

THE NATIONAL BLUEPRINT FOR BIODEFENSE

IMMEDIATE ACTION NEEDED TO
DEFEND AGAINST BIOLOGICAL THREATS

REPORT OF THE BIPARTISAN COMMISSION ON BIODEFENSE

April 2024



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A REPORT BY THE
BIPARTISAN COMMISSION ON BIODEFENSE

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EX OFFICIO MEMBERS

Yonah Alexander, PhD

William B. Karesh, DVM

Rachel Levinson, MA

Lewis Libby, JD

Rajesh Panjabi, MD

Gerald W. Parker, DVM, PhD

George Poste, DVM, PhD, DSc

Tevi Troy, PhD

STAFF

Asha M. George, DrPH, Executive Director

Ambika Bumb, PhD, Deputy Executive Director

Robert H. Bradley, Policy Principal

John T. O'Brien, MS, Research Principal

Patricia de la Sota, Operations Manager

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Finally, we thank all who defend our Nation against biological threats. We see what they do and commend them for their tireless efforts.

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PREFACE

April 17, 2024

When we issued the first edition of our *National Blueprint for Biodefense* eight years ago, we stated that the United States was not sufficiently prepared for impending biological threats. Then, as today, we acknowledged that while some biological events were inevitable, their devastating impacts were not. We know now that had our country expeditiously implemented the 33 recommendations we made in that report, COVID-19 would not have taken such a deadly toll on our citizens and economy. This failure to act resulted in loss of life, societal disruption, and loss of confidence in our government. Despite having made some progress, the Nation remains dangerously vulnerable to a biological event.

As we all seek to turn the page on COVID-19, policymakers risk losing the progress made over the last three years. Our Nation can no longer wait for a biological event to occur and only then respond to it, expending enormous resources because we did not invest in biodefense. America must change its biodefense cadence from on-again/off-again to on all the time. Inevitably, there will be some subsequent pandemics and other biological events that will be worse than COVID-19, and similar responses will not suffice if we hope to save lives, preserve our economic strength, and buttress national security.

This Commission examines US national defense against biological attacks, emerging and reemerging infectious diseases, and accidental releases of biological agents. We continue to witness diseases exploiting gaps in national biodefense, and hasty attempts to shore up one vulnerability that only lead to exposing many others. This weakness is why we continue to scrutinize national prevention, deterrence, preparedness, detection and surveillance, response, attribution, recovery, and mitigation (efforts that comprise the spectrum of biodefense activities).

We credit Congresses from the 103rd on, as well as successive Administrations (led by Presidents William J. Clinton, George W. Bush, Barack H. Obama, Donald J. Trump, and Joseph R. Biden) with directing, mandating, developing, implementing, and overseeing policies and programs intended to strengthen national biodefense. Nevertheless, 22 years after the last report of the US Commission on National Security/21st Century, 19 years after the report of the National Commission on Terrorist Attacks Upon the United States, 18 years after the report of the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass

Destruction, 15 years after the report of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, and 8 years after we released our *National Blueprint for Biodefense*, fractionated governmental activities remain insufficient to meet and overcome many biological threats to America.

As leaders in the Executive and Legislative Branches of government, the members of this Commission have both contributed to national biodefense and shared responsibility for its shortcomings. Since the inception of this bipartisan effort in 2014, this is the Commission's 14th report, containing 36 recommendations and 185 action items to help our government eliminate its shortfalls. Instead of spouting criticisms, we offer solutions that address the full range of biological threats and the activities necessary to defend against them. We urge leaders throughout the government to accept the recommendations in this report and implement them fully.

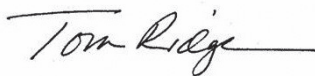
Success depends on exercising authority, political will, recognition, and foresight regarding the breadth and severity of biological threats to the Nation. We still believe that America needs top-level national leadership of the biodefense enterprise to address this problem head-on. We also believe that the United States, its allies, and partners in industry, academia, and nongovernmental organizations can eliminate pandemics entirely in 10 years by fully implementing the recommendations we made in our earlier report, *The Apollo Program for Biodefense*. Ending pandemics is more achievable today than landing on the Moon was in 1961. Our Nation has the right stuff. We can do what it takes—if we want to.

We repeat here what we said in 2014: *We have no choice—the Nation must take action to defend against the biological threat.* Apathy, inability to focus, and poor prioritization resulted in over one million deaths and over six million hospitalizations due to COVID-19. No matter one's political loyalty, we can all agree that America and the global community must prevent the same or worse from occurring again. We are confident that implementing the recommendations contained in this *National Blueprint for Biodefense* and our previous reports will better secure our country and the world.

This problem is not insurmountable. If we take and demand action now, we can save lives. What greater calling or responsibility could we have?



Joseph I. Lieberman
CHAIR



Thomas J. Ridge
CHAIR

SCENARIO

The following hypothetical opening remarks by the chair of a congressional joint inquiry provide context for this report by portraying a biological attack sufficient to cause the catastrophic consequences warned of by the Bipartisan Commission on Biodefense. The scenario describes how a biological agent could target humans and animals, how it could emerge, some of the key interagency capabilities required to address the agent and its impacts, and the consequences of failure.

JOINT INQUIRY INTO ADMINISTRATION AND CONGRESSIONAL ACTIONS BEFORE AND DURING THE BIOTERRORIST ATTACKS OF JULY 4, 2025

US HOUSE OF REPRESENTATIVES PERMANENT SELECT COMMITTEE ON INTELLIGENCE AND US SENATE SELECT COMMITTEE ON INTELLIGENCE

CHAIR: I call this first hearing of the Joint Inquiry to order. Nine weeks ago, some nation or terrorist group—we still do not know who—attacked the Nation’s Capital and other US cities with biological weapons as we celebrated Independence Day. The infectious agent they used killed at least 280,000 Americans and infected at least 400,000 throughout the country in a single day, in addition to the 200,000 dead and 800,000 sickened animals. These numbers will increase as the disease spreads. Many of our own colleagues and staff here in Congress fell ill and died. Coordinated attacks in allied nations in the days that followed killed tens of thousands more.

We are now hearing that the terrorists conducted smaller scale attacks in American cities and localities prior to the July 4 incidents to test our defenses and gauge our responses. These smaller scale attacks went largely unnoticed.

Laboratory tests confirm that Nipah virus caused the disease, but we still do not know what methods our adversaries used to infect humans and spread the disease among livestock in rural communities.

Animals and people were sick for more than a month before we realized what had happened. While the virus is in the same family as other common human and animal viruses, most American veterinarians and physicians had never seen Nipah virus before, which delayed recognition. 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, while still retaining a mortality rate of over 40%.

For years before this, many experts said that although nation states and terrorist organizations aspired to use biological weapons, they lacked the leadership, organizational wherewithal, infrastructure, expertise, and social support to develop and deploy them.

Despite these assessments, our adversaries conducted the deadly biological attacks of July 4 here and throughout the world. They took advantage of

- our failure to eliminate the vulnerabilities revealed during the COVID-19 pandemic;
- our failure to conduct sufficient biological intelligence activities to indicate an imminent attack;
- our failure to achieve early detection of the biological agent and our failure to identify the source of exposure in a timely way;
- our failure to rapidly identify and recognize its occurrence in livestock;
- our failure to rapidly identify the disease in people;
- our failure to consistently fund public health and health care preparedness;
- our failure to stockpile sufficient medical countermeasures; and
- our failure to communicate effectively within the government, to our allies, and most importantly, to the American people.

Ultimately, our adversaries took advantage of our failure to make biodefense a top national priority. It is especially painful to me and the other leaders of committees throughout Congress that we failed in our duty to gather the necessary information and data, connect the dots, produce intelligence, and prevent and attribute these attacks.

Sadly, much as the 9/11 Commission observed in its analysis of the attacks of 2001, the attacks of 2024 can be ascribed to failures to heed many warnings and commit to preventing biological events from affecting our national security.

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

- The diplomatic, intelligence, law enforcement, and military communities failed to discover intent and provide advanced warning of well-planned and direct attacks on the United States and its interests overseas.
- The Department of Agriculture, Department of Defense, Department of Health and Human Services, and Department of Homeland Security failed to detect the biological agent upon release.

There were, and continue to be, failures to respond effectively:

- The Department of Agriculture and Department of Health and Human Services still have no way to prevent additional infections, treat exposed people and animals effectively, thwart the establishment of pathogens in new reservoirs, or prevent the disease from becoming permanently established in the United States.
- The Department of Agriculture, Department of Defense, Department of Homeland Security, Department of Health and Human Services, and Department of Justice failed in their initial efforts at attribution.

As I speak, critical infrastructure owners and operators and emergency service providers are struggling valiantly to do their jobs while keeping their own families safe in the absence of adequate protection. Our military is splitting resources to help with domestic response and operations overseas, and the Intelligence Community is spread thin trying to prevent our enemies from taking further advantage of our vulnerabilities to biological and other threats.

Our national leadership at all levels—federal and non-federal—failed to heed the advice of the 9/11 Commission, the Weapons of Mass Destruction Commission, the Bipartisan Commission on Biodefense, and many other experts who warned of the dangers of biological terrorism and warfare. They failed to appreciate the gravity of the biological threat, generate political will, and take action in the face of looming danger, even when COVID-19 demonstrated how severe a biological threat could be.

We are convening this hearing today to discover exactly what happened, how this leadership failure occurred, and what our Nation must do to recover from these attacks. We also intend to determine what it will take to prevent additional attacks and ensure our country has done all it can to be prepared for the next biological event in case these efforts fall short.

Over the next three weeks, this Joint Inquiry will hear from the Secretary of State, the Secretary of Defense, the Attorney General, and the Director for National Intelligence to explain why they missed indications of the impending use of biological weapons and why we still do not have a biodefense attribution apparatus in place of the same caliber as we have for nuclear attribution.

Second, we will hear from the Secretary of Agriculture, the Secretary of Health and Human Services, and the Secretary of Homeland Security to explain why (after COVID-19 and other biological events that affected our Nation previously) their extraordinary challenges in surveillance, detection, identification, response, recovery, and mitigation persist.

Third, we will hear from academics, the Bipartisan Commission on Biodefense, and other nongovernmental groups that issued warnings previously, to better understand the recommendations they issued and where the Nation and the world stood in implementing those recommendations before these events occurred.

The Ranking Member and I have discussed these bioterrorist attacks at great length. Let me assure the American people that while our political ideologies may differ, we agree that this Committee will fully investigate what happened, seek to identify the adversaries responsible for this outrage, and hold the Administration and Congress (including ourselves) accountable for failing to prevent and prepare adequately for these events and their consequences. Today's hearing will certainly not be our last.

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

EXECUTIVE SUMMARY

The biological threat has not abated. In fact, the threat has intensified.

In the ten years that have passed since we formed this Commission, millions of Americans and people around the world have died from a catastrophic pandemic. Economies and world travel were shut down. COVID-19 reminded us of how vulnerable we all are, no matter where we live. We again learned the painful lesson that public communication and trust are essential for biodefense to be effective.

Wars are now being waged in Europe and the Middle East involving (either directly or indirectly) nations known to be developing biological weapons. These conflicts raise the threat of biological warfare which could result in many casualties and much suffering.

The first *National Blueprint for Biodefense*, released by the Bipartisan Commission on Biodefense in October 2015, may have seemed theoretical and alarmist at the time, but it was painfully and tragically real.

Extensive research supports what we all witnessed together firsthand: biological threats hold the power to devastate our way of life. The question remains not if, but when, we confront another biological event, whether it be a biological weapons attack or another pandemic. Modern science and technology hold the keys to ensuring that we can intelligently and confidently prepare, respond, and recover.

In the wake of COVID-19 and today's global unrest, there is nothing theoretical about the need to implement the 37 recommendations presented in the pages that follow in the 2024 *National Blueprint for Biodefense*. Each of these recommendations is the result of an exhaustive review of the gaps in current federal policies and procedures—gaps that leave us all unnecessarily vulnerable to a biological incident.

HIGHLIGHTED RECOMMENDATIONS

- **Strong national biodefense requires sustained leadership from the White House.** This report recommends reinforcing White House leadership of the national biodefense enterprise.

Congress should amend the National Security Act of 1947 to codify the role of the National Security Advisor as the leader of national biodefense.

Further, Congress should establish a Deputy National Security Advisor to perform the day-to-day duties and responsibilities of national biodefense and global health security.

This is the bottom line: 15 federal departments, 9 independent agencies, and 1 independent institution currently have biodefense responsibilities. One federal department cannot tell other departments and agencies what to do. Only the White House has that authority. This recommendation addresses that problem.

- **A comprehensive National Biodefense Strategy is critical to success.** Every future Administration must ensure that the National Biodefense Strategy keeps pace with the rapidly evolving and increasing biological threat.

That is why this report calls for a quadrennial biodefense review that would culminate in an updated National Biodefense Strategy and Implementation Plan submitted to Congress by the White House. The threats change. Technology changes. Our biodefense must also change.

It is critical that the federal government engage in both biodefense policy and technology development to permanently eliminate pandemics as a national threat. As such, the Strategy must address science and technology needs for biodefense, as outlined in the Commission's 2021 report on *The Apollo Program for Biodefense*.

- **Much has been learned about the Nation's response to the COVID-19 pandemic. At the top of the list is the need to reduce pathogen transmission indoors.** Built environments such as offices, healthcare facilities, schools, and airplanes allow for easier transmission of dangerous pathogens, particularly those communicated most effectively via respiratory pathways.

While the US exerts significant effort to engineer and defend such indoor environments against fires, earthquakes, and floods, far less effort is put into engineering and protecting indoor environments against pathogens. That gap likely resulted in significant loss of life during the COVID-19 pandemic.

New technologies to reduce transmission on surfaces (including self-sterilizing and fomite-neutralizing materials) are available now. However, the most promising public health interventions involve improving indoor air quality.

Accordingly, Congress should amend the Public Health Service Act to produce a research and development plan for reducing pathogen transmission in built environments. Among other things, this plan should address the integration of indoor biological detection technologies.

- **US investment in medical countermeasure development is dangerously insufficient and requires emergency funding from Congress each time America faces a biological event affecting national security.** This panic-and-neglect cycle is a bad approach that results in needless loss of life.

Each time a crisis emerges (be it H1N1, Zika, Ebola, or COVID-19), Congress eventually appropriates emergency supplemental funding to enable the rapid development of drugs and vaccines and shore up our country's declining public health infrastructure. The devastating impact of this myopic strategy was made clear in the early months of the COVID-19 pandemic. Emergency funding came only after nearly two months of disagreement between Congress and the White House about precise needs and funding levels. Moreover, failure to follow this funding with sustainable annual appropriations threatens to undo much of the progress made during the pandemic. That is why we must prioritize, fund, incentivize, and align investments in medical countermeasures across all stakeholders before the next pandemic or biological attack occurs.

The list of action items needed to accomplish this goal is long. It begins with a requirement that the National Institute of Allergy and Infectious Diseases create a specific biodefense budget plan that is responsive to priority national requirements and includes ways to transition medical countermeasures more easily from early-stage development to advanced research and development. Time saved equals lives saved.

- **Biological events (either naturally or human-generated) affect critical infrastructure and immediately place our national, economic, and public health security in great jeopardy.** Imagine waking up to the news that you cannot drink the water in your home because a deadly pathogen was intentionally released into your water system, survived water treatment, and propagated despite the volume of water. Now expand that to include your entire city, state, or region, and that you and millions of others will not be able to use the water in their home for months, perhaps longer.¹ Our lives will immediately be turned upside down.

Moreover, it is highly unlikely that a biological event will affect just one critical infrastructure sector. An event might affect several (if not many) sectors directly, with cascading impacts on others. Remember that the anthrax events of 2001 affected or involved 11 sectors. This is why we must prioritize the protection of critical infrastructure against biological threats.

- **Replacing BioWatch with a national biological detection system that actually works.** This Commission has argued, and continues to argue, that 20 years after its implementation, the potential of BioWatch remains unrealized. Put simply, BioWatch is a waste of money that hinders the ability of first responders in our Nation's largest cities to detect biological events before they produce illness or death in humans, animals, or plants.

Congress should amend the Homeland Security Act of 2002 to direct the Secretary of Homeland Security to replace ineffectual BioWatch technology using other technologies that are already known to work. We cannot afford to be caught flat-footed by an airborne pathogen in huge population centers.

We understand that our recommendations are comprehensive and numerous. We know that the US government will not be able to implement them all at once. But we also know that if our country adopted everything in this report, our people would be well protected from the next biological attack or naturally occurring pandemic—just as our people would have been, had the United States implemented all of our recommendations from our 2015 *Blueprint for Biodefense*.

**These are not just words on pages.
This is a call for immediate action.**



**Figure 1. Conspectus of the
*National Blueprint for Biodefense***



LEADERSHIP

- National leadership and management
- National biodefense strategies and reviews
- Unified biodefense budget
- Congressional agenda for biodefense



INTELLIGENCE, ATTRIBUTION, AND DETERRENCE

- Biological intelligence management
- Biological attribution for decision-making
- Biological and Toxin Weapons Convention
- Biological threat reduction
- Federal Select Agent Program overhaul
- Artificial intelligence/life science risk management
- Unified biodefense budget
- Congressional agenda for biodefense



SCIENCE AND TECHNOLOGY

- The Apollo Program for Biodefense
- Next-generation personal protective equipment
- Pathogen transmission reduction in built environments
- Incorporation of national defense science and technology
- Astrobiodefense
- Regulatory process improvement
- Medical countermeasure investment
- Medical countermeasure innovation



PREPAREDNESS

- Stockpile supply, distribution, and dispensing
- Centers for Disease Control authorization
- Public health security workforce
- Stratified biodefense hospital system
- Warfighter biodefense
- Clinical infection control guidelines
- School biodefense
- Critical infrastructure biodefense
- State, Local, Tribal, Territorial biological emergency preparedness



DETECTION AND SURVEILLANCE

- BioWatch replacement
- National diagnostic testing for biological events
- Public health data infrastructure and collection during biological emergencies
- Integrated biosurveillance



RESPONSE, RECOVERY, AND MITIGATION

- Biodefense resources for State, Local, Tribal, Territorial emergency services
- Public health biological emergency funding, guidance, and waivers
- Laboratory response networks for biodefense
- National decontamination and remediation of the environment after biological events
- Global public health response to biological events

Table 1. Recommendations and Action Items from the *National Blueprint for Biodefense*

LEADERSHIP

1	Reinforce White House leadership of the national biodefense enterprise.
	a. Provide biodefense policy and strategy advice and assistance to the President of the United States. b. Codify responsibilities of the National Security Advisor for biodefense. c. Codify and maintain a White House Directorate for Biodefense and Global Health Security. d. Add responsibilities for pandemic recovery and mitigation to the White House Office of Pandemic Preparedness and Response Policy. e. Assign responsibilities to the White House Office of Science and Technology Policy for coordinating biodefense research and development. f. Assign responsibilities to the White House National Economic Council for the bioeconomy. g. Provide dedicated appropriations for biodefense activities undertaken by the White House. h. Elevate Department of Defense Weapons of Mass Destruction leadership. i. Establish an Assistant Secretary of Agriculture for National and Homeland Security.
2	Implement, maintain, and update a comprehensive national biodefense strategy.
	a. Institute a quadrennial national biodefense review. b. Produce a national biodefense science and technology plan. c. Produce departmental and agency biodefense strategies. d. Conduct and implement a quadrennial military biodefense posture review.
3	Unify biodefense budgeting.
	a. Institutionalize biodefense as a discreet portfolio at the Office of Management and Budget. b. Strengthen the annual crosscutting biodefense budget analysis. c. Develop a budget plan for the National Biodefense Strategy. d. Align budget items to the National Biodefense Strategy. e. Provide predictable and multi-year funding for biodefense programs. f. Produce a future years biodefense budget program plan. g. Develop and submit a unified biodefense budget request.
4	Establish a clear congressional agenda to ensure national biodefense.
	a. Establish a congressional working group on biodefense. b. Convene annual biological threat briefings to Congress. c. Establish biodefense subcommittees or make biodefense the focus of existing subcommittees in the House of Representatives and Senate. d. Align biodefense appropriations and budgets.

INTELLIGENCE, ATTRIBUTION, AND DETERRENCE

5

Increase, improve, and prioritize management of biological intelligence.

- a. Create a National Intelligence Manager for Biological Threats.
- b. Make biological weapons programs and related activities a discrete intelligence topic.
- c. Increase biological threat expertise within, and available to, the Intelligence Community.
- d. Permanently authorize Section 702 of the Foreign Intelligence Surveillance Act to protect the Nation against biological attacks.
- e. Increase federal domestic biological intelligence efforts.
- f. Enable fusion centers to address the biological threat.

6

Better support and inform decisions based on biological attribution.

- a. Establish a national biological attribution decision-making apparatus.
- b. Make the Federal Bureau of Investigation responsible for the National Bioforensic Analysis Center.
- c. Update US Postal Inspection Service biological investigation and attribution capabilities.
- d. Draw upon the Smithsonian Institution for assistance with biological attribution.

7

Increase support for the Biological and Toxin Weapons Convention.

- a. Increase Department of State staff support for the Biological and Toxin Weapons Convention.
- b. Propose increasing staff for the Biological and Toxin Weapons Convention Implementation Support Unit.

8

Strengthen biological threat reduction.

- a. Clarify international biodefense capacity-building roles and responsibilities.
- b. Develop and implement a plan to counter misinformation and disinformation about co-operative threat reduction programs.
- c. Update National Science Foundation grant funding policy for dual-use, gain-of-function, and enhanced pathogen research.
- d. Update and implement a DNA/RNA synthesis screening framework.

9

Review and overhaul the Federal Select Agent Program.

- a. Undertake a major reassessment of the Federal Select Agent Program.
- b. Overhaul the Federal Select Agent Program.

10

Combat risks from the convergence of artificial intelligence and the life sciences.

- a. Identify risks posed by the convergence of artificial intelligence and the life sciences.
- b. Develop an artificial intelligence/life sciences risk assessment framework.
- c. Develop an artificial intelligence/life sciences risk reduction strategy.

SCIENCE AND TECHNOLOGY

11 Establish *The Apollo Program for Biodefense*.

- a. Develop vaccine candidates for prototype pathogens (see *Recommendation 18*).
- b. Develop therapeutic drugs in advance of outbreaks (see *Recommendation 18*).
- c. Develop flexible and scalable manufacturing of pharmaceuticals (see *Recommendation 18*).
- d. Develop needle-free methods of drug and vaccine administration (see *Recommendation 18*).
- e. Identify and increase ubiquitous sequencing (see *Recommendation 29*).
- f. Develop minimally- and noninvasive infection detection (see *Recommendation 29*).
- g. Develop massively multiplexed detection capabilities (see *Recommendation 29*).
- h. Develop rapid point-of-use diagnostics (see *Recommendation 29*).
- i. Establish digital pathogen surveillance (see *Recommendation 31*).
- j. Develop a national public health data system (see *Recommendation 30*).
- k. Bolster the national pathogen surveillance and forecasting center (see *Recommendation 31*).
- l. Develop next-generation personal protective equipment (see *Recommendation 12*).
- m. Suppress pathogen transmission in the built environment (see *Recommendation 13*).
- n. Establish comprehensive laboratory biosafety and biosecurity (see *Recommendation 34*).
- o. Screen DNA synthesis providers and users and purchase genetic material from verified vendors (see *Recommendation 8*).

12 Extend and develop next-generation personal protective equipment to guard against biological threats.

- a. Extend the shelf-life of personal protective equipment stockpiled for use in biological emergencies.
- b. Research and develop next-generation personal protective equipment for use in healthcare settings and areas containing or contaminated with biological agents.
- c. Transfer technology for biodefense personal protective equipment throughout the public and private sectors.

13 Reduce pathogen transmission in built environments.

- a. Conduct research on pathogen transmission reduction in built environments.
- b. Develop and advance technologies to reduce viability and transmission of pathogens in built environments.
- c. Reduce pathogen transmission in built environments.
- d. Develop health-based biodefense standards for reducing pathogen transmission in built environments.

14 Integrate national defense science and technology.

- a. Integrate military research to defend the warfighter against biological threats.
- b. Produce a defense biotechnology inventory.
- c. Facilitate defense technology transition.
- d. Address military biodefense research gaps.

15 Defend against astrobiological threats.

- a. Authorize the Office of Planetary Protection.
- b. Establish a planetary biodefense board.

16 Improve regulatory processes.

- a. Authorize or approve innovative technologies before, during, and after biological events.
- b. Incorporate lessons learned from pandemics into regulatory processes.

17 Invest in medical countermeasures.

- a. Require a biodefense budget plan from the National Institute of Allergy and Infectious Diseases.
- b. Fund the medical countermeasure enterprise to no less than authorized levels.
- c. Reestablish multi-year biodefense funding for medical countermeasure procurement.
- d. Eliminate Office of Management and Budget review of BioShield procurements.

18 Innovation in medical countermeasures.

- a. Review existing medical countermeasure programs.
- b. Develop vaccine candidates for prototype pathogens.
- c. Develop antiviral drugs in advance of outbreaks.
- d. Develop needle-free methods of drug and vaccine administration.
- e. Develop flexible and scalable manufacturing of pharmaceuticals.
- f. Set requirements for all biological agents deemed material threats to the Nation.
- g. Establish an antigen bank.
- h. Establish regional food and agriculture advanced development and manufacturing.

PREPAREDNESS

19 Strengthen stockpile supply and distribution.

- a. Assess the mission, goals, and objectives of the Strategic National Stockpile.
- b. Authorize provision of expiring biodefense vaccines to first responders and critical infra-structure personnel.
- c. Develop a strategy and implementation plan for distributing at-home diagnostic tests and therapeutics.
- d. Produce a comprehensive framework for medical countermeasure distribution and dispensing.
- e. Require periodic evaluation of smallpox medical countermeasure stockpile needs in consideration of the threat.
- f. Fund state-level stockpiles for biodefense.
- g. Determine logistics and funding needs to forward deploy stockpiled biodefense assets.
- h. Implement forward stockpile deployments of national stockpiles for biodefense.
- i. Improve, expand, enhance, and sustain state, local, tribal, and territorial training to receive and distribute stockpile contents during biological events.
- j. Authorize and bolster the National Veterinary Stockpile.
- k. Develop and pre-position medical countermeasures in military areas of operation.

20 Authorize the Centers for Disease Control and Prevention.

- a. Authorize the Centers for Disease Control and Prevention.

21 Increase the public health security workforce.

- a. Provide direct hiring authority for mission critical biodefense positions.
- b. Provide flexible pay authorities during biological emergencies.
- c. Enable hiring of reemployed annuitants during biological emergencies.
- d. Employ Medical Reserve Corps volunteers during biological emergencies.
- e. Establish an emergency response-ready cadre fund for the Centers for Disease Control and Prevention.
- f. Ensure military health care and public health readiness for biological events.

22 Establish a stratified biodefense hospital system.

- a. Stratify hospitals for biodefense.
- b. Develop biodefense accreditation standards, incentives, and reimbursements for each stratum.
- c. Establish medical surge capability and capacity for large-scale biological events.
- d. Authorize the Regional Disaster Health Response System.

23 Strengthen biodefense of warfighters.

- a. Increase military biodefense health care, public health, and research.
- b. Restore health care and public health infrastructure for biodefense.

24 Produce clinical infection control guidelines.

- a. Develop clinical infection control guidelines before biological events occur.
- b. Obtain and incorporate feedback regarding clinical infection control guidelines during biological events.

25 Enable schools to protect against biological threats.

- a. Actively manage biological events in school settings.
- b. Issue biodefense guidance to schools throughout the Nation so they are better prepared.
- c. Develop and distribute high-quality educational resources about biological events in school settings.
- d. Implement effective disease control strategies for school settings.

26 Protect critical infrastructure against biological threats.

- a. Defend critical infrastructure against biological threats.
- b. Manage biological risk to critical infrastructure.
- c. Estimate critical infrastructure sector needs for vital medical countermeasures and essential medical supplies.
- d. Ensure execution of national critical functions by taking sector-specific biodefense actions.

27 Redouble efforts to bolster state, local, tribal, and territorial biological emergency preparedness.

- a. Assess and strengthen state and territorial biodefense activities.
- b. Authorize and provide sustained funding for the Public Health Infrastructure Grant Program.
- c. Provide robust funding for Public Health Emergency Preparedness cooperative agreements.
- d. Make Public Health Emergency Preparedness cooperative agreement funding available directly to the tribes.
- e. Authorize a Vaccine for Adults Program.
- f. Help the homeless and those living in low-income housing prevent, prepare for, and respond to biological events.
- g. Provide additional biodefense planning and technical assistance to the territories and freely associated states.
- h. Reduce barriers to transporting resources to territories and freely associated states during biological emergencies.
- i. Bolster tribal biological emergency preparedness.
- j. Implement national food and agro-biodefense policies.
- k. Address plant biodefense research and development.
- l. Address gaps in plant emergency preparedness.
- m. Revise, implement, and comply with the National Agriculture and Food Defense Strategy.
- n. Authorize the Extension Disaster Education Network.
- o. Make tribal land-grant universities eligible for capacity formula funding.

DETECTION AND SURVEILLANCE

28 Replace BioWatch.

- a. Implement a domestic biological detection research and development plan.
- b. Replace outdated BioWatch technology.

29 Develop national diagnostic testing for biological events.

- a. Establish a biodefense diagnostics coordination group.
- b. Develop and implement a national diagnostics plan.
- c. Develop rapid point-of-use diagnostics.
- d. Develop and deploy plant disease diagnostics.
- e. Develop minimally- and non-invasive infection detection.
- f. Maintain a diagnostic test kit for each disease that stockpiled vaccines address.
- g. Increase diagnostics reimbursement and testing for diseases likely to impact national security.
- h. Identify and increase ubiquitous sequencing.
- i. Develop massively multiplexed detection capabilities.

