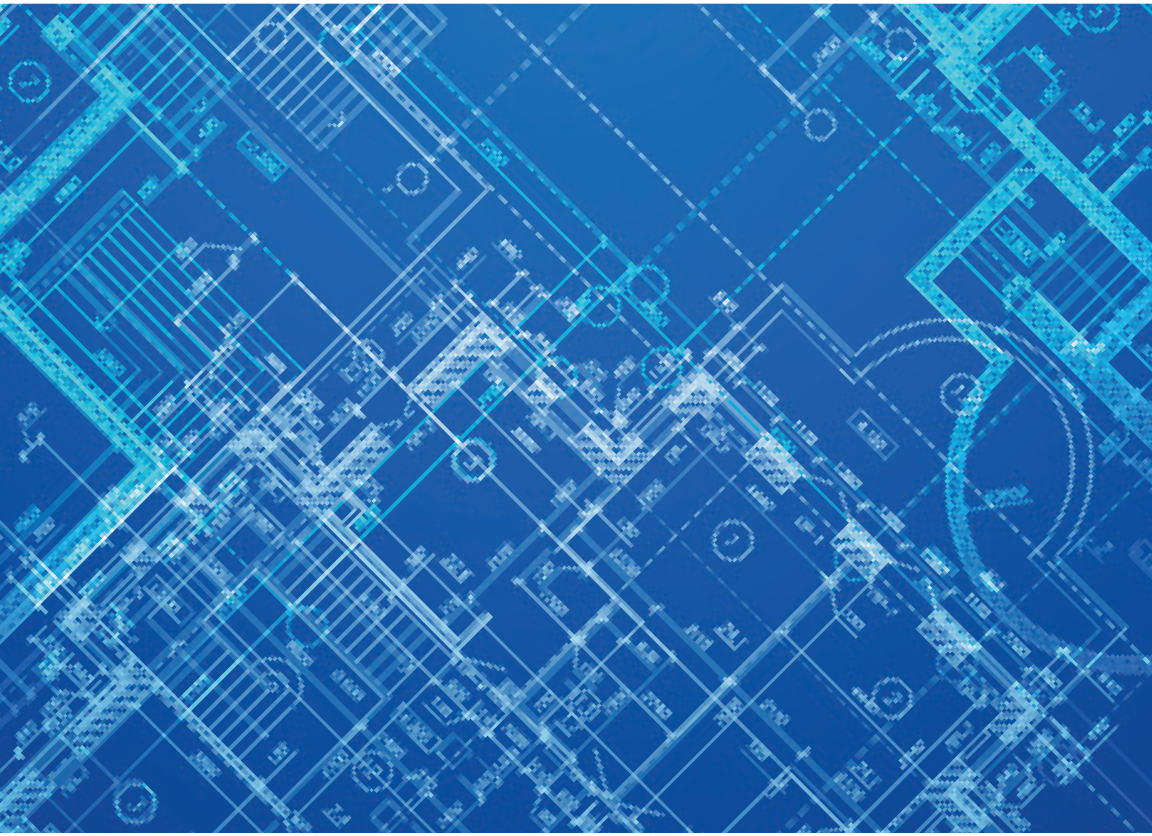
A NATIONAL BLUEPRINT FOR BIODEFENSE:

LEADERSHIP AND MAJOR REFORM NEEDED TO OPTIMIZE EFFORTS

BIPARTISAN REPORT OF THE BLUE RIBBON STUDY PANEL ON BIODEFENSE

October 2015



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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 Blue Ribbon Study Panel on Biodefense to assess how much 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 are bypassing 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 Panel (through public meetings, targeted interviews, and extensive research) examined the national state of defense against biological attacks and emerging and reemerging infectious diseases, of the order 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 Panel, 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 Blue Ribbon Study Panel on Biodefense was established in 2014 to assess gaps and provide recommendations to improve U.S. biodefense. The Panel – supported by a suite of distinguished ex officio members and staff with deep 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 Study Panel. 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 Panel'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 alone 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. They 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, much of it in the near term. 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 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. And 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 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 Intelligence Community 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 provided billions 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 (DOS) 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 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 Intelligence Community (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, spreading throughout the United States, and 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 closure of certain laboratories that tested for suspected bioterrorist agents.[26] Exacerbating the problem was 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, 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, typically, 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 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 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 that leverages 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)
- Homeland Security Presidential Directive (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 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.** 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.

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, increasing 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 FY 2002, the last appropriation (FY 2015) 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 dependent 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.

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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 Panel, "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 ISACs, 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 FY 2017 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 (IND) 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 (PREP) 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 FY 2004-2013 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 FY 2006 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 FY 2013, 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 FY 2014 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 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 Blue Ribbon Study Panel 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 Blue Ribbon Study Panel on Biodefense was established in 2014 to inform U.S. biodefense and provide recommendations for change. The Panel – 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 Panel 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 Panel.

FORMAL PANEL 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 Panel, 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. Panel 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 Panel and ex officio review.

SATELLITE WORKSHOPS

The activities of the Panel 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 Panel. 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 Panel to consider.

ANALYSIS

Qualitative methods were used to analyze all of this information. The Panel 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 Panel's own experience. Throughout the process, the five questions defined previously provided the basis for assessment. This approach allowed the Panel, 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 Panel 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 Panel 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 Study Panel Satellite Meetings

Presentation of findings and recommendations from satellite meetings held in support of the Study Panel

- 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
DOL	U.S. Department of Labor
DOS	U.S. Department of State
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
IND	investigational new drug
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
PREP	Public Readiness and Emergency Preparedness
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 Panel received financial support from many organizations. Each of these contributors enthusiastically provided the funding needed to promote the efforts of the Panel. Without their substantial support, the Panel 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
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- 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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Two institutions quickly stepped up to host the initiative: Hudson Institute provided an excellent venue for the Panel's public meetings, deep subject matter expertise, and an administrative home base that allowed the day-to-day activities of the Panel 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 Panel 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 Panel are listed in Appendix C. Their contributions were invaluable. Their perspectives (based on years in public service, the field, and elsewhere) helped the Panel identify areas in which efforts were lagging and informed the Panel's recommendations for action. Enthusiastic Capitol Hill staff juggled their Members' schedules to ensure that congressional input was received. Many Hill staff also encouraged us to establish the Panel from the very beginning, came to its public sessions, facilitated informal meetings with their bosses, and worked with the Panel 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 Panel'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 Panel 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 Panel 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.

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6 Discussions of the threat in this report have been informed not only by experts who presented to the Study Panel, 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 Blue Ribbon Study Panel 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.

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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.

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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.

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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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81 For proposed language, see H.R. 3299, Sec. 2, 114th Congress.

82 For proposed language, see H.R. 3299, Sec. 3, 114th Congress.

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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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