of policy initiatives could drive technological innovation for biodefense on the scale of an Apollo program?

PRELIMINARY RESEARCH

The Commission reviewed previous research efforts; scientific studies; previous U.S. government research and development programs; and federal strategies, plans, funding, and research and development programs related to defense against naturally occurring, accidentally released, and intentionally introduced biological threats and catastrophic biological risks. This review: (1) allowed for an assessment of the comprehensiveness and effectiveness of research and development efforts for biodefense; and (2) determined direction for an Apollo Program for Biodefense. This review also informed the structure and topics of a formal meeting of the Commission, and interviews and roundtables with subject matter and government experts.

INTERVIEWS OF EXPERTS

The Commission conducted interviews with 66 academic, industry, non-governmental, and governmental experts to inform the recommendations contained in this report. Experts were invited to participate based on their prior knowledge of and experience with public health security, technological development, biosecurity, and biodefense. Staff protected the privacy of each expert to speak openly and candidly, and did not attribute opinions to the institutions, organizations, agencies, departments, or employers with which they were affiliated. Opinions were considered on aggregate. This report contains the views of the Commission and not necessarily those of individual experts.

ROUNDTABLES

The Commission hosted four roundtables at which experts discussed challenges and solutions that an Apollo Program for Biodefense should address in the following areas:

- Ambitious pathogen biosurveillance innovations;
- Improving PPE and built environments;
- Advancing medical countermeasures to combat biological threats; and
- Ambitious improvements to microbial forensics and attribution.

The Commission held these roundtables using virtual platforms in September 2020. Participants came from a diverse range of backgrounds, including academia, industry, non-governmental organizations, and government. To encourage frank and open discussion, the Commission held these roundtables under Chatham House Rule. Staff provided questions to participants in advance to help facilitate discussion. During these roundtables, participants discussed ambitious proposals, and solutions for a wide range of biological threats.

ANALYSIS

Commission staff used qualitative methods to analyze information and data obtained during the literature review, interviews, and roundtables conducted. Staff synthesized and evaluated ideas, feedback and suggestions given, alongside the individual expert interviews and literature review, to help inform the development of this report. Staff further evaluated findings and recommendations considering the Commissioners' own experiences. Staff did not use statistical and other quantitative methods for this analysis.

LIMITATIONS

Several biodefense programs and policies; intelligence, raw data, and documents; appropriations and budget documents; and other sensitive information are classified or otherwise unavailable. The Commission did not review these materials. The Commission produced this report in keeping with time constraints associated with funding for this activity.

APPENDIX C: INTERVIEWED EXPERTS

The Bipartisan Commission on Biodefense thanks the following individuals for their contributions. The final version of this report reflects the aggregated view of all evidence gathered by the Commission and does not necessarily represent the view of any individual expert. All experts' opinions were their own and not those of the organizations with which they are affiliated.

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THE ATHENA AGENDA

ADVANCING THE APOLLO PROGRAM FOR BIODEFENSE

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PREFACE

On September 12, 1962, President John F. Kennedy spoke to the nation and said those immortal words, "We choose to go to the Moon in this decade and do the other things — not because they are easy but because they are hard."

These words could have been written off as an impossible challenge doomed to fail. Instead, it galvanized the country and brought us together for the benefit of all humankind.

Today, we are faced with our own seemingly impossible challenge: we must stop pandemics before they can ever take hold again. And just like the race to the Moon, it will take our best and brightest to reach our final destination. But most importantly, it will take all of us coming together once again for the common good.

Each of us is experiencing firsthand the devastating effects of pandemics. It is becoming painfully obvious that we must put an end to this threat and prevent them once and for all.

Despite all the turmoil and grief of the past two years, there is hope. We developed a vaccine in less than a year, pushing technology and innovation beyond what was thought possible, and we created new treatments and diagnostics. Yet, while we stemmed the tide and averted an even greater catastrophe, we might not be so lucky next time. Whether natural, accidental, or deliberate, infectious disease threats are increasing in frequency and severity. It is a question of when, not if, the next pandemic arrives.

It is for this very reason that we must act now. Fortunately, there are those who have already answered the call and joined forces to advocate for an Apollo Program for Biodefense. Our nation has a history of accomplishing remarkable things when we put our minds to it. From a system of highways that connected the country to a global positioning system that helps us find our way, our country has always been able to achieve what has never been done before, particularly when we take on technological challenges.

But this challenge will take sustained bipartisan support and stalwart leadership. Both public and private sectors must work together, with the private sector providing expertise and capital to support research, clinical trials, regulatory expertise, and manufacturing

scale, while government supports fundamental research and incentives for innovation. And since this problem is a threat to all, we must work with other countries in a US-led initiative, strengthening our international relationships and harnessing other countries and international stakeholders as our partners in this fight.

The Apollo Program for Biodefense will not focus on a singular track, but rather involve the pursuit of multiple, parallel, groundbreaking solutions that together will end the frequency and severity of these emerging threats. We will create a world where we can detect new pathogens and continually trace them from the source, and where we can distribute rapid point-of-use tests to every household in the country within days of detection. Instant capture of test data will generate real-time situational awareness to optimize decisions so that already-in-hand treatments can be effectively and efficiently rolled-out.

While we achieve these goals, we will advance other areas of knowledge across the whole spectrum of science, technology, engineering, and mathematics. These advancements will inspire scientists, physicians, healthcare personnel, engineers, and data scientists to operate in an integrated innovation ecosystem that encourages high risk, high reward research. They will also support entrepreneurial investment within agile regulatory frameworks and public policies to adapt to the growing complexity of the threat spectrum.

Living through this pandemic created momentum to produce technologies and solutions that we previously lacked the will or resources to pursue. We must build on that progress and push for greater advances that will protect us from the next infectious disease threat.

We envision a time when people will look back and wonder how we ever let infectious diseases wreak havoc on our society—how we ever tolerated seasonal flu, let alone viruses like COVID-19.

This noble and extraordinary mission can be fully realized by the end of this decade. However, this will require visionary leadership and a commitment to implement intellectual, financial, and infrastructure investments, along with purposeful and proactive construction of relevant public-private partnerships. Success will also depend on forceful actions to transcend current institutional silos and technical constraints, while also avoiding the historical cycles of crisis and ‘out of sight, out of mind’ policies. The time is now.

"The Apollo Program for Biodefense will not focus on a singular track, but rather involve the pursuit of multiple, parallel, groundbreaking solutions that together will end the frequency and severity of these emerging threats.

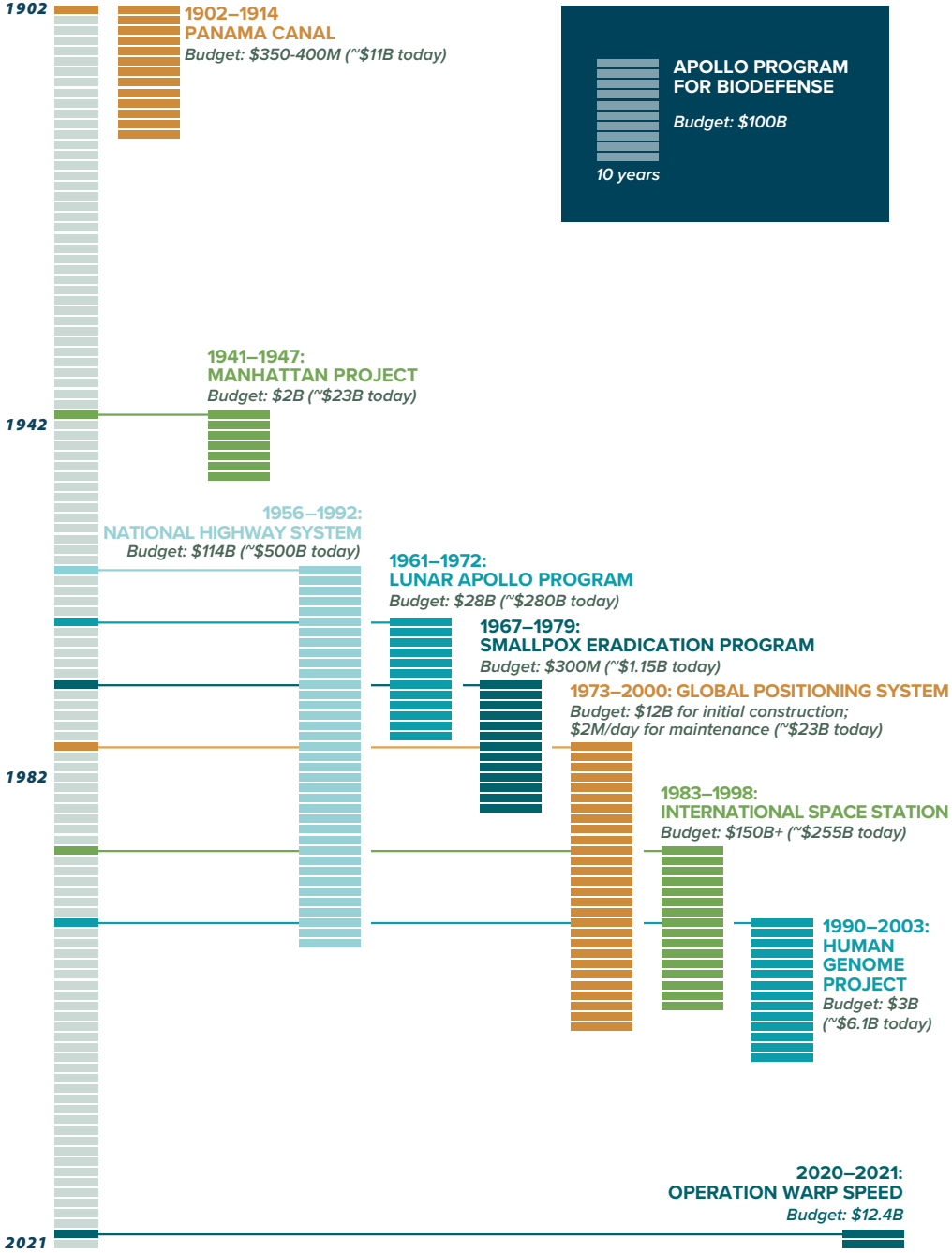
EXECUTIVE SUMMARY

The Bipartisan Commission on Biodefense warned that the United States was woefully unprepared for biological threats and that the risk to the Nation was rising rapidly in our baseline 2015 report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts.*[1] A little over six years later, the US experience with COVID-19 and the proliferation of biological weapons programs[2] continue to validate our original findings.

Since we released *The Apollo Program for Biodefense: Winning the Race Against Biological Threats* in January 2021, the world has yet to surmount COVID-19. Nearly one million American deaths and more than $16 trillion[3] in US economic losses have made COVID-19 the deadliest pandemic in this country's history and the costliest domestic catastrophe since the Great Depression. This pandemic has killed over six million people around the world,[4] ravaged health systems,[5] destroyed economies,[6] and exposed destabilizing divisions within[7] and among countries.[8] And yet, the Commission remains convinced that COVID-19 is not a once-in-a-century pandemic. Another biological event will occur much earlier than that.[9]

The risk of naturally occurring pandemics grows as biodiversity is reducing due to deforestation and diminished wildlife habitat quality. The exploitation of wildlife through hunting and trade facilitates opportunities for animal–human interactions and zoonotic disease transmission. Furthermore, advances in DNA sequencing, gene-editing, and synthetic biology (among others) hold the promise of profound advances in healthcare, crop and environmental sustainability, and economic growth. Unfortunately, these are dual-use technologies that could yield accidental, unintended, and deliberate misuse by creating deadly pathogens or disrupting ecological balances. Examples include the accidental release of smallpox from a laboratory in the United Kingdom,[10] engineering of a deadly strain of influenza by a professor in the Netherlands,[11] inadvertent self-injection of Ebola by an experienced scientist in Russia,[12] and the unintended escape of Brucellosis from an industrial facility in China.[13]

Figure 1. United States Grand Programs.



Our country must decide to make the prevention and deterrence of the next biological incident top priorities. We cannot simply afford to focus on the response to the current pandemic, but must work to put in place mitigation measures to reduce the impact of future biological events. Continuing vulnerabilities revealed by biological threats increase the likelihood that our enemies will attack our country with biological weapons,[14] especially as advances in science and technology make it easier to produce such weapons.

Throughout our country's history, our government has risen to seemingly impossible challenges by pursuing grand programs. It was hard to imagine landing a person on the Moon in 1961 when President John F. Kennedy committed the United States to achieving that goal in 10 years. Our country accomplished the Apollo 11 mission 9 years later, with 161 days to spare. The United States can similarly put an end to pandemics within a decade.

The Athena Agenda: Advancing The Apollo Program for Biodefense **contains additional recommendations to execute The Apollo Program, building on the Commission's previous work and taking into consideration the efforts of current and former Administrations and Congresses. This report provides the following specific governance and technology recommendations to implement The Apollo Program for Biodefense and identifies the US government organizations responsible for leadership and accountability, though certain actions may require or benefit from public-private partnerships.**

Figure 2. Recommendations in the Athena Agenda and their federal implementers.

ATHENA AGENDA RECOMMENDATIONS: GOVERNANCE

Fully Implement the National Blueprint for Biodefense
a. Prioritize innovation over incrementalism in medical countermeasure development
b. Fully prioritize, fund, and incentivize the medical countermeasure enterprise
c. Reform Biomedical Advanced Research and Development Authority contracting
d. Incentivize development of rapid point-of-care diagnostics
e. Develop a 21st Century-worthy environmental detection system
f. Review and overhaul the Select Agent Program
g. Lead the way towards establishing a functional and agile global public health response apparatus
Implementer: White House, Congress, Federal government

Implement The Apollo Program for Biodefense (or its equivalent)
a. Produce a National Biodefense Science and Technology Strategy
Implementer: White House (National Security Council (NSC)), Office of Science and Technology Policy (OSTP)
b. Implement The Apollo Program for Biodefense (or its equivalent)
Implementer: Congress, White House (NSC, OSTP, Office of Management and Budget (OMB), Department of State (DOS)), Department of Commerce (DOC), Department of Defense (DOD), Department of Education (ED), Department of Homeland Security (DHS), Department of Labor (DOL), Department of the Interior (DOI), Department of Transportation (DOT), Department of Health and Human Services (HHS), Department of Agriculture (USDA), Director of National Intelligence (DNI), Environmental Protection Agency, National Aeronautics and Space Agency (NASA), National Science Foundation (NSF)
c. Require a cross-cutting budget for The Apollo Program for Biodefense (or its equivalent)
Implementer: White House (OMB)

Provide appropriations to implement The Apollo Program for Biodefense (or its equivalent)
a. Appropriate funds for those federal departments and agencies contributing to The Apollo Program for Biodefense (or its equivalent).
Implementer: Congress
b. Provide multi-year budget authority
Implementer: Congress

Continued

Produce a comprehensive mid- and post-crisis report on continuity of government for COVID-19

Implementer: Congress, White House (NSC), Federal Emergency Management Agency (FEMA)

Revamp regulatory processes and policies to authorize or approve innovative technologies before, during, and after biological events

Implementer: Food and Drug Administration (FDA)/HHS

a. Modernize and accelerate approval pathways for platform technologies to produce medical countermeasures

Implementer: Congress, FDA/HHS

b. Incorporate lessons learned from COVID-19

Implementer: Congress, FDA/HHS

Develop a strategy and implementation plan for distributing at-home tests and therapeutics

Implementer: Congress, Assistant Secretary for Preparedness and Response (ASPR)/HHS, United States Postal Service

Support urgently needed public health measures for research during biological events

Implementer: Congress, National Institutes of Health (NIH)/HHS

Improve risk communications and build public trust

Implementer: Centers for Disease Control and Prevention (CDC)/HHS

a. Develop a strategy for crisis and risk communications that builds public trust

Implementer: White House, HHS, CDC/HHS

ATHENA AGENDA RECOMMENDATIONS: TECHNOLOGY

Develop at least one vaccine candidate for each of the 26 viral families that infect humans

Implementer: Congress, HHS, DOD, USDA

Develop a suite of broad-spectrum antiviral drugs.

Implementer: Congress, HHS, USDA, DOD

Develop a strategy for the rapid development of a virus-specific antiviral during an emerging outbreak.

Implementer: Congress, HHS

Review previous advanced manufacturing capability efforts for technologies for medical countermeasures

Implementer: Congress, DOD, HHS

Continued

Expand advanced manufacturing capability for platform technologies for medical countermeasures

Implementer: Congress, DOD, HHS

Produce a research and development plan for needle-free methods of drug and vaccine administration

Implementer: HHS, DOD, USDA

Increase US sequencing capability and capacity

Implementer: Congress, HHS, DOD, Department of Energy (DOE), USDA

Identify the need for portable sequencing capabilities

Implementer: HHS, DOD, USDA, DHS

Develop affordable portable sequencing

Implementer: HHS, DOD, USDA

Further develop the ability to detect infections with minimally- and non-invasive methods

Implementer: Congress, HHS, DOD, USDA

Advance massively multiplexed detection capabilities

Implementer: Congress, DOD, HHS, DHS

Invest in point-of-use diagnostics

Implementer: HHS, NIH/HHS

Develop a plan for rapid development, approval, scaling, acquisition, procurement, and distribution of point-of-use diagnostic tests

Implementer: HHS, NIH/HHS, DOD

Invest in digital pathogen surveillance

Implementer: Congress, HHS, DOD, USDA, DOI, Department of Veterans Affairs (VA)

Improve data interoperability to enhance information sharing

Implementer: Congress, HHS, DOD, USDA, DOI, VA, DNI

Establish a National Public Health Data System

Implementer: Congress, HHS, DOD, USDA, DHS, VA

Integrate data within the National Public Health Data System

Implementer: HHS

Continued

Secure data and ensure data integrity for the National Public Health Data System

Implementer: HHS, DHS

Authorize the Center for Forecasting and Outbreak Analytics

Implementer: Congress

Assess biosurveillance capabilities across the federal government

Implementer: Congress, HHS, DOD, USDA, DHS

Develop next-generation personal protective equipment

Implementer: Congress, HHS, DOD, NASA, DOL

Transfer technology for personal protective equipment throughout the federal government

Implementer: Congress, DOD

Support research on pathogen transmission in built environments

Implementer: Congress, HHS, DHS, ED, DOT

Develop and advance technologies that can reduce pathogen viability and transmission in built environments

Implementer: Congress, HHS, DHS, DOD, ED, DOT

Reduce pathogen transmission in built environments

Implementer: Congress, FEMA, General Services Administration (GSA), DHS

Review adequacy of biosafety and biosecurity standards, practices, and oversight to identify gaps, needs, and upgraded approaches

Implementer: HHS, National Science Advisory Board for Biosecurity (NSABB), DOD, DOE

Address laboratory biosafety and biosecurity challenges

Implementer: Congress, HHS, CDC, USDA

Develop and support implementation of a strategy to screen DNA synthesis providers and users

Implementer: Congress, OSTP, HHS, DOC

Require entities to purchase genetic material from verified vendors

Implementer: Congress, Purchasing entities

THE BIOLOGICAL THREAT LANDSCAPE

Biological threats to the Nation continue to expand and increase, multiplying so rapidly that current biodefense capabilities struggle to keep pace. About one million (more than 1 in 334) Americans have died.[15] Thousands still die every day as the virus continues to mutate and evolve. While optimism exists that we are on the threshold of the pandemic to endemic shift in COVID-19, we must be vigilant to monitor risk from additional SARS-CoV-2 variants. And yet, the pathogens that threaten us in the future may be deadlier and easier to transmit.

Other naturally occurring diseases persistently challenge countries and people throughout the world. We should not over-engineer or optimize our biodefense infrastructure by myopic focus on coronaviruses to the exclusion of all other pathogens. We need to recognize and address the diversity of potential biological threats. For example, we cannot ignore the relentless increase of antimicrobial resistance to existing therapies. Even if a virus causes the next pandemic, we will still need effective antibiotics to treat secondary bacterial infections, a leading cause of death during the 1918 influenza pandemic.

Humans, animals, and plants are all at biological risk. Interconnected transportation networks, food production methods, disruptive climate changes, poor land use practices, and increased or previously unusual human-wildlife interactions all contribute to the increasing risk and frequency of pandemics.[16,17] Zoonoses affecting humans and animals currently comprise 75 percent of emerging infectious diseases throughout the world.[18] As devastating as COVID-19 has been to our global and national economies, other microbial threats to human health could prove far worse. A disease affecting agriculture (e.g., African Swine Fever, wheat blast) could prove devastating.

The next biological event could be natural, human-generated, or accidental. As the scale and complexity of research studies on pathogens expands, the risk of potential laboratory accidents must be accorded appropriate assessment. In late 2019, a Brucellosis outbreak occurred at a vaccine production and research facility in Lanzhou, China, spread to more than 10,000 people, and extended into the following year.[19] In December 2021, the first local case of COVID-19 in over a month occurred after an infected mouse bit a worker in a high-containment laboratory in Taiwan.[20] As countries invest in building more laboratories, we can expect laboratory accidents to increase. At least 20 of the 59 Biosafety Level Four (BSL-4) laboratories worldwide were built in the past decade and most are located in densely populated areas.[21] Human error, limited understanding of how novel disease characteristics defy previously effective safety and security measures, and continued confusion about which biosafety level requirements apply to diseases that do not fit neatly into specific categories all challenge current laboratory biosafety and biosecurity programs. It is also easier now than ever[22] to obtain and modify pathogens, increasing the chances of pandemics due to laboratory accidents.

> Meanwhile, science is advancing far faster than our national determination to acknowledge the biological threat.

At the same time, the threat of a human-generated biological event continues to rise. While COVID-19 dominated worldwide attention, biological weapons programs rose to the fore once again. In April 2021, the Department of State (DOS) declared that Russia and North Korea possess and maintain active offensive biological weapons programs, that Iran has not abandoned its intent to conduct research and development of offensive biological agents, and that China has engaged in dual-use activities that may be in violation of the Biological Weapons Convention.[23] These programs obviously started well before the State Department made this statement. It is possible that Russia never ended its Soviet-era program, and for years, North Korea has essentially admitted its pursuit of the asymmetric advantage that biological weapons afford. According to Director of National Intelligence Avril D. Haines, the pandemic has driven China and Russia to gain geopolitical advantage through vaccine diplomacy and highlighted the importance of public health to national security.[24] Nation states and terrorist groups continue to develop and obtain advanced biotechnology in an effort to establish battlefield superiority, and the current conflict in

Ukraine raises global risks once again.[25] Dual-use science and technology research in the biological arena could help develop, produce, and maintain biological weapons.[26] Additionally, the lesser priority placed on counter- and nonproliferation of biological weapons allows these arms to race forward without the same impediments placed on other types of weapons of mass destruction.

Meanwhile, science is advancing far faster than our national determination to acknowledge the biological threat. Synthetic biology, genetic engineering, and the transdisciplinary convergence of biology with other fields (e.g., chemistry, engineering, computing, artificial intelligence (AI)) are advancing quickly. Concerns about security and health come up against the pursuit of science for the benefit of humanity. Policy and defense doctrine are not keeping pace. That lawmakers are only addressing the biosecurity implications of technologies such as the application of CRISPR-Cas9 (a technology widely used in the global research and development community), indicates that our lawmakers and agencies do not fully comprehend the scale of the biological threat or the rate at which it is growing.

Robust national biodefense must identify and defeat the diverse array of biological threats facing us. We can eliminate the threat of pandemics—whether natural, human-generated, or accidental—in ten years with The Apollo Program for Biodefense. The Athena Agenda provides recommendations and action items to ensure the Program moves forward.

ADVANCING THE APOLLO PROGRAM FOR BIODEFENSE

GOVERNANCE

The need to control COVID-19 created momentum to produce many technologies that we previously lacked the will and resources to pursue before the pandemic began. We need to build on that progress and push for technological advances to protect us from the next biological threat. These can come to fruition by the end of this decade, but only with leadership, resources, and interest that go beyond technical constraints and the usual crisis-neglect cycle timelines.

As with the effort to eradicate smallpox, we have the opportunity to do what once may have seemed impossible. We should not accept biological threats as inevitable when *The Apollo Program for Biodefense* can prevent outbreaks from spreading worldwide or occurring in the first place. While outbreaks may be inevitable, pandemics are not. The following ambitious recommendations have the potential to reshape our world if adopted and implemented fully.[27]

In September 2021, the Biden Administration released a plan to transform US capabilities to prevent, prepare for, and respond rapidly and effectively to, future pandemics and other high consequence biological events.[28] The American Pandemic Preparedness Plan addresses urgent needs and opportunities to protect the United States against biological threats and many of the technology priorities the Commission identified in its previous report, *The Apollo Program for Biodefense*. While the Administration requested $65.3 billion for this effort over 7 to 10 years, the Commission still believes that the appropriate amount is at least $10 billion a year, every year, for 10 years. The Commission recommended that a dedicated Deputy Assistant to the President within the National Security Council should lead the implementation of The Apollo Program for Biodefense, and that the Director of the Office of Science and Technology Policy should play an integral role in the prioritization and development of required technology capabilities for the Program.[29]

Building on the successes of Operation Warp Speed, we need to establish a sustainable system among the Department of Health and Human Services (HHS), Department of Defense (DOD), and other federal departments and agencies that enables the United States to respond rapidly to all biological threats and prevent deadly pandemics. This will require departments and agencies to evaluate their current biodefense capabilities and postures holistically within each organization,[30] and ensure centralized White House coordination of these activities.

The government must provide strong leadership, a clear mission, and sufficient resources to achieve The Apollo Program for Biodefense. An ambitious plan necessarily diverges from the *status quo*. The government must coordinate efforts, incentivize research, work with other countries, and ensure that each agency, company, nongovernmental organization, and laboratory understands how they fit into the plan to achieve this vision. Additionally, the government must ensure that technologies developed by The Apollo Program for Biodefense remain operational after the initial 10-year period has elapsed. Lastly, the public and private sectors must work together to find sustainable business models that support continuous defense against, and readiness to respond to, biological events. The Commission intends to address the critical need for private sector engagement in a separate report.

RECOMMENDATION: Fully Implement the *National Blueprint for Biodefense*.

The Administration and Congress should fully implement the Commission's 2015 *A National Blueprint for Biodefense* with special focus on the following recommendations and action items from that report:

- **Recommendation 27: Prioritize innovation over incrementalism in medical countermeasure development.**[31]
  - Prioritize innovation in medical countermeasures at agencies with biodefense responsibilities.
  - Exploit existing innovation.
  - Revolutionize development of medical countermeasures for emerging infectious diseases with pandemic potential.
  - Establish an antigen bank.
- **Recommendation 28: Fully prioritize, fund, and incentivize the medical countermeasure enterprise**.[32]
  - Fund the medical countermeasure enterprise to no less than authorized levels.
  - Reestablish multi-year biodefense funding for medical countermeasure procurement.
  - Address prioritization and funding for influenza preparedness.
  - Improve the plan for incentivizing the private sector and academia.

- **Recommendation 29: Reform Biomedical Advanced Research and Development Authority (BARDA) contracting**.[33] (*Note: Action Items a and c have already been accomplished*.)
  - Leverage previously provided authorities.
- **Recommendation 30: Incentivize development of rapid point-of-care diagnostics**.[34]
  - Develop requirements for rapid point-of-care diagnostics for all material biological threats and emerging infectious diseases.
- **Recommendation 31: Develop a 21st Century-worthy environmental detection system**.
  - Fund the development of advanced environmental detection[35] systems to replace BioWatch.
  - Replace BioWatch Generation 1 and Generation 2 detectors.
- **Recommendation 32: Review and overhaul the Select Agent Program**.[36]
  - Undertake a major reassessment of the Select Agent Program.
  - Overhaul the Select Agent Program.
- **Recommendation 33: Lead the way towards establishing a functional and agile global public health response apparatus**.[37]
  - Convene human and animal health leaders.
  - Establish the response apparatus.

RECOMMENDATION: Implement The Apollo Program for Biodefense (or its equivalent[38]).

White House initiatives enable the Executive Branch to embark on new programs without having to wait for months and years for dedicated congressional authorization. However, initiatives that are not congressionally authorized run the risk of ending if subsequent Administrations do not agree the program is needed. Developing a National Biodefense Science and Technology Strategy annex to the National Biodefense Strategy is a crucial first step towards creating the capabilities needed to defend against all biological threats and prevent pandemics in this decade.

- **Action Item a. Produce a National Biodefense Science and Technology Strategy.** The President should instruct the National Security Advisor, in coordination with the Director of the Office of Science and Technology Policy, to produce an annex to the National Biodefense Strategy that describes how the government will execute the 15 technology priorities found in The Apollo Program for Biodefense and assess its ability to leverage the private sector.[39] The National Security Advisor and Director of the Office of Science and Technology Policy should commence producing the annex immediately and complete it within 180 days.

- **Action Item b. Implement The Apollo Program for Biodefense (or its equivalent[40]).** Congress should amend the National Security Act of 1947 (P.L. 80-253, 61 Stat 495) to direct the National Security Advisor, in coordination with the Director of the Office of Science and Technology Policy, to authorize the Biodefense Steering Committee (previously established by the Trump Administration to oversee implementation of the National Biodefense Strategy) and establish an authorized subcommittee to oversee implementation of the National Biodefense Science and Technology Strategy annex to the National Biodefense Strategy. The Director of the Office of Science and Technology should chair this subcommittee, and members should include the Secretary of State, Secretary of Agriculture, Secretary of Defense, Secretary of Education, Secretary of Health and Human Services, Secretary of Commerce, Secretary of Homeland Security, Secretary of the Interior, Secretary of Labor, Secretary of Transportation, Administrator of the Environmental Protection Agency, Administrator of the National Aeronautics and Space Administration, Director of the Office of Management and Budget, Director of National Intelligence, and Director of the National Science Foundation. Congress should direct this subcommittee to implement the National Biodefense Science and Technology Strategy annex to the National Biodefense Strategy no later than two years following completion of the Annex.
- **Action Item c. Require a cross-cutting budget for The Apollo Program for Biodefense (or its equivalent[41]).** In accordance with Recommendation 4 of *A National Blueprint for Biodefense* to unify biodefense budgeting, Congress should amend the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283) to require the Office of Management and Budget (OMB) to provide a cross-cutting budget for the National Biodefense Science and Technology annex to the National Biodefense Strategy as a component of the unified biodefense budget already required by law.[42] This budget submission should request additional dedicated funding—above existing biodefense funding—to support the implementation of the annex.

RECOMMENDATION: Provide appropriations to implement The Apollo Program for Biodefense (or its equivalent[43]).

Congress should provide funding to accomplish the goals of the Program and align it with the magnitude of current and future threats. Multi-year funding breaks the cycle of crisis/panic and neglect by providing predictable and stable time horizons for planning and investment in research, development, production, and work force recruitment and retention.

- **Action Item a. Appropriate funds for those federal departments and agencies that contribute to The Apollo Program for Biodefense (or its equivalent[44]).** Congress should appropriate funding to support implementation of the goals of the National Biodefense Science and Technology annex to the National Biodefense Strategy. Congress should align these appropriations with the annual unified biodefense budget submission and fund annex activities at no less than $10 billion each fiscal year. Critically, appropriations to support the Annex should add to—not supplant—existing federal biodefense funding, programs, and policies.

- **Action Item b. Provide multi-year budget authority.** Congress should include multi-year budget authority in appropriations for implementing the goals of the National Biodefense Science and Technology annex to the National Biodefense Strategy. The budget authority should cover annex activities for the next ten years. Congress should allocate this budget authority in accordance with the roles, responsibilities, and goals of the annex to facilitate long-term research, development, testing, and acquisition of biodefense technologies and medical countermeasures.

RECOMMENDATION: Produce a comprehensive mid- and post-crisis report on continuity of government for COVID-19.

Congress should amend the Robert T. Stafford Disaster Relief and Emergency Assistance Act (P.L. 100-707) to direct the Administrator of the Federal Emergency Management Agency, through National Security Council (NSC) coordination, to produce a comprehensive COVID-19 mid- and post-crisis report (including lessons observed) examining how COVID-19 affected each department and agency's operations and continuity of government as a whole. Agency internal evaluations provided to the Federal Emergency Management Agency (FEMA) should (1) address impacts on workforce management and safety, mission fulfillment, technology, and security; and (2) identify needed additional resources. Agencies should complete these evaluations within one year after enactment. Congress should direct the Administrator of the Federal Emergency Management Agency to use these agency internal evaluations and other information to produce a whole-of-government assessment and develop pandemic continuity of government recommendations. The Administrator should submit this assessment and recommendations to Congress and the Biodefense Steering Committee for incorporation into the National Biodefense Strategy within two years of enactment.

RECOMMENDATION: Revamp regulatory processes and policies to authorize or approve innovative technologies before, during, and after biological events.

The Food and Drug Administration (FDA) will play a significant role in reviewing many of the technologies that comprise The Apollo Program for Biodefense. FDA conducted a lessons-learned review through an independent organization as part of its Pandemic Recovery and Preparedness Plan Initiative.[45] FDA must move quickly to incorporate these lessons learned from the response to COVID-19 into its policies and practices, so that it can authorize or approve new diagnostics within days of the emergence of any new virus, variant, or mutation, and authorize or approve new vaccines and therapeutics within 100 days. To ensure public confidence in the safety and efficacy of the products the agency approves during public health emergencies, measures must be taken to create and institutionalize procedures and processes to insulate FDA experts and regulatory activities from undue political pressure.

- **Action Item a. Modernize and accelerate approval pathways for platform technologies to produce medical countermeasures.** Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services to further develop and implement a regulatory framework for review and approval of medical countermeasure platform technologies that (1) expedites approvals for platforms with validated safety profiles to rapidly deploy during a biological event caused by a novel pathogen; (2) incorporates lessons learned from the rapid authorization of COVID-19 mRNA vaccine platforms and the lack of rapid authorization of other platforms (e.g., monoclonal antibodies); and (3) sets clear requirements for the private sector to obtain authorization with this process. Congress should direct the Secretary to implement this process within one year of enactment.
- **Action Item b. Incorporate lessons learned from COVID-19.** Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services to implement lessons learned throughout the ongoing pandemic through regulations and subregulatory guidance to address how the agency can enhance its (1) ability to partner efficiently with the private sector in conducting real-time, rolling reviews of pre-clinical, clinical, and manufacturing data and by enhancing coordination across relevant agency centers for combination products and other products that require cross-center expertise; (2) communication and transparency with private sector sponsors and, as appropriate, the public, especially with respect to the types and specificity of data and goalposts needed for authorization of classes of medical products; (3) approaches to remote clinical trial mechanisms and inspections, including pre-established coordination mechanisms with foreign government inspection regimes; (4) facilitation of organized and prioritized clinical trial networks to rapidly test and evaluate potential vaccines and therapeutics; (5) capability, as appropriate, to evaluate vaccines, therapeutics, and other interventions for their potential to reduce transmission, in addition to their potential to reduce disease severity; (6) guidance on how to streamline development and regulatory review of modifications of previously authorized vaccines, therapeutics, and diagnostics to address changes in a dangerous pathogen over time, as well as second-generation products built using the same technological platform and/or combination vaccines addressing families of related viruses or variants—as either continuous development of the previously authorized vaccines or from a new vaccine standpoint; (7) guidance on how to develop vaccines and therapeutics for tropical or neglected diseases and combination vaccines for pathogens and/or variants that are on the US government's pathogen priority list; (8) use of predictive biomarkers, AI-based models, and real-world evidence to accelerate authorization of biomedical products, especially during a public health emergency, with established mechanisms to monitor and evaluate such use on a real-time basis; and (9) ability to insulate FDA experts from political pressure.

RECOMMENDATION: Develop a strategy and implementation plan for distributing at-home tests and therapeutics.

Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Postmaster General of the United States, to develop a strategy and implementation plan for rapidly deploying at-home tests and various forms (i.e. needle-free) of drugs and therapeutics directly to the public, using the United States Postal Service, within 48 hours of the declaration of a biological event by the Secretary of Health and Human Services. The Retail Pharmacy Program should assess the lessons learned so that a similar structure can be re-implemented when needed.

RECOMMENDATION: Support urgently needed public health research during biological events.

Congress should amend the Public Health Service Act (P.L. 78-410) to clarify that recipients of funding from the Public Health Emergency Fund can utilize it to fund time-sensitive research about an ongoing biological event that causes a public health emergency. Congress should authorize the use of this funding to investigate, collate, and analyze available information about the biological threat, transmission methods, mitigation measures, long-term mental and physical impacts on infected individuals, inequities in the application of public health measures, and other related issues. Congress should require the Secretary of Health and Human Services to submit a report to Congress regarding any such research funded by the Public Health Emergency Fund within 180 days of utilizing the Fund for this purpose.

RECOMMENDATION: Improve risk communications and build public trust.

Even with advances in technology, establishing public trust and communicating to the public challenged the United States throughout the pandemic. Guidelines consistently confused the public regarding masks, testing, vaccines, and other measures. The lack of public trust led to vaccine hesitancy and lower vaccination rates. Leveraging evidence-based methods for public communication to support policy is critical for public health. For example, an AI-powered interactive website answering common questions about Centers for Disease Control and Prevention (CDC) guidelines would help citizens know when to isolate and test after exposure based on user inputs.

- **Action Item a. Develop a strategy for crisis and risk communications that builds public trust**: The Secretary of Health and Human Services, in coordination with the White House and other departments, should develop a comprehensive strategy for risk communications and building public trust during biological events. This strategy should (1) contain an evaluation of lessons learned from risk and science communication failures throughout the COVID-19 pandemic; (2) provide evidence-based communication methods informed by current social and behavioral science research; (3) detail strategies to combat

misinformation; (4) identify technologies that could aid in delivering clear communications and guidance to the public; and (5) describe how to use social media and search engine platforms to improve communications. The Secretary should complete the strategy within six months and implement the strategy within one year of completion.

DEVELOP VACCINE CANDIDATES FOR PROTOTYPE PATHOGENS

Vaccine development is a time-consuming endeavor that has traditionally taken several decades per pathogen. Advances in many fields have enabled new approaches to vaccine development with much shorter timelines.[46] However, even with these innovations, vaccine development is a multi-step process that takes precious time.

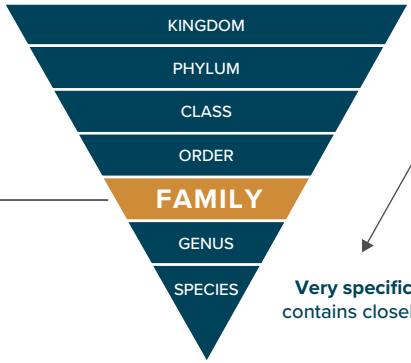
Fortunately, vaccine development for one pathogen is often translatable to other pathogens in the same viral family.[47] Thus, the extent to which we have previously invested in vaccine development against the same or related pathogens determines our capacity to rapidly develop a vaccine against a new pathogen.[48]

Although scientists frequently discover new viral species that infect humans, the number of viral families that these species belong to has plateaued. Therefore, by investing in vaccines for at least one prototype pathogen in each of the 26 viral families known to infect humans, we could reduce the global burden of infectious disease while simultaneously preparing for the next unknown biological threat. These efforts would also help develop a strong and diverse research community, better prepare us to address new threats rapidly as they emerge, and prevent the need for difficult and blunt interventions.

By investing in research and development at home and providing resources to international public-private partnerships, the United States could provide leadership and coordination globally, while also enabling the Nation's talent to lead scientifically. Operation Warp Speed demonstrated that new approaches in vaccine development (such as mRNA platform technology) can drastically shorten the timeline from decades to months. Operation Warp Speed has generated significant momentum for vaccine development capability that should continue beyond the COVID-19 pandemic to prevent the next.

We should continue research to validate generalizability. When we need to use the same vaccine approach in the future, rapid entry into Phase 1 clinical trials will be possible by leveraging data from previous clinical trials. For pathogens that are currently endemic and that frequently cause outbreaks, clinical trials should progress through Phase 2 and 3, to serve affected populations and provide a stronger basis for efficacy for a given vaccine design.[49]

Figure 3: Viral families of concern to human health.



26

Viral Families that Infect Humans


Adenoviridae


Anelloviridae


Arenaviridae


Astroviridae


Bornaviridae


Bunyaviridae


Caliciviridae


Coronaviridae


Filoviridaea


Flaviviridae


Hepadnaviridae


Hepeviridae


Orthomyxoviridae


Papillomaviridae


Paramyxoviridae


Parvoviridae


Picobirnaviridae


Picornaviridae


Pneumoviridae


Polyomaviridae


Poxviridae


Reoviridae


Retroviridae


Rhabdoviridae


Delta


Togaviridae

Viruses in the same family have similar features that can be targeted for medical countermeasure development.

Had we created a vaccine for SARS-CoV-1, a coronavirus that causes severe acute respiratory syndrome known as SARS, past early-stage development and animal studies, we could have produced a vaccine for SARS-CoV-2 even faster. Accordingly, having already developed a vaccine for SARS-CoV-2, we will be further ahead when we develop and trial vaccines for variants or other coronaviruses within that family. Moderna and the National Institutes of Health (NIH) developed the first batch of mRNA vaccine for SARS-CoV-2, just 25 days after China released the genomic sequence, and gave their first clinical trial participant a dose just 63 days later.

In March 2021, the Biden Administration proposed The American Jobs Plan which called for $30 billion in funding over four years (in addition to an initial investment of $10 billion from The American Rescue Plan) to protect against future pandemics.[50] Part of this funding would go towards the development of prototype vaccines through Phase I and II trials, test technologies for the rapid scaling of vaccine production, and sufficient production capacity in an emergency.[51] The Administration rolled this proposal into its September 2021 American Pandemic Preparedness Plan,[52] a 10-year $65.3 billion plan that also included dramatically improving and expanding our arsenal of vaccines, therapeutics, and diagnostics. In March 2022 at the Global Pandemics Preparedness Summit, the Coalition for Epidemic Preparedness Innovations similarly pledged $1.535 billion to develop effective vaccines within 100 days of identification of an epidemic or pandemic threat.[53]

RECOMMENDATION: Develop at least one vaccine candidate for each of the 26 viral families that infect humans.

Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense and Secretary of Agriculture, to (1) identify at least one pathogen from each of the 26 viral families that affect humans to target for vaccine development, taking the diversity of viruses and priority pathogens into consideration;[54] (2) establish sustainable public-private partnerships with industry and academia for research and development; (3) develop a vaccine candidate for each viral family that infects humans; (4) advance vaccine development for endemic pathogens through Phase 2 and 3 clinical trials to serve affected populations; (5) advance vaccine development for pathogens that are not endemic through Phase 1 clinical trials to demonstrate safety; and (6) submit an annual progress report to Congress.