30 Improve national public health data infrastructure and collection during a biological emergency.

- a. Establish a National Public Health Data System.
- b. Develop a data interoperability plan.
- c. Form data sharing agreements in Advance of biological events.
- d. Improve the collection and sharing of data among the federal government, private sector organizations, and other non-federal entities during a biological emergency.

31 Integrate and improve biosurveillance.

- a. Establish a biosurveillance federal advisory committee.
- b. Establish a food and agricultural biosurveillance planning committee.
- c. Modernize and expand national biosurveillance.
- d. Establish digital pathogen surveillance.
- e. Collect and share food, agriculture, plant, and wildlife disease data.
- f. Implement targeted plant biosurveillance.
- g. Strengthen territorial biosurveillance and data collection.
- h. Bolster the national pathogen surveillance and forecasting center.

RESPONSE, RECOVERY, AND MITIGATION

32

Provide emergency service providers with the resources they need to respond to biological events in their communities.

- a. Assess state, local, tribal, and territorial emergency medical service capabilities to respond to domestic biological terrorism and warfare.
- b. Establish a biological emergency response assistance program.
- c. Inform the delivery of emergency medical services during biological events and other national emergencies.
- d. Expand medical necessity rules for pre-hospital emergency medical services reimbursement.
- e. Provide food and agriculture biological emergency response technical assistance.
- f. Establish biological event direct assistance for tribal first responders.

33

Ensure consistent and adequate public health emergency funding and guidance.

- a. Provide robust public health emergency funding.
- b. Clarify eligibility for biological disaster assistance under the Stafford Act.
- c. Delineate federal assistance to non-federal governments for public health emergency response.
- d. Support urgently needed public health measures for research during biological events.
- e. Make emergency public health research eligible for homeland security grant funding.
- f. Allow emergency waiver authorities for beneficiaries and the uninsured during public health crises.

34

Buttress all laboratory networks that test for biological agents.

- a. Authorize all laboratory networks that test for biological agents.
- b. Establish requirements for all laboratory networks that test for biological agents.
- c. Authorize national laboratories collaborative biodefense research in the virtual environment.
- d. Eliminate the risk of accidental release during hazardous biological material transport by constructing and maintaining an incinerator for Fort Detrick, MD.
- e. Reduce the risk of funding shortfalls at military laboratories that conduct biodefense research.
- f. Review adequacy of laboratory biosafety and biosecurity standards, practices, and oversight.
- g. Review laboratory biosafety and biosecurity capabilities and challenges.

35

Increase national environmental decontamination and remediation capacity.

- a. Make the Environmental Protection Agency responsible for environmental decontamination and remediation after biological incidents.
- b. Exercise environmental remediation plans.
- c. Conduct studies of those exposed to biological agents

36

Lead the establishment of a functional and agile global public health emergency response apparatus.

- a. Sustain US contributions to international global health security and related programs.
- b. Develop a global public health response strategy for biological events.
- c. Strengthen the role of the Office of Foreign Disaster Assistance.
- d. Allow use of Commodity Credit Corporation funding to protect against global biological threats to food and agriculture.

THE BIOLOGICAL THREAT IS REAL AND GROWING



Our Nation faces biological threats that can result in millions of fatalities and trillions of dollars in economic losses. The federal government acknowledges the seriousness of this threat and funds a wide spectrum of activities across many departments and agencies to address it. These efforts demonstrate recognition of the problem and a distributed attempt to find solutions. Still, successive Administrations and Congresses do not give the biological threat the same level of attention as they do other threats. While the United States now has a national strategic plan for biodefense and an estimate of federal expenditures to achieve that plan's goals and objectives, there is still no centralized position in the Executive Branch sufficiently empowered to lead all of biodefense for America.

Biological threats—including biological warfare and bioterrorism—are not new. The United States engaged in a biological warfare program from 1943 to 1969,² 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 hostile nations.³ The United States eventually decided that it would be too difficult to control, and operate in areas contaminated with, disease agents and ceased its program to produce biological weapons in 1976. After that, our country shifted to a defense-only program. Believing that other nations also ceased their programs, the United States then reduced the priority placed on addressing biological weapons threats.

The former Soviet Union began its biological weapons program in the 1920s. While it signed onto the Biological and Toxin Weapons Convention (BWC) and claimed that it discontinued its biological weapons program in the 1970s, Soviet defectors revealed information indicating that the program continued into at least the 1990s, producing thousands of tons of weaponized biological agents and the weapons themselves, and renewing our apprehension.⁴ Russia has never 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 using agents like HIV and Ebola to attack opponents of apartheid.⁵ President Clinton grew concerned enough to direct White House staff to work with the Department of Justice, the Intelligence Community, and others to evaluate various biological attack scenarios

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Figure 2. Impact of the Anthrax Events of 2001 on Critical Infrastructure



and assess federal efforts to defend against them. After a flurry of briefings and the implementation of new programs during the Clinton Administration to strengthen domestic biodefense against high-impact events such as bioterrorism and pandemic influenza, investments waned until the anthrax events of 2001 again revived interest.

Following the anthrax attacks of 2001 (which killed 5 Americans and sickened 17), several devastating biological events occurred leading up to the COVID-19 pandemic. The SARS-CoV-1 epidemic in 2002 resulted in 774 deaths. The world faced the H1N1 influenza pandemic in 2009 that resulted in at least 284,000 deaths worldwide. While the H1N1 pandemic did not turn out to be as deadly as initially feared, it was a stress test for the world on managing an infectious respiratory pathogen. Shortly thereafter, MERS-CoV emerged in 2012 bearing responsibility for at least 937 deaths to date, and continuing to cause illnesses. Then there were the Ebola outbreaks in West Africa from 2014–2016 causing 11,300 deaths and global panic due to its high morbidity and mortality rates. The Zika virus challenged the world in 2016, that caused thousands of cases of microcephaly in infants and lifelong sickness that will continue to be a long-term problem. While these are some of the most well-known infectious disease events to occur between 2001 and 2020, we must not forget that seasonal influenza kills 400,000 people worldwide on average annually. This means that in addition to the many lives lost from these more notable events, the world has lost around 7.6 million lives due to influenza alone in the 18 years between the anthrax attacks and the emergence of COVID-19.

The biological threat has not abated. In keeping with our prediction in 2015, deadly naturally occurring diseases and accidental exposures have impacted, and continue to impact, the United States. Additionally, the Department of State has concluded that Russia and North Korea possess active offensive biological weapons programs, and that China and Iran may also.⁶

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The Department of Defense (DOD) in its 2023 Countering WMD Strategy⁷ stated that over the next decade, the United States must remain prepared for acute and persistent biological threats from China, Iran, North Korea, Russia, and violent extremist organizations. They raised significant concerns about China, Russia, and North Korea not complying with the BWC. Despite our recent and continuing experience with COVID-19, many still do not appreciate the extent, severity, and reality of biological threats. It remains unclear as to whether America's leaders have the political will to prevent these threats from becoming real.

Commission meetings since 2014 have focused on a range of biological threats facing the Nation, including pathogenic threats to food and agriculture, biological weapons, bioterrorism, insufficient laboratory biosafety and security, naturally occurring pandemics, and potential misapplications of synthetic biology. Expert witnesses made clear that all of these biological threats are growing more (not less) serious. Current and former federal officials, as well as private sector experts,⁸ have called for increased activity to defend the nation against biological threats.

INTENTIONAL

The Department of State assesses that China, Iran, North Korea, and Russia continue to engage in biological weapons-specific or dual-use research activities, and fail to comply with the BWC.⁹ New state programs can still access caches of incompletely destroyed or buried biological weapons materials from old state programs,¹⁰ and then smuggle them to other regions for use by today's militaries and terrorist organizations.¹¹ Weapons that once consumed a great deal of time and resources to make now take far less, and what the United States could accomplish more than 40 years ago, others can accomplish today.¹² International crises like the fall of Afghanistan, the Russian invasion of Ukraine, and the attacks on Israel have also increased the potential threat of biological weapons use.

Syria previously conducted biological weapons research utilizing anthrax, plague, botulism, smallpox, aflatoxin, cholera, and camelpox.¹³ Former Central Intelligence Agency (CIA) officials talk about the pursuit of biological weapons by other nation states and terrorist organizations that seek to kill 60–70% of targeted populations.¹⁴

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The previous and current Russian biological weapons program is thought to involve anthrax, plague, tularemia, glanders, brucellosis, Q-fever, and botulism. Al Qaeda is said to have pursued anthrax, botulism, and plague.¹⁵ There are also reports that the Islamic State of Iraq and the Levant (ISIL, also known as Da'esh) possesses the tools and know-how to produce biological weapons.¹⁶ Advanced science is now everywhere and easier to exploit, lowering the bar for the malevolent use of synthetic biology, genetic modification, artificial intelligence (AI), and other processes to create combined and modified organisms for biological weapons that would not need advanced or military-grade delivery mechanisms.

Today, nation states and terrorists can more easily obtain resources necessary to produce biological weapons¹⁷ than in years past. Traditional as well as newly organized terrorist organizations,¹⁸ domestic militia groups,¹⁹ and lone wolves²⁰ express intent to use biological weapons and show some capacity to develop them. Advances in synthetic biology and biotechnology now make it easier to modify, develop, and combine dangerous pathogens, expanding the number and types of biological weapons²¹ and making it more difficult to accurately comprehend the enormity of the threat.²²

Significant advancements in physics marked the 20th century, and remarkable progress in biology now marks the 21st century. Advances in biotechnology and synthetic biology lower the technical barrier required to produce biological agents with catastrophic potential. They also allow for enhancing the deadliness of these weapons and transmissibility of the diseases they contain, increasing the potential consequences of biological attacks beyond that of naturally occurring threats. For example, Canadian researchers synthesized horsepox in 2016, using only the DNA sequence. Horsepox is closely related to smallpox, meaning bad actors could use information from this research to produce a biological weapon from scratch. Progress in synthetic biology will soon lead to the proliferation of benchtop DNA synthesis machines that would function much like a 3D printer but for DNA sequences. Previously, these machines were large and expensive, requiring significant training to operate. They could only produce short DNA segments that researchers would need to stitch together manually to produce full length sequences. Companies aim to make these machines smaller, cheaper, easier to use without any prior biology or chemistry experience, and able to print full-length complete genomes. The governance of these machines will be complicated as the technology diffuses internationally.

As the biological data, human health, and cyber domains become more interconnected and interdependent, security lapses in one arena could greatly affect security in others. For example, state actors conducted cyberattacks to extract biological information during the COVID-19 pandemic.²³ Biological attacks in the future will likely occur in tandem with cyberattacks because our

adversaries understand their interconnectedness and cascading impacts. As the biotechnology sector continues to grow rapidly, cyber-intrusions will become more common. Increasing reliance on automation and outsourcing makes biotechnology infrastructure a target.

The amount of biological data the world generates also continues to rise exponentially. The COVID-19 pandemic illuminated the immense value of collecting large sets of biological data and leveraging advanced analytics and artificial intelligence AI to gain insights from those data. The same techniques could be used to develop more potent biological weapons than previously imagined.²⁴

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NATURAL

The increasing number of naturally occurring biological events (e.g., Ebola, Zika, COVID-19, Mpox) remind us that such diseases will continue to impact human, animal, and plant health with considerable frequency in the future. The incidence of infectious disease events more than doubled from the 1940s to the 1960s.²⁵ The rate of such events surged higher in the 1980s and continues to rise now.²⁶ The diversity of infectious disease outbreaks also increased significantly since 1980, with more than half caused by zoonotic diseases (that originate in animals and are transmissible to humans, also known as zoonoses).²⁷

Zoonoses are increasing in frequency and represent most emerging infectious diseases in the human population today. For example, influenza variants often arise from birds and swine, and when mutations occur that allow for transmission to humans, mortality rates have been as high as 60%. Other examples of zoonoses include West Nile Virus, SARS-CoV-1, MERS, and Ebola. Humans are likely to have little to no immunity against emerging zoonoses. As such, zoonoses put the human population at significant risk for pandemics. The United States is also at great risk for diseases that affect plants (e.g., blight), crops (e.g., wheat blast) and food (e.g., antimicrobial-resistant E. coli).

COVID-19 has taken the lives of over one million Americans and nearly seven million people worldwide while exposing vulnerabilities in the Nation's and the world's

biodefense. Pandemic and highly pathogenic influenzas challenge the globe every year and result in the loss of tens of thousands of human, and millions of animal lives.²⁸ Globally prevalent diseases mutate and defeat the countermeasures we currently possess to treat them.²⁹ Some naturally occurring diseases also devastate food and agriculture products and supplies, harming millions of people and weakening the US economy. America can no longer believe that devastating biological events like the COVID-19 pandemic are rare, once-in-a-century, occurrences.

Some human activities facilitate disease emergence and spread. A range of factors (e.g., rising population, globalization, ease of international travel, climate change, urbanization, land-use change, increased human-animal contact, agricultural/animal husbandry practices) also contribute to the significantly increasing risk and frequency of naturally occurring infectious disease outbreaks that can lead to pandemics with severe consequences.

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ACCIDENTAL

The possibility remains that SARS-CoV-2 arose and spread due to an accidental release in Wuhan, China. There are several different ways an accident could have occurred if this is the case. A researcher could have become infected by collecting samples in the wild without proper personal protective equipment (PPE) and then introduced it into their community unknowingly. Researchers could have also accidentally become infected by working with the virus in too low a biosafety level environment, allowing the virus to escape inadvertently.

Laboratory accidents occur frequently and can result in the release of harmful pathogens and the infection of laboratory personnel. Both could spread disease to surrounding communities. Insufficient attention to laboratory biosafety also contributes to the biological threat. Significant proven cases of poor biosafety that

resulted in unintended release of disease include *Bacillus anthracis* from Russian laboratories in 1979,³⁰ *Burkholderia pseudomallei* from a Tulane University research center in 2014,³¹ *Bacillus anthracis* from a US military laboratory at Dugway Proving Grounds in 2015,³² and Brucellosis from a vaccine production and research facility in Lanzhou, China in 2019.³³ At least 170 accidental releases of Select Agents were reported in 2022.³⁴

The risk of a catastrophic accidental release continues to rise as nations build more high containment laboratories and conduct more high-risk biological research. From 2001–2021, nations throughout the world built at least 20 of the 59 Biosafety Level Four (BSL-4) laboratories in 23 countries, mostly in densely populated urban areas. By 2023, the number increased significantly to 69 labs with 51 in operation, 15 planned, and 3 under construction in 27 countries.³⁵ Opportunities for human error, limited understanding of novel disease characteristics, and confusion about diseases that do not fit neatly into specific categories, all challenge current laboratory biosafety and biosecurity programs and regulations throughout the world.

Poor biosecurity increases the biological threat.³⁶ Even some of the highest-level US government laboratories have fallen short in this regard. For example, in 2001, a suspected insider allegedly removed anthrax from the US Army Medical Research Institute on Infectious Disease (USAMRIID) and used it to perpetrate the anthrax attacks that year.³⁷ Later, decades-old vials marked as containing smallpox virus were found in 2014 in a Food and Drug Administration (FDA) freezer on the campus of the National Institutes of Health (NIH), even though previous searches had been conducted to consolidate all remaining US stocks at the Centers for Disease Control and Prevention (CDC).³⁸ Major mishaps at the CDC that same year resulted in investigations, inspections, congressional hearings, and closures of laboratories that tested for biological agents in suspected terrorist events.³⁹ These biosecurity breaches resulted in the temporary (yet extended) restriction of laboratory activities and closure of laboratories that performed critical testing and research necessary to meet and reduce the biological threat, diminishing our national security.

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Global catastrophic biological risks are defined as biological threats and vulnerabilities that could lead to sudden, extraordinary, widespread disasters beyond the collective capability of national and international public and private sectors to control. If unchecked, global catastrophic biological risks would lead to great suffering, loss of life, and sustained damage to national governments, international relationships, economies, societal stability, and global security. The potential loss of life from a global catastrophic biological risk could be at least 100 million deaths.⁴⁰ Dual-use research conducted in BSL-4 and some lower-containment laboratories contribute to these risks. As dual-use research continues to produce and modify dangerous pathogens, existential risks are well within the realm of possibility, even if research is conducted with the best of intentions.

With new tools come potential dangers. The world lacks sufficient frameworks for responsible stewardship of these new technologies and activities. We cannot allow them to run unabated until after unintended consequences occur.

While biological agents themselves have long posed security concerns, biological information is increasingly becoming a security concern itself. Information hazards arise from the dissemination of true information that may cause harm. Biological information hazards can result from dual-use research. For example, in 2001, a group of Australian researchers published a paper detailing how they modified mousepox virus (closely related to smallpox) to evade vaccine protection in immunized mice.⁴¹ In another example, in 2011, a virologist in the Netherlands presented work about how his research group was able to make H5N1 avian influenza transmissible between humans.⁴² Bad actors could replicate these experiments for nefarious purposes. There is no consensus within the scientific community or beyond about what constitutes dangerous research and how certain research of concern should be overseen and regulated. Tension also occurs between the scientific research community and the national security community about how to deal with some information hazards and what should be classified.

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PREVIOUS COMMISSIONS EXPRESSED CONCERN

Some of our political leaders do appreciate the large and multifaceted nature of the biological threat. Previous commissions took the threat seriously, noted the potential for significant impact, and called for action. The US Commission on National Security/21st Century (also known as the Hart-Rudman Commission) in 1999 recognized the potential for epidemics to become pandemics and the dual-use nature of scientific discoveries.⁴³ The Commission on Terrorist Attacks on the United States (also known as the 9/11 Commission) in 2004 echoed Hart-Rudman and wrote that more than two dozen terrorist groups were pursuing biological materials and high-level government leaders were expressing varying levels of concern regarding this threat.⁴⁴ The Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction (WMD) (also known as the Robb-Silberman Commission) in 2005 joined the Hart-Rudman and 9/11 Commissions in their concern and described in great detail the failings and weaknesses of the Intelligence Community regarding the biological threat.⁴⁵ Finally, the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (also known as the Graham-Talent Commission) in 2008 reaffirmed the findings of these previous commissions and determined that the priority placed on addressing the biological threat simply did not ensure national security.⁴⁶ Despite observations made, and alarms sounded, by these Commissions and our Bipartisan Commission on Biodefense over more than 20 years, the United States has failed to marshal enough resources and effort to defend against the biological threat.

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LEADERSHIP



NATIONAL LEADERSHIP AND MANAGEMENT

Strong national biodefense requires strong, sustained leadership from the White House. All fifteen federal departments, nine independent agencies, and one independent institution possess biodefense responsibilities. One federal department cannot tell other departments and agencies what to do. Only the White House has the authority to do that. Administrations change White House leadership for biodefense frequently, often during biological crises.

The Bush Administration created a Special Assistant to the President for Health and Biodefense and made that position and its staff part of the Homeland Security Council (HSC) that President Bush established on October 8, 2001, shortly after the terrorist events of September 11, 2001. The Bush Administration also retained staff positions in the National Security Council (NSC) to address biological weapons and pandemic influenza. Upon taking control of the White House, the Obama Administration merged the staff for the NSC and the HSC. Following the H1N1 influenza pandemic, the Obama Administration eliminated the position of Special Assistant to the President for Health and Biodefense but created a temporary position to coordinate the response to Ebola four years later. The Obama Administration subsequently considered the Commission's recommendation to put the Vice President of the United States in charge of the biodefense enterprise but decided instead to reinstate a directorate in the NSC for Global Health Security and Biodefense. Subsequently, the Trump Administration eliminated that NSC directorate but retained the responsibility for biodefense by the National Security Staff, only to subsequently create a temporary position to coordinate the US national response to COVID-19. The Biden Administration reinstated the Global Health Security and Biodefense Directorate in the NSC in 2021. After observing the on-again off-again cavalcade of temporarily appointed czars for biological crises, Congress mandated the creation of the Office of Pandemic Preparedness and Response Policy in the Executive Office of the President through the Consolidated Appropriations Act, 2023 (P.L. 117-328). This office did not replace or absorb the NSC Directorate for Global Health Security and Biodefense. The new Office and existing Directorate split responsibilities for biodefense, making implementation more difficult than Congress realized.

Biodefense governance is important, as is remaining competitive in the global bioeconomy. However, many in government have yet to grasp the full implications of the vulnerabilities to future societal stability, economic prosperity and military strength posed by major policy gaps in biodefense and the bioeconomy. Much as Congress determined that the Intelligence Community required reform following the intelligence failures of the attacks of September 11, 2001, our national biodefense enterprise requires and deserves bold, empowered leadership to unify and direct federal activities in support of state, local, tribal, and territorial (SLTT) authorities and other stakeholders to address biological threats.

Recommendation 1: Reinforce White House leadership of the national biodefense enterprise.

ACTION ITEMS:

- a. **Provide biodefense policy and strategy advice and assistance to the President of the United States.** In support of the President of the United States and under the leadership of the Assistant to the President for National Security Affairs (also known as the National Security Advisor), the Office of the Vice President (OVP), NSC, Domestic Policy Council (DPC), National Economic Council (NEC), Office of Pandemic Preparedness and Response Policy (OPPRP), and Office of Science and Technology Policy (OSTP) should advise and assist the President on the development and implementation of biodefense policy and strategy.
- b. **Codify responsibilities of the National Security Advisor for biodefense.** Congress should amend the National Security Act of 1947 (P.L. 80-253) to codify the role of the National Security Advisor as the (1) leader of the national biodefense enterprise; and (2) principal adviser to the President, Councils and Offices in the Executive Office of the President, and other elements of the White House for biodefense matters under the purview of the NSC, including national security impacts (including military) of the global bioeconomy and that of other countries. The National Security Advisor should (consistent with the National Biodefense Strategy and its Implementation Plan) ensure synchronous efforts among the NSC, HSC, DPC, NEC, OPPRP, and OSTP to (1) update and execute the National Biodefense Strategy and its Implementation Plan; (2) coordinate with the Director of the Office of Management and Budget in developing a unified annual biodefense budget submission, and provide guidance to federal departments and agencies for the submission of biodefense budget requests; (3) establish objectives, priorities, and guidance for federal biodefense activities; (4) facilitate no fewer than one annual national level exercise for biodefense; and (5) develop and issue a government-wide after-action report following each large-scale biological event affecting the United States.
- c. **Codify and maintain a White House Directorate for Biodefense and Global Health Security.** Congress should amend the National Security Act of 1947 (P.L. 235-61 Stat.496; U.S.C. 402) to (1) establish a Deputy National Security Advisor for Biodefense and Global Health Security; and (2) maintain in perpetuity a discreet, robust biodefense activity of the NSC in the form of the Directorate for Global Health Security and Biodefense overseen by this Deputy National Security Advisor.

- d. **Add responsibilities for pandemic recovery and mitigation to the White House Office of Pandemic Preparedness and Response Policy.** Congress should amend the PREVENT Pandemics Act of 2022 (part of the Consolidated Appropriations Act, 2023, P.L. 117-328) to direct the Director of the Office of Pandemic Preparedness and Response Policy, in addition to preparedness and response, to (1) provide advice, within the Executive Office of the President, on pandemic recovery and mitigation policy; (2) serve as the principal advisor to the President on all matters related to pandemic recovery and mitigation policy; (3) coordinate federal activities to recover from and mitigate pandemic threats; (4) oversee federal activities to assess recovery from, and mitigation of, pandemic threats; (5) identify opportunities to leverage current and emerging technologies and medical countermeasures (MCM) to advance pandemic recovery and mitigation goals of the federal government; (6) ensure the interdepartmental working group evaluates national pandemic recovery and mitigation issues; and (7) review applicable federal strategies, policies, procedures, and after-action-reports to identify gaps and inefficiencies related to pandemic recovery and mitigation.
- e. **Assign responsibilities to the White House Office of Science and Technology Policy for coordinating biodefense research and development.** The President should direct OSTP to coordinate, and prevent overlap of, forward-looking (at least a decade or more into the future) biodefense research and development that maximizes the benefits of science and technology to prevent, deter, prepare for, detect, respond to, attribute, recover, and mitigate future biological threats. The Office should consult with, and must be responsive to, OPORP, the NSC Directorate for Biodefense and Global Health Security, and other elements of the White House addressing biodefense to understand gaps and requirements.
- f. **Assign responsibilities to the White House National Economic Council for the bioeconomy.** The President should direct the NEC to coordinate policy-making for the domestic and global bioeconomies, give policy advice about the bioeconomy (including attaining and sustaining US competitiveness in this arena) to the President, ensure that policy decisions and programs are consistent with the President's goals for the US bioeconomy, and monitor implementation of the President's economic policy agenda as it applies to the bioeconomy. The Assistant to the President for Economic Policy and the Director of the National Economic Council should add policy experts in the bioeconomy to the staff of the Council. The NEC should consult with the NSC Directorate for Biodefense and Global Health Security on issues of importance to both the NEC and the NSC.

- g. **Provide dedicated appropriations for biodefense activities undertaken by the White House.** Congress should appropriate dedicated funds for biodefense activities undertaken by the NSC, OVP, DPC, NEC, OPFRP, and OSTP.
- h. **Elevate Department of Defense Weapons of Mass Destruction leadership.** Congress should amend the Goldwater-Nichols Department of Defense Reorganization Act of 1986 (P.L. 99-433) to establish the position of Under Secretary of Defense for Nuclear, Chemical, and Biological Defense at the Department of Defense. The President should appoint this position with the advice and consent of the Senate. Subject to the authority, direction, and control of the Secretary of Defense, the Under Secretary should be responsible, and provide overall direction and supervision, for (1) the development, implementation, coordination, and integration of nuclear, chemical and biological defense activities across DOD; (2) at least quadrennial biodefense, chemical defense, and nuclear defense posture reviews to refresh and inform the Department's biological, chemical, and nuclear defense activities; and (3) other such duties and powers as the Secretary of Defense may prescribe. Congress should establish the separate positions of Assistant Secretary of Defense for Nuclear Defense, Assistant Secretary of Defense for Chemical Defense, and Assistant Secretary of Defense for Biological Defense to report directly to the Under Secretary of Defense for Nuclear, Chemical, and Biological Defense.
- i. **Establish an Assistant Secretary of Agriculture for National and Homeland Security.** Congress should amend Section 218 of the Federal Crop Insurance Reform and Department of Agriculture Reauthorization Act of 1994 (P.L. 103-354) to establish the position of Assistant Secretary of Agriculture for National and Homeland Security. This position should (1) serve as the Department lead for developing and coordinating policy with regard to defense of the Nation's food and agriculture, against biological and other threats; (2) serve as the Department lead for global health policy; and (3) assume responsibility for the Department's bioeconomy responsibilities from the USDA Office of the Chief Economist. Congress should place all responsibilities, personnel, and resources of the Department of Agriculture (USDA) Office of Homeland Security under the authority of the Assistant Secretary. Congress should also direct the Secretary of Agriculture to develop a strategy, implementation plan, and funding requirements to increase biodefense subject matter expertise at the USDA Office of National and Homeland Security. The Secretary should deliver this strategy and implementation plan to Congress no later than 180 days after enactment.

NATIONAL BIODEFENSE STRATEGIES AND REVIEWS

The Trump Administration produced the first National Biodefense Strategy in 2018, in keeping with our recommendation for the development of such a strategy in our 2015 *National Blueprint for Biodefense*. Before that, the federal government relied on numerous disparate and uncoordinated policies and strategies to address biological threats. The 2018 National Biodefense Strategy incorporated a modest implementation plan for how the federal government would achieve its biodefense mission, goals, and objectives. In 2022, the Biden Administration released an updated National Biodefense Strategy and Implementation Plan, including further detail on roles and responsibilities. The White House also issued National Security Memorandum 15 in 2022 to provide guidance to federal departments and agencies on the implementation process.⁴⁷

Every future Administration should ensure that the Strategy keeps pace with the rapidly evolving and increasing biological threat. In addition, the Strategy should also address science and technology needs for biodefense, such as those outlined in our 2021 report on *The Apollo Program for Biodefense*, the American Pandemic Preparedness Plan, and related elements of the President's Budget Request. The federal government must engage in biodefense policy, science, and technology to permanently eliminate pandemics as a national threat.

The COVID-19 pandemic continues to reveal gaps in government policies to defend the Nation against biological threats. Most departments and independent agencies with biodefense responsibilities lack their own individual biodefense strategies which naturally inhibits needed coordination of comprehensive efforts within the US government to defend against biological threats.

Recommendation 2: Implement, maintain, and update a comprehensive national biodefense strategy.

ACTION ITEMS:

- a. **Institute a quadrennial national biodefense review.** Congress should direct the National Security Advisor to conduct a major quadrennial review of the fifteen Cabinet departments, nine independent agencies, and one independent institution with biodefense responsibilities. This review should culminate in a report and updated National Biodefense Strategy and Implementation Plan submitted by the White House on behalf of the Executive Branch to Congress.

- b. **Produce a national biodefense science and technology plan.** The Director of the Office of Science and Technology Policy, in concert with the Deputy National Security Advisor for Biodefense and Global Health Security, should develop and implement a national biodefense science and technology plan that focuses on the technology priorities provided in the Commission's 2021 report on *The Apollo Program for Biodefense*. The Administration should align this plan with the goals of the National Biodefense Strategy and its Implementation Plan.
- c. **Produce departmental and agency biodefense strategies.** Congress should amend the National Security Act of 1947 (P.L. 235 – 61 Stat. 496; U.S.C. 402) to direct all fifteen Cabinet departments, nine independent agencies, and one independent institution with biodefense responsibilities to produce their own biodefense strategies and accompanying implementation plans that show how they will support the goals and objectives of the National Biodefense Strategy.
- d. **Conduct and implement a quadrennial military biodefense posture review.** The Secretary of Defense should conduct a quadrennial biodefense posture review. This review should develop and/or update doctrine for biodefense activities with the input and full concurrence of the Joint Chiefs of Staff. The Biodefense Posture Review should inform DOD scientific research and development, training, and other activities necessary for biodefense. The Secretary of Defense should provide annual briefings about the current biodefense posture of the Department to Congress.

