BIODEFENSE INDICATORS

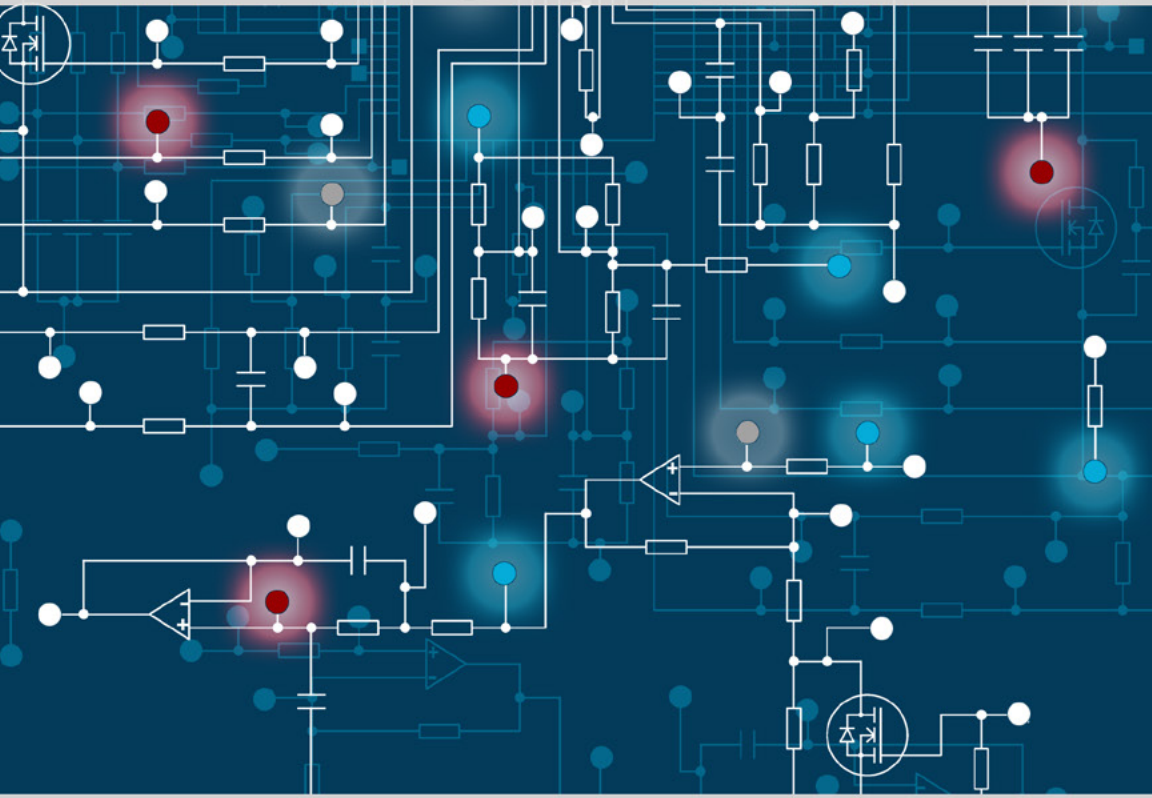
BIPARTISAN COMMISSION ON BIODEFENSE

Formerly the Blue Ribbon Study Panel on Biodefense

ONE YEAR LATER, EVENTS OUTPACING FEDERAL EFFORTS TO DEFEND THE NATION

A Bipartisan Report of the Blue Ribbon Study Panel on Biodefense

December 2016



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BLUE RIBBON STUDY PANEL ON BIODEFENSE

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ABOUT THE BLUE RIBBON STUDY PANEL ON BIODEFENSE

Recommending and promoting changes to U.S. policy and law to strengthen national biodefense while optimizing resource investments.

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BLUE RIBBON STUDY PANEL ON BIODEFENSE

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PREFACE

Early in 2016, the Alliance for Biosecurity, Blue Ribbon Study Panel on Biodefense, and Trust for America's Health polled American perceptions of biosecurity preparedness in the United States. Nearly 80 percent of respondents expressed concern that naturally occurring infectious diseases threaten our citizens. Nearly nine out of ten believed that terrorists might use biological weapons against the United States and our allies. The American public clearly understands that the biological threat is real and that our government is not doing enough to address it. We agree. More than ever, governmental bureaucracies adapt slowly, while nature, terrorists, and nation-states move more quickly.

Even before we initiated our examination of U.S. biodefense in 2014, we understood that our nation was not prepared. As we came together to develop the Panel's agenda, Ebola was just starting to percolate in West Africa, where it had never appeared before. By October 2015, when we issued our bipartisan report, *A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts*, the Ebola crisis revealed serious deficiencies in both federal and international public health and biodefense efforts. Clearly, the federal leadership needed to optimally plan for, and handle, a major infectious disease outbreak was still not in place.

The events related to Zika only served to reaffirm this conclusion. Zika revealed weaknesses in U.S. resilience to outbreaks and public health. Insufficient advance prioritization of funding; the inability to rapidly develop, approve, and field medical countermeasures; and an unacceptable politicized response continue to render us weak, even as biological events increasingly threaten the nation.

The Blue Ribbon Study Panel on Biodefense assessed the spectrum of biodefense efforts from prevention to recovery, and developed detailed recommendations for the federal government to improve and optimize these efforts. We determined that our government could achieve specific actions within one, three, or five years. We directed each recommendation toward either the White House, a department or agency within the Executive Branch, the Congress, or a combination of these. The purpose of this report, *Biodefense Indicators: One Year Later, Events Outpacing Federal Efforts to Defend the Nation*, is to provide an assessment of how much progress has been made in implementing the short-term, one-year action items.

We began our work before Ebola spread out of West Africa. We issued our report before Zika reached the U.S. mainland and Puerto Rico. Another biological event will certainly challenge the nation soon. We urge the incoming Administration and the new Congress to very carefully consider the limited progress to date and emplace needed leadership to rapidly implement our *Blueprint for Biodefense.*

THE THREAT

In February 2016, President Barack H. Obama requested the transfer of funds originally designated for the procurement of medical countermeasures (MCM) for those pathogens deemed by the Department of Homeland Security (DHS) to pose material threats to national security. Driven primarily by the urgent need to respond to Zika, the President sought to redirect those funds. Senator Richard Burr, Senator Lamar Alexander, Representative Fred Upton, and Representative Susan Brooks sent a strongly worded letter to the Secretary of Health and Human Services, Sylvia Burwell, arguing against this move. We concur.

It is difficult to reconcile an action such as this with statements from other high-level officials that otherwise acknowledge the threat. Director of National Intelligence (DNI) James Clapper testified before the Senate Committee on Armed Services and the Senate Select Committee on Intelligence on February 9, 2016 that dual-use biological materials and individuals with the expertise to use them move easily in our globalized economy. He acknowledged that the proliferation of new biotechnologies designed for the greater good will also increase the creation and risk of potentially harmful biological agents.

In April 2016, the Kenyan National Police reported that it foiled a plot linked to the Islamic State of Iraq and the Levant (ISIL, also known as Da'esh) that

involved medical experts with plans to unleash an anthrax attack in that country. United Nations (U.N.) Secretary General Ban Ki-moon addressed the U.N. Security Council in August, stating that the world is ill-prepared to deal with a biological weapons attack and expressing concern that the consequences of such an assault could far exceed those of a chemical or radiological attack.