DEVELOP THERAPEUTIC DRUGS IN ADVANCE OF OUTBREAKS

At the very beginning of an outbreak of a novel pathogen, our best pharmaceutical line of defense will be those drugs that have either already been approved by the FDA, or those that have advanced far into clinical trials and can be rapidly deployed. For example, Remdesivir—a drug with a validated safety profile in Phase 1 clinical trials against

Ebola, and that had preclinical data showing activity against multiple viruses— including coronaviruses—was able to rapidly proceed into Phase 3 clinical trials and was the first drug to receive an Emergency Use Authorization from the FDA. While Remdesivir was not panacea for patients admitted to the hospital, previous trials made the rapid pace at which Phase 3 trials started possible. Unfortunately, drugs like Remdesivir are rare due to systematic underinvestment by the pharmaceutical industry in the development of treatments for acute viral diseases.

To ensure that we have a multitude of drugs ready at the beginning of the next pandemic, we need to make investments in the development of multi-pathogen therapeutics—those that can be effective against multiple phylogenies of viruses.[55,56,57] Previous efforts to develop multi-pathogen therapeutics have largely targeted direct-acting small molecule antivirals. However, new modalities are emerging that may result in increased breadth and potency and which warrant extra investment, including host-directed antivirals and monoclonal antibodies targeting regions conserved across multiple viral species.[58,59] Funding the development of a diverse repertoire of multi-pathogen therapeutics through Phase 1 clinical trials—and, for endemic pathogens that currently affect populations throughout the world, Phase 2 and 3 clinical trials—would ensure that we could treat patients as early as possible in an outbreak, no matter the pathogen. Also, we can gain valuable information about the process of drug development that would inform efforts to develop even more effective therapeutics after an outbreak has occurred and the specific viral pathogen identified.[60]

Since we are uncertain of what the next biological threat will be, the traditional approach of developing a therapeutic for a single virus after it emerges will not adequately prepare us. Multi-pathogen antiviral therapeutics could address a broad spectrum of viral pathogens, much like antibiotics can address multiple bacterial pathogens.

Some of this work is underway by federal agencies. Between 2011–2019, the National Institute for Allergy and Infectious Diseases (NIAID) invested about $245 million in research on broad-spectrum antiviral therapeutics.[61] This relatively small amount of funding helped to advance viral targeting.[62] In 2020 and 2021, the DOD Defense Advanced Research Projects Agency (DARPA) invested about $88 million in promising solutions through its Pandemic Prevention Platform program, which aims to develop a scalable adaptable, rapid response platform capable of developing sufficient medical countermeasures within 60 days of identifying a novel threat.[63,64] The Biomedical Advanced Research and Development Authority (BARDA) was well positioned to advance broad spectrum antiviral development, but before COVID-19 began, only 1.5 percent (1/67) of BARDA's grants or investments were for such therapeutics.[65] Additionally, congressional funding for BARDA is insufficient to accomplish their mission.

Existing examples of broad-spectrum antivirals include faviparavir and alisporivir.[66] The government of Japan approved faviparavir to treat multiple strains of influenza virus,

and clinical trials are ongoing to test its effectiveness against COVID-19.[67,68] Alisporivir is effective against dengue, SARS-CoV-1, and hepatitis C, yet industry decided to not pursue the drug because they questioned its profitability.[69,70] While an argument can be made for the federal government to pay entirely for the development of broad-spectrum antivirals, at the very least, the private sector needs advance market commitments and other incentives from the government to prevent market failures that could preclude such development.

RECOMMENDATION: Develop a suite of broad-spectrum antiviral drugs.

Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense and Secretary of Agriculture, to (1) develop novel broad-spectrum antiviral therapeutics; (2) establish sustainable public-private partnerships with industry and academia for research and development; (3) advance antiviral development for endemic pathogens through Phase 2 and 3 clinical trials to serve affected populations; (4) advance antiviral development for pathogens that are not endemic through Phase 1 clinical trials to demonstrate safety; and (6) submit an annual progress report to Congress.

RECOMMENDATION: Develop a strategy for the rapid development of a virus-specific antiviral during an emerging outbreak.

The Secretary of Health and Human Services should develop a strategy for the accelerated development of a virus-specific antiviral against a novel and specific disease during an emerging outbreak. This plan should address: (1) research and development processes; (2) the pathway to provide resources to conduct emergency research; (3) public-private partnerships for accelerated development; and (4) regulatory considerations. The strategy should delineate roles, responsibilities, and timeframes for bringing antivirals to market under accelerated development. This strategy should be submitted to Congress no later than one year after enactment of this requirement.

DEVELOP FLEXIBLE AND SCALABLE MANUFACTURING OF PHARMACEUTICALS

Following the successful development of therapeutics and vaccines against a novel pathogen, they must be rapidly manufactured at scale, both initially for clinical trials and later for distribution to the public. Currently, many of the drug and vaccine modalities that we rely on are not readily amenable to both flexible and scalable manufacturing. Small molecule drugs often require multiple steps to synthesize, and each requires its own set of reaction conditions that may vary by temperature, pressure, and reagents, as well as different isolation and purification steps. As a result, manufacturing processes for small molecules are often specific to each drug, making it difficult to repurpose existing facilities to scale manufacturing of a new drug.

Recombinant proteins form the basis of the plurality of vaccine and therapeutic candidates developed specifically against COVID-19. While existing manufacturing infrastructure supports large-scale recombinant protein production, the need to use cell culture for their production increases the time required to produce each batch of vaccine. Also, each protein may require its own expression, isolation, purification, and formulation conditions, making it difficult to repurpose existing facilities for the development and manufacturing of a new recombinant protein. Recombinant protein-based vaccines were, therefore, months behind leading vaccine candidates in entering COVID-19 clinical trials.

These leading vaccine candidates largely rely on platform technologies (i.e., technologies that use the same processes for manufacturing, formulation, and delivery of a drug or vaccine against multiple different pathogens). Such platform technologies typically involve genetically encoding the therapeutic or vaccine candidate in mRNA, DNA, or a viral vector, enabling the production of different therapeutic or vaccine candidates simply by changing a genetic sequence.[71] As a result, a facility designed to manufacture a therapeutic or vaccine candidate using a platform technology against one pathogen could be quickly repurposed against a new pathogen without much need to make changes to physical infrastructure or established production processes.[72]

The US government should broadly invest in the advancement of platform technologies to ensure that therapeutic and vaccine candidates against the next pandemic pathogen can be rapidly manufactured at scale. Certain technical challenges that stand in the way of platform technologies becoming more broadly utilized could be overcome with further research. For example, unstable viral vectored and mRNA vaccines require constant refrigeration, complicating the logistics of their distribution to the public. Research into formulations that would reduce the dependence on a cold chain for distribution could significantly increase the utility of these vaccines. Also, mRNA and DNA vaccines had previously lacked significant validation in human clinical trials. Further clinical experience with these nucleic acid-based vaccines would allow us to iteratively improve their safety and efficacy profiles. Finally, while much research effort has gone towards the development of vaccine candidates that leverage platform technologies, the same cannot be said for therapeutic candidates that leverage the same technologies. Monoclonal antibodies are drugs that are currently produced as recombinant proteins, making them expensive and time-consuming to manufacture. If we develop and produce them using platform technologies instead, they might be significantly more scalable in a pandemic. We need further preclinical and clinical research to validate the applicability of platform technologies to the delivery of therapeutics.

With enough investment in their maturation, platform technologies might eventually become well-established as a means of producing pharmaceutical products during and between pandemics, ensuring that we would always have a large, manufacturing base that could be rapidly redirected to produce medical countermeasures at the beginning of a pandemic. Also, if we can build up a strong track record of safety and efficacy for a given

platform in the clinic, we can benefit from more flexible regulatory standards for products developed using that platform subsequently. Streamlining manufacturing and regulatory approval processes that platform technologies might enable could allow us to develop, manufacture, test, and distribute medical countermeasures in months, not years, ultimately saving countless lives and livelihoods in the next pandemic.[73]

One way in which HHS supports public-private partnerships is through Centers for Innovation in Advanced Development and Manufacturing (CIADMs).[74] DOD similarly supports Advanced Development and Manufacturing centers for medical countermeasures.[75] Unfortunately, CIADMs failed to deliver on the promise of rapid medical countermeasures manufacturing during the COVID-19 pandemic. Problems plagued the Centers, most notably quality control issues at one facility in 2021, Emergent BioSolutions, that resulted in a brief disruption to the manufacturing and supply of COVID-19 vaccines at a critical time in the response to the pandemic.[76] At the end of 2021, only one CIADM remains at the Texas A&M University System.[77] Over the past three decades, the government has repeatedly failed to establish these partnerships and facilities as envisioned.[78] In *Biodefense in Crisis,* the Commission recommended that the Secretary of Health and Human Services conduct a comprehensive review of existing medical countermeasure programs, including CIADMs.[79] The government must work to expand national capability to scale up manufacturing rapidly in response to future biological events, but also must learn from the problems with previously established CIADMs and apply those lessons learned to future initiatives.

The FDA supports flexible and scalable manufacturing of pharmaceuticals by issuing guidance on emerging technologies, reviewing and approving medical products, and advancing regulatory science.[80] However, the agency has limited experience with platform technologies for medical countermeasures. If existing or future platforms could quickly produce a vaccine or therapeutic in response to a novel biological threat, we must ensure that the FDA establishes clear regulatory procedures in place for review and authorization so that the public would benefit from their use.

RECOMMENDATION: Review previous advanced manufacturing capability efforts for technologies for medical countermeasures.

Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Defense and the Secretary of Health and Human Services to conduct a joint review of previous advanced manufacturing capability efforts. The review should (1) identify the problems and challenges that plagued previous efforts and their sustainability, especially within the context of the COVID-19 pandemic (including supply chain and stockpiling issues); (2) provide recommendations to address those problems; and (3) identify opportunities to modernize and improve manufacturing capabilities. The Secretary of Defense and Secretary of Health and Human Services should submit the review to Congress no later than one year after enactment.

RECOMMENDATION: Expand advanced manufacturing capability for platform technologies for medical countermeasures.

Drawing on the results of the joint review above, the Secretary of Defense and the Secretary of Health and Human Services should develop a plan to expand advanced manufacturing capability for platform technologies. The plan should (1) articulate how many advanced manufacturing centers the Nation needs to rapidly scale up production of medical countermeasures; (2) identify potential private sector partners who could host these centers; and (3) articulate how these centers should operate during non-crisis periods to ensure their ability to respond quickly during an emergency. Congress should also appropriate funding to support flexible and scalable manufacturing of medical countermeasures to meet future needs.

DEVELOP NEEDLE-FREE METHODS OF DRUG AND VACCINE ADMINISTRATION

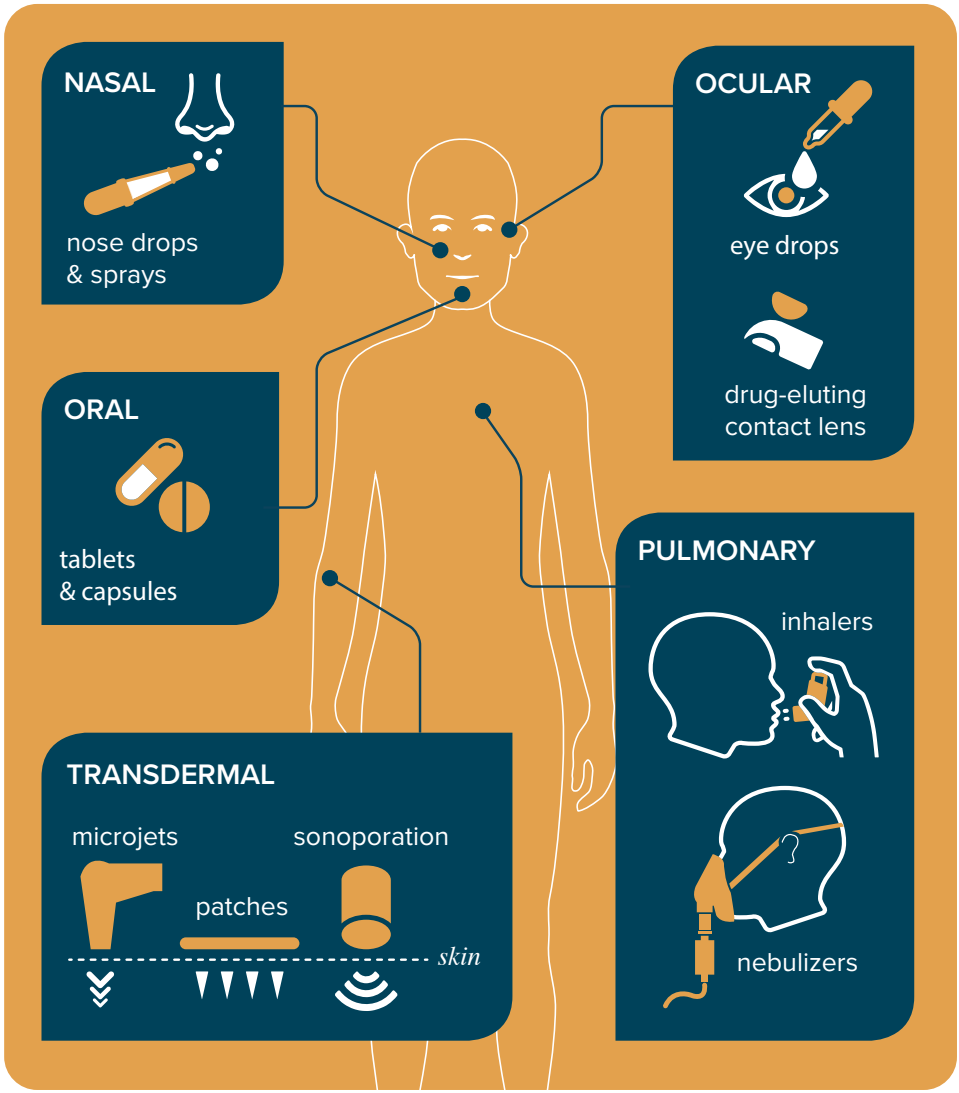
Once discovered, developed, and manufactured, we still need to distribute drugs and vaccines to the public. Today, most drugs and vaccines that would be useful during a pandemic require intravenous or intramuscular delivery—and thus, a healthcare provider to administer them. During a global pandemic, there may not be enough healthcare workers available to help treat or vaccinate the world's population, especially in countries with less-developed healthcare systems. Also, the widespread fear of needles reduces the population uptake of a new vaccine.[81] Thus, we need new methods of drug and vaccine delivery that would enable self-administration so that these medical countermeasures reach the most individuals possible.

Several different technologies exist that could facilitate the self-administration of drugs and vaccines. Microneedle patches—which are bandage-like patches that enable the simple delivery of a drug or vaccine through the skin—have been extensively investigated for influenza vaccine delivery, and have the advantage of reduced reliance on a cold chain for storage and transportation, and pain-free administration.[82] Intranasal or inhalable drugs or vaccines may also enable self-administration and would deliver the medical countermeasure to the respiratory tract, which would be of particular medical benefit against a respiratory pathogen.[83] Finally, while oral delivery is common for small molecule drugs, it has seen limited use with biologic drugs and vaccines. If technical barriers in oral delivery could be overcome, this method of administration could be the most readily adopted by patients. We could deliver self-administrable drugs and vaccines through the mail or patients could pick them up at their local pharmacy, greatly reducing the logistical challenges of delivering these pharmaceuticals to potentially billions of people.

The US government should invest in the advancement of the aforementioned technologies which enable transdermal (microarray patches), intranasal, inhalable, and oral delivery of drugs and vaccines. We can deliver pharmaceuticals that use these methods by developing

them for infectious diseases for which needle-based delivery is currently predominant (e.g., influenza, measles), which can serve as proving grounds for these technologies. We should advance these pharmaceuticals through at least Phase 1 clinical trials to enable timely evaluation of initial pharmacokinetics (for drugs) or immunogenicity (for vaccines). However, we should take care to ensure that any devices required for delivery are easy to use and manufactured on a large scale. With further advancement of self-administered vaccines, we could dramatically streamline the process by which we get life-saving treatments and vaccines to the public.[84]

Figure 4: Needle-free forms of drugs and vaccine administration.



Examples of promising technologies that could streamline the delivery of treatments and vaccines to the public include pain-free microneedle patches, delivery by mouth, delivery through the nose, and delivery through inhalation. These alternative methods allow for self-administration and have reduced logistical burdens associated with them, ensuring better public access. The federal government has funded limited work during the current pandemic toward these types of technologies. Aside from remdesivir, ritonavir-boosted nirmatrelvir (Paxlovid) and molnupiravir are the two authorized COVID-19 antivirals treatments available and both are oral pills. The US government purchased 20 million treatment courses of Paxlovid in late 2021.[85] BARDA,[86,87] the National Science Foundation (NSF),[88] and NIAID[89] have also invested in research on needle-free vaccines for diseases such as influenza and COVID-19. The BARDA Beyond the Needle program is developing technologies to make drugs and vaccines easier to administer and more widely available without needles and distribution burdens.[90]

RECOMMENDATION: Produce a research and development plan for needle-free methods of drug and vaccine administration.

The Secretary of Health and Human Services should, in coordination with the Secretary of Defense and Secretary of Agriculture, produce a plan for pursuing research and development of needle-free methods for drug and vaccine administration. The plan should address: (1) steps these departments will take to complete Phase 1 and subsequent clinical trials of newly developed technologies for currently circulating diseases like influenza and COVID-19; (2) lessons learned from those research efforts and their potential application to other pathogens; (3) how to coordinate these efforts with the prototype vaccine and antiviral initiatives recommended above; (4) research and development of new methods and capabilities for needle-free administration; (5) reformulation of current drugs and vaccines for needle-free administration; and (6) how needle-free delivery routes will be taken into consideration during the drug and vaccine development process.

IDENTIFY AND INCREASE UBIQUITOUS SEQUENCING

Nucleic acid sequencing (i.e., the reading of genetic material) is now widespread and has seen orders of magnitude decreases in cost, while simultaneously achieving increases in throughput. Sequencing provided the critical information to identify SARS-CoV-2 as a novel threat and enabled that information to travel around the world *faster* than the virus, enabling the design and manufacture of medical countermeasures. While impressive, it has substantially more to offer.

Metagenomic sequencing, the reading of all genetic material from a sample, offers advantages that many other capabilities struggle to rival.[91] All pathogens have

genetic material and produce tell-tale signs in an infected individual, known as host-responses. Sequencing allows us to read these signals, and is crucial for early detection, characterization of pathogens, epidemiological tracking, attribution, and development of other biotechnologies generally. Crucially, sequencing offers the ability to detect pathogens without looking for a specific threat, which is essential to identifying novel pathogens, whether natural or engineered.

Despite continued advances, often outpacing Moore's law, sequencing technology has critical bottlenecks to achieving the ubiquity, simplicity, and affordability needed.[92] If realized, sequencing could become routine in the clinical setting, as well as in high-risk low-resource areas of the world, expanding access to the most capable diagnostic tool. Sequencing could serve as the diagnostic for diseases generally and permit novel pathogen detection early and beyond our borders. All this, while also being robust against genetic changes in pathogens and offering the details needed to track, and ultimately reduce pathogen transmission.

To advance sequencing, we must increase investments in novel sequencing modalities, prioritizing methods enabling miniaturization and decreases in reagents or even reagent-free sequencing. Coupled with research and development focused on microfluidics and on-chip sample preparation, we can realize the vision of truly hand-held, affordable, easily operated sequencers. Decreasing the cost and applying advances in bioinformatics to the output would enable sequencing to become ubiquitous and permit the incorporation of sequencers into several products and settings that are currently prohibitive.[93] Sequencing broadly and frequently would provide a baseline understanding of the genetic material around us, permitting the early detection of new threats, while providing the critical diagnostic capacity needed to reduce the global infectious disease burden.[94]

The United States continues to lag behind other countries in terms of the number of virus genomes sequenced throughout the COVID-19 pandemic. For example, the United Kingdom sequences 9 percent of COVID-19 cases, while the United States only sequences 1 percent.[95] The United States also reports results more slowly and does not distribute sequencing capacity well (i.e., a small number of labs are doing much of the sequencing). While some technical bottlenecks remain in achieving an appropriately comprehensive sequencing capability, the United States can ramp up efforts significantly now and better engage existing capabilities. Essential efforts are underway to work with academic and public health laboratories, but fragmentation of the US healthcare system makes it difficult to collect information about samples. Furthermore, new strategies for undertaking genomic surveillance should be expanded. For example, the CDC has been trying to increase sequencing to track COVID-19.[96] The United States needs to expand its capability to monitor all pathogens, not just COVID-19. Towards that end, the American Rescue Plan contained $1.7 billion to strengthen and expand activities.[97]

RECOMMENDATION: Increase US sequencing capability and capacity.

Congress should amend the 21st Century Cures Act (P.L. 114-255) to direct the Secretary of Health and Human Services, Secretary of Defense, Secretary of Energy, and Secretary of Agriculture to develop a plan to increase pathogen agnostic metagenomic sequencing capability and capacity in the near- and long-term. The plan should (1) identify where sequencing capability and capacity currently lie in public sector laboratories, academic and research center laboratories, and other laboratory networks; (2) articulate how to identify sequencing capability and capacity in private sector laboratories; (3) provide an estimate of funding needed to expand capability and capacity in these laboratories; (4) explore the use of financial incentives to collect more samples in healthcare and wastewater settings; (5) set standards for the quality of information that should accompany each sample; (6) describe coordination with international partners to further sequencing development; and (7) describe how to achieve ubiquitous sequencing in the next five years. The Secretary of Health and Human Services, Secretary of Defense, and Secretary of Agriculture should deliver this plan to Congress within one year of enactment.

RECOMMENDATION: Identify the need for portable sequencing capabilities.

The Secretary of Health and Human Services should, in coordination with the Secretary of Defense, Secretary of Agriculture, and Secretary of Homeland Security, identify portable sequencing end-users and the sequencing capabilities they need in the federal government; states, localities, tribes, and territories (SLTT); healthcare settings; and ports-of-entry. The Secretary should take no longer than 180 days to identify these needs.

RECOMMENDATION: Develop affordable portable sequencing.

The Secretary of Health and Human Services should, in coordination with the Secretary of Defense and Secretary of Agriculture, develop a research and development plan that can make fielding portable sequencing in non-laboratory settings more affordable. The plan should (1) identify research efforts to produce portable sequencing devices in the public and private sectors; (2) address the miniaturization of these devices; (3) decrease or eliminate the reagents needed by these devices; and (4) address the integration of sequencing with microfluidics, on-chip sample preparation, and advances in bioinformatics. The Secretary should take no longer than one year to produce this plan.

DEVELOP MINIMALLY- AND NON-INVASIVE INFECTION DETECTION

The detection of an infection is most commonly pathogen-specific and initiated after the onset of symptoms or suspected exposure. Detection at this point is often too late and can miss both asymptomatic and pre-symptomatic infections where unsuspecting individuals may spread the disease further. In response to an outbreak, it should be

possible to deploy simple point-of-person tests to detect infections and guide resources for interventions, but these types of tests will not be available immediately. Even once they are available, tests will not be continuously conducted and must be done at some interval. New sensing capabilities, though, such as non-invasive volatolomics (the detection of volatile compounds emitted by an individual) and wearables could permit constant passive monitoring of markers of infection without interfering with or inconveniencing our daily lives. Furthermore, non-invasive and minimally-invasive detection techniques could provide avenues to monitor high-risk, high-concern, and sentinel populations for infections, without disrupting daily life.

We are on the verge of the ability to detect whether the body is currently infected with any pathogen, known or unknown, through the interrogation of host biomarkers. Increasingly, we can also detect infection indicators non-invasively through advances in wearables[98] and volatolomics.[99] These techniques can accurately measure digital biomarkers (e.g., physiological, biometric, biophysical, biochemical, mobility, and circadian rhythm changes) constantly and longitudinally, and detect subtle changes from an established baseline indicative of the onset of infection. This allows the device to prompt the user to change behavior or seek a clinical diagnosis.

Minimally invasive technologies (i.e., those that permit sample acquisition without pain, discomfort, inconvenience, or risk) would also facilitate molecular diagnostics for the identification of pathogens. This capability would allow for the detection of pre-symptomatic exposure, and asymptomatic infection and spread without the need for individuals to present in a clinical setting, allowing for early detection and substantially improved monitoring of novel biological threats.

Sensors are already shrinking in size, becoming more affordable, and increasingly capable. Yet, there is a need for more work on the integration and analytic systems that would permit drawing rapid inferences from them. We should make investments in the development of sensing and sampling capabilities, as well as testing of technologies to fully understand their potential and challenges. Additionally, particular attention should be given to the privacy of users of any device undertaking constant monitoring to prevent exploitation by malicious actors. If achieved, we could build the ability to detect novel and seasonal infections into our environment, while also facilitating advances in telemedicine and pushing capabilities into more austere areas.[100]

Throughout the COVID-19 pandemic, we have been primarily reliant on invasive methods of detection. For example, the National Aeronautics and Space Administration (NASA) received funding from HHS to develop a non-invasive detection method based on volatolomics to detect pathogens like COVID-19, called the E-Nose.[101] In the private sector, Ōura, the developer of a wearable smart ring, collects data from wearers to detect COVID-19.[102,103] Other examples of non- and minimally-invasive infection detection technologies include face masks that can detect the presence of pathogens, smart lenses

that can measure intraocular pressure, electronic tattoos that monitor stress markers, smart clothing that can measure skin temperature, smartwatches, and microneedle patches.[104] Despite promising preliminary data,[105] none of these technologies have yet matured to broader use by the public or health officials. These detection methods require further investment. The BARDA Division of Research, Innovation, and Ventures (DRIVe) program is working to advance such technologies through its Early Notification to Act, Control, and Treat program by partnering with innovators to develop non- and minimally-invasive technologies that enable early detection of biological threats.

For most of these technologies, privacy concerns and public participation must take into consideration during data collection. For example, small monetary incentives have been shown to increase public uptake.[106] The public sector must lay the policy groundwork to collect and aggregate data, build public confidence, engage with the private sector, and address privacy and incentive concerns.

RECOMMENDATION: Further develop the ability to detect infections with minimally- and non-invasive methods.

Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, Secretary of Defense, and Secretary of Agriculture to (1) identify ongoing public and private sector research and development of minimally- and non-invasive infection detection technologies; (2) determine their potential for, and challenges with, utilization; (3) develop a funding plan to advance research and development in this arena; (4) identify the data sets and integration and analytics systems needed to draw rapid conclusions from these technologies; and (5) implement newly developed advanced technologies and methods of detection within three years from enactment.

DEVELOP MASSIVELY MULTIPLEXED DETECTION CAPABILITIES

Historically, diagnostic capabilities were specific to the pathogen, slow, and expensive. Single-pathogen diagnostics require clinical suspicion and are not readily available, or available at all, for some pathogens. If we suspect multiple pathogens, then we would need to run several assays, thereby increasing the cost and time to a diagnosis. Multiplexed detection capabilities address these challenges and bring new benefits by simultaneously testing for multiple pathogens, resistance genes, biomarkers, and analytes in a single simple assay.[107] Massively multiplexed detection capabilities in the form of pan-viral and pan-microbial assays have also been demonstrated, ushering in a new paradigm for diagnostics.[108]

Syndromic panels via multiplexed PCR assays (e.g., those used to test for approximately 25 of the pathogens most associated with respiratory infections) are currently available in many parts of the world, but do not include most known pathogens. While adequate for most

presentations of infectious disease, crucially, these panels do not cover less common and novel pathogens. Massively multiplexed panels can address these limitations by including virtually all known human pathogens and even detect novel pathogens based on conserved sequence homology[109] (i.e., the ability to detect similar regions in a pathogen's genetic tree). While the ability to detect almost any known pathogen is a tremendous advantage, for wide deployment, these arrays will need to become cheaper, more robust, simpler to operate, and faster. They must also achieve high sensitivity and specificity and ultimately be interpretable to clinicians.

To bring about these capabilities, the United States should make massively multiplexed assays a priority and provide funding for their research, development, and prototyping. New CRISPR-based massively multiplexed panels are particularly promising.[110] Other methods beyond these techniques have also been demonstrated previously, and new methods may also be possible. We should prioritize techniques enabling the tests to move out of centralized laboratories, and especially those that can operate in resource-constrained settings. The detection of viral pathogens for any host, including agricultural plants and animals, rapidly and with confidence would provide a capability to complement metagenomic sequencing and pathogen-specific point-of-person diagnostics.[111]

Research into these capabilities is currently ongoing through public-private partnerships established by DARPA, Defense Threat Reduction Agency, and NIH, and these technologies have advanced significantly throughout the pandemic.[112,113,114] DARPA should build on that progress by working to transition these technologies to others so they are sustained and further developed over time. NIH can also play a larger role in ensuring these capabilities realize their full potential through its Rapid Acceleration of Diagnostics (RADx) initiative.[115] BARDA seems well-positioned and can be more involved in advancing these detection technologies. As noted in the Commission's October 2021 report, *Saving Sisyphus: Advanced Biodetection for the 21st Century*, the Department of Homeland Security (DHS) is also involved and should further explore these capabilities to help defend the Nation against biological threats.[116]

RECOMMENDATION: Advance massively multiplexed detection capabilities.

Congress should amend the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283) to direct the Secretary of Defense, in coordination with the Secretary of Health and Human Services and Secretary of Homeland Security, to develop and advance massively multiplexed detection capabilities. They should (1) assess ongoing research and development of massively multiplexed detection capabilities across the public and private sectors; (2) identify candidate technologies with the most beneficial performance characteristics for clinical applications, environmental monitoring, detection of novel pathogens by looking for conserved regions, identification of host-based biomarkers, and orthogonal detection mechanisms; (3) develop a five-year plan for funding research and development of such technologies in the public and private sectors; (4) submit an annual progress report to Congress detailing progress, current capabilities, and future directions for research and development; and (5) implement these technologies and methods within five years of enactment.

DEVELOP RAPID POINT-OF-USE DIAGNOSTICS

Rapid point-of-use diagnostics, also known as point-of-person or point-of-need diagnostics, are tests that can rapidly identify an infection wherever the individual is located. Point-of-use diagnostics stand in contrast to clinically administered diagnostics, which often require transportation to centralized laboratories, and days or weeks before rendering results.

In accordance with Recommendation 30 of the *National Blueprint for Biodefense*[117] and the recommendations made in *Diagnostics for Biodefense: Flying Blind with No Plan to Land*,[118] the Commission urges the US federal government to pursue rapid point-of-use diagnostics and the FDA to develop pathways for diagnostics to be approved for their public health potential to reduce community transmission.[119] Rapid testing can enable detection. Tests that take more than three days to produce a result are essentially useless in the context of outbreak control since beyond that point contract tracing becomes increasingly difficult.

Point-of-use diagnostics should be considered public health instruments, as opposed to simply clinical tools. Rapid tests should be readily available, minimally-invasive, portable, and user-friendly (i.e., easy to conduct and interpret). The end goal is to integrate point-of-person diagnostics with public health data systems. These tests can also extend testing to communities and populations that cannot readily access care.[120] Smartphone apps and other digital tools can aid in both the use and interpretation of results, as well as make results available to public health authorities. Rapid low-cost tests also allow for repeated use, which can be essential for novel pathogens with unknown incubation time, and for essential and frontline workers with multiple potential exposures. In the absence of such diagnostics, testing through a centralized laboratory will only increase the risk of spread by requiring individuals to present themselves publicly (especially in the case of extremely contagious pathogens). Additionally, a longer wait time places too much faith in a person's ability to quarantine for the appropriate duration.[121]

The United States experienced numerous challenges with the development, approval, manufacture, and distribution of new point-of-use diagnostic tests during the COVID-19 pandemic. Without these tests, we rely on centralized laboratory diagnostics that can sometimes take days to return results and initially took weeks, slowing response and the imposition of quarantine measures. Further, public guidance from federal agencies is muddled as to the use and interpretation of point-of-use tests, resulting in reduced test uptake, and preventing the types of public health screening initiatives deployed successfully in other peer countries.

RECOMMENDATION: Invest in point-of-use diagnostics.

The Secretary of Health and Human Services should (1) provide adequate funding to expand NIH RADx public-private partnerships in its annual budget request for the next five years; (2) invest in research and development of rapid point-of-use diagnostics for pathogens with

pandemic potential (in addition to COVID-19); (3) invest in research and development of diagnostics that test for multiple pathogens; (4) invest in research and development of nucleic acid based tests; (5) invest in research and development of rapid point-of-use diagnostic tests using a variety of sample types; and (6) invest in development of proven diagnostic technologies for widespread use against pathogens with pandemic potential.

RECOMMENDATION: Develop a plan for rapid development, approval, scaling, acquisition, procurement, and distribution of point-of-use diagnostic tests.

The Secretary of Health and Human Services should develop a plan to rapidly approve, develop, scale, acquire, procure, and deploy point-of-use diagnostic tests throughout the Nation in response to a biological event. The plan should (1) require the development of rapid point-of-use diagnostics following the initiation of diagnostics that require laboratory confirmation for a novel biological threat; (2) delineate the activities of the NIH RADx Executive Committee, Tech Governance Committee, Tech Working Group, and Underserved Populations Governance Committees[122] in engaging with DOD and the private sector to develop and scale diagnostic capabilities rapidly; (3) describe the processes for quick approval, acquisition, and procurement of rapid point-of-use diagnostics; (4) detail how these committees will rapidly deploy diagnostics across the country; (5) describe the process for making instructions easier to understand and less complicated; and (6) address simplified reporting to public health departments.

Develop a plan for rapid development, approval, scaling, acquisition, procurement, and distribution of point-of-use diagnostic tests.

ESTABLISH DIGITAL PATHOGEN SURVEILLANCE

Digital pathogen surveillance systems, which use internet-based and other electronically available data (e.g., medical bulletins, search queries, social media), have shown some improvement in recent years, including the provision of early warning signs for COVID-19. These systems, which have the potential for near real-time warning ability, international detection, and automated operation, could complement more traditional public health surveillance systems. With access to international airline routes, known disease networks, and anonymized mobility data, to name a few, we can predict the spread of infection and focus on resources and interventions in advance of outbreaks.

Limited access to information, poor integration of public and private data, and failure to bring the best talent and latest innovations to solve the problem of real-time digital surveillance

have limited the capability of extant systems to detect biological events early enough to respond effectively and contain the threat. By leveraging advances in machine learning, and in particular natural language processing,[123] we can continuously track vast amounts of data and filter the noise to provide relevant information to public health experts. This information is useful to prompt further investigation, allocate resources, and inform clinicians and public health authorities about potential pathogens to consider in their routine work.

The federal government should implement a system that monitors biological threats within and outside of US borders. We should leverage data sources (e.g., medical bulletins, livestock reports, satellite data, social media, online forums), in concert with the National Pathogen Surveillance and Forecasting Center ensuring data interoperability. The government should clear obstacles to access necessary data, incentivize innovation in the field through inducement prizes, and fund long-term efforts to continuously update the system with new data and capabilities as they become available.[124]

A few private sector companies have been using these technologies since the beginning of the pandemic.[125] In fact, BlueDot picked up a cluster of cases in Wuhan on December 30 and sent alerts to its customers nine days before the World Health Organization (WHO) alerted the world.[126] More government support and involvement are necessary to advance this technology and expand its availability. The HHS Office of the National Coordinator for Health Information Technology could assist with information sharing efforts,[127] and the Intelligence Community (IC) (e.g., the Office of the Director of National Intelligence Open Source Enterprise) could contribute to and reduce mis- and disinformation that corrupts this information flow with respect to biological threats.[128,129]

RECOMMENDATION: Invest in digital pathogen surveillance.

Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, Secretary of Defense, Secretary of Agriculture, Secretary of the Interior, and Secretary of Veterans Affairs to (1) identify end-user needs for digital pathogen surveillance systems; (2) define clear performance requirements for the private sector; (3) provide incentives for the private sector to advance capabilities; (4) establish public-private partnerships with industry entities that have demonstrated pathogen surveillance capabilities; and (5) strengthen ongoing digital pathogen surveillance efforts throughout the government.

RECOMMENDATION: Improve data interoperability to enhance information sharing.

Congress should amend the Public Health Service Act (P.L. 78 -410) to direct the Secretary of Health and Human Services, Secretary of Defense, Secretary of Agriculture, Secretary of the Interior, and Secretary of Veterans Affairs, in coordination with the Director of National Intelligence, to develop a pathogen data interoperability plan to enhance information sharing among federal departments and agencies, the IC, industry, academia,

and nongovernmental organizations. This plan should (1) describe the structure of an information sharing network among these entities; (2) include data reporting standards to ensure interoperability; (3) consider the potential effects of cyberattacks and mis- and disinformation on these systems; and (4) implement this plan within one year of enactment.

DEVELOP A NATIONAL PUBLIC HEALTH DATA SYSTEM

As past outbreaks and the current pandemic have demonstrated, reliable, accurate, and comprehensive data is necessary for effective decision making during a crisis. Without timely and relevant information, it is not possible to prioritize resources and interventions, coordinate efforts, and respond in a manner the American people deserve. Although it is an enormous undertaking, a National Public Health Data System would provide the capabilities needed to effectively address the spectrum of biological threats.[130] To be successful, the system must be able to efficiently integrate, curate, and analyze data in a timely manner from federal, and SLTT public health agencies.[131]

The Coronavirus Aid, Relief, and Economic Security (CARES) Act provided the CDC with $500 million for public health data modernization and to support system-to-system interoperability and cloud-based centralized repositories. These efforts, while ongoing, will hopefully provide a strong foundation for future efforts to further ensure that data are simple to gather and deposit (while preserving privacy), available in real-time, and secured against cyberattacks. We should design continuous and timely integration of emerging technologies and data streams into the system from the start, with aims of reducing the burden of reporting and keeping outputs from the system simple to interpret and act on.

Our priority should be to establish and sustain a national and integrated public health data capability. With this foundation, we could integrate additional capabilities as they become available or advanced (e.g., digital pathogen surveillance, new streams of clinical and laboratory data, access to electronic health records, anonymized human movement, new visualization capabilities, improved analytics). The government should continue to prioritize public health data and sustain investments in both the maintenance and advancement of the system.[132]

Throughout the pandemic, the lack of a national public health data system to integrate and share information among SLTT and federal entities slowed response and left many communities blind to the spread of disease. It also prevented the establishment of an effective integrated national pathogen surveillance and forecasting capability.

The CDC launched the Data Modernization Initiative in 2020 to (1) strengthen data reporting, management, and analytics across federal and SLTT public health departments and agencies; (2) conduct improved and expanded surveillance of current and future public health threats; (3) help their staff pursue innovation and build state-of-the-art data science skills; (4) deliver guidance the public can trust by integrating nationwide standards for data access and

exchange; (5) bolster systems that link real-time data about emerging health threats; (6) create innovative pandemic-ready solutions for timely and complete data reporting to CDC; and (7) integrate nationwide standards for efficient and secure data access and exchange.[133] Unfortunately, CDC did not start the Initiative before COVID-19 began.

RECOMMENDATION: Establish a National Public Health Data System.

Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense, Secretary of Agriculture, Secretary of Homeland Security, and Secretary of Veterans Affairs, to establish a national public health data system that expands on current data modernization efforts. They should (1) identify all relevant and available federal, SLTT, and private sector data streams; (2) determine and build the federal and SLTT technological capabilities needed to sustain the system over time; (3) ensure ease of data entry by including end-users in the development and beta-testing process; (4) de-identify personal data and protect privacy; (5) compile and integrate relevant data streams no later than two years after enactment; (6) ensure that the System will support timely and transparent access by the public; (7) provide funding and technical support to SLTT to enable them to contribute to this system; and (8) establish the system no later than three years after enactment.

RECOMMENDATION: Integrate data within the National Public Health Data System.

The Secretary of Health and Human Services should develop a plan to integrate data in the National Public Health Data System. The plan should (1) describe how information will flow and how federal, SLTT, academic, and healthcare entities will gather data; and (2) set data reporting and collection standards to ensure interoperability.

RECOMMENDATION: Secure data and ensure data integrity for the National Public Health Data System.

The Secretary of Health and Human Services should, in coordination with the Secretary of Homeland Security, develop a data security and integrity plan for the National Public Health Data System. The plan should (1) describe how HHS and DHS will secure and defend the System against cyberattacks; and (2) address how HHS and DHS will prevent and respond to the introduction of mis- or disinformation into the System.

ESTABLISH A NATIONAL PATHOGEN SURVEILLANCE AND FORECASTING CENTER

An integrated real-time national pathogen surveillance and forecasting center with advanced capabilities to detect and model naturally occurring, accidentally released, and intentionally introduced biological threats does not currently exist. The abilities to identify and forecast threats rapidly is critical at the beginning of an outbreak and the understanding of infectious

disease prevalence, including seasonal pathogens, are essential components of public health planning and response.[134] Aggregating diverse data sources in real-time and forecasting infectious disease outbreaks are necessary to prevent or rein in the spread of biological threats. Improved forecasting through modeling also allows for better projection of the pandemic potential that a threat poses and aids in the prioritization of resources, mobilization of a response, and initiation of countermeasure development and deployment.[135]

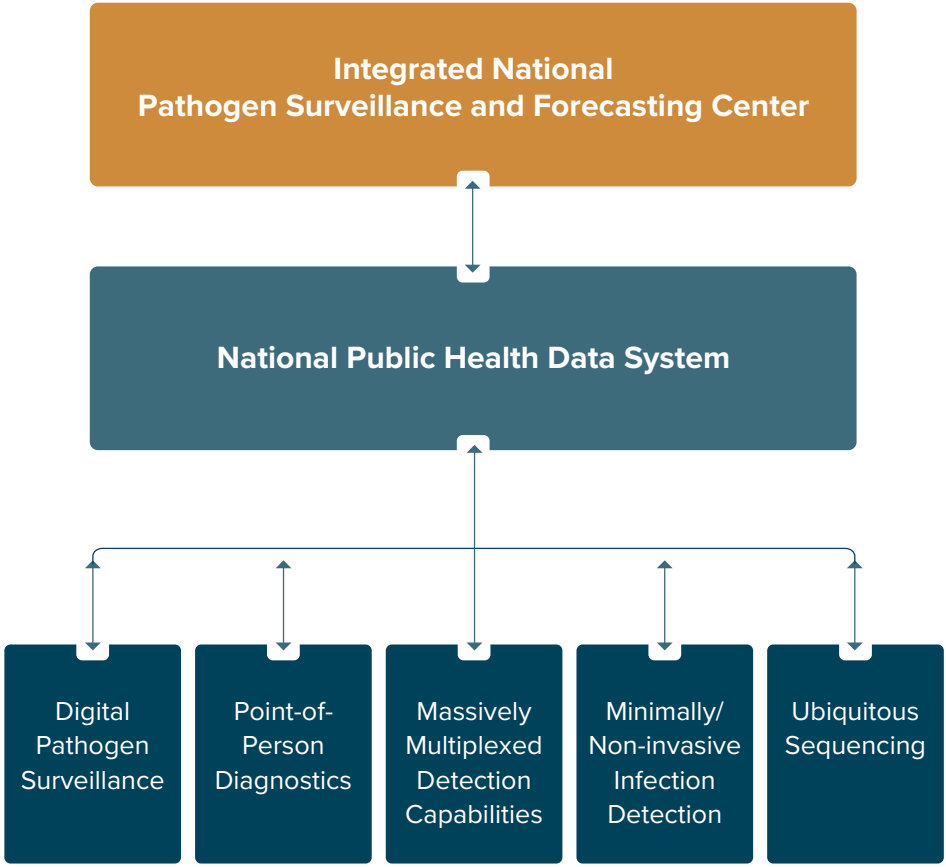
Current infectious disease forecasting capabilities rely on data that are sometimes unavailable for weeks. An assortment of academic groups usually coordinates to create a forecast, but they must be able to gather and analyze data quickly for it to be accurate and useful. The United States should be ahead of the curve, take these threats more seriously, and establish a permanent National Pathogen Surveillance Forecasting Center. This center would maintain forecasting capacity, improve science, and invest resources in the building and maintenance of the best models, pipeline, and community of researchers. Furthermore, the Center should integrate the National Public Health Data System and aggregate information from clinical molecular diagnostics, distributed sentinel surveillance, digital pathogen surveillance, laboratory biosafety monitoring, and animal and environmental pathogen surveillance. This would allow for improved detection of novel biological threats and a better understanding of rapidly evolving outbreaks and attacks.