UNIFIED BIODEFENSE BUDGET

Until recently, the government neither reviewed nor regularly reported federal investments in biodefense activities. Nongovernmental groups conduct assessments of federal biodefense spending (for unclassified programs and activities), and previously estimated federal government spending near \$6 billion annually on biodefense programs.⁴⁸ However, without a common understanding of what is meant by biodefense, the Office of Management and Budget (OMB), House Committee on Appropriations and Senate Committee on Appropriations, and private sector organizations produce differing totals. The COVID-19 pandemic demonstrated that existing funding levels were inadequate, but a unified biodefense budget aligned to the National Biodefense Strategy and Implementation Plan would have identified spending gaps and duplications sooner.

Recognizing the value of connecting biodefense expenditures to biodefense policy, in 2020 Congress passed legislation requiring the Director of the Office of Management and Budget to develop and issue an annual biodefense crosscut analysis in accordance with the Commission's recommendation for a biodefense crosscut.⁴⁹ The OMB submitted the first of these annual assessments in January 2023, and reported that in Fiscal Year 2022 the federal government had spent

approximately \$12 billion on biodefense activities across 16 departments and agencies.⁵⁰ While this assessment was a promising start, the OMB neither further delineated biodefense expenditures by each department and agency nor detailed how those expenditures aligned with the responsibilities assigned to each entity by the National Biodefense Strategy and Implementation Plan. In addition, the OMB has not indicated whether it intends to utilize this assessment to determine future biodefense spending needs, or to develop a unified biodefense budget submission for the Fiscal Year 2025 budget request and future budget requests.

A unified approach to budgeting would enhance congressional oversight and allow the White House to better determine whether current programs are in keeping with the President's priorities. Using these data, OMB, NSC, and OPPrP could more easily identify and eliminate duplicative federal efforts in the biodefense space. Additionally, many biodefense activities would greatly benefit from multiyear funding. The biodefense enterprise is no different from the national defense enterprise, which can engage in multiyear procurements for many of its programs.⁵¹ Research and development of innovative MCM and biodefense technologies would benefit from long-term certainty in funding.

Table. 2 Federal Entities with Biodefense Responsibilities

Departments	
Department of Agriculture	Department of Interior
Department of Commerce	Department of Justice
Department of Defense	Department of Labor
Department of Education	Department of State
Department of Energy	Department of the Treasury
Department of Health and Human Services	Department of Transportation
Department of Homeland Security	Department of Veterans Affairs
Department of Housing and Urban Development	
Independent Agencies	
Central Intelligence Agency	National Science Foundation
Environmental Protection Agency	Office of the Director of National Intelligence
General Services Administration	United States Postal Service
National Aeronautics and Space Administration	United States Agency for International Development
National Nuclear Security Administration	
Independent Institution	
Smithsonian Institution	

Recommendation 3: Unify biodefense budgeting.

ACTION ITEMS:

- a. **Institutionalize biodefense as a discreet portfolio at the Office of Management and Budget.** Congress should amend the William M. (Mac) Thornberry National Defense Authorization Act of 2021 (P.L. 116-283) to require the designation of a Program Associate Director in OMB to manage the entire biodefense budget portfolio. Congress should also require the Administration to categorize biodefense as a cross-agency priority goal in accordance with the Government Performance and Results Act (GPRA) Modernization Act of 2010 (P.L. 111-352) and develop metrics in keeping with the National Biodefense Strategy and Implementation Plan. The Deputy Director for Management at OMB, through the Performance and Personnel Management Directorate and in conjunction with the biodefense Program Associate Director, should work with the White House on the creation and implementation of performance targets for the biodefense cross-agency priority goal. Departments and agencies should base their budget requests to OMB on performance and outcome measures that exceed GPRA requirements.
- b. **Strengthen the annual crosscutting biodefense budget analysis.** Congress should amend Section 363 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283) to require additional detail and assessment of biodefense spending across the federal government as part of the statutorily mandated annual biodefense crosscut. Congress should direct the Director of the Office of Management and Budget to require an annual biodefense data call as part of its budget submissions and to inform its biodefense crosscut.
- c. **Develop a budget plan for the National Biodefense Strategy.** The National Security Advisor should coordinate with the Director of the Office of Management and Budget to develop a multi-year budget plan for execution of the National Biodefense Strategy and Implementation Plan. This plan should identify budget amounts, appropriations, and expenditures for each requirement identified by the National Biodefense Strategy and Implementation Plan. As part of the development process for this plan, the Director of the Office of Management and Budget should audit performance and identify whether requirements are still appropriate. The National Security Advisor and the Director of the Office of Management and Budget should update this plan concurrently with future updates to the National Biodefense Strategy and Implementation Plan.

- d. **Align budget items to the National Biodefense Strategy.** The Director of the Office of Management and Budget should require that all budget requests pertaining to biodefense show how they support the National Biodefense Strategy. Federal departments and agencies with biodefense responsibilities should develop annual biodefense professional judgment budgets reflecting their funding needs to address biological threats and how those needs align with National Biodefense Strategy responsibilities. The Director of the Office of Management and Budget should submit these budgets to Congress alongside the annual budget request.
- e. **Provide predictable and multi-year funding for 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 Deputy National Security Advisor for Biodefense and Global Health Security and Director of the Office of Management and Budget determine would benefit from such forward funding. Additionally, federal departments and agencies should provide multi-year grants, contracts, and/or cooperative agreements wherever possible to sustain federal programs that require multiple years for research, development, implementation, and execution, as well as private sector incentives to participate and partner with the government.
- f. **Produce a future years biodefense budget program plan.** Congress should amend 31 U.S.C. § 1105(a) to establish a Future Years Biodefense Budget Program requiring the Director of the Office of Management and Budget to submit to Congress a yearly Future Years Biodefense Budget Program plan with the President's Budget Request. The plan should include estimated expenditures and proposed appropriations for at least the current and four succeeding fiscal years. Congress should require the Director of the Office of Management and Budget to ensure that expenditure estimates and proposed appropriations for any fiscal year are consistent with the total estimated expenditures and appropriations deemed necessary to support the biodefense projects, programs, and activities of all departments and agencies.
- g. **Develop and submit a unified biodefense budget request.** The Director of the Office of Management and Budget should provide an integrated biodefense budget request to Congress annually. This submission should be a holistic presentation of all department and agency biodefense requests across the federal government, ensuring that the overall President's Budget Request aligns with the National Biodefense Strategy and aids congressional appropriations and related authorization decisions. The following should comprise the request: (1) the biodefense budget crosscut conducted per the data call described above; (2) the performance outcomes for biodefense Programs, Projects, and Activities (PPAs); (3) an explanation for how PPAs contribute to the goals and objectives of the National Biodefense Strategy; and (4) a five-year Future Years Biodefense Budget Program plan.

CONGRESSIONAL AGENDA FOR BIODEFENSE

Many federal departments and agencies possess biodefense responsibilities: Thirty-two congressional committees possess oversight authority and one or two subcommittees per committee claim specific purview (see Table 3). Of course, not all these committees conduct oversight consistently and many important activities escape congressional oversight.

The biodefense issue areas most frequently assessed by Congress (e.g., threat awareness, biosurveillance and biodetection, MCM) comprise only a subset of the broad range of issues that require substantial oversight. With some notable exceptions, most of the oversight (particularly through hearings) occurs in reaction to biological events. Most reactive oversight consists of post-event reviews of major missteps in federal program execution.

The COVID-19 pandemic drew the public's attention to the biological threat in an unprecedented way. Congress initially followed by holding dozens of hearings on COVID-19. Congressional appropriations surged to address the threat, and Congress expanded biodefense authorities to address the next threat.⁵² Even with these achievements, in the midst of the worst pandemic to affect America in a century, Congress rapidly shifted its attention to address other priorities as the immediate threat receded. Congress should strengthen oversight, authorization, and appropriations for federal biodefense efforts to efficiently adapt our Nation's laws and strengthen federal defense against the growing biological threat.

Table 3. Congressional Committees with Biodefense Jurisdiction

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

Recommendation 4: Establish a clear congressional agenda to ensure national biodefense.

ACTION ITEMS:

- h. **Establish a congressional working group on biodefense.** At the beginning of each Congress, House and Senate leadership should establish a bipartisan, bicameral congressional working group on biodefense. The Chairs and Ranking Members, or Members designated by the Chair or Ranking Member of each committee with biodefense jurisdiction (see Table 3), should comprise this entity. This group should meet regularly to (1) develop recommendations for congressional leaders to ensure national biodefense; (2) develop budgetary figures for overall biodefense spending; and (3) bring biodefense appropriations into alignment with authorization.
- i. **Convene annual biological threat briefings for Congress.** At the start of each congressional session, each committee with biodefense jurisdiction should, in accordance with House and Senate rules, convene for an annual in-depth classified biological threat briefing.
- j. **Establish biodefense subcommittees or make biodefense the focus of existing subcommittees in the House of Representatives and Senate.** The Chairs of committees with biodefense responsibilities should establish biodefense subcommittees, or add biodefense to the focal areas of existing subcommittees, and charge them with oversight, investigations, and legislation over federal biodefense activities within the committees' jurisdictions. The subcommittees should address federal biodefense activities between biological events and take the lead in authorizing or reauthorizing biodefense programs. The subcommittees should hold no fewer than one biodefense hearing each year.
- k. **Align biodefense appropriations and budgets.** Congressional appropriators should to the best of their ability ensure that annual appropriations legislation is in line with the annual unified biodefense budget submission. The House Committee on Appropriations and Senate Committee on Appropriations should request annual biodefense budget briefings from OMB. Appropriators should require annual reporting from the NSC on the implementation of the National Biodefense Strategy. The House Committee on the Budget and Senate Committee on the Budget should hold an annual joint hearing to discuss the OMB biodefense crosscut, and the unified biodefense budget submission.

INTELLIGENCE, ATTRIBUTION, AND DETERRENCE



BIOLOGICAL INTELLIGENCE MANAGEMENT

Determining intent to develop biological weapons to use against the United States is an enormous intelligence challenge. Despite the dire consequences and concerns associated with the biological threat, Congress has not provided, nor has the Intelligence Community dedicated, resources to collect information, analyze it, and produce intelligence about biological threats to the same extent as other threats. The ubiquity of knowledge necessary to weaponize biological agents also prevents the Intelligence Community from using more traditional nation-specific or expertise-specific approaches to intelligence collection. Additionally, the Intelligence Community 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 Intelligence Community ignores the biological threat. Most intelligence agencies, and the National Counterproliferation and Biosecurity Center and National Counterterrorism Center in the Office of the Director of National Intelligence, engage in or support biological intelligence activities. However, the vast nature of the biological threat is out of proportion with the limited resources and emphasis assigned to it by the Intelligence Community.

The Director of National Intelligence finds it difficult to enable Intelligence Community agencies to establish and maintain relationships and develop new strategies to collect information. Multiple agencies address various aspects of the biological threat and do not coordinate well with each other.

Partially as a result of these challenges, the Intelligence Community has not produced a comprehensive unclassified analysis of the biological threat. Only four sentences in the 2023 Worldwide Threat Assessment describe the biological threat as compared to many paragraphs for other threats. Despite acknowledgment by senior leaders in the Intelligence Community that the biological threat is real and threatens the United States, the treatment of this threat in the Worldwide Threat Assessment appears to be an afterthought. Why this occurred when other elements of the Intelligence Community have written and released unclassified reports containing far more information in them (e.g., the Department of State Verification and Compliance report) is unclear.

The Intelligence Community's assessment of the origins of COVID-19 provides evidence of disjointed analysis of biological threats.⁵³ The eight agencies in the Intelligence Community tasked with developing this assessment of how COVID-19 began still have not reached a definitive conclusion: four have low confidence in natural origin; two have some confidence in the laboratory origin, with the Department of Energy (DOE) expressing low confidence and the Federal Bureau of Investigation (FBI) expressing moderate confidence;⁵⁴ and two could not decide either way.

The Commission previously recommended the creation of a National Intelligence Manager for Biological Threats. In 2019, then Director of National Intelligence Dan Coats responded to this recommendation by assigning that responsibility to the Director for the National Counterproliferation Center. Subsequent Directors of National Intelligence maintained this assignment but did not dedicate sufficient resources to the Center to enable it to address this threat. Congress sought to rectify this problem and ensure that the Center focused on biological weapons proliferation when it changed the name of the Center to the National Counterproliferation and Biosecurity Center and expanded the Center's authorities to include the management of intelligence on emerging foreign biological threats, including diseases with pandemic potential. However, this congressional action has yet to produce desired results.

Section 702 of the Foreign Intelligence Surveillance Act allows for the Intelligence Community to obtain (for foreign intelligence purposes) the communications of foreigners located outside of the United States who use US communications service providers. The intelligence produced contributes directly to US national security while requiring that the Department of Justice and Intelligence Community safeguard privacy and civil liberties. All three branches of the US government oversee compliance. About 60% of the President's Daily Brief contains 702 information. Information obtained in accordance with 702 informs our government's understanding of illicit plans to (1) bring drugs into America; (2) attack US military personnel; (3) attack US critical infrastructure; (4) obtain components needed to build WMD; (5) conduct terrorist attacks on the United States and its interests overseas; (6) recruit or deploy spies in the United States; and (7) invest in US companies. This law ensures that the US government can quickly obtain critical information while protecting the rights of Americans. Intelligence based on 702 is also vital in the protection of the United States against biological attacks. Our country must retain 702 authorities because they are critical to biodefense.

Information sharing with non-federal entities also poses a significant challenge. Much of the available information about current and potential biological threats is classified. Recognizing this, the Intelligence Community attempts to declassify some of this information and share it with non-federal governments. For example, the Joint Counterterrorism Assessment Team (part of the Office of the Director for National Intelligence) conducts research, produces, and disseminates counterterrorism information to non-federal governments. Still, the federal government has found it difficult to overcome institutional prohibitions against sharing information with non-federal personnel. As a result, this program does not function as originally intended.

Partly to solve the intelligence problem, some local police (e.g., the New York City Police Department) created their own intelligence capabilities to develop intelligence

and distribute information to others within their locality. Few such programs exist, however, and most only address the biological threat in small part. The Nation's fusion centers could contribute to understanding the biological threat better in their areas of responsibility. The Federal Emergency Management Agency (FEMA) and the Department of Homeland Security (DHS) Office of Intelligence and Analysis provide technical assistance to fusion centers.

The FBI plays a vital role in countering biological threats, whether they are naturally occurring, accidental, or deliberate. The FBI has the authority and responsibility to investigate any articulated threat involving a biological agent. The FBI contributes to intelligence activities by providing microbial forensic testing and analysis of suspected agents at the National Bioforensic Analysis Center (NBFAC), which is part of the National Biodefense Analysis and Countermeasures Center (NBACC). The Bureau also collaborates with the rest of the Intelligence Community to gather information on adversaries' capabilities and intentions to use biological weapons, but has yet to establish biological attribution capabilities equal to the current threat.

Recommendation 5: Increase, improve, and prioritize management of biological intelligence.

ACTION ITEMS:

- a. **Create a National Intelligence Manager for Biological Threats.** The Director of National Intelligence should create and officially name a National Intelligence Manager for Biological Threats and ensure that this National Intelligence Manager interacts with other National Intelligence Managers who address some other aspects of the biological threat.
- b. **Make biological weapons programs and related activities a discrete intelligence topic.** The Director of National Intelligence should direct the National Intelligence Manager for Biological Threats to work with other agencies in the Intelligence Community to assign priorities to countries and non-state actors as they relate to biological weapons research, development, programs, and activities that would enable these countries and actors to engage in biological warfare and terrorism. The Intelligence Community should broaden its focus to address classes of biological agents as well as individual diseases. The NSC Deputy National Security Advisor for Biodefense and Global Health Security, other biodefense personnel at the White House, and Congress should receive regular briefings about biological intelligence efforts.

- c. **Increase biological threat expertise within, and available to, the Intelligence Community.** Each member agency of the Intelligence Community should (1) develop better strategies to engage with outside expertise (e.g., from industry, academia, nongovernmental organizations, governmental agencies that are not part of the Intelligence Community) when characterizing the biological threat; (2) ensure that scientific and other expertise within the Community is sufficient to address current and future biological threats; (3) ensure diversity and turnover occurs among private sector experts to foster new thinking and enable the Community to obtain the latest information on current biological advances and threats; and (4) eliminate the use of single government contractors to obtain and funnel inputs from private sector experts to members of the Intelligence Community.
- d. **Permanently authorize Section 702 of the Foreign Intelligence Surveillance Act to protect the Nation against biological attacks.** Congress should repeal subsection 403(b) of the FISA Amendments Act of 2008 (P.L. 110-261) to remove the termination clause for the authorities provided by Section 702 of the Foreign Intelligence Surveillance Act of 1978 (50 USC 1881a) and maintain those authorities in perpetuity.
- e. **Increase federal domestic biological intelligence efforts.** The Director of the Federal Bureau of Investigation should (1) increase collection and analysis of information, and distribution of intelligence regarding domestic biological crime and terrorism, including with regard to anti-government and anti-authority violent extremists who seek to obtain and use biological weapons; and (2) assign at least one FBI special agent dedicated to addressing biological crime and terrorism in every FBI field office.
- f. **Enable fusion centers to address the biological threat.** The Administrator of the Federal Emergency Management Agency 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 sources.

BIOLOGICAL ATTRIBUTION FOR DECISION-MAKING

Attribution means the ability to identify the source and origin of a biological event, whether natural, accidental, or intentional. Attribution is critical because it (1) helps hold accountable those who perpetrate biological warfare and terrorism or violate international norms; (2) deters attacks by demonstrating ability to determine who is responsible; (3) informs response and recovery efforts by providing situational awareness and evidence; and (4) enhances biodefense measures by identifying the gaps and vulnerabilities that led to a biological event.

Attribution is always difficult. It becomes increasingly so with the involvement of multiple investigators and when crimes and attacks involve unusual weapons. When biological attacks occur, attribution efforts must correctly identify perpetrators, pathogens, and their sources. Lack of access to data, cooperation, and transparency, however, create significant obstacles and limitations. Establishing an effective attribution capability would greatly enhance national security, diplomacy, and public trust.

The COVID-19 pandemic painfully revealed the severe limitations of US and global biological attribution capabilities. We still do not clearly understand from where or how this virus originated. The United States also lacks a formal decision-making apparatus to assist leaders in addressing biological crimes. The current informal system lacks standards for burdens of proof, requirements for source information, and standards for acceptable evidence, information, and intelligence. Response exercises rarely take biological attribution into consideration. The Nation's existing biological attribution capabilities are fragmented and limited in scope.

The NBFAC (part of NBACC) conducts technical analyses in support of federal law enforcement and other investigations and attempts to coordinate multi-agency microbial forensic efforts. However, the DHS Science and Technology Directorate (which administers the NBACC) struggles to coordinate with and serve other agencies, because it is not an operational organization and its scientific goals often run at cross-purposes to those of the operational organizations seeking to use the Center. As a result, agencies often decline to work with or utilize the Center. The FBI is the primary customer of the NBFAC, and the only agency that submits specimens for examination by the Center. The Bureau already functionally manages the NBFAC, and possesses the credibility and influence needed to allow the NBFAC to fulfill its national role in microbial forensics and biological attribution. Although DHS owns the NBACC and provides funding to support its activities, funds provided by the FBI only support the NBFAC.

The US Postal Inspection Service (USPIS) played a crucial role in investigating the anthrax attacks of 2001 that killed 5 people and infected 17 others through letters laced with anthrax spores sent in the mail. The Inspection Service joined forces with the FBI and other law enforcement agencies to form the Amerithrax Task Force which conducted a complex 9-year investigation that involved interviewing 10,000 witnesses, recovering 6,000 pieces of evidence, gathering 5,730 environmental samples, and scrutinizing over 1,000 possible suspects. The Inspection Service also enhanced mail screening, improved intelligence gathering, trained postal inspectors, and installed biodetection systems in every mail processing facility across the United States and its territories. However, over 20 years after the anthrax attacks, attribution capabilities as well as the capabilities of our adversaries have advanced. For

example, bad actors could potentially order pathogen DNA from synthesis providers online and have them shipped anywhere in the US for use against our population. These advancements call for the USPIIS to update and reevaluate its investigative procedures surrounding biological threats.

The Smithsonian Institution is composed of 19 museums, 9 research centers (which include laboratories), the National Zoo, and 144 affiliated museums. The federal government provides about 80 percent of the Smithsonian's funding, while private donations and private funds provide the remaining 20 percent. The Smithsonian follows biosecurity and biosafety guidelines at its laboratories and plays a significant role in working to counter smuggling of antiquities, some of which could contain living or dead microorganisms. It also supports the attribution efforts of federal law enforcement and other agencies.

Recommendation 6: Better support and inform decisions based on biological attribution.

ACTION ITEMS:

- a. **Establish a national biological attribution decision-making apparatus.** The Secretary of State, Secretary of Defense, Secretary of Health and Human Services, Secretary of Homeland Security, Attorney General, Director of National Intelligence, and Director of the Federal Bureau of Investigation should jointly develop, plan for, and establish a national biological attribution apparatus to inform decision-making. The plan should articulate department and agency roles, responsibilities, and requirements, as well as requirements for adjudicating attribution information and informing decisions following any biological event with national security implications.
- b. **Make the Federal Bureau of Investigation responsible for the National Bioforensics Analysis Center.** Congress should amend the Antiterrorism and Effective Death Penalty Act of 1996 (P.L. 104-132) and make the FBI responsible for the NBFAC, its administration, and its activities, including interagency support and coordination. Congress should reallocate appropriations accordingly by moving the funds that DHS puts towards supporting the Center to the FBI. Congress should authorize the Center, and the House Committee on the Judiciary and Senate Committee on the Judiciary should increase their oversight over the Center's activities and attribution activities undertaken by the FBI.

- c. **Update US Postal Inspection Service biological investigation and attribution capabilities.** The US Postmaster General should (1) share information and best practices with other postal and shipping stakeholders⁵⁵ about detecting, identifying, and tracing biological threats sent through the mail; (2) invest in advanced technologies and equipment, (e.g., machine learning) to improve its ability to collect and analyze forensic evidence from suspicious mail items (e.g., DNA, fingerprints, chemical signatures, animal and plant parts); (3) update protocols and procedures for handling and processing biological samples, ensuring the safety of its personnel and the integrity of evidence; (4) train and educate the USPIS workforce on the latest techniques and tools for attribution; and (5) host regular exercises and simulations with postal and shipping stakeholders to test and evaluate its attribution capabilities and readiness.
- d. **Draw upon the Smithsonian Institution for assistance with biological attribution.** The Secretary of the Smithsonian Institution should (1) upon request, assist US federal law enforcement investigators with access to its collections, information regarding preservation, data, and analysis for the purposes of biological attribution.

BIOLOGICAL AND TOXIN WEAPONS CONVENTION

The Department of State (DOS) should take a more active role in promoting the BWC as a key instrument for preventing the development, production, stockpiling, and use of biological weapons. The DOS Office of the Biological Policy Staff leads interagency efforts on the BWC, including chairing meetings, coordinating the preparation and submission of annual confidence-building measures, and promoting efforts to enhance universal adherence to, and effective implementation of, the Convention by other states parties.

The United States is currently working with other states parties to strengthen the operation of the BWC in such areas as assessing and managing risks arising from developments in science and technology, facilitating responsible conduct of the life sciences, ensuring effective national implementation of BWC obligations (including those associated with biosafety and biosecurity), enhancing transparency and confidence building among parties; and organizing to provide assistance in the event of a suspicious outbreak or alleged use of biological weapons.

Unlike the Chemical Weapons Convention (CWC), the BWC lacks an adequate verification mechanism for investigation and attribution of biological events. The BWC Implementation Support Unit only has a handful of staff at any given time, lacking the larger staff of the CWC. Challenges with compliance and verification affect all countries (including the United States), making implementation of the BWC much more difficult than the CWC.

Recommendation 7: Increase support for the Biological and Toxin Weapons Convention

ACTION ITEMS:

- a. **Increase Department of State staff support for the Biological and Toxin Weapons Convention.** The Secretary of State should direct the DOS Office of the Biological Policy Staff to (1) lead the development and implementation of a comprehensive strategy for advancing US objectives for the BWC in coordination with other federal stakeholders; (2) strengthen collaboration with academia, industry, and other non-governmental organizations that possess expertise and interest in biodefense and biosecurity issues to contribute to the BWC process; (3) increase transparency and accountability regarding US biodefense activities and programs, and encourage other BWC states parties to do the same through regular reporting, information-sharing, and confidence-building measures; and (4) lead the development of a verification mechanism that would enhance the credibility and effectiveness of the BWC.
- b. **Propose increasing staff for the Biological and Toxin Weapons Convention Implementation Support Unit.** The Secretary of State should submit a formal proposal to the Convention to increase the number of staff for the BWC Implementation Support Unit. The Secretary should propose that in addition to the three current staff: (1) all five permanent members of the United Nations Security Council should provide at least one staff member to the Implementation Support Unit; and (2) the ten non-permanent members of the Security Council also appoint at least one staff member to support the Implementation Support Unit.

BIOLOGICAL THREAT REDUCTION

During recent biological events, including the 2014–2015 Ebola outbreak in West Africa and the COVID-19 pandemic, the Defense Threat Reduction Agency (DTRA) developed innovative solutions for addressing the needs of both the US military and civilians. Vaccines, therapeutics, and the Transportation Isolation System⁵⁶ are just a few examples of the agency's accomplishments. DTRA works with the Department of Health and Human Services (HHS) and the United States Agency for International Development (USAID) to accomplish international biodefense goals, but there is no formal understanding between them when it comes to their respective roles and responsibilities. Clarifying their roles in biodefense would improve coordination, collaboration, and impact on partner countries.

The DTRA Cooperative Threat Reduction Program continues to be a prime target for misinformation and disinformation, especially regarding biological weapons. Russian state media, diplomats, and propagandists have grossly mischaracterized the Program's activities since at least 2018, claiming without evidence that the United States is running biological weapons laboratories in Ukraine. During the first morning of the invasion of Ukraine, propagandists took to social media, claiming that Russia was invading to shut down US biological weapons laboratories there. Russia previously used a similar playbook during their 2008 invasion of Georgia. Both DOD and DOS cooperative threat reduction programs actively work to combat these disinformation campaigns, but they need a formal strategy to counter misinformation and disinformation.

Information-based attacks also erode the ability of the United States to help countries build their public health capacity. They also impede interaction between countries and the United States for fear that an adversary like Russia will target these other countries with misinformation as well.

The National Science Foundation (NSF) does not fund dual-use research of concern (DURC) and gain-of-function research of concern but allows for research that could create enhanced potential pandemic pathogens (ePPP).⁵⁷ Since these three (DURC, gain-of-function, and ePPP research) overlap, it is not clear what NSF funds and under what conditions. NSF updated its policy in January 2023,^{58,59} but the language surrounding DURC, gain-of-function, and ePPP research remains confusing. For example, NSF specifically prohibits gain-of-function research with biological agents associated with the 2015 US Government Policy on Dual Use Research of Concern, in which there are 15 agents listed.⁶⁰ However, NSF will fund research that involves the creation, transfer, or use of ePPP under special circumstances where the potential benefits to society far outweigh the risks. Revisions to DURC and ePPP research oversight and guidelines⁶¹ that will apply to all federally funded research may resolve these issues.

Recommendation 8: Strengthen biological threat reduction.

ACTION ITEMS:

a. **Clarify international biodefense capacity-building roles and responsibilities.**

The Secretary of Defense should direct the Director of the Defense Threat Reduction Agency to enter into a Memorandum of Understanding with HHS and USAID to clarify roles and responsibilities for building biodefense capabilities internationally in execution of the Global Health Security Agenda and other federal policies. These agreements should address how each federal entity selects partner countries, and the feasibility of coordination of effort with each country.

- b. **Develop and implement a plan to counter misinformation and disinformation about cooperative threat reduction programs.** The Secretary of Defense, in coordination with the Secretary of State, should develop a strategy for countering mis- and disinformation about military biodefense, including cooperative threat reduction programs. The Secretary should submit this strategy to Congress no later than 180 days after enactment.
- c. **Update National Science Foundation grant funding policy for dual-use, gain-of-function, and enhanced pathogen research.** The Director of the National Science Foundation should update at least annually the Foundation's grant funding policy for DURC, gain-of-function research of concern, and the creation of novel ePPP.
- d. **Update and implement a DNA/RNA synthesis screening framework.** Once every four years, the Director of the Office of Science and Technology Policy should develop an updated screening framework with requirements for providers and users of synthetic biology services that meet or exceed those of current gene sequence and customer screening best practices.⁶² Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Commerce, to implement the framework, maintain a list of verified vendors, and provide information regarding these providers, users, and vendors to the FBI to help with attribution. Congress should amend the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283), Public Health Service Act (P.L. 78-410), Homeland Security Act (P.L. 107-296), Agriculture Improvement Act of 2018 (P.L. 115-334), and National Science Foundation Act of 1950 (P.L. 81-507) to require any entity receiving a federal grant or engaging in a cooperative agreement related to synthetic DNA and RNA to purchase their synthetic materials from vendors that (1) adhere to the requirements of the updated screening framework to minimize risk; and (2) address gene synthesis screening, customer screening, record keeping, order refusal and reporting, and regulatory compliance.