Several terrorist groups, including al Qaeda and ISIL, continue to work to develop biological weapons. A 2015 report for European Parliament thoroughly examined the threat and clearly warned member countries of and other countries near the European Union that they must take the biological capacities of terrorist groups seriously. Since then, Belgium and Morocco found direct evidence of terrorist interest in and attempted use of biological weapons. Belgium apprehended members of ISIL, finding them in possession of biological material intended for use in rudimentary biological weapons. The Nigerian Army intercepted poisoned fish allegedly brought to the region by Boko Haram terrorists. Turkish officials revealed plans by ISIL to contaminate Turkish water sources with *Francisella tularensis* (the biological agent that causes tularemia). France, Germany, the Netherlands, Sweden, the United Kingdom, the North Atlantic Treaty Organization (NATO), and other allies of the United States are training to counter, and holding conferences to address, the use of biological weapons by terrorists. Experts in Israel also believe that terrorists will use biological agents and weapons as soon as they can control the spread of the diseases they produce.

At the same time, global public health responses to naturally occurring infectious diseases also cause concern. As our Panel worked to assess biological threats, vulnerabilities, and consequences, Ebola arose in West Africa and took the lives of more than 11,000 people. Experts fear that the next Ebola outbreak simmers, waiting to recur. With some parallels, the U.S. public watched Zika spread from South America and make its way north to Puerto Rico and Florida, while our lawmakers argued over whether, how, and at what resource level the federal government should respond. Our insufficient responses to these events revealed substantial weaknesses in our public health system – the same fragile system we will rely on for much larger outbreaks, epidemics, and pandemics.

The accidental release of pathogens from laboratories also remains a threat. The 2015 annual report of the Federal Select Agent Program described 233 potential occupational exposures or releases of biological select agents and toxins outside of the primary barriers of biocontainment in that one year. This statistic reminds us that deadly agents could spread from the 291 laboratories in the United States registered to work with select agents, if they do not take sufficient safety and security precautions. Despite advances in biocontainment and our ability to deactivate and attenuate organisms, laboratory safety remains inadequate. Our highest-level laboratories continue to release organisms accidentally and in some cases, unknowingly.

The scope of the bio-threat, as well as potential measures to mitigate it, were laid out very clearly last October in the bipartisan report of the Blue Ribbon Study Panel on Biodefense chaired by former Senator Joe Lieberman and former Homeland Security Secretary Tom Ridge. As with the cyber threat, the international community's response to this issue lags behind the technology driving it. Effectively countering this danger requires the development of national and international strategies, along with a consensus of the laws, standards, and authorities that will be needed.

— Central Intelligence Agency Director John O. Brennan

Council on Foreign Relations, June 29, 2016

STATUS OF IMPLEMENTATION

In 2015, the Blue Ribbon Study Panel on Biodefense put forward 33 recommendations that, if implemented, would dramatically and quickly improve our biodefense. They addressed the need for enhanced federal coordination, optimized collaboration with non-federal partners (particularly in the private sector), and timely adoption of innovative solutions to overcome technological and governance challenges. The majority of our recommendations required action by the White House or by the departments and agencies that comprise the Executive Branch. The most important recommendation, given the absence of centralized coordination, was for the President to appoint the Vice President as the leader of federal biodefense efforts. This is the single best action the Administration can take to resolve the continued challenges in biodefense. The ad hoc implementation of our other recommendations in the absence of this leadership will only result in more of the same uncoordinated effort.

While few of our recommendations require statutory authorization, Congress maintains a critical role in oversight and appropriations for all of them. Our most important recommendation for Congress is for the House and Senate to develop joint, comprehensive oversight agendas. We harbor no illusions that this will be easy, but we know it is necessary.

Alone, each recommendation facilitates some degree of positive change. Together, they provide a blueprint for biodefense capable of addressing 21st Century biological threats and meeting public expectations of the government to deal with them.

IMPLEMENTER, TERM, AND ASSESSED STATUS BY RECOMMENDATION

LEGEND

Action Status: ✓ *Completed* ≈ *Partial Action* X *Inaction*

Terms to Execute: **S** *Short-term Action (1 yr. or less)* **M** *Medium-term Action (1-3 yrs.)* **L** *Long-term Action (3-5 yrs.)*

Action Status for medium- and long-term action items not assessed.

For acronyms, see list on pages 53-55.

Recommendation Action Item	Implementer	Term	Action Status
1. Institutionalize biodefense in the Office of the Vice President of the United States.			
A. Empower the Vice President with jurisdiction and authority.	White House	S	X
B. Empower the Vice President with budget authority.	White House	S	X
2. Establish a Biodefense Coordination Council at the White House, led by the Vice President.			
A. Require broad federal participation.	White House	S	X
B. Invite broad non-federal stakeholder participation.	White House	S	X
C. Structure the Council for consensus and accountability.	White House	S	X
3. Develop, implement, and update a comprehensive national biodefense strategy.			
A. Collate the whole of biodefense policy.	White House	S	≈
B. Identify requirements within all extant policies.	White House	S	≈
C. Assess spending history and value.	White House	M	
D. Produce the National Biodefense Strategy of the United States of America and its Implementation Plan.	White House	M	
E. Develop a gap analysis based on this comprehensive strategy.	Congress	M	
F. Institute a major quadrennial biodefense review.	White House	L	
4. Unify biodefense budgeting.			
A. Develop and execute a mandatory annual biodefense call for data.	White House, Congress	S	≈
B. Conduct a cross-cutting biodefense budget analysis.	White House	S	X
C. Align budget items to the National Biodefense Strategy of the United States of America.	White House	M	
D. Provide predictable and multi-year funding for all biodefense programs.	White House, Federal Government	M	

Recommendation Action Item	Implementer	Term	Action Status
5. Determine and establish a clear congressional agenda to ensure national biodefense.			
A. Develop joint congressional oversight agendas.	Congress	**S**	**x**
6. Improve management of the biological intelligence enterprise.			
A. Create a National Intelligence Manager for Biological Threats.	DNI	**S**	**x**
B. Make biological weapons programs and related activities a discrete intelligence topic.	DNI	**S**	**≈**
C. Address bystanders.	DNI	**M**	
D. Distribute assessments.	DNI	**S**	**≈**
7. Integrate animal health and One Health approaches into biodefense strategies.			
A. Institutionalize One Health.	White House	**M**	
B. Develop a nationally notifiable animal disease system.	APHIS	**M**	
C. Prioritize emerging and reemerging infectious diseases.	HHS, USDA, DOD	**M**	
8. Prioritize and align investments in medical countermeasures among all federal stakeholders.			
A. Ensure National Institutes of Health research supports civilian medical countermeasure priorities.	White House	**M**	
B. Ensure funding allocations are appropriate to meet the need.	White House	**M**	
C. Require a biodefense spend plan from the National Institute of Allergy and Infectious Diseases.	White House, Congress, NIAID	**S**	**x**
9. Better support and inform decisions based on biological attribution.			
A. Establish a national biological attribution decision-making apparatus.	White House	**M**	
B. Place the Federal Bureau of Investigation in charge of the National Bioforensics Analysis Center.	Congress	**S**	**x**

Recommendation Action Item	Implementer	Term	Action Status
10. Establish a national environmental decontamination and remediation capacity.			
A. Include the Federal Emergency Management Agency in efforts to address remediation.	White House	**S**	**x**
B. Assign responsibility to the Environmental Protection Agency for environmental decontamination and remediation.	Congress	**S**	**x**
C. Conduct studies of those exposed to disease-causing agents.	White House, Congress	**M**	
11. Implement an integrated national biosurveillance capability.			
A. Implement the National Strategy for Biosurveillance.	White House	**S**	**x**
12. Empower non-federal entities to be equal biosurveillance partners.			
A. Create an interagency biosurveillance planning committee.	DHS	**S**	**x**
13. Optimize the National Biosurveillance Integration System.			
A. Assess the viability of the National Biosurveillance Integration System as the prime integrator of biosurveillance information.	White House	**S**	**x**
B. Incentivize data sharing.	White House	**M**	
14. Improve surveillance of and planning for animal and zoonotic outbreaks.			
A. Increase opportunities for animal health data collection.	Congress, DHS	**M**	
B. Fund the National Animal Health Laboratory Network at a level that allows it to achieve success.	White House, Congress	**S**	✓
C. Develop guidance for the serious implications of companion animal and wildlife zoonoses.	CDC, FEMA, APHIS, Congress	**M**	