Effective modeling also requires reliable data and a thorough understanding of pathogen transmission and available public health interventions. Additionally, it is also necessary to have data on historical trends of transmission, population mobility, and individual decisions in response to public health threats.[136] Forecasting success will also depend on the ability to communicate and relay relevant information in an effective manner (e.g., through visualizations or other dashboards) to decision makers. As some have noted, weather forecasting through the National Weather Service successfully takes advantage of, and integrates data from automated weather stations, radar sites, and satellites; maintains archival data; and progressively improves forecasts.

The ability to forecast the trajectory of a pathogen rapidly and reliably is crucial for the United States to address seasonal infectious diseases, and to prepare for and respond to emerging and engineered threats. By establishing a National Pathogen Surveillance and Forecasting Center as a permanent federal institution, the United States could advance these capabilities and ensure future preparedness.[137]

The CDC established the Center for Forecasting and Outbreak Analytics in August of 2021 to inform public health decision making. The American Rescue Plan provided the Center with initial funding to predict outbreaks through modeling and forecasting, expand data sharing and integration, establish standards to maximize data interoperability, and communicate results to stakeholders.[138] DOD, the national laboratories, and the private sector could all assist in the development of accurate forecasting algorithms for the Center to use. The Center would also benefit from the integration of, and access to, data generated throughout the government.

Figure 5. Data collected from relevant Technology Priorities should feed into a National Public Health Data System and used for pathogen surveillance and forecasting.



RECOMMENDATION: Authorize the Center for Forecasting and Outbreak Analytics.

Congress should amend the Public Health Service Act (P.L. 78-410) to authorize the Center for Forecasting and Outbreak Analytics.

RECOMMENDATION: Assess biosurveillance capabilities across the federal government.

Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense, Secretary of Agriculture, and Secretary of Homeland Security, and in collaboration with the national laboratories and the private sector, to (1) assess biosurveillance capabilities and relevant data

streams across the government to incorporate into the Center for Forecasting and Outbreak Analytics; (2) develop effective algorithms that produce accurate forecasts for the Center; (3) request an annual review by the National Laboratories and National Academies of Sciences to help identify problems, challenges, and potential improvements, and provide technical assistance to the federal government; (4) develop an interoperability strategy for integrating data into the Center; and (5) develop plans to ensure data interoperability and integration, provide data security and integrity, prevent and respond to cyberattacks on the Center, and prevent and respond to the introduction of mis- or disinformation into the Center's data streams.

DEVELOP NEXT-GENERATION PERSONAL PROTECTIVE EQUIPMENT

Personal protective equipment (PPE) can be used to protect against a broad-spectrum of biological threats. However, the current state of PPE burdens its users, requires experience in proper usage, is seldomly reusable, is not widely available to all populations, and does not properly fit everyone (e.g., children).[139] Additionally, since the primary goal of PPE is to prevent the wearer from becoming infected, not enough emphasis has been placed on preventing the wearer from infecting others. Shortages of PPE leave frontline and essential workers at risk, threatening their health and reducing their capacity to respond.

The COVID-19 pandemic has highlighted limitations in our knowledge of PPE and exposed an inadequate ability to rapidly scale up production. However, the pandemic has also catalyzed efforts to make PPE reusable, spurred new ideas about respirator designs, seen the advent of personalized PPE, and eventually brought new production capacity to fruition. While these efforts mark advancements, focused research efforts and innovative approaches could achieve much more.

To develop the next generation of PPE, we should make innovations in the following areas: 1) reusable, sterilizable, and self-disinfecting equipment; 2) modular designs responsive to a wide range of threats, including those which go beyond biological threats; 3) personalization to ensure adequate protection, comfort, and attractiveness; 4) rapid production from widely available materials without supply vulnerabilities; 5) the ability to neutralize pathogens; 6) sensing capabilities to detect potential exposures; and 7) protection beyond traditional masks, respirators, gloves, gowns, etc., that safeguard the wearer without burden. The government should invest in and incentivize the development of these PPE innovations through inducement prize challenges, intramural and extramural research and development efforts, advance purchase commitments and consistent acquisition, and use-inspired basic research programs, such as DARPA's Personalized Protective Biosystem effort. Establishing distributed capacity will ensure PPE is available in advance, and maintaining capability will ensure increased production and surge in response to a threat. Additionally, the government should develop standards and metrics for the evaluation of all forms of PPE to quantify capabilities, standardize comparisons, and assess progress.[140]

The government has invested in the research and development of next-generation PPE. For example, NIH invested in the research and development of a smart mask that changes colors when exposed to COVID-19.[141] A team at the NASA Jet Propulsion Laboratory developed a 3D printable Powered Air-Purifying Respirator with custom filters and commercial off-the-shelf components to help provide more PPE during the COVID-19 pandemic,[142] making the design, components, and production guide openly available. NASA also worked with hospitals during the pandemic to develop new methods and technologies for decontaminating PPE.[143] Additionally, the private sector also invests in developing next generation PPE.[144] In fact, many companies participated in the 1448 submissions to the "Mask Innovation Challenge: Building Tomorrow's Mask", led by BARDA DRIVe and the National Institute for Occupational Safety and Health, to develop innovative masks to provide protection from respiratory pathogens such as SARS-CoV-2.[145] However, the government needs to update standards for public use of PPE (e.g., cloth masks) to ensure adequate protection against infectious disease threats.

RECOMMENDATION: Develop next-generation personal protective equipment.

Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense, the Secretary of Labor, and the Administrator of the National Aeronautics and Space Administration, to (1) assess ongoing research and development of next-generation PPE in the public and private sector; (2) provide a funding plan for advancing research and development in the public and private sectors; (3) clearly provide criteria and metrics to the private sector; and (4) develop next generation PPE for use in healthcare settings and against biological threats within one year of enactment.

RECOMMENDATION: Transfer technology for personal protective equipment throughout the federal government.

Congress should amend the Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96–480) (94 Stat. 2311) and the Federal Technology Transfer Act (P.L. 99-502), 15 U.S.C 3710 to direct the Secretary of Defense to establish a technology transfer center to facilitate the sharing of PPE technology with and by other federal departments and agencies, and the private sector.

SUPPRESS PATHOGEN TRANSMISSION IN THE BUILT ENVIRONMENT

Transmission of most known pathogens occurs in human-built environments (e.g., offices, healthcare facilities, schools, public transportation, planes) via air, droplets, and fomites.[146] While we have exerted significant effort to engineer and make the built

environment robust against fires, earthquakes, and other threats, we have put little effort into engineering and making our world robust against pathogens. Suppressing pathogen transmission, especially in high-risk and high-traffic spaces, would reduce the spread of infectious diseases, extinguish some outbreaks, and buy critical time to combat more aggressive pathogens. With permanent incorporation into the environment, we could continuously defend against threats, even prior to detection, and without the dramatic changes in human behavior needed to reduce pathogen transmission.[147]

To reduce the effective transmissibility of most airborne, droplet, vector-borne, and fomite transmitted pathogens, we should make investments in:

- affordable air filtration and sterilization systems
- deliberate design of airflows
- self-sterilizing surfaces
- easily sterilized materials, robust against harsh sterilization
- robotic and autonomous integrated sterilization
- fomite neutralizing technologies
- integrated real-time pathogen sensing capabilities

Conducting pilot studies in select high-risk environments would help to achieve a deeper understanding of how to re-engineer the built environment to reduce pathogen transmission before eventually expanding implementation throughout all population dense environments in the Nation. We should fund research and development efforts to foster a field of study and discover innovative technologies to further advance capabilities. As part of a modernization effort, the federal government should invest in technologies to retrofit current infrastructure, such as HVAC systems and public transport, and incentivize the incorporation of suppression technologies into new production through tax credits and grants, before ultimately incorporating proven aspects into regulation.[148]

During the course of the COVID-19 pandemic, the government has helped strengthen the built environment against pathogen transmission by retrofitting existing, and setting standards for new, infrastructure. For example, several recent stimulus packages provided significant funding to schools to help retrofit their buildings for safe in-person learning during COVID-19,[149] although it is unclear the extent to which these investments were targeted and whether congressional and federal oversight was sufficient.[150] The General Services Administration (GSA)[151] and the DHS Cybersecurity and Infrastructure Security Agency could play a larger role in reducing pathogen transmission in the federal built environment. Further, since the private sector possesses many applicable technologies,[152] the government should establish partnerships with industry and academia for research, development, acquisition, and procurement of technologies.

RECOMMENDATION: Support research on pathogen transmission reduction in built environments.

Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security, Secretary of Education, and Secretary of Transportation to produce a research and development plan for reducing pathogen transmission in built environments, including transportation environments such as vehicles, buses, trains, and planes. The plan should (1) provide an assessment across the federal government and private sector of ongoing technology research and development for reducing pathogen transmission in built environments, including monitoring and detection technologies; (2) include a funding plan for advancing research and development in the federal government and incentivizing the private sector to engage in research and development (including pilot programs); (3) articulate criteria and metrics to measure, monitor, and assess the success of how well certain technologies reduce pathogen transmission in built environments; and (4) include a timeline for implementation within one year of enactment.

RECOMMENDATION: Develop and advance technologies that can reduce pathogen viability and transmission in built environments.

The Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security, the Secretary of Defense, the Secretary of Education, and the Secretary of Transportation should (1) establish a program to develop and refine technologies that reduce pathogen transmission in built environments, including transportation environments such as vehicles, buses, trains, and planes; and (2) develop building code standards that apply these technologies and pathogen reduction best practices. Congress should amend the Public Health Service Act (P.L. 78-410) to require the Secretary to submit a progress and findings report within one year of enactment and annually thereafter.

RECOMMENDATION: Reduce pathogen transmission in built environments.

Congress should amend Homeland Security Act (P.L. 107-296) to (1) require SLTT to update building codes to factor in standards and requirements for reducing pathogen transmission in newly built environments, including transportation environments such as vehicles, buses, trains, and planes, as a requirement for participation in the Homeland Security Grant Programs administered by FEMA; (2) authorize appropriations to retrofit existing GSA and other federally owned and leased facilities to reduce pathogen transmission in the built environment; and (3) establish a federal grant program administered by FEMA to offer assistance to SLTT to reduce pathogen transmission in their built environments.

ESTABLISH COMPREHENSIVE LABORATORY BIOSAFETY AND BIOSECURITY

While high-containment laboratories already have an impressive number of safeguards in place, they could benefit from continuously updated research given the high risks involved. Recent biosafety lapses have included smallpox, anthrax, and contagious strains of influenza.[153,154] Indeed, some believe the 1977 H1N1 pandemic arose from a lab accident or botched vaccination experiment.[155] Additionally, the recent rapid proliferation of pandemic research has implications for dual-use risks and laboratory biosafety.[156]

Our risk tolerance in laboratories worldwide[157] working with biological threats should be comparable to that of air travel, where safety is engineered into the airlines and airports, and monitoring occurs constantly to detect and prevent human-generated and technology-based accidents. A constant focus on and prioritization of safety ensures that the complex and previously risky nature of flight can be undertaken safely.

We continuously innovate automobile safety technologies (e.g., lane departure warnings, blind spot monitoring, pedestrian detection). We should apply a similar approach to laboratory biosafety. This includes the refinement of current capabilities, analogous to advances in airbags for automobiles, to the introduction and rigorous testing of new technologies. Ultimately, we may realize the benefits of high-containment laboratory work while minimizing the risks to the greatest extent possible by developing pathogen monitoring capabilities, improved engineering controls, and risk assessment and analysis tools.[158] While training personnel is essential and the core of biosafety,[159] insider threats should also be more seriously considered, and safeguards put in place to deter and prevent any malicious behavior.

Additional funding is necessary for the study of laboratory accidents and the development and testing of new capabilities and tools to achieve comprehensive laboratory biosafety systems.[160,161] These should be tested in safe environments, continuously incorporated into current high-containment labs, and ultimately integrated into all biosafety labs.[162]

The Department of Labor (i.e., Occupational Safety and Health Administration); HHS (CDC and NIH); United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service; Department of Transportation (DOT); and Department of Commerce (DOC) are primarily responsible for the regulation and oversight of the possession, use, or transfer of infectious agents, toxins, or other biological hazards.[163] Additionally, the NIH National Science Advisory Board for Biosecurity (NSABB) addresses issues related to biosecurity and dual-use research at the request of the United States Government.[164]

The Nation's BSL-4 laboratory operators need to come together in coordination with the CDC to determine how to ensure best safety practices, including greater transparency regarding accidents in these facilities, incentivize accident reporting and data collection, and strengthen laboratory biosafety and biosecurity through policy adjustments and innovative technologies. The increasing risk of a catastrophic accidental release from one of these laboratories means regulators must implement changes now before a disaster occurs. HHS,[165,166] DHS, DOD, and USDA should invest more in research to improve laboratory biosafety and invest more to ensure appropriate facility maintenance, workforce training, and practice oversight.

RECOMMENDATION: Review adequacy of biosafety and biosecurity standards, practices, and oversight to identify gaps, needs, and upgraded approaches.

The Secretary of Health and Human Services, in partnership with the DOD and Department of Energy (DOE), should request the NSABB to assess (1) the potential for innovation in laboratory biosafety; (2) potential outcomes of those innovations; and (3) current goals for next-generation technology in laboratory biosafety. The Secretary should take no longer than 180 days to complete this assessment.

RECOMMENDATION: Address laboratory biosafety and biosecurity challenges.

Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, to conduct an annual review of laboratory biosafety capabilities and challenges. The Secretaries should direct the Director of the Centers for Disease Control and Prevention to (1) conduct this review in coordination with at least one representative from each BSL-4 laboratory in the country; (2) identify potential innovations and policies to improve laboratory biosafety; (3) articulate ongoing challenges in laboratory biosafety, especially with regard to accident prevention, accident reporting, and needed funding for accident detection; and (4) provide goals and milestones for implementing improvements. The Secretary of Health and Human Services should complete the first review within 180 days of enactment.

TECHNOLOGIES TO DETER AND PREVENT BIOLOGICAL ATTACKS

The ability to investigate, analyze evidence, and attribute deliberate biological events is essential for both deterrence and response to a deliberate or accidental threat.[167] As tools are developed and the barriers to engineering pathogens continue to decrease, the number of possible actors may increase. Technologies are required to ensure safety is built in and capabilities developed in advance to prevent and deter action.

Unfortunately, biological attribution, genetic engineering detection, and microbial forensic techniques have only made small strides since the anthrax attacks of 2001. In the two decades since, there have been advancements in machine learning and physical characterization techniques, and artificial intelligence evolved from an "AI winter" to "AI summer." However, we have yet to see these technologies extensively applied, despite recent academic studies and government programs hinting at their impressive capabilities.[168,169] In particular, it should be possible to harness advances in machine learning techniques from several disciplines and apply them to distinguish natural and engineered DNA and to inform attribution. Training these machine learning tools will require access to relevant datasets which we must establish in advance.

Once developed, these capabilities could be broadly deployed and integrated into routine laboratory, clinical, and environmental settings as sentinels monitoring for engineered pathogens, in addition to being available for forensics applications. To advance these techniques, the federal government should make use of its investment capability and inducement prizes, as this would encourage the application of their capabilities developed for other applications to these problems. With additional dedicated funding to research, develop, acquire, and operate such technologies, as well as maintain the relevant repositories, we could establish a robust and known capability to detect, analyze, and attribute biological threats.[170]

The public and private sectors can leverage ongoing research and development to further biological attribution technologies. The Intelligence Advanced Research Projects Activity has seen success developing these technologies through its Functional Genomic and Computational Assessment of Threats (known as Fun GCAT) and Finding Engineering-Linked Indicators (known as FELIX) programs.[171,172] The private sector has successfully used prize competitions to significantly advance biological attribution technologies,[173] and some organizations have provided detailed roadmaps for broad-scale implementation.[174]

While these technologies show great promise, there is no up-to-date guidance or set of requirements for their use. For example, HHS issued guidance (with no requirements) for DNA synthesis providers in 2010.[175] But without a legal requirement saying otherwise, a bad actor can simply order malicious DNA from a company that does not screen their

customers or orders. Some State governments (e.g., in California[176] and Maryland[177]) recently considered establishing requirements for providers. They would require providers to register with either the International Gene Synthesis Consortium (IGSC)[178] or a health department to confirm they meet or exceed IGSC standards. The government should use these state efforts to inform development and implementation of national standards. Ideally, federal agencies would at least require any entity receiving a grant in the life sciences to purchase their synthetic DNA from an IGSC or federally approved vendor.

RECOMMENDATION: Develop and support implementation of a strategy to screen DNA synthesis providers and users.

Congress should amend the National Science and Technology Policy, Organization, and Priorities Act of 1976 (P.L. 94-282) to direct the Director of the Office of Science and Technology Policy to develop an updated screening framework with requirements for providers and users of synthetic biology services that meet or exceed those of the current gene sequence and customer screening best practices. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Commerce, to implement the framework.

RECOMMENDATION: Require entities to purchase genetic material from verified vendors.

Congress should amend the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283), the Public Health Service Act (P.L. 78-410), the Homeland Security Act (Public Law 107-296), the Agriculture Improvement Act of 2018 (P.L. 115-334), and the National Science Foundation Act of 1950 (P.L. 81-507) to require any entity receiving a federal grant or engaging in a cooperative agreement related to synthetic DNA and RNA to purchase their synthetic materials from vendors that follow gene sequence and customer screening best practices to minimize risk and that address gene synthesis screening, customer screening, record keeping, order refusal and reporting, and regulatory compliance.[179]

CONCLUSION

In this Athena Agenda, we have offered recommendations with identified executors to advance The Apollo Program for Biodefense (or its equivalent) and achieve its mission to take pandemic threats off the table within the next 10 years. Now is the time to embark on this mission.

We can choose how we will manage biological risk. Within weeks of recognizing the existence of SARS-CoV-2, scientists mapped its entire genome and proceeded to develop and produce vaccines faster than ever before. They accomplished these previously unimaginable feats because of forward-looking programs, such as the Human Genome Project.

We have the opportunity today to implement in The Apollo Program for Biodefense (or its equivalent) and accomplish a grand mission that will:

- Save millions of lives
- Reduce the risk of hospitalization and disabilities
- Greatly improve and accelerate pharmaceutical manufacturing of breakthrough drugs
- Develop needle-free methods of delivery that decrease vaccine hesitancy
- Identify infectious disease outbreaks and the pathogens that cause them within hours of occurrence
- Test for hundreds of different pathogens with a single diagnostic
- Obtain rapid test results in less than 15 minutes
- Increase non-federal biosurveillance data
- Forecast infectious disease cases and deaths into the future
- Develop air filtration with the ability to reduce biological aerosols almost entirely

In this Athena Agenda, we have offered recommendations with identified executors to advance The Apollo Program for Biodefense (or its equivalent) and achieve its mission to take pandemic threats off the table within the next 10 years. Now is the time to embark on this mission—not only because it will achieve the goal of a pandemic-free world, but also because we can implement many of the components of The Apollo Program for Biodefense immediately to address our shortcomings in combatting the COVID-19 pandemic. Leaders around the world must take a hard look at the past two years and decide if the death and suffering so many people have endured is an experience worth risking again—especially as the biological threat continues to grow. The pandemic revealed our innovative powerhouse. The Apollo Program for Biodefense is unquestionably feasible if America commits to take on this grand challenge for the protection of life and the betterment of humanity.

We are at a turning point and closer to ending pandemics today than many would think. It is time to harness America's ingenuity, optimism, and wealth to achieve victory over biological threats.

APPENDIX A: GAPS AND SHORTCOMINGS IN BIODEFENSE

We are at the mercy of biological threats and associated health, economic, and other devastating consequences if we do not address the glaring gaps and shortcomings that prevent us from defending the nation against biological threats. Biodefense suffers constantly from a lack of adequate time, investment, innovation, capability and capacity, preparedness, quick response ability, data, and governance. If we are to execute The Apollo Program for Biodefense and achieve its mission to eliminate pandemics in 10 years, we must fill these gaps and eliminate these shortcomings.

LACK OF TIME

The development of new vaccines, therapeutics, other medical countermeasures, laboratory diagnostics, and biosurveillance systems takes far too long to enable quick response. For example, even with Operation Warp Speed and previous research into coronavirus vaccines, it still took the public and private sectors almost a year to produce viable vaccine candidates, and that timeframe was considered quick (as compared to vaccine development in non-crisis situations). While we take the time to develop and implement needed response measures, humans, animals, and plants fall ill and die.

LACK OF INVESTMENT

Having under-invested before biological events occur, we cannot respond quickly when these events arise. We also spend more money in the push to get what we need to contain the spread and impact of diseases than we would have had we paid in advance. Without sufficient investment, scientific efforts languish, promising programs grind to a halt, and technology advances slowly. Time and time again, we look back belatedly and bemoan our lack of consistent, committed investment. The short-term investments made in developing a vaccine for SARS (caused by SARS-CoV-1) and the decision to cease investing in these efforts before producing a vaccine certainly came back to haunt us during COVID-19.

LACK OF INNOVATION

While the United States values scientific breakthroughs and innovative technologies, we choose to rely on current options and justify purchasing them to bolster our preparedness without allowing for the possibility of better, more useful technologies over time. This problem is not unique to the biological arena. For example, despite innovations in communications technology production of fiber optic cables that could run underground, FEMA chose repeatedly to purchase poles and wire to replace telephone systems destroyed when hurricanes hit Hawaii. They did so because contracts to purchase them were already in place and the Agency knew that it could quickly reestablish communications by doing so.[180] It was not until Hawaii declined this federal support entirely that FEMA issued contracts for fiber optic cables to replace the antiquated system. Similarly, the world depends on archaic egg-based vaccines for the same reasons. Innovations are needed in science, technology, and bureaucracy.

LACK OF CAPABILITY AND CAPACITY

During non-emergency situations, current capabilities and capacities meet most needs and are rarely overwhelmed by ordinary events. However, those same capabilities and capacities proved inadequate during the responses to even small-scale biological incidents. The inability to scale up and expand manufacturing and other activities further exacerbates this problem.

LACK OF PREPAREDNESS

Preparedness costs money and is often viewed as an unnecessary expense in the absence of events requiring response. Yet when these events inevitably occur, the cost to respond is inversely proportional to investments in preparedness. From a business perspective (including the business of government), it makes sense to spend less overall by investing in preparedness–but only if we believe that events will occur that require responses. If we believe these events will not occur or occur so seldomly that someone else will respond, we will not invest in preparedness. National policy revolves around perceptions. Since we believe other nations may attack us, we support military preparedness activities and requirements. But even the military loses resources when times goes by without incident or attack. Similarly, support for public health drops to abysmally low levels because the profession successfully eliminates and controls so many diseases, injuries, and harmful behaviors that the public and funders no longer believe they will re-emerge or even continue to exist.

LACK OF QUICK RESPONSE CAPABILITY

For years, our country prided itself on its ability to respond to health crises. We still value this capability so much so that we optimize daily response activities (e.g., those undertaken by hospital emergency departments) at the expense of others (e.g., preventive screening). Without prevention, deterrence, surveillance, and detection, biological events affecting national security prove that the Nation is not able to respond quickly and that our initial response efforts are inadequate to meet the need. Large-scale events are particularly challenging. We need medical countermeasures, diagnostic tests, and data analysis immediately, but can rarely produce them quickly. Rapid response requires prior investment, preparedness, and implementation of mitigation efforts. It should come as no surprise that we cannot respond swiftly to biological events without prior investments in preparedness—but nevertheless, we are always surprised.

LACK OF ADEQUATE DATA

As with the Industrial Age, the Information Age emphasizes production (in this case, of data and information). Unfortunately, data quality varies radically, with even high- and low-quality data virtually indiscernible. Access to data also varies, so existing data may be inaccessible. Health care data and public health data systems are disjointed and usually unable to share information. These data-related issues prevent rapid alerts, accurate disease forecasts, understanding where and how epidemics grow into outbreaks (and by extension, epidemics and pandemics), and whether efforts to contain the spread of diseases are successful. Data and data-related inadequacies also impede surveillance and detection efforts.

LACK OF GOVERNANCE

For many years, it was considered either too difficult to address the biological threat, not a priority, or unnecessary to address separately from the chemical threat. High-level White House interest declined precipitously after President Richard Nixon shut down the US offensive biological weapons program in 1976. However, the biological threat never fully escaped White House attention. All presidential administrations since the Wilson Administration have dedicated at least a few staff to addressing pandemic influenza and biological weapons. Similarly, Congress has consistently paid some attention over the years, increasing and decreasing the number of congressional committees addressing the threat as biological events occurred and subsided. Regardless of the threat or severity of the threat, Congress and the White House continue to rush to overcome policy shortcomings and limited funding to help the United States respond when biological events occur. Our protracted experience in addressing COVID-19 proves this point. Without comprehensive governance adeptly knitting together the miscellaneous activities undertaken by all Cabinet agencies, eight independent agencies, and one independent institution, as well those executed by non-federal governments, academia, industry, and nongovernmental organizations, these weaknesses in biodefense will remain. It is only a matter of time before naturally occurring, accidentally released, or intentionally introduced pathogens and biological agents take advantage of these gaps and shortcomings and exploit the vulnerabilities they create.

CONCLUSION

We can meet and defeat the biological threat by embarking on The Apollo Program for Biodefense with its Athena Agenda. We have accomplished other grand projects in the past. By incorporating the success factors of previous impactful programs listed in Appendix B, we can ensure success.

APPENDIX B: HISTORICAL GRAND PROJECTS

Previously accomplished grand projects successfully accomplished their goals and objectives. We can learn from the factors that made them successful and apply them to The Apollo Program for Biodefense as well. A clearly defined mission, priorities, and goals serve as the foundation of any grand project. Strong leadership and support from the White House and Congress have also been essential to spur needed innovative research and development in the public and private sectors. Additionally, military involvement in, and international collaboration on, grand projects have been common success factors in the past. **From the Panama Canal in 1914 to Operation Warp Speed in 2021, the following factors led to the success of many grand projects:**

- **Clear mission, priorities, and goals**
- **White House leadership**
- **Congressional appropriations and support**
- **Innovative research and development**
- **Public-private partnerships**
- **Military involvement**
- **International collaboration**

Figure 6. Grand programs and the factors that led to their success.

1902–1914:
Panama Canal

Western powers have contemplated passage through the Panama Isthmus since the 16th century. For many years, American legislators considered whether to pursue a new project in Nicaragua or resume French efforts in Panama. Congress eventually put this debate to rest when it enacted the Spooner Act of 1902 (also referred to as the Panama Canal Act, 32 Stat. 481). President Theodore Roosevelt supported Panama's separation from Colombia and dealt directly with the Panamanian government since the Colombians rejected America's proposed financial terms for the project.

Top Priority:
To facilitate trade and expedite military travel between the Atlantic and Pacific Oceans

Budget:
$350–400 million (~$11 billion today)

Elements of Success:

- Clearly articulated mission, priorities, and goals
- White House leadership
- Congressional appropriations and support
- Military involvement and management
- Congressional funding
- Innovative research and development
- Private sector involvement
- Military involvement
- Understanding the failures of the French campaign
- Innovative architectural ideas
- Partnership with the Panamanian government

Continued

1941–1947:
Manhattan Project

This project enabled the United States to build a nuclear weapon and effectively determine the outcome of World War II. Furthermore, the existence of the bomb itself established the United States as the world's first superpower.

Top Priority:
To ensure the national security of the United States

Budget:
$2 billion (~$23 billion today)

Elements of Success:

- Clearly articulated mission, priorities, and goals
- White House leadership
- Congressional appropriations and support
- Innovative research and development
- Private sector involvement
- Military involvement
- Research contributions from the United Kingdom and Canada
- Wartime economy
- Access to natural resources in the United States

Continued

1956–1992:
National Highway System

The need for an interstate highway system reemerged after World War II and culminated in the National Interstate and Defense Highway Act of 1956 (also known as the National Interstate Act, P.L. 84-627). The American public supported President Dwight D. Eisenhower's plans for the system because they understood that efficient transportation was essential to their national defense and interstate commerce. Competent leadership established standardized features (e.g., use of odd numbers for north-south and even numbers for east-west interstates, uniform color scheme for signs, strategically placed access points).

Top Priority:
To prepare for a war fought on domestic soil

Budget:
$114 billion (~$500 billion today)

Elements of Success:

- Clearly articulated mission, priorities, and goals
- White House leadership
- Congressional appropriations and support
- Innovative research and development
- Private sector involvement
- Military involvement
- Clear and easy to understand standards
- Federal funding (as opposed to the previous system that relied heavily on state funds)
- Access to important natural resources
- Availability of models used by other countries

Continued

1961–1972:
Lunar Apollo Program

The Lunar Apollo Program was established to compete against the Former Soviet Union's progress in space. It is often assumed that the Apollo missions received a greenlight because Soviets had successfully launched Sputnik into space. While this certainly played a role in convincing Congress, President John F. Kennedy's self-perceived failure in the Bay of Pigs invasion combined with NASA's lack of progress prior to the Vostok I launch actually prompted executive approval. Kennedy later remarked that a US space program would be the "highest kind of national priority," thereby shifting attention from the Cold War in Latin America to the unlimited potential of space.

Top Priority:
To land on the Moon ahead of the Former Soviet Union

Budget:
$28 billion (~$280 billion today)

- Elements of Success:
- Clearly articulated mission, priorities, and goals
- White House leadership
- Congressional appropriations and support
- Innovative research and development
- Private sector involvement
- Military involvement
- Strong central leadership
- Engineering capabilities in the private sector
- Competition with the Former Soviet Union

Continued

1967–1979:
Smallpox Eradication

This program called for an international effort, and as such, the United States played an important leadership role by donating vaccines and appointing its own epidemiologists like Dr. Donald A. (D.A.) Henderson to positions of authority within the WHO. Accordingly, the last confirmed case of smallpox occurred in 1978 in the United Kingdom, the result of a laboratory accident.

Top Priority:
To eradicate smallpox

Budget:
$300 million (~$1.15 billion today)

Elements of Success:

- Clearly articulated mission, priorities, and goals
- White House leadership
- Congressional appropriations and support
- Innovative research and development
- Private sector involvement
- Military involvement
- International cooperation (with no resistance from countries in which smallpox was endemic on grounds of sovereignty)
- Decades of research

Continued

1973–2000:
Global Positioning System

The creation of our Global Positioning System (GPS) was a national security project that began in response to the Former Soviet Union's Sputnik launch. American scientists quickly deduced that they could pinpoint where a satellite was in orbit using the Doppler effect. Afterward, the US began testing inverse applications of that theory. The initial GPS technology served as the cornerstone for nuclear deterrence policy and as an offensive measure.

Top Priority:
To identify the location of enemy ships, aircrafts, and personnel

Budget:
$12 billion for initial construction; $2 million a day for maintenance (~$23 billion today)

Elements of Success:

- Clearly articulated mission, priorities, and goals
- White House leadership
- Congressional appropriations and support
- Innovative research and development
- Private sector involvement
- Military involvement
- Previous technological advancements
- Competition with the Former Soviet Union

Continued

1983–1998:
International Space Station

At a meeting on December 1, 1983, to discuss commerce and trade, NSC staffer Gil Rye and political strategist Craig L. Fuller stressed the benefits that the International Space Station (ISS) could bring to the US economy, specifically with regards to private sector growth. The primary goal of ISS research was to understand the effects of space on the human body and find solutions for extended space travel. In pursuing this research, NASA also discovered innovations that had everyday applications on Earth (e.g., scratch-resistant lenses, rubber molding used in shoes, polymer fabric used in firefighter suits, computer mouses, improvements to Lasik eye surgery).

Top Priority:
To develop a scientific laboratory, manufacturing and maintenance facility, and potential staging base for future space travel to the Moon, Mars, and other remote parts of the solar system

Budget:
$150 billion (~$255 billion today)

Elements of Success:

- Clearly articulated mission, priorities, and goals
- White House leadership
- Congressional appropriations and support
- Innovative research and development
- Private sector involvement
- Military involvement
- Academic involvement
- International collaboration

Continued

1990–2003:
Human Genome Project

The Human Genome Project (HGP) was a purely scientific endeavor that eventually yielded benefits for molecular medicine, mutation identification, and forensic science, as well as improved understanding of human evolution. Progress in forensic science expedited the identification of dangerous criminals. Private sector involvement also played a key role.

Top Priority:
To identify the base pairs that make up human DNA of its own volition

Budget:
$3 billion (~$6.1 billion today)

Elements of Success:

- Clearly articulated mission, priorities, and goals
- White House leadership
- Congressional appropriations and support
- Innovative research and development
- Private sector involvement
- International scientific and financial contributions

Continued

2020–2021:
Operation Warp Speed

For this project, the government partnered with the private sector to develop, approve, and distribute COVID-19 vaccines at an unprecedented pace. The decision to engage in this effort was due to the public health emergency created by COVID-19. National leadership mobilized as many resources as possible in an effort to create a vaccine.

Top Priority:
To develop vaccines for COVID-19

Budget:
$12.4 billion

Elements of Success:

- Clearly articulated mission, priorities, and goals
- White House leadership
- Congressional appropriations and support
- Innovative research and development
- Public-private partnerships
- Military involvement
- International collaboration
- Reduced bureaucracy that would otherwise slow down research

For more than 100 years, these success factors have been common to nearly every grand program or project undertaken by the United States. The Apollo Program for Biodefense will have the best opportunity to succeed if it incorporates these elements. The Program will require a clear mission with set priorities and milestones for achieving goals. Success will also require White House leadership and adequate, sustained funding from Congress. Public-private partnerships will be necessary to harness innovative technology developments and bring them to fruition. As demonstrated with Operation Warp Speed, the Program will also need military involvement to provide logistics and support. Finally, success will require international collaboration because biological threats do not respect borders. History repeatedly demonstrates that if we incorporate these factors, we can successfully accomplish previously unimaginable feats.

The following sections provide insight into the personal and political triggers that drove important decisions and mistakes made during the execution of these projects.

NATIONAL PRIORITIES

Grand historical projects in the United States are justified consistently on the grounds of three distinct priorities: (1) national security, (2) the economy, and (3) public health or science. This order is hierarchical and supported by the frequency, funding, and time allocated by the government. Additionally, these factors are widely articulated in the legislative records, administrative correspondences, and biographies of leading political figures.

The President of the United States has a direct line to the American people, and as such, can influence legislative decisions by galvanizing society at large. Alternatively, in the absence of Congressional approval, there may enough federal funding available at the President's discretion to implement at least some recommendations from The Apollo Program for Biodefense by extension, Cabinet members and those in charge of federal departments and agencies also have tremendous influence.[181]

Support can also be acquired by emphasizing unforeseen or lesser-known outcomes that might occur because of residual effects from grand projects. Take for instance construction of the Panama Canal. At face value, connecting the Atlantic and Pacific oceans had predictable upsides for international trade. However, when the Canal underwent expansions in 2016, this set a new design standard for cargo ships (respectively called the Neo-Panamax) and forced US cities to make architectural changes to their ports, thus leading to the creation of trans-shipment hubs and a new multi-billion-dollar industry; all of which were not predictable at the time the decision to expand was made.[182,183,184]

The United States has benefited from NASA's research on the ISS in a variety of unanticipated ways. The primary goal of ISS research was to understand the effects of space on the human body and find solutions for extended space travel; but in doing so, NASA discovered innovations that had an application in everyday life. Among these discoveries include the development of scratch-resistant lenses, rubber molding used in athletic sneakers, polymer fabric used in firefighter suits, computer mouses, and improvements to Lasik eye surgery.[185,186]

First and foremost, The Apollo Program for Biodefense addresses significant and immediate national security concerns. Wars are a cyclical trend in the modern world and can manifest as all-out conflicts, proxy wars, or even decisions on economic policy. Given that peace is elusive to those with an interest in the affairs of others, the United States has not been an exception to this rule since its emergence as a superpower, whereupon it fully embraced interventionist policies. Nevertheless, with every conflict, the opportunity for drastic, if not radical change, always presents itself. National security is a topic that will never go away; it is etched into the forefront of every policymaker's mind regardless of party allegiance.

For over a century, national security concerns have dictated American political discourse. Under President Woodrow Wilson, the United States abandoned its long-held isolationist views to become a major player in global affairs. Following the next three decades of turmoil, which featured both world wars and growing anti-colonial sentiments in developing countries, traditional Western powers like the United Kingdom, France, and Germany, could no longer vie for superpower status, and as a result, only the United States and Soviet Union remained as contenders. In turn, this set the stage for the Cold War that would dominate US policy for the next 50 years.

As such, many of the grand historical projects implemented were rationalized by a need to contain Soviet influence in the developing world. For example, despite appearing as largely scientific endeavors, both the ISS and original Apollo Program were conceived as countermeasures to the Soviet Union's progress. With respect to Apollo, it is often assumed that the mission received a greenlight because Soviets had successfully launched Sputnik into space. While this certainly played a role in convincing Congress, it was not the proverbial straw that broke the White House's back. Ultimately, it was President John F. Kennedy's self-perceived failure in the Bay of Pigs invasion combined with NASA's lack of progress prior to the Vostok I launch that prompted executive action.[187,188] Kennedy later remarked that a US space program would be the "highest kind of national priority," thereby shifting attention in the Cold War from Latin America to the unlimited potential of space.

In contrast, US research in space is conducted from the ISS. At the time of its conception in 1984, the ISS was intended for exclusive use by the United States, to strengthen US military prowess, and promote economic growth. A year earlier, Reagan had also introduced plans for the Strategic Defense Initiative, a missile defense system that could shoot down

intercontinental ballistic missiles from space, thereby eliminating the threat of nuclear war for good. Both ultimately failed and plans to build the space station evolved into an international project between five independent agencies, which ironically included the reformed Soviet Union state of Russia and excluded China.

Current tensions between the US and China are reaching new heights.[189,190] As a result, China portrayed themselves to the world as a leader in global health, which in turn has major implications for our national security.

For nearly 50 years, decisions regarding US activity in space were motivated by fears that the Soviet Union would exceed American technological capabilities or perceived by the rest of the world as such. The same logic should apply to our present need for a robust and thorough biodefense program. The purpose of The Apollo Program for Biodefense is not to encourage an arms race, but rather keep Americans, and by extension the rest of humanity, safe from future pandemics. Given our understanding of the original Apollo mission and construction of the ISS, The Apollo Program for Biodefense should succeed as a national security measure not only by protecting the US against biological threats, but also by rebuilding American status in the international community as a nation that can keep its own people safe.

In addition to the space program, the United States also enacted two other large national security projects during the Cold War era: construction of the national highway system between 1956 and 1992, and creation of GPS technology in 1973. Under President Dwight D. Eisenhower, the nation took significant strides to improve domestic infrastructure as a means for ensuring the US military could navigate within America if attacked.[191,192]

The creation of our GPS was also a national security program that began in response to the Soviet Union's Sputnik launch. American scientists discovered that they could pinpoint where a satellite was in orbit using the Doppler effect. Shortly thereafter, the US began testing inverse applications of that capability to develop GPS. The initial GPS technology served dual functions: first, as a cornerstone for nuclear deterrence policy, and second, as an offensive measure to identify the location of enemy ships, aircrafts and perhaps, even individual soldiers.[193] These priorities changed in 1983 when a Soviet interceptor shot down a Korean passenger jet that had strayed from its intended route and into prohibited airspace. With an understanding that GPS could have prevented this incident, the Reagan Administration made it available for civilian use with the caveat that they would jam some signals to preserve US military tactical advantages.[194,195]

Furthermore, the American tradition of promptly responding to national security threats by authorizing grand projects dates to before the Cold War, as exemplified by the Manhattan Project. President Franklin D. Roosevelt's decision to begin work on a nuclear weapon was motivated primarily out of fear that Germany would have a decisive advantage in World War II and thus, consolidate its control over all of Europe. At the time, the United States took a

neutral position in the conflict; but secretly, it had begun preparing for a number of different outcomes. Ultimately, the Manhattan Project was a success and it resulted in the creation of the world's first atomic bomb. This in turn secured Allied victory in World War II by forcing Japan to surrender after the bombings of Hiroshima and Nagasaki. Likewise, The Apollo Program for Biodefense can pacify risks posed by biological threats through deterrence by denial,[196] which transcends beyond the capabilities of rival nations, terrorist networks, and specific individuals, to nature itself.

The Apollo Program for Biodefense would yield unprecedented economic benefits that ensure a healthy, functioning labor force, have the potential to create jobs, and protect the current and future integrity of the US economy. After national security, the economy reigns supreme on the extensive list of national priorities. People typically vote based on how their bottom line is affected; namely factors spanning from taxes and employment to quality of life and access to resources. As such, most grand historical projects had significant economic implications. Projects like the national highway system and GPS, while decided on the grounds of national security, both had foreseeable and unforeseeable economic benefits. Additionally, public health programs have an inherent effect on the economy because the most valuable resource in any nation is the health and well-being of its citizens and workforce. Since the United States is currently recovering from a recession that spurred on by COVID-19, many Americans are eager to see improvements to the economy.