FEDERAL SELECT AGENT PROGRAM OVERHAUL

The USDA, Department of Commerce, HHS, Department of Labor, and Department of Transportation, and regulate and oversee the possession, use, or transfer of infectious agents, toxins, or other biological hazards.⁶³ Additionally, the NIH National Science Advisory Board for Biosecurity (NSABB) addresses biosecurity and dual-use research at the request of the federal government.

The USDA and CDC jointly administer the Federal Select Agent Program (FSAP). Established in 2003, the Program oversees the possession, use, and transfer of

biological select agents and toxins that have the potential to pose a severe threat to human, animal, or plant health; or animal or plant products. The FSAP currently covers 68 select agents and toxins. The program reviews the list at least every two years to decide whether to add or delete agents or toxins.

The existing FSAP is becoming obsolete. Information, knowledge, and equipment to produce new pathogens have become increasingly available in the years since the establishment of the FSAP. Pathogens are also not the only problem. Biological weapons development could also use biological materials and certain biotechnologies (e.g., DNA synthesis machines, bioregulators, small peptides) that fall outside of the current regime.

Policies to modernize FSAP must clarify (1) the purpose of the FSAP; (2) rationale for its rules; (3) criteria for changing the select agent list; (4) barriers preventing full implementation of the FSAP; (5) the value of a dynamic characteristic-based approach for restricted agents and toxins versus the current, static, list-based approach; (6) challenges associated with inspections; (7) how to maximize federal and private investments in biodefense; and (8) how to incorporate a nonpunitive process for addressing problems.

Recommendation 9: Review and overhaul the Federal Select Agent Program.

ACTION ITEMS:

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

Congress should amend the Pandemic and All-Hazards Preparedness Act (P.L.109-417) to require the NSABB to conduct a systematic, evidenced-based, comprehensive assessment of the FSAP. This assessment should include extensive consultation with all stakeholders. The NSABB should: (1) evaluate all pertinent strategies, laws, and guidance related to the FSAP; (2) identify key drivers of safety and security lapses; and (3) identify regulatory burdens in the FSAP that stifle research and innovation. The NSABB should produce a report that includes specific and actionable recommendations for revising FSAP regulations and their implementation to improve biosecurity and biosafety and to incentivize laboratory certification of registration under the program. The Secretary of Health and Human Services should submit the first NSABB report and related recommendations to Congress, distribute the report to the Secretary of Agriculture, Secretary of Defense, and the NSC no later than 180 days after enactment, and update progress every two years.

- b. **Overhaul the Federal Select Agent Program.** The Secretary of Agriculture, Secretary of Commerce, Secretary of Defense, Secretary of Health and Human Services, Secretary of Homeland Security, Secretary of Labor, Secretary of Transportation, and Attorney General should undertake a comprehensive review and modernization of the Program, based on the recommendations of the NSABB and input from other sources as appropriate. The overhaul should include the development of a revised program strategy/scope; notice of proposed rulemaking and public comment periods; and promulgation of new rules. All new rulemaking must increase laboratory biosafety and biosecurity and minimize bureaucratic burdens.

ARTIFICIAL INTELLIGENCE/ LIFE SCIENCE RISK MANAGEMENT

AI increases life science capabilities and lowers tacit knowledge necessary to perform tedious laboratory tasks. As the development of technologies accelerates and access to these technologies increases, the possibility of biological weapons attacks and other high-consequence biological events also increases. The convergence of AI and the life sciences poses numerous risks that we know of now, and more will arise as time goes on. It is now possible to use openly available AI and large language models to help develop novel pathogens and biological weapons. For example, when researchers changed the parameter of an AI model used for drug development, they also found that the model could produce compounds for existing and novel chemical weapons.⁶⁴

Humanity can use AI tools for every step in the synthetic biology development cycle.⁶⁵ We can also use AI during the design step of this cycle to identify optimal mutations that could enhance a pathogen's severity. It can not only assist in the design step of the process, but it can also support the building and testing phases to lesser degrees. The rise of AI-enabled cloud labs to automate procedures that previously required firsthand knowledge to perform tasks could further widen the pool of individuals performing certain biology experiments. Cloud labs could allow a malicious actor to conduct synthesis and subsequent tests undetected and more easily. Bad actors may soon be able to use these technologies and advancements to perform completely hands-off, in silico designing, building, and testing of a novel or recreated pathogen.

The American Association for the Advancement of Science Center for Science, Technology, and Security Policy, the FBI Biological Countermeasures Unit, and the United Nations Interregional Crime and Justice Research Institute produced a risk assessment framework for big data in the life sciences in 2015.⁶⁶ Other US departments and agencies, such as the Department of Commerce National Institute for Standards and Technology, DOD, HHS, and DHS Cybersecurity and Infrastructure Security Agency (CISA) should also play a significant role in addressing these risks. Since

then, big data, AI tools, and the life sciences have advanced significantly. The Nation urgently needs to develop new risk assessment frameworks and regulatory policies to prevent potential catastrophic biological events as these technologies converge.

AI will change the technology innovation landscape profoundly. It will catalyze unprecedented opportunities for US competitiveness to address grand challenge problems in health, agriculture, and environmental sustainability. These accomplishments will also provide a powerful vehicle for soft diplomacy in US-led global development initiatives to counter China's Belt-and-Road initiative. AI will also dramatically expand dual-use threats and the need for new surveillance technologies and regulatory oversight policies.

While the White House acknowledges that AI represents an inflection point that will test political and technical leadership on multiple fronts, few federal departments or agencies are positioned to address its convergence with biodefense. Apart from DOD, no federal department or agency has clearly articulated a vision for their AI strategy. Industry, in contrast, has made AI a high priority for investment. The United States should reasonably view China as a peer or perhaps ahead of the US in AI applications in multiple fields (e.g., biotechnology, synthetic biology) affecting biodefense and the bioeconomy.

Recommendation 10: Combat risks from the convergence of artificial intelligence and the life sciences.

ACTION ITEMS:

- a. **Identify risks posed by the convergence of artificial intelligence and the life sciences.** Congress should amend Division E of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283) to charge the National Artificial Intelligence Initiative Interagency Committee with identifying risks posed by, and identifying regulatory issues surrounding, the convergence of AI and the life sciences.
- b. **Develop an artificial intelligence/life sciences risk assessment framework.** Congress should amend Division E of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283) to direct the National Artificial Intelligence Initiative Interagency Committee to take currently identified AI/life science risks into account and develop and update a risk assessment framework. The Committee should update the framework annually, taking changes in science and technology into account. The Committee should submit current risk assessments and accompanying frameworks to Congress on an annual basis.

c. **Develop an artificial intelligence/life sciences risk reduction strategy.**

Congress should amend Division E of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283) to direct the National Artificial Intelligence Initiative Interagency Committee to produce an AI/life sciences risk reduction strategy. This strategy should (1) take previously issued AI/life sciences risk assessments into account; (2) address human monitoring and regulation of AI activities; (3) identify regulatory avenues for restricting the use of potentially dangerous biological research in large language models and other AI tools; (4) propose solutions, regulatory policies, and ways to work with the private sector to prevent AI/life science threats from materializing. The Committee should submit this strategy to Congress on an annual basis.

SCIENCE AND TECHNOLOGY



THE APOLLO PROGRAM FOR BIODEFENSE

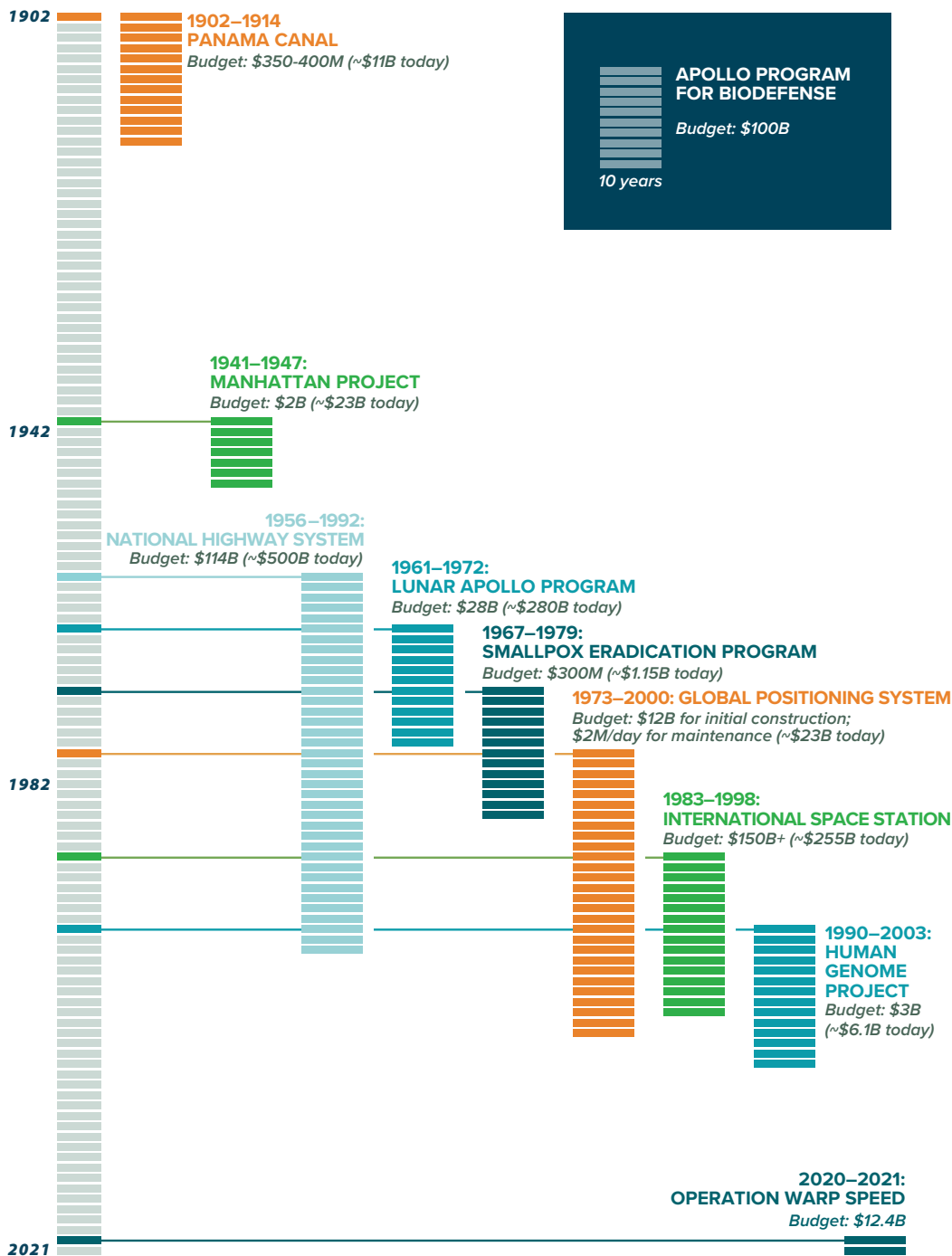
Technology holds great promise. Within weeks of recognizing the existence of COVID-19, scientists mapped its entire genome and developed and produced vaccines faster than ever before. They accomplished these previously unimaginable feats because of forward-looking programs (e.g., Human Genome Project, advanced research programs that previously led to many vaccines currently used to treat a variety of diseases). Nonetheless, we failed to adequately harness scientific and technological capabilities, and undermined response efforts by failing to implement new strategies and defenses. We have an unknown period to address those shortcomings before the next devastating pandemic occurs.

The need to control COVID-19 created momentum to produce many technologies that we previously lacked the will and resources to pursue before the pandemic began. We need to build on that progress and push for technological advances to protect us from the next biological threat. Our Nation rises to seemingly impossible challenges by pursuing grand programs. The United States can similarly put an end to pandemics within a decade, but only with leadership, resources, and interest that go beyond technical constraints and the usual crisis-neglect cycles.

The United States should leverage basic research portfolios to study pathogens of concern, conduct pre-clinical and clinical testing of priority and prototype pathogens, develop products to detect and treat the diseases they cause. These programs must involve domestic, international, private, and public sector partners.

The Commission proposed *The Apollo Program for Biodefense* in 2021 to undertake targeted research and development to detect and continually trace any new pathogen from the source, distribute rapid point-of-use tests to every household and farm in the country within days of that detection, have effective treatments already in-hand, and develop and rollout vaccines in weeks rather than years. This ambitious program, at about \$10 billion annually for ten years, would be a small fraction of the trillions in costs incurred by the COVID-19 pandemic and would contribute immensely to our country's public health, economic, and national security.

Figure 3. US Grand Programs



Recommendation 11: Establish The Apollo Program for Biodefense.

ACTION ITEMS:

While these action items comprise The Apollo Program for Biodefense, they are also part of other recommendations in the National Blueprint for Biodefense. They are inextricably linked.

- a. **Develop vaccine candidates for prototype pathogens.**
See Recommendation 18b
- b. **Develop therapeutic drugs in advance of outbreaks.**
See Recommendation 18c
- c. **Develop flexible and scalable manufacturing of pharmaceuticals.**
See Recommendation 18e
- d. **Develop needle-free methods of drug and vaccine administration.**
See Recommendation 18d
- e. **Identify and increase ubiquitous sequencing.**
See Recommendation 29h
- f. **Develop minimally- and non-invasive infection detection.**
See Recommendation 29e
- g. **Develop massively multiplexed detection capabilities.**
See Recommendation 29i
- h. **Develop rapid point-of-use diagnostics.**
See Recommendation 29c
- i. **Establish digital pathogen surveillance.**
See Recommendation 31d
- j. **Develop a national public health data system.**
See Recommendation 30a
- k. **Bolster the national pathogen surveillance and forecasting center.**
See Recommendation 31h
- l. **Develop next-generation personal protective equipment.**
See Recommendation 12b
- m. **Reduce pathogen transmission in the built environment.**
See Recommendation 13c
- n. **Establish comprehensive laboratory biosafety and biosecurity.**
See Recommendation 34g
- o. **Screen DNA synthesis providers and users and purchase genetic material from verified vendors.**
See Recommendation 8d

PERSONAL PROTECTIVE EQUIPMENT

Despite protecting against a broad spectrum of biological threats, current PPE burdens its users, requires experience in proper usage, is seldomly reusable, is not widely available to all, and may not fit properly (e.g., children).⁶⁷ Additionally, since the primary goal of PPE is to prevent the wearer from becoming infected, not enough emphasis has been placed on preventing the wearer from infecting others. Shortages of PPE leave frontline and essential workers at risk, threatening their health and reducing their capacity to respond.

The public and private sectors have made some investments in the research and development of next-generation PPE. For example, the NIH invested in the research and development of a smart mask that changes colors when exposed to COVID-19.⁶⁸ A team at the National Aeronautics and Space Administration (NASA) Jet Propulsion Laboratory developed a 3D printable powered air-purifying respirator with custom filters and commercial off-the-shelf components to help provide more PPE during the COVID-19 pandemic.⁶⁹ NASA also worked with hospitals during the pandemic to develop new methods and technologies for decontaminating PPE.⁷⁰ Many companies participated in the Mask Innovation Challenge: Building Tomorrow's Mask program, sponsored by the Biomedical Advanced Research and Development Authority (BARDA) Division of Research, Innovation, and Ventures (known as DRIVE) and the National Institute for Occupational Safety and Health, to develop innovative masks to provide protection from respiratory pathogens such as SARS-CoV-2.⁷¹ These efforts, however, are too few.

Currently available PPE is not (1) reusable, sterilizable, or self-disinfecting; (2) modular in design to respond to a wide range of threats; (3) adequately personalized to ensure protection, comfort, and attractiveness; (4) able to scale up production rapidly using widely available materials; (5) able to neutralize pathogens; (6) able to detect exposure; and (7) able to go beyond traditional masks, respirators, gloves, and gowns that safeguard without burdening the wearer. The government could invest in, and incentivize the development of, PPE innovation through inducement prize challenges, intramural and extramural research and development efforts, advance purchase commitments and consistent acquisition, and use-inspired basic research programs (e.g., Defense Advanced Research Projects Agency (DARPA) Personalized Protective Biosystem). Establishing distributed capacity would ensure PPE is available before biological events and maintaining manufacturing capability would ensure increased production and surge in response to biological threat. Additionally, standards and metrics for the evaluation of all forms of PPE would help quantify capabilities, standardize comparisons, and assess progress.⁷²

The COVID-19 pandemic revealed gaps in our knowledge of PPE and ability to rapidly scale up production. However, the pandemic also catalyzed efforts to make PPE reusable, spur innovative ideas about respirator designs, personalize the equipment, and increase manufacturing capacity. These efforts mark advancements but innovation and focused research efforts could achieve much more.

Recommendation 12: Extend and develop next-generation personal protective equipment to guard against biological threats.

ACTION ITEMS:

- a. **Extend the shelf-life of personal protective equipment stockpiled for use in biological emergencies.** Congress should amend the Federal Food, Drug, and Cosmetic Act (P.L. 75-717) to authorize the Commissioner of the Food and Drug Administration to extend the expiration date of eligible FDA-approved PPE stockpiled for use during biological emergencies. Congress should direct the Commissioner to (1) coordinate with the Assistant Secretary of Labor for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health at the CDC to develop criteria and a process for this shelf-life extension program; and (2) submit a report detailing the program to Congress no later than a year after enactment and annually thereafter.
- b. **Research and develop next-generation personal protective equipment for use in healthcare settings and areas containing or contaminated with biological agents.** The Secretary of Health and Human Services, in coordination with the Secretary of Defense, Secretary of Labor, and Administrator of the National Aeronautics and Space Administration, should (1) provide criteria and metrics to assess ongoing research and development of next-generation PPE in the public and private sectors; (2) provide a funding plan for advancing research and development in the public and private sectors; and (3) develop next generation PPE for use in healthcare settings and areas containing or contaminated with biological agents within one year of enactment.
- c. **Transfer technology for biodefense personal protective equipment throughout the public and private sectors.** Congress should amend the Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480) (94 Stat. 2311) and the Federal Technology Transfer Act (P.L. 99-502, 15 U.S.C 3710) to direct the Secretary of Defense to establish a technology transfer center that facilitates sharing of PPE technology with and by other federal departments and agencies, SLTT governments, and the private sector.

PATHOGEN TRANSMISSION REDUCTION IN BUILT ENVIRONMENTS

Disease transmission readily occurs when people live and work in enclosed spaces in built environments (e.g., buildings, airplanes, trains, subways, and other conveyances) via air, droplets, and fomites (i.e., contaminated materials or surfaces).⁷³ The United States exerts significant effort to engineer and defend built environments against fires, earthquakes, floods, and other weather-related impacts. For example, airlines have greatly reduced airborne transmission of diseases in plane cabins.⁷⁴ Suppressing pathogen transmission (especially in high-risk, high-traffic spaces),⁷⁵ would reduce the spread of infectious diseases, extinguish some outbreaks by never allowing them to spread, and buy more time to combat aggressive pathogens. We could continuously defend against threats (even prior to detection and without dramatic changes in human behavior) by permanently incorporating technologies that suppress pathogen transmission in built environments.⁷⁶

Although self-sterilizing materials and fomite-neutralizing technologies (e.g., copper-alloy surfaces)⁷⁷ help suppress pathogen transmission, the most promising interventions involve improving indoor air quality. Improved air filtration and indoor ventilation can reduce the transmission of COVID-19 by 80%.⁷⁸ Accordingly, to reduce the effective transmission of most airborne, droplet, vectorborne, and fomite transmitted pathogens, the United States should invest in the following:

- Affordable air filtration and sterilization systems;
- Tailored airflow design;
- Self-sterilizing surfaces;
- Easily sterilized materials (unaffected by harsh sterilization);
- Robotic and autonomous integrated sterilization;
- Fomite neutralizing technologies;
- Integrated real-time pathogen-sensing capabilities; and
- Germicidal ultraviolet light.

The federal government took steps to improve outdoor air quality through the Clean Air Act of 1963 (P.L. 88-206), first authorized by Congress as a program in the US Public Health Service before the creation of the Environmental Protection Agency (EPA) in 1971. This Act greatly improved health, benefited the economy, and reduced deaths.^{79,80} Unfortunately, much of the federal government has not taken similar action. The CDC issued updated guidance on building ventilation in May 2023.⁸¹ However, the public and private sectors struggled to implement this guidance. Revolutionizing indoor air quality will require the involvement of more federal entities and technological solutions in addition to ventilation.^{82,83}

Recommendation 13: Reduce pathogen transmission in built environments.

ACTION ITEMS:

- a. **Conduct research on pathogen transmission reduction in built environments.** The Secretary of Health and Human Services, in coordination with the Secretary of Education, Secretary of Homeland Security, Secretary of Transportation, Administrator of the Environmental Protection Agency, and Administrator of the General Services Administration should produce a joint research and development plan for reducing pathogen transmission in built environments, including transportation environments. The plan should (1) include criteria and metrics to measure, monitor, and assess how well technologies reduce pathogen transmission in built environments; (2) provide an assessment across the public and private sectors of ongoing technology research and development for reducing pathogen transmission in built environments, including monitoring and detection technologies; (3) address funding needs for advanced research and development in the public sector and incentivizes for research (including pilot programs) and development by the private sector; (4) address the integration of indoor biological detection technologies; and (5) include a timeline for implementation within one year of enactment.
- b. **Develop and advance technologies to reduce viability and transmission of pathogens in built environments.** The Secretary of Health and Human Services, in coordination with the Secretary of Defense, the Secretary of Education, Secretary of Homeland Security, Secretary of Transportation, Administrator of the Environmental Protection Agency, and Administrator of the General Services Administration should establish a program to (1) develop and refine technologies that reduce pathogen transmission in built environments; (2) develop building code standards that apply these technologies and pathogen reduction best practices; and (3) submit a progress report (including findings) to Congress annually.
- c. **Reduce pathogen transmission in built environments.** Congress should amend the Homeland Security Act (P.L. 107-296) to (1) require SLTT entities to update building codes that factor in standards and requirements for reducing pathogen transmission in newly built environments as a requirement for participation in the Homeland Security Grant Programs administered by FEMA; (2) establish a dedicated federal grant program administered by FEMA to offer assistance to SLTT entities to reduce pathogen transmission in their built environments; and (3) authorize appropriations to retrofit existing General Services Administration and other federally owned and leased facilities to reduce pathogen transmission in the built environment.

- d. **Develop health-based standards for reducing pathogen transmission in built environments.** Congress should amend the Clean Air Act of 1963 (P.L. 88-206) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense, the Secretary of Education, Secretary of Homeland Security, Secretary of Transportation, Administrator of the Environmental Protection Agency, and Administrator of the General Services Administration, to develop health-based standards, requirements, and regulations for improving indoor air quality and reducing pathogen transmission in built environments. These entities should develop requirements for various technologies and solutions (e.g., germicidal ultraviolet light) that address more than just ventilation. The Secretary should deliver these requirements, standards, and regulations to Congress no later than one year after enactment.

INTEGRATE NATIONAL DEFENSE SCIENCE AND TECHNOLOGY

The Department of Defense bears responsibility for protecting the Nation's warfighters from all threats, including attacks with biological and other WMD. The Department has long recognized the need to develop innovative technologies and countermeasures to address biological agents deployed by our adversaries, yet organizational elements within the Department do not coordinate their biodefense research and development activities. The lack of coordination increases the risk of leaving capability gaps unaddressed and making duplicative biodefense investments.

Federal law requires the Secretary of Defense to encourage the transfer of technology between the Department's laboratories and research centers, and those of other federal and non-federal agencies, academic institutions, and individuals, to further the goals of the National Security Strategy for the National Technology and Industrial Base.⁸⁴ The Domestic Technology Transfer Program facilitates the sharing of technologies with Department partners, particularly those in the private sector.⁸⁵ However, the Department does not have an established process for its various research and development entities to share biodefense technologies internally.

As illustrated by its investments in genomic vaccine technology years before these advances would prove critical in the rapid creation of COVID-19 vaccines, DARPA is known for its mission to identify and create ways to combat future threats. Despite their successes, however, the Agency has trouble finding homes for its technologies within DOD and elsewhere. Program directors would benefit from additional understanding of biodefense capability gaps throughout the Department and federal government. One example of the difficulties the Agency faces is with the SIGMA+ program, an effective biodetection technology with far better outcomes

than those of BioWatch. While SIGMA+ technology still needs improvement, some metropolitan areas fielded and already use it in their day-to-day operations. The program was supposed to end after five years but DOD gave it an extension for another three years to the end of Fiscal Year 2023. Now that this program has ended, technology development halted and the metropolitan areas who utilize this technology need to fund its continued maintenance and operations without support from the federal government.

Recommendation 14: Integrate national defense science and technology.

ACTION ITEMS:

- a. **Integrate military research to defend the warfighter against biological threats.** The Under Secretary of Defense for Research and Engineering should develop an integrated biodefense research plan for DOD. This plan should include an assessment of existing DOD biodefense research and development activities and how they support the goals of the National Defense Strategy, National Security Strategy, and National Biodefense Strategy. The Under Secretary should identify opportunities throughout DOD for uptake of technologies developed by DARPA and other Department research programs.
- b. **Produce a federal biotechnology inventory.** Congress should amend the National Defense Authorization Act to require the Secretary of Defense, in coordination with the Secretary of Agriculture, Secretary of Energy, Secretary of Health and Human Services, Secretary of Homeland Security, and Director of National Intelligence to (1) produce an unclassified biotechnology inventory with a classified annex; (2) identify and categorize all biodefense technologies developed or in development, including technology readiness levels; (3) provide brief descriptions of sought after applications for these technologies; and (4) submit this inventory to Congress within 180 days of enactment.
- c. **Facilitate defense biotechnology transition.** The Secretary of Defense should establish a process for transitioning biotechnologies (especially those developed by DARPA) throughout DOD. The Secretary should submit a plan and corresponding directive detailing this process no later than 180 days after enactment.
- d. **Address military biodefense research gaps.** The Director of the Defense Advanced Research Projects Agency should identify biodefense research gaps within DOD and realign Agency research and development investments to generate needed research. The Director should submit an annual report to the Secretary of Defense describing any changes in biodefense research and development based on capability needs.

ASTROBIODEFENSE

Human exploration of the solar system and beyond continues, and with that exploration, biological risk increases. Probes or humans visiting extraterrestrial environments must not introduce organisms from Earth into those environments. Conversely, they also must ensure that they do not bring back any extraterrestrial or mutated terrestrial microbes that could pose a threat to Earth's human, animal, plant, or ecosystem health or the Moon. While it may seem farfetched, some microorganisms survive exposure to space-like conditions (e.g., tobacco mosaic virus, poliovirus, bacteriophage T1). Other pathogens remain viable in extreme environments and might survive space as well. Spaceflight also increases the virulence of some bacteria in infection models.

Spaceflight sometimes reactivates viruses (e.g., herpes, Epstein-Barr, varicella-zoster, cytomegalovirus) and increases viral shedding in astronauts. A human infection in a space-like environment could pose a significant threat to everyone on board. Additionally, spaceflight severely weakens the immune systems of astronauts, making them more susceptible to terrestrial and extraterrestrial diseases. Research involving organisms already occurs in space and we expect it to increase, thereby also increasing the risk of accidental releases and exposures. Finally, considering the intense competition to explore and dominate space, other planets, moons, and asteroids, we cannot rule out the use of biological weapons to eliminate contenders.

Astrobiodefense aims to identify, characterize, and manage biological threats emerging at the intersection of space exploration and infectious disease. We must act now to address these threats before they materialize.

NASA has a long history of engaging in biosafety and biodefense (e.g., quarantine measures taken during the Apollo missions).⁸⁶ The NASA Office of Planetary Protection works to prevent forward contamination (the transfer of organisms and other contamination from Earth to other celestial bodies) and backward contamination (the transfer of organisms and other contamination from other celestial bodies to Earth) as a result of spaceflight. The NASA Office of the Chief Medical Officer works to ensure the health and safety of astronauts during spaceflight and extraterrestrial exploration. The NASA Biosafety Review Board works to identify, evaluate, control, and prevent biological hazards in accordance with health and safety regulations.⁸⁷ NASA assesses and assigns a biosafety level to all payloads containing biological materials. The Biosafety Review Board also establishes requirements to identify and assess biohazardous materials in payloads and ground-based experiments.⁸⁸ Still, NASA can and should do more.

Much of the technology NASA develops and uses to protect astronauts from infection, sterilize environments, and detect life forms also have applications for biodefense (e.g.,

technologies that improve indoor air quality or biodetection). Biosafety technologies developed for space travel likely have significant applications to biodefense on Earth. Congress mandated that NASA transfer technology for civilian use, but other federal departments and agencies are often not aware of the NASA technology transfer program,⁸⁹ capabilities, and potential contributions to biodefense.

Recommendation 15: Defend against astrobiological threats.

ACTION ITEMS:

- a. **Authorize the Office of Planetary Protection.** Congress should amend the National Aeronautics and Space Act of 1958 (P.L. 85-568) to authorize the NASA Office of Planetary Protection to (1) prevent forward contamination (contamination of celestial bodies by Earth terrestrial organisms, organic materials, and organic volatile materials carried or released by spacecraft); and (2) prevent backward contamination (contamination of Earth and the Moon by extraterrestrial life, organisms, organic materials, organic volatile materials, and bioactive molecules in returned samples and spacecraft from celestial bodies) in accordance with the US Space Priorities Framework.⁹⁰
- b. **Establish a planetary biodefense board.** The Administrator of the National Aeronautics and Space Administration should establish a Planetary Biodefense Board, co-chaired by the NASA Planetary Protection Officer and Chief Health and Medical Officer, to (1) review standards and requirements for sample return missions; (2) inform the National Space Council and other parts of the White House of biodefense issues and concerns; and (3) collaborate with DOD, HHS, DHS, Federal Aviation Administration, and other federal departments and agencies on astrobiological research and other efforts.