Recommendation Action Item	Implementer	Term	Action Status
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.	DHS	**M**	
B. Provide medkits to emergency service providers and their families.	CDC, FDA, ASPR	**M**	
C. Establish reasonable personal protective equipment guidelines and requirements in advance of a biological event.	HHS	**S**	x
16. Redouble efforts to share information with state, local, territorial, and tribal partners.			
A. Strengthen the Joint Counterterrorism Assessment Team.	DNI	**S**	x
B. Strengthen the ability of local police intelligence units to address the biological threat.	DOJ, DNI	**S**	x
C. Enable fusion centers to address the biological threat.	FEMA, DHS I&A	**S**	x
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.	White House, Congress	**S**	✓
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.	Congress, HHS, DOL	**S**	x
B. Institute a process for obtaining and incorporating feedback regarding clinical infection control guidelines during biological events.	White House	**S**	≈
C. Require training based on these guidelines.	HHS, DOL	**M**	
19. Minimize redirection of Hospital Preparedness Program funds.			
A. Cap Hospital Preparedness Program management and administration costs at three percent.	Congress	**S**	≈
B. Assess the impact of the Hospital Preparedness Program.	Congress, ASPR	**M**	
20. Provide the financial incentives hospitals need to prepare for biological events.			
A. Adopt a disaster preparedness portfolio.	CMS	**M**	
B. Link Centers for Medicare and Medicaid Services incentives and reimbursement to new accreditation standards.	Congress	**M**	

Recommendation Action Item	Implementer	Term	Action Status
21. Establish a biodefense hospital system.			
A. Stratify hospitals.	HHS	**S**	≈
B. Develop accreditation standards for each stratum.	CMS	**M**	
C. Associate Centers for Medicare and Medicaid Services funding.	CMS	**M**	
22. Develop and implement a Medical Countermeasure Response Framework.			
A. Produce a comprehensive framework to guide medical countermeasure distribution and dispensing planning.	ASPR, CDC, FEMA	**M**	
23. Allow for forward deployment of Strategic National Stockpile assets.			
A. Determine logistics and funding needs.	CDC	**S**	≈
B. Implement forward deployments.	White House, CDC	**M**	
24. Harden pathogen and advanced biotechnology information from cyber attacks.			
A. Develop and implement a security strategy for stored pathogen data.	White House	**M**	
B. Provide the research community with tools and incentives to secure its data.	Federal Government, USDA, HHS	**M**	
C. Develop cyber-threat information-sharing mechanisms for the pathogen and advanced biotechnology communities.	White House, DHS, ICE	**M**	
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.	DOS	**S**	≈
B. Set U.S. goals for the Biological and Toxin Weapons Convention and determine the conditions necessary to achieve them.	White House, DOS	**S**	≈
C. Develop three actionable recommendations for Biological and Toxin Weapons Convention verification.	DOS	**M**	
D. Establish better biological weapons sentencing guidelines in statute.	Congress	**M**	

Recommendation Action Item	Implementer	Term	Action Status
26. Implement military-civilian collaboration for biodefense.			
A. Conduct a review of military-civilian collaborative efforts.	DOD	**S**	≈
B. Establish military-civilian biodefense collaboration.	Congress	**M**	
C. Clarify parameters for military support to civilian authorities in response to a domestic biological attack.	DOD, White House	**M**	
D. Update and implement military biodefense doctrine.	DOD, White House	**M**	
27. Prioritize innovation over incrementalism in medical countermeasure development.			
A. Prioritize innovation in medical countermeasures at agencies with biodefense responsibilities.	BARDA	**S**	**X**
B. Exploit existing innovation.	NIAID, BARDA, DASD Chem/Bio	**S**	**X**
C. Revolutionize development of medical countermeasures for emerging infectious diseases with pandemic potential.	BARDA, NIAID, DASD Chem/Bio, APHIS, DHS S&T	**M**	
D. Establish an antigen bank.	NIAID, BARDA, DASD Chem/Bio, APHIS, DHS S&T	**M**	
28. Fully prioritize, fund, and incentivize the medical countermeasure enterprise.			
A. Fund the medical countermeasure enterprise to no less than authorized levels.	Congress	**S**	≈
B. Re-establish multi-year biodefense funding for medical countermeasure procurement.	White House, Congress	**S**	**X**
C. Address prioritization and funding for influenza preparedness.	ASPR	**S**	**X**
D. Improve the plan for incentivizing the private sector and academia.	ASPR, DASD Chem/Bio	**S**	**X**
29. Reform Biomedical Advanced Research and Development Authority contracting.			
A. Return contracting authority to the Biomedical Advanced Research and Development Authority.	ASPR	**S**	**X**
B. Leverage previously provided authorities.	BARDA	**S**	≈
C. Eliminate Office of Management and Budget review of BioShield procurements.	Congress	**S**	≈

Recommendation Action Item	Implementer	Term	Action Status
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.	BARDA	**M**	
31. Develop a 21st Century-worthy environmental detection system.			
A. Fund the development of advanced environmental detection systems to replace BioWatch.	Congress, White House, DHS	**S**	≈
B. Replace BioWatch Generation 1 and 2 detectors.	DHS	**L**	
32. Review and overhaul the Select Agent Program.			
A. Undertake a major reassessment of the Select Agent Program.	Congress	**S**	**X**
B. Overhaul the Select Agent Program.	USDA, HHS, Congress	**M**	
33. Lead the way toward establishing a functional and agile global public health response apparatus.			
A. Convene human and animal health leaders.	DOS	**S**	≈
B. Establish the response apparatus.	DOS, White House	**M**	

ACTION STATUS

This report provides a detailed assessment of federal activity toward implementing our one-year action items. Of 46 items, we assess partial progress toward 17, and completion of only 2. Congress appropriated funding for two important programs – the National Animal Health Laboratory Network and the Public Health Emergency Preparedness grant program – at recommended levels. Yet critical recommendations to instate authoritative White House leadership, establish a meaningful interagency planning body, develop a comprehensive national biodefense strategy, and unify the budget remain missing, along with myriad other necessary programmatic changes.

The following pages provide detailed descriptions of the status of these 46 items, and identify the implementer designated to complete each item. "Completed" means that the responsible party or parties took the necessary action, completing the item. "Partial Action" means that the designee(s) took some steps toward implementation. "Inaction" means that the designee(s) took no action. In some cases, Congress took action to address our recommendations, instead of the White House, departments, or agencies which we had designated as implementers. These efforts do not impact our assessment of the status of implementation of an item, but we do acknowledge and

appreciate them. We based our analysis on information obtained through outreach to the Executive and Legislative Branches, as well as review of legislation, budgets, and other public documents.

LEADERSHIP

Recommendation		Completed	Partial Action	Inaction
1	A			x
	B			x

RECOMMENDATION 1: INSTITUTIONALIZE BIODEFENSE IN THE OFFICE OF THE VICE PRESIDENT OF THE UNITED STATES.

A. Empower the Vice President with jurisdiction and authority.
Implementer: White House
Status: Inaction

The White House did not institutionalize biodefense in the Office of the Vice President. Vice President Biden met with the Panel in December 2015, expressed concern regarding the biological threat, and agreed that the White House could better manage federal efforts to address the threat. More recently, the White House consolidated responsibilities for global health security, countering biological threats, medical preparedness, and biosurveillance under a new National Security Council (NSC) staff position – Senior Director for Global Health Security and Biodefense – and reorganized the NSC staff structure to improve its response to biological events. This new position,

while welcome, does not meet our recommendation to establish leadership in an official who can act on behalf of the President with the Executive Branch and the Congress. Further, despite the new NSC position, other NSC staff continue to retain responsibility for other aspects of biodefense (e.g., crisis response and nonproliferation), maintaining portfolio fragmentation.