Despite the Panama Canal finalizing construction efforts just days before the start of World War I and allowing US naval forces to support war efforts in both the Pacific and Atlantic theaters during World War II, this grand project was primarily driven by the desire to facilitate international trade. Its origin dates back as early as the 16th century when several European nations contemplated undertaking construction efforts on the Panamanian isthmus. Americans were sold on the idea as early as 1788, when Thomas Jefferson approached Spain to build a canal in one of its colonies. However, it wasn't until 1902 that the US finally embarked on its mission to construct a canal after taking the reins from France who had previously spent 13 years trying to build one.[197,198]

The Panama Canal remains one of the only historical grand projects primarily advanced as an economic policy. The ideologies surrounding western expansion, combined with the Industrial Revolution and rise of US global influence, resulted in concerns over the speed of international trade. By constructing the Canal, the US not only eased burdens on the shipping industry for itself, but it also inherited a way to generate profit from foreign countries. Though France had failed miserably in its campaign—which left over 22,000 workers dead and $280 million wasted—the United States remained undeterred and pressed onward, all for the sake of economic growth. To that end, Americans lent support to Panamanian independence from Nicaragua in exchange for the opportunity to construct and operate a canal on their soil.[199,200,201]

Many of the efforts that were conceived for national security reasons also had economic implications. Both Apollo and the ISS led to the creation of new technologies for use in everyday life and provided private sector opportunities for engineering companies like Boeing. The Manhattan Project, which was established strictly as a war effort, created jobs for nearly 120,000 Americans at a time when overall employment was low. And as previously touched upon, the national highway system and creation of GPS yielded exponential benefits for domestic travel, which ultimately led to a wider range of job opportunities and market spending for the public.

In addition to causing a recession, COVID-19 has completely altered conventional aspects of the US economy by unveiling which jobs or industries are expendable, disrupting the flow of education, exacerbating the spread of dis- and misinformation, and creating a work from home environment. Future pandemics have the potential to collapse national economies in their entirety.

The Apollo Program for Biodefense has the public health benefit of imbuing the United States with the capability to prevent future pandemics and eliminate catastrophic biological threats to humanity's long-term survival. Public health is an important priority for the government as exemplified by the eradication of smallpox during the 1970s following a global vaccination campaign led by WHO. The program called for an international effort, and as such, the United States played an important leadership role by donating vaccines and appointing its own epidemiologists like Donald Henderson to positions of authority within WHO.[202] Accordingly, the last confirmed case of smallpox was recorded in 1978 in the United Kingdom, resulting from a lab accident.[203] Unfortunately, since both the United States and the Soviet Union continue to have access to smallpox samples, it still poses a viable threat to society. Furthermore, advancements in biotechnology now allow individuals with the proper knowledge to replicate smallpox in laboratories.

In 1990, the United States initiated the HGP with the primary goal of determining the base pairs that make up human DNA. Originally planned by the Reagan Administration, the HGP was a purely scientific endeavor that eventually yielded benefits for molecular medicine, identifying mutations, forensic science, and understanding human evolution. Additionally, progress in forensic science had national security implications by expediting the discovery and interception of individuals who pose a danger to the public.[204]

Lastly, and most recently, the Trump Administration enacted Operation Warp Speed to develop vaccines for COVID-19. This project enabled the government to partner with the private sector to develop, approve, and distribute COVID-19 vaccines at an unprecedented pace. Ultimately, this decision was a public health necessity made in response to the enormous impact of COVID-19. At the time of its approval, the United States was on track to reach 100,000 deaths, which would have been more than the total number of war-related deaths since 1975.[205,206] This may sound relatively inconsequential today, given that we have already exceeded a death toll of about one million people.

Economic factors played a role in this decision as well. During the second fiscal quarter of 2020, GDP growth in the US fell by an astounding 31.4%, while unemployment rose to its highest rate since World War II at roughly 14.7%.[207] For the Americans who continued to have jobs, millions were still placed on furlough, and several signature industries of the US economy like leisure, service, and travel were left in complete disarray.

The government initiated the eradication of smallpox and Operation Warp Speed because allowing hundreds of thousands of people to die would have been politically disastrous and ethically wrong. Failing to implement proactive measures that can prevent future pandemics is likewise immoral. The further we move away from 2020, the less urgency we have on our side. Even though smallpox did not suddenly spike in the 1970s, US foreign policy still gravitated towards more involvement with other countries, and as such, the necessity to address the disease began to mount in the minds of our national leaders. Overall, these examples set a precedent for enacting ambitious, large-scale science and public health programs.

LOGISTICAL MANAGEMENT

Success depends on consistent leadership and adequate funding ensured over a lengthy period. Adequate funding over a lengthy period has played a vital role in the success of nearly every grand historical project. Funding approved by Congress and earmarked for specific projects provides buffer room for experimentation and error in the early stages of a project, which often proves vital in the long run. On the other hand, funds that are available for the President to use at his or her discretion can run afoul of several issues like limited time for research and preparation, opinion shifts within an administration, or even complete administration changes after a new election cycle.

When Congress approved the national highway system, they restructured funding through the National Interstate Act that directed the government to pay 90% of the costs of construction. Prior to this, states were responsible for 50%, a percentage many opined to be unfair and in violation of the federalist principles long held within the United States. As a result, the government was able to commandeer interstate resources and labor at an expeditious rate, which ultimately led to the domestic travel system we enjoy today.[208] Furthermore, the government continues to maintain and repair national highways with funding appropriated by Congress.

Similarly, the creation and maintenance of the GPS system requires a continuous stream of funding. The initial construction cost of GPS satellites is estimated around $12 billion and US taxpayers continue to spend approximately $2 million a day for maintenance. These expenses are justified by the widespread use and application of GPS in everyday life.

On the other hand, original plans for a space station exemplify what happens when funding is not secured over an extended period of time. The US initially sought to control

a space station exclusively. However, after Congress refused to front a larger bill, the Clinton Administration had to salvage plans by striking a deal with outside space agencies, thereby splitting ownership and control over the station. The ISS has since been operated concurrently by five distinct space agencies that collectively represent fifteen nations: NASA (United States), Roscosmos (Russia), JAX (Japan), CSA (Canada), and ESA (Europe).[209] Although these agreements secured the requisite funding and ultimately provided the United States with the ability to regularly conduct science experiments from space, they also restrict Americans from being able to prevent outside access and fulfill clandestine objectives, which were certainly among the original priorities for having a station in the first place.

While implementing The Apollo Program for Biodefense, the Executive Branch should seek out international partnerships and incentivize the private sector to play a role in advancing technology. As previously touched upon with the ISS, international partnerships can prove effective when there is lack of Congressional support at home. However, it is more ideal for the United States to retain its independence and seek out partnerships that result in the sharing of ideas rather than in equal control over projects. The best example of this occurred during construction of the Panama Canal. Under the French campaign that lasted from 1881 to 1894, operations were directed at the helm of Ferdinand de Lesseps who had previously found success in constructing the Suez Canal.[210] However, de Lesseps severely underestimated weather conditions in Panama and dismissed alternative design proposals like those suggested by Philippe Bunau-Varilla.[211] Ultimately, this contributed to France's failure, of which American leaders subsequently acknowledged and took precautions to avoid repeating the same mistakes. Unlike de Lesseps, American military leaders who oversaw construction embraced the novel ideas set forth by Bunau-Varilla and were able to succeed.[212]

In addition to seeking out international partners, collaborating with the private sector can boost innovation, as shown by Operation Warp Speed. In 2020, the government successfully incentivized participation from private companies to develop a COVID-19 vaccine. This directly led to the creation of Moderna's vaccine, as they were one of eight private corporations who received funding.

Similarly, NASA now contracts with private companies like SpaceX, who in recent years has sent new modules and improvements to the ISS, as the trend of private exploration continues to rise.[213] Private sector involvement also played a key role during the HGP. A private company was able to capitalize on the data made available by the project and apply for patents on thousands of genes. Additionally, projects like the Brain Research through Advancing Innovative Neurotechnologies (known as BRAIN) Initiative, the National Nanotechnology Initiative, and the Advanced Research Projects Agency Network (known as ARPANET) that created a technological foundation for the internet, all relied on executive funding provided to private research institutions and companies to achieve their intended goals.

CONCLUSION

Historical grand projects give us an understanding of how national priorities are consistently determined. The best course for implementing The Apollo Program for Biodefense begins with the Executive Branch because the President can speak directly to the people and inspire a collective call to action. History also reveals that larger programs tend to carry a number of unpredictable positive residual effects. Furthermore, grand historical projects provide lessons on how The Apollo Program for Biodefense can be effectively implemented. This includes securing Congressional funding for an extended period because discretionary funds available to the Executive Branch can run afoul of rapid priority changes.

The Apollo Program for Biodefense will take several years to fully blossom, and some technologies and capabilities will take more time to develop than others. However, implementing these recommendations should be the highest priority given our current experience with the COVID-19 pandemic. US leaders should seek out international partners and induce competition in the private sector to ensure that we consider all possible alternatives and expedite the rate of innovation.

In conclusion, The Apollo Program for Biodefense requires an all-hands-on-deck approach to effectively address the national security, economic, and public health issues looming over current US biodefense policy or lack thereof. We have an opportunity to change the course of history and enact measures to prevent the occurrence of future pandemics. There is no greater calling than to ensure the survival of our species.

History also reveals that larger programs tend to carry a number of unpredictable positive residual effects.

APPENDIX C: METHODOLOGY

The Bipartisan Commission on Biodefense was established in 2014 to inform US biodefense and provide recommendations for change. The Commission, supported by academia, foundations, and industry, determines where the United States falls short in addressing bioterrorism, biological warfare, and emerging and reemerging infectious diseases.

RESEARCH QUESTIONS

To develop The Apollo Program for Biodefense, we developed the following research questions.

Technology Priorities and Needed Capabilities

- What should be the top priorities for an Apollo Program for Biodefense?
- Are investments in the development of technologies commensurate with the challenge of biodefense?
- Is new funding required?
- What should we be doing that we are not already doing to address biological threats more adequately with technology?
- How will the biological threat landscape evolve over the next decade and what technologies are needed to ensure preparedness?
- How can the public and private sectors contribute to an Apollo Program for Biodefense?
- How can we be sure that new technologies for biodefense have limited dual-use potential?

- How will technological convergence shape the biological threat landscape moving forward? What should be taken into consideration?
- What sorts of policy initiatives could drive technological innovation for biodefense on the scale of an Apollo program?

Historical Grand Projects: Aspects of Successful Models

- How did national leadership decide on the top priority for each of these programs?
- What elements of the constructs for these programs made them successful?
- What high-impact outcomes resulted and how were they connected to these elements?
- How did industry, academia, the military, and civilian government work together to form alliances and other public-private partnerships for overall program success?
- What roles did the Administration, White House staff, and Congress play in leadership, management, administration, communication, authorization, and appropriations?
- How were scientists identified, chosen, recruited, and included in these programs?
- How did the military lead, participate in, or otherwise engage in these programs?
- How did these programs contribute to or affect national security?

How These Aspects Could be Applied to an Apollo Program for Biodefense

- What should be the top priority for this Program?
- Should the top or first priority for the Program be the development and production of a universal influenza vaccine?
- What should be the elements of a new construct for biodefense?
- What specific extremely high-impact outcomes could result?
- How can the government, academia, and corporate America contribute?
- How best should the Administration lead this Program? What specific actions should the White House take to bring the program to fruition?
- How best should Congress support this Program? What specific actions should Congress take to bring the project to fruition?
- Which leading scientists should play a significant role in the Program?
- What role should the military play in leading, coordinating, or managing this Program?
- What are the implications of the Program for national security?

PRELIMINARY RESEARCH

The Commission reviewed previous research efforts; scientific studies; previous US government research and development programs; and federal strategies, plans, funding, and research and development programs related to defense against naturally occurring, accidentally released, and intentionally introduced biological threats and catastrophic biological risks. This review allowed for an assessment of the comprehensiveness and effectiveness of research and development efforts for biodefense; and determined direction for an Apollo Program for Biodefense. This review also informed the structure and topics of a formal meeting of the Commission, and interviews and roundtables with subject matter and government experts.

FORMAL MEETINGS

During three formal meetings to address and inform a grand project for biodefense, Commissioners, ex officio members, and staff received (1) information regarding current relevant national policy, legislative issues, and departmental and agency programmatic activities; and (2) statements from current and former Members of Congress, current and former federal officials, state, and local representatives, thought leaders, and subject matter experts. Commission staff summarized the major insights, areas for improvement, and recommendations articulated by meeting speakers, and conducted preliminary high-level analysis of each day-long meeting.

INTERVIEWS OF EXPERTS

The Commission conducted interviews with 66 academic, industry, non-governmental, and governmental experts to inform the recommendations contained in this report. Experts were invited to participate based on their prior knowledge of and experience with public health security, technological development, biosecurity, and biodefense. Staff protected the privacy of each expert to speak openly and candidly, and did not attribute opinions to the institutions, organizations, agencies, departments, or employers with which they were affiliated. Opinions were considered on aggregate. This report contains the views of the Commission and not necessarily those of individual experts.

ROUNDTABLES

The Commission hosted four roundtables at which experts discussed challenges and solutions that an Apollo Program for Biodefense should address in the following areas:

- Innovative pathogen biosurveillance
- Improved PPE and built environments that prevent the transmission of disease
- Advanced medical countermeasures to combat biological threats
- Improved microbial forensics and attribution

The Commission held these roundtables using virtual platforms in September 2020. Participants came from a diverse range of backgrounds, including academia, industry, non-governmental organizations, and government. To encourage frank and open discussion, the Commission held these roundtables under Chatham House Rule. Staff provided questions to participants in advance. During these roundtables, participants discussed ambitious proposals and solutions for a wide range of biological threats.

ANALYSIS

Commission staff used qualitative methods to analyze information and data obtained during the literature review, meetings, interviews, and roundtables. Staff examined the oral statements provided by meeting speakers. Staff synthesized and evaluated ideas, feedback, and suggestions to help inform the development of the Athena Agenda to execute The Apollo Program for Biodefense. Staff further evaluated findings and recommendations with additional policy research and interviews with subject matter experts and former high-level government officials, as well as in light of the Commissioners' own experiences. Throughout the process, the research questions defined previously provided the basis for assessment. Staff did not use statistical and other quantitative methods for this analysis.

LIMITATIONS

Several biodefense programs and policies; intelligence, raw data, and documents; appropriations and budget documents; and other sensitive information are classified or otherwise unavailable and, accordingly, were not reviewed by the Commission.

APPENDIX D: MEETING AGENDAS

A MANHATTAN PROJECT FOR BIODEFENSE: TAKING BIOLOGICAL THREATS OFF THE TABLE

July 11, 2019
58 E 68th St, New York, NY 10065

OBJECTIVE
Inform Panel deliberations on how best to create a national, public-private research and development undertaking to defend the United States against biological threats.

SCHEDULE

9:00 – 9:15 am Opening Remarks

9:15 – 10:15 am
Panel One – Case Study: Pursuit of Universal Influenza Vaccine Federal and military officials, and an academic representative, discuss efforts to develop universal influenza vaccine, the challenges associated with science and funding, arguments for and against such an approach, and what it will take to get it across the finish line.

Alan Embry, PhD
Chief, Respiratory Diseases Branch, National Institute of Allergy and Infectious Diseases, National Institutes of Health

Blake Bextine, PhD, MA
Acting Deputy Director, Biological Technologies Office, Defense Advanced Research Projects Agency

Ren Sun, PhD
Distinguished Professor, Molecular & Medical Pharmacology and Bioengineering; Associate Dean for Postdoctoral Affairs, David Geffen School of Medicine; Associate Vice Provost for Internationalization, University of California Los Angeles

10:15 – 11:15 am Panel Two – Local View on Biological Threats and Requirements
Representatives from the New York City departments of police, health and transit discuss the biological threat from their perspective, what they need to defend against it, challenges in interacting with the federal government to achieve adequate biodefense of New York City, and requirements they believe a Manhattan Project for Biodefense should be addressed.

John O'Connell
Deputy Chief and Commanding Officer of the Counterterrorism Division, New York City Police Department

Beth Maldin Morgenthau, MPH
Deputy Commissioner, New York City Department of Health and Mental Hygiene

Michael Gemelli
Manager, Environmental Monitoring and Emergency Response, Counterterrorism and Security Initiatives, New York City Transit, Department of Security

11:15 – 11:30 am Break

11:30 – 12:30 pm Panel Three – Federal and Military Contributions
Representatives from federal and military agencies discuss cutting edge biodefense research, challenges associated with this research, and requirements for what they would consider a Manhattan Project for Biodefense.

Robert P. Kadlec, MD, MTM&H, MS (Colonel US Air Force – Retired)
Assistant Secretary for Preparedness and Response, US Department of Health and Human Services

Deydre S. Teyhen, PhD, DPT, OCS (Colonel US Army)
Commander, Walter Reed Army Institute of Research, Medical Research and Materiel Command, US Army

12:30 – 1:00 pm Break

1:00 – 1:45 pm Luncheon Keynote – Graphic History of Germ Warfare
Scholar and New York Times best-selling author provides historical perspective on biological warfare and bioterrorism, discusses the need for a Manhattan Project for Biodefense, and addresses the value of pop culture as a tool to educate and inform the public, government, and the private sector.

Max Brooks
Nonresident Fellow, Modern War Institute at West Point; Nonresident Fellow, Brent Scowcroft Center for Strategy and Security, Atlantic Council; Author, World War Z, The Zombie Survival Guide, The Harlem Hellfighters, and Germ Warfare: A Very Graphic History

1:45 – 2:00 pm Break

2:00 – 3:15 pm Panel Four – Non-Federal Contributions
Private sector representatives discuss needs, resource requirements, and business risks associated with their research contributions to the national biodefense enterprise and potential contributions to a Manhattan Project for Biodefense.

Monique K. Mansoura, PhD, MBA
Executive Director, Global Health Security and Biotechnology, The MITRE Corporation

Patricia Falcone, PhD, MS
Deputy Director for Science and Technology, Lawrence Livermore National Laboratory

Akhila Kosaraju, MD
President and Co-Founder, Variant Bio; former Vice President for Global Development, SIGA Technologies; former Special Assistant to the Assistant Secretary of Defense for Health Affairs, Department of Defense

3:15 – 3:30 pm Closing Remarks and Adjourn

THE BIOLOGICAL EVENT HORIZON: NO RETURN OR TOTAL RESILIENCE

September 24, 2020
(Virtual)

OBJECTIVE

Provide the Bipartisan Commission on Biodefense with a better understanding of emerging biological threats and innovative technology for biodefense.

SCHEDULE

9:00 – 9:30 am Opening Remarks

9:30 – 10:25 am Panel One: Congressional Perspective
Sitting Members of Congress discuss the role of the Legislative Branch in addressing biological threats.

Representative Susan Brooks (R-IN)
Member, Subcommittee on Health, Committee on Energy and Commerce, US House of Representatives

Representative Diana DeGette (D-CO)
Chair, Subcommittee on Oversight and Investigation, Committee on Energy and Commerce, US House of Representatives

10:25 am – 11:40 am Panel Two: Emerging Biological Risks
Academic and non-governmental representatives discuss emerging biotechnological risks and how biological threats like COVID-19 are becoming increasingly common.

Jaime Yassif, PhD
Senior Fellow, Global Biological Policy and Programs, Nuclear Threat Initiative

Sohini Ramachandran, PhD
Associate Professor of Biology, Director of Graduate Studies for the Center for Computational Molecular Biology, Associate Professor of Computer Science, Brown University

Nita Madhav, MSPH
Chief Executive Officer, President, and Board Member, Metabiota

11:40 am – 12:40 pm Panel Three: The Future of Biodefense
A non-governmental representative and a former federal official discuss emerging technologies and ways to improve federal efforts to harness this new technology for biodefense.

Kavita M. Berger, PhD
Director, Board on Life Sciences, National Academies of Sciences

Luciana Borio, MD
Vice President, Technical Staff, In-Q-Tel; Former Director for Medical and Biodefense Preparedness, Food and Drug Administration

12:40 – 12:45 pm Closing Remarks and Adjourn

THE ATHENA AGENDA: EXECUTING THE APOLLO PROGRAM FOR BIODEFENSE

December 8, 2021
1201 Pennsylvania Avenue, NW, Suite 400, Washington, DC 20004

OBJECTIVE

Provide the Bipartisan Commission on Biodefense with a better understanding of: (1) ongoing federal efforts to implement The Apollo Program for Biodefense; (2) the role of the private sector in implementing The Apollo Program for Biodefense; and (3) how the public and private sectors can fully implement The Apollo Program for Biodefense by the end of the decade.

SCHEDULE

10:00 – 10:30 am Opening Remarks

10:30 am – 11:15 pm
Panel Two: Executive Perspective
A government official discusses the role of the Executive Branch in ensuring that the public and private sectors work together to achieve The Apollo Program for Biodefense by the end of the decade.

> **Eric S. Lander, DPhil**
> Science Advisor to the President; Director, Office of Science and Technology Policy

11:15 am – 12:00 pm
Panel One: Congressional Perspective
A Member of Congress provide their views about the role of the Legislative Branch in implementing The Apollo Program for Biodefense.

> **Senator Richard Burr (R-NC)**
> Ranking Member, Committee on Health, Education, Labor and Pensions, and Chair, Subcommittee on Labor, US Senate

12:00 pm – 12:45 pm
Lunch and Video

12:45 – 1:50 pm

Panel Three: A Vision for Something Greater

Experts discuss their visions for what The Apollo Program for Biodefense could look like and how the public and private sectors can work together to achieve that goal.

The Honorable Tara O'Toole, MD, MPH
Executive Vice President, In-Q-Tel; former Under Secretary for Science and Technology, Department of Homeland Security

Jacob L. Swett, DPhil
Co-founder, altLabs; Visiting Scientist, Biodesign Institute, Arizona State University

Syra Madad, DHSc
Senior Director, System-wide Special Pathogens Program, New York City Health + Hospitals

1:50 – 2:55 pm

Panel Four: Coordinating Efforts and Strategic Direction

Two current and one former government official discuss the role of the federal government in achieving The Apollo Program for Biodefense by the end of the decade.

Stephen M. Hahn, MD
Chief Medical Officer, Preemptive Medicine and Health Security Initiative, Flagship Pioneering; Former Commissioner, US Food and Drug Administration

Sandeep Patel, PhD
Director, Division of Research, Innovation, and Ventures (DRIVe), Biomedical Advanced Research and Development Authority, US Department of Health and Human Services

Brandi C. Vann, PhD
Deputy Assistant Secretary of Defense for Chemical and Biological Defense Programs, US Department of Defense

2:55 – 3:10 pm *Break*

3:10 pm – 4:15 pm

Panel Five: Fostering Innovation at Scale

Experts discuss the role of the private sector and academia in achieving The Apollo Program for Biodefense by the end of the decade.

May Chu, PhD
Clinical Professor, Department of Epidemiology, Colorado School of Public Health; former Assistant Director of Public Health, Office of Science and Technology Policy; Executive Office of the President (Obama); former Director, Diagnostic Reference Laboratory for Bacterial Zoonotic Diseases, Centers for Disease Control and Prevention

Akhila Kosaraju, MD
CEO and President, Phare Bio; former Special Assistant to the Assistant Secretary of Defense for Health Affairs, US Department of Defense

Dan Wattendorf, MD
Director, Innovative Technology Solutions, Bill & Melinda Gates Foundation

4:15 – 4:30 pm Closing Remarks and Adjourn

GLOSSARY

Artificial Intelligence
The theory and development of computer systems able to perform tasks that normally require human intelligence.

Built environment
Human-made environments (e.g., offices, healthcare facilities, schools, public transportation, planes) where transmission of most known pathogens occur.

CRISPR
Clustered Regularly Interspaced Short Palindromic Repeat.

CRISPR-Cas9
Clustered Regularly Interspaced Short Palindromic Repeat, Associated Protein 9.

COVID-19
Coronavirus disease 2019.

Cyberology
The science, study, and theory of cyberspace and cybernetics, including communications over computer networks, Internet-connected systems and data centers, computerized systems, communications, and automatic control systems in both machines and living things.

Digital biomarkers
Detectable physiological, biometric, biophysical, biochemical, mobility, and circadian rhythm changes that occur when a pathogen infects the body.

Digital pathogen surveillance
Systems that use internet-based and other electronically available data (e.g., medical bulletins, search queries, social media) to provide real-time warning of infectious disease events.

DNA
Deoxyribonucleic acid.

DNA synthesis screening
Computer algorithms that scan commercial DNA synthesis orders for potential harmful biological agents.

Host-responses
The genetic and biological signs an individual produces when infected with a pathogen.

Immunogenicity
The ability of a foreign substance to provoke an immune response.

Inhalable administration
The delivery of a therapeutic or vaccine to an individual by breathing it into their lungs.

Intranasal administration
The delivery of a therapeutic or vaccine to an individual by spraying it in their nose.

Machine learning
The use and development of computer systems that can learn and adapt without following explicit instructions to analyze and draw inferences from patterns in data.

Massively multiplexed detection
Detection capabilities that can test for multiple pathogens, resistance genes, biomarkers, and analytes in a single simple assay.

Metagenomic sequencing
The reading of all genetic material from a sample.

Microfluidics
Instruments that use small amounts of liquid on a microchip to do laboratory tests.

Minimally- and non-invasive infection detection
Detection and diagnostic methods that permit sample acquisition, data collection, or early warning without pain, discomfort, inconvenience, or risk.

Monoclonal antibodies
Laboratory-produced molecules that act as substitute antibodies that can restore, enhance, or mimic the immune system's attack on cells.

mRNA
Messenger RNA.

Multi-pathogen therapeutic drugs
Also known as broad-spectrum therapeutics, these are drugs that can be effective against a wide variety of pathogens.

Multiplexed PCR assays
PCR tests that can identify approximately 25 of the pathogens most associated with respiratory infections, but do not include most known or novel pathogens.

Needle-free administration
The delivery of therapeutics and vaccines that are pain-free, cause minimal discomfort, convenient, and easy to distribute at scale.

Nucleic-acid sequencing
The reading of genetic material.

Oral administration
The delivery of a therapeutic or vaccine to an individual by ingesting it.

Pharmacokinetics
The study of the bodily absorption, distribution, metabolism, and excretion of drugs.

Platform technologies
Technologies that use the same processes for manufacturing, formulation, and delivery of a drug or vaccine against multiple different pathogens.

Rapid point-of-use diagnostics
Also known as point-of-person or point-of-need diagnostics, these are tests that can rapidly identify an infection wherever the individual is located.

RNA
Ribonucleic acid.

Prototype pathogen
A pathogen from a viral family that is used to develop platform vaccines or therapeutics for all pathogens in that family.

Sequence homology
The ability to detect similar regions in a pathogen's genetic tree.

SARS
Severe acute respiratory syndrome.

SARS-CoV-1
Severe acute respiratory syndrome-coronavirus-1.

SARS-CoV-2
Severe acute respiratory syndrome-coronavirus-2.

Transdermal administration
The delivery of a therapeutic or vaccine to an individual through their skin.

Ubiquitous sequencing
The routine use of sequencing in clinical and environmental settings that would result in a baseline understanding of the genetic material around us, permitting the early detection of new threats, while providing the critical diagnostic capacity needed to reduce the global infectious disease burden.

Volatolomics
The detection of volatile compounds emitted by an individual.

ACRONYMS

AI	Artificial Intelligence
ASPR	Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
BSL-4	Biosafety Level Four
CDC	Centers for Disease Control and Prevention
CIADM	Centers for Innovation in Advanced Development and Manufacturing
DARPA	Defense Advanced Research Projects Agency
DHS	Department of Homeland Security
DNI	Director of National Intelligence
DOC	Department of Commerce
DOD	Department of Defense
DOE	Department of Energy
DOI	Department of the Interior
DOL	Department of Labor
DOS	Department of State
DOT	Department of Transportation
ED	Department of Education
DRIVe	Division of Research, Innovation, and Ventures
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
GPS	Global Positioning System
GSA	General Services Administration
HGP	Human Genome Project
HHS	Department of Health and Human Services
IC	Intelligence Community
IGSC	International Gene Synthesis Consortium
ISS	International Space Station
NASA	National Aeronautics and Space Administration
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NSABB	National Science Advisory Board for Biosecurity
NSC	National Security Council

Continued

NSF	National Science Foundation
OMB	Office of Management and Budget
OSTP	Office of Science and Technology Policy
PPE	Personal protective equipment
RADx	NIH Rapid Acceleration of Diagnostics
SLTT	State, Local, Tribal and Territorial governments
USDA	Department of Agriculture
VA	Department of Veterans Affairs
WHO	World Health Organization

ENDNOTES

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[24] "The effects of the current pandemic will obviously continue to strain governments and societies over the coming year, fueling humanitarian and economic crises, political unrest, and geopolitical competition as countries, such as China and Russia, seek advantage through "vaccine diplomacy" to build influence and in some cases demand accessions from other governments. Countries with high debts or that depend on oil exports, tourism, or remittances face particularly challenging recoveries, while others will turn inward or be distracted by other challenges. The critical impact of the pandemic has also served to highlight the importance of public health to national security." Haines, A. (2021). Remarks as prepared for delivery by The Honorable Avril Haines Director of National Intelligence. Annual Threat Assessment. Opening Statement. Senate Select Committee on Intelligence. Office of the Director of National Intelligence. Retrieved from: https://www.dni.gov/index.php/newsroom/congressional-testimonies/congressional-testimonies-2021/item/2206-dni-haines-opening-statement-on-the-2021-annual-threat-assessment-of-the-u-s-intelligence-community.

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[30] For instance, in November 2021, the Secretary of Defense issued a biodefense vision memorandum for senior Pentagon leadership, combatant commanders, and defense agency and DOD field activity directors to direct the department to undertake a comprehensive Biodefense Posture Review. The memorandum identified three guiding principles for the posture review: (1) unify efforts through an empowered, collaborative, and integrated approach to biodefense across the department; (2) modernize DOD operations to optimize capabilities, capacity, resilience, and readiness; and (3) synchronize biodefense planning with the National Defense Strategy, efforts of other Federal departments and agencies, and allies and partners to support national biodefense efforts in alignment with national goals and strategy. Secretary of Defense. (2021). Memorandum for Senior Pentagon Leadership, Commanders of the Combatant Commands, Defense Agency, and DOD Field Activity Directors, Subject: Biodefense Vision. Washington, DC: Department of Defense. Retrieved from: https://media.defense.gov/2021/Dec/03/2002903201/-1/-1/0/BIODEFENSE-VISION-FINAL.PDF.

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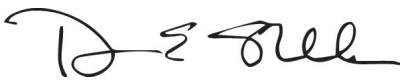

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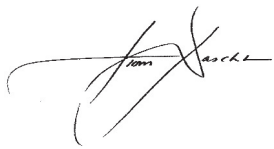

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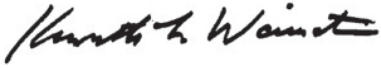

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PREFACE

October 28, 2015

To the President, Congress, and the American People:

The United States is underprepared for biological threats. Nation states and unaffiliated terrorists (via biological terrorism) and nature itself (via emerging and reemerging infectious diseases) threaten us. While biological events may be inevitable, their level of impact on our country is not.

We convened the Bipartisan Commission on Biodefense to assess what has been done to address the biological threat and what remains undone. Despite significant progress on several fronts, the Nation is dangerously vulnerable to a biological event. The root cause of this continuing vulnerability is the lack of strong centralized leadership at the highest level of government.

Crisis after biological crisis has forced the United States to act. Naturally occurring threats such as influenza, Ebola, and Chikungunya bypass borders to emerge in nations oceans away, and exact a continued toll. The Islamic State of Iraq and the Levant (also known as ISIL and Da'esh) is devastating the Middle East while espousing the value of biological weapons for their ability to cause massive loss of life. The U.S. government has mishandled extremely dangerous viruses and bacteria in some of its highest level laboratories. The Nation lacks the leadership, coordination, collaboration, and innovation necessary to respond.

This Commission (through public meetings, targeted interviews, and extensive research) examined the national state of defense against biological attacks and emerging and reemerging infectious diseases, that could cause catastrophic loss of life, societal disruption, and loss of confidence in our government. We scrutinized the status of prevention, deterrence, preparedness, detection, response, attribution, recovery, and mitigation – the spectrum of activities deemed necessary for biodefense by both Republican and Democratic Administrations, and many experts outside of government. We identified substantial achievements, but we also found serious gaps and inadequacies that continue to leave the Nation vulnerable to threats from nature and terrorists alike.

Successive presidents, beginning with William J. Clinton and followed by George W. Bush and Barack H. Obama, enacted policies intended to strengthen national biodefense. As a result, many federal departments and agencies took action and the majority of these programs received bipartisan congressional support. Yet fourteen years after the last report of the U.S. Commission on National Security/21st Century, eleven years after the report of the National Commission on Terrorist Attacks upon the United States, ten years after the report of the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction, and seven years since the report of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, the insufficiency of our myriad and fragmented biodefense activities persists because biodefense lacks focused leadership. Capable individuals oversee elements at the department and agency levels, but no steward guides them collectively.

As leaders in past administrations and congresses, we, the members of the Commission, had a role in our national biodefense and we share responsibility for its shortcomings. Our intent is to help remedy the correctable shortfalls by identifying specific short-, medium-, and long-term programmatic, legislative, and policy actions in this report. We urge those in leadership positions to implement our recommendations with utmost haste. Lives are in the balance.

We provided this charge to ourselves – without a commission from Congress or the President – and tried not to duplicate the work of previously mandated commissions and appointed panels. Instead, we built on and contemporized their insights, observations, and recommendations. While we originally intended to assess both biological and chemical threats, we came to believe that the more immediate concern regarding loss of life is the biological threat and that in focusing on it there will be collateral benefits for dealing with the chemical threat as well.

Biodefense touches many aspects of society, falling within the purview of national security, homeland security, public health security, and economic security. As such, it requires an enterprise approach – eliminating stovepipes; transcending agency-centric activity; drawing upon stakeholders throughout government, academia, and the private sector; and recognizing the extraordinary breadth of the challenge – to provide flexible solutions that address the full spectrum of the threat. Most importantly, the Nation needs an overarching leader who recognizes the severity of the biological threat and possesses the authority and political will to defend against it. This top-level leader, together with leaders throughout the enterprise, must guide efforts and ensure that the combined impact of biological threats, vulnerabilities, and consequences are managed using a common biodefense strategy.

As former Secretary of the Navy Richard Danzig told us, "We don't really get to choose what we have to prepare for." We have no choice – the Nation must take action to defend against the biological threat. We have done much already, but we need the leadership only a top-level official can bring to bear to optimize the biodefense enterprise. We believe that our recommendations will make America more secure, and we will continue to monitor actions taken to improve our national biodefense posture. If you take and demand action now, you can save lives. There is no greater calling or responsibility.

Joseph I. Lieberman
CHAIR

Thomas J. Ridge
CHAIR

EXECUTIVE SUMMARY

BACKGROUND

The Bipartisan Commission on Biodefense was established in 2014 to assess gaps and provide recommendations to improve U.S. biodefense. The Commission – supported by a suite of distinguished ex officio members and staff with extensive expertise in science, policy, intelligence, and defense; institutional hosting through Hudson Institute and the Inter-University Center for Terrorism Studies at Potomac Institute for Policy Studies; and funds from academia, foundations, and industry – determined where the United States is falling short of addressing biological attacks and emerging and reemerging infectious diseases.

Individuals from all levels of government, industry, academia, and advocacy provided their perspectives at a series of four day-long meetings with the Commission. They addressed the pillars of biodefense outlined in Homeland Security Presidential Directive (HSPD) 10:

THREAT AWARENESS

biological warfare related intelligence; assessments; anticipation of future threats

PREVENTION AND PROTECTION

proactive prevention; critical infrastructure protection

SURVEILLANCE AND DETECTION

attack warning; attribution

RESPONSE AND RECOVERY

response planning; mass casualty care; risk communication; medical countermeasure (MCM) development; decontamination

REPORT ORGANIZATION

The Nation has made some progress with biodefense and this report does not dismiss this. Rather than catalog success, however, this report delineates areas needing improvement and provides key recommendations to address them. Although challenges undoubtedly exist in all of the capability areas needed for biodefense, this report describes that subset brought to the Commission's attention as being the most problematic. It also pushes beyond the limits of HSPD-10 to urge greater inclusion of issues like animal health and global engagement as key components of the biodefense mission. This report contains proposals for an effective leadership construct and a renewed governance structure. It provides a detailed blueprint for reform with action items that are categorized by time to completion (summarized in Table 1): short-term (in one year or less); medium-term (within one to three years); and long-term (within three to five years).

THE CHALLENGE OF LEADERSHIP

Simply put, the Nation does not afford the biological threat the same level of attention as it does other threats: There is no centralized leader for biodefense. There is no comprehensive national strategic plan for biodefense. There is no all-inclusive dedicated budget for biodefense.

The Nation lacks a single leader to control, prioritize, coordinate, and hold agencies accountable for working toward common national biodefense. This weakness precludes sufficient defense against biological threats. A leader must, therefore, take charge of our Nation's response to biological crises, as well as day-to-day activities in the absence of such crises.

Leadership of biodefense should be institutionalized at the White House with the Vice President. This office can be imbued with the authority of the President to coordinate agencies, budgets, and strategies across the government in a way that no other position can.

THE NEED FOR LEADERSHIP TO ACHIEVE COORDINATION AND ACCOUNTABILITY

Inter-governmental and multi-disciplinary efforts are needed to adequately defend the Nation against biological threats. Centralized, effective leadership is necessary to direct and harmonize these efforts, but because this is lacking, biodefense activities are insufficiently coordinated. This problem can largely be resolved through the leadership of the Vice President and the establishment of a White House Biodefense Coordination Council.

The coordination problem is exacerbated by the lack of a comprehensive biodefense strategy and a unified approach to budgeting, both vital to any strategic interagency effort. Congressional oversight efforts are hampered by the lack of these important components, insufficient awareness of the threat, and inadequate oversight among committees. These challenges could be alleviated in part through regular and in-depth intelligence briefings for Members of Congress, and implementation of joint congressional oversight agendas.

The lack of coordination at the highest levels impacts a variety of downstream areas of critical importance, including: intelligence activities; full consideration of the interrelationships among animal, environmental, and human health; coordination of MCM development; attribution of bioterrorist acts; and environmental decontamination and remediation. These critical areas demand better integration and clear prioritization, aligned with funding and investment, in order to inform stakeholders across the biodefense spectrum and enable them to execute a strategy once it is developed.

THE NEED FOR LEADERSHIP TO ELEVATE COLLABORATION

U.S. biodefense is not, nor should it be, a solely federal function. The impact of biological events, while felt nationally, will be addressed locally. The federal government must aid in strengthening state, local, territorial, and tribal biodefense capabilities and increase the support and access provided to them far beyond current levels.

Rapid and accurate identification of a pathogen moving through humans, animals, or the environment is absolutely necessary, yet significant advances in such identification remain elusive. The federal government must implement a nationally integrated biosurveillance capability, dramatically improve environmental biosurveillance, and substantially augment collection and incorporation of animal data into human biosurveillance systems.

The Nation must also demonstrate support for emergency services through improved training, enhanced personal protection, and better intelligence sharing. We must commit reasonable

and sustained levels of financial support to state, local, territorial, and tribal health departments. The federal government must also increase support to hospitals, through tighter management of Hospital Preparedness Program funds, development of Centers for Medicare and Medicaid Services incentives, and accreditation of select hospitals as biodefense specialty centers.

Public-private partnerships are fundamental to any efforts toward development, distribution, and dispensing of MCM. We must produce a MCM response framework that is predicated on non-federal input, collaboration, and implementation, and that allows for pre-deployment of stockpiles. Finally, the federal government must lead efforts to secure vulnerable pathogen data.

THE NEED FOR LEADERSHIP TO DRIVE INNOVATION

The innovative process of scientific discovery is inherently fraught with uncertainty. Yet biodefense efforts urgently call for a much greater focus on innovation than ever before – because biological threats are imminent, biological vulnerabilities have existed for too long, and the complexity of the threat requires equally complex solutions. Biodefense also requires sustained prioritization and funding to ensure that success realized thus far is maintained, and that opportunity and innovation are pursued.

We must revolutionize the development of MCM for emerging infectious diseases, fully fund and incentivize the MCM enterprise, and remove bureaucratic hurdles to MCM innovation. We must develop a system for environmental detection that leverages the ingenuity of industry and meets the growing threat. We must overhaul the Select Agent Program to enable a secure system that simultaneously encourages participation by the scientific community. Finally, we must help lead the international community toward the establishment of a fully functional and agile global public health response apparatus.

CONCLUSIONS

We have reached a critical mass of biological crises. Myriad biological threats, vulnerabilities, and consequences have collectively and dramatically increased the risk to the Nation. These threats have also, we believe, garnered the attention of enough people who understand the threat is real, want to mobilize and take action, and can provide for effective national biodefense.

Leadership moves America forward. A central and authoritative leader – who, by recommendation of this report, is the Vice President – can foster substantial progress in biodefense. Once installed as this leader, the Vice President (and the interagency team of experts who will work to realize the strategic vision of the Executive and Legislative Branches) can also foster substantial progress, much of it in the near term. This is especially true for coordinating federal activities, forging intersectoral partnerships, and revolutionizing the ways in which we approach this mission space.

Dramatic improvements are within our reach if we follow a national blueprint for biodefense, establish leadership, and engage in major reform efforts that build on the good work that is already in place.