REGULATORY PROCESS IMPROVEMENT

The FDA plays a significant role in reviewing many of the technologies that comprise national biodefense. The FDA conducted a lessons-learned review through an independent organization as part of its Pandemic Recovery and Preparedness Plan Initiative. The FDA must move quickly to incorporate lessons learned from the response to COVID-19 into its policies and practices so it can more quickly authorize or approve new diagnostics within days of the emergence of any new virus, variant, or mutation, and authorize or approve new vaccines and therapeutics within 100 days. Measures must be taken to create and institutionalize procedures and processes to insulate FDA experts and regulatory activities from undue political pressure in order to ensure public confidence in the safety and efficacy of the products the agency approves during public health emergencies.

Recommendation 16: Improve regulatory processes.

ACTION ITEMS:

- a. **Authorize or approve MCM platform technologies before, during, and after biological events.** The Secretary of Health and Human Services should direct the Commissioners of the Food and Drug Administration to further develop and implement a regulatory framework for review and approval of MCM platform technologies that (1) encourages submission before an a biological event becomes an emergency; (2) expedites approvals for platforms with validated safety profiles to rapidly deploy during a biological event caused by a novel pathogen; (3) incorporates lessons learned from the rapid authorization of COVID-19 mRNA vaccine platforms and the slow authorization of other platforms; and (4) explains and sets clear requirements for the private sector to obtain authorization using this process. The Commissioner should develop the framework within 180 days and the Secretary should implement it within one year of development.
- b. **Incorporate lessons learned from pandemics into regulatory processes.** The Secretary of Health and Human Services should direct the Commissioner of the Food and Drug Administration to incorporate lessons learned from COVID-19 and other pandemics into regulations and sub-regulatory guidance to (1) partner with the private sector in reviewing pre-clinical, clinical, and manufacturing data and coordinate across relevant agency centers for combination products and products that require cross-center expertise; (2) communicate with private sector sponsors and the public (as appropriate) about the types and specificity of data needed for authorization of classes of medical products; (3) conduct remote clinical trials and inspections, including pre-established coordination mechanisms with foreign government inspection regimes; (4) facilitate organized and prioritized clinical trial networks to rapidly test and evaluate potential vaccines and therapeutics; (5) evaluate vaccines, therapeutics, and other interventions for their potential to reduce disease transmission, severity, and mortality; (6) streamline development and regulatory review of modifications of previously authorized vaccines, therapeutics, and diagnostics, to address changes in a dangerous pathogen over time, as well as significant applicable changes in science and technology⁹¹; (7) use predictive biomarkers, AI-based models, and real-world evidence to accelerate authorization of biomedical products, especially during a public health emergency, with established mechanisms to monitor and evaluate such use in real-time; and (8) justify increased funding for FDA emergency preparedness, response, and MCM activities. The Secretary should report the implementation of these lessons to Congress annually.

MEDICAL COUNTERMEASURE INVESTMENT

The responsibility for developing MCM for biological threats rests primarily with the National Institute of Allergy and Infectious Diseases (NIAID, which focuses on early-stage research) and BARDA (which focuses on advanced research and development). Their efforts lack coordination, transparency to stakeholders and Congress, and funding commensurate with the threat.

The Institute does not submit an annual plan to Congress that describes how research investments made by NIAID connect to a specific list of BARDA requirements for MCM. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) does submit a five-year budget plan⁹², and the 21st Century Cures Act (P.L. 114-255) requires submission of this plan no later than March 1 of each year (although in practice PHEMCE often misses this deadline). Even though that submission breaks down the multi-year budget by agency (including for the NIAID), it does not capture the NIAID spending plan in helpful detail. The plan also differs dramatically from the President's Budget Request and is subject to change. Congress and BARDA must understand the ways in which NIAID investments specifically address BARDA MCM requirements, but the existing five-year PHEMCE plan does not clearly fulfill this requirement.

Despite the PHEMCE multiyear budget, BARDA spending plans are similarly opaque to stakeholders and Congress. A requirement-setting process helmed by the newly renamed Administration for Strategic Preparedness and Response (ASPR) drives BARDA procurements. Engagement in the process does not occur at regular intervals and BARDA discloses the requirements to stakeholders and Congress in an ad hoc, piecemeal fashion. This challenges private sector planning and congressional oversight. Collaboration between NIAID and BARDA improved during the COVID-19 pandemic, enabling faster development of MCM. They also took steps to advance next-generation breakthroughs to stay ahead of COVID-19 through the \$5 billion Project NextGen Initiative.⁹³ However, both entities must sustain and institutionalize these relationships to ensure national readiness for the next biological event. They must also eliminate duplication of efforts and focus on those respective portions of the MCM development pathway where they have developed expertise and relationships.

US investment in medical countermeasure development is dangerously insufficient. This lack of adequate funding for the US MCM enterprise necessitates emergency funding each time the Nation faces a biological event affecting national security. For example, Congress appropriated emergency supplemental funding to enable the rapid development of MCM for COVID-19 as it did when faced with the H1N1, Zika, and Ebola crises. However, the COVID-19 funding came only after nearly two

months of disagreement between Congress and the White House regarding precise needs and funding levels. The delay pushed back the timeline for federal COVID-19 MCM efforts, although BARDA did repurpose funds from other programs to make investments in COVID-19 vaccines and therapeutics as a stopgap before Congress acted. The early months of the COVID-19 pandemic made the devastating impact of this shortsighted strategy clear. The federal government's failure to continue to fund efforts to produce MCM for two other coronaviruses (SARS (Severe Acute Respiratory Syndrome) in 2003 and MERS (Middle East Respiratory Syndrome) in 2012) delayed the COVID-19 vaccine research process at the possible cost of tens of thousands of lives.

We know that the development of any drug or vaccine candidate is a risky, lengthy, and expensive process. The commercial market is limited for most of these MCM until a pandemic or smaller outbreak occurs that affects national security. As such, only the federal government can incentivize development of these products. The federal government must identify and leverage a variety of strategies and incentives to stimulate private sector development and manufacturing 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 anthrax MCM).

Congress established Project BioShield to incentivize MCM development and created BARDA to plan for and execute advanced development and procurement of MCM, both in partnership with the private sector. Congress recognized that private sector confidence in a government market for MCM requires multi-year funding, transparent long-term strategies, and more flexible contracting mechanisms. Whereas private and public investment primarily addresses specific, known, high-priority threats, BARDA fills a gap to develop flexible MCM and platforms to use against previously unknown disease threats. Since its launch, BARDA has obtained numerous FDA approvals, licensures, and clearances in technological and medical fields. Additionally, BARDA supported many biomedical products for the COVID-19 response. This early effort was a resounding success. However, the ability of the federal government to partner successfully with the private sector wanes as the initial tranche of multi-year funding expired and Congress began appropriating annual funding insufficient to meet the need expressed by BARDA. In recent years, Congress, policy leaders, and industry executives proposed a variety of incentives to reinvigorate medical countermeasure development, 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 determined by DHS to be material threats.

The Administration and Congress must provide additional incentives to encourage private sector investment that complements government commitments and ensures investment in MCM that the BioShield Special Reserve Fund does not now support (e.g., for emerging infectious diseases, influenza). The public and private sectors should cooperatively discuss, develop, and implement a set of incentives that may include other transactional authority and other authorities, and creative financing methods (e.g., securitization of a medical countermeasure asset portfolio). This effort should consider the cost to government, political feasibility to authorize, and palatability to industry. BARDA and industry should work together to determine and recommend the most effective incentives for small biotechnology companies, large pharmaceutical companies, and those in between.

Congress should return to multiyear funding to fulfill the promise of Project BioShield, similar to its commitment to national defense. Congress should rightly retain budgeting flexibility and caps on advance appropriations to ensure the integrity of allocations.

Improving federal government contracting practices will better enable the federal medical countermeasure enterprise to meet mission requirements. Legacy and current contracting practices are still not sufficiently transparent, implemented, predictable, or flexible enough to accommodate efficient MCM development or optimize industry participation. Recent efforts by HHS to reduce regulatory barriers for industry (both before and during the COVID-19 pandemic) encouraged growth in MCM public-private partnerships. However, procurement and contracting restrictions continue to constrain additional participation by the private sector.

For example, current regulatory review processes unnecessarily slow contract approvals. When Congress created Project BioShield in 2004, DHS provided the program's funding while HHS administered the program, resulting in the need for an OMB review. Now that HHS houses all BioShield funds and procurement responsibilities, OMB review of contracts already approved and funded by HHS is unnecessary and slows MCM procurements. Congress eliminated the OMB review of Project BioShield procurements in 2016.⁹⁴ However, even with this statutory relief, OMB still requires BARDA to provide justifications for budget variances greater than five percent. Before executing procurement decisions, BARDA also must seek approval from OMB and wait a minimum of 10 days.

Although BARDA successfully helped many MCMs obtain full FDA approval since its inception,⁹⁵ many lack commercial viability. As the sole customer of MCM vital to the national interest, the federal government must sustain funding to maintain access to these items for future biological events. Purchases by the Strategic National Stockpile (SNS) sustain some products but funding is insufficient to maintain all these countermeasures. The Stockpile should not prioritize BARDA products over others that meet assessed needs.

Recommendation 17: Invest in medical countermeasures for biological agents and diseases.

ACTION ITEMS:

- a. **Require a biodefense budget plan from the National Institute of Allergy and Infectious Diseases.** Concurrent with the President's annual budget request, Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Director of the National Institute of Allergy and Infectious Diseases to submit annually a plan to Congress that describes in detail the goals for NIAID MCM research investments, including the transition to advanced research, development, and procurement planning at BARDA. The Director of the National Institute of Allergy and Infectious Diseases should include ways to transition MCM more easily from early-stage development to advanced research and development.
- b. **Fund the medical countermeasure enterprise to no less than authorized levels.** Congress should provide appropriations for MCM initiatives conducted by the BioShield Special Reserve Fund, BARDA, Advanced Research Projects Agency for Health, and SNS consistent with authorized levels for these initiatives. Appropriations for these initiatives should address needs identified by the National Strategy for Biodefense.
- c. **Reestablish multi-year biodefense funding for medical countermeasure procurement.** The President (in the President's Budget Request) and Congress should (1) reestablish multi-year funding and advanced appropriation for Project BioShield; (2) institute a 10-year advanced appropriation for the Special Reserve Fund; and (3) provide multi-year funding for Public Health Emergency Preparedness grants to enable SLTT to procure MCM.
- d. **Eliminate Office of Management and Budget review of BioShield procurements.** Congress should amend the 21st Century Cures Act (P.L. 114-255) to eliminate OMB review of BioShield procurement contracts. Congress should require OMB to certify that they do not require BARDA to submit BioShield procurement decisions for review or BioShield budget variance justifications.

MEDICAL COUNTERMEASURE INNOVATIONS

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

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

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

Vaccine or antigen banks can store ready-to-use vaccines or antigens that can aid in the rapid development of MCM. Storing antigens in banks has the advantage of keeping concentrated stocks with prolonged retention of potency in low temperature

US investment in medical countermeasure development is dangerously insufficient.

storage. These banks can also provide appropriate serotypes and strains, alone or in combination, as needed.⁹⁶

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

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

Advanced development and manufacturing (ADM) centers could help increase domestic veterinary medical countermeasure manufacturing. The history of those programs suggests that poor management and contracting loopholes prevented success, but with proper oversight and funding, ADM activities would be helpful to the veterinary sector.

Recommendation 18: Innovation in medical countermeasures.

ACTION ITEMS:

- a. **Review existing medical countermeasure programs.** The Secretary of Health and Human Services should (1) review existing medical countermeasure programs, policies, and assets, including the Centers for Innovation in Advanced Development and Manufacturing, comprehensively; (2) use these findings to inform budget requests; and (3) deliver this review to Congress annually. Based on this review, Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Agriculture and Secretary of Defense, to (1) develop an interagency product transition plan to hasten advanced development of promising MCM; and (2) deliver this plan to Congress within one year of enactment and every five years thereafter.

Figure 4. Viral families of concern to human health.



- b. **Develop vaccine candidates for prototype pathogens.** The Secretary of Health and Human Services, in coordination with the Secretary of Agriculture and Secretary of Defense, should (1) identify at least one pathogen from each of the 26 viral families that affect humans to target for vaccine development, taking the diversity of viruses and priority pathogens into consideration; (2) establish sustainable public-private partnerships with industry and academia for research and development; (3) develop a vaccine candidate for each viral family, placing emphasis on vaccine platforms; (4) advance vaccine development for endemic pathogens through Phase 2 and Phase 3 clinical trials to serve affected populations; (5) advance vaccine development for pathogens that are not endemic through Phase 1 clinical trials to demonstrate safety; (6) submit an annual progress report to Congress; and (7) provide a liability relief fund for companies developing these vaccine candidates.
- c. **Develop antiviral drugs in advance of outbreaks.** The Secretary of Health and Human Services, in coordination with the Secretary of Agriculture and Secretary of Defense should (1) develop novel broad-spectrum antiviral therapeutics; (2) establish sustainable public-private partnerships with industry and academia for research and development; (3) advance antiviral development for endemic pathogens through Phase 2 and Phase 3 clinical trials to serve affected populations; (4) advance antiviral development for pathogens that are not endemic through Phase 1 clinical trials to demonstrate safety; (5) maintain and adequately resource the Antiviral Drug Discovery Centers for Pathogens of Pandemic Concern; and (6) submit an annual progress report to Congress about these efforts. The Secretary of Health and Human Services should also develop a strategy for the accelerated development of a virus-specific antiviral against a novel and specific disease during an emerging outbreak. This strategy should address the following: (1) research and development processes; (2) providing resources to conduct emergency research; (3) public-private partnerships for accelerated development; and (4) regulatory considerations. The strategy should delineate roles, responsibilities, and timeframes for bringing monoclonal antibodies/antivirals to market under accelerated development. The Secretary should submit this strategy to Congress within one year.
- d. **Develop needle-free methods of drug and vaccine administration.** The Secretary of Health and Human Services should, in coordination with the Secretary of Agriculture and Secretary of Defense, produce a plan for pursuing research and development of needle-free methods for drug and vaccine administration. The plan should address the following: (1) steps these departments will take to complete Phase 1 and subsequent clinical trials of newly developed technologies for currently circulating diseases (e.g., influenza, COVID-19); (2) lessons learned from those research efforts and their potential application to other pathogens; (3) how to coordinate these efforts with the prototype vaccine and antiviral initiatives recommended above; (4) research and development of new methods and capabilities for needle-free administration; (5) reformulation of current drugs and vaccines for needle-free administration; and (6) how needle-free delivery routes will be taken into consideration during drug and vaccine development processes.

- e. **Develop flexible and scalable manufacturing of pharmaceuticals.** The Secretary of Defense and the Secretary of Health and Human Services should conduct a joint review of previous advanced manufacturing capability efforts. The review should (1) identify the problems and challenges (including supply chain and stockpiling issues) which affected previous efforts (including before and during the COVID-19 pandemic); (2) provide recommendations to address those problems; and (3) identify opportunities to modernize and improve manufacturing capabilities. The Secretary of Defense and Secretary of Health and Human Services should submit this review to Congress. Drawing on the results of the joint review above, the Secretary of Defense and the Secretary of Health and Human Services should develop a plan to expand advanced manufacturing capability for platform technologies. The plan should (1) articulate how many advanced manufacturing centers the nation needs to rapidly scale up production of MCM; (2) identify potential private sector partners who could host these centers; and (3) articulate how these centers should operate during non-crisis periods to ensure their ability to respond quickly during an emergency.
- f. **Set requirements for all biological agents deemed material threats to the Nation.** The Secretary of Health and Human Services should (1) formally set requirements (independently of budgetary considerations) for all biological agents deemed by the DHS to pose material threats to the Nation; (2) update these requirements every three years or within six months of a newly issued material threat determination; (3) share these requirements with the private sector in a manner that does not compromise national security; and (4) deliver these requirements to Congress within three months of setting new requirements.
- g. **Establish an antigen bank.** Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Director of the National Institute of Allergy and Infectious Diseases, Director of the Biomedical Advanced Research and Development Authority, in coordination with the Deputy Assistant Secretary of Defense for Chemical and Biological Defense, Administrator of the Animal and Plant Health Inspection Service, and the Under Secretary for Science and Technology at DHS, to establish an antigen bank for existing human and animal pathogens that can be used with platform technologies to rapidly develop vaccines and therapeutics for use in an emergency.
- h. **Establish regional food and agriculture advanced development and manufacturing.** The Secretary of Agriculture should establish regional food and agriculture ADMs at land-grant and other universities in partnership with industry. USDA should oversee activities to develop this capacity and test and evaluate these MCM at the National Bio- and Agro-Defense Facility.

PREPAREDNESS



STOCKPILE SUPPLY, DISTRIBUTION, AND DISPENSING FOR BIOLOGICAL EVENTS

The best antiviral, vaccine, or ventilator is useless if not delivered promptly to those that need it. The current SNS distribution and dispensing system is inadequate and unacceptable. The likelihood that MCM could reach individuals in short timeframes on a mass scale is still exceptionally low. This program lacks clear and consistent directives for, and coordination with, SLTT governments; clear goals and objectives for response; and sufficient consideration of various scenarios (e.g., repeated or simultaneous attacks). These problems predate COVID-19 and response to the pandemic demonstrated that these problems remain. The program has yet to address certain logistical questions (e.g., how long it will take SLTT personnel to break down pallets, how long until the SNS resupplies multi-dosage medications) of concern to many localities.

The SNS itself requires a reassessment of its mission and resources. The Stockpile was supposed to have enough supplies to support response to a biological attack in one or two metropolitan areas, not the nationwide response demanded during the early days of the COVID-19 pandemic. Public expectations were far greater than what the Stockpile was able to provide. Congress should expand the scope of the Stockpile to address future biological events.

We need to explore strategies to better prepare and protect such front-line responders, especially when resources already exist that could help. For example, many first responders cannot afford, or do not have access to, vaccines that protect against biological agents like anthrax, but short-dated, surplus anthrax vaccine doses owned by the federal government expire monthly by the hundreds of thousands. Not all first responders are at risk of exposure to the same biological agents and some already manage that exposure (e.g., when a biological agent is endemic in their area). Currently, no assessment of biological risk to first responders exists that could help guide allocation of expiring vaccines from the SNS to them.⁹⁷

The Nation lacks a workable national MCM distribution system that it can activate quickly and rely on to work in an emergency. A national, stakeholder driven MCM response framework would provide structure and guidance for local planning efforts. Many federal hazard planning documents address MCM distribution from SNS cache sites to local destinations, but localities often do not adopt these plans because they were not involved in their development. It remains unclear how federal, SLTT, private sector, and nongovernmental partners can coordinate regional distribution and local dispensing operations. The federal government needs to help Public Health Emergency Preparedness cooperative agreement recipients address performance measures, processes, shared services, roles and

responsibilities, technologies, and resources needed to effectively distribute and dispense MCM from the SNS in their plans.

Some localities have demonstrated their ability to take charge of MCM distribution and dispensing quickly and responsibly. For example, New York City has practiced setting up points-of-distribution so well that responders would be ready to serve their populace hours before federal assets arrive. However, the ASPR (and before them, the CDC) has thus far been unwilling to forward deploy assets to qualified jurisdictions. Recently, Congress considered and encouraged the establishment of state-level stockpiles, but such efforts will require resources, leadership, and time to come to fruition. The government should support forward deployments to all jurisdictions that prove themselves capable of handling SNS contents and dispensing them efficiently, not just New York City.

Stockpiled smallpox vaccines proved valuable during the 2022 Mpox outbreaks in the United States. However, the decision by the Biden Administration to deploy smallpox countermeasures from the SNS to respond to Mpox and replace those stocks with vaccines obtained from one company (which could not quickly meet the demand by the United States and other countries due to lack of manufacturing capacity) raises questions about the readiness of the Nation for a smallpox attack from a terrorist or nation state. Stockpiling decisions for smallpox have not historically factored in the possibility of using these MCM for threats other than smallpox. Though 42 USC 247d-6b(a)(2) requires annual threat-based reviews of the contents of the SNS, the statute does not currently require this review to consider the threat of all orthopox viruses that smallpox vaccines, antivirals, and therapeutics could treat.

The National Veterinary Stockpile (NVS) serves as the animal counterpart to the SNS and maintains an inventory of resources to assist in the response to threats to animal agriculture. Many components of both stockpiles could be used in support of each other. Despite serving such an important role, Congress has never authorized the NVS. Although some supplies (e.g., PPE, depopulation equipment) have been distributed from this stockpile and used successfully in recent outbreaks, NVS contents and management remain inadequate. For example, during the 2015 outbreak of Highly Pathogenic Avian Influenza, and the more recent, sustained outbreak of the disease that began in 2022, the NVS possessed millions of doses of avian influenza vaccines. However, USDA never deployed those vaccines in response to either outbreak because they treat different strains of influenza. Congress created the National Animal Vaccine and Veterinary Countermeasures Bank in 2018 to bolster the government's access to animal vaccines,⁹⁸ but the NVS needs additional assessment and funding to ensure a robust response to biological threats to animal agriculture.

Recommendation 19: Strengthen stockpile supply and distribution.

ACTION ITEMS:

- a. **Assess the mission, goals, and objectives of the Strategic National Stockpile.** The Assistant Secretary for Preparedness and Response at HHS should assess SNS resource requirements, considering available biological threat intelligence, lessons learned from the COVID-19 pandemic, nation state biological weapons programs, and terrorist aspirations to conduct biological attacks. This assessment should determine resource needs for the SNS, including the extent to which it should contain MCM for specific biological agents, instead of, or in addition to, PPE, cotton swabs, ventilators, and other essential medical supplies. The Administration and Congress should use this assessment to inform the President's Budget Requests and subsequent congressional appropriations. Congress should direct the Comptroller General of the United States to evaluate SNS contents and suppliers, including resource needs to meet the mission, goals, and objectives determined by the Assistant Secretary for Preparedness and Response. The Comptroller General should submit this report to Congress no later than one year after enactment.
- b. **Authorize provision of expiring biodefense vaccines to first responders and critical infrastructure personnel.** Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services to establish a program to provide eligible vaccines in the SNS nearing the end of their labeled dates of use to emergency response providers and critical infrastructure workers who voluntarily consent and who are at high risk of exposure. The Secretary of Health and Human Services should establish criteria for vaccine eligibility for use, including the following: (1) the vaccine is not otherwise allotted for other purposes; and (2) the provision of the vaccine will not reduce, or otherwise adversely affect, the ability to meet projected requirements for the vaccine during a public health emergency. The Secretary should submit annual reports to Congress regarding the progress made by the program, the number and types of vaccines provided, and the development and implementation of relevant criteria. Congress should require the Secretary to submit the first of these reports no later than one year after enactment.
- c. **Develop a strategy and implementation plan for distributing at-home diagnostic tests and therapeutics.** Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Postmaster General of the United States, to (1) develop a strategy and implementation plan for using the United States Postal Service (USPS) to rapidly distribute at-home tests and various forms (i.e., needle-free) of drugs and therapeutics directly to the public within 48 hours of the determination

of a biological event by the Secretary of Health and Human Services; and (2) assess lessons learned by the Retail Pharmacy Program from the COVID-19 pandemic, so the HHS and the USPS can implement a similar program again when needed.

- d. **Produce a comprehensive framework for medical countermeasure distribution and dispensing.** The Assistant Secretary for Preparedness and Response and Director of the Centers for Disease Control and Prevention at HHS, and Administrator of the Federal Emergency Management Agency should work with SLTT, and other non-federal partners to 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, including bureaucratic impediments associated with a federal-only distribution system.
- e. **Require periodic evaluation of smallpox medical countermeasure stockpile needs in consideration of the threat.** Congress should amend the Public Health Service Act (P.L. 78-410) to require the Secretary of Health and Human Services, in consultation with the Secretary of Defense, to include an assessment of orthopox viruses that could be treated by SNS vaccines, antivirals, and therapeutics as part of the annual threat-based review required by 42 USC 247d-6b(a)(2). Such examination should also consider smallpox vaccine, antiviral, and therapeutic needs for the stockpile considering the potential use of these MCM to treat other orthopox viruses.
- f. **Fund state and territorial stockpiles for biodefense.** Congress should amend Section 2409 of the Consolidated Appropriations Act, 2023 (P.L. 117-328) to make territories eligible for participation in the pilot program to support the establishment of non-federal strategic stockpiles. Congress should appropriate no less than \$10 billion to support the creation of state and territorial stockpiles in accordance with this program. Congress should require recipients to develop a plan for establishing these stockpiles, create threat-based criteria for determining stockpile inventory, and assess funding needs for long-term sustainment of these stockpiles.
- g. **Determine logistics and funding needs to forward deploy stockpiled biodefense assets.** Congress should amend the Public Health Service Act (P.L. 78-410) to require the Assistant Secretary for Preparedness and Response at HHS to determine the necessary assessment, logistical, and funding requirements to forward deploy SNS assets, and recommend criteria for determining requirements for participating jurisdictions, accounting for, and aligning with, the potential establishment of state and territorial stockpiles. Based on this assessment, the Assistant Secretary for Preparedness and Response should submit to Congress a plan and associated funding needs to execute forward deployments to jurisdictions within one year of enactment.

- h. **Implement forward deployments of the Strategic National Stockpile for biodefense.** After establishing requirements, the President should request funding to support forward deployments to communities that have demonstrated readiness. Quantities to meet the needs of the first 24 hours of response should move to high-threat or high-density areas that demonstrate an ability to stand up points-of-distribution faster than the SNS can deliver contents to these jurisdictions. The Assistant Secretary for Preparedness and Response should require HHS grantees and those who wish to establish points-of-distribution without HHS grants to support efforts in these areas to plan for, and execute the establishment of, points-of-distribution faster than the SNS can deliver.
- i. **Improve, expand, enhance, and sustain state, local, tribal, and territorial training to receive and distribute stockpile contents during biological events.** The Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention at HHS should work with SLTT public health departments and other non-federal government stakeholders to improve existing SNS training offerings, taking into consideration currently limited SLTT abilities to distribute the contents of SNS pallets upon receipt. The Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention should build on previous experiences working with private sector entities (e.g., pharmacy chains, hospitals) to distribute pharmaceuticals for public health purposes, include this private sector utilization option in plans, and train accordingly. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Assistant Secretary for Preparedness and Response, in coordination with the Director of the Centers for Disease Control and Prevention, to develop and make training pallets immediately available for some naturally occurring infectious diseases (e.g., orthopox viruses, influenza) and biological agents (e.g., smallpox and organisms used in recent biological attacks) in addition to those deployed for anthrax.
- j. **Authorize and strengthen the National Veterinary Stockpile.** Congress should amend the Agriculture Improvement Act of 2018 (P.L. 115-334) to authorize the NVS. Congress should require the Secretary of Agriculture to conduct an annual analysis of the NVS that identifies persistent capability gaps and costs associated with achieving the National Security Memorandum 16 goal of deploying sufficient high-consequence animal disease MCM within 24 hours of a high-consequence or catastrophic animal disease outbreak affecting human health or the economy. The assessment should (1) prioritize the pathogens identified on the USDA High-Consequence Foreign Animal

Diseases and Pests list; (2) examine inventory management challenges; (3) gauge implementation of lessons learned from NVS exercises; and (4) report progress towards coordination with the SNS, National Animal Vaccine and Veterinary Countermeasures Bank, and relevant DOD efforts. The Secretary should submit the first such assessment to Congress no later than one year after enactment. Based on this assessment, the Secretary should determine the level of funding needed for these efforts and address those needs in USDA annual budget requests.

- k. **Develop and pre-position medical countermeasures in military areas of operation.** The Commander of the USAMRIID should conduct research, develop MCM based on that research, and use risk-based assessments to recommend prepositioning of those MCM in areas where outbreaks are likely to occur throughout the world. The Secretary of Defense should then forward deploy MCM resources to where DOD personnel are located and are at biological risk, and extend MCM protocols to deploying personnel.

CENTERS FOR DISEASE CONTROL AND PREVENTION AUTHORIZATION

The Public Health Service Act of 1944 authorizes the Secretary of Health and Human Services to take action to prevent the introduction and spread of infectious diseases. The Secretary of Health and Human Services delegates this authority to the Director of the Centers for Disease Control and Prevention to monitor and thwart threats to public health. During the COVID-19 pandemic, many criticized CDC for multiple missteps and failures. Confusing and delayed guidance, mishaps with diagnostic testing, slow response, and limited surveillance data hampered the agency's disease control efforts. In response to this criticism, the CDC announced a plan to overhaul the agency. This plan addressed reporting structures, reorganizing, gathering data, and dispensing public health guidance.

The CDC and Congress must acknowledge and systematically address the agency's chronic challenges with data collection and management, unified budgeting, workforce development, operational and surge capacities, guidance, non-federal partnerships, and global health mission requirements. The agency depends on bits and pieces of authorization in a variety of bills and the direction provided by appropriations. This lack of comprehensive authorization language specific to the CDC creates inefficiencies.

Recommendation 20: Authorize the Centers for Disease Control and Prevention.

ACTION ITEM:

- a. **Authorize the Centers for Disease Control and Prevention.** Change text to: Congress should amend the Public Health Service Act (P.L. 78-410) to explicitly authorize the CDC in statute. Such authorization must clearly delineate the mission, roles, and responsibilities of the agency. Congress should also amend Section 305(c) of the Public Health Service Act to require the CDC Strategic Plan to address challenges identified by the annual emergency response and preparedness reports required by Section 2801(d) of the Public Health Service Act.