B. Empower the Vice President with budget authority.
Implementer: White House
Status: Inaction

President Obama did not extend authority to Vice President Biden to review and advise on all department and agency biodefense budgets, and to work with the Director of the Office of Management and Budget (OMB) to direct budget submissions.

COORDINATION

Recommendation		Completed	Partial Action	Inaction
2	A			X
	B			X
	C			X
3	A		≈	
	B		≈	
4	A		≈	
	B			X
5	A			X
6	A			X
	B		≈	
	D		≈	
8	C			X
9	B			X
10	A			X
	B			X
11	A			X

RECOMMENDATION 2: ESTABLISH A BIODEFENSE COORDINATION COUNCIL AT THE WHITE HOUSE, LED BY THE VICE PRESIDENT.

A. Require broad federal participation.
Implementer: White House
Status: Inaction

The White House did not establish a Biodefense Coordination Council. The NSC did continue its

pre-existing engagement with the departments and agencies through its Interagency Policy, Deputies, and Principals Committees. The White House requires department and agency participation in these committees, some of which addressed specific biodefense issues over the past year. However, this piecemeal approach does not meet the need for a formalized council established at the Deputy Secretary level. S. 2967, the *National Biodefense Strategy Act of 2016*, would establish the Council. At the time of writing, this bill was before the full Senate for consideration.

B. Invite broad non-federal stakeholder participation.
Implementer: White House
Status: Inaction

The White House did not establish the Council and thus did not populate it with non-federal stakeholders. The White House Office of Science and Technology Policy (OSTP), per its normal process, continued to solicit feedback from the private sector; state, local, territorial, and tribal (SLTT) governments; science and higher education communities; and other nations to develop and implement science and technology policies and budgets. The OSTP President's Council of Advisors on Science and Technology (PCAST) depended on academia to inform several reports addressing biodefense, systems engineering in healthcare, agricultural preparedness, drug innovation, influenza vaccine, and H1N1 influenza. These activities, however, continued to take place outside of the needed Biodefense Coordination Council structure. S. 2967

would establish the Council with non-federal stakeholder participation.

C. Structure the Council for consensus and accountability.
Implementer: White House
Status: Inaction

The White House did not establish the Council and, therefore, did not establish measures of consensus and accountability.

RECOMMENDATION 3: DEVELOP, IMPLEMENT, AND UPDATE A COMPREHENSIVE NATIONAL BIODEFENSE STRATEGY.

A. Collate the whole of biodefense policy.
Implementer: White House
Status: Partial Action

In its May 2016 Statement of Administration Policy on H.R. 4909, the *National Defense Authorization Act for Fiscal Year 2017*, the White House acknowledged that the Executive Branch works under several existing biodefense-related Presidential Policy Directives and stated that the development of a comprehensive biodefense strategy was, therefore, unnecessary. It also stated that NSC staff have been working with departments and agencies to develop, coordinate, implement, and review biodefense efforts. The Panel is aware that the NSC had initiated a thorough review of biodefense policy, but it is not clear whether or how this important work will be further used,

since the White House has rejected the need for a comprehensive strategy. S. 2967 would call for the President to develop a National Biodefense Strategy that aligns all federal efforts to establish an effective, unified biodefense enterprise. H.R. 4909 would require the Secretary of Agriculture, Secretary of Defense, Secretary of Health and Human Services, and Secretary of Homeland Security to develop a joint biodefense strategy, calling for an inventory of existing policies and plans as the first step of that process. At the time of writing, Congress had not passed either Act.

B. Identify requirements within all extant policies.
Implementer: White House
Status: Partial Action

As a component of their efforts to identify existing policies and strategies, the NSC and OSTP identified requirements described within applicable biodefense legal and policy instruments. S. 2967 and H.R. 4909 would capture this recommendation.

RECOMMENDATION 4: UNIFY BIODEFENSE BUDGETING.

A. Develop and execute a mandatory annual biodefense call for data.
Implementer: White House, Congress
Status: Partial Action

OMB collects some biodefense data in accordance with Presidential Policy Directive 2, but these data do not address the full spectrum of activities

undertaken by the entire biodefense enterprise. S. 2967 would require such data collection.

B. Conduct a cross-cutting biodefense budget analysis.
Implementer: White House
Status: Inaction

The White House did not complete the data call and, therefore, did not conduct a cross-cutting biodefense budget analysis.

RECOMMENDATION 5: DETERMINE AND ESTABLISH A CLEAR CONGRESSIONAL AGENDA TO ENSURE NATIONAL BIODEFENSE.

A. Develop joint congressional oversight agendas.
Implementer: Congress
Status: Inaction

Congressional leadership did not develop joint congressional oversight agendas at the start of the second session of the 114th Congress. Congress also did not hold joint-committee and joint-chamber hearings in accordance with our recommendation. While eight House and seven Senate Committees did hold 34 biodefense-related oversight hearings – demonstrating significant interest – these hearings were not components of established, comprehensive, and strategic oversight agendas.

RECOMMENDATION 6: IMPROVE MANAGEMENT OF THE BIOLOGICAL INTELLIGENCE ENTERPRISE.

A. Create a National Intelligence Manager for Biological Threats.

Implementer: Director of National Intelligence
Status: Inaction

The DNI did not create this position. Within the Office of the Deputy Director of National Intelligence, National Intelligence Managers (NIMs) develop Unifying Intelligence Strategies for geographic and topic areas that help members of the Intelligence Community (IC) collaborate on high-priority intelligence issues. While several existing NIMs address various aspects of the biological threat as part of their portfolios, no single person addresses the entire issue, ensures adherence to a unifying intelligence strategy, arbitrates conflicts between the NIMs, or coordinates IC efforts to address the biological threat. S. 3017, the *Senate Intelligence Authorization Act for FY 2017*, would direct the DNI to analyze organizational requirements and responsibilities, including potentially creating new positions, one of which could be a NIM for Biological Threats. At the time of writing, Congress had not signed the Act into law.

B. Make biological weapons programs and related activities a discrete intelligence topic.
Implementer: Director of National Intelligence
Status: Partial Action

The IC continues to determine whether and how it should assign priorities to the biological weapons programs and activities of countries and non-state actors, and to classes of biological agents. Through its Biological Sciences Advisory Group, the IC interacts with private sector experts, but the Group does not foster analytical outreach or collaboration. The IC recognizes the need for scientific and other relevant knowledge within the Community, but made no significant attempts to increase expertise over the past year.

D. Distribute assessments.
Implementer: Director of National Intelligence
Status: Partial Action

The IC dedicates some intelligence and scientific resources to collection and analysis, but at insufficient levels to address the biological threat adequately. While the IC generated biological threat-related products, it did not produce and distribute needed comprehensive biological threat assessments to all members of the biodefense enterprise.

RECOMMENDATION 8: PRIORITIZE AND ALIGN INVESTMENTS IN MEDICAL COUNTERMEASURES AMONG ALL FEDERAL STAKEHOLDERS.

C. Require a biodefense spend plan from the National Institute of Allergy and Infectious Diseases.
Implementer: White House, Congress, National Institute of Allergy and Infectious Diseases
Status: Inaction

The National Institute of Allergy and Infectious Diseases (NIAID) did not produce a biodefense spend plan. NIAID receives the majority share of biodefense funding for MCM, but a lack of transparency means it remains unclear whether and how its expenditures match the threats prioritized by the Biomedical Advanced Research and Development Authority (BARDA). The Public Health Emergency Medical Countermeasures Enterprise now provides a multiyear budget to Congress, but the budget does not demonstrate how technology will transition from NIAID to BARDA.

RECOMMENDATION 9: BETTER SUPPORT AND INFORM DECISIONS BASED ON BIOLOGICAL ATTRIBUTION.