TABLE 1: RECOMMENDATIONS AND ACTION ITEMS

Recommendation			Term to Execute		
	Action Item		Short	Medium	Long
1	**Institutionalize biodefense in the Office of the Vice President of the United States.**				
	a	Empower the Vice President with jurisdiction and authority.	•		
	b	Empower the Vice President with budget authority.	•		
2	**Establish a Biodefense Coordination Council at the White House, led by the Vice President.**				
	a	Require broad federal participation.	•		
	b	Invite broad non-federal stakeholder participation.	•		
	c	Structure the Council for consensus and accountability.	•		
3	**Develop, implement, and update a comprehensive national biodefense strategy.**				
	a	Collate the whole of biodefense policy.	•		
	b	Identify requirements within all extant policies.	•		
	c	Assess spending history and value.		•	
	d	Produce the National Biodefense Strategy of the United States of America and its Implementation Plan.		•	
	e	Develop a gap analysis based on this comprehensive strategy.		•	
	f	Institute a major quadrennial biodefense review.			•
4	**Unify biodefense budgeting.**				
	a	Develop and execute a mandatory annual biodefense call for data.	•		
	b	Conduct a cross-cutting biodefense budget analysis.	•		
	c	Align budget items to the National Biodefense Strategy of the United States of America.		•	
	d	Provide predictable and multi-year funding for all biodefense programs.		•	
5	**Determine and establish a clear congressional agenda to ensure national biodefense.**				
	a	Develop joint congressional oversight agendas.	•		
6	**Improve management of the biological intelligence enterprise.**				
	a	Create a National Intelligence Manager for Biological Threats.	•		
	b	Make biological weapons programs and related activities a discrete intelligence topic.	•		
	c	Address bystanders.		•	
	d	Distribute assessments.	•		

Recommendation			Term to Execute		
	Action Item		Short	Medium	Long
7	**Integrate animal health and One Health approaches into biodefense strategies.**				
	a	Institutionalize One Health.		•	
	b	Develop a nationally notifiable animal disease system.		•	
	c	Prioritize emerging and reemerging infectious diseases.		•	
8	**Prioritize and align investments in medical countermeasures among all federal stakeholders.**				
	a	Ensure National Institutes of Health research supports civilian medical countermeasure priorities.		•	
	b	Ensure funding allocations are appropriate to meet the need.		•	
	c	Require a biodefense spend plan from the National Institute of Allergy and Infectious Diseases.	•		
9	**Better support and inform decisions based on biological attribution.**				
	a	Establish a national biological attribution decision-making apparatus.		•	
	b	Place the Federal Bureau of Investigation in charge of the National Bioforensics Analysis Center.	•		
10	**Establish a national environmental decontamination and remediation capacity.**				
	a	Include the Federal Emergency Management Agency in efforts to address remediation.	•		
	b	Assign responsibility to the Environmental Protection Agency for environmental decontamination and remediation.	•		
	c	Conduct studies of those exposed to disease-causing agents.		•	
11	**Implement an integrated national biosurveillance capability.**				
	a	Implement the National Strategy for Biosurveillance.	•		
12	**Empower non-federal entities to be equal biosurveillance partners.**				
	a	Create an interagency biosurveillance planning committee.	•		
13	**Optimize the National Biosurveillance Integration System.**				
	a	Assess the viability of the National Biosurveillance Integration System as the prime integrator of biosurveillance information.	•		
	b	Incentivize data sharing.		•	
14	**Improve surveillance of and planning for animal and zoonotic outbreaks.**				
	a	Increase opportunities for animal health data collection.		•	
	b	Fund the National Animal Health Laboratory Network at a level that allows it to achieve success.	•		
	c	Develop guidance for the serious implications of companion animal and wildlife zoonoses.		•	

Recommendation		Term to Execute		
	Action Item	Short	Medium	Long
15	**Provide emergency service providers with the resources they need to keep themselves and their families safe.**			
	a Provide vaccines to responders who request them.		•	
	b Provide medkits to emergency service providers and their families.		•	
	c Establish reasonable personal protective equipment guidelines and requirements in advance of a biological event.	•		
16	**Redouble efforts to share information with state, local, territorial, and tribal partners.**			
	a Strengthen the Joint Counterterrorism Assessment Team.	•		
	b Strengthen the ability of local police intelligence units to address the biological threat.	•		
	c Enable fusion centers to address the biological threat.	•		
17	**Fund the Public Health Emergency Preparedness cooperative agreement at no less than authorized levels.**			
	a Appropriate Public Health Emergency Preparedness funding to authorized levels or the President's request, whichever is higher.	•		
18	**Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.**			
	a Standardize the development of clinical infection control guidelines before biological events occur.	•		
	b Institute a process for obtaining and incorporating feedback regarding clinical infection control guidelines during biological events.	•		
	c Require training based on these guidelines.		•	
19	**Minimize redirection of Hospital Preparedness Program funds.**			
	a Cap Hospital Preparedness Program management and administration costs at three percent.	•		
	b Assess the impact of the Hospital Preparedness Program.		•	
20	**Provide the financial incentives hospitals need to prepare for biological events.**			
	a Adopt a disaster preparedness portfolio.		•	
	b Link Centers for Medicare and Medicaid Services incentives and reimbursement to new accreditation standards.		•	
21	**Establish a biodefense hospital system.**			
	a Stratify hospitals.	•		
	b Develop accreditation standards for each stratum.		•	
	c Associate Centers for Medicare and Medicaid Services funding.		•	

Recommendation			Term to Execute		
	Action Item		Short	Medium	Long
22	**Develop and implement a Medical Countermeasure Response Framework.**				
	a	Produce a comprehensive framework to guide medical countermeasure distribution and dispensing planning.		•	
23	**Allow for forward deployment of Strategic National Stockpile assets.**				
	a	Determine logistics and funding needs.	•		
	b	Implement forward deployments.		•	
24	**Harden pathogen and advanced biotechnology information from cyber attacks.**				
	a	Develop and implement a security strategy for stored pathogen data.		•	
	b	Provide the research community with tools and incentives to secure its data.		•	
	c	Develop cyber-threat information-sharing mechanisms for the pathogen and advanced biotechnology communities.		•	
25	**Renew U.S. leadership of the Biological and Toxin Weapons Convention.**				
	a	Continue to strengthen implementation of the Biological and Toxin Weapons Convention where U.S. support is unequivocal.	•		
	b	Set U.S. goals for the Biological and Toxin Weapons Convention and determine the conditions necessary to achieve them.	•		
	c	Develop three actionable recommendations for Biological and Toxin Weapons Convention verification.		•	
	d	Establish better biological weapons sentencing guidelines in statute.		•	
26	**Implement military-civilian collaboration for biodefense.**				
	a	Conduct a review of military-civilian collaborative efforts.	•		
	b	Establish military-civilian biodefense collaboration.		•	
	c	Clarify parameters for military support to civilian authorities in response to a domestic biological attack.		•	
	d	Update and implement military biodefense doctrine.		•	
27	**Prioritize innovation over incrementalism in medical countermeasure development.**				
	a	Prioritize innovation in medical countermeasures at agencies with biodefense responsibilities.	•		
	b	Exploit existing innovation.	•		
	c	Revolutionize development of medical countermeasures for emerging infectious diseases with pandemic potential.		•	
	d	Establish an antigen bank.		•	

Recommendation			Term to Execute		
	Action Item		Short	Medium	Long
28	**Fully prioritize, fund, and incentivize the medical countermeasure enterprise.**				
	a	Fund the medical countermeasure enterprise to no less than authorized levels.	•		
	b	Re-establish multi-year biodefense funding for medical countermeasure procurement.	•		
	c	Address prioritization and funding for influenza preparedness.	•		
	d	Improve the plan for incentivizing the private sector and academia.	•		
29	**Reform Biomedical Advanced Research and Development Authority contracting.**				
	a	Return contracting authority to the Biomedical Advanced Research and Development Authority.	•		
	b	Leverage previously provided authorities.	•		
	c	Eliminate Office of Management and Budget review of BioShield procurements.	•		
30	**Incentivize development of rapid point-of-care diagnostics.**				
	a	Develop requirements for rapid point-of-care diagnostics for all material biological threats and emerging infectious diseases.		•	
31	**Develop a 21st Century-worthy environmental detection system.**				
	a	Fund the development of advanced environmental detection systems to replace BioWatch.	•		
	b	Replace BioWatch Generation 1 and 2 detectors.			•
32	**Review and overhaul the Select Agent Program.**				
	a	Undertake a major reassessment of the Select Agent Program.	•		
	b	Overhaul the Select Agent Program.		•	
33	**Lead the way toward establishing a functional and agile global public health response apparatus.**				
	a	Convene human and animal health leaders.	•		
	b	Establish the response apparatus.		•	

SCENARIO

The following hypothetical situation, told from the perspective of a congressional Committee Chairman, provides context for this report by portraying a biological attack sufficient to cause the catastrophic consequences with which this report is concerned. The scenario describes the different populations (human, animal) an agent could target and from which it could emerge, some of the key interagency capabilities required to address the agent and its impacts, and the consequences of failure in these capability areas.

SCENARIO

JOINT INQUIRY INTO ADMINISTRATION AND CONGRESSIONAL ACTIONS BEFORE AND AFTER THE BIOTERRORIST ATTACKS OF 2016

U.S. SENATE, SELECT COMMITTEE ON INTELLIGENCE AND U.S. HOUSE OF REPRESENTATIVES, PERMANENT SELECT COMMITTEE ON INTELLIGENCE

I call the Joint Inquiry Committee to order. Nine weeks ago, terrorists unleashed insidious biological attacks on our Nation's Capitol during our Independence Day celebrations. The infectious agent they used ultimately led to the deaths of 6,053 Americans. Many of our own colleagues and staff fell ill and died. Thousands more were killed in coordinated attacks in allied nations in the days that followed.

The attack here in Washington, D.C. used aerosol delivery devices we could see, but did not know contained dangerous organisms. We discovered later that other attacks had already begun elsewhere in the Nation, using methods we have yet to identify that spread the disease among livestock in rural communities.

Delays in recognition – because most veterinarians and physicians had never seen Nipah virus – meant animals and people were sick for more than a week before we realized what had happened. Now we are being told that the virus, which in nature does not spread easily among people, was genetically modified to increase its ability to spread from animal to animal, animal to person, and person to person.

Biological agents have now been used again to attack the United States, defying predictions and hopes that this would never happen. Obviously, those predictions were wrong.

For years, the Intelligence Community (IC) and others said that although terrorists intended to develop and use biological weapons, they lacked the leadership, organizational wherewithal, infrastructure, expertise, and social support to actually develop and deploy them.

We were also told that there are lines beyond which even terrorists would not tread.

Despite these assurances, terrorists have now used biological weapons to conduct attacks here and throughout the world. The basis of their capability has become painfully clear: they have the leadership, numbers, funding, infrastructure, and expertise to achieve large-scale goals and objectives.

Their multipronged attacks occurred within a very short timeframe – just one week.

The terrorists were successful because the government – including Congress – failed. They took advantage of our failure to achieve early environmental detection of the agent, failure to quickly recognize its occurrence in livestock, failure to rapidly diagnose the disease caused in sick patients, failure to consistently fund public health and health care preparedness, failure to establish sufficient medical countermeasure stockpiles, failure to make sure that non-traditional partners communicate. Ultimately, they took advantage of our failure to make biodefense a top national priority.

Sadly, much as the 9/11 Commission observed in its analysis of the attacks of 2001, the attacks of 2016 occurred because of another "failure of imagination."

SCENARIO

There were failures of prediction, early warning, and detection:

- The IC failed to warn of a well-planned and direct attack on the United States and its global interests.
- HHS, USDA, and DHS failed to detect the biological agent upon release.

There were and continue to be failures to respond appropriately:

- HHS and USDA still have no way to treat exposed people or animals.
- The CDC, USDA, DHS, FBI, and DOD failed at their initial efforts at identification and attribution.
- Critical infrastructure is faltering because workers cannot or will not report to their jobs because they lack protection.
- Emergency service professionals are struggling valiantly to do their jobs, all while keeping their own families safe, in the absence of adequate protection.
- DOD must remove itself from the domestic response while it redirects resources and expertise to defend the United States against enemies seeking to take advantage of these vulnerabilities.

The Nation failed to heed the advice of the 9/11 Commission, the WMD Commission, and many other experts who warned of the dangers of biological terrorism and warfare.

We must now add the failure to appreciate the threat, generate political will, and take action in the face of looming danger.

This is only the second time in the history of Congress that two permanent committees have joined to conduct a bicameral investigation, the first being for the 9/11 investigation. We are holding this hearing today to find out exactly what happened, how this leadership failure occurred, and what needs to be done to recover from these attacks. We also intend to see what it will take to prevent additional attacks and to make sure we have done all we can to be prepared in case these efforts fall short. We will hear from three panels of witnesses:

First, from the four governors of the states and one U.S. territory where these biological attacks occurred.

Second, from the Secretary of State, the Secretary of Defense, the Attorney General, and the Director for National Intelligence, whom we call upon to explain why they missed indications of the impending use of biological weapons.

Third, from the Secretary of Agriculture, the Secretary of Health and Human Services, and the Secretary of Homeland Security, whom we ask to explain their extraordinary challenges in surveillance, detection, identification, response, and attribution.

The Chair now recognizes the Ranking Member of the Committee for an opening statement.

INTRODUCTION: THE CHALLENGE OF LEADERSHIP

The biological threat carries with it the possibility of millions of fatalities and billions of dollars in economic losses. The federal government has acknowledged the seriousness of this threat and has provided billions of dollars in funding for a wide spectrum of activities across many departments and agencies to meet it. These efforts demonstrate recognition of the problem and a distributed attempt to find solutions. Still, the Nation does not afford the biological threat the same level of attention as it does other threats: There is no centralized leader for biodefense. There is no comprehensive national strategic plan for biodefense. There is no all-inclusive dedicated budget for biodefense.

Biological threats – including biological warfare, bioterrorism, and infectious disease – are not new. The United States engaged in a biological warfare program from 1943 to 1969[1] not only to develop biological weapons for offensive use, but also to develop programs and countermeasures to help defend against the use of biological weapons by the former Soviet Union and other enemies.[2] The United States eventually decided that the use of biological weapons could not achieve military aims without resulting in questionable control of both affected areas and the disease imparted by these weapons. We shifted to a defense-only program thereafter, allowing for civilian agencies to address the dangers associated with naturally occurring infectious diseases. The passage of time during which we believed that other nations had ceased their own offensive biological weapons programs led us to reduce the priority placed on addressing biological threats.

The former Soviet Union began its biological weapons program in the 1920s. While the Soviet Union signed onto the Biological and Toxin Weapons Convention (BWC) and claimed to have discontinued its biological weapons program in the 1970s, Soviet defectors and other sources relayed that the program continued into the 1990s, producing thousands of tons of weaponized biological agents and the weapons themselves, and renewing apprehension.[3] Today, Russia still has not allowed inspectors into all of its facilities capable of producing biological weapons. South Africa also built and maintained an arsenal into the 1990s with the intent of using agents like human immunodeficiency virus (HIV) and Ebola on opponents of apartheid.[4] For these and other reasons, President William J. Clinton became concerned and directed White House staff to evaluate the veracity of various biological scenarios and assess federal efforts to build defenses against intentionally introduced and naturally occurring biological events. After a flurry of briefings and the implementation of new programs to improve domestic biodefense against high-impact events such as bioterrorism and pandemic influenza, investments eventually began to wane until the anthrax attacks in 2001 again revived interest.

The biological threat has not abated. At some point, we will likely be attacked with a biological weapon, and will certainly be subjected to deadly naturally occurring infectious diseases and accidental exposures, for which our response will likely be insufficient. There are two reasons for this: 1) lack of appreciation of the extent, severity, and reality of the biological threat; and 2) lack of political will. These conditions have reinforced one another.

This chapter addresses the following:

I. The Biological Threat is Real and Growing

II. Previous Commissions Have Expressed Concern

III. The United States Lacks Centralized Biodefense Leadership

I. THE BIOLOGICAL THREAT IS REAL AND GROWING

Current and former federal officials, as well as a number of private sector experts,[5] believe that the biological threat is real and growing, and urge increased activity to defend the nation against it.[6] This biological threat is multifaceted. Unlike other threats, those that are biological in nature can be borne of malicious intent, more benign human activity, or simple chances of nature.

The Department of State assesses that China, Iran, North Korea, Russia, and Syria continue to engage in dual-use or biological weapons-specific activities and are failing to comply with the BWC.[7] Caches of incompletely destroyed or buried biological weapons materials from old state programs[8] can now be accessed again by new state programs, and then smuggled to other regions for use in today's wars and by today's terrorists.[9] Weapons that once consumed a great deal of time and resources to make now take far less, and it is reasonable to believe that what the United States could accomplish more than 40 years ago, others can accomplish now.[10]

The resources necessary to produce biological weapons[11] are more easily obtained by states and terrorists than in years past.[12] For example, regarding ISIL, former Representative Mike Rogers believes that, "the longer they have freedom of operation in any space that contains those kinds of elements, I think that's dangerous to the United States and our European allies."[13] Additionally, terrorist organizations,[14] domestic militia groups,[15] and lone wolves[16] have expressed intent to use and shown some capacity to develop biological weapons. Advances in science have led to a convergence of biology and chemistry, and an ability (through synthetic biology) to create and combine agents. All of this progress has expanded the number and types of potential biological weapons[17] and made it more difficult to fully comprehend the enormity of the threat.[18]

Discerning surreptitious intent to develop biological weapons that could inflict catastrophic effects on the United States is an enormous intelligence challenge. Despite the dire consequences associated with and its own abiding concern about the biological threat, the IC has neither been provided with nor itself dedicated sufficient resources to collect, analyze, and produce intelligence regarding the biological threat to the same extent as it has with other types of threats. The ubiquity of knowledge necessary to weaponize biological agents also prevents the IC from using more traditional nation-specific or expertise-specific approaches to intelligence collection. Additionally, the IC has not been able to invest in or hire sufficient numbers of scientists and others with needed expertise and ability to participate in biological intelligence activities. This is not to say that the IC has made no attempts at collection, analysis, and dissemination of intelligence relevant to the biological threat. However, the vast nature of the threat is out of proportion with the limited resources and emphasis dedicated to addressing it by the IC as well as those that task and request information from the IC.

Pandemic and highly pathogenic influenzas challenge the globe every year and result in the loss of thousands of human and frequently millions of animal lives, respectively.[19] Globally prevalent diseases for which countermeasures have already been developed are mutating and defeating what little we have to treat them.[20] Emerging diseases – such as Dengue fever and Chikungunya – are occurring with greater frequency and spreading throughout the United States, but lack treatments. Naturally occurring diseases can also devastate livestock, crops, and dairy or produce supplies, harming millions of people and producing a debilitating effect on the U.S. economy.

Accidents can also result in the release of harmful pathogens. Some laboratory leaders have paid insufficient attention to the details necessary to ensure laboratory biosafety and have inadvertently contributed to the biological threat. Poor biosafety resulted in the unintended release of anthrax from Russian laboratories in 1979,[21] anthrax from a U.S. military laboratory at Dugway Proving Grounds in 2015,[22] and *Burkholderia pseudomallei* from a Tulane University research center in 2014.[23] These incidents underscore how much we still have to learn about the hardiness of biological agents, the checks necessary to ensure biosafety standards are being met, and the science of how long it takes laboratories to realize that previously effective procedures no longer work.

Poor biosecurity also increases the biological threat.[24] Even our highest level government laboratories have fallen short in this regard. For example, in 2001, anthrax was illicitly removed from the U.S. Army Medical Research Institute on Infectious Disease and used in the perpetration of the anthrax attacks that year. Decades-old vials of smallpox virus were found in a U.S. Food and Drug Administration (FDA) freezer on the campus of the National Institutes of Health (NIH) in Bethesda, Maryland in 2014, even though previous searches had been conducted in order to fulfill the requirement that all remaining U.S. stocks be consolidated at the Centers for Disease Control and Prevention (CDC).[25] Major mishaps at the CDC that same year resulted in investigations, inspections, congressional hearings, and closures of certain laboratories that tested for suspected bioterrorist agents.[26] Exacerbating the problem was the fact that these breaches of biosecurity resulted in the temporary (yet extended) restriction of laboratory activities and closure of laboratories that perform critical testing and research necessary to meet and reduce the biological threat – leaving the Nation with diminished capability to secure itself.

II. PREVIOUS COMMISSIONS HAVE EXPRESSED CONCERN

Some leaders in the political community have indeed appreciated the large and multifaceted nature of the biological threat, including the members of earlier commissions. Each referenced the biological threat, took this threat seriously, noted the potential for significant impact, and called for action. The U.S. Commission on National Security/21st Century (Hart-Rudman, 1999, 2000, and 2001) recognized the potential for epidemics to become pandemics and the dual-use nature of scientific discoveries.[27] The Commission on Terrorist Attacks on the United States (9/11 Commission, 2004) echoed Hart-Rudman and posited that more than two dozen terrorist groups were pursuing biological materials but that high-level government leaders were expressing varying levels of concern regarding this threat.[28] The Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction (WMD) (Robb-Silberman, 2005) joined the Hart-Rudman and 9/11 Commissions in their concern and described in excruciating detail the failings and weaknesses of the IC regarding the biological threat.[29] Finally, the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (Graham-Talent, WMD Commission, 2008) reaffirmed the findings of these previous commissions and determined that the priority placed on addressing the biological threat was too low to ensure national security.[30] Despite the observations made by these commissioners over more than 20 years, and despite action and progress in some areas, no one has yet taken the lead to address this threat in a strategic and coordinated fashion.

III. THE UNITED STATES LACKS CENTRALIZED BIODEFENSE LEADERSHIP

The centralization of leadership at the highest levels of government is the norm only for those issues deemed to require such centralization. These are typically matters fundamental to the well-being of the Nation (e.g., national security, homeland security, economic security). Occasionally, a subset of these rises to the fore: counterterrorism, influenza pandemic preparedness, or an acute economic crisis. In these cases, an official is often placed in charge, sometimes permanently, but often only temporarily.

The United States has utilized a number of options for centralizing leadership around issues of national importance. These include: 1) placing a federal department or agency official in charge; 2) assigning responsibility to White House staff; 3) naming a czar; or 4) placing an elected official in charge. The last three Presidential Administrations have taken one or more of these approaches to address biodefense, with varying levels of success, and with only partial centralization. What each approach lacked was a figure whose job it was to ensure that all of the federal government was strategically working toward the common goal of comprehensive biodefense.

PLACING A FEDERAL DEPARTMENT OR AGENCY OFFICIAL IN CHARGE

The dissolution of the United States' offensive biological weapons program in 1969 forced a change in the offensive/defensive leadership paradigm for biological threats. Dropping the offensive program, assuming a defensive-only posture, and increasing commitments from other nations that they were not developing or using biological weapons meant that the Department of Defense (DOD) would no longer take a primary leadership role in biodefense.

The Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) – departments with the responsibility for addressing the impact of biological threats to humans, animals, and plants – did not take up the mantle of leadership or were not successful when they tried. For example, HHS was unable to effectively lead other members of the Executive Branch to produce a national strategy for pandemic influenza. This requirement was initially assigned to the Department of Health, Education and Welfare by President James E. Carter in 1977 and carried over when the new HHS was created in 1980. It was subsequently removed from HHS by President George W. Bush and finally fulfilled by the White House when it produced the National Strategy for Pandemic Influenza in 2005 and the Implementation Plan for this Strategy in 2006.

In accordance with the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006 (P.L. 109-417), Congress mandated that the HHS Assistant Secretary for Preparedness and Response (ASPR) be responsible for interagency coordination of preparedness for and response to biological events. Congress also intended for the ASPR to be a (and some would argue *the*) leader of national biodefense efforts, although the statute is limited to preparedness and response elements of biodefense. The ASPR played a role in managing some aspects of the recent Ebola crisis (e.g., overseeing the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) MCM efforts, administering Ebola supplemental funding for hospital preparedness). However, President Barack H. Obama did not place the ASPR in charge of overall Ebola response coordination, having chosen instead to name a coordinator independent of the departments and agencies. Even if the ASPR had coordinated this and other biological crises in their entirety, in reality there is no mandate for the ASPR

to lead all interagency activities across the entire biodefense enterprise. Further, it is unclear how leadership and coordination on the part of the ASPR would fit within the requirements of the National Response Framework, especially since mention of the ASPR was removed from the Framework when it was last updated.

There are also presidential and congressional mandates and intent for the Secretary of Homeland Security to lead and coordinate interagency activities in support of homeland security – addressing biological and chemical attacks, accidents, or events affecting the homeland. In 2009, then-Secretary of Homeland Security Janet Napolitano took charge of the interagency response to the H1N1 influenza pandemic, prior to the confirmation of Secretary of Health and Human Services Kathleen Sebelius. The Department of Homeland Security (DHS) followed some of its plans for leadership and coordination, but set aside others even within the Department (e.g., making last minute changes to previously established and exercised plans, identified leaders, and responsibilities that had originally been assigned to the U.S. Coast Guard). When DHS experienced limited success in leading and coordinating interagency efforts during the H1N1 pandemic, the White House took over.

ASSIGNING RESPONSIBILITY TO A MEMBER OF THE WHITE HOUSE STAFF

Since the establishment of the National Security Council (NSC) staff, at least one staff member has addressed some aspect of biodefense. Some of the appointments have been strategic and forward-looking; others have been reactive to events. The first person to formally address biodefense policy at the White House was an assistant surgeon general from the U.S. Public Health Service, detailed to the NSC by Secretary of Health and Human Services Donna Shalala in 1998. This dedicated biodefense policy position was eliminated following the 2000 election. In the months following the attacks on September 11, 2001 and the anthrax attacks shortly thereafter, a variety of White House staff and detailees were assigned to work on anthrax specifically and biodefense more generally. In 2002, Assistant to the President Tom Ridge created a biodefense directorate in the newly formed Homeland Security Council (HSC) and staffed it with a Special Assistant to the President and three additional full-time professionals. This office remained in place within the HSC through the end of the Bush Administration. Following the 2008 election, President Obama merged the HSC staff with the NSC staff and eliminated this biodefense office. Instead, he distributed various biosecurity functions throughout the NSC, including the WMD Terrorism and Threat Reduction, Development and Democracy, and Resilience Directorates. (President Obama did appoint a WMD Coordinator, discussed below, but this position was not focused on biodefense). When Ebola emerged in the United States in 2014, the President appointed a dedicated Ebola czar to coordinate the U.S. government's response from the White House.

Opinions vary regarding the effectiveness of the present NSC organizational construct to address biodefense. Some argue that its efforts are fractionated, while others contend that the wider variety of staff involved allows for broader involvement of multiple policy offices across the spectrum of biodefense activities. While it is possible for other White House councils and offices to address biodefense,[31] they generally only do so when a specific biodefense issue affects a prominent ongoing responsibility (such as when the White House National Economic Council assessed the impact of a foot-and-mouth disease outbreak on the U.S. economy). Regardless of specific title or location in the chain of command, the imprimatur of the President can help overcome the challenges faced by multiple federal departments and agencies that must act and work together to achieve biodefense aims.

This goal was one of the reasons that Congress – through the Implementing Recommendations of the 9/11 Commission Act of 2007 (P.L. 110-53, herein referred to as the 9/11 Act) – created the Office of the U.S. Coordinator for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. The 9/11 Act specifies that this Office house a Coordinator and Deputy Coordinator, appointed by the President and responsible for serving as the principal advisors to the President on all matters relating to WMD proliferation and terrorism. The 9/11 Act goes on to make this Coordinator (often referred to as the WMD Coordinator) responsible for developing a comprehensive national strategy and individual policies to combat WMD proliferation and terrorism, incorporating (among other things): measurable targets and milestones with which to hold agencies accountable; identification of gaps, duplications, and inefficiencies in existing programs and initiatives; plans to strengthen and expand the scope of existing programs and initiatives; new and innovative programs to address emerging challenges and threats; coordination among the various federal agencies involved in addressing this threat; and plans to strengthen U.S. commitment to international non-proliferation efforts.

President George W. Bush did not implement this recommendation. President Obama named Dr. Gary Samore as the WMD Coordinator in 2009, without submitting him for the Senate confirmation called for in statute. His focus was far more on nuclear threats than biological. Upon Dr. Samore's departure, Dr. Elizabeth Sherwood Randall took on these and additional responsibilities as the Coordinator on Defense Policy, Countering Weapons of Mass Destruction and Arms Control in 2013 (also without being Senate confirmed) but left that position a year later when she became the Deputy Secretary of Energy. The position of the WMD Coordinator is not currently filled. The difficulty of subjecting White House staff to congressional mandate is that it is up to the President to decide how best to manage his or her staff, not Congress. A mandated position also may not fit logically within organizational constructs that change as Administrations and their priorities change. Congress implicitly seems to respect this Presidential authority and has not forced the issue of ensuring that any President fill this position.

NAMING A CZAR

Certain topics achieve distinction as having national impact, but require more subject matter expertise and focused effort than departments and agencies in the Executive Branch can afford to dedicate. The term czar is occasionally and informally used to identify the individual the President has appointed to address such an issue if it is high priority and of great interest. Czars are political appointees that may or may not be confirmed by the Senate, with positions that may or may not carry over from one Administration to another. While czars often enjoy a higher profile than other members of the White House staff, those that do not hold institutionalized or authorized positions often lack sufficient authority or power to enact necessary change because they oversee only one particular part of policy. A number of czars have addressed various biological threats, including avian influenza, Ebola, and terrorism.[32]

PLACING AN ELECTED OFFICIAL IN CHARGE

Little has been done to establish a strong, well-funded, centralized authority overseeing national efforts in biodefense. This lack of high level and centralized leadership prevents critical problems from receiving proper focus and attention within the Executive Branch. It also weakens those efforts that exist among the agencies that strive to work in the absence of such leadership. While it is the nature of democracies to be reactive, reactionary policies and programs do not serve the Nation's best interest when it comes to the biological threat. Time and again, the United States has been forced to respond to intentional, naturally occurring, and accidental biological events,

with real human, animal, environmental, and financial costs. These complex interagency responses can either be reactive, or they can be planned, funded, and exercised ahead of time under the guidance of a centralized leader.

The President should retain flexibility to address biodefense at the White House in whatever way he or she chooses. However, such flexibility should not continue to result in the absence of a concentrated and continuous effort across Administrations. Further, if the White House takes charge or is expected to take charge of every significant biological event, then this responsibility should be institutionalized.

This responsibility can be institutionalized in a number of offices in the White House, including that of the Vice President. The Vice President has a direct line to the President and, when imbued with authority as the President's proxy, can act on his or her behalf. There is precedent for Vice Presidents assuming responsibility for various initiatives. For example, President William Jefferson Clinton appointed Vice President Albert A. Gore to lead the National Performance Review[33] in 1993 and made the Vice President responsible for translating the recommendations of the Review into improved government performance and results. The Vice President's leadership was critical to producing a bill that was sent to Congress to address these requirements. While Congress did not pass that bill, it did produce and pass the Government Performance and Results Act (GPRA), which addressed many of the Review's recommendations. Vice President Gore retained responsibility for seeing that the Act was implemented and personally held the Executive Branch accountable in this regard.

The primary goal of centralization is to place the coordination and oversight responsibility in a location that will have sufficient authority regardless of personalities or party in power, and in a position with the ability to make executive decisions. The Vice President possesses these attributes.

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.

ACTION ITEMS:

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.

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 (OMB).

The Nation has not come to fully appreciate the severity of the biological threat and our leaders have not demonstrated the political will to fully address it. We must address these shortcomings by prioritizing the following areas: 1) coordination and accountability among federal departments and agencies; 2) collaboration between federal and non-federal stakeholders; and 3) innovation that addresses both lingering and novel problems. The chapters that follow explore each of these in turn.

CHAPTER 1: THE NEED FOR LEADERSHIP IN ACHIEVING COORDINATION

Biodefense necessitates complex and sophisticated multi-disciplinary efforts, successful navigation of which requires coordination among government, academia, and industry. Centralized effective leadership is necessary to align these efforts. Because such leadership is lacking, federal biodefense activities are insufficiently coordinated. Authority and responsibilities are dispersed among many cabinet agencies, without the benefit of a single leader to provide directives and receive reports. Thus, while outcomes of individual department and agency efforts may or not be successful, no one is held fully accountable for the necessary outcomes of a mission-oriented and integrated biodefense enterprise.

This problem is further complicated by the lack of a comprehensive biodefense strategy. A decade of profusion of policy directives indicates well-intentioned efforts to facilitate progress, yet the staggering number has resulted in a fragmented enterprise made less stable as Administrations pass from one to the next and priorities change. Additionally, a unified approach to budgeting is a vital part of any strategic interagency effort, and this is lacking as well. This undoubtedly means that spending is redundant in some areas and deficient in others.

The lack of coordination manifests in a variety of areas of critical importance to biodefense: the gathering and dissemination of intelligence; consideration of animal health and one health approaches as central tenets of health security; prioritization of emerging threats; and investment in areas including MCM, bioterror attribution, and decontamination and remediation.

Congressional oversight and legislation are critical for ensuring that the biodefense enterprise works. Congressional efforts have been hampered, however, by the lack of a comprehensive and cohesive biodefense strategic plan from the Executive Branch, as well as extensive cross-committee jurisdiction that often dilutes congressional focus.

This chapter addresses coordination and accountability in the following areas:

I. The Imperative for Cogent Governance
II. Improving Intelligence Community Efforts
III. Recognizing and Institutionalizing the One Health Concept
IV. Coordinating Medical Countermeasure Efforts
V. Establishing an Attribution Apparatus
VI. Taking Charge of Decontamination and Remediation

I. THE IMPERATIVE FOR COGENT GOVERNANCE

NEED FOR A COORDINATING BODY AT THE WHITE HOUSE

To address cross-sectoral issues, organizations often form coalitions. Agencies within the federal government sometimes create coalitions of their own volition. However, competing priorities and demands more often dominate their day-to-day activities and drive them to operate independently. The White House has also established coalitions to achieve certain aims, but

these efforts to obtain consensus have at times resulted in diluted strategies and plans that all stakeholders can agree on but which do little to move the needle.[34]

As many as a dozen departments and agencies participate in biodefense,[35] a mission space with governmental and nongovernmental members and activities authorized, ordered, and guided by various statutes, presidential directives, and other policy documents. Some of these departments and agencies show substantial initiative and execute on big or important ideas in biodefense; others work in a supportive capacity; still others engage temporarily, sporadically, or with limited enthusiasm. More than fifty political appointees[36] have been given some part of the biodefense mission, but largely act independently. Because of the scope of this scheme, these appointees often have little awareness of similar or potentially synergistic activities throughout the federal government, creating an inefficient and costly system that may not meet overarching mission objectives. A much more coordinated approach is called for to leverage the resources of the Nation that exist beyond those of the federal government.

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, territories, tribes, and industry. Such an approach can help smooth the competing priorities and demands that drive organizations to operate independently.

ACTION ITEMS:

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.

b. **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.[37]

c. **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.

A SINGLE, COMPREHENSIVE, AND HARMONIZED STRATEGY IS NEEDED

The sheer number of federal documents that address biodefense indicates significant interest in the subject and intent to deal with it through statute and executive direction (Table 2). In addition to or as a result of the documents listed in Table 2, the Executive Branch has promulgated numerous other policy and planning documents, which only add to the spectrum of requirements.

These include the National Strategy for Pandemic Influenza (2005) and its associated Implementation Plan (2006); the updated National Response Framework (2008), its Biological Incident Annex, and other associated annexes;[38] the 2014 PHEMCE Strategy and Implementation Plan (2014); and the National Strategy for Countering Biological Threats (2009). Together, these provide a foundation for federal biodefense activities. But the large number of documents reflects a system that has become too fragmented to be enforced and implemented in a coherent, prioritized, and unitary fashion. Biodefense for the 21st Century (HSPD-10) was the most comprehensive strategic biodefense document at the time it was drafted. Defense of United States Agriculture and Food (HSPD-9), however, was issued independently and the two directives are distinct. HSPD-10 is now more than a decade old and numerous other related policy directives have been issued and important programs begun since then. The National Strategy for Countering Biological Threats, which by title sounds like a comprehensive document, is actually more focused on supporting a subset of mission areas outlined in HSPD-10, largely with respect to international efforts.

Operating in the absence of a comprehensive biodefense strategy has made the need for comprehensive biodefense planning clear. Many additional planning documents often only address isolated elements of biodefense (e.g., post-exposure prophylaxis for certain bioterrorist agents) or individual diseases (e.g., pandemic influenza) and are not always incorporated into broader plans. Additionally, many of the plans developed over the past decade used models of naturally-occurring infectious diseases rather than weaponized pathogens.[39] DHS, DOD, HHS, and USDA made assumptions about the time and resources needed to treat severely ill persons and animals exposed to biological agents, but have not reexamined these suppositions in light of recently declassified information from the U.S. biological weapons program.

The lack of a comprehensive, cohesive, and regularly updated strategy has resulted in disorganization and confusion, particularly as Administrations change and the institutional knowledge associated with them is lost. Biodefense planning has become driven by agencies with requirements that may or may not meaningfully contribute to national biodefense. A single, comprehensive, and harmonized strategy to pull these myriad documents together is lacking.

TABLE 2: EXAMPLES OF BIODEFENSE DIRECTIVES, PUBLIC LAWS, AND TREATIES[40]

PRESIDENTIAL DIRECTIVES

- National Security Decision Memorandum (NSDM) 35 (1969)
- NSDM- 44 (1970)
- HSPD 4, the National Strategy to Combat Weapons of Mass Destruction (2002)
- HSPD-7, Critical Infrastructure Identification, Prioritization, and Protection (2003)
- HSPD-8, National Preparedness (2011)
- HSPD-9, Defense of United States Agriculture and Food (2004)
- HSPD-10, Biodefense for the 21st Century (2004)
- HSPD-18, Medical Countermeasures Against Weapons of Mass Destruction (2007)
- HSPD-21, Public Health and Medical Preparedness (2007)
- Presidential Policy Directive 2, National Strategy for Countering Biological Threats (2009)

PUBLIC LAWS

- The Biological Weapons Anti-terrorism Act of 1989 (P.L. 101-298)
- The Chemical and Biological Weapons Control and Warfare Elimination Act of 1991 (P.L. 102-182)
- The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (P.L. 107-56)
- The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188)
- The Homeland Security Act of 2002 (P.L. 107-296)
- The Project BioShield Act of 2004 (P.L. 108-276)
- The Pandemic and All-Hazards Preparedness Act of 2006 (P.L. 109-417)
- Implementing Recommendations of the 9/11 Commission Act of 2007 (P.L. 110-53)
- The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5)
- A multitude of appropriations laws that contain additional requirements

INTERNATIONAL TREATIES, PARTNERSHIPS, AND INSTRUMENTS

- Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (1974)
- The Australia Group (1985)
- United Nations Security Council Resolution 1540 (2004)
- International Health Regulations (2005)
- Global Health Security Agenda (2014)

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.

ACTION ITEMS:

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 introduced, and naturally occurring biological threats.

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 catalogue 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.[41]

c. **Assess spending history and value.** The Director of OMB 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.

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.

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.

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.

UNIFYING THE BIODEFENSE BUDGET

Nearly $80 billion was spent on biodefense from FY2001 through FY2014.[42] The majority of this was put toward multi-hazard programs and about 10 percent toward biodefense-only initiatives. Allocations for individual programs or mission spaces have risen and declined depending on the circumstances of the day, but in general, about $6 billion is annually spent on biodefense and related hazards. It is difficult to determine the adequacy of this funding level in the absence of an interagency biodefense strategy and a unified biodefense budget.

Awareness on the part of OMB of budgetary requirements and expenditures does not empower any part of the Executive Branch to control, coordinate, or prioritize biodefense activities. There is no unified concept or determination of what is meant by biodefense, leading OMB, House and Senate Committees on Appropriations, and private sector organizations to calculate differing budgetary totals. While some aspects of organizational budgets and appropriations bills are classified and many biodefense activities overlap with non-security public health efforts, these are not reasons to give up on determining how much is and should be spent on each element of biodefense. A unified approach to budgeting would enhance congressional oversight and allow the White House to better determine whether ongoing programs are aligned with the President's priorities. Additionally, many biodefense activities would greatly benefit from multiyear funding. The biodefense enterprise is no different from the national defense enterprise, which receives multiyear funding for a variety of its programs.

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.

ACTION ITEMS:

a. **Develop and execute a mandatory annual biodefense call for data.** The President and congressional appropriators should require the Director of OMB 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.

b. **Conduct a cross-cutting biodefense budget analysis.**[43] Using the information collected in the data call, the Vice President and the Director of OMB 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.

c. **Align budget items to the National Biodefense Strategy of the United States of America**. The Director of OMB 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 cross-cut.

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 OMB determine would benefit from such forward funding. Additionally, departments and agencies should provide multi-year grants, contracts, and/or cooperative agreements wherever possible.

MORE COMPREHENSIVE OVERSIGHT IS NEEDED

Congressional oversight, appropriations, authorizations, and investigations of Executive Branch activities are essential. The 9/11 Commission and the WMD Commission recommended that Congress reform its dysfunctional homeland security oversight system. To this day, that oversight remains fragmented across at least 108 committees and subcommittees that claim some authority through Senate and House rules for homeland security oversight.[44] In biodefense, about two-dozen committees have authority for oversight, with one to two subcommittees per committee maintaining specific purview. Actual oversight, however, seems to occur among only a handful of interested committees. While this can prevent oversight discordance, it also means that some important activities escape congressional oversight altogether.

Frequently, the topics that the more active committees assess (e.g., threat awareness, biosurveillance and detection, MCM) comprise only a small subset of the broad range of issues that require substantial oversight. With some notable exceptions, most of the oversight (particularly through hearings) that occurs is in reaction to an event. Proactive oversight agendas are limited. The most common topics are frequently conducted as post hoc reviews of major missteps of federal program execution or how the government is managing current outbreaks. Many of the issues that deserve more congressional oversight are discussed in this report, and include IC activities to address the biological threat, adequacy of funding, animal disease surveillance (particularly zoonotic diseases), challenges in biological attribution, and military/civilian collaboration in biological research and development (R&D). Congress must exercise its authority on these issues more proactively, comprehensively, and in a coordinated manner.

Lacking an end-to-end strategy for biodefense, however, Congress must guess how responsibilities and requirements should fit together. This makes effective oversight much more difficult. Further, the extensive cross-committee jurisdiction described can dilute Congressional focus. The problem is less that there are too many committees exercising oversight jurisdiction, and more that they need to exercise that jurisdiction more frequently. Congress needs to lean forward, determine in which areas it has neglected oversight, develop a dedicated oversight agenda, and exercise it to ensure the entire biodefense mission space is addressed. (See Appendix A for suggested topics for the congressional oversight agenda.) Finally, Members of Congress are often insufficiently briefed on the threat, and as a result, may not deal with it urgently. This must change.

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.

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.

II. IMPROVING INTELLIGENCE COMMUNITY EFFORTS

The IC is addressing the biological threat, but overall, the Community is unable to adequately collect and analyze intelligence due to insufficient resource allocation. The priority level placed on addressing the threat is not high enough to warrant the reallocation of resources (including human) necessary for increased collection, analysis, and distribution. This means that the Director of National Intelligence (DNI) is unable to dedicate sufficient human and other resources, enable IC agencies to establish or maintain relationships necessary for collection, or develop new strategies to gather information. The efforts the IC has been able to execute thus far are not well coordinated, with various agencies addressing different aspects of the threat. Additionally, the IC has taken some information that bystanders (those who are near to malevolent actors but are not directly involved in their actions) may possess into consideration, but has not been able to institute a full-scale program dedicated to this collection. For these reasons, the IC has not produced the sort of comprehensive analysis of the biological threat that it has for other threats.