PUBLIC HEALTH SECURITY WORKFORCE

The COVID-19 pandemic revealed the awful consequences of both immediate and long-standing workforce shortages in public health. Staffing shortages and burnout resulted in a lack of critical expertise and disruptions in the federal response to the pandemic. The CDC and the ASPR struggled to surge and maintain their workforces.

On January 31, 2020, then Secretary of Health and Human Services Alex Azar declared a public health emergency for the United States due to COVID-19. On March 6 of that year, through the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Public Law 116–123) Congress provided direct-hire authority to HHS to help fight COVID-19. Direct-hire authority allows federal agencies to employ candidates directly (i.e., without using standard hiring procedures) in competitive service career, career-conditional, term, or temporary positions for which the Office of Personnel Management determines that there is a severe shortage of candidates or a critical need to fill positions that traditional hiring procedures cannot fill. Such flexibility typically shortens the time needed to fill a position from more than a year to a few months. This proved helpful to HHS during the COVID-19 pandemic.

Outside of an ongoing crisis, DOD possesses direct-hire and other authorities to provide overtime and danger pay. This allows them to recruit and retain a skilled workforce more easily. Similar authorities would help HHS ensure its workforce is technically skilled and knowledgeable about federal mechanisms to respond to threats to public health security.

The United States Public Health Service Commissioned Corps (USPHS) deployed more than 4,000 personnel in response to COVID-19. Their efforts included assisting with repatriation efforts, providing care to some of the first American patients, and

developing the Nation's testing strategy. The increasing biological threat demands assessment whether the Service has what it requires to address modern challenges to biodefense.

Congress authorized the creation of a Ready Reserve Corps in the USPHS in 2010 and expanded compensation and benefits for Corps personnel during the COVID-19 pandemic.⁹⁹ A decade after that authorization, the Trump Administration began building this Corps. The Corps increases the number of USPHS personnel available for emergency deployments. The Biden Administration requested \$14 million for the USPHS Ready Reserve Corps, \$2 million for USPHS readiness and training activities, and \$4 million for its Public Health and Emergency Response Strike Team.

According to the DOS, Russia and North Korea possess active offensive biological weapons programs. The DOS also notes that both China and Iran are pursuing research activities of concern and potential applicability to biological weapons, and that there is insufficient evidence to show that these countries ever ceased their previously established biological weapons programs. Terrorist organizations also pursue biological weapons. The US military must assume that other countries and more terrorist organizations will seek to develop and use biological weapons and must prepare accordingly. The military needs healthcare and public health personnel trained to deal with biological attacks, far beyond the education received in civilian schools of medicine and public health. Outsourcing healthcare to the private sector will not work in this case, but outsourcing naturally decreases the number of military personnel capable of responding to biological attacks on warfighters and the geographic areas in which they operate. Readiness to address the use of biological weapons and agents on military personnel is now unclear, even as biological threats increase.

Recommendation 21: Increase the public health security workforce.

ACTION ITEMS:

a. **Provide direct-hiring authority for mission critical biodefense positions.**

Congress should amend Title 5 of the US Code and Title 5 of the Code of Federal Regulations to provide the Secretary of Health and Human Services with direct-hire authority to hire individuals for mission-critical biodefense positions (similar to the authorities given to the Secretary of Defense under 5 US. Code § 9905). The Secretary should be able to make these appointments without regard to Title 5, Sections 3309-3319 of the US Code, which prescribes veterans preference, rating and ranking applicants, and increasing the number of eligible candidates from which a selecting official may choose. Congress should direct the Secretary of Health and Human Services to report annually on the use of this authority, beginning one year after enactment.

- b. **Provide flexible pay authorities during biological emergencies.** Congress should amend Title 5 of the US Code to provide the Secretary of Health and Human Services with flexible pay authorities to (1) provide overtime and danger pay to employees serving in disease conditions that threaten their well-being; and (2) waive the statutory pay cap on aggregate basic and premium pay during biological emergency response. The Secretary should submit an annual report to Congress on the use of this authority, beginning one year after enactment.
- c. **Enable hiring of reemployed annuitants during biological emergencies.** Congress should amend Title 5 of the US Code to allow the Secretary of Health and Human Services to waive maximum hour or dual compensation restrictions for reemployed annuitants for up to one year, so that HHS can use reemployed annuitants to fill full-time roles during biological emergency response.
- d. **Employ Medical Reserve Corps volunteers during biological emergencies.** Congress should amend the Public Health Service Act (P.L. 78-410) to allow the Secretary of Health and Human Services to employ Medical Reserve Corps volunteers as time-limited federal employees for biological emergency response and recovery efforts.
- e. **Establish an emergency response-ready cadre fund for the Centers for Disease Control and Prevention.** Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Director of the Centers for Disease Control and Prevention to dedicate two percent of all appropriated line-item funding accounts to a response-ready cadre fund for staff (distinct from the USPHS Commissioned Corps) who can quickly deploy for public health and biological emergencies as designated by the Secretary of Health and Human Services or the Director of the Centers for Disease Control and Prevention. These staff will return to their regular duties after event resolution. Congress should require the Director of the Centers for Disease Control and Prevention to report the funding levels and utilization of this account annually.
- f. **Ensure military healthcare and public health readiness for biological events.** The Assistant Secretary of Defense for Health Affairs should assess military healthcare and public health readiness and determine the number of military healthcare and public health personnel necessary to address the threats of biological weapons and agents to military personnel domestically and deployed overseas. As part of this assessment, the Assistant Secretary of Defense for Health Affairs should consider (1) rotations of personnel deployed to areas known or suspected to be threatened by biological weapons and agents; and (2) healthcare and public health needs associated with biological attacks on major metropolitan areas and areas with critical infrastructure of interest to the DOD.

STRATIFIED BIODEFENSE HOSPITAL SYSTEM

The Nation lacks a stratified biodefense hospital system, similar to other hospital systems that stratify according to specialized capabilities (e.g., trauma, stroke, cardiac care, burns). Establishment of this system will require federal guidance and incentives for hospital participation, as well as standards for each stratum. This system would require all hospitals to demonstrate the ability to surge medically, assess sick patients, and recognize biological agents as well as emerging and reemerging infectious diseases that negatively impact national and public health security. All hospitals should also be able to stabilize patients within 48 hours and refer patients to higher-level hospitals as needed. Higher level hospitals would provide increasingly specialized care. Without such a system, hospitals respond to biological events individually, spontaneously, and without coordination, as we saw during the COVID-19 pandemic.

The federal government has yet to establish and sufficiently incentivize hospitals to create such a system. Previously, HHS leveraged funding from the response to the 2014–2015 Ebola Outbreak in West Africa to establish Regional Emerging Special Pathogen Treatment Centers. Additionally, HHS piloted a similar concept with the Regional Disaster Health Response System. This pilot program currently operates in four metropolitan jurisdictions and could help inform a broader, nationwide organization.¹⁰⁰ The program already demonstrated utility in assisting with COVID-19 response coordination in these jurisdictions. Should the program deliver desired results, implementation of a nationwide system will require robust funding to enable hospitals to participate. This will require more than just additional funding for the Hospital Preparedness Program.

Recommendation 22: Establish a stratified biodefense hospital system.

ACTION ITEMS:

- a. **Stratify hospitals for biodefense.** The Secretary of Health and Human Services should establish a stratified system of hospitals with increasing levels of capability to treat patients affected by biological attacks and other events involving highly pathogenic infectious diseases. Hospitals should use a categorical rather than disease-specific approach. Where possible, the Secretary should add biodefense responsibilities to Accountable Care Organizations, trauma centers, and hospital coalitions.

- b. **Develop biodefense accreditation standards, incentives, and reimbursements for each stratum.** The Administrator of the Centers for Medicare and Medicaid Services should develop accreditation standards with The Joint Commission, DNV-Healthcare, Accreditation Commission for Health Care, and Center for Improvement in Healthcare Quality, as well as certification and licensure associated with each level. Congress should authorize the Centers for Medicare and Medicaid Services (CMS) to provide funding to those hospitals that meet these new accreditation standards for bioterrorism and other highly infectious disease preparedness.
- c. **Establish medical surge capability and capacity for large-scale biological events.** The Administrator of the Centers for Medicare and Medicaid Services should plan and require hospitals that receive CMS funding to plan for biological events that will require them to surge medically before these events happen. In addition to the CDC, the Occupational Safety and Health Administration (OSHA) should issue guidelines and performance standards for medical surge in this context, again, before biological events occur. Congress should amend the Social Security Amendments of 1965 (P.L. 89-97) to direct the Administrator to submit an annual review to the Secretary of Health and Human Services of the implementation of the 2016 Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers.¹⁰¹ This review should assess additional funding and authority needs to implement the rule, and include a strategy for strengthening healthcare provider biological disaster planning over the next five years.
- d. **Authorize the Regional Disaster Health Response System for biodefense.** Congress should amend the Public Health Service Act (P.L. 78-410) to authorize the HHS Regional Disaster Health Response System. Congress should direct the Secretary of Health and Human Services to produce a plan to regionalize biodefense preparedness and response through the Regional Disaster Health Response System with criteria and benchmarks to guide implementation. The Secretary of Health and Human Services should submit this plan to Congress no later than 180 days after enactment. Congress should also appropriate additional funding on a multiyear basis to commit resources and enable program participants to plan confidently.

WARFIGHTER BIODEFENSE

The delivery of health care during military actions (including war) is of particular concern. Long transit times between areas of operation and locations of health care delivery (e.g., between Afghanistan and Germany) put injured and ill military personnel at greater risk. It is also unrealistic to expect that private sector and foreign health care establishments will understand how to provide the specialized

care needed to treat military personnel who sustain injuries and illnesses during combat, especially if enemies use biological weapons. The active-duty military must increase and maintain such expertise.

As usually occurs during times of relative peace, the US military draws down its personnel and resources, sometimes including its healthcare and public health infrastructure. Leaders in DC are often faced with balancing cutting costs with maintaining readiness for threats that may not be currently or obviously present. Calls continue to eliminate organizations (e.g., USAMRIID) in favor of shifting dollars to contracts and technically reducing the size of the active-duty military and its costs. This increases pressure on these organizational elements to fight for their existence while simultaneously trying to address, in this case, increasing biological threats to our warfighters and the Nation itself. America cannot afford to lose these assets while nation states engage in active offensive biological weapons programs and terrorist organizations try to obtain and use biological weapons and agents against their perceived enemies.

Recommendation 23: Strengthen biodefense of warfighters.

ACTION ITEMS:

- a. **Increase military biodefense healthcare, public health, and research.**
Congress should amend the National Defense Authorization Act to direct the Secretary of Defense to increase military healthcare, public health, and research activities to ensure that needed expertise and knowledge remains resident in the active duty military sufficient to address the current needs and requirements of battlefields and warfighters, especially with regard to confirmed and suspected active offensive biological weapons programs and the threatened use of biological weapons. Congress should increase appropriations accordingly.
- b. **Restore military healthcare and public health infrastructure for biodefense.**
Congress should amend the National Defense Authorization Act to direct the Secretary of Defense to (1) improve and increase military healthcare and public health infrastructure (including laboratories), personnel, and training; (2) ensure adequate capacity, quality, and efficiency of healthcare delivery, public health management, and medical services in support of combat operations; (3) improve the ability to treat military personnel (including animals) operating in a theater contaminated by the use of biological weapons by enemies during combat; and (4) authorize increased appropriations to support these activities.

CLINICAL INFECTION CONTROL GUIDELINES

During the Ebola outbreak of 2014 and during subsequent biological events affecting the Nation (e.g., H1N1 influenza pandemic, COVID-19 pandemic) hospital preparedness varied widely. A few hospitals were well prepared to serve as treatment centers for infected patients, but the vast majority were unprepared and struggled to catch up. Historically, OSHA has developed and issued PPE and clinical guidelines to hospitals, but the CDC sometimes also issues guidelines without working with or adequately consulting OSHA. Flawed guidelines released by the CDC to hospitals, 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 reduce already insufficient levels of preparedness and lead to overwhelming resource shortages, as painfully illustrated by COVID-19. Although many hospitals become far more proficient and capable of handling patients after diseases spread and create outbreaks, epidemics, and pandemics, as time passes, crises lessen and cases desist, making it less likely that these institutions will maintain the same level of infectious disease-specific proficiency over time.

Recommendation 24: Produce clinical infection control guidelines.

ACTION ITEMS:

- a. **Develop clinical infection control guidelines before biological events occur.** Congress should amend the Pandemic and All-Hazards Preparedness Act (P.L.109-417) to direct the Secretary of Health and Human Services and the Secretary of Labor to jointly develop and implement a process involving public and private sector experts to produce clinical guidelines for treatment, infection control, use of PPE, waste management, and other activities needed in hospitals and other healthcare delivery settings. 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. **Obtain and incorporate feedback regarding clinical infection control guidelines during biological events.** During a crisis, the Secretary of Health and Human Services and the Secretary of Labor should convene a standing group of experts (including those from outside of the federal government) that reviews feedback from federal, SLTT, and private health care facilities, and meets at least weekly to evaluate, update, and reissue clinical guidance. The Secretary of Health and Human Service and the Secretary of Labor should regularly provide training on how to implement the guidelines.

SCHOOL BIODEFENSE

The Department of Education (DOEd) insists that the CDC and CISA fulfill all biodefense responsibilities for educational institutions, but this statement is at odds with actions taken by the Department to address current and previous biological events. Together with other federal agencies or alone, DOEd addressed the anthrax events of 2001, influenza pandemics, COVID-19, and outbreaks involving other potentially deadly diseases that occurred in educational settings, demonstrating that some biodefense responsibilities not only belong to, but are already undertaken by, the DOEd. For example, school nurses¹⁰² engage in critical preparedness and response activities as educators, liaisons between schools and local health departments, and consultants in school settings, and they receive some of their guidance and resources from DOEd. The Department has also transmitted guidance to schools, students, and their families about biological events affecting national security (the most recent being COVID-19¹⁰³) and looks to continue doing so. The Department of the Interior (DOI) also shares responsibilities for school biodefense because it is responsible for educational activities on reservations throughout America.¹⁰⁴ However, both Departments need additional resources to fulfill their biodefense responsibilities.

Recommendation 25: Enable schools to protect against biological threats.

ACTION ITEMS:

- a. **Actively manage biological events in school settings.** Congress should amend the Department of Education Organization Act of 1979 (P.L. 96-88, 43 U.S.C. 1451) to direct the Secretary of Education and Secretary of the Interior, in coordination with the Secretary of Health and Human Services and Secretary of Homeland Security, to minimize disruptions to learning, physiological, and mental illnesses and access to quality education in school settings from naturally occurring, accidentally released, or intentionally introduced infectious diseases in educational settings.
- b. **Issue biodefense guidance to schools throughout the Nation so they are better prepared.** Congress should amend the Elementary and Secondary Education Act of 1965 (P.L. 89-10) to direct the Secretary of Education and the Secretary of the Interior, with input from SLTT departments of health, to convey clear and consistent information and guidance to SLTT schools on (1) the impact of biological events that could or do affect schools; and (2) disease prevention, preparedness, response, control, recovery, and mitigation measures (e.g., vaccination, testing, masking, ventilation, social distancing, cleaning, remote learning) recommended by the CDC and SLTT departments of health.

- c. **Develop and distribute high-quality educational resources about biological events in school settings.** The Secretary of Education and Secretary of the Interior, with input from SLTT departments of health, should support the development and dissemination of high-quality educational resources and materials for students, parents, teachers, and school administrators regarding how to prevent, identify, respond to, communicate about, recover from, and mitigate naturally occurring and accidentally released diseases affecting, and biological attacks that impact, education and schools.
- d. **Implement effective disease control strategies for school settings.** The Secretary of Education and Secretary of the Interior should provide sufficient funding and resources to SLTT educational institutions to implement strategies in school settings recommended by the CDC, Substance Abuse and Mental Health Services Administration, and SLTT departments of health to effectively (1) prevent, prepare for, detect, respond to, recover from, and mitigate biological events; (2) address academic, social, emotional, and mental health needs of students, faculty, staff, and families affected by biological events; and (3) monitor and evaluate the impact of biological events that impact school operations, student learning, and educational equity to inform policy decisions and produce and disseminate best practices for effective disease prevention and control in school settings.

CRITICAL INFRASTRUCTURE BIODEFENSE

When biological events occur, they affect critical infrastructure and put our national, economic, and public health security in jeopardy. The DHS Critical Infrastructure Security Agency bears a great deal of responsibility in this arena and should build on previous activities to manage and reduce biological risk to critical infrastructure. All sector specific federal agencies, private owners and operators of the individual sectors, must also help defend critical infrastructure against biological threats.

It is highly unlikely that a biological event will affect just one critical infrastructure sector. As with the anthrax events of 2001 and COVID-19, an event might affect some or all sectors directly, indirectly impacting other sectors. Multiple sectors often need to execute national critical functions together, further complicating matters.

A biological event could affect sectors in diverse ways and to varying extents, making it impossible for them to pull together efficiently. Our Nation's critical infrastructure stood, but it did not stand firm, in the face of COVID-19. Targeted action

will alleviate the strain caused by the next biological event, preventing cascading failures throughout critical infrastructure.

Sectors and sector specific federal agencies should maintain awareness of the disease environment in which critical infrastructure operates. The critical infrastructure community cannot expect the federal government to know where disease is occurring at any given moment or to communicate information it does possess directly to the sectors. When biological events begin to affect infrastructure and national security, CISA may decide to monitor the spread of disease and communicate relevant information to the sectors. However, the Agency may have other priorities, especially if it incorrectly assumes that other federal programs are responsible for communication.

Biological events reveal vulnerabilities in critical infrastructure and its ability to continue operating. COVID-19 most recently revealed vulnerabilities in the ability to deliver medical care, support public health, provide public safety, and to operate with workforce restrictions. Sectors need to identify and eliminate vulnerabilities to biological attacks, accidental releases of organisms from laboratories and other facilities that contain them, and naturally occurring diseases before the next biological event occurs. While all critical infrastructure sectors are vulnerable to biological events, the nature of those vulnerabilities (and the actions needed to ameliorate them) are specific to each sector.

Sectors and sector-specific federal agencies should engage in proactive planning to mitigate the impact of biological events on critical infrastructure. When natural disasters like earthquakes occur, localities take action to prevent them from adversely affecting communities if and when they occur again. This preventive work is called mitigation. The critical infrastructure community cannot assume that COVID-19 will be a once-in-a-century event. The ability to mitigate the impacts of biological events on critical infrastructure varies by sector. While each sector may not be able to obtain, stockpile, and provide everything their employees need to remain healthy and keep infrastructure running during a biological event, sector leadership can determine what they need in advance to support and protect their most essential critical infrastructure workers.

Figure 5. Source of Biological Risk by Critical Infrastructure Sector

SECTOR		AT BIOLOGICAL RISK	COULD BE USED TO SPREAD DISEASE	HOUSE ORGANISMS
	COMMUNICATIONS	●		
	ENERGY	●		
	INFORMATION TECHNOLOGY	●		
	NUCLEAR REACTORS, MATERIALS, AND WASTE	●		
	COMMERCIAL FACILITIES	●	●	
	DAMS	●	●	
	EMERGENCY SERVICES	●	●	
	FINANCIAL SERVICES	●	●	
	CHEMICAL	●	●	●
	CRITICAL MANUFACTURING	●	●	●
	DEFENSE INDUSTRIAL BASE	●	●	●
	FOOD AND AGRICULTURE	●	●	●
	GOVERNMENT FACILITIES	●	●	●
	HEALTHCARE AND PUBLIC HEALTH	●	●	●
	TRANSPORTATION SYSTEMS	●	●	●
	WATER AND WASTEWATER	●	●	●

Recommendation 26: Protect critical infrastructure against biological threats.

ACTION ITEMS:

- a. **Defend critical infrastructure against biological threats.** Congress should amend the Homeland Security Act of 2002 (P.L. 107-296) to direct the Secretary of Homeland Security, in coordination with the Secretary of Agriculture, Secretary of Defense, Secretary of Energy, Secretary of Health and Human Services, Secretary of Transportation, Secretary of the Treasury, Administrator of the Environmental Protection Agency, Administrator of the Food and Drug Administration, and Director of the General Services Administration (i.e., leaders of the sector specific federal agencies), to develop and implement plans to defend the critical infrastructure for which they are responsible against biological threats. The Secretary of Homeland Security should deliver these plans to Congress within one year of enactment.
- b. **Manage biological risk to critical infrastructure.** The President should direct the Secretary of Homeland Security to formally establish a biological risk management program at CISA to (1) identify biological risk management activities in which it previously engaged and that would be helpful to reinstate permanently; (2) use the Agency's partnerships with the intelligence and law enforcement communities to obtain the actionable intelligence and information it needs to inform proactive risk and emergency management, and make decisions about protecting critical infrastructure from biological threats; (3) establish in-house subject matter expertise and analytical capability to support infrastructure biodefense requirements; and (4) lead coordination of cross-sector biological risk management activities for national critical functions. The Secretary of Homeland Security should require the Director of the Cybersecurity and Infrastructure Security Agency to (1) report information to sector-specific federal agencies about disease events that affect, or could affect, critical infrastructure assets in all 16 sectors, and those private sector owners and operators of critical infrastructure; (2) determine what should be done if a naturally occurring disease outbreak, accidental pathogen release, or biological attack significantly affects critical infrastructure; (3) identify national critical functions most vulnerable to biological threats; and (4) work across all sectors to manage biological risk.
- c. **Estimate critical infrastructure needs for vital medical countermeasures and essential medical supplies.** The Secretary of Homeland Security should direct the Director of the Cybersecurity and Infrastructure Security Agency to require the sectors to, at a minimum, use their experiences with COVID-19, the 2009–2010 H1N1 influenza pandemic, and the anthrax events of 2001 to estimate needs for PPE, essential medical supplies, and cleaning materials. The Director should identify core supplies and medicines, estimate costs to procure and distribute them, and report this information annually to Congress and sector leaders.

- d. **Ensure execution of national critical functions by taking sector-specific biodefense actions.** The Administration should direct all critical infrastructure sectors and sector-specific federal agencies to (1) maintain awareness of biological threats; (2) understand how and where they are vulnerable to biological threats; (3) predict the consequences of a variety of biological events that would affect their sectors if they occurred; (4) prevent and deter biological events from occurring that affect their sectors; (5) prepare for biological events; (6) detect biological events when they occur at or near their facilities; (7) respond to biological events efficiently and effectively; (8) work with law enforcement and public health officials, as well as corporate security professionals, as they investigate the cause and nature of these events; (9) coordinate with public and private sector partners to help their facilities and the communities in which they reside recover from biological events; and (10) mitigate the impact of future biological events by establishing protections and measures to help their facilities and personnel withstand attacks, accidents, and naturally occurring outbreaks.

STATE, LOCAL, TRIBAL, AND TERRITORIAL BIOLOGICAL EMERGENCY PREPAREDNESS

Infectious diseases impact national security and easily cross borders. Federal support for SLTT public health emergency preparedness is, therefore, an important use of taxpayer dollars. The CDC Public Health and Emergency Preparedness (PHEP) cooperative agreements are the primary way in which federal funding supports non-federal public health emergency preparedness. These cooperative agreements enable SLTT governments to conduct several critical activities (e.g., purchasing electronic disease surveillance systems, establishing local emergency operations centers, expanding laboratory infrastructure, hiring epidemiologists and laboratorians, training employees in emergency response protocols).

Although the biological threat has only grown, PHEP funding levels have not kept pace. Before the COVID-19 pandemic, presidential administrations often touted the success of the program while simultaneously scaling back their budget requests for it. Funding levels reached a high of \$940 million in Fiscal Year 2002, gradually receded, and then rose to \$735 million in fiscal year 2023.¹⁰⁵ Cooperative agreement conditions allowed state, local, and territorial recipients to establish capabilities, but then required recipients to assume funding responsibility to maintain those capabilities. This is not a reasonable concept for public health emergency preparedness. Withholding dedicated emergency preparedness funds may preserve federal bottom lines, but it diminishes national preparedness.

Congress appropriated funding to strengthen the Nation's public health infrastructure in response to the COVID-19 pandemic.¹⁰⁶ Through the Public Health Infrastructure Grant (PHIG) program, the CDC awarded \$3.2 billion in late 2022 to state, local, and territorial public health departments to build public health capacity to address future health threats, including biological events. This investment is critical given the lack of increases for other programs like the Public Health Infrastructure Grant cooperative agreements. Congress subsequently appropriated additional funding for the PHIG program, including \$350 million in Fiscal Year 2023. However, building public health capacity to meet current and future biological threats needs additional, sustained funding.

The US system of federalism affords states a great deal of autonomy. The state governors, territorial governors and administrators, mayors, and other elected officials are powerful and responsible for setting goals and objectives for their own jurisdictions. They can and must set their own requirements for preparedness, response, and recovery well before biological events occur. Non-federal officials do not have to wait for Congress or the federal government to act before establishing health care and public health expectations in their jurisdictions. Indiana Governor Eric J. Holcomb established the Governor's Public Health Review Commission in 2021 to examine the state's public health system and make recommendations.¹⁰⁷ Governor Holcomb then took up the Commission's recommendations and enacted public health policy changes and funding increases.

American Indian and Alaska Native tribes are sovereign entities with inherent authority to govern themselves and their own governance structures. They are not, however, eligible to enter into their own PHEP cooperative agreements with the CDC. Instead, the CDC requires the tribes to work within the framework of state and local public health entities to receive Public Health and Emergency Preparedness cooperative agreement support, sometimes as part of a pass-through arrangement. Planning and training must also take into consideration the specific needs of the tribes and territories that face different logistics and resource challenges than the rest of the Nation.

Low-income and homeless populations are more vulnerable to infectious diseases due to lack of access to primary care, poor overall health, and other factors that contribute to adverse health outcomes. The Department of Housing and Urban Development has the authorities and resources to bring to bear to help address this problem and can reduce the impact of biological events by providing funding, guidance, and waivers for programs that assist low-income households and the homeless in urban areas.

Although much of the Nation's biodefense activity focuses on the threat to humans, a biological event impacting plants, food, and agriculture could devastate our country. The Food and Agriculture Critical Infrastructure Sector produces, processes, and delivers the systems and commodities that feed billions of people and animals throughout the United States and overseas. Agriculture, food, and related industries contributed \$1.264 trillion (5.4%) to the US gross domestic product in 2021¹⁰⁸ As one of the largest sectors of the US economy, protecting this sector is a matter of national security. Despite this sector's importance, animal and plant health biodefense receive comparatively little attention from policymakers. For example, the NVS (the animal health equivalent of the SNS) received around \$6 million in Fiscal Year 2023 for MCM, equipment, protective equipment, and other supplies, compared to \$965 million for the SNS.¹⁰⁹

African Swine Fever and other animal diseases that could devastate our country's economy and food supply lack effective and approved MCM, putting increased pressure on agricultural inspections, biosurveillance, and biosecurity practices to detect, track, and prevent the spread of these diseases. Animal culling remains the primary means of response to an outbreak, with devastating financial effects on the national food supply and impacted farms. As demonstrated by outbreaks of Highly Pathogenic Avian Influenza, our food and agriculture enterprise remains vulnerable to biological threats.

Federal food and agro-biodefense efforts are not only underfunded, they are uncoordinated. The USDA Office of Homeland Security should serve an important role in coordinating the Department's efforts to address biological and other national security threats. Several key functions of the Office should help address human, animal, plant, and environmental health as they interact, but the Office currently lacks sufficient expertise to do so effectively. Congress exacerbated the problem by leaving the Office chronically underfunded and undermanned, appropriating just under \$1.4 million for it in Fiscal Year 2023.¹¹⁰ The Office currently answers to the Assistant Secretary for Administration (not the Secretary of Agriculture), and the Department does not prioritize its efforts highly.

The Food and Drug Administration Food Safety Modernization Act (P.L. 111-353, signed into law in 2011) required the development and implementation of a national agricultural and food defense strategy.¹¹¹ USDA and HHS jointly issued the Strategy in 2015. The Strategy addressed federal roles and responsibilities for food- and agro-biodefense preparedness and response and included an implementation plan. The strategy addressed academia in general, but it did not specifically address

the unique role of universities in helping to defend food and agriculture against biological threats. USDA and HHS surveyed 32 states in 2019 to assess efforts to implement the Strategy. However, USDA and HHS did not advocate for any other concrete steps for implementation.¹¹²

Policymakers can bolster food and agro-biodefense by taking advantage of land grant and other universities suited for this role. Universities interact with many federal departments and agencies including the DOE, HHS, and DOI United States Geological Survey.¹¹³ The USDA National Institute of Food and Agriculture administers federal funding dedicated to supporting land-grant university research and extension activities.¹¹⁴ The National Institute of Food and Agriculture requires institutions to submit project plans for individual grant awards, but the agency does not coordinate research and extension activities conducted by the land-grant universities. One non-federal model for coordination is the Coalition for Epi Response Engagement and Science comprised of Colorado State University, Kansas State University, Iowa State University, Texas A&M University, University of California-Davis, University of Nebraska-Lincoln, and University of Nebraska Medical Center.¹¹⁵ This coordinating entity focuses on diagnostics and surveillance, MCM and manufacturing, and outreach and engagement.¹¹⁶

When it comes to preparedness, response, recovery, and mitigation, cooperative extension programs and experiment stations serve farmers and ranchers by identifying, and providing them with, agricultural and mechanical best practices. This mission has evolved over the years to address other topics that individual states and the land-grant universities have identified as priorities for the communities they serve, commensurate with available funding. Historically, public health preparedness has focused on human public health, paying far less attention to agricultural public health preparedness. Cooperative extension agents that have assumed this role have proven invaluable for preparedness planning, training, education, and all-hazard response, as well as obtaining reimbursements under the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988 (P.L. 100-707). Some states have augmented cooperative extension staffing to engage in preparedness initiatives and have routinely deployed cooperative extension agents and other land-grant university capabilities for crisis response. This expanded mission provides new research opportunities for faculty, and life-long learning opportunities for students preparing them for community leadership roles in the future.