B. Place the Federal Bureau of Investigation in charge of the National Bioforensics Analysis Center.
Implementer: Congress
Status: Inaction

The National Bioforensics Analysis Center (NBFAC), administered by the DHS Science and Technology

Directorate (S&T), provides nearly all its services to the Federal Bureau of Investigation (FBI). This inefficient arrangement creates an unnecessary layer of bureaucracy for the primary end-user – the FBI – which should have housed the NBFAC from its inception. OMB, DHS S&T, and the FBI have begun discussing requirements for hand-off. Congress has not yet acted to enable this transfer.

RECOMMENDATION 10: ESTABLISH A NATIONAL ENVIRONMENTAL DECONTAMINATION AND REMEDIATION CAPACITY.

A. Include the Federal Emergency Management Agency in efforts to address remediation.
Implementer: White House
Status: Inaction

OSTP considered and worked on biological response and recovery policy (including environmental decontamination and remediation) issues in prior years, but did not include a representative from the Federal Emergency Management Agency (FEMA) in those meetings. While the OSTP National Security and International Affairs Division did include FEMA in efforts to leverage science and technology to improve disaster preparedness this past year, these efforts did not address remediation.

B. Assign responsibility to the Environmental Protection Agency for environmental decontamination and remediation.
Implementer: Congress
Status: Inaction

Six Senate Committees and six House Committees exercise jurisdiction over the Environmental Protection Agency (EPA). None amended statute to place the EPA Administrator in charge of environmental decontamination and remediation after biological accidents or attacks. Congress also did not provide funding for bioremediation to the EPA or any other federal agency.

RECOMMENDATION 11: IMPLEMENT AN INTEGRATED NATIONAL BIOSURVEILLANCE CAPABILITY.

A. Implement the National Strategy for Biosurveillance.
Implementer: White House
Status: Inaction

The White House released the National Strategy for Biosurveillance in July 2012 and committed to producing an accompanying implementation plan by December 2012. The White House sub-Interagency Policy Committee that coordinated the development of the Strategy drafted an implementation plan, but did not publish or implement it.

COLLABORATION

Recommendation		Completed	Partial Action	Inaction
12	A			x
13	A			x
14	B	✓		
15	C			x
16	A			x
	B			x
	C			x
17	A	✓		
18	A			x
	B		≈	
19	A		≈	
21	A		≈	
23	A		≈	
25	A		≈	
	B		≈	
26	A		≈	

RECOMMENDATION 12: EMPOWER NON-FEDERAL ENTITIES TO BE EQUAL BIOSURVEILLANCE PARTNERS.

A. Create an interagency biosurveillance planning committee.
Implementer: Department of Homeland Security
Status: Inaction

The Secretary of Homeland Security did not establish this committee or make it the nexus for

active collaboration among federal, non-federal, and non-governmental partners. In support of national biosurveillance, the DHS Office of Health Affairs collaborates with interagency partners, but while documents such as the National Biosurveillance Integration Center Concept of Operations describe various working groups, none exists for biosurveillance planning.

RECOMMENDATION 13: OPTIMIZE THE NATIONAL BIOSURVEILLANCE INTEGRATION SYSTEM.

A. Assess the viability of the National Biosurveillance Integration System as the prime integrator of biosurveillance information.
Implementer: White House
Status: Inaction

The NSC did not examine the National Biosurveillance Integration System (NBIS) to determine whether it yields useful information. DHS recognizes that it cannot fulfill congressional intent for NBIS if it cannot fully access needed federal and non-federal biosurveillance data and information, but the Department continues to try to make the System work while interagency issues confound its utility.

RECOMMENDATION 14: IMPROVE SURVEILLANCE OF AND PLANNING FOR ANIMAL AND ZOONOTIC OUTBREAKS.

B. Fund the National Animal Health Laboratory Network at a level that allows it to achieve success.
Implementer: White House, Congress
Status: Completed

Congress funded the National Animal Health Laboratory Network at its authorized level in H.R. 2029, the *Consolidated Appropriations Act of 2016*. This positive action is primarily U.S.-centric, and further U.S. government activity will need to address gaps in international biosurveillance capabilities.

RECOMMENDATION 15: PROVIDE EMERGENCY SERVICE PROVIDERS WITH THE RESOURCES THEY NEED TO KEEP THEMSELVES AND THEIR FAMILIES SAFE.

C. Establish reasonable personal protective equipment guidelines and requirements in advance of a biological event.
Implementer: Department of Health and Human Services
Status: Inaction

The Secretary of Health and Human Services did not commission the Institute of Medicine to examine current personal protective equipment (PPE) research and requirements in consideration of

potential biological threats. While the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) established and coordinated interagency working groups to address supply disruptions concerning PPE during public health emergencies, the ASPR did not establish guidelines and other requirements for PPE. The Centers for Disease Control and Prevention (CDC) provides general guidance for ongoing use of PPE in health care settings and by emergency medical services, but it only makes specific recommendations to tailor this guidance after an outbreak occurs in or affects the United States.

RECOMMENDATION 16: REDOUBLE EFFORTS TO SHARE INFORMATION WITH STATE, LOCAL, TERRITORIAL, AND TRIBAL PARTNERS.

A. Strengthen the Joint Counterterrorism Assessment Team.
Implementer: Director of National Intelligence
Status: Inaction

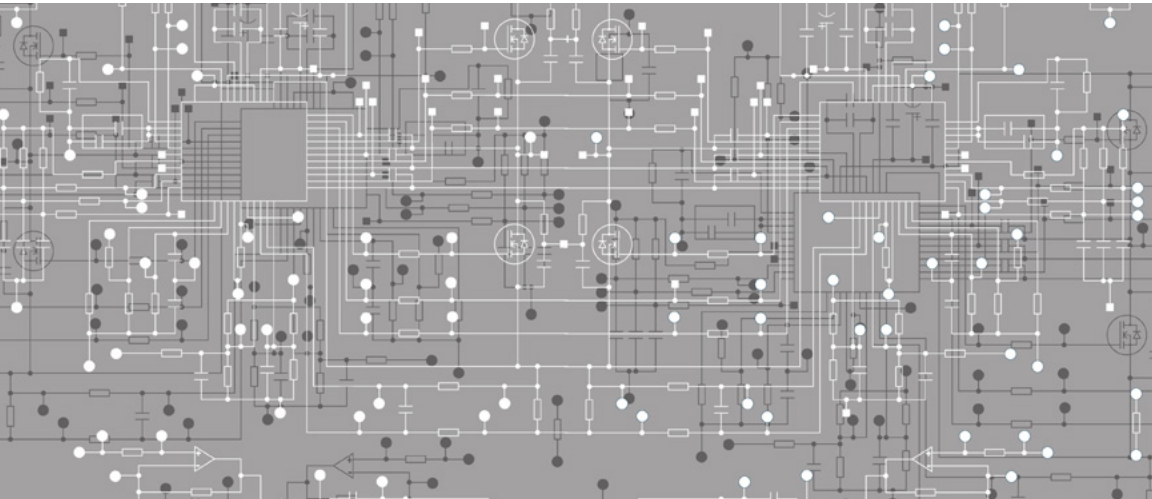
The Office of the DNI did not improve upon partnerships that form the basis of the Joint Counterterrorism Assessment Team (JCAT) because it believes the Team already functions well. The DNI did not solicit feedback from state and local members of the Team on how JCAT can function in a way that allows these stakeholders to participate more fully and provides more value to them. Thus, these personnel continue to struggle to advocate for the intelligence needs of SLTT partners.

B. Strengthen the ability of local police intelligence units to address the biological threat.
Implementer: Department of Justice, Director of National Intelligence
Status: Inaction

The Attorney General and the DNI did not share analytic methods relevant to local police intelligence units to assist in the development of more robust and effective biological threat analysis.