Recommendation 6

Improve management of the biological intelligence enterprise. The Director of National Intelligence (DNI) should address the biological threat in the same way that other issues have been handled that cut across multiple intelligence agencies.

ACTION ITEMS:

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

b. **Make biological weapons programs and related activities a discrete intelligence topic.** The DNI should ensure that the IC assigns priorities to countries and non-state actors as they relate to biological weapons programs and activities. The IC should broaden focus to address classes of biological agents, as opposed to individual diseases. The IC 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.

c. **Address bystanders.** The DNI should ensure that the IC develops intelligence collection strategies that address bystanders, who may be able to provide useful information.

d. **Distribute assessments.** The DNI should ensure that the IC 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.

III. RECOGNIZING AND INSTITUTIONALIZING THE ONE HEALTH CONCEPT

Among the bioterror threats for which DHS has issued a Material Threat Determination (MTD), all, except for smallpox, are zoonotic, meaning that they reach human beings through animals. The same holds true with the threat of emerging infectious disease.[45] Sixty percent of infections due to emerging infectious diseases are leaping into the human population via animals (with 72 percent of these coming from wildlife) and at an accelerating rate.[46]

HSPD-10 requires disease surveillance of and detection in both human and animal populations. Divisions between human and animal health are artificial, since most pathogens of concern often affect both. Viewing them as parts of a whole is what defines a One Health approach to healthy populations. Together, human, animal, and environmental health comprise a dynamic and interconnected system that requires leadership and a strategic and coordinated approach to pull together traditionally fragmented divisions of expertise, responsibility, and authority while working effectively at the human-animal interface.[47]

Efforts to achieve human health must be grounded in an ecological understanding of the entire health picture. While there has been some good work toward this end – for example, the development of a Rift Valley Fever vaccine for ruminants that in turn helps prevent transmission to humans – conversations about the protection of human health by controlling or avoiding emerging infectious diseases in an animal host are in general extremely limited. This is likely due to the

distributed nature of health-related responsibilities across the federal government, with a given department or agency typically supporting either human health or animal health, but not both (and with wildlife authorities rarely included at all). This is also due to the lack of leadership vision to recognize the interconnectedness of health across species.

Inadequate attention and funding is even more severe in the animal and environmental health sectors than in public health. It is hard to believe that the United States lacks a nationally reportable list of animal diseases in domestic and wild animals comparable to that for humans. The USDA does require the reporting of foreign animal diseases (e.g., foot-and-mouth disease), and the United States participates in reporting of animal diseases to the World Organization for Animal Health (OIE). Yet reporting for domestic animal diseases is not required. Such a system would allow much greater information availability and coordination of effort across the government and with non-government stakeholders. In 2014, the USDA published a concept paper on what such a reporting system would look like.[48] It is time to move from concept to implementation. Reporting of animal diseases would allow for quicker response, reduced impacts on animal and human health, and better informed priorities regarding livestock infectious diseases.

A One Health approach can also inform priorities for human infectious diseases. When it became clear in 2014 that no countermeasures for Ebola were ready for the largest Ebola outbreak the world had ever seen, many policy conversations that followed were about priorities. We must have a means of determining what to fund with finite resources. The threats and risks among agents of both bioterror and emerging infectious diseases are equally serious. MTDs have been very important for the prioritization of activities around biodefense, yet there is no analogous prioritization system for emerging diseases.

The only way to direct multi-agency resources to where they are most needed, and to prevent the now-common approach of governing reactively through emergency supplemental funding, is to approach emerging infectious disease threats more strategically. Creating an emerging infectious disease priority list meaningful enough for utility across biodefense efforts and flexible enough to meet unexpected threats and the emergence of new diseases will not be easy. An inflexible list could allow unexpected and novel pathogens to blindside biodefense efforts. Different agents have drastically diverse effects on human health, human psychology, animal health, the environment, and the economy. Therefore, different stakeholders will place varying values on each pathogen.[49]

When developed correctly with built-in flexibility, however, an emerging infectious disease priority list could help drive an organized and strategic approach to biodefense. Information of the kind that programs like the U.S. Agency for International Development's EPT PREDICT program afford is critical to the integrity of any such listing. A careful, thoughtful, adaptable, and transparent approach to developing the prioritization methodology is also important, as is a methodically developed and highly deliberate effort to consider the public health, economic, and security implications of a spectrum of pathogens and pathogen groups.

Recommendation 7

Integrate animal health and One Health approaches into biodefense strategies. Effective solutions for defense against emerging infectious disease and bioterror threats lie at the interface of human, animal, and environmental health.

ACTION ITEMS:

a. **Institutionalize One Health. T**he 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.

b. **Develop a nationally notifiable animal disease system.** The Administrator of the USDA Animal and Plant Health Inspection Service (APHIS), working with the Director of the Department of the Interior (DOI) 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, territories, tribes, and other owners of disease information. USDA should afford DHS, HHS, and other agencies engaged in biodefense access to the data in this system.

c. **Prioritize emerging and reemerging infectious diseases.** 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, MCM development, and any activities revealed as gaps per action item 3e.

IV. COORDINATING MEDICAL COUNTERMEASURE EFFORTS

NIH is a basic research institution, created more than a century ago to organize the medical research efforts of the federal government.[50] The culture of basic research at NIH is distinct from the applied research culture of the Biomedical Advanced Research and Development Authority (BARDA). This poses a challenge to interagency coordination, but one that is surmountable.

Per HSPD-10 and the Project BioShield Act of 2004 (P.L. 108-276), NIH must work with DHS, DOD, and other agencies to shape and execute an aggressive MCM research program. The establishment of the PHEMCE, an interagency coordinating body, has enabled better coordination along these lines, but it is still not optimal, particularly in terms of aligning NIH and

BARDA. The lack of coordination and focus speaks to the critical need to fashion a national strategy that establishes national funding priorities, not institutional ones. NIH's National Institute of Allergy and Infectious Diseases (NIAID) conducts research that is exceptionally important to defense against biological terrorism and emerging infectious diseases. All NIAID biodefense research, however, must be conducted with a transparent and strategic connection to end-user requirements.

Federally-funded scientific investigators are more likely to engage in early stage research, rather than to use the more private sector approach of focusing on specific product goals and end-user needs. This is one reason that Ebola MCM were not available when they were needed. In order to construct and implement an overarching vision, the PAHPA required a PHEMCE strategy and implementation plan, as well as a coordinated five-year budget plan that would update Congress and stakeholders on the entire MCM enterprise. This includes: basic research at NIH; advanced R&D at BARDA; approval, clearance, licensure, and authorized use of products; and procurement, stockpiling, maintenance and replenishment in the Strategic National Stockpile (SNS) at CDC. The 2014 PHEMCE report and multiyear budget described roles for each department and agency and how they would meet PHEMCE's overarching goal to supply civilian MCM. Congress must conduct the detailed oversight that is necessary to ensure that these goals are being met.

NIH receives more than a billion dollars for biodefense annually ($1.7 billion enacted in FY 2014 for the PHEMCE portfolio), primarily administered by NIAID for early stage R&D. Of the $1.7 billion at NIAID, only 15 percent ($257 million) is spent on agents determined to be material threats. Further, only $415 million is provided to BARDA annually for advanced development of biodefense MCM candidates.[51] It is unclear why advanced development – the far more costly stage of MCM development – is funded at a fraction of the amount of early R&D. The biopharmaceutical industry invests more than half of its budget in advanced development, while at DOD the number is only about 30 percent, and at HHS, only 10 percent.[52] Investment strategies must match product development goals. The PHEMCE has worked to address this by submitting a multiyear budget to Congress, in which NIAID spending was included. The level of detail, however, offers limited insight into NIAID's specific spending priorities for the numerous MCM candidates in its portfolio.

Recommendation 8

Prioritize and align investments in medical countermeasures among all federal stakeholders. The success of the MCM enterprise will be predicated on a highly coordinated approach among the PHEMCE partners to prioritize and budget for the right countermeasures.

ACTION ITEMS:

a. **Ensure National Institutes of Health research supports civilian medical countermeasure priorities.** The Vice President should ensure that PHEMCE priorities, as well as those agents that have been determined to be material threats, guide NIH biodefense research investments and ensure delivery of MCM candidates that address PHEMCE MCM priorities.

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 an MTD, and the proportion of funding allocated for early R&D of MCM candidates versus advanced R&D, 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.

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

V. ESTABLISHING AN ATTRIBUTION APPARATUS

The ability to attribute crimes to their perpetrators is a necessary component of effective prosecution. Attribution is a challenge in any context, and becomes increasingly difficult with the involvement of numerous investigators and when unusual or novel weapons are used to execute crimes. This is the case with biocrimes, biological terrorism, and biological warfare. When biological agents are used for attacks, not only must crimes be attributed to particular perpetrators, but the pathogens and their sources must also be correctly identified. The United States has yet to fully establish this capability due to the inherent challenges associated with microbial forensic techniques and related analysis.

The law enforcement and public health communities have clear responsibilities for the investigations that fall under their respective domains. The intelligence, defense, and scientific communities also have important roles to play. Some excellent work, largely initiated by the Federal Bureau of Investigation (FBI), has established cross-pollination among these communities. Yet the work is complicated. Representatives from these groups must align and support one another's investigations. This must occur despite differences in information sharing norms and requirements among these communities, and there being no single community that is in charge of the others for the purposes of attribution. Compounding

this challenge is the occasional addition of other communities (e.g., agriculture, commerce, homeland security, wildlife) as well as classification issues that result in some duplication of effort and parallel activities. The need for close coordination and collaboration is clear, but arrangements among all of these communities have yet to be formalized. Further, each of the principal agencies in these communities lacks the resources, processes, and infrastructure necessary to establish a system that meets the variety of tactical, operational, and strategic needs for attribution.

There is also no formal decision-making apparatus in place to assist leaders in addressing biological crimes and other events. The informal system lacks standards for and burdens of proof; requirements for source information; and standards for acceptable evidence, information, and intelligence. Response exercises rarely take attribution into consideration.

The National Bioforensics Analysis Center (NBFAC), part of the DHS National Biodefense Analysis and Countermeasures Center, conducts technical analyses in support of federal law enforcement investigations and attempts to coordinate multi-agency biological forensic efforts. The NBFAC has not become the resource for biological forensics the Nation needs. The DHS Science and Technology (S&T) Directorate (which administers the NBFAC) has struggled to coordinate with and serve other agencies, because it is not an operational organization and because its scientific goals sometimes run at cross-purposes to those of the operational communities it could serve. As a result, agencies sometimes decline to work with or utilize NBFAC. The FBI is by far the primary user of the NBFAC, and the facility should have been under the purview of the FBI from its inception.

Recommendation 9

Better support and 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 analysis. There is no formal apparatus that uses attribution information to inform decisions.

ACTION ITEMS:

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 DNI 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.

b. **Place the Federal Bureau of Investigation in charge of the National Bioforensics Analysis Center.** The FBI is the primary customer of NBFAC and has the needed credibility and influence to allow NBFAC 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 NBFAC, its administration, and its activities, including interagency support and coordination. Congress should reallocate appropriations accordingly. Congress should also increase its oversight over NBFAC activities.

VI. TAKING CHARGE OF DECONTAMINATION AND REMEDIATION

NEED FOR ADDITIONAL RESEARCH

Environmental remediation is the application of countermeasures to eliminate an agent from a geographically defined area. Additional research is needed to develop standards and protocols for the elimination or reduction of new infections caused by pathogens hiding in a particular environment. Natural environments are not pristine and often contain microbes at low levels tolerated by humans. Returning an environment to its baseline level after an event cannot be accomplished without first having measured the baselines, and this has not been systematically attempted. Further, while the Environmental Protection Agency (EPA) has issued some remediation guidance,[53] it seems no agency is statutorily responsible for deciding when an affected area has been sufficiently decontaminated, remediated, and cleared for re-occupancy.

Decontamination is also an issue in need of substantial additional effort. The Executive Branch is aware of this and a number of departments and agencies coordinate with each other and collaborate with the Office of Science and Technology Policy (OSTP) to study environmental decontamination and remediation.[54] For example, a number of government agencies have collaborated to study remediation needs according to certain scenarios. Unfortunately, the results of these studies are of limited utility because many of these scenarios were extremely specific and cannot necessarily be applied to the wide variety of potential biological agents that could be used in an attack. Additionally, OSTP has since determined that research using disease- and scenario-specific approaches to determining remediation requirements is extremely costly.

The DHS S&T Directorate and Office of Health Affairs (OHA) partner with OSTP to conduct studies to determine post-biological event environmental decontamination and remediation requirements. Yet environmental remediation is an element of recovery, an aspect of emergency management addressed by the Federal Emergency Management Agency (FEMA). Further, the release of biological agents may also create an emergency in a locality that may qualify for FEMA grants and other assistance. For these reasons, FEMA should also be at the table for these OSTP conversations and studies.

DOD and EPA conduct research in this area, with more limited efforts undertaken by other agencies (e.g., DHS, HHS, USDA). Both civilian and military programs are challenged by insufficient funds, increased resistance of microbes to materials and treatments that would be used to decontaminate and remediate the environment after the release of biological agents, the

large number of organisms that could be used in biological weapons, and the potential for those weapons to end up in a variety of environmental contexts, from air to water to soil.

NEED TO MANDATE RESPONSIBILITY FOR ENVIRONMENTAL DECONTAMINATION AND REMEDIATION

The EPA often inspects areas for accidental releases of biological agents and requests have been made of the Agency to conduct environmental decontamination and remediation following biological releases. The collection of environmental specimens to inform these activities can be difficult, however, when the EPA works with others (who may not be sufficiently trained) to collect environmental samples in support of these activities.[55] The EPA also uses a lengthy process to determine whether it should take responsibility for remediating an environment that has been contaminated with biological agents. This is because the EPA's history of holding companies responsible for having released contaminants into the environment (e.g., Superfund activities) does not align well with biological releases. The EPA may decide it should not remediate an area itself, instead providing options for decontamination and remediation that can be executed by others, including non-federal governmental agencies, academia, and industry. However, areas remain contaminated and unsafe during the time it takes to make a decision.

Recalling that the EPA initially balked at taking responsibility for remediating the congressional offices that were affected by the anthrax events of 2001, it is still unclear exactly who should be held responsible for environmental remediation when biological agents have been released accidentally or intentionally. Cost is a significant factor (e.g., estimates for the remediation of the Brentwood postal facility were as high as $130 million more than ten years ago[56]). There is no funding held in reserve for bioremediation by the EPA or any other agency. Some agency must be made responsible for biological environmental remediation and for coordinating similar and contributing efforts by other federal agencies. HSPD-10 states that the EPA coordinates with other departments and agencies in developing standards, protocols, capabilities, strategies, guidelines, and plans – but it does not make the EPA responsible for conducting biological remediation or decontamination, or for coordinating efforts with other agencies to do so.

NEED FOR COORDINATED EFFORTS TO MONITOR HEALTH AND THE ENVIRONMENT AFTER EXPOSURE

Long-term monitoring is needed to ensure that pathogen contamination is reduced or eliminated, and that those affected (i.e., humans, animals, plants) are not re-exposed, do not suffer initially unnoticed reactions to the pathogens, and have not become pathogen reservoirs. Long-term monitoring of health has been undertaken for those exposed to a variety of contaminants during 9/11 response and recovery operations. However, the opportunity to participate in similar studies was not offered to those potentially exposed to anthrax on Capitol Hill in 2001. If there were any low-level immunological responses to the use of this biological agent, they were likely missed because no one was looking for them.

Some monitoring is undertaken after confirmed or suspected exposure, but not necessarily as a matter of policy or urgency. DOD monitors some military personnel exposed to a variety of contaminants. Other agencies (e.g., DOI, HHS, USDA) also monitor personnel exposed to pathogens in the course of their work, but only when the need seems dire. We are wasting the opportunity to ensure human and animal health and a clean environment, and to gather data on how biological agents impact health and the environment. Exposed individuals deserve better than to discover that they have been infected, or that countermeasures are not working, only after they have become obviously ill.

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, bioterror threats, and emerging infectious diseases.

ACTION ITEMS:

a. **Include the Federal Emergency Management Agency in efforts to address remediation.** The Vice President should ensure that FEMA is included in interagency efforts led by OSTP and other federal efforts to study and determine policy regarding remediation after biological attacks.

b. **Assign responsibility to the Environmental Protection Agency for environmental decontamination and remediation.** Congress should amend the National Environmental Policy Act of 1969[57] to place the Administrator of the EPA 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.

c. **Conduct studies of those exposed to disease-causing agents.** The Vice President and Congress should require the Secretaries of DOD, DOI, HHS, USDA, and the Department of Veterans Affairs (VA) 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.

CHAPTER 2: THE NEED FOR LEADERSHIP IN ELEVATING COLLABORATION

Recognizing that complex policy problems cannot be addressed by a single agency, the GPRA Modernization Act of 2010 (P.L. 111-352) required all federal agencies to collaborate on everything from information sharing to operations.[58] Applied to biodefense, the paradigm described must move beyond federal agencies and out to other levels of government and nongovernmental stakeholders.

While some activities are inherently federal, many of the most complex policy problems require input from and actions by these non-federal stakeholders to achieve success. Biodefense is an excellent example of such a complex policy problem. State, local, territorial, and tribal governments and nongovernmental partners carry out many critical biodefense activities from preparedness to recovery, but are often not consulted during policy development.

The federal government must also drastically increase the support provided to jurisdictions to allow them to build and sustain their biodefense capabilities. The rapid and accurate identification of pathogens moving through humans, animals, or the environment is a foundational capability, yet significant advances in biosurveillance and detection remain elusive because of technological barriers and bureaucratic challenges to effective collaboration and cooperation. The emergency services sector has been calling for increased support for some time, especially in terms of protective measures and access to threat information. Dwindling federal financial support has left hospitals and local health departments unable to fully prepare to serve their communities. Local communities are struggling to assure their populations that they can deliver the contents of the SNS quickly in a public health emergency. Finally, private and academic laboratories and other stakeholders struggle to prevent cybersecurity breaches to databases containing sensitive pathogen information.

Collaboration among industry, academia, and local health authorities – and a leader, such as the Vice President, who is willing to promote and hold federal agencies accountable for this collaboration – are needed to overcome these challenges.

This chapter addresses collaboration in the following areas:

I. Achieving an Integrated Biosurveillance and Biodetection Capability
II. Supporting Emergency Preparedness
III. Creating Incentives for Hospital Preparedness
IV. Advancing Planning for Medical Countermeasure Distribution and Dispensing
V. Dealing with Cyber Threats to Pathogen Security
VI. Reengaging with the Biological and Toxin Weapons Convention
VII. Moving Beyond Defense Support to Civil Authorities

I. ACHIEVING AN INTEGRATED BIOSURVEILLANCE AND BIODETECTION CAPABILITY

Surveillance and detection are the means by which we achieve the earliest possible situational awareness for biological events that affect people, animals, the food supply, and the environment. They are fundamental capabilities that enable us to prevent or mitigate the consequences of these events. They also enable protection of national and local critical infrastructure, and support response and recovery operations.

Optimal surveillance and detection require a nationwide array of sensors and detectors at many levels, interconnected and working in parallel. This system must be expansive and address many aspects of disease spread, including human health (e.g., clinical, diagnostic), animal health (e.g., livestock, wildlife, companion), and sociocultural events (e.g., mass gatherings, burials). Surveillance and detection systems need to work quickly, indicating the presence of an agent in hours, not days or weeks. Such a capability can usefully inform rapid response operations, saving lives and other resources. Along with this capability, methods for information sharing between surveillance and biodefense partners are also needed. Many stakeholders could benefit from improved communication and real-time awareness.

HSPD-10 described ongoing federal efforts in 2004 to develop "an integrated and comprehensive attack warning system to rapidly recognize and characterize the dispersal of biological agents in human and animal populations, food, water, agriculture, and the environment." At the time this system was proposed, it was bold, far-reaching, and necessary. Attempts thus far to accomplish it have been timid, narrow, and unsuccessful. As of 2015, the United States still lacks a nationwide, population-based disease surveillance system for human health. This is unacceptable.

The White House has failed to prioritize integrated biosurveillance and Congress has failed to mandate interagency participation, causing this insufficiency. As a result, an implementation plan to establish this capability has not yet been issued. Although the National Strategy for Biosurveillance was issued in 2012, it was very high level and lacked an accompanying implementation plan. The White House has drafted the plan, but as of publication of this report, has not yet released it. Without such a plan, interagency coordination and stakeholder involvement are far from optimal. The delay is likely due to the extreme interagency and stakeholder difficulties with information sharing, and insufficient leadership to make solving those difficulties a priority.[59]

Recommendation 11

Implement an integrated national biosurveillance capability. The White House must finalize and release the implementation plan for the National Strategy for Biosurveillance.

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, territorial, tribal, 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 current U.S. system consists of myriad surveillance and detection systems, operated by numerous agencies at many levels of government and within the private sector, with some working better than others and many not communicating with one another. Lower-level reporting into government systems – the key to early disease identification – is often delayed or provides too little data to provide real-time warning. Additionally, existing systems do not necessarily support existing response concepts of operations. For instance, the current system of syndromic surveillance – that which depends upon open source information, voluntary reporting of protected data, and astute clinical identification – lags behind the precise and timely communication of information needed to adequately support rapid response.

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, territorial, and tribal jurisdictions, as well as non-governmental stakeholders.

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 partners. This group will clarify and coordinate the response and recovery goals, objectives, and activities of federal, state, local, territorial, and tribal agencies and non-governmental partners following the determination that a biological event has occurred.

By statute, DHS is charged with "integrating and analyzing data relating to human health, animal, plant, food, and environmental monitoring systems."[60] The National Biosurveillance Integration System (NBIS) was envisioned to fulfill this charge and to provide early warning. Despite the best of intentions, DHS has been unable to meet this mandate, in large part because other federal agencies were not required in the statute to share data or information with DHS. For example, NBIS does not have real-time access to CDC syndromic data, USDA food animal epidemiologic data, or VA hospital data. Laboratory data are only incorporated insofar as information is reported by state, local, territorial, and tribal departments of health into other systems that feed NBIS. Plenty of data are available, but agencies have little impetus for voluntarily sharing it, and no leader is forcing the issue. DHS continues to pursue access to this information, but is years behind where Congress and the Administration expected the system to be.

The lack of required interagency sharing of surveillance data means that NBIS can only function properly if the White House forces it to work. Without a strong and enforced executive order requiring agencies to cooperate on biosurveillance and detection, share data, and staff such a venture comprehensively, NBIS will continue to fail to fulfill its mandate.

Sensitive and specific biosurveillance can be attained only through a distributed network of activities. Medical records, clinical laboratory data, food recall data, human and animal pharmaceutical consumption, food and animal health surveillance, and water and air quality monitoring are examples of existing troves of data that could be shared with NBIS with the necessary leadership, correct approach, and comprehensive agreements. In return, the data owners could receive aggregated NBIS data, analyses, or other incentives.

A process must be put in place to provide for such mutually beneficial data sharing. Ownership is a barrier to interagency and private-to-public data sharing, but this challenge is not insurmountable. The collection and sharing of data in support of data owners' daily business processes – access to analytics, awareness of big-picture trends – could provide incentives to data owners to participate. Pilot programs have successfully shared surveillance and detection data within a limited number of states. The trusted third party model may also be successful for information sharing. Under this model, an independent third party builds trust, and coordinates data sharing and administration of a cloud-based temporary data storage system designed to feed into a national biological common operating picture. No government ownership or long-term data storage on government servers occurs in this model, which should help satisfy many of the concerns of data owners.

Recommendation 13

Optimize the National Biosurveillance Integration System. NBIS must be optimized to meet its potential as both an early warning and a situational awareness system capable of working across the interagency.

ACTION ITEMS:

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 NBIS 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.

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 NBIS, or a different construct as determined by the NSC and Congress.

Animal health surveillance should not be segregated from the model of comprehensive biosurveillance described. What if, instead of simply identifying the location of an insidious zoonotic outbreak, one could identify its reservoir, the place in the animal world where it is hiding?

Livestock health surveillance is currently performed for the benefit of agriculture and food animal production. These data are typically unavailable on a regular basis to federal agencies with surveillance responsibilities outside of the USDA. Likewise, systematic collection of companion animal health data that would help detect any significant changes in the prevalence of zoonotic illness relevant to human health is almost entirely lacking. Enormous volumes of data exist, such as through franchised veterinary hospital systems with electronic medical records, and veterinary diagnostic laboratories, but these are untapped resources. Similarly, surveillance data of wildlife infectious diseases are collected disparately among federal agencies, non-federal governmental agencies, universities, and nongovernmental organizations. Their programs are not currently designed to provide comprehensive biosurveillance, nor to generate readily available information for other federal agencies with surveillance responsibilities.

The National Animal Health Laboratory Network (NAHLN), an effort to detect biological threats to the Nation's food animals, is necessary for effective biosurveillance. The NAHLN is a public-private cooperative effort between the USDA, the American Association of Veterinary Laboratory Diagnosticians, and publicly funded state veterinary diagnostic laboratories. The collective and integrated work of its members allows for improved detection of emerging and zoonotic diseases, which helps protect animal health, public health, and the food supply. The veterinary diagnostic labs that are members are quite literally on the front lines of disease detection. Established in 2002, the NAHLN is funded through a combination of grants, fee-for-testing services, and administrative support from USDA. It has struggled to maintain even $10 million worth of annual funding, its appropriations cut over the years to pay for other programs. As a result, the laboratories are unable to meet the threat and have at times eliminated positions and testing capacity for foreign animal diseases. Ten million dollars is a very small price to pay to protect one of America's major industries and portals for disease emergence. After the NAHLN struggled for years to obtain sufficient funding, in 2014 Congress authorized a specific funding line at $15 million per year.[61] NAHLN must be funded to this authorized level in order to meet the need.

Finally, although the establishment of policies to guide the emergency management of companion animals was strongly pursued following Hurricanes Katrina and Rita, there is little evidence of infectious disease management guidance and planning for animals following the Ebola crisis. The cost of quarantine and care for a single dog in Texas suspected of Ebola exposure was nearly $27,000.[62] No formal, federal collaborative efforts are in place to develop plans or guidance that meaningfully and comprehensively incorporate policies, procedural recommendations, and requirements for dealing with a zoonotic infection that may be borne by dogs, cats, other companion animal species, or wildlife.

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 it into analysis of human data. Agencies must also plan for major impacts of companion animal and wildlife zoonoses.

ACTION ITEMS:

a. **Increase opportunities for animal health data collection.** Congress should fund and facilitate enhanced opportunities for data collection at the livestock and wildlife levels via DHS, DOI, and USDA. The Secretary of Homeland Security, via NBIS, should further DHS collaborations with federal, state, local, territorial, tribal, and private sector entities that collect animal health data. Establishing partnerships with these stakeholders for data and information sharing will require incentives.

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 NAHLN at its authorized levels.

c. **Develop guidance for the serious implications of companion animal and wildlife zoonoses.** The Director of the CDC and the Administrators of FEMA and APHIS, in collaboration with non-federal stakeholders, should develop guidance for states, localities, territories, and tribes to handle companion animal infections in the event of a major zoonotic disease outbreak. States, localities, territories, and tribes can then base their own planning requirements on this guidance. Congress should amend the Robert T. Stafford Disaster Relief and Emergency Assistance Act[63] to require the Administrator of FEMA to ensure that state, local, territorial, and tribal emergency preparedness and response plans address the handling of zoonoses of companion animals and wildlife.

II. SUPPORTING EMERGENCY PREPAREDNESS

The Emergency Services Sector is a critical infrastructure sector that is the Nation's first line of defense for preventing, preparing for, responding to, and recovering from incidents of many kinds, including biological threats. This sector consists of law enforcement, fire and emergency

services, emergency management, emergency medical services, and public works. It is the sector responsible for the protection of the 15 other critical infrastructure sectors as defined by DHS.[64] While not included in the DHS definition, public health responders also provide critical emergency services following a biological threat. All of these responders are ready at any time to deal with an extraordinary number of potential incidents. While DHS, HHS, and other agencies have done good work to equip and train responders to address biological threats, gaps remain.

MEDICAL COUNTERMEASURES AND OTHER PROTECTIVE MEASURES FOR FIRST RESPONDERS NEEDED

Emergency services providers are subject to a disproportionate threat because they work in the midst of disasters.[65] Research demonstrates that communities will be at a disadvantage during a biological crisis if essential response personnel feel that they or their families are insufficiently protected.[66] For example, only 20 percent of paramedics in one survey said they would remain on duty without a vaccine and protective gear – a number that rose to 91 percent if these protections were provided.[67]

Any material threat to homeland security is a threat not just to the general population, but also to the responders who will serve them.[68] After an MTD was issued for anthrax, and because a vaccine was available in surplus, discussions began about whether this vaccine should be offered to first responders. Short-dated, surplus anthrax vaccine doses owned by the federal government expire by the hundreds of thousands each month and are discarded. A voluntary vaccination program for anthrax or other threats for which vaccines are available could boost preparedness and has had significant bipartisan support in Congress.[69] DHS has been formulating a pilot program to provide anthrax vaccine to emergency services providers for more than half a decade. In 2015, due to bureaucratic delays and inability to establish the needed occupational health system to administer such a program, there is still no program that provides this minimal protection to the protectors.

In addition to vaccines, the government could make available other MCM to emergency services providers. The CDC conducted a pilot in St. Louis, Missouri in 2005 to pre-position antibiotic kits (known as medkits) in the homes of emergency service providers. The goal was to provide protection for these responders and their families in the event of an emergency. The pilot was considered a success and demonstrated that these professionals could manage the kits without misusing them. Similar pilots with the U.S. Postal Service (USPS) proved the same. To date, these initiatives have not been implemented as programs, in part because some public health officials remain concerned about misuse. Although an FDA Emergency Use Authorization (EUA) or other means of temporarily eliminating regulatory hurdles would be required for medkits, the pilots demonstrate this can be done.

Non-pharmaceutical interventions are just as important. Recommendations regarding the type and use of personal protective equipment (PPE) to protect against biological events are available, and range from gloves and masks to military-grade protective over-garments. Most responders only possess the PPE necessary to operate within current community environments and only after decades of experiences with HIV and influenza. Specific standards or guidelines for PPE are still needed, and their development will require special attention to unique requirements of the various emergency services subsectors.[70]

Recommendation 15

Provide emergency service providers with the resources they need to keep themselves and their families safe. This will fulfill the Nation's commitment to these professionals while also helping to ensure their participation in the event of a biological emergency.

ACTION ITEMS:

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.

b. **Provide medkits to emergency service providers and their families.** The Director of the CDC, the Commissioner of the FDA, and the ASPR should finalize plans for prepositioning medkits with emergency service providers and their families, and request annual funding to implement the program.

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 (IOM) to examine current PPE research and requirements in light of potential biological threats. The IOM should conduct this assessment in conjunction with the National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration (OSHA), and representatives from all of the major emergency service associations.

THREAT INFORMATION INSUFFICIENTLY SHARED WITH EMERGENCY SERVICES

Emergency service providers might be able to better target their efforts to address biological threats and protect themselves if they had more information regarding the threat, relevant vulnerabilities, and potential consequences.[71] Yet much of the available information about current and potential biological threats is often classified. Recognizing this, the IC has attempted to declassify at least some of this information and provide it to non-federal governmental entities. For example, state, local, territorial, and tribal first responders and public safety professionals, as well as federal intelligence analysts from the National Counterterrorism Center, DHS, and FBI, are members of the Joint Counterterrorism Assessment Team (JCAT, resident in the Office of the DNI). The team strives to jointly research, produce, and disseminate counterterrorism intelligence to non-federal governmental entities.[72] Still, the federal government has found it difficult to overcome institutional prohibitions against sharing information with non-federal personnel. As a result, these programs do not function as originally intended.

Partly to solve this problem, some local police entities have developed their own intelligence function, allowing them to develop intelligence and distribute information to others within their locality. While police departments continue to develop and implement their own intelligence programs in various areas, these programs are far from ubiquitous and only address the biological threat in small part.

Recommendation 16

Redouble efforts to share information with state, local, territorial, and tribal partners. Emergency service providers are valid customers of threat-related information. The IC must recognize this, work to eliminate barriers, and share more information with the emergency services sector about the biological threat.

ACTION ITEMS:

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

b. **Strengthen the ability of local police intelligence units to address the biological threat.** The Attorney General and the DNI should share analytic methods relevant to these units to assist in the development of more robust and effective biological threat analysis.

c. **Enable fusion centers to address the biological threat.** The Administrator of FEMA and the DHS 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 partners.

EMERGENCY PREPAREDNESS SUPPORT FOR LOCAL HEALTH DEPARTMENTS CANNOT BE ALLOWED TO WANE

Infectious diseases impact national security and easily cross borders. Federal support for state, local, territorial, and tribal public health emergency preparedness is, therefore, a reasonable use of taxpayer dollars. The CDC's Public Health and Emergency Preparedness (PHEP) cooperative agreements are the primary avenue by which federal funding reaches state, local, territorial, and tribal health departments to support public health emergency preparedness. More than $10 billion has reached 62 PHEP jurisdictions since the program began in 2002.[73]

PHEP funds support activities such as the purchase of electronic disease surveillance systems, establishment of local emergency operations centers, expansion of laboratory infrastructure, hiring of epidemiologists and laboratorians, and training of employees in emergency response protocols. Although the biothreat has grown since 2002, the funding to address the potential impact of that threat through PHEP activity has declined relentlessly since its initiation (due to both decreased Presidential Budget Requests and reduced congressional appropriations). Since a high of $940 million in FY2002, the last appropriation (FY2015) was $661 million. The FY2016 request would further reduce that amount to $643.6 million.

Administrations have touted the success of the program while simultaneously scaling back their budget requests. Some federal grant programs have been grounded in the notion that the grants may be used to establish capabilities, at which point grantees can transition the funding responsibility for maintaining those capabilities to themselves. This is not a reasonable

concept for public health emergency preparedness. State, local, territorial, and tribal health budgets have been decimated since the financial crisis of 2008. Withholding dedicated emergency preparedness funds may preserve federal bottom lines, but it further diminishes national preparedness.

Recommendation 17

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

ACTION ITEM:

a. **Appropriate Public Health Emergency Preparedness funding to authorized levels or the President's request, whichever is higher.** Congress authorized $641.9 million per year from FY2013-2017.[74] Congress demonstrated a willingness to fund more than this in FY2015, and should at a minimum meet the President's request for FY2016. More importantly, the Administration and Congress should reverse the downward slide of funding for this program that is vital to supporting the activities of public health departments that benefit not only their own population centers but those of the entire country.

III. CREATING INCENTIVES FOR HOSPITAL PREPAREDNESS

Hospitals have received varying levels of support to prepare for biological events, especially bioterrorism and pandemic influenza. Prior to the establishment of the HHS Hospital Preparedness Program (HPP) in 2002, hospitals undertook preparedness activities,[75] but without dedicated federal funding. Since its inception, the HPP has been a small component of overall spending on hospital preparedness. While the HPP expanded in 2012 to include all healthcare facilities, funding was reduced to $250 million from an original appropriation of $645 million in 2003. OSHA has issued guidance for decades, and the Joint Commission (previously the Joint Commission on Accreditation of Healthcare Organizations), Det Norske Veritas, Health Facilities Accreditation Program, and Center for Improvement in Healthcare Quality – all healthcare accrediting agencies – have introduced preparedness criteria into their accreditation requirements. Additionally, hospitals have attempted to address preparedness for bioterrorism and other infectious disease events as part of their overall disaster preparedness.[76] Certain requirements associated with highly infectious diseases and low frequency biological events fit well within hospital disaster preparedness frameworks designed to address earthquakes, hurricanes, and other disasters, but other requirements do not.

HOSPITAL INFECTION CONTROL CHALLENGED BY EBOLA

During the Ebola outbreak of 2014, it became clear that hospital preparedness varied widely. A few hospitals were well prepared to serve as treatment centers for infected patients, but the vast majority of others were completely unprepared and struggled to catch up. Historically, OSHA has developed and issued PPE guidelines to hospitals, but in a sudden turn, the CDC did so regarding Ebola and without working with or adequately consulting OSHA. As a result, the guidelines initially issued by CDC were insufficient to meet the needs of hospitals. Flawed guidelines released by the CDC to hospitals (which addressed issues not under CDC purview, such as PPE and hospital operations), inadequate coordination between CDC and OSHA regarding federal messaging and waste management, poor training regarding the implementation of the requirements described in those guidelines, and insufficient attention paid to some potentially useful hospital disaster plans exacerbated already insufficient levels of preparedness. The prior operating assumption – that all healthcare facilities should prepare to manage patients instead of proposing a system for identification and transfer to special treatment locations – led to overwhelming resource and training requirements during the Ebola crisis. Although many hospitals became far more proficient and capable of handling Ebola patients, the passage of time since the last Ebola case and the lack of additional patients coming to the United States make it unlikely that the same level of serious infectious disease-specific proficiency will be maintained.

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 relevant 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.

ACTION ITEMS:

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 PPE, 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.

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, territorial, tribal, and private health care facilities, and meets at least weekly to evaluate, update, and reissue clinical guidance.

c. **Require training based on these guidelines.** The Secretary of Health and Human Service and the Secretary of Labor should regularly provide training for end users in the implementation of the guidelines.

OPTIMIZING HOSPITAL PREPAREDNESS FUNDING

Federal funding for hospital preparedness[77] represents approximately 1/100th of one percent of the Nation's total healthcare spending.[78] This relatively small amount of money, coupled with the need to coordinate across health care systems and communities, drove the development of hospital coalitions. Still, hospital coalitions have been unable to make up for insufficient funding.

In response to the Ebola events, HHS provided grants through HPP designed to help hospitals become more proficient in addressing Ebola.[79] The funding represents less than 12 cents per American over five years. As important as Ebola-related hospital preparedness funding has been, disease-specific funding is the most inefficient, costly manner in which to fund preparedness for biological events. Politically, reacting in this manner is an understandable result of needing to take some action. Practically, this reaction is unsustainable and it is unclear how much of a contribution disease-specific hospital preparedness grants will make to overall hospital preparedness.

The HPP has experienced progressively reduced funding, with the exception of the recent limited increases associated with Ebola. Further reducing the amount of HPP funding available, the ASPR routinely keeps back 7-10 percent of the grant funds for administrative expenses despite its receiving dedicated appropriations to fund its own operations.[80] No more than three percent of funds should go toward management and administration. The HPP has never received the full support it needs from Congress or presidential administrations since its inception. In order to determine how much HPP funding is necessary to ensure hospitals are prepared for biological and other events, a thorough evaluation of the costs, successes, and failures of the HPP is called for.

Recommendation 19

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

ACTION ITEMS:

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 HPP funds go directly to HPP grantees.[81]

b. **Assess the impact of the Hospital Preparedness Program.** Congress should task the GAO to evaluate the impact of HPP grants on hospital preparedness. This evaluation should address, at a minimum: 1) the extent to which the goals of the HPP are being met; 2) how HPP funds should be allocated (e.g., based on risk); and 3) whether funding for the HPP is sufficient.[82] The ASPR and Congress should then use the results of the evaluation to determine reforms and funding needed to optimize the program.

FUNDING ASSOCIATED WITH ACCREDITATION

Hospitals also qualify for funding via the Centers for Medicare and Medicaid Services (CMS) at HHS by fulfilling accreditation requirements for various specialties. Accreditation is a critical node in this complicated system that attempts to link performance to payment. However, preparedness for bioterrorism and other deadly infectious disease events has not been incorporated into either hospital accreditation or funding requirements arising out of CMS.[83]

Healthcare accrediting agencies are aware of the need for preparedness and have issued planning guidelines to address it. Joint Commission leadership has testified before Congress and others on the need to prepare for bioterrorism and other exigent circumstances. However, these deeming entities have not issued standards specific to bioterrorism preparedness or preparedness for highly infectious diseases. Instead, for example, the Joint Commission includes such biological events as one among many hazards included in the term all-hazards and requires an all-hazards emergency management plan, hazard vulnerability self-assessments, familiarity with the Incident Command System, and exercising of plans. During Joint Commission visits, assessors evaluate the plan and how well trained staff are for all hazards. The goal of this approach is to develop and maintain a strong foundation upon which all hazards – including bioterrorism and highly infectious disease events – can be managed well.[84] Opportunities exist as part of health delivery reform to improve hospital preparedness for disasters and biological threats, including through the application of the ASPR National Healthcare Preparedness Guidelines.[85] If biothreat preparedness were also made an accreditation requirement, the potential for increased CMS funding – far greater than that available via the HPP – should provide a strong financial incentive for hospitals to prepare for biological events.

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.

ACTION ITEMS:

a. **Adopt a disaster preparedness portfolio.** The Administrator of CMS, in conjunction with ASPR, 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 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.

b. **Link Centers for Medicare and Medicaid Services 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.

NEED FOR A FORMALIZED STRATIFIED HOSPITAL SYSTEM

It is not necessary or prudent for every hospital in the United States to possess and maintain the same capability for treating patients affected by intentionally introduced and naturally occurring biological events.[86] Ebola demonstrated that this is an unrealistic expectation, prompting the CDC to introduce a three-tiered system to more strategically allocate resources and response efforts.[87] Today, Ebola patients can be treated at a hospital among the tiers deemed capable of providing necessary care in properly controlled environments, assuring the safety of the patient, health care workers, and anyone within and surrounding these hospitals.

A stratified hospital system similar to that utilized for Ebola and other specialized pathologies (e.g., trauma, stroke, cardiac care, burns, pediatrics) is needed for infectious diseases. Such a system would require all hospitals to attain the ability to assess patients in order to recognize bioterror agents, as well as emerging and reemerging infectious diseases. All hospitals would also be able to stabilize patients within 48 hours, and then refer patients quickly to higher-level hospitals for more definitive care. Other levels of hospitals would be able to provide increasingly specialized care, depending on the status of these patients. Biodefense responsibilities could also be added to Accountable Care Organizations, trauma centers, and hospital coalitions. Ebola funding available via the HPP can help establish this system, but more must be done to formalize it and increase its functionality. This could include exploration of reimbursement enhancements via the previously mentioned specialties.

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.

ACTION ITEMS:

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.

b. **Develop accreditation standards for each stratum.** The Administrator of CMS should develop accreditation standards by or 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.