Recommendation 27: Redouble efforts to bolster state, local, tribal, and territorial biological emergency preparedness.

ACTION ITEMS:

- a. **Assess and strengthen state and territorial biodefense activities.** Each US governor should convene a governor's biodefense commission to evaluate the ability of their states and territories to address biological threats. The governors should task these commissions with assessing the capabilities of the biodefense enterprise, including performance in recent public health emergencies and disasters, and identifying opportunities for improvement. Membership should include current and former SLTT officials, former legislators, and members of academia, coalitions, associations, and industry. Commissioners should meet monthly for the first year following the commission's establishment, and annually thereafter. No later than a year after establishment, each commission should submit to their respective governor a report with their findings and recommendations. The governors should enact policies to implement these recommendations and incorporate the findings into their annual budgets. Each commission should continue to assess and submit updated reports to their governor on a biennial basis, including progress made towards implementing the recommendations. Congress should appropriate additional funding for annual PHEP cooperative agreement allocations to support the establishment and sustainment of these commissions by all US states and territories.
- b. **Authorize and provide sustained funding for the Public Health Infrastructure Grant Program.** Congress should amend the Public Health Service Act (P.L. 78-410) to authorize the Public Health Infrastructure Grant Program. Congress should direct the Secretary of Health and Human Services to expand the program to support public health infrastructure investments for federally recognized American Indian and Alaska Native tribes, in addition to states, localities, and territories. Congress should direct the Secretary to develop a five-year strategy for the investments made under this program and submit that strategy to Congress no later than 180 days after enactment.
- c. **Provide robust funding for Public Health Emergency Preparedness cooperative agreements.** Congress should appropriate annual funding to PHEP cooperative agreements at no less than the amount authorized in statute or the President's Budget Request, whichever is higher. Congress should direct the Director for the Centers for Disease Control and Prevention to submit an annual assessment of public health infrastructure and identify funding needs to address preparedness shortfalls.

- d. **Make Public Health Emergency Preparedness cooperative agreement funding available directly to the tribes.** Congress should amend the Public Health Service Act (P.L. 78-410) to authorize and fund the CDC to make PHEP tribal cooperative agreements directly available to the 574 federally recognized American Indian and Alaska Native tribes (if they choose to participate), establish eligibility criteria, increase CDC PHEP cooperative agreement program funding and operations accordingly, and increase CDC staff to address tribal needs in this regard.
- e. **Authorize a Vaccines for Adults program.** Congress should amend the Social Security Act (P.L. 74-271) to authorize a Vaccines for Adults program, modeled on the Vaccines for Children Program authorized by Section 1928 of the Social Security Act. Congress should require the Director of the Centers for Disease Control and Prevention to work with the Administrator of the Centers for Medicare and Medicaid Services to expand access by uninsured adults to routine and biological event vaccines recommended by the Advisory Committee on Immunization Practices at no cost and cover provider fees and program operations. Congress should appropriate long-term mandatory funding for the program.
- f. **Help the homeless and those living in low-income housing prevent, prepare for, and respond to, biological events.** Congress should amend the Department of Housing and Urban Development Reform Act of 1989 (PL 102-235) to direct the Secretary of Housing and Urban Development to (1) make programs to prevent, prepare for, and respond to biological events in urban areas eligible for the Emergency Solutions Grants program, the Continuum of Care program, and the Community Development Block Grant program; (2) provide guidance and technical assistance on how to prevent and manage the spread of infectious diseases in shelters, encampments, and other settings where low-income households and the homeless reside or receive services; and (3) ensure that Continuum of Care program leadership coordinates its infectious disease planning and response efforts with service providers for the homeless, health care providers, public health authorities, and others relevant partners.
- g. **Provide additional biodefense planning and technical assistance to the territories and freely associated states.** The Director of the Centers for Disease Control and Prevention should provide territories and freely associated states with technical assistance to plan for large-scale biological events, focusing on preparedness goals and regular exercises to test the capabilities of their healthcare and public health systems. Plans should take existing resource limitations into account and maximize available assets to help the territories and freely associated states better prepare for, respond to, recover from, and mitigate public health crises and large-scale biological events.

- h. **Reduce barriers to transporting resources to territories and freely associated states during biological emergencies.** Congress should amend Section 27 of the Merchant Marine Act of 1920 (P.L. 66-261) to allow automatic, emergency exemptions from Jones Act shipping requirements whenever the Secretary of Health and Human Services declares a public health emergency, or when the President issues an Emergency Declaration or Major Disaster Declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (P.L. 100-707) that applies to Alaska, Hawaii, or the territory and freely associated state in question. Congress should also direct the Secretary of Homeland Security and Administrator of the Federal Emergency Management Agency, in coordination with the Secretary of Defense, Secretary of Health and Human Services, Secretary of State, Secretary of Transportation, and other relevant federal agencies, to (1) evaluate challenges to transporting supplies and personnel to US territories and freely associated states immediately before and during biological and other public health emergencies; (2) develop recommendations to address those challenges; and (3) produce a deployment strategy that assigns roles and responsibilities throughout the federal government. As part of this evaluation, FEMA should consult with the territories and freely associated states, US states that may be called upon to support territorial and freely associated state emergency response, associations with territorial members or interests, and the American Red Cross.
- i. **Bolster tribal biological emergency preparedness.** The Director of the Centers for Disease Control and Prevention, in collaboration and coordination with the Director of the Indian Health Service, should provide annual guidance and technical assistance to help tribal health departments with preparedness for, and response to, biological and other public health emergencies. Through its Center for State, Tribal, Local, and Territorial Support, and Office of Tribal Affairs and Strategic Alliances, the CDC should utilize permanent tribal liaisons to conduct regular outreach and education to tribal governments (including direct consultations and site visits when requested) regarding funding opportunities and use of public health preparedness funds. The CDC should also place tribal liaisons in each of its other centers to ensure that they consider tribal needs. Federal technical assistance should address tribal public health emergency preparedness and response, the conduct of exercises, and how to establish and meet preparedness and response-oriented performance goals. Congress should also increase appropriations to the Indian Health Service for the purpose of strengthening tribal epidemiology centers. The Indian Health Service should develop criteria for allocating resources to the tribal epidemiology centers, in consultation with tribal representatives and the National Indian Health Board.

- j. **Implement national food and agro-biodefense policies.** Congress should amend the National Defense Authorization Act, Agriculture Improvement Act of 2018 (P.L. 115-334), Public Health Service Act (P.L. 78–410), and Homeland Security Act of 2002 (107-296) to direct the Secretary of Agriculture, Secretary of Defense, Secretary of Health and Human Services, Secretary of Homeland Security, and other departments and agencies with food and agro-biodefense responsibilities to develop departmental implementation plans for the National Biodefense Strategy, the National Security Memorandum on Strengthening the Security and Resilience of United States Food and Agriculture (National Security Memorandum 16), and the National Food and Agriculture Defense Strategy. Congress should require departments and agencies to submit these plans no later than 180 days after enactment, and to provide annual status updates on implementation, including any funding requirements for implementation.
- k. **Address plant biodefense research and development.** Congress should amend the Agriculture Improvement Act of 2018 (P.L. 115-334) to require the Secretary of Agriculture to develop a plant biodefense research and development plan. This plan should include activities to study novel and durable host plant resistant strategies that can help defend against the introduction of newly emerging and recurrent high consequence plant pathogens and pests into global food systems. The plan should also include funding requirements to address biological threats and timelines for conducting this research. The Secretary should publicly post this research plan, submit it to Congress within one year of enactment, provide annual implementation updates to Congress, and refresh the plan quadrennially.
- l. **Address gaps in plant emergency preparedness.** The Secretary of Agriculture should review existing USDA plant health efforts and submit to Congress a report no later than 180 days after enactment outlining capability gaps and funding needs to strengthen defense against biological threats to plant health. This report should consider the possibility of multiple plant pests and pathogens emerging simultaneously. Congress should authorize the use of the Commodity Credit Corporation to provide funding in support of additional plant health preparedness activities through the Plant Pest and Disease Management and Disaster Prevention Program. The Secretary should specifically address plant health threats as part of a department-wide biodefense strategy.

- m. **Revise, implement, and comply with the National Agriculture and Food Defense Strategy.** Congress should amend Section 108 of the Food and Drug Administration Food Safety Modernization Act (P.L. 111-353) to require the Secretary of Agriculture and the Secretary of Health and Human Services, in coordination with the Secretary of Education and the Secretary of Homeland Security, to identify and incorporate the research conducted by universities (supported with federal dollars), as well as relevant land-grant food and agro-biodefense activities, in the next iteration of the National Agriculture and Food Defense Strategy. Congress should require the Secretary of Agriculture and Secretary of Health and Human Services to coordinate with other federal departments and agencies charged with food and agro-biodefense responsibilities to implement the strategy no later than one year after enactment, and to update the Strategy on a quadrennial basis as required by statute.
- n. **Authorize the Extension Disaster Education Network.** Congress should amend the Agriculture Improvement Act of 2018 (P.L. 115-334) to authorize the Extension Disaster Education Network and require the Secretary of Agriculture, in coordination with the Administrator of the Federal Emergency Management Agency, to develop a cooperative extension food and agriculture preparedness and response framework for land-grant universities. The process to develop this framework should include the identification of preparedness resource requirements, needed appropriations to support participating land-grant cooperative extension programs, and the determination of any new authorities needed to enable effective food and agriculture biological crisis response.
- o. **Make tribal land-grant universities eligible for capacity formula funding.** Congress should amend the Hatch Act (P.L. 49-314) and the Smith-Lever Act (P.L. 63-95) to make tribal land-grant universities eligible for capacity formula funding under those statutes, along with the Tribal College Research Grants Program and the Tribal Colleges Extension Program. Congress should waive the funding match requirement associated with these programs for tribal land-grant institutions. Congress should also appropriate funding for the establishment of dedicated biodefense research and extension activities at these universities. In addition, Congress should amend the Higher Education Opportunity Act (P.L. 110-315) to authorize additional funding for establishing or strengthening extension activities at tribal land-grant universities. Congress should explicitly add extension programs as an authorized activity for Department of Education grants to tribal colleges and universities. The Secretary of Agriculture, in coordination with the Secretary of Health and Human Services, should also provide technical assistance (including on site) to all tribal land-grant universities working to establish or expand existing food- and agro-biodefense extension activities, and engage in regular communication with, and outreach to, these universities.

DETECTION AND SURVEILLANCE



BIOWATCH REPLACEMENT

Effective environmental surveillance improves pathogen identification and, most importantly, provides early warning of a biological event. Currently, the federal government collects limited data on water and soil contamination and lacks requirements that would incorporate these data into a federal database. Further, our system of environmental biodetectors has not progressed significantly since their initial deployments 20 years ago.

The White House launched the Nation's environmental biodetection program, BioWatch, in 2003. BioWatch is a DHS system of nationally distributed detectors that sample the air for a select number of pathogens in a few dozen cities. Non-federal public health laboratories then analyze the samples. Its potential remains unrealized 20 years later. As of 2023, BioWatch uses the same technology (i.e., manual filter collection and laboratory polymerase chain reaction testing) as it did at its inception. The technological limitations of the system include (1) reliance on winds blowing in optimal directions; (2) taking up to 36 hours to alert for the possible presence of a pathogen; (3) inability to determine whether live organisms were released; (4) inability to differentiate between normal background bacteria and harmful pathogens; and (5) inability to identify atypical threats beyond those in the testing protocol. Compounding these issues, the federal agencies involved in determining what to do with BioWatch test results often disagree as to which course of action to take and do not always consult non-federal public health and other government officials, even though many response decisions fall to state and local leadership.

External evaluations by the Government Accountability Office (GAO) and the DHS Office of the Inspector General have repeatedly raised concerns about the program, as has this Commission.¹¹⁷ While some non-federal officials acknowledge that BioWatch technology does not work, they hesitate to come out against the program, fearing the loss of the funding and other support provided by DHS to run the BioWatch program. Others believe that the technology could work under extremely limited conditions and want to keep it in place because something that might work is better than having nothing at all.

DHS has twice attempted to acquire next generation technology for BioWatch in response to these concerns, including with the new Biodetection in the 21st Century program that the Department has turned on and off several times. The DHS Science and Technology Directorate is responsible for research and development outside of the Department's operational components. The DHS Office of Countering Weapons of Mass Destruction, however, pursues its own research and development activities, but does not have well-defined research and development authority.¹¹⁸ The Directorate understands the need to develop new technology to replace BioWatch and previously fielded a new attempt in two states, but that technology has not transferred to the Office.

Figure 7. BioWatch Replacement Decision Tree



The courses of action are clear. If DHS is unable or unwilling to execute ANY of the steps in the process described above, Congress should terminate the BioWatch program and redirect biodefense funding to long-term biodefense research and development.

The Department of Defense engages in its own biodetection research and acquisition programs, as do some other agencies (e.g., NASA). While the needs of civilians, warfighters, astronauts, and others are different, the science behind environmental biodetection is not. These departments and agencies do not coordinate their environmental detection efforts or leverage each other's advances. Together or independently (and with congressional pressure and oversight) these Departments could develop a detection system capable of meeting today's threats with 21st century ingenuity and replace the ineffective system currently in place.

Recommendation 28: Replace BioWatch.

ACTION ITEMS:

- a. **Implement a domestic biological detection research and development plan.** Congress should amend the Homeland Security Act of 2002 (P.L. 107-296) to direct the Secretary of Homeland Security to (1) obtain current intelligence and information about the biological threat and redefine the mission of the BioWatch program within 180 days of enactment; (2) produce and implement a long-term research and development plan for BioWatch that includes collaboration with BARDA, DARPA, and NASA, and incorporates input from industry, academia, and the national laboratories within 180 days after enactment; (3) direct the National Academies of Sciences to conduct annual external evaluations to identify gaps and potential failure points, and recommend contingency requirements in the event prospective technology does not perform as expected or intended; and (4) develop testing protocol prototypes with support and evaluation from federal departments and agencies and industry in the environments in which BioWatch detectors will or could be deployed, involve officials from these jurisdictions in this prototype testing, and obtain an external evaluation of prototypes to help identify the most promising technologies to achieve the BioWatch mission no later than one year after enactment.
- b. **Replace outdated BioWatch technology.** Congress should amend the Homeland Security Act of 2002 (P.L. 107-296) to direct the Secretary of Homeland Security to (1) identify BioWatch replacement technologies, determine where to place detectors and other equipment throughout the Nation, and acquire at least three technologies that can meet BioWatch mission requirements and the needs of newly identified BioWatch jurisdictions within 90 days following the conclusion of the initial results of the BioWatch research and development program; (2) procure and send this newly acquired biodetection technology to BioWatch jurisdictions, test new equipment and laboratory protocols, exercise use, and establish new agreements with public

health laboratories in BioWatch jurisdictions to conduct tests and provide other laboratory support within one year after procuring suitable biodetection technology; and (3) replace old BioWatch with piloted newer Biodetection for the 21st Century equipment, end contracts for laboratory testing, and remove federal government contractors from public health laboratory facilities no later than eighteen months after acquisition and procurement of replacement technology. Congress should establish and provide appropriations for a dedicated grant program to assist public health laboratory activities.

NATIONAL DIAGNOSTIC TESTING FOR BIOLOGICAL EVENTS

The symptoms caused by many emerging diseases and biological agents (e.g., high fever, muscle aches, lethargy) can be non-specific. We must develop advanced molecular diagnostics, particularly when new biological threats emerge. Without access to definitive diagnostic tests for new pathogens, healthcare providers are unlikely to differentiate illnesses caused by these diseases from more common and routine infections.

Academia, industry, and government came together during COVID-19 to develop new testing approaches and strategies. For example, rapid, self-administered testing emerged as a critical tool during the COVID-19 pandemic and is now under development for influenza and other infectious diseases. HHS must prioritize these investments, institutionalize the partnerships and contracting mechanisms, and apply the lessons learned from the NIH Rapid Acceleration of Diagnostics (RADx) and other initiatives developed during the COVID-19 pandemic to other pathogens. During a crisis, advanced diagnostic technologies must move swiftly through the development pipeline toward commercialization and broad availability. Previously, USDA, DOD, and HHS did not prioritize the development of diagnostics for Ebola and other threats for which the government and industry spent billions to develop vaccines and therapeutics. These Departments invested heavily in therapeutics for treatment and far less in diagnostics for detection.

This shortsighted approach does not serve the Nation. While these technological solutions require significant investment up front, the information they provide can facilitate decision-making when responding to a biological threat. Accurate diagnostics can spare vaccines, treatments, and quarantine, saving valuable time and limited resources. Furthermore, diagnostics could provide forensic clues for attribution and justify actions based on this information with increasingly sophisticated profiling of the molecular signatures of biological agents.

Recommendation 29: Develop national diagnostic testing for biological events.

ACTION ITEMS:

- a. **Establish a biodefense diagnostics coordination group.** Congress should amend the Pandemic and All-Hazards Preparedness Act (P.L.109-417) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense and the Secretary of Agriculture, to establish a new coordination group to address (1) development of innovative rapid diagnostic solutions and increase testing across the Nation; (2) elimination of related supply chain disruptions; (3) pursuit of advances in diagnostic technology; (4) identification of lessons learned from the failure to produce a scalable diagnostic test early in the COVID-19 pandemic; (5) determination of how to improve development processes and more rapidly produce diagnostics when biological events occur in the future; (6) definition of the roles of the involved agencies; (7) evaluation of the Tri-Agency Task Force for Emergency Diagnostics, Laboratory Diagnostics Task Force, and any other relevant federal efforts; and (8) proposal of improvements for effectiveness, sustained collaboration, and rapid response. The coordination group should include (1) federal and non-federal government officials; (2) representatives from commercial, academic, and clinical laboratories; and (3) animal, plant, and human public health laboratories.
- b. **Develop and implement a national diagnostics plan.** The Biodefense Diagnostics Coordination Group should develop and implement a national plan to (1) organize and optimize the development and deployment of testing throughout the United States; (2) identify and determine how to overcome the complex logistical and administrative impediments posed by government bureaucracies, commercial self-interest, and inefficient acquisition mechanisms; (3) overcome these impediments; (4) identify and determine how to overcome supply shortages that prevent testing; (5) seek alternative diagnostic methods that would require different supplies (so as to relieve strain on the supply chain); and (6) evaluate strategies that could alleviate pressure on the supply chain (which must be complemented by a low positivity rate and robust test and trace capabilities to provide value). The coordination group should prioritize rapid point-of-care and point-of-need diagnostics, especially those with low reliance on reagents.

- c. **Develop rapid point-of-use diagnostics.** The Secretary of Health and Human Services should expand the NIH RADx public-private partnerships initiative to ensure the program is able to respond to future pandemics. The Secretary should also assess and advance research and development in (1) rapid point-of-use diagnostics for pathogens with pandemic potential (in addition to COVID-19); (2) diagnostics that test for multiple pathogens; (3) nucleic acid-based tests; (4) rapid point-of-use diagnostic tests using a variety of sample types; and (5) proven diagnostic technologies for widespread use against pathogens with pandemic potential.

The Secretary of Health and Human Services should also develop a plan to rapidly approve, develop, scale, acquire, procure, and deploy point-of-use diagnostic tests throughout the nation in response to a biological event. The plan should (1) require the development of rapid point-of-use diagnostics following the initiation of diagnostics that require laboratory confirmation for a novel biological threat; (2) fund the development of a multiplex assay for deployment in clinical settings, alongside sequencing capability; (3) delineate the activities of the NIH RADx Executive Committee, Tech Governance Committee, Tech Working Group, and Underserved Populations Governance Committees when engaging with the public and the private sectors to develop and scale diagnostic capabilities rapidly; (4) describe the processes for quick approval, acquisition, and procurement of rapid point-of-use diagnostics; (5) detail how these committees will rapidly deploy diagnostics across the country; (6) describe the process for making instructions easier to understand and less complicated; and (7) address simplified reporting to public health departments.

- d. **Develop and deploy plant disease diagnostics.** The Secretary of Agriculture should develop a Plant Health Diagnostics Strategy and associated implementation plan. This strategy should align with existing federal strategies, policies, and plans, and should delineate activities to develop and deploy new diagnostics to detect biological threats to plant health. The Secretary should assess funding requirements for research to implement the Strategy and should address these needs in annual budget requests.
- e. **Develop minimally- and non-invasive infection detection.** The Secretary of Health and Human Services, Secretary of Agriculture, and Secretary of Defense should (1) identify ongoing public and private sector research and development of minimally- and noninvasive infection detection technologies; (2) determine the potential for, and challenges with, their utilization; (3) develop a funding plan to advance research and development in this arena; (4) identify the data sets and integration and analytics systems needed to draw rapid conclusions from these technologies; and (5) implement newly developed advanced technologies and methods of detection. The Secretary of Health and Human Services, Secretary of Agriculture, and Secretary of Defense should submit the funding plan to Congress.

- f. **Maintain a diagnostic test kit for each disease that stockpiled vaccines address.** The Secretary of Agriculture, Secretary of Defense, and Secretary of Health and Human Services should request adequate resources for the NVS, SNS, and defense stockpiles respectively to maintain one diagnostic test kit for each disease addressed by MCM in the stockpiles. In the President's Budget Request, the Administration should request resources to incentivize the development of rapid point-of-care diagnostic devices for high-consequence pathogens and add them to the stockpiles.
- g. **Increase diagnostics reimbursement and testing for diseases likely to impact national security.** Congress should amend the Protecting Access to Medicare Act of 2014 (PL 113-93) to direct the Administrator for the Centers for Medicare and Medicaid Services to increase reimbursement for point-of-care and point-of-need diagnostic tests for diseases that could impact national security as identified by the Secretary of Agriculture, Secretary of Defense, Secretary of Health and Human Services, Secretary of Homeland Security, and Director of National Intelligence, and increase reimbursement for testing of these diseases.
- h. **Identify and increase ubiquitous sequencing.** The Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, Secretary of Defense, and Secretary of Homeland Security, should identify portable sequencing end-users and the sequencing capabilities they need in the federal government; SLTT; healthcare settings; and ports-of-entry. The Secretary of Health and Human Services should obtain this information within 180 days.

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

Congress should additionally amend the 21st Century Cures Act (P.L. 114-255) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Agriculture and Secretary of Defense, to develop a research and development plan to make fielding portable sequencing in non-laboratory settings more affordable. The plan should (1) identify research efforts to produce portable sequencing devices in the public and private sectors; (2) address the miniaturization of these devices; (3) decrease or eliminate the reagents needed by these devices; and (4) address the integration of sequencing with microfluidics, on-chip sample preparation, and advances in bioinformatics. The Secretary of Health and Human Services should deliver this plan to Congress within one year of enactment.

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

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

PUBLIC HEALTH DATA INFRASTRUCTURE AND COLLECTION DURING BIOLOGICAL EMERGENCIES

As past outbreaks and pandemics demonstrated, impactful and effective decision-making during a crisis depends on reliable, accurate, and comprehensive data. Timely and relevant information make it possible to prioritize resources and interventions, coordinate efforts, and respond in a manner the American people deserve.

Unfortunately, our country lacks a national public health data system to integrate and share information among SLTT and federal entities. The COVID-19 pandemic made the real-world impacts of this data gap clear. Throughout the pandemic, many communities were left blind to the spread of disease and America had to depend on other countries (e.g., Israel, United Kingdom) to gain needed insights about how the virus behaved and spread. Even with a Public Health Emergency declaration, the CDC spent months negotiating separate data sharing agreements with each state and territory, further hindering information gathering efforts. The lack of effective information sharing prevented effective integrated national pathogen surveillance and forecasting.

In another example, requirements in the Paperwork Reduction Act of 1995 (P.L. 104-13) significantly hamper the ability of HHS to quickly gather data (including voluntary data) from patients, during an ongoing crisis. This law requires federal agencies to first seek public comment concerning the proposed collection of information through a published 60-day Federal Register Notice (FRN). Following the conclusion of the 60-day public comment period and after HHS approves, the agency must publish a second 30-day FRN. This FRN notifies the public that the agency has submitted a clearance request to the OMB for review and that the public has an opportunity to provide comment to the OMB concerning the final clearance package. The Paperwork Reduction Act grants authority to the OMB to review and approve federally conducted and sponsored data collections involving ten or more respondents. Information collection activities may not begin before the OMB approval and the review process often significantly delays the gathering of critical data during a crisis.

The CDC launched the Data Modernization Initiative in 2020¹¹⁹ to (1) strengthen data reporting, management, and analytics across federal and SLTT public health departments and agencies; (2) conduct improved and expanded surveillance of current and future public health threats; (3) help their staff pursue innovation and build state-of-the-art data science skills; (4) deliver guidance the public can trust by integrating nationwide standards for data access and exchange; (5) bolster systems that link real-time data about emerging health threats; (6) create innovative

pandemic-ready solutions for timely and complete data reporting to CDC; and (7) integrate nationwide standards for efficient and secure data access and exchange. Unfortunately, the CDC did not start the Initiative before COVID-19 began. Furthermore, their lack of statutory authority to collect data from SLTT significantly constrains what the Initiative can achieve.

A national public health data system would provide the capabilities needed to effectively address the spectrum of biological threats. The system must be able to efficiently integrate, curate, and analyze data in a timely manner from federal and SLTT public health agencies to be successful. We must establish and sustain a national and integrated public health data capability with the capacity to integrate additional capabilities (e.g., digital pathogen surveillance, new streams of clinical and laboratory data, access to electronic health records, anonymized human movement, new visualization capabilities, and improved analytics) as they become available. The government should continue to prioritize public health data and sustain investments in both the maintenance and advancement of the system.

Recommendation 30: Improve national public health data infrastructure and collection during biological emergencies.

ACTION ITEMS:

- a. **Establish a National Public Health Data System.** Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, Secretary of Defense, Secretary of Homeland Security, and Secretary of Veterans Affairs, to establish a national public health data system that expands on current data modernization efforts. The Secretary should (1) identify relevant and available federal, SLTT, and private sector data streams; (2) de-identify personal data and protect privacy; (3) determine and build the federal and SLTT technological capabilities needed to sustain the System over time; (4) ensure ease of data entry by including end users in the development and beta-testing process; (5) compile and integrate relevant data streams no later than two years after enactment; (6) ensure that the System will support timely and transparent access by the public; (7) provide funding and technical support to SLTT to enable them to contribute to this System; (8) establish the System no later than three years after enactment; (9) describe how information will flow and how federal, SLTT, academic, and healthcare entities will gather data; (10) set data reporting and collection standards to ensure interoperability; (11) describe how HHS and DHS will protect System against cyberattacks; and (12) address how HHS and DHS will prevent and respond to the introduction of mis- or disinformation into the System.

- b. **Develop a data interoperability plan.** Congress should amend the PREVENT Pandemics Act (P.L. 117-328) to require the Director of the Center for Forecasting and Outbreak Analysis to create a data interoperability plan with interagency partners. This plan should (1) describe the structure of an information sharing network among these entities; (2) include data reporting standards to ensure interoperability; (3) consider the potential effects of cyberattacks and mis- and disinformation on these systems; and (4) implement this plan within one year of enactment.
- c. **Form data sharing agreements in advance of biological events.** Congress should amend the Public Health Service Act (P.L. 78-410) to require states and territories participating in Public Health Emergency Preparedness cooperative agreements to negotiate and develop standing data sharing agreements with the CDC that can be immediately activated for the duration of a Public Health Emergency declaration. States and territories should finalize these agreements no later than a year after enactment and revised on a biennial basis or upon request from states and territories. The CDC should incorporate these agreements into any large-scale data sharing arrangement such as a National Public Health Data System.
- d. **Improve the collection and sharing of data among the federal government, private sector organizations, and other non-federal entities during a biological emergency.** Congress should amend the Public Health Service Act (P.L. 78-410) to require healthcare providers, facilities, suppliers, pharmacies, laboratories, service organizations, and SLTT government agencies to provide data on cases, hospitalizations, deaths, and vaccinations to HHS during a public health emergency. Congress should also require the Secretary of Health and Human Services to share information and data gathered with these entities and develop and execute a related education campaign.

INTEGRATED BIOSURVEILLANCE

Biosurveillance is the systematic collection, analysis, and dissemination of data relevant to biological events. As past outbreaks and COVID-19 demonstrated, reliable, accurate, and comprehensive data are necessary for effective decision-making during a crisis. Biosurveillance can help to identify and characterize biological agents, monitor their spread and impact, assess the risk and vulnerability of populations, and inform public health authorities and other stakeholders. Biosurveillance can also support the evaluation and improvement of biodefense policies and practices, as well as the development and deployment of countermeasures such as vaccines, diagnostics, and therapeutics. Biosurveillance

is essential for enhancing the preparedness and resilience of nations and communities against biological threats, whether they are natural, accidental, or deliberate.

Investments in plant health receive less attention than threats to animal health. Annual appropriations for the National Plant Diagnostic Network fall well below those for the National Animal Health Laboratory Network, despite similar funding authorizations in statute.¹²⁰ Stagnant funding for the National Plant Diagnostic Network and other plant health initiatives threaten to erode what capabilities we possess to detect, track, and respond to wheat blast and other biological threats to plant health. The diversity and sheer number of plants, and therefore, plant pathogens of concern, eclipse animal health and creates a complicated threat picture where multiple, smaller biological events affecting plant health simultaneously could drain our Nation's resources and impact human health and the economy as much as or more than a single, catastrophic event. Developing a complex response apparatus that can address multiple plant threats at a time demands additional planning and resources that the Administration and Congress have yet to invest in for this sector.