C. Enable fusion centers to address the biological threat.
Implementer: Federal Emergency Management Agency, Department of Homeland Security Office of Intelligence and Analysis
Status: Inaction

The FEMA Administrator and the DHS Under Secretary for Intelligence and Analysis provide technical assistance to fusion centers. Activities in 2016 did not build upon previous efforts to enable fusion centers to work with members of the public health and other relevant communities to address the biological threat.



RECOMMENDATION 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.
Implementer: White House, Congress
Status: Completed

H.R. 2029, the *Consolidated Appropriations Act, 2016*, exceeded both the President's request and the authorized level for Public Health Emergency Preparedness funding. Note that neither the President nor the Congress returned funding to levels they provided in the years following the anthrax events of 2001.

RECOMMENDATION 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.
Implementer: Congress, Department of Health and Human Services, Department of Labor
Status: Inaction

Congress did not direct HHS and the Department of Labor (DOL) to implement a process to develop clinical guidelines for treatment, infection control,

use of PPE, waste management, and other activities needed in the hospital setting to address biological events, in advance. HHS and DOL continue instead to address individual outbreaks (e.g., Zika) as they occur. The Administration, which could have taken the initiative without explicit congressional authorization, did not direct the CDC and Occupational Safety and Health Administration (OSHA) to identify and publicly communicate specific steps for this process. The CDC (specifically the National Institute for Occupational Safety and Health, NIOSH) and OSHA did work together to develop guidance to protect health care and outdoor personnel from occupational exposure to Zika virus.

B. Institute a process for obtaining and incorporating feedback regarding clinical infection control guidelines during biological events.
Implementer: White House
Status: Partial Action

The White House did not direct the Secretary of Health and Human Services and the Secretary of Labor to create a standing group of experts to review feedback from federal, SLTT, and private health care facilities and meet weekly to evaluate, update, and reissue clinical guidelines during biological events. However, OSHA and NIOSH did solicit input from private sector experts as they developed Zika guidelines.

RECOMMENDATION 19: MINIMIZE REDIRECTION OF HOSPITAL PREPAREDNESS PROGRAM FUNDS.

A. Cap Hospital Preparedness Program management and administration costs at three percent.
Implementer: Congress
Status: Partial Action

A provision in the introduced version of H.R. 3299, the *Strengthening Public Health Emergency Response Act of 2016*, would have addressed this recommendation, but the House Committee on Energy and Commerce voted to remove it because some Members did not believe this approach would mitigate the financial inefficiencies within the grant program. HHS reported to the Panel that it regularly withholds about 5.6% of the program's funds, while states withhold about 21%. HHS, therefore, believes that it would be better to reduce state withholding. Neither Congress nor HHS ensured in the last year that the greatest amount of funding reached intended recipients for a grant program that is already too small to achieve its purpose.

RECOMMENDATION 21: ESTABLISH A BIODEFENSE HOSPITAL SYSTEM.

A. Stratify hospitals.
Implementer: Department of Health and Human Services
Status: Partial Action

HHS did not establish a biodefense hospital system. They did not stratify hospitals to incorporate recognition, identification, and mitigation at lower level

institutions, and rapid assured referral with surge capacity. However, the ASPR did issue grants to increase the capacity of some hospitals to respond to Ebola, an approach that the ASPR and stakeholders hope will lend itself to other infectious diseases. The Secretary of Health and Human Services did not add biodefense responsibilities to Accountable Care Organizations, trauma centers, and hospital coalitions to expand their capabilities. The Secretary did approve and allow the Administrator for the Centers for Medicare and Medicaid Services (CMS) to finalize a rule regarding minimal emergency preparedness requirements for Medicare and Medicaid providers and suppliers to address biological events and other emergencies.

RECOMMENDATION 23: ALLOW FOR FORWARD DEPLOYMENT OF STRATEGIC NATIONAL STOCKPILE ASSETS.

A. Determine logistics and funding needs.
Implementer: Centers for Disease Control and Prevention
Status: Partial Action

The CDC worked with the top ten Urban Area Security Initiative cities to assess their MCM dispensing capabilities, capacity, and timeliness. The CDC also addressed forward deployments, warehouse redistribution, and process improvements. One city has partially justified advance receipt of Strategic National Stockpile (SNS) assets and is continuing to work with the CDC toward receipt of forward deployments. CDC experience with this process will

inform its determination of assessment, logistical, and other requirements to forward deploy assets to other jurisdictions.

RECOMMENDATION 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.
Implementer: Department of State
Status: Partial Action

Although the Secretary of State did not lead efforts to revitalize the Biological and Toxin Weapons Convention (BWC), the United States did continue to support the BWC financially. The United States also participated in discussions during the April and August 2016 BWC preparatory meetings, as well as the Eighth BWC Review Conference in November 2016, to identify and establish substantive national implementation measures that reduce the threat of biological weapons. The United States co-convened meetings and submitted several working papers in advance of the August 2016 BWC preparatory meeting, recommending that parties to the BWC routinely determine the impact of cutting-edge science and technology (e.g., gene drives) and invite more subject matter experts to assist with these determinations.

B. Set U.S. goals for the Biological and Toxin Weapons Convention and determine the conditions necessary to achieve them.
Implementer: White House, Department of State
Status: Partial Action

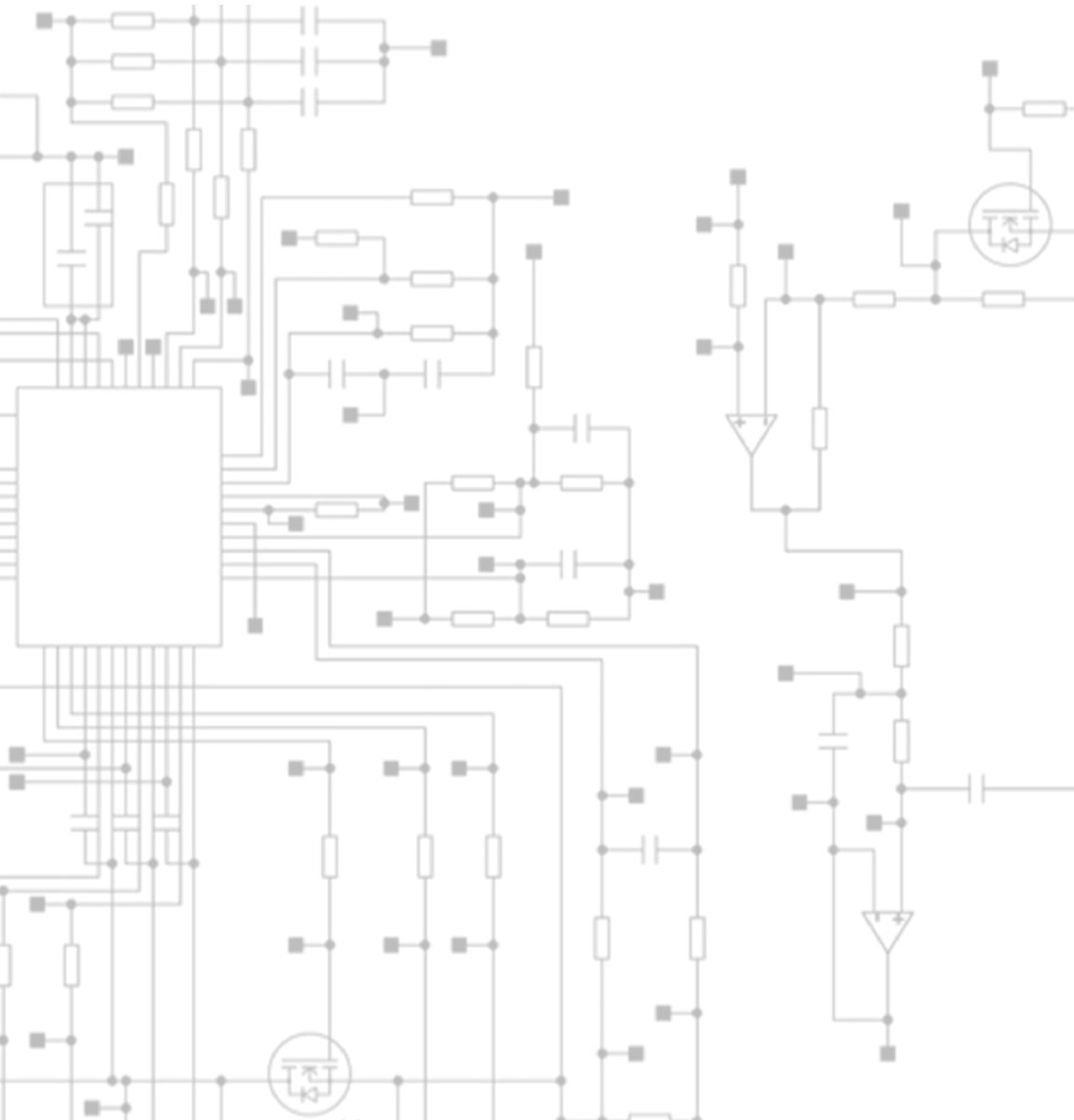
NSC staff, with the Department of State (DOS) and other involved federal agencies, used the intervals leading up to BWC review conferences to determine some desired outcomes. However, the Secretary of State did not employ a high-level emissary to press these issues with other parties to the treaty in advance of these conferences. The Administration set several goals for the BWC and began exploring conditions necessary to achieve them, particularly regarding the need to evaluate the impact of relevant advances in science and technology.