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

IV. ADVANCING PLANNING FOR MEDICAL COUNTERMEASURE DISTRIBUTION AND DISPENSING

The CDC manages the SNS, a cache of pharmaceuticals, medical supplies, and equipment stored to protect the American public in the event of a major chemical, biological, radiological, or nuclear (CBRN) incident severe enough to strain local resources. The MCM contained therein are only as good as our ability to provide them in a timely way to the people who need them. The CDC and a number of its federal, non-federal government, and private sector partners have worked hard to develop plans for distributing and dispensing SNS contents to the locales that need them. PHEP agreements require exercises toward these ends. Many experts, however, are unconvinced that SNS contents can reach massive numbers of people in the short time in which they are required (as few as 48 hours for certain infectious diseases).

NATIONAL MASS PROPHYLAXIS MUST DEPEND ON NON-FEDERAL INPUT, PLANNING, AND IMPLEMENTATION

The current distribution and dispensing system is insufficient and unacceptable. The likelihood that needed MCM could reach individuals in short timeframes on a mass scale is still not a reality. One study found as recently as 2012 that the MCM response architecture lacks clear, centralized leadership; clear and consistent directives for and coordination of state, local, territorial, and tribal

government plans; clear goals and objectives for response; sufficient imagination to consider alternative scenarios such as repeat or simultaneous attacks; and sufficient funding for health departments.[88] These remain unresolved problems. Additionally, certain logistical questions (e.g., how long it will take to break down pallets, how long until multi-dosage medications are resupplied) have not yet been addressed and are a concern for most localities.

A now-defunct program would have leveraged the delivery capacity of the USPS to deliver MCM to residences. Pilot programs showed a willingness on the part of certain locales and volunteer postal carriers to carry out this task. They also demonstrated that such a USPS delivery plan is highly complex, requiring hundreds of potential routes to be served; an enormous drain on law enforcement resources (a sworn officer would be required to chaperone each carrier); and a dependency on high levels of training and exercising, as well as sustained, annual federal funding.

While some cities could benefit from this approach, an optimal national mass prophylaxis capability will have to reach far beyond the USPS and into private delivery companies, pharmaceutical chains, and volunteer healthcare worker coalitions. Various modalities (e.g., distribution by large employers, regional pharmacies, healthcare facilities, non-governmental organizations) have often been discussed, but our primary dependence still remains on the static open point of dispensing (POD) model, which cannot alone meet the need.[89]

Unresolved issues in the distribution and dispensing of MCM must be addressed. The Nation lacks a workable national MCM distribution system that can be activated quickly and counted upon to work in an emergency. One reason for this is that a national, stakeholder-driven MCM response framework is missing; such a framework would provide structure and guidance for local planning efforts. MCM distribution from the cache sites to local destinations is often addressed in federal hazard planning documents intended for use by local jurisdictions that do not adopt them, frequently because they are not really at the table during their development. It remains unclear how regional distribution and local dispensing operations can best be coordinated among federal, state, local, territorial, tribal, private sector, and nongovernmental partners. The federal government needs to assist PHEP grantees with integrating performance measures, processes, shared services, roles and responsibilities, technologies, and resources needed to implement a truly functional distribution and dispensing architecture for MCM into their plans.

In order for any distribution and dispensing plan to be successful, the CDC must issue clinical utilization guidance for the MCMs in the stockpile. Such guidance helps local health officials understand who should get which vaccine or treatment, which diseases they should screen for prior to dispensing, and who is at risk for complications. The CDC has delayed issuing clinical guidance for years in some cases. If an outbreak were to occur tomorrow, even if the assets were already in place, health officials would not necessarily know how to allocate them. This is a special concern for vulnerable populations (e.g., children, elderly, immunocompromised) who require guidance specific to their status. The Vice President should hold the CDC accountable for this extremely important component of MCM planning.

Recommendation 22

Develop and implement a Medical Countermeasure Response Framework. A stakeholder-driven framework for solving continued challenges in operational MCM response will provide greater assurance that distribution and dispensing can be achieved quickly, efficiently, and safely.

ACTION ITEM:

a. **Produce a comprehensive framework to guide medical countermeasure distribution and dispensing planning.** Together with non-federal partners, the ASPR, the Director of the CDC, and the Administrator of FEMA should identify requirements and capacities needed to achieve successful distribution and dispensing of MCM from the SNS 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 beyond 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.

LACK OF MCM PLANNING PREVENTS FORWARD DEPLOYMENT OF THE SNS

While planning for the challenges described above can be resolved in the medium term with the advent of the framework called for in Recommendation 22, the CDC can institute near-term change in advance of that. Some localities have worked hard to demonstrate their ability to quickly and responsibly take charge of MCM distribution and dispensing. For example, New York City is now so well practiced in setting up PODs that responders would be ready to serve their populace hours before CDC assets even arrive. The CDC, however, has thus far been as unwilling to forward deploy assets to qualified cities. Given that the United States is already behind in developing a fully functional system for the distribution and dispensing of MCM, the government should support forward deployments to jurisdictions that prove themselves capable of handling SNS contents and dispensing them efficiently.

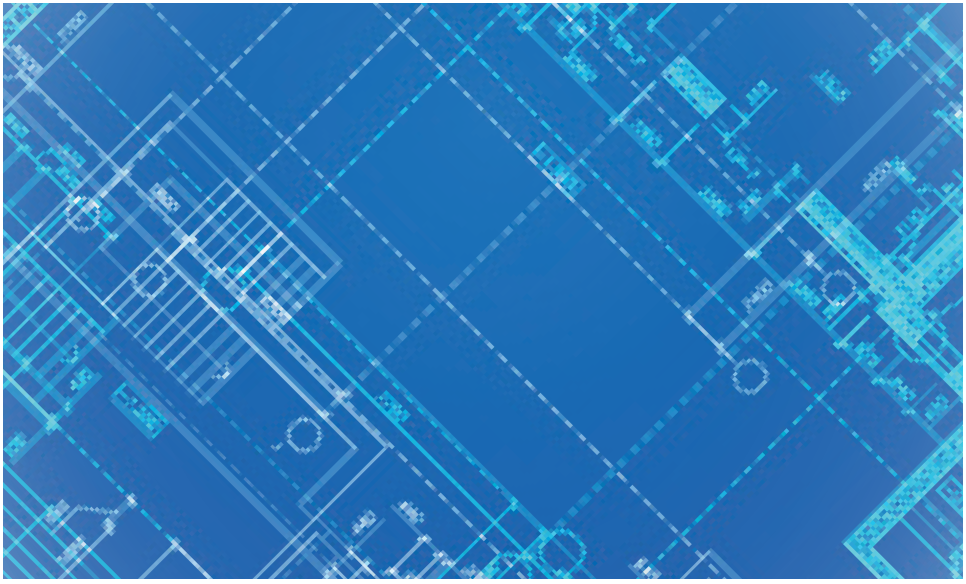
Recommendation 23

Allow for forward deployment of Strategic National Stockpile assets. Pre-deployment of SNS caches to those jurisdictions that have demonstrated the capability to appropriately handle SNS contents will vastly improve preparedness.

ACTION ITEMS:

a. **Determine logistics and funding needs.** The Director of the CDC should determine the necessary assessment, logistical, and funding requirements to forward deploy SNS assets.

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 PODs faster than SNS medications can be delivered to these jurisdictions and subsequently distributed to PODs. The Director of CDC should actively encourage leaders of other major urban areas to plan for and demonstrate ability to stand up PODs faster than SNS medications can currently be delivered.



V. DEALING WITH CYBER THREATS TO PATHOGEN SECURITY

Despite the overwhelming benefits that digital information technologies bring to biodefense, they simultaneously create portals for malicious intent.[90] The FBI, other federal departments and agencies, and the private sector are working to address vulnerabilities where biology meets cyberspace. But the work is nascent, and the United States is not yet well positioned to address cyber threats that affect the biological science and technology sectors.

Senator Sheldon Whitehouse told the Commission, "There is a considerable bank of information on biological warfare dating back to the biological warfare planning of the United States and the Soviet Union fifty years ago…Unlike a nuclear warhead, that information can travel very readily, and in the hands of terrorists or others who wish us harm, it can be very dangerous. So how do we control the proliferation of that bank of information our countries built back in those days?"[91] Not only does this historical information still pose a risk, but so does the body of knowledge about pathogens that has expanded since that time. In the modern day, the sharing of data via cloud computing, the growth of big data in the life sciences, and private and/or government networks that contain biotechnology know-how and/or pathogen information are a particular risk.

While a cyber attack on any health-related system could have enormous consequences to health security and care delivery, an area of particular relevance to biodefense and biosecurity is the vulnerability of pathogen-related data. Such information is commonly shared via the cloud or non-secure networks during the course of scientific business. Genetic sequences of pathogens (including those of the most serious threat agents) may be shared. The databases that contain this kind of information are as vulnerable to hacking as any other, and adversaries could

use their contents to gather intelligence on U.S. defensive capabilities, or even to engineer bioweapons. Life sciences research is also pushing further into big data analytics, a method by which enormous amounts of data are captured, integrated, and analyzed to reveal trends. The storage of any huge datasets, whether in the cloud or on secure servers, allows for scientific advancements, but also creates enormous vulnerabilities, as made clear in 2014-2015 with several attacks on health insurance provider databases.[92,93]

Additionally, biotechnology companies, universities, and government research laboratories store large amounts of networked information on biotechnology. This information includes advanced methods for genetic engineering, bio-manufacturing technologies, and emerging trends in biomedicine. These databases are targets for intellectual property crimes, industrial espionage, and intelligence gathering. Should these biotechnology databases fall into the wrong hands, rogue nations or other malefactors could use them to accelerate their biological terrorism and weapons programs.

Theft, misuse, or tampering with pathogen data should be considered a national security matter. If cloud-based data sharing, storage, and analysis are to be used for disease research, detection, and characterization, technical and non-technical security measures must be developed and implemented to ensure that no data stored or shared in the cloud are inappropriately manipulated or destroyed. A strategy for sharing information regarding cyber threats, securing pathogen data, and preventing national security breaches is needed. In addition, pursuant to President Obama's Executive Order on cybersecurity,[94] the federal government is in the midst of integrating cybersecurity risk assessments and obligations into all of its procurements. Federally-supported pathogen research projects, however, have not yet been included in that revised procurement model. Any time federal dollars are to be spent on pathogen and MCM research, cybersecurity concerns must factor into funding awards, and addressing these concerns should constitute an obligation for the funding recipients, much in the way select agent researchers are already obligated to comply with Select Agent Program (SAP) security regulations. The additional adoption of more stringent voluntary measures on the part of researchers should be encouraged and rewarded.

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 cybersecurity threat in this sector.

ACTION ITEMS:

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.

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.[95] The Secretary of Agriculture and the Secretary of Health and Human Services should incorporate these standards into any new SAP regulations promulgated per Recommendation 32.

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 (ICE) 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.

VI. REENGAGING WITH THE BIOLOGICAL AND TOXIN WEAPONS CONVENTION

The BWC is a legally binding treaty that entered into force in 1975. Signatory nations agree to never "develop, produce, stockpile or otherwise acquire or retain microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes."[96] To date, 173 nations have become parties to the convention,[97] but at least five of these countries (China, Iran, North Korea, Russia, and Syria) are suspected of engaging in biological weapons activities despite BWC ratification.[98]

The BWC does not absolutely prohibit the use of biological agents or toxins, but instead prohibits their use as or in biological weapons. The BWC allows these agents and toxins to be used for peaceful purposes, including research and the development of MCM, protective equipment, and detection systems. Such peaceful work can cross the line into offensive work, and a well-known shortcoming of the BWC is that it lacks a verification system to sufficiently restrain countries from engaging in offensive biological weapons programs.

The United States has not been satisfied with any previously proposed verification and compliance (including sentencing) protocols because they neither adequately or realistically address prohibited activities nor allow for clear judgments on compliance to be made. The serious concerns about the development of an unsuitable verification regime caused the United States to withdraw from the fifth review conference in 2001, which threatened the viability of the BWC. The United States did rejoin the review conference when it resumed in 2002, but continues to harbor reservations about verification and compliance with the Convention.[99]

Despite concerns about BWC implementation, the United States remains a signatory to the BWC and continues to participate in BWC review conferences that occur every five years and annual Meeting of States Parties and Expert Meetings. Given their experience with the 2001 review conference, member nations tread lightly on the topic of verification and compliance, while hoping that such a regime can and will be developed eventually. When the United States withheld support of the verification protocol put forward in 2001, it left a leadership void that has never been filled adequately since.

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 BWC to prevent it from exerting leadership in an arena that requires more than diplomatic support of the treaty.

ACTION ITEMS:

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 BWC 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.

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 BWC 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.

c. **Develop three actionable recommendations for Biological and Toxin Weapons Convention verification.** Prior to the next BWC 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 BWC. 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.

d. **Establish better biological weapons sentencing guidelines in statute.** Congress should amend the Biological Weapons Anti-Terrorism Act of 1989[100] and the USA PATRIOT Act[101] to include more specific sentencing guidelines, taking into better account the real and growing possibility that biological weapons will be used in the United States.

VII. BUILDING UPON DEFENSE SUPPORT TO CIVIL AUTHORITIES

DOD possesses resources and expertise that would be applicable in certain civilian contexts. Recognizing this, DOD has established some doctrine in support of civil authorities.[102] U.S. Northern Command has taken on a number of responsibilities for providing support to civil authorities and in executing those responsibilities, and has managed to foster some of the military-civilian collaboration needed for biodefense. Collaborative biodefense efforts (e.g., biosurveillance, pandemic planning) for the most part, however, are not formalized and there are no clear measures in place to ensure that they will be sustained. Additionally, these efforts do not reach far enough to address the needs of the entire Nation for biodefense.

Despite the importance of DOD's role in providing support to civilian authorities in response to domestic bioincidents, doctrinal clarity for this role is lacking. DOD has not established strong interfaces with the federal, state, local, territorial, and tribal agencies that would be involved in responding to a major biological attack against the United States. Should an event occur, while many suggest that the military should be called upon to assist civilians, there are no clear policies for the integration of military assets and the delegation of decisions to DOD decision-makers and the National Command Authority (NCA) that might be required.

DOD has significant knowledge that it could transfer to the civilian sector in the way of planning, logistics, response, operating in contaminated environments, science, technology, and many other matters. DOD and its civilian counterparts should engage in continuous transfers and exchanges of information to strengthen biodefense and the ability of the civilian sector to pull its own weight in a large-scale biological event – especially if military and other DOD personnel are called away to defend the Nation overseas.

DOD force protection and projection are imperiled by the threat of both bioweapons and naturally occurring infectious diseases. Yet U.S. warfighter preparedness for and protection against biological attacks is inadequate. DOD assets and force readiness overseas and within the homeland could be dangerously compromised by a major biological event. Scant consideration has been given to how operations would be conducted in biologically contaminated environments caused by a biological attack or by exposure to infectious disease when engaging in combat or providing humanitarian assistance.

Current military biodefense doctrine and policy falls short of adequately protecting the warfighter and ensuring that military operations continue unimpeded. Civilian policy also falls short of adequately protecting first responders and ensuring their activities continue unimpeded. Both civilian and military operators share many similar requirements for protection in biologically contaminated environments. However, mechanisms to encourage and develop collaboration between these communities are weak and are in need of greater support by both public and private sector leaders.

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.

ACTION ITEMS:

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 Armed Services Committees.

b. **Establish military-civilian biodefense collaboration.** 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 House and Senate Armed Services Committees' oversight agendas.

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 NCA in the event of a biological attack.

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 for ensuring that this doctrine has been refreshed and/or developed with the input and full concurrence of the Joint Chiefs of Staff. DOD should base scientific R&D, training, and other activities necessary for biodefense on this doctrine.

CHAPTER 3: THE NEED FOR LEADERSHIP IN DRIVING INNOVATION

Governments are not known for taking innovative approaches to managing problems or to seeking high risk/high payoff scientific and technological solutions. The public sector has traditionally discouraged this kind of creative and cutting-edge thinking, in contrast to the private sector, which thrives on it.[103]

Scientific discovery is inherently fraught with uncertainty, and policymakers have difficulty making enormous investments that may or may not result in viable scientific and technological solutions.[104] Innovation usually involves investment risk which, in turn, challenges policy makers. This is especially true with regard to low probability/high consequence events and in the absence of immediate threats.

It is reasonable for federal agencies to approach their missions with deliberation and well-established solutions. However, some problems call for greater urgency and innovation – because they are imminent threats, because the vulnerabilities underlying them have existed for too long, or because their complexity requires equally complex solutions. Biodefense falls into each of these categories. A problem like defending a nation from biological threats is inherently difficult to solve because it consists of overlapping subsets of problems, is addressed by diverse stakeholders with distinct agendas, and attracts problem solvers from a variety of organizations with different values – characteristics that can impede even a definitive statement of the problem.[105]

These complex problems require extraordinary coordination and collaboration, as well as innovative solutions. The government must be innovative in the very way it organizes to solve the problem (e.g., establishing agile and flexible procurement processes) and in developing requirements for the technologies it needs to solve the problem (e.g., progressive MCM that could redefine modern preparedness). Our leaders must give priority to innovative approaches to engaging industry and others toward needed solutions in areas like diagnostics, detection, biosurveillance informatics, personal and collective protection, remediation, and attribution. Recent guidance from OMB on FY2017 science and technology priorities emphasizes that agency budget requests should include funding for innovative programs in biosurveillance and in countering WMD.[106] This guidance must be taken seriously by every agency with a role to play in these areas; and henceforth, funding for innovation in science and technology should be the norm. Innovation in technological solutions, regulatory approaches, and even operations is fundamental to solving the biothreats problem. Creative thinking must permeate the strategic visions of all agencies that fund biodefense, not only those with specific charges to be innovative. The United States should be the first to innovate in biodefense, as we have in so many other areas. The alternative is that we fall behind and become beholden to other nations, or that we are simply unprepared for the next attack, outbreak, or pandemic. Our leaders must internalize that forward and creative thinking and ensure its pervasiveness.

This chapter addresses innovation in the following areas:

I. Incentivizing Civilian Medical Countermeasure Development

II. Leaping Ahead to a Modern State of Biodetection

III. Removing Select Agent Program Impediments to Innovation

IV. Implementing New Approaches to Global Health Response

I. INCENTIVIZING CIVILIAN MEDICAL COUNTERMEASURE DEVELOPMENT

The WMD Commission argued that a nation prepared with MCM is one that can take threat agents off the table.[107] MCM development stands out as an area in which innovation can move biodefense along by leaps and bounds. But these advancements will not occur without bold leadership, strategic initiatives, creative thinking, and more disruptive advancements. While we must not ignore long-standing, successful technologies that have yielded useful tools (e.g., traditional vaccines) to address specific biological threats, we still must push the envelope on next-generation technologies, innovations to address genetically engineered pathogens, and tools that allow for rapid assessment of immune triggers and for extremely rapid vaccine and therapy development and production. All of these, furthermore, can be linked to innovative acquisition strategies.

A systemic risk-averse culture has emerged that is stifling MCM innovation. If this continues to evolve, progress on biodefense objectives will be curtailed and the still nascent biodefense industry will have little incentive to participate. Innovation must become ingrained in current policies and practices to take advantage of the technologies available today and in the future.

Government and industry have successfully partnered to innovate before, and they can do so again. For example, during Operation Desert Storm and later deployments in the mid 1990s, DOD needed to deploy vaccines and therapeutics for operational use under clinical investigational protocols to protect soldiers from biological and chemical warfare threats and endemic infectious diseases. This required alternative thinking and risk tolerance on the part of policy makers, program leaders, and the FDA to use investigational new drug products in combat environments. This experience spurred further innovative thinking and legislative solutions that culminated in the emergency use authorities provided in the Project BioShield Act of 2004.

More recently, when Ebola emerged in 2014, the only MCM candidates available were in very early stages of development. The U.S. government and industry partners rose to this challenge and rapidly transitioned three experimental vaccines and one therapeutic into clinical development in fewer than three months. Although the rapid development and collapsed clinical trial design and implementation are not the optimal way of doing business, this was nevertheless a remarkable achievement requiring forward thinking and risk tolerance. Some lessons and disruptive ideas are emerging that build on the most positive and useful aspects of that experience.

NEW MODELS FOR MCM DEVELOPMENT

The Nation remains unprepared for known, unknown, and unexpected threats. The collective experiences described previously suggest that non-traditional development and surge models are not only a plausible way to deal with this challenge, but should become the planned strategy. The foundations that would allow this kind of progressive approach already exist: for example, BARDA has a statutory mission to promote "innovation to reduce the time and cost of countermeasure and product advanced R&D."[108] And Congress recently demonstrated interest in a substantial shift at NIH when it proposed an NIH Innovation Fund at $2 billion annually.[109]

The risks and the subsequent approach needed vary by pathogen, and this must be thought through strategically on a detailed, case-by-case basis. Non-traditional development and surge models should be considered – not just for humans, but also for animals. A formal strategy is needed to operationalize the capabilities and capacities needed to rapidly

identify immunogenic components, deliver antigen payloads in platform technologies, quickly manufacture MCM using flexible and adaptable technologies, and rapidly distribute MCM to affected populations in response to unanticipated and new threats, while decreasing the need for expensive and inefficient stockpiling. The federal government should work closely with industry to develop new strategies that strike the right balance between stockpiling MCM against known high consequence/low probability threats, and surge manufacturing for emerging and unknown threats.

The DOD had a transformational medical technologies initiative that was paving the way to develop capabilities that would enable rapid pathogen characterization, antigen identification, and platform technology approaches. Despite early success, the initiative was reduced in scope largely due to criticism that it was too risky and funding could be better used on traditional CBRN equipment and technologies. The DOD should consider initiating a similar medical technologies initiative today, challenging the risk-averse culture and leading the way for other agencies to follow.

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 solution to boldly meeting the biological threat.

ACTION ITEMS:

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 MCM tied to BARDA requirements. The Director of BARDA 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 of these agencies to secondarily review proposals rejected as being too risky.

b. **Exploit existing innovation.** The Director of NIAID, the Director of BARDA, and the Deputy Assistant Secretary of Defense (DASD) for Chemical and Biological Defense should coordinate to identify at least five promising novel technologies (including platform technologies) that could ultimately be applied to MCM development for material threats. The most promising candidates (with sufficient safety and efficacy data to meet FDA standards) that enable using multiple antigens on an existing platform should be developed. If needed, FDA should develop a new approval pathway for these technologies.

c. **Revolutionize development of medical countermeasures for emerging infectious diseases with pandemic potential.** The Director of BARDA, in coordination with the Director of NIAID and the DASD for Chemical and Biological Defense, should establish a program to rapidly develop MCM 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 be as transparent as possible to academic and industry partners during this process. The Administrator of APHIS, in coordination with the DHS Under Secretary for Science and Technology and the Director of NIAID, should do the same for animal vaccine candidates, with similar transparency to academia and industry.

d. **Establish an antigen bank.** The Director of NIAID, the Director of BARDA, the DASD for Chemical and Biological Defense, the Administrator of APHIS, and the DHS 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.

FUNDING MCM INITIATIVES TO APPROPRIATE LEVELS

The development of any drug or vaccine candidate is a risky, lengthy, and expensive process. The challenges with MCM are even greater, because there is limited-to-no commercial market for these products and because the opportunity costs for doing this contract work for the government are too high for most experienced and innovative companies.

The federal government has, therefore, recognized that it alone can incentivize MCM development. It alone can account for intelligence, pathogen virulence, and the potential products already in development, and from there develop a plan for infectious disease threats that employs differing strategies and incentives. Given that some products may have viable commercial markets (e.g., antibiotics), limited commercial markets (e.g., acute radiation syndrome treatments), or no commercial market (e.g., pandemic influenza, tularemia, and Chikungunya MCM), a spectrum of strategies and incentives must be identified and leveraged to stimulate private sector development and manufacturing.

The legislative underpinnings for this are already present. Congress established Project BioShield and created BARDA to work with the biotechnology and pharmaceutical industry to plan and execute advanced development and procurement of MCM. The laws that established and funded Project BioShield and BARDA recognized that multi-year funding, transparent long-term strategies, and other incentives to include more flexible contracting mechanisms were required to garner industry's participation in solving biodefense problems. The Public Readiness and Emergency Preparedness Act (P.L. 109-148) extensions to reduce tort liability are also very important statutory tools for incentivization, but the declarations under this Act for anthrax, smallpox, botulism, acute radiation syndrome, and pandemic influenza expire at the end of 2015 and must be reissued and extended by the Secretary of Health and Human Services before that time to ensure the continued participation of private sector partners.

BARDA was formed in 2006 and established a solid track record working with industry as a partner to develop and procure MCM for pathogens that DHS has determined pose material threats to the Nation.[110] Approximately $6 billion from FY2004–FY2013 in advanced development and procurements allowed for the development and delivery of 12 MCM to the SNS. Another $6 billion was provided in emergency supplement funding in FY2006 to support pandemic influenza preparedness in accordance with the National Strategy for Pandemic Influenza. Given that the cost of bringing a single drug to the commercial market can be in excess of $2 billion,[111] this investment is efficient and demonstrates the value of risk sharing through public-private partnerships (PPP). Twelve MCM, however, are not nearly enough considering the number and diversity of threats we face. This number could be doubled by 2018 if future congressional appropriations for the BioShield Special Reserve Fund (SRF) are adequate.

At the end of FY2013, the original advanced appropriation for MCM procurements via the SRF[112] expired, and the supplemental pandemic influenza[113] balances were exhausted shortly thereafter. The SRF and pandemic influenza programs became subject to annual appropriations in FY2014 and have experienced dramatic decreases in funding. Viewed against authorized levels, the project BioShield funding shortfall alone could be as much as $1.53 billion by 2018, eroding trust in the partnership model, resulting in fewer MCM, and leaving national security threats on the table. The shift from the advance-appropriated model to an annual appropriations process is highly questionable, given the relative success of the program, bipartisan support for it, and the lack of any decrease in the threat. It has even been questioned by the Director of BARDA.[114] The expiration of the SRF eliminated the guaranteed market that allowed companies and venture capitalists to more easily make the case for investing their own capital in innovative MCM development. It also diminished the flexibility of the U.S. Government to use these no-year funds to respond to an unexpected threat without the need for a supplemental appropriation.

The best way to incentivize industry to a level that allows it to participate in biodefense programs and pursue truly innovative ideas is to: 1) fund MCM development to legislatively authorized levels; 2) re-establish multiyear advanced appropriations through the SRF; and 3) eliminate bureaucratic hurdles within the partnership. To further enhance the environment for innovation, especially as the partnership model between government and industry evolves, many have urged Congress and BARDA to adopt other incentives that would invigorate MCM developers. Government, policy thought leaders, and industry have proposed a variety of incentives including success-based milestone payments and monetary prizes; minimum procurements/advanced market commitments; guaranteed pricing; patent extensions; orphan drug status expansions; wild-card exclusivity; transferable data exclusivity extensions; and priority review vouchers for pathogens that DHS has determined to be material threats.

These proposals vary in their cost to government, their political feasibility to authorize, and, critically, in their palatability to the companies for which they are designed. BARDA and industry should convene to determine and recommend the most effective incentives beyond congressional appropriations. Recommendations for incentives should be designed for small biotechnology companies, large pharmaceutical companies, and those in between. The array of business models necessitates a variety of incentives.

Recommendation 28

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

ACTION ITEMS:

a. **Fund the medical countermeasure enterprise to no less than authorized levels.** Congress should immediately fund MCM initiatives through BARDA, the SRF, and the SNS 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 outlined in this report.

b. **Re-establish multi-year biodefense funding for medical countermeasure procurement.** The President and Congress should re-establish multi-year funding for Project BioShield, thus re-establishing the marketplace while building and maintaining capabilities. A 10-year advanced appropriation for the SRF is entirely appropriate.

c. **Address prioritization and funding for influenza preparedness.** At least every five years, the ASPR, in coordination with all government 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 ASPR 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.

d. **Improve the plan for incentivizing the private sector and academia.** The ASPR and DASD for Chemical and Biological Defense should convene non-governmental stakeholders to identify meaningful incentives which are independent of congressional appropriations for MCM 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 MCM development, and requesting congressional authorization for those that would require it.

REMOVING BUREAUCRATIC HURDLES TO MCM INNOVATION

Improving federal government contracting practices will enable the federal MCM enterprise to meet mission requirements. Legacy and current contracting practices are still not sufficiently transparent, uniformly implemented, predictable, or flexible enough to accommodate efficient MCM development, or to optimize industry participation to achieve U.S. government biodefense preparedness objectives. The evolving government-wide, risk-averse culture is a contributing factor and a growing disincentive for the very companies that the government needs to meet its requirements.

For example, the DOD MCM program utilizes an acquisition system that has evolved over the years for weapons systems. This acquisition model has been modified to some degree to accommodate life science applications and FDA regulatory requirements, but its use for vaccines has mixed to poor results with at least two vaccine candidates lingering in advanced development for almost 15 years.

DOD and Army acquisition leadership recently acknowledged that traditional and legacy acquisition strategies are hindering progress and industry participation for all biodefense technologies, including medical. The Army is now implementing new and innovative acquisition strategies including the use of other transaction authority (OTA) for MCM.[115] Army leadership should be commended for implementing innovative acquisition and contracting strategies.

BARDA should similarly reduce unnecessary hurdles and implement innovative acquisition strategies, to include making greater use of OTA, as Congress originally intended when authorizing BARDA. The contracting authorities available to BARDA (like OTA) go beyond traditional Federal Acquisitions Regulation mechanisms, but these expanded authorities have only been used to establish one (non-Ebola) partnership to date. Additionally, BARDA should reestablish its own internal contracting authority, rather than rely on the separate ASPR Office of Acquisitions Management, Contracts and Grants. This would reduce unnecessary bureaucratic delays, improve efficiency and decision making, and enhance BARDA program effectiveness and accountability. Finally, when Project BioShield was created in 2004, its funding was derived from DHS while the program was administered by HHS, resulting in the need for OMB review. Now that all BioShield funds and procurement responsibilities are housed at HHS, an OMB review of contracts already approved and funded by HHS is unnecessary and slows MCM procurements.

Recommendation 29

Reform Biomedical Advanced Research and Development Authority contracting. A variety of statutory and organizational issues impede nimble and efficient contracting by BARDA, leading to delays in the availability of MCM.

ACTION ITEMS:

a. **Return contracting authority to the Biomedical Advanced Research and Development Authority.** Contracting authority should be the exclusive responsibility of BARDA. The ASPR should administratively reinstate BARDA as the sole authority to negotiate, award, and administer its own advanced research, development, and procurement contracts. If the ASPR fails to do so, Congress could mandate this.[116]

b. **Leverage previously provided authorities**. BARDA should prioritize the use of OTA and consider any other appropriate flexible contracting authorities for BioShield and advanced development contracts.

c. **Eliminate Office of Management and Budget review of BioShield procurements.** Congress should amend the Public Health Service Act to eliminate OMB review of BioShield procurement contracts.[117]

DEVELOPMENT OF RAPID POINT-OF-CARE DIAGNOSTICS LARGELY IGNORED

A rapid point-of-care diagnostic test would have significantly improved management of the Ebola outbreak abroad and in the United States – perhaps more than anything else. If it had been available, it would have significantly improved quarantine and isolation decisions at home and abroad, and saved countless lives. Ebola screenings of suspected patients were often based on little more than thermometer readings and a series of questions. While an assay was quickly fielded under an EUA, it was not a rapid and patient-side device of the kind that could exist by the hundreds or thousands in clinics and be used by anyone with limited training. The absence of such tests for many threats makes it difficult to ascertain the full scope of an incident, reliably distinguish infected from uninfected individuals, and determine appropriate intervention strategies.

Most physicians are not trained to recognize the early symptoms caused by emerging diseases or select agent pathogens. Initial symptoms (e.g., high fever, muscle aches, lethargy) that infected individuals exhibit for most biothreats are non-specific. Rapid recognition of illness caused by a novel biothreat against the background noise of more common and routine infections is, therefore, unlikely without access to definitive diagnostic tests for the new pathogen.

We must push hard to develop advanced molecular diagnostics in order to move beyond old technology and the incremental improvement of new technology. With the proper investment, we can get there. The technologies needed for the quick patient-side diagnostics of the kind used in doctors' offices to screen for influenza exist or are in development. However, their development has not been prioritized for Ebola and other threats on which the government and industry have spent billions on vaccines and therapeutics. From anthrax to influenza, the investment has been almost solely in drugs with a dearth of focus on diagnostics, and certainly not rapid point-of-care diagnostics.

This is extremely short sighted. These technological solutions require significant investment up front, but they can be highly leveraged when integrated into a biological response architecture. They spare vaccines, treatments, and the necessity for quarantine or isolation when they are not needed, saving valuable resources. Furthermore, increasingly sophisticated profiling of the molecular signatures of biothreat agents is also valuable in the event of a bioattack, potentially providing informative forensic clues for attribution and justification for actions based on this information.

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.

ACTION ITEM:

a. **Develop requirements for rapid point-of-care diagnostics for all material biological threats and emerging infectious diseases.** The Director of BARDA should determine the suite of rapid diagnostics that are 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 MCM incentive discussions per action item 28d apply and strong efforts should be made to provide companies with participation incentives.

II. LEAPING AHEAD TO A MODERN STATE OF BIODETECTION

Effective environmental surveillance improves pathogen identification and, most importantly, provides early warning. The federal government collects limited data on water and soil contamination, and lacks requirements that would incorporate any such data into a federal database. The biodetectors designed to inform biosurveillance of the air (commonly referred to as environmental detection) have not progressed significantly since their initial deployments.

The BioWatch program was launched in 2003 with great urgency, but its potential remains unrealized. As of 2015, BioWatch uses the same technology – manual filter collection and laboratory polymerase chain reaction testing – as it did twelve years ago. BioWatch is a DHS system of nationally distributed detectors that sample the air for a select number of bioterror pathogens in a few dozen cities. Non-federal public health laboratories then analyze the samples. The technological limitations of the system are many: 1) it relies on winds blowing in optimal directions; 2) it can take up to 36 hours to alert the possible presence of a pathogen; 3) specimens are inactivated, preventing determinations of whether live organisms were released; 4) it cannot differentiate between normal background bacteria and harmful pathogens; and 5) it cannot identify atypical threats. Beyond the scientific limitations are challenges in execution. For instance, federal agencies involved in determining what to do with test results often disagree as to what course of action should be taken and do not always consult non-federal public health and other leaders, even though many response decisions ultimately must fall to local leadership.

The entire BioWatch system is dying for lack of innovation. DHS attempted and failed to acquire next-generation BioWatch technology (Generation 3) that could have reduced time-to-detection to as few as six hours. Even if the acquisition had been successful, the system would still have been flawed: like the current system, it would have addressed only a small number of biological agents, inactivated them, and relied on non-random air currents. To date, no fully automated, tested, and evaluated autonomous detection system has been deployed that adequately addresses the airborne biological threat or sufficiently provides operational response information. Yet technological advances in sequencing and other relevant technology exist and could be fostered with clear requirements, meaningful PPP, and strongly focused innovation.

DHS R&D efforts are the responsibility of the S&T Directorate. OHA within DHS, however, pursued its own R&D activity in support of the Generation 3 effort, ultimately wasting time and funding. Congress should remind DHS leadership that DHS S&T and OHA have distinct – not overlapping – responsibilities. R&D efforts fall squarely and only in the purview of S&T per statute.[118] Simultaneously, DOD engages in its own biodetection research and acquisition programs. While the needs of civilians and warfighters are generally distinct, the science behind environmental detection is not. DOD and DHS must better coordinate their environmental detection efforts and leverage each other's advances. Together (and with congressional oversight) these departments can develop a detection system capable of meeting today's threats with 21st century ingenuity and replace the ineffective civilian system currently in place.

Recommendation 31

Develop a 21st 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.

ACTION ITEMS:

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 states, localities, territories, and tribes at the earliest stages of requirement development. DHS must also develop a standardized integration strategy and training requirements based on these discussions.

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.

III. REMOVING SELECT AGENT PROGRAM IMPEDIMENTS TO INNOVATION

The primary federal program to prevent the misuse of pathogens and toxins is the SAP, administered jointly by the CDC and USDA.[119] This program has functioned as an impediment to would-be attackers. Yet the regulatory regime of the SAP does not fully address underlying issues in pathogen safety and security, including how to prevent and deal with human error, how to ensure standards for safety and security awareness are met, and how to be more transparent within statutory confines about lapses and problems with the system. It is time for a complete review followed by a comprehensive overhaul.

Information, knowledge, and equipment to produce pathogens de novo (known as synthetic biology) have become increasingly available in the years since the SAP's establishment. Therefore, restriction of access to pathogens already secured in laboratories has decreased impact today. Furthermore, pathogens are not the only problem. Non-pathogens (e.g., bioregulators, small peptides) could also be used in biological weapons and yet fall outside of the current regulatory regime. SAP regulations can also reach burdensome levels that make the scientific workforce resistant to engaging in much needed biomedical research and provide minimal or no enhancement of biosafety or biosecurity.[120] SAP

regulations also fail to recognize the reality of select agents presenting in animal diagnostic samples, and the nature of the work that veterinary diagnostic laboratories must, therefore, do to keep the Nation and its animals safe and healthy.

Policymakers must address: discrepancies among the purpose of the SAP, rationale for its regulations, and criteria for determining which agents are added or removed from the list; barriers to full implementation of the SAP; the value of a dynamic characteristic-based approach for restricted agents and toxins versus the current, static list-based approach; challenges associated with inspections; whether federal and private investments in biodefense are maximized; and how to implement a restorative (rather than punitive) process for addressing problems.

The program has been reviewed, but the recommendations of the 2009 report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight were never fully implemented.[121] An undeniable problem with this task force is that it was co-chaired by HHS and the USDA, the very agencies that administer the program. A different approach to identifying problems and ensuring that solutions are implemented is needed. Hopefully, the results of a Request for Public Comment by OSTP regarding the impact of SAP regulations[122] will lead to a rigorous and comprehensive assessment of the program.[123] The focus of the overhaul should be less about whether we can secure stocks of pathogens, and more about whether we can control the proliferation of information, predict the nature of the changing biological threat, and ingrain a culture of security awareness within the biomedical research community.

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.

ACTION ITEMS:

a. **Undertake a major reassessment of the Select Agent Program.** Congress should direct the National Science Advisory Board for Biosecurity (NSABB, a federal advisory committee authorized in the Public Health Service Act) to undertake a systematic, evidence-based assessment of the SAP. This assessment should include extensive consultation with all stakeholders, including the regulated community and the law enforcement and intelligence communities. NSABB should evaluate all pertinent strategies, laws, and guidance related to the SAP; identify key drivers of safety and security lapses; and identify regulatory burdens in the SAP that stifle research and innovation. The report should include specific and actionable recommendations for revising SAP regulations and their implementation in order to improve security and safety and to incentivize laboratory certification under the program. NSABB should provide the assessment and recommendations for program overhaul to the Secretary of Health and Human Services, the Secretary of Agriculture, and the Vice President within six months. The report should also be made public and provided to Congress shortly thereafter.

b. **Overhaul the Select Agent Program.** Based on the recommendations of the NSABB 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 as necessary; and promulgation of new rules as necessary. 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 over all proposed rules for the program.

IV. IMPLEMENTING NOVEL APPROACHES TO GLOBAL HEALTH RESPONSE

International cooperation is a key element in implementing global health strategies.[124] Through the Global Health Security Agenda (GHSA), the United States and its international partners collaborate to prevent and mitigate the biological risk and to promote global health security as an international priority.[125] The GHSA was formally announced in 2014, setting a five-year agenda for prevention, detection, and response. It represents an ambitious plan to meet global gaps in surveillance, detection, and MCM availability. U.S. activities include establishing emergency operations centers, strengthening laboratory biosecurity in developing nations, partnering with international animal health authorities to rapidly detect and manage animal diseases, and implementing and strengthening the International Health Regulations and OIE reporting capacities.

Although the United States has helped build biosurveillance infrastructure in nations throughout the world where emerging diseases are likely to arise, Ebola proved that current efforts failed to achieve adequate surveillance capacity, and warning signs went unheeded. While there is disagreement over where exactly the failure occurred in terms of detecting Ebola and communicating that detection, health officials did seem to underestimate the timing and scope of the disease's transmission and were blinded by preconceptions that Ebola was a disease of the jungle and would not spread to cities.[126,127] Senator Richard Burr characterized the Ebola outbreak as a "total breakdown of global detection."[128]

Nowhere is the fragility of the human-animal disease boundary more pronounced than in developing nations, from where the majority of new infectious agents are emerging.[129] Urban areas are nucleation points for infectious disease risk and their populations are dramatically increasing in many of these countries. Because these nations often lack both public health and animal health infrastructures, their capacity for early and effective surveillance and mitigation efforts is challenged. Multilateral bodies like the World Health Organization (WHO) and OIE must, therefore, support the development of in-country activities and capabilities to meet international standards, prevent cross-border spread of disease, and reduce the risk of accidentally or intentionally introduced biological threats. As a voting member of and major donor to both the WHO and OIE, and as a resource-rich nation with enormous public health expertise, the United States has an obvious role to play at the forefront of these efforts.

Investment in prevention would reduce the much higher cost of outbreak response and MCM. When prevention efforts fail, early detection and rapid response systems are needed to quickly resolve outbreaks before they spread. Global prevention and response capacity will not come from the WHO; it must come from nations who agree to make it a priority. The geographic hotspots at highest risk for these disease events have been identified[130] and further refined by recent analyses.[131] What remains desperately needed is an off-the-shelf logistical enterprise at the ready to insert public health resources into areas where infectious diseases with pandemic potential are percolating after local resources have been overwhelmed.[132] It was widely thought before the 2014 Ebola outbreak that the WHO was sufficiently equipped for this kind of rapid and large-scale response. It is not.

Logistical expertise and resources are critical enablers for quick and effective outbreak response. WHO does not possess sufficient logistical assets to fulfill this requirement. While other public sector (e.g., U.S. Transportation Command, the North Atlantic Treaty Organization) and private sector (e.g., Federal Express, DHL) organizations are proven logistical powerhouses, they are not regularly called upon to help. No individual organization or nation should take on this task alone. Rather, a PPP that incorporates a variety of logistical organizations, as well as others that would support such an effort (e.g., pharmaceutical companies) is clearly necessary.

The recent Ebola outbreak happened not because any single institution or nation failed, but because they failed collectively.[133] Together with their partners, the United States should leverage the GHSA to develop a global public health response capacity and build international threat awareness, reach consensus on priorities, improve regional and cross-border surveillance, and increase regional MCM stockpiling and distribution plans. The effectiveness of the effort will be only as good as the strategy by which it is implemented and the level of funding it receives. If we fail to aggressively fund and implement multilateral activities such as these, we risk something potentially much worse than Ebola.

Recommendation 33

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

ACTION ITEMS:

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 GHSA and bilateral and multilateral agreements.

b. **Establish the 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 PPP. The President should request any required new funding via the unified biodefense budget.

APPENDIX A: PROPOSED CONGRESSIONAL OVERSIGHT HEARINGS

The value of congressional oversight in ensuring that federal departments and agencies are meeting congressional and other mandates, and doing so in a coordinated fashion, cannot be overstated. These proposed hearing topics reflect major recommendations outlined in the report, as well as additional ideas for consideration.

ISSUE	SUMMARY	HOUSE COMMITTEE(S)	SENATE COMMITTEE(S)
The Threat	Four commissions and the Bipartisan Commission on Biodefense have expressed concern about the threat and the inability of the IC to modify or develop new methods to collect, analyze, and disseminate biological intelligence. What has changed since the release of the Robb-Silberman Commission report? Has the IC redirected resources to address this growing threat? If so, to what extent? What has the IC done to increase information sharing with state and local governments regarding the biological threat? (See Recommendation 16.)	• Permanent Select Committee on Intelligence • Judiciary • Homeland Security	• Select Committee on Intelligence • Judiciary • Homeland Security and Governmental Affairs
Animal Disease Reporting	A nationally notifiable animal disease system akin to the existing system for human disease would enhance surveillance and detection of biological threats. A proposed National List of Reportable Animal Diseases has been offered by the USDA, but not yet implemented. What diseases should be on such a list? How could the list be part of a larger system by which states and other owners of disease information could willingly and comfortably report disease incidence? (See Recommendation 14.)	• Agriculture • Homeland Security • Natural Resources	• Agriculture, Nutrition and Forestry • Environment and Public Works • Homeland Security and Governmental Affairs
BARDA's Mission Space	BARDA's scope is being expanded to include development of MCM for antimicrobial resistant pathogens irrespective of ties to bioterrorism. How might this expansion require diversion of BARDA funding away from its original mission and force it to compete for additional funding? What level of funding is necessary to ensure that BARDA's statutory mission space in CBRN and emerging infectious disease is fully met?	• Appropriations • Energy and Commerce • Homeland Security	• Appropriations • Health, Education, Labor and Pensions • Homeland Security and Governmental Affairs
Biodefense Strategy	The United States lacks a unifying biodefense strategy. The unification of myriad federal biodefense mandates into a coherent strategy could serve as a backbone for progress and accountability. What should the elements of a unified national strategy for biodefense be? (See Recommendation 3.)	• Agriculture • Armed Services • Budget • Energy and Commerce • Homeland Security • Oversight and Government Reform	• Agriculture • Armed Services • Budget • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs

ISSUE	SUMMARY	HOUSE COMMITTEE(S)	SENATE COMMITTEE(S)
Biosurveillance	The United States lacks a comprehensive biosurveillance and detection capability. An integrated biosurveillance function exists in statute, but has been difficult to realize. What would it take to bring the agencies with biosurveillance responsibilities together in a trusted, information-sharing environment? What is the needed end state for a continuous capability to detect, validate, and warn of any biological threat within U.S. borders? How would the participation of data owners be incentivized and ensured? (See Recommendations 11, 12, 13.)	• Agriculture • Energy and Commerce • Homeland Security • Natural Resources • Oversight and Government Reform • Veterans' Affairs	• Agriculture • Environment and Public Works • Energy and Natural Resources • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs • Veterans' Affairs
Budgeting	Lacking a unified approach to budgeting, biodefense budget requests are spread across a dozen departments and agencies. What is the best way to consolidate biodefense programs into a cross-cutting analysis? What would a unified biodefense budget look like and how could it best be utilized? (See Recommendation 4.)	• Budget	• Budget
Cyber Vulnerabilities to the Life Sciences	Laboratory and research databases, as well as the expanding use of biotech information technology (e.g., monitors, sensors) within and outside of the government, contain information about pathogens that allows for great advances in biomedical science. It also creates a serious vulnerability. Where are the weak links in storage of life science information? What technologies exist or need to be developed to protect them? How can federal grant agreements and procurement contracts create a driving force for incentivizing protection of this information? (See Recommendation 24.)	• Energy and Commerce • Homeland Security • Oversight and Government Reform • Science, Space, and Technology • Permanent Select Committee on Intelligence • Transportation and Infrastructure	• Health, Education, Labor and Pensions • Commerce, Science, and Transportation • Homeland Security and Governmental Affairs • Select Committee on Intelligence
Food Supply Protection and Response	The Food and Agriculture critical infrastructure sector is a distributed and highly complex system. Many efforts have been made to reduce the vulnerabilities of this system to terrorism and other insults. HSPD-9 (2004) and DHS's sector specific plan (2010) provide a foundation for the protection of this sector. Have the plans been updated, exercised, and sufficiently funded? Are they integrated with related efforts in biosurveillance, attribution, and decontamination standards? How will federal agencies (including the FDA and CDC) respond if there is a terrorist attack affecting the food supply? How can PPP in this area be improved? What efforts and funding are still required in biosurveillance and MCM to protect livestock? In decontamination and remediation to bring food processing plants back on line after an incident?	• Agriculture • Energy and Commerce • Homeland Security • Natural Resources	• Agriculture, Nutrition and Forestry • Environment and Public Works • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs

ISSUE	SUMMARY	HOUSE COMMITTEE(S)	SENATE COMMITTEE(S)
Global Health Response	A global public health response apparatus that can react quickly and insert public health teams to respond to human and animal outbreaks is lacking. What is the current capacity and in what ways is it not meeting the need? How can international efforts be evaluated and better coordinated? What is the status of current global health reserve programs and how can they show more progress? What level of funding would be necessary? What lessons can be learned from the 2014 Ebola outbreak? (See Recommendation 33.)	• Agriculture • Armed Services • Foreign Affairs • Energy and Commerce • Natural Resources	• Agriculture • Armed Services • Foreign Relations • Health, Education, Labor, and Pensions
MCM Innovation	The Ebola outbreak demonstrated that being caught in an outbreak situation without MCM puts us at serious risk. And yet, there were some signs that our MCM apparatus could at least partially rise to the occasion with alacrity. What is a good strategy for mustering needed resources rapidly enough to get some candidates off the shelf and into clinical trials? How can the U.S. government catalyze development of MCM for naturally emerging infectious diseases with pandemic potential? (See Recommendations 27, 28.)	• Armed Services • Energy and Commerce	• Armed Services • Health, Education, Labor, and Pensions
Military-Civilian Biodefense Collaboration	The military provides support to civil authorities in accordance with established doctrine. However, it is unclear how much of this occurs in regard to biodefense. Military-civilian collaboration on biodefense would be beneficial to both sectors, especially as regards force protection (for the military sector) and responder protection (for the civilian sector). To what extent is collaboration between these sectors occurring now? What barriers and opportunities exist for collaborating on biodefense? What is needed to make this collaboration happen? (See Recommendation 26.)	• Armed Services • Agriculture • Energy and Commerce • Homeland Security • Permanent Select Committee on Intelligence • Science, Space and Technology • Transportation and Infrastructure	• Armed Services • Agriculture, Nutrition and Forestry • Commerce, Science, and Transportation • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs • Select Committee on Intelligence
Origin of Active Pharmaceutical Ingredients (API)	By some reports, 80% of API is manufactured outside of the United States, with the majority of these coming from India and China. Increasingly, critical products are made with API sourced outside of the United States. Does foreign sourcing of such material from developing countries improve U.S. ability to stockpile, or does it create vulnerability? What lessons can be learned from the current oncology drug shortage? Are there ways to develop U.S. opportunities for manufacturing the kinds of materials these nations currently supply, while aligning with free trade agreements and fostering innovation? Are existing agreements like the Trade Agreements Act being fully enforced? Could U.S. companies be incentivized to innovate toward this end?	• Armed Services • Energy and Commerce • Foreign Affairs • Homeland Security • Judiciary • Veteran's Affairs	• Armed Services • Foreign Relations • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs • Judiciary • Veteran's Affairs

ISSUE	SUMMARY	HOUSE COMMITTEE(S)	SENATE COMMITTEE(S)
PHEMCE Coordination of MCM Efforts	Investment strategies for MCM must match product development goals. In what ways are the members of the PHEMCE still uncoordinated, from budget submissions to priority setting to procurements? Are funding allocations for participants appropriate to meet the need? What should be included in a NIAID biodefense spend plan to ensure its utility? How can Congress ensure that PHEMCE priorities and agencies meet requirements to address biological agents that have received MTDs and emerging and reemerging infectious diseases that are on the proposed priority list per Recommendation 7? (See Recommendation 8.)	• Appropriations • Energy and Commerce • Homeland Security	• Appropriations • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs
Select Agent Program (SAP)	The SAP was established by Congress to better secure pathogens that, if stolen, could enable enemies to more easily develop biological weapons. Since its inception, however, SAP requirements seem to have become increasingly burdensome. How difficult is it to obtain necessary permissions to conduct research with select agents? How long does it take on average to receive permission (how many months, years)? How effective have USDA and the CDC been in administering the program? What efforts have been made to harmonize these rules with those of foreign countries to account for select agent use outside of the United States? (See Recommendation 32.)	• Energy and Commerce • Armed Services • Judiciary	• Health, Education, Labor, and Pensions • Armed Services • Judiciary
Vulnerable Populations	The needs of vulnerable populations must be considered in all biodefense planning. Children, the elderly, the disabled, the immunocompromised, and other at-risk groups require unique planning and resources, in everything from risk communication to MCM development and dispensing. Has the vision of the PAHPA for leaders to recognize and address the health security needs of children and other vulnerable populations been met? Where are continued gaps in planning and implementation?	• Homeland Security • Energy and Commerce • Veterans' Affairs	• Homeland Security and Governmental Affairs • Health, Education, Labor, and Pensions • Veteran's Affairs

APPENDIX B: METHODOLOGY

The Bipartisan Commission on Biodefense was established in 2014 to inform U.S. biodefense and provide recommendations for change. The Commission – supported by a suite of ex officio members; institutional hosting through Hudson Institute and the Inter-University Center for Terrorism Studies at Potomac Institute for Policy Studies; and funds from academia, foundations, and industry – set out to determine where the United States has fallen short of addressing bioterrorism, biological warfare, and emerging and reemerging infectious diseases.

RESEARCH QUESTIONS

In order to address the gaps in the biodefense enterprise and the biodefense body of knowledge, the following research questions were developed:

1) Are our priorities correct?
2) Are our investments commensurate with the challenge?
3) Can we benefit by rebalancing investments or is new funding required?
4) What have we done that has brought a significant return on investment?
5) What else should we be doing that we are not?

PRELIMINARY RESEARCH

The Commission reviewed previous research efforts; scientific studies; reports by congressional and presidential commissions (including the U.S. Commission on National Security/21st Century, Commission on Terrorist Attacks on the United States, Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction, and Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism); presidential directives; statute and proposed legislation; GAO reports; and federal strategies, plans, budgets, organizational constructs, and programs related to defense against deliberately introduced and naturally occurring biological events with catastrophic potential. This review: 1) allowed for an assessment of the comprehensiveness of efforts to address the postulated and actual biodefense challenges they were intended to meet; and 2) determined how the understanding of the threat, the knowledge base, and elements of the biodefense enterprise should change in light of this assessment. This review also informed the structure and topics of the four formal meetings of the Commission.

FORMAL COMMISSION MEETINGS

The four formal meetings were organized around the pillars of U.S. national biodefense policy (as articulated in National Security Presidential Directive 33 and Homeland Security Presidential Directive 10) – threat awareness, prevention and protection, surveillance and detection, and response and recovery. During each of these day-long meetings, members of the Commission, ex officio members, and study staff received: 1) information regarding current relevant national policy, legislative issues, and departmental and agency programmatic activities; and 2) statements from current and former Members of Congress, current and former federal officials, state and local representatives, thought leaders, and subject matter experts. Commission staff summarized the major insights, areas for improvement, and recommendations articulated by meeting speakers, and conducted preliminary high-level analysis of each day-long meeting for Commission and ex officio review.

SATELLITE WORKSHOPS

The activities of the Commission were enhanced by four meetings held by biodefense stakeholders. Four groups agreed to hold satellite workshops at which they convened experts and discussed key biodefense issues in-depth. They presented their findings at the third public meeting of the Commission. These meetings were hosted by the: MESH Coalition in Indianapolis, Indiana (on hospital preparedness); New York City Department of Health and Mental Hygiene in New York, New York (on major urban area concerns, ranging from environmental detection to MCM dispensing); the Texas A&M University Health Sciences Center in College Station, Texas (on the human-animal interface in biodefense); and the Alliance for Biosecurity in Washington, DC (on MCM research, development, and procurement). These groups identified specific areas in need of policy, legislative, programmatic, and resource improvement for the Commission to consider.

ANALYSIS

Qualitative methods were used to analyze all of this information. The Commission examined the oral and written statements provided by meeting speakers and developed a table that mapped their findings and recommendations to the capabilities required in HSPD-10. Each finding and recommendation was then further evaluated by various means, including additional policy research and interviews with subject matter experts and former high level officials, as well as in light of the Commission's own experience. Throughout the process, the five questions defined previously provided the basis for assessment. This approach allowed the Commission, ex officio members, and staff to identify continuing organizational, legal, policy, and programmatic issues and recommend specific near-, medium-, and long-term solutions. Statistical and other quantitative methods were not used for this study. The study is not considered pseudo-qualitative/quasi-quantitative.

STUDY LIMITATIONS

Funding and other resource constraints prevented the Commission from performing site visits. In addition, a number of biodefense programs and policies; intelligence, raw data, and documents; appropriations and budget documents; and other sensitive pieces of information are classified or otherwise unavailable, and were not reviewed by the Commission as this was a wholly unclassified endeavor.

APPENDIX C: MEETING AGENDAS AND SPEAKERS

All meetings were held at Hudson Institute, Washington, D.C.

MEETING 1: THREAT AWARENESS DECEMBER 4, 2014

Congressional Perspective

- The Honorable Richard Burr – United States Senator, North Carolina, and Chairman, Senate Select Committee on Intelligence

Panel One: WMD Commission Perspectives

The relevance of the WMD Commission's past work, its assessment of the potential threat, and its evaluation of U.S. preparedness efforts

- Senator James M. Talent, J.D. – Senior Fellow, American Enterprise Institute
- Colonel Randall Larsen, USAF (ret.) – Former Executive Director, Congressional Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism

Lunch Keynote

The threat

- The Honorable Richard J. Danzig, J.D. – Director, Center for a New American Security

Panel Two: Executive Branch Perspectives

Contemporary insights on the nature of the chemical and biological threats, and the ability of the Department of Homeland Security, Intelligence Community, and Congress to define the risks

- The Honorable Tara O'Toole, M.D., M.P.H. – Executive Vice President, In-Q-Tel
- The Honorable Michael Moodie, M.A. – Former Assistant Director for Multilateral Affairs, U.S. Arms Control and Disarmament Agency
- George Poste, D.V.M., Ph.D. – Director, Complex Adaptive Systems Institute, Arizona State University

Panel Three: Non-Governmental Perspectives

The potential enabling role that modern technology affords states, non-states, and individuals to conduct biological and chemical terrorism

- Peter J. Roman, Ph.D. – President, WIT Consulting LLC
- W. Seth Carus, Ph.D. – Distinguished Research Fellow, National Defense University
- Keith H. Wells, Ph.D. – Senior Consultant, BioProcess Technology Consultants

MEETING 2: PREVENTION AND PROTECTION JANUARY 14, 2015

Panel One: Biological Arms Control, Cooperative Threat Reduction, the Global Health Security Agenda, and Quarantine

International challenges and opportunities in reducing the risk from biological threats

- Daniel M. Gerstein, Ph.D., M.S.N.S.S., M.M.A.S., M.S.O.R. – RAND Corporation
- David R. Franz D.V.M., Ph.D. – Former Commander, United States Army Medical Research Institute of Infectious Disease
- Elizabeth E. Cameron, Ph.D. – Director, Countering Biological Threats, National Security Council staff
- Michael A. Stoto, Ph.D. – Professor of Health Systems Administration and Population Health, Georgetown University

Lunch Keynote

First responder protection

- William F. Raub, Ph.D. – Public Health Consultant

Panel Two: Biosecurity, the Select Agent Program, and Synthetic Biology

Understanding the challenges of laboratory research in the context of modern threats, regulatory regimes, and new technologies

- Timothy Lu, M.D. Ph.D. – Associate Professor, Massachusetts Institute of Technology
- Thomas G. Ksiazek, D.V.M., Ph.D. – Professor, Department of Pathology, University of Texas Medical Branch

Panel Three: Resilience, Biodeterrence, First Responder Vaccination, and Agricultural Defense

Means of creating a society resilient to biological threats through deterrence, public health and animal health measures, and protections for first responders

- Jeffrey Levi, Ph.D. – Executive Director, Trust for America's Health
- Bruce E. Miller, O.E., M.S. – Assistant to the Vice President for Homeland Security, Office of the Vice President (2001-2009)
- Sgt. Mark R. Landahl, Ph.D. – Supervisor, Frederick County (MD) Sheriff's Office
- Curt J. Mann, D.V.M. – Principal, Empryse Group

Panel Four: Insights on Ebola and Pandemic Influenza Response

Real-world outbreaks and the ways in which they have demonstrated U.S. strengths and weaknesses, particularly with respect to medical countermeasures

- Robin Robinson, Ph.D. – Director, HHS/Biomedical Advanced Research and Development Authority (BARDA)
- Monique K. Mansoura, Ph.D., M.B.A. – Head, Medical Countermeasures & Government Affairs, Americas, Novartis Influenza Vaccines
- Daniel Lucey, M.D., M.P.H. – Adjunct Professor Georgetown University Medical and Law Centers, & School of Foreign Service

MEETING 3: SURVEILLANCE AND DETECTION MARCH 12, 2015

Congressional Perspective

- The Honorable Sheldon Whitehouse – United States Senator, Rhode Island

Panel One: The Biosurveillance and Detection Landscape

Key elements of effective biosurveillance and detection, and continued challenges in the effectiveness of ongoing efforts

- Julie Louise Gerberding, M.D., M.P.H. – Executive Vice President, Strategic Communications, Global Public Policy, & Population Health, Merck & Co., Inc.
- Julie E. Fischer, Ph.D. – Associate Research Professor of Health Management and Policy, The Milken Institute School of Public Health, The George Washington University
- Norman M. Kahn – Former Director, Intelligence Community Counter-Biological Weapons Program

Panel Two: Environmental Surveillance and Detection

Technological and policy challenges to early and reliable detection of environmentally dispersed biological and chemical agents

- The Honorable Jeffrey Runge, M.D. – Former Assistant Secretary for Health Affairs and Chief Medical Officer, U.S. Department of Homeland Security
- Denise Pettit, Ph.D. – Assistant Director, North Carolina State Laboratory of Public Health
- Eric Joseph Van Gieson, Ph.D. – Senior Director, Diagnostics and Biosurveillance Innovation, MRIGlobal

Lunch Keynote

The human-animal interface

- William B. Karesh, D.V.M. – Executive Vice President for Health and Policy, EcoHealth Alliance

Panel Three: Clinical Surveillance and Detection

Key elements of an effective clinical surveillance and detection architecture, and impediments and opportunities to increase situational awareness for early and accurate disease detection and clinical diagnosis

- Dan Didier, M.D., Ph.D. – Head of Public Health, Thermo Fisher Scientific
- Daniel P. Desmond – Founder, The SIMI Group, Inc.
- Deborah G. Rosenblum, M.A. – Executive Vice President, The Nuclear Threat Initiative
- Robert W. VanDine – Chief Government Affairs, RPS Diagnostics, Inc.

Panel Four: Law Enforcement, Attribution, and the Lone Wolf

Law enforcement activities, attribution of deliberate acts, and the problem of the lone wolf

- Randall S. Murch, Ph.D., M.S. – Professor in Practice, School of Public and International Affairs, Virginia Polytechnic Institute and State University (Virginia Tech)
- Yonah Alexander, Ph.D. M.A.– Professor and Director, Inter-University Center for Terrorism Studies
- Edward H. You, M.S. – Supervisory Special Agent, Biological Countermeasures Unit, Weapons of Mass Destruction Directorate, Federal Bureau of Investigation

Panel Five: Read-outs from Commission Satellite Meetings

Presentation of findings and recommendations from satellite meetings held in support of the Commission

- Elizabeth G. Posillico, Ph.D. – President & CEO, Elusys Therapeutics, Inc.
- Gerald W. Parker, D.V.M., Ph.D., M.S. – Vice President for Public Health Preparedness and Response, Texas A&M University Health Science Center
- Beth Maldin Morgenthau, M.P.H. – Assistant Commissioner, Office of Emergency Preparedness and Response, NYC Department of Health and Mental Hygiene
- Timothy Stephens, M.A. – CEO, MESH Coalition

MEETING 4: RESPONSE AND RECOVERY APRIL 1, 2015

Congressional Perspective

- The Honorable Mike Rogers – Former Chairman, House Permanent Select Committee on Intelligence (2011-2015), and Distinguished Fellow, Hudson Institute

Panel One: Pre-event Activities and Emergency Response

Pre-event and post-event planning, including the challenges faced by first responders and hospitals, and the role of DOD and other federal agencies

- Chief G. Keith Bryant – President and Chairman of the Board, International Association of Fire Chiefs
- Matthew Minson, M.D. – Senior Advisor for Health Affairs, Texas Engineering Extension Service, Texas A&M University
- Carter Mecher, M.D. – Senior Medical Advisor, Office of Public Health, Department of Veterans Affairs

Panel Two: Public Health Response

Challenges of real-time epidemiology and other tools for characterizing the spread of disease or a large-scale chemical event throughout United States and elsewhere

- James Terbush, M.D., M.P.H. – Senior Partner, Martin, Blanck and Associates
- Suzet M. McKinney, Dr.P.H., M.P.H. – Deputy Commissioner, Bureau of Public Health Preparedness and Emergency Response, Chicago Department of Public Health
- Melissa S. Hersh, M.A. – Principal, Hersh Consulting, LLC

Lunch Keynote

Thinking about readiness at scale, and with imagination

- Irwin Redlener, M.D. – Director, National Center for Disaster Preparedness, Columbia University

Panel Three: Pharmaceutical Response

Response requirements for medical countermeasures, including the need for extremely rapid development, distribution, and dispensing

- Anne S. De Groot, M.D. – EpiVax, Inc. CEO/CSO
- Daniel J. Abdun-Nabi, J.D. – President & Chief Executive Officer, Emergent BioSolutions Inc.
- Michael W. Chervenic, M.B.A. – Managing Director, Stokes Evans
- Jude M. Plessas – Executive Manager, Countermeasures Delivery and Distribution, United States Postal Service

Panel Four: Recovery and Mitigation

Recovery and mitigation, including the challenges posed by cutting edge technology, lack of agreement regarding agency responsibilities, resilience, and implications for future preparedness

- Kavita M. Berger, Ph.D. – Scientist, Gryphon Scientific
- Michael J. Hopmeier, M.S.M.E. – President, Unconventional Concepts, Inc.
- Kenneth W. Staley, M.D., M.P.A. – Former Director for Biodefense Policy, Homeland Security Council

Panel Five: Leadership

The unique challenges and opportunities for leaders in biodefense, and the need to expand the ranks

- RADM Kenneth Bernard, M.D., D.T.M&H, USPHS (Ret.) – Adviser on Security and Health, Former Special Assistant to the President for Biodefense
- Lisa E. Gordon-Hagerty, M.P.H. – President, Tier Tech International, Inc.
- Colonel Robert Kadlec, M.D., USAF (Ret.) – Former Special Assistant to the President and Senior Director for Biodefense Policy, Homeland Security Council

APPENDIX D: ACRONYMS

API	active pharmaceutical ingredients
APHIS	Animal and Plant Health Inspection Service
ASPR	Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
BWC	Biological and Toxin Weapons Convention
CBRN	chemical, biological, radiological, and/or nuclear
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
DASD	Deputy Assistant Secretary of Defense
DHS	U.S. Department of Homeland Security
DNI	Director of National Intelligence
DOD	U.S. Department of Defense
DOI	U.S. Department of the Interior
EPA	U.S. Environmental Protection Agency
EUA	Emergency Use Authorization
FBI	Federal Bureau of Investigation
FDA	U.S. Food and Drug Administration
FEMA	Federal Emergency Management Agency
GAO	Government Accountability Office
GHSA	Global Health Security Agenda
GPRA	Government Performance and Results Act
HSPD	Homeland Security Presidential Directive
HHS	U.S Department of Health and Human Services
HIV	human immunodeficiency virus
HPP	Hospital Preparedness Program
HSC	Homeland Security Council
IC	Intelligence Community
ICE	Immigration and Customs Enforcement
IOM	Institute of Medicine
ISAC	Information Sharing and Analysis Center
ISIL	Islamic State of Iraq and the Levant (also known as Da'esh)
JCAT	Joint Counterterrorism Assessment Team
MCM	medical countermeasure(s)
MTD	Material Threat Determination
NAHLN	National Animal Health Laboratory Network
NBIS	National Biosurveillance Integration System
NBFAC	National Bioforensics Analysis Center
NCA	National Command Authority
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIM	National Intelligence Manager
NSABB	National Science Advisory Board for Biosecurity
NSC	National Security Council
NSDM	National Security Decision Memorandum
OHA	Office of Health Affairs
OIE	World Organization for Animal Health
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
OTA	other transaction authority
PAHPA	Pandemic and All-Hazards Preparedness Act
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHEP	Public Health Emergency Preparedness program
POD	point of dispensing
PPE	personal protective equipment
PPP	public-private partnership(s)
R&D	research and development
S&T	Science and Technology
SAP	Select Agent Program
SNS	Strategic National Stockpile
SRF	Special Reserve Fund
WHO	World Health Organization
WMD	weapon(s) of mass destruction
USDA	U.S. Department of Agriculture
USPS	U.S. Postal Service
VA	U.S. Department of Veterans Affairs

APPENDIX E: FINANCIAL SPONSORS

The Commission received financial support from many organizations. Each of these contributors enthusiastically provided the funding needed to promote the efforts of the Commission. Without their substantial support, the Commission and its report would not have been possible. For this and for their commitment to biodefense, we thank them.

- Bavarian Nordic
- Biotechnology Industry Organization (BIO)
- Dalrymple & Associates, LLC
- Elusys Therapeutics, Inc.
- Emergency Services Coalition for Medical Preparedness
- Emergent BioSolutions Inc.
- HWC (formerly Hassett Willis and Company)
- Luminex Corporation
- MESH Coalition
- The Nuclear Threat Initiative (NTI)
- Open Philanthropy Project
- PharmAthene, Inc.
- REGENXBIO Inc.
- SIGA Technologies, Inc.
- Smith Richardson Foundation, Inc.
- Texas A&M University

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The Bipartisan Commission on Biodefense exists because of the foresight, forbearance, and perpetual optimism of Dr. Robert Kadlec. Bob understood that as much progress as had been made in the national effort to prevent and prepare for biological threats, it is not yet enough. He knew that with the right impetus, we could do much more, and he envisioned this Commission as a means to that end. We are glad he did.

Two institutions quickly stepped up to host the initiative: Hudson Institute provided an excellent venue for the Commission's public meetings, deep subject matter expertise, and an administrative home base that allowed the day-to-day activities of the Commission to proceed efficiently; and the Inter-University Center for Terrorism Studies at the Potomac Institute for Policy Studies offered their space, financial resources, and profound expertise in the roots of terrorism to lend further credential to the initiative. The Commission and its report came to fruition because of the willingness of these organizations to support this endeavor.

We thank our financial sponsors for the outstanding support they provided to make this initiative a reality. They are listed in Appendix E.

The many speakers who graciously and enthusiastically accepted invitations to address the Commission are listed in Appendix C. Their contributions were invaluable. Their perspectives (based on years in public service, in the field, and elsewhere) helped the Commission identify areas in which efforts were lagging and informed the Commission's recommendations for action. Enthusiastic Capitol Hill staff juggled their Members' schedules to ensure that congressional input was received. Many Capitol Hill staff also encouraged us to establish the Commission from the very beginning, came to its public sessions, facilitated informal meetings with their bosses, and worked with the Commission in hopes that its final product would be received by a Congress willing to act upon it. Similarly, many individuals in the Executive Branch were supportive of the Commission's activities and helped inform our findings and recommendations. We thank them for their dedication to this cause.

Several organizations hosted workshops to delve deeply into specific issue areas. Representatives presented their findings to the Commission and contributed substantially to the report. These organizations were the Alliance for Biosecurity, MESH Coalition, the New York City Department of Health and Mental Hygiene, and the Texas A&M University Health Science Center.

Many other individuals and organizations unable to participate in the public meetings also provided information to the Commission for consideration. Ms. Megan Reeve Snair and many others reviewed and provided feedback on the draft report. Input from subject matter experts and stakeholders helped shape the report in many ways. There are far too many contributors to name, but we thank them all for their exceptional commitment to biodefense.

ENDNOTES

1 Franz, D.R., Parrott, C.D., & Takafuji, E.T. (1997). The U.S. Biological Warfare and Biological Defense Programs. In F.R. Sidell, E.T., Takafuji, & Franz, D.R. (Eds.), Medical Aspects of Chemical and Biological Warfare (p. 426). Washington, DC: Office of the Surgeon General of TMM Publications.

2 From 1943 to 1969, the United States learned how to weaponize, distribute, combine, manipulate, and counteract many biological agents (e.g., Bacillus anthracis, Clostridium botulinum, Coxiella burnetii, Francisella tularensis, Germiston virus, Puccinia graminis, Sendai virus, Staphylococcal Enterotoxin B, Venezuelan equine encephalitis virus, and Yersinia pestis), as well as anti-materiel organisms.

3 Schram, M. (2003). Russian Bio-Shock: Soviet Secrets Dumbfound U.S. Intelligence. In Avoiding Armageddon: Our Future, Our Choice: Companion to the PBS series from Ted Turner Documentaries (pp. 186-196). New York, NY: Basic Books.

4 Miller, J., Engelberg, S., & Broad, W. (2001). Germs: Biological Weapons and America's Secret Wars (p. 150). New York, NY: Simon & Schuster.

5 Inter-University Center for Terrorism Studies. (2014). Reassessing the WMD Challenges: The Next Phase. Washington, DC: Potomac Institute for Policy Studies.

6 Discussions of the threat in this report have been informed not only by experts who presented to the Commission, but also by classified and unclassified intelligence information. No classified information is discussed. Unclassified information that may have otherwise been useful to the discussion was not actually included if doing so would result in classified statements, particularly regarding the activities of the Intelligence Community. Discussions of the threat and of intelligence actions related to it are, therefore, necessarily high level and not highly specific.

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8 For example, an estimated 100-200 tons of weaponized anthrax were buried by Russia on Vozrozhdeniye Island in the Aral Sea in 1988, incompletely destroyed, and never properly secured after the island came under the control of Kazakhstan and Uzbekistan. Even if only 50 tons of the weaponized anthrax on Vozrozhdeniye Island remains, this one source of anthrax unaccounted for is 45 million times larger than the 5 grams used in the U.S. anthrax attacks of 2001. Pala, C. (2003, March 22). Anthrax Buried for Good. The Washington Times.

9 The smuggling of biological agents and weapons from poorly secured, previously established stockpiles – such as areas where the Soviets buried anthrax – is of concern, particularly through those countries surrounding the Middle East. Nations containing smuggling routes; inadequate border control systems, export laws, and export controls; and groups or individuals that could help to smuggle biological agents and weapons are all at risk, including the United States.

10 Advances in and diffusion of biological expertise, technology, and information have accelerated and led to the democratization of the capabilities and capacity necessary to produce biological agents and weapons throughout the world.

11 Advanced science and technology are necessary for the production of biological weapons, as are laboratories, physical space in which to conduct necessary experimentation and production, personnel trained in laboratory science, and military and other planners who know how best to utilize such weapons.

12 Resources and intent alone do not result in the immediate capability to produce biological agents or weapons. See Vogel, K.M. (2008). Framing Biosecurity: An Alternative to the Biotech Revolution Model? Sci Pub Pol, 35(1):45–54.

13 Rogers, M. (Speaker). (2015, April 1). Meeting 4 of the Bipartisan Commission on Biodefense: Response and Recovery.

14 Alexander, Y. & Swetnam, M. (2012). Al-Qa'ida: Ten Years After 9/11 and Beyond. Arlington, VA: Potomac Institute for Policy Studies.

15 Nothing prevents U.S. citizens who are bioscience professionals from joining domestic militia groups, although U.S. laws do prohibit these professionals from removing biological agents from laboratories and developing biological weapons in the United States. U.S. domestic militia members have produced ricin and sarin on a larger scale than they had previously, demonstrating increasing capabilities. Valla, E.J. & Comcowich, G. (2008). Domestic Terrorism: Forgotten but Not Gone. In J.H. Norwitz (Ed.), Armed Groups: Studies in National Security, Counterterrorism, and Counterinsurgency (p. 176). Washington, DC: U.S. Government Printing Office.

16 Lone wolves are individuals who do not operate within the organizational constructs offered by militias, domestic violent extremist groups, or terrorist groups. Lone wolves are more difficult to track than domestic militia groups. As with members of ISIL, lone wolves have left social mores behind. A lone wolf who obtains biological agents or weapons should be expected to use them with little hesitation. Additionally, U.S. citizens who sympathize with ISIL and likeminded groups may present an equal or even greater danger than terrorist groups.

17 Kuntz, C. (2012). Biodefense: When Technology Goes Global. Washington, DC: Center for Strategic and International Studies.

18 Potomac Institute for Policy Studies. (1991). Conference on Countering Biological Terrorism: Strategic Firepower in the Hands of Many? Arlington, VA: Potomac Institute for Policy Studies.

19 For example, the influenza season takes an estimated 3,000–49,000 U.S. lives annually. Thompson, M.G., Shay D.K., Zhou, H., Bridges, C.B., Cheng, P.Y., et al. (2010). Updated Estimates of Mortality Associated with Seasonal Influenza through the 2006–2007 Influenza Season. MMWR, 59(33), 1057–1062.

20 Extremely drug resistant tuberculosis is just one example of a reemerging disease that we had hoped to eradicate, but which is evading the medicines currently at our disposal. Our inability to prevent the misuse of antimicrobials, combined with the ability of organisms to mutate and outpace development of new countermeasures, means that diseases we thought we had conquered remain with us. Organisms can also be intentionally manipulated to worsen their effects. Intentionally over-using antimicrobials to produce drug-resistant diseases, purposely convincing people to avoid vaccination, and deliberately spreading infectious diseases will weaken any population, making them easier to control and defeat.

21 Anthrax was accidentally released in 1953 and 1979 from laboratories in Russia when a maintenance worker neglected to replace an air filter.

22 Chappell, B. (2015, May 28). Live Anthrax Was Mistakenly Sent to 9 States and a U.S. Military Base. The Two-Way: Breaking News from NPR. Retrieved from http://www.npr.org/sections/thetwo-way/2015/05/28/410220914/live-anthrax-was-mistakenly-sent-to-9-states-and-a-u-s-military-base.

23 Centers for Disease Control and Prevention (2015, March 13). Conclusion of Select Agent Inquiry into Burkholderia pseudomallei Release at Tulane National Primate Research Center [Press release]. Retrieved from http://www.cdc.gov/media/releases/2015/s0313-burkholderia-pseudomallei.html.

24 Biosecurity builds on biosafety rules and procedures, adding other requirements to ensure that those disease agents that could be used to produce biological weapons are properly secured.

25 Centers for Disease Control and Prevention. (2014, July 8). CDC Media Statement on Newly Discovered Smallpox Specimens [Press release]. Retrieved from: http://www.cdc.gov/media/releases/2014/s0708-NIH.html.

26 Some employees at the CDC failed in extremis to establish and execute proper biosecurity procedures in 2014, having improperly: 1) inactivated specimens; 2) designed research; 3) decontaminated laboratories; 4) secured refrigerators; 5) restricted access; 6) trained personnel; and 7) transferred specimens. The CDC Director, Dr. Thomas, stated that "...these incidents should never have happened and the lack of adequate procedures and oversight that allowed them to happen are totally unacceptable." Frieden T. (2014, July 16). Hearing testimony before the Subcommittee on Oversight and Investigations, Energy and Commerce Committee, U.S. House of Representatives: Review of CDC Anthrax Lab Incident.

27 The United States Commission on National Security/21st Century. (1999). New World Coming: American Security in the 21st Century, Major Themes and Implications, Report on the Emerging Global Security Environment for the First Quarter of the 21st Century (p. 63). Washington, DC: U.S. Department of Defense.

28 The National Commission on Terrorist Attacks Upon the United States. (2004). The 9/11 Commission Report: Final Report of the National Commission on Terrorist Attacks Upon the United States. New York, NY: W.W. Norton & Company.

29 The Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction. (2005). Report to the President of the United States. Charleston, SC: BookSurge, LLC.

30 Graham, B., & Talent, J. (2008). World at Risk: The Report of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (pp.23–42). New York, NY: Vintage Books.

31 Patterson, B. (2000). The White House Staff Inside the West Wing and Beyond. Washington, DC: Brookings Institution Press.

32 Examples include Stewart Simonson (Bird Flu Czar), Ron Klain (Ebola Czar), and Richard Clarke (Terrorism and Counter-terrorism Czar).

33 The National Performance Review was a task force on government performance.

34 The National Strategy for Biosurveillance is an example.

35 Determinations of the number of departments and agencies that contribute to biodefense depend on how biodefense is defined. See: Sell, T. K., & Watson, M. (2013). Federal Agency Biodefense Funding, FY2013–FY2014. Biosecur Bioterror, 11(3), 196–216, which describes nine departments and agencies based on an analysis of budget documents. See also H.R. 2356, Sec. 104, 112th Congress, which called for the inclusion of 12 departments and agencies in a biodefense budget analysis.

36 Larsen, R., Boddie, C., Watson, M., Gronvall, G.K., Toner, E., et. al. (2015). Jump Start (pp. 56-7). Baltimore, MD: University of Pittsburgh Medical Center, Center for Health Security.

37 The World War II War Production Board provides an example of this kind of council.

38 In addition to the Biological Incident Annex of the National Response Plan, other annexes related to the response to biological incidents are the Public Health and Medical Services Annex, Oil and Hazardous Materials Response Annex, and Agriculture and Natural Resources Annex.

39 The behavior of weaponized pathogens differs from naturally occurring biological agents in terms of incubation rates, disease severity, and other characteristics.

40 Many of these are discussed in: Polin, D. (2009, May 15). A U.S. Biodefense Strategy Primer. LLNL-TR-413042. Livermore, CA: Lawrence Livermore National Laboratory.

41 For example, the Office of Science and Technology Policy can work through each document to identify gaps in capabilities that could be mitigated by innovations in science and technology.

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47 The "predominance of zoonoses among emerging infectious diseases illustrates the central role of the animal-human-ecosystem interface and informs the One Health paradigm." Institute of Medicine. (2015). Emerging Viral Diseases: The One Health Connection: Workshop Summary (p.10). Washington, DC: National Academies Press.

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49 Brookes, V.J., Hernandez-Jover, M., Black, P. F., & Ward, M. P. (2015). Preparedness for emerging infectious diseases: pathways from anticipation to action. Epidemiol Infect, 143(10), 2043–2058.

50 National Institutes of Health. The NIH Almanac. Retrieved from http://www.nih.gov/about/almanac/historical/chronology_of_events.htm#eighteenhundred.

51 Based on Commission analysis of appropriations.

52 Korch, G. (2010, February 23). Optimizing the Medical Countermeasure Product Pipeline from the Science Base through Advanced Development. Paper presented at The Public Health Emergency Medical Countermeasures Enterprise: Innovative Strategies to Enhance Products from Discovery through Approval. Institute of Medicine, Washington, DC.

53 U.S. Environmental Protection Agency. Models, Tools and Applications for Homeland Security Research. Retrieved from http://www2.epa.gov/homeland-security-research/models-tools-and-applications-homeland-security-research#tab-3.

54 National Science and Technology Council. (2013). Biological Response and Recovery Science and Technology Roadmap. Washington, DC: The Executive Office of the President.

55 For example, after a biological release at Tulane University, Tulane's primate center staff collected the environmental samples while EPA team members directed where and how many samples were collected. Young, A. (2015, March 5). Deadly Bacteria Release Sparks Concern at Louisiana Lab. USATODAY. Retrieved from http://www.usatoday.com/story/news/2015/03/01/tulane-primate-bio-lab-bacteria-release/24137053/.

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57 Environmental Policy Act of 1969, P.L. 91–90, 42 U.S.C. §4321 et seq. (2006).

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65 Institute of Medicine. (2007). Emergency Medical Services at the Crossroads. Washington, DC: National Academies Press.

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69 Bicameral and bipartisan legislation introduced in the 114th Congress calls for such a program: H.R. 1300 and S. 1915. H.R. 1300 passed the House unanimously on July 29, 2015.

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73 The jurisdictions include all 50 states, 8 territories, and 4 major urban areas. See Lister, S.A. (2014, October 9). Funding History for Public Health and Hospital Preparedness Grants to States. Washington, DC: Congressional Research Service.

74 Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, P.L. 113-5, 42 U.S.C. §§ 247, 284, and 300; 21 U.S.C. 355, 360, and 361.

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79 U.S. Department of Health and Human Services. (2015, February 20). HHS invests in enhancing domestic preparedness efforts for Ebola [Press release]. Retrieved from http://www.hhs.gov/news/press/2015pres/02/20150220a.html.

80 Based on Commission analysis of appropriations received by ASPR versus amounts sent to recipients, more than $60 million over the last three fiscal years has been retained for management and administration.

81 For proposed language, see H.R. 3299, Sec. 2, 114th Congress.

82 For proposed language, see H.R. 3299, Sec. 3, 114th Congress.

83 The process for incorporating preparedness for bioterrorism and other deadly infectious disease emergencies has begun in part. See Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; A Proposed Rule by the Centers for Medicare & Medicaid Services. FR Doc 2013–30724 (27 December, 2013).

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116 For proposed language, see H.R. 3299, Sec. 6, 114th Congress.

117 For proposed language, see H.R. 3299, Sec. 5, 114th Congress.

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119 The Public Health Security and Bioterrorism Preparedness Act of 2002, P.L. 107–188, 42 U.S.C., defined and authorized the regulation of select agents and toxins.

120 For example, laboratory personnel currently spend many hours engaged in the bureaucratically tedious process of inventory control of select agent pathogens, but this has little security meaning when applied to biological organisms. While it is important to know that a laboratory stores a particular pathogen, it is of little meaning to know that the laboratory stores either two tubes or three of a replicating biological organism.

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