RECOMMENDATION 26: IMPLEMENT MILITARY-CIVILIAN COLLABORATION FOR BIODEFENSE.

A. Conduct a review of military-civilian collaborative efforts.
Implementer: Department of Defense
Status: Partial Action

The Department of Defense (DOD) did not undertake a formal review of previous and current efforts to collaborate with civilian counterparts and partners. However, the Department did participate in meetings to discuss collaboration regarding

a wide variety of issues (e.g., conflict prevention, crisis response, disaster preparedness, humanitarian assistance, surgery, trauma care, and vaccine development). Some military and civilian efforts continued to operate in parallel, with no discernible improvement in communication between the two sectors on biodefense.



INNOVATION

Recommendation		Completed	Partial Action	Inaction
27	A			X
	B			X
28	A		≈	
	B			X
	C			X
	D			X
29	A			X
	B		≈	
	C		≈	
31	A		≈	
32	A			X
33	A		≈	

RECOMMENDATION 27: PRIORITIZE INNOVATION OVER INCREMENTALISM IN MEDICAL COUNTERMEASURE DEVELOPMENT.

A. Prioritize innovation in medical countermeasures at agencies with biodefense responsibilities.
Implementer: Biomedical Advanced Research and Development Authority
Status: Inaction

BARDA did not devote at least ten percent of its FY2016 budget request to fund innovative technologies to address a broad spectrum of biological threats. The struggle to field an MCM for Zika virus underscores urgent deficiencies in MCM innovation.

B. Exploit existing innovation.
Implementer: National Institute of Allergy and Infectious Diseases, Biomedical Advanced Research and Development Authority, Deputy Assistant Secretary for Chemical and Biological Defense
Status: Inaction

The Director of NIAID, the Director of BARDA, and the Deputy Assistant Secretary of Defense for Chemical and Biological Defense (DASD Chem/Bio) did not coordinate to identify at least five promising novel technologies applicable to MCM development for material threats. Individually, these agencies have sought or evaluated some platform capabilities for improved response to emerging threats, but they did not work together in this regard.

RECOMMENDATION 28: FULLY PRIORITIZE, FUND, AND INCENTIVIZE THE MEDICAL COUNTERMEASURE ENTERPRISE.

A. Fund the medical countermeasure enterprise to no less than authorized levels.
Implementer: Congress
Status: Partial Action

Congress doubled the annual appropriation to the BioShield Special Reserve Fund in H.R. 2029, the *Consolidated Appropriations Act, 2016*. They also substantially increased advanced development funding. Yet the FY 2017 President's Budget Request fell short by at least $160 million for Project

BioShield. We are perplexed by this decreased request in light of Ebola, Zika, and the continued threat of bioterrorism. It is now up to the House and Senate to make up the difference and appropriate the full level of required funding.

B. Re-establish multi-year biodefense funding for medical countermeasure procurement.
Implementer: White House, Congress
Status: Inaction

Neither the President nor Congress re-established multi-year funding for Project BioShield. Thus, the marketplace for MCM remains at significant risk. Without a multi-year appropriation (like the 10-year advanced appropriation for the Special Reserve Fund that expired in 2013), government commitment to industry for developing biothreat vaccines, therapeutics, and diagnostics appears weak and short-term.

C. Address prioritization and funding for influenza preparedness.
Implementer: Assistant Secretary for Preparedness and Response
Status: Inaction

The ASPR continues to work on influenza preparedness, and informed the Panel that it recently launched a new seasonal influenza vaccine initiative by leveraging investments in pandemic influenza preparedness funding. However, the ASPR did not confirm that it would review – or has reviewed, at least once every five years – existing pandemic

influenza assets or assess their ability to fulfill pandemic preparedness goals. While *seasonal* influenza is an important public health problem, *pandemic* influenza is a national security problem. Many federal pandemic influenza vaccine assets were purchased about a decade ago and budgets have fallen dramatically since then. The CDC recently showed that the licensed H5N1 vaccine would not have protected humans from the highly pathogenic strain that caused a massive poultry epidemic in the Midwest in 2015. The absence of a regular and transparent assessment of capabilities for and gaps in pandemic influenza preparedness must be addressed, as should more effective engagement with industry. Additional congressional oversight is needed.

D. Improve the plan for incentivizing the private sector and academia.
Implementer: Assistant Secretary for Preparedness and Response, Deputy Assistant Secretary of Defense for Chemical and Biological Defense
Status: Inaction

The ASPR and DASD Chem/Bio did not convene stakeholders to mutually identify the set of incentives that are needed for industry and feasible for government. Industry – the only provider of MCM – thus continues to operate in an incentives vacuum and with uncertain federal commitment to the MCM enterprise.

RECOMMENDATION 29: REFORM BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY CONTRACTING.

A. Return contracting authority to the Biomedical Advanced Research and Development Authority.
Implementer: Assistant Secretary for Preparedness and Response
Status: Inaction

The Office of the ASPR continued to defend its decision to retain the contracting authority it previously removed from BARDA. H.R. 3299 and S. 2055, the *Medical Countermeasure Innovation Act of 2016*, would require transition of this authority back to BARDA. As of the time of this writing, Congress had not voted on either bill.

B. Leverage previously provided authorities.
Implementer: Biomedical Advanced Research and Development Authority
Status: Partial Action

BARDA used its Other Transaction Authority (OTA) once since October 2015. This raises to two the number of OTA-based awards BARDA has issued since its inception. The Panel encourages further use of flexible funding authorities where appropriate.

C. Eliminate Office of Management and Budget review of BioShield procurements.
Implementer: Congress
Status: Partial Action

H.R. 3299 and S. 2055 both amend the *Public Health Service Act* to eliminate the artifactual and bureaucratic burden of OMB contract review.

RECOMMENDATION 31: DEVELOP A 21ST CENTURY-WORTHY ENVIRONMENTAL DETECTION SYSTEM.

A. Fund the development of advanced environmental detection systems to replace BioWatch.
Implementer: Congress, White House, Department of Homeland Security
Status: Partial Action

In S. 3001, the *Department of Homeland Security Appropriations Act of 2017*, Congress expresses frustration with the prolonged review by DHS of DOD environmental biodetection systems, and provides an additional $12 million to accelerate research and development underway at DHS S&T for autonomous, real-time field screening technologies and related purposes. DHS S&T began partnering in October 2016 with the U.S. Army Edgewood Chemical Biological Center to test and evaluate DOD biodetection technology for civilian use and to advance SenseNet, an indoor biodetection program that seeks to improve performance while cost-sharing via commercial application. The White House did not require departments to engage in a formal process for the sharing of biodetection

information and technology. The White House must take responsibility for determining a federal vision for environmental biodetection.

RECOMMENDATION 32: REVIEW AND OVERHAUL THE SELECT AGENT PROGRAM.

A. Undertake a major reassessment of the Select Agent Program.
Implementer: Congress
Status: Inaction

Congressional committees continued oversight of the Federal Select Agent Program. However, Congress has yet to require a thorough re-examination of the Program. Several Executive Branch advisory bodies provided after-action reports and recommendations to improve the existing program, but none comprehensively reassessed it.

RECOMMENDATION 33: LEAD THE WAY TOWARD ESTABLISHING A FUNCTIONAL AND AGILE GLOBAL PUBLIC HEALTH RESPONSE APPARATUS.

A. Convene human and animal health leaders.
Implementer: Department of State
Status: Partial Action

The Secretary of State did not convene human and animal health leaders to evaluate current public health response mechanisms or develop a strategy or implementation plan for this purpose. However,

the United States participated in multilateral meetings held by the U.N. and supported the pre-existing Global Health Security Agenda (GHSA) assessment process that measures individual country capacity to prevent, detect, and respond to infectious disease threats. The DOS also worked to increase non-governmental engagement in the GHSA, including some non-governmental human and animal health leaders. U.S. leadership on animal health is especially important given that the GHSA process is becoming very focused on human health and not according sufficient priority to the animal-based zoonotic disease threat to human populations.

CONCLUSION AND CALLS TO ACTION

In 2005, the following appeared in *The New York Times*:

> We recommend that this administration work with Congress, public health officials, the pharmaceutical industry, foreign governments and international organizations to create a permanent framework for curtailing the spread of future infectious diseases.

Former Senator Richard Lugar and Senator Barack Obama wrote these words. It is even more urgent that we respond to them today.

Many of our political leaders acknowledge that the biological threat is real and growing, and that our government continues to allow other issues of the day to distract from necessary efforts to ensure national biodefense. The biological and political events of the past year demonstrated that our nation remains woefully under-prepared for dangerous biological incidents. The federal government continues to be much better organized and able to address threats posed by weapons of mass destruction other than biological weapons.

We acknowledge positive efforts over the past year on the part of the White House, Congress, and federal departments and agencies. We also recognize that these efforts do not adequately address the biological threat. The discrete activities that comprise these efforts do not share near-term defense goals or a whole-of-government budgetary approach to achieving them. Incremental progress does not enable the public and private sectors to handle emergent, let alone catastrophic, biological events.

The federal government could have – and should have – completed 46 of the action items associated with our recommendations within one year. In the year since we published the *Blueprint for Biodefens*e, the government made some progress on 17 of these, but only completed two.

Once again, we call upon the next President to institutionalize leadership of biodefense at the White House in the Office of the Vice President. The siloed biodefense enterprise inherited by the new President needs much greater centralized focus – focus that vice-presidential leadership can provide. Addressing and paying for zoonotic disease detection and response, security threats to agriculture, cyber vulnerabilities of the life sciences, military to civilian technology transfer, and many other cross-cutting challenges will inform the Panel's agenda for the coming year. We urge the next Administration to overcome these challenges and we look forward to working together to improve our nation's biodefense.

We call upon the 115th Congress to establish a joint oversight agenda for biodefense. This agenda should be shared among the biodefense committees of jurisdiction, and between the chambers. We also strongly urge congressional leadership to remove the major jurisdictional hurdles that stymie oversight of homeland security in general and biodefense in particular. Widespread claims regarding biodefense jurisdiction have led to unnecessary disputes over real and perceived legislative purview. Jurisdictional disputes have adversely impacted congressional ability to provide unified oversight over hundreds of millions of dollars of biodefense initiatives and to properly inform appropriations decisions. As we wrote in a letter to Chairman Pete Sessions of the House Committee on Rules:

> We have become increasingly concerned that more than 20 congressional Committees have biodefense jurisdiction, but only a small handful spend any time actually focusing on biodefense. This selective oversight reflects insufficient congressional engagement related to many of the most significant biodefense challenges America faces. Conversely, fragmented jurisdiction has at times resulted in excessive interest, leading to unnecessary disputes over real and perceived legislative purview. Our Panel identified major flaws in three DHS programs designed to protect Americans from biological threats; jurisdictional disputes, however, have adversely impacted Congress' ability to provide unified oversight over hundreds of millions of dollars'

> worth of such biodefense initiatives. This situation is emblematic of Congress' broader inability to reauthorize DHS in more than 15 years. The time has come to provide for a single, primary DHS oversight committee in the House and Senate so that proper congressional direction can be provided across the DHS mission space, and Executive Branch power can be checked.

One of the most glaring issues we examined in 2015 was the disconnectedness of department-level biodefense budgets. Budgetary division and insufficient advanced planning for predictable emerging infectious disease events negatively impact federal governance of biodefense. The prolonged 2016 debate over Zika funding illuminated the need to correct the current, reactive budgeting and appropriations posture. It is neither sustainable nor necessary to fund responses to these crises through emergency supplementals. We know that major infectious diseases will continue to emerge. The increasing frequency of outbreaks from emerging pathogens and the recognition that they are of zoonotic origin concern us. We expect these trends to continue for many years to come, producing novel infections and creating pandemics against which we cannot adequately defend.

Emergency funding for biological incidents may occasionally be required, but should not be the default mechanism for providing the biodefense enterprise with the financial resources it needs to save lives. We must build biodefense into budgets before these predictable crises occur.

As Panel Members of the Blue Ribbon Study Panel on Biodefense, we remain committed to addressing the biological threat. We look forward to ongoing collaboration with the White House, Congress, departments and agencies, and non-governmental partners toward this end. In the coming year, we will continue to assess implementation, examine pressing topics, and address other issues newly demanding attention.

ACRONYMS

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
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
DASD	Deputy Assistant Secretary of Defense
DASD Chem/Bio	DASD for Chemical and Biological Defense
DHS	U.S. Department of Homeland Security
DHS I&A	DHS Office of Intelligence and Analysis
DHS S&T	DHS Science and Technology Directorate
DNI	Director of National Intelligence
DOD	U.S. Department of Defense
DOJ	U.S. Department of Justice
DOL	U.S. Department of Labor
DOS	U.S. Department of State
EPA	U.S. Environmental Protection Agency
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration

FEMA	Federal Emergency Management Agency
GHSA	Global Health Security Agenda
HHS	U.S. Department of Health and Human Services
IC	Intelligence Community
ICE	U.S. Immigration and Customs Enforcement
ISIL	Islamic State of Iraq and the Levant (also known as Da'esh)
JCAT	Joint Counterterrorism Assessment Team
MCM	medical countermeasure(s)
NATO	North Atlantic Treaty Organization
NBFAC	National Bioforensics Analysis Center
NBIS	National Biosurveillance Integration System
NIAID	National Institute of Allergy and Infectious Diseases
NIM(s)	National Intelligence Manager(s)
NIOSH	National Institute for Occupational Safety and Health
NSC	National Security Council
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration

OSTP	Office of Science and Technology Policy
OTA	Other Transaction Authority
PCAST	President's Council of Advisors on Science and Technology
PPE	personal protective equipment
SLTT	state, local, territorial, and tribal
SNS	Strategic National Stockpile
U.N.	United Nations
U.S.	United States
USDA	U.S. Department of Agriculture