Recommendation 31: Integrate and improve biosurveillance.

ACTION ITEMS:

- a. **Establish a biosurveillance federal advisory committee.** Congress should amend the Public Health Service Act (P.L. 78 -410) to require the Secretary of Health and Human Services to establish a biosurveillance Federal Advisory Committee. Members should include SLTT, industry, nongovernmental, and academic representatives. The committee should examine the Department's biosurveillance activities and produce recommendations for strengthening national biosurveillance. The Secretary should submit these recommendations to Congress no later than 180 days after enactment.
- b. **Establish a food and agricultural biosurveillance planning committee.** Congress should amend the Agriculture Improvement Act of 2018 (P.L. 115-334) to require the Secretary of Agriculture to establish a biosurveillance Federal Advisory Committee. Members should include SLTT, industry, nongovernmental, and academic representatives. The committee should develop recommendations to strengthen USDA national food and agriculture biosurveillance activities. The Secretary should submit these recommendations to Congress no later than 180 days after enactment and annually thereafter.

- c. **Modernize and expand national biosurveillance.** Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Director of the Centers for Disease Control and Prevention to (1) update and harmonize its list of Nationally Notifiable Diseases; (2) modernize, standardize, extend, and integrate disease reporting, monitoring, and surveillance across the Nation; and (3) include wastewater surveillance and syndromic surveillance in its national surveillance program. Congress should also amend Section 319C-1 of the Public Health Service Act to require states and territories participating in Public Health Emergency Preparedness cooperative agreements to comply with changes made to National Notifiable Disease System reporting requirements and expand data reporting and access.
- d. **Establish digital pathogen surveillance.** The Secretary of Health and Human Services, Secretary of Defense, Secretary of Agriculture, Secretary of the Interior, and Secretary of Veterans Affairs should (1) identify end-user needs for digital pathogen surveillance systems; (2) define clear performance requirements for the private sector; (3) provide incentives for the private sector to advance capabilities; (4) establish public-private partnerships with industry entities that have demonstrated pathogen surveillance capabilities; and (5) strengthen ongoing digital pathogen surveillance efforts throughout the government.

Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, Secretary of Agriculture, Secretary of Defense, Secretary of the Interior, and Secretary of Veterans Affairs, in coordination with the Attorney General and Director of National Intelligence, to develop a pathogen data interoperability plan to enhance information sharing among federal departments and agencies, the Intelligence Community, industry, academia, and nongovernmental organizations. This plan should (1) describe the structure of an information sharing network among these entities; (2) include data reporting standards to ensure interoperability; (3) address the potential effects of cyberattacks and mis- and disinformation on these systems; (4) include an integrated medical data and contagion spread modeling tool; and (5) be implemented within one year of enactment.

- e. **Collect and share food, agriculture, plant, and wildlife disease data.** Congress should increase annual appropriations for the USDA National Wildlife Disease Program, to enhance data collection from livestock and wildlife by the USDA and Department of Interior. Congress should amend the Agriculture Improvement Act of 2018 (P.L. 115-334) and 43 U.S.C. 1451 to direct the Secretary of Agriculture and the Secretary of the Interior to assess existing data sharing authorities and activities, and to submit a report to Congress that identifies shortfalls and statutory changes to enhance livestock, wildlife, and plant life

data sharing. Congress should also amend the Homeland Security Act of 2002 to direct the Secretary of Homeland Security to increase coordination with other federal, state, local, tribal, territorial, and private sector entities that collect animal health data and facilitate additional opportunities to share information.

- f. **Implement targeted plant biosurveillance.** The Director of the USDA Agricultural Research Service should conduct research to identify geography areas where new plant pathogens and pests will emerge, and to better understand their potential impacts on natural and managed plant systems.
- g. **Strengthen territorial biosurveillance and data collection.** Congress should amend the Public Health Service Act (P.L. 78-410) to require the Secretary of Health and Human Services, in coordination with the Secretary of State, Secretary of Agriculture, Secretary of Defense, and Secretary of Homeland Security, to develop and enhance the biosurveillance capabilities of each US territory and freely associated state. This includes close collaboration with the territorial and freely associated state governments to establish permanent monitoring systems with technical and diagnostic reach back to the CDC and the procurement of technologies such as mobile information sharing.
- h. **Bolster the national pathogen surveillance and forecasting center.** Congress should amend Section 2825 of the Public Health Service Act (P.L. 78-410) to direct the Center for Forecasting and Outbreak Analytics to develop and maintain a strategic plan, update the plan quadrennially, address the role of the Center within the CDC in the plan, describe how the Center supports the mission of the CDC, and how this plan fits into the overall CDC strategic plan. The Center should share the first strategic plan with Congress within 180 days of enactment. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, Secretary of Defense, Secretary of Interior, and Secretary of Homeland Security, and in collaboration with the national laboratories and the private sector to (1) assess biosurveillance capabilities and relevant data streams across the government to incorporate into the Center for Forecasting and Outbreak Analytics; (2) develop effective algorithms that produce accurate forecasts for the Center; (3) request an annual review by the National Laboratories and National Academies of Sciences to help identify problems, challenges, and potential improvements, and provide technical assistance to the federal government; (4) develop an interoperability strategy for integrating data into the Center; and (5) develop plans to ensure data interoperability and integration, provide data security and integrity, prevent and respond to cyberattacks on the Center, and prevent and respond to the introduction of mis- or disinformation into the Center's data stream.

RESPONSE, RECOVERY, AND MITIGATION



BIODEFENSE RESOURCES FOR STATE, LOCAL, TRIBAL, AND TERRITORIAL EMERGENCY RESPONSE

Local EMS, firefighters, and police will be among the first to respond to certain biological incidents, particularly those deliberate in origin and probably overt (e.g., letters containing anthrax sent to media office in 2001). In most cases, they will not know with which disease they are dealing. It will be too early for anything but cursory, preliminary diagnosis and identification. Threats affect these responders disproportionately because they work with insufficient data in the midst of emergencies and disasters.

Emergency Medical Services (EMS) providers receive inadequate funding and reimbursements for the prehospital emergency health care that they provide. CMS and commercial insurance reimburse EMS solely for transportation services (i.e., when EMS transport patients to hospitals) in keeping with the transportation responsibility given to ambulances staffed by paramedics more than 50 years ago. Today, however, emergency medical service professionals are also responsible for pre-hospital health care, and in some rural areas, for public health. Despite the dependence of patient survival and other outcomes on high-quality and immediate treatment well before entering a hospital or other health care establishment, emergency medical service professionals receive very few additional reimbursements or payments for the health care they deliver. Reimbursement-based funding requires emergency medical service personnel to provide services in routine and disaster situations before reimbursement occurs and does not pay for their readiness activities beforehand.

Historically, public health preparedness has focused on human public health, paying far less attention to agricultural public health preparedness. The federal government must engage with SLTT officials to strengthen capabilities to respond to events affecting food and agriculture. The zoonotic nature of many emerging infectious diseases can exacerbate a biological event.

Animal EMS operate separately from human EMS.¹²¹ Most traditional human EMS professionals lack the training necessary to treat animals properly. Dedicated personnel, authorities, coordination, and training would elevate animal health standards of care following a biological or other event that impacts animal agriculture.

The Nation's land-grant universities can provide additional support in assessing emergency management activities for food and agriculture. During the COVID-19 pandemic, these institutions provided assistance with the response, including laboratory diagnostic testing, genomic sequencing, infectious disease modeling, development

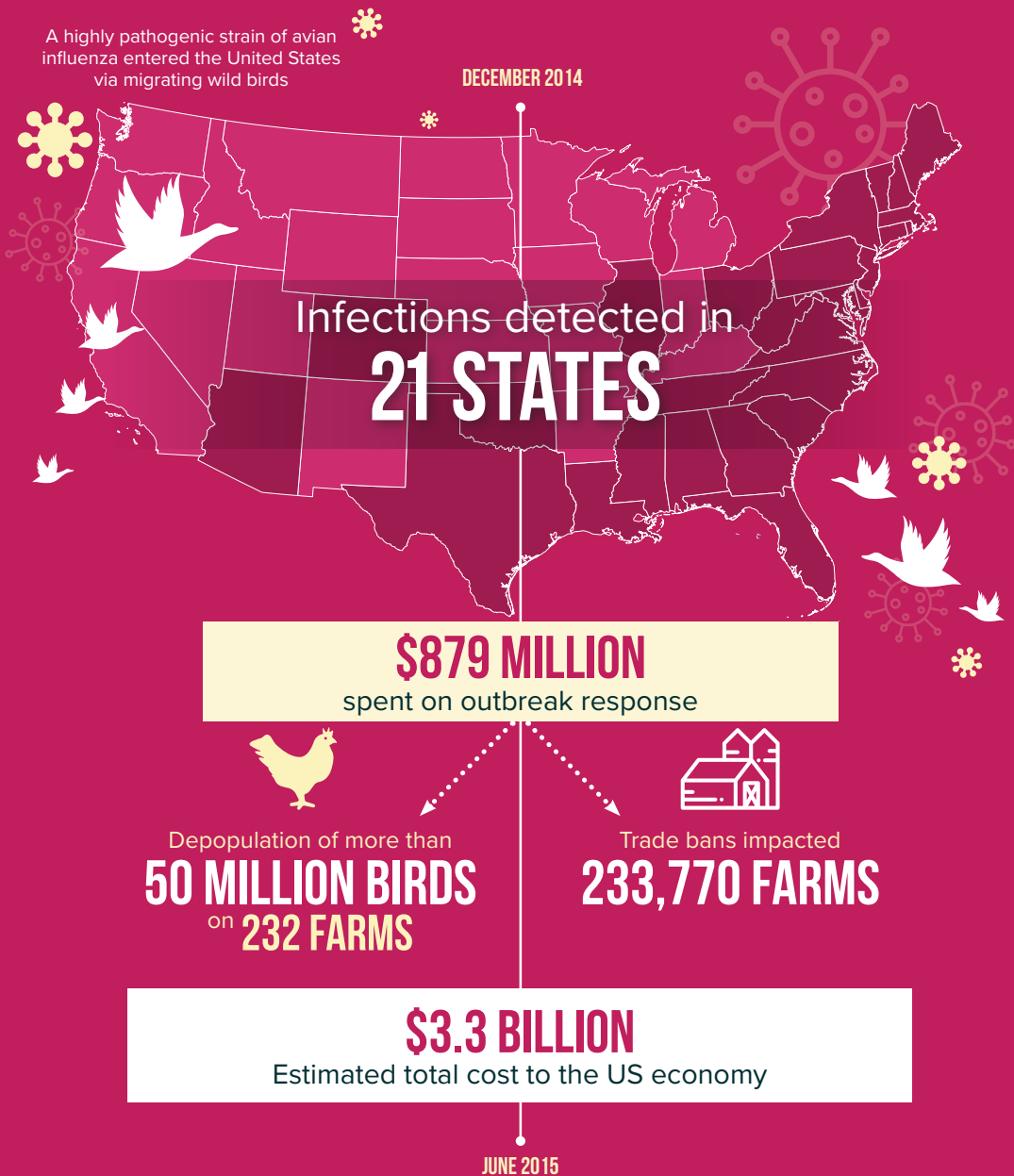
of community-based protective measures, vaccine distribution to underserved and rural communities, situational awareness between county and state authorities, public education, and local public service announcements. Land-grant universities can further contribute research and community connections to SLTT support for animal EMS. Having a trusted voice with an ability to effectively translate technical knowledge into plain language is an invaluable resource, especially in times of crisis.

Recommendation 32: Provide emergency service providers with the resources they need to respond to biological events in their communities.

ACTION ITEMS:

- a. **Assess state, local, tribal, and territorial emergency medical service capabilities to respond to domestic biological terrorism and warfare.** Congress should amend the Public Health Service Act (P.L. 78-410) and the Defense Against Weapons of Mass Destruction Act of 1996 (Title XIV, P.L. 104-201) to require the Secretary of Defense, Secretary of Health and Human Services, Secretary of Homeland Security, and Secretary of Transportation to conduct a national EMS assessment, and periodic, comprehensive, and independent reviews and evaluations regarding the extent and quality of EMS provided throughout the nation. Congress should direct the Secretary of Health and Human Services to prepare and submit annually to Congress a report on EMS that includes the following: (1) an evaluation of the adequacy of EMS in the United States, including but not limited to the ability of SLTT EMS to provide EMS, in response to domestic terrorist incidents involving biological weapons; (2) an evaluation of the extent to which the CMS, other health insurance programs, and all federal EMS grant programs adequately reimburse such services; (3) an evaluation of the alignment of preparedness grant funds for EMS across all grantmaking federal agencies; and (4) recommendations for legislation needed to provide adequate SLTT EMS.
- b. **Establish a biological emergency response assistance program.** The Secretary of Defense, Secretary of Health and Human Services, Administrator of the Federal Emergency Management Agency, and Administrator of the Environmental Protection Agency should provide SLTT emergency medical service personnel and other first responders with training and expert advice regarding emergency response to the use or threatened use of biological weapons, including biological WMD, biological agents, and related materials. Assistance available under this program should include training in the use, operation, and maintenance of equipment for (1) detecting biological agents; (2) monitoring the presence of such biological agents; (3) protecting emergency personnel and the public; and (4) decontamination.

- c. **Inform the delivery of emergency medical services during biological events and other national emergencies.** The Secretary of Health and Human Services, in coordination with the Secretary of Defense and Secretary of Transportation, and in consultation with the Administrator of the Federal Emergency Management Agency, should provide criteria, guidance, and instructions to inform the delivery of EMS during biological large-scale events, mass casualty events, disasters, and other national emergencies, in keeping with Emergency Support Function-8. The Secretary of Health and Human Services should direct the Department of Health and Human Services Assistant Secretary for Preparedness and Response to provide technical assistance, subject matter expertise, and direct program services to help SLTT EMS prepare for, respond to, and recover from biological large-scale events, mass casualty events, disasters, and other biological national emergencies.
- d. **Expand medical necessity rules for pre-hospital emergency medical services reimbursement.** Congress should amend the Social Security Amendments of 1965 (P.L. 89-97) to direct the Administrator of the Centers for Medicare and Medicaid Services, in collaboration with the Assistant Secretary for Preparedness and Response and EMS providers, to expand medical necessity rules for EMS reimbursement, ensuring comprehensiveness without reimbursing unnecessary ambulance trips, while also providing necessary pre-hospital healthcare to all patients requiring such services without prior inquiry as to the ability to pay. This may include mechanisms such as amending the Social Security Act to make EMS a provider type, as recommended previously by the National Academies of Science, Engineering and Medicine.
- e. **Provide food and agriculture biological emergency response technical assistance.** The Secretary of Agriculture should work with the land-grant and other universities to develop SLTT food and agriculture emergency response personnel and provide other SLTT first responders with training and technical assistance regarding emergency response to the use or threatened use of agricultural WMD or biological agents that affect food, animal health, plant health or agricultural materials and activities (e.g., textiles, biofuels). The program should incorporate food and crop scientists, public health experts, and veterinarians from land-grant and other universities to provide technical assistance covering the full range of response needs for biological incidents involving food and agriculture. Assistance available under this program should include training in the use, operation, and maintenance of equipment to (1) detect biological agents in food and agriculture environments; (2) monitor for the presence of such biological agents in food and agriculture facilities and environments; and (3) decontaminate food and agriculture facilities and environments.

Figure 6. Highly Pathogenic Avian Influenza Outbreak of 2014.

In December 2014, a highly pathogenic strain of avian influenza entered the United States via migrating wild birds. The ensuing outbreak resulted in the largest animal health disaster ever experienced by the United States. Federal and state governments spent \$879 million on outbreak response. The outbreak impacted 21 states, lasted until the middle of 2015, and led to the depopulation of more than 50 million birds on 232 farms. Subsequent trade bans impacted as many as 233,770 farms. The total cost to the US economy was estimated at \$3.3 billion.

f. **Establish biological event direct assistance for tribal first responders.**

Congress should amend the Public Health Service Act (P.L. 78-410) and the Homeland Security Act of 2002 (P.L. 107-296) to direct the Secretary of Health and Human Services and Secretary of Homeland Security to identify current statutes, programs, and policies that direct funding and public health information through state or local governments to tribal EMS, police, fire, and dispatchers. Congress should direct the Secretary of Health and Human Services and the Secretary of Homeland Security to submit a report within 90 days of enactment detailing steps they intend to take to increase direct federal assistance to tribal first responders, both before and during a biological event. This report should also identify any laws that require amendment to facilitate this move.

PUBLIC HEALTH BIOLOGICAL EMERGENCY FUNDING, GUIDANCE, AND WAIVERS

Successful response to a biological event depends upon the commitment of readily available funding before an event occurs. The availability of these funds allows federal and SLTT agencies to begin responding without waiting for congressional action. Delaying our Nation's response until Congress provides supplemental appropriations may come at a great cost in lives and money. This pre-commitment of funds must be at levels exceeding those currently available for public health emergency preparedness, response, and recovery activities.

One such funding source is the Public Health Emergency Fund (42 US Code § 247d (b)). Congress has not explicitly appropriated any money for the Public Health Emergency Fund since 1993. This leaves Congress unable to determine if the Fund could work as originally conceived. There is also no consensus among nonfederal biodefense stakeholders regarding needed funding level or how use of the Fund would improve response to public health emergencies.

Congress must examine the utility of the Fund and clearly identify triggers for its use. Currently, the Department of the Treasury can only disperse funds when the Secretary of Health and Human Services makes a public health emergency declaration. However, the public health community may need funding to get ahead of biological threats before they reach the nation's borders, well before such a declaration. Congress has yet to consider additional triggers (e.g., presidential declaration) to release resources from the Public Health Emergency Fund. Congress acknowledged the role of the Fund by including language in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22) that updated and clarified the range of activities covered by the Fund.¹²² Although the law also required assessments of the Fund by the HHS Assistant Secretary for Preparedness and Response and the GAO, Congress only required them to do so once. The Fund continues to lack consistent reporting and oversight structures.

Other emergency funding sources (e.g., Commodity Credit Corporation, Disaster Relief Fund, CDC Infectious Diseases Rapid Response Reserve Fund) may also apply should a catastrophic biological event occur, although they can neither replace nor augment appropriations made for other federal departments and agencies. Though Congress has supported the Rapid Response Reserve Fund as the primary avenue for public health emergency response funding in recent years, only the CDC can use it, leaving other HHS responding elements without access to those monies. The Rapid Response Reserve Fund also lacks sufficient funding to fully support CDC or other HHS emergency response activities.¹²³

FEMA previously considered and developed guidelines for pandemic influenza and the possibility of providing assistance to states and territories under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (P.L. 100-707).¹²⁴ However, the Agency determined that such events only qualified for limited Stafford Act assistance. Recognizing the severity of a global pandemic, in March 2020, President Donald J. Trump issued a National Emergency Declaration regarding COVID-19.¹²⁵ The President subsequently issued Emergency and Major Disaster declarations for all states, territories, and 49 federally-recognized tribes to respond to the threat.¹²⁶ The Agency should apply the lessons learned from this experience and make SLTT governments eligible for assistance from the Disaster Relief Fund.

Recommendation 33: Ensure consistent and adequate public health emergency funding and guidance.

ACTION ITEMS:

- a. **Provide robust public health emergency funding.** Congress should (1) amend the Public Health Service Act (P.L. 78-410) to authorize no less than \$10 billion for the Public Health Emergency Fund; (2) appropriate no less than that authorized level for the Public Health Emergency Fund; (3) commit to regular annual appropriations utilizing a consistent methodology and no-year funding for the Public Health Emergency Fund, similar to the funding mechanism for the Disaster Relief Fund; (4) determine eligibility criteria for assistance; (5) establish robust accountability mechanisms; and (6) provide guidance on triggers for use of the Public Health Emergency Fund, which may or may not include a declaration of a public health emergency. The Administration and Congress should consider the input of SLTT recipients when developing these triggers.
- b. **Clarify eligibility for biological disaster assistance under the Stafford Act.** The FEMA Administrator should conduct an after-action assessment of COVID-19 disaster relief activities. Based on this assessment, the Administrator should update and clarify SLTT eligibility for direct federal assistance during declared public health emergencies involving pandemic influenza and other biological agents.

- c. **Delineate federal assistance to non-federal governments for public health emergency response.** The Secretary of Health and Human Services and the FEMA Administrator should apply lessons learned from COVID-19 response and provide (1) a report on the assistance they will offer SLTT during future large-scale biological events; (2) a plan for future coordination; and (3) additional guidance for SLTT officials regarding federal public health emergency response assistance and coordination. In addition to the information regarding federal responsibilities found in the National Response Framework, the Secretary of Health and Human Services and the FEMA Administrator should establish a memorandum of understanding to better define the SLTT assistance they each would provide during large-scale biological events.
- d. **Support urgently needed public health measures for research during biological events.** Congress should amend the Public Health Service Act (P.L. 78-410) to clarify that recipients of funding from the Public Health Emergency Fund can utilize it to fund time-sensitive research about an ongoing biological event that causes a public health emergency. Congress should authorize the use of this funding to investigate, collate, and analyze available information about the biological threat, transmission methods, mitigation measures, long-term mental and physical impacts on infected individuals, inequities in the application of public health measures, and other related issues. Congress should require the Secretary of Health and Human Services to submit a report to Congress regarding any such research funded by the Public Health Emergency Fund within 180 days of utilizing the Fund for any purpose.
- e. **Make emergency public health research eligible for homeland security grant funding.** Congress should amend the Homeland Security Act of 2002 (P.L. 107-296) to make emergency public health research an explicit allowable expense of the State Homeland Security Grant Program and the Urban Area Security Initiative. Such eligible expenses should include time-sensitive research about an ongoing biological event that impacts the health and safety of first responders during a declaration under the Stafford Act (P.L. 100-707) or the declaration of a public health emergency. Congress should require the FEMA Administrator to submit a report to Congress annually regarding any such research conducted using funding from the Program and Initiative.
- f. **Allow emergency waiver authorities for beneficiaries and the uninsured during public health crises.** Congress should amend Section 1135 of the Social Security Act (P.L. 74-271) to direct the Secretary of Health and Human Services to (1) require coverage of unapproved drugs, vaccines, or devices under an Emergency Use Authorization, and other items and services used to treat pandemic disease during a public health emergency; (2) waive patient cost-sharing for vaccines authorized under an Emergency Use Authorization;

and (3) waive the patient cost-sharing of the administration of such vaccines. Congress should allow reimbursements to Part C and Part D plan sponsors for drug, vaccine, device, and administration costs (including costs associated with vaccine counseling) not incorporated in their bids if the estimated cost exceeded 0.1 percent of national average per capita costs. Congress should require the Secretary of Health and Human Services to provide certification and advanced written notice to Congress before exercising this authority.

LABORATORY RESPONSE NETWORKS FOR BIODEFENSE

During a biological event, public health and public safety officials need to identify the organism involved in order to respond effectively and efficiently. Decision-making, disease management, and law enforcement depend on the availability of quick, and geographically close, laboratory testing. Not all laboratories, however, possess the same capabilities. As with hospitals, they lend themselves naturally to stratification and the creation of networks.

Currently, laboratory networks exist that test biological agents and infectious diseases that could affect national security. The CDC worked with the FBI and Association of Public Health Laboratories (APHL) to establish the Laboratory Response Network (LRN) for Bioterrorism in 1999, enabling all states and some localities throughout the Nation to identify biological agents. As the first among national laboratory networks (many of which are still in nascent developmental stages more than 20 years later), the LRN proved its mettle by testing thousands of white powder specimens during the anthrax events of 2001. It continues to test many specimens suspected of containing anthrax, other biological agents, and a variety of dangerous pathogens (e.g., SARS-CoV-2, influenza, MERS-CoV, Ebola, Zika). The Network's laboratories use standardized protocols to provide valid and reliable results to decision makers and discoverable information for legal proceedings.

Despite the remarkable success of the LRN and its partnerships with non-traditional public health agencies (e.g., law enforcement) and private institutions (e.g., clinical laboratories, university laboratories), Congress has yet to authorize the Network. This poses a problem for congressional oversight, especially since several types of laboratories (both public and private sector) comprise the LRN and receive funding from a variety of governmental sources. Dedicated funding for the LRN is also at risk whenever Congress decreases or changes appropriations for the CDC (which provides funding to SLTT health departments via the Public Health Emergency Preparedness Cooperative Agreement), and to the Association of Public Health Laboratories to support the operations and management of the LRN through its own cooperative agreement with the CDC.

Other established laboratory networks are in various stages of development. These include the following: DOD Laboratory Network (funded by DOD), Environmental Response Laboratory Network (funded by EPA), Food Emergency Response Network (funded by USDA and FDA), National Animal Health Laboratory Network (funded by USDA), National Plant Diagnostic Network (funded by USDA), and the Veterinary Laboratory Investigation and Response Network (funded by FDA). Of these, Congress has authorized only the National Animal Health Laboratory Network. Each of these networks organizes differently with varying member laboratories. All stratify to some extent, and all but the DOD Laboratory Network claim some nonfederal governmental laboratories as members. Federal departments and agencies provide varying levels of support to these networks and do not place equal priority on the development of needed laboratory capability and capacity. The resultant patchwork is weak, with insufficient congressional oversight and inadequate appropriations.

During the COVID-19 pandemic, the DOE national laboratories (under the auspices of the National Nuclear Security Administration) mobilized on a national scale to bring together and apply their scientific and technical capabilities during the crisis. With biological science and technology expertise distributed across the 17 national laboratories and the need to unify their efforts against COVID-19, DOE launched the National Virtual Biotechnology Laboratory (NVBL). The NVBL took advantage of DOE user facilities (e.g., light and neutron sources, nanoscale science centers, sequencing and biological characterization facilities, high-performance computer facilities) to address challenges in responding to COVID-19. The NVBL collaborated extensively with researchers, both in academia and industry. The Department also made user facilities widely available.

Learning from the experience of NVBL, the DOE Office of Science established the Biopreparedness Research Virtual Environment (BRaVE) initiative to support and accelerate basic research through a continued collaborative effort among the national laboratories. These labs can help decipher host-pathogen real-time dynamics, study molecular interactions, accelerate design and manufacturing of materials for PPE, and conduct epidemiological modeling of multiscale ecosystems. With additional resources, the national labs could produce new experimental techniques, interventions, and mitigation strategies for biological threats.

Military laboratories also provide the Nation with unique capabilities and resources to defend against biological threats. Part of the US Army Medical Research and Development Command (MRDC), USAMRIID works to protect warfighters from biological threats, and identify and investigate infectious disease outbreaks and other threats to public health. Research conducted by USAMRIID leads to MCM (e.g., vaccines, therapeutics, diagnostics) and information that benefit both military personnel and civilians.

Currently, DOD works to consolidate the bulk of MRDC laboratories within the DHA to improve coordination. The Department also conducts various studies to determine the benefits and drawbacks of consolidating all of its medical and biological research laboratories. Consolidation of laboratories under DHA could help improve coordination and eliminate redundant research efforts but could also deprive individual branches of dedicated laboratory assets that understand the support their unique missions.

Under the current framework for Army laboratories, however, funding for research and funding for laboratory operations and maintenance are misaligned. The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) and DTRA control biological and medical research funding. The Army bears the costs associated with laboratory stewardship (i.e., laboratory infrastructure, operations, maintenance, and personnel). Both DTRA and JPEO-CBRND award contracts to the private sector, but they do not provide adequate funding to the laboratories themselves for stewardship. Entities or individuals who want to fund research at Army laboratories such as USAMRIID often provide overhead to deal with the operating costs of conducting research at the facility. However, the amount of overhead funding given is significantly lower than that provided for academic institutions and can lead to shortfalls in funding for research conducted at these military facilities throughout the fiscal year.

Recommendation 34: Buttress all laboratory networks that test for biological agents.

ACTION ITEMS:

- a. **Authorize all laboratory networks that test for biological agents.** Congress should amend the (1) annual National Defense Authorization Act to authorize the Defense Laboratory Network under the auspices of the DOD; (2) National Environmental Policy Act (P.L. 91-190) to authorize the Environmental Response Laboratory Network under the auspices of the EPA; (3) Agriculture Improvement Act of 2018 (P.L. 115-334) and Federal Food, Drug, and Cosmetic Act (P.L. 75-717) to authorize the Food Emergency Response Network under the auspices of USDA and FDA respectively; (4) Public Health Service Act (P.L. 78-410) to authorize the LRN under the auspices of HHS; (5) Agriculture Improvement Act of 2018 (P.L. 115-334) to authorize the National Plant Diagnostic Network under the auspices of USDA; and (6) Federal Food, Drug, and Cosmetic Act (P.L. 75-717) to authorize the Veterinary Laboratory Investigation and Response Network under the auspices of the FDA. Congress should direct each of these departments and agencies to enter into cooperative agreements, contracts, grants, or other legal instruments with eligible laboratories to formalize these networks. Congress should require those territories with animal health, environmental health, plant health, and public health laboratories to join these networks.

- b. **Establish requirements for all laboratory networks that test for biological agents.** The Secretary of Agriculture, Secretary of Defense, Secretary of Health and Human Services, Administrator of the Environmental Protection Agency, and Commissioner of the Food and Drug Administration, should establish laboratory (1) standards and interoperable data formats; (2) capacity and capability needed to utilize standardized test procedures, reference materials, and equipment; (3) laboratory biosafety and biosecurity jobs and requirements; (4) quality management system requirements; (5) chain-of-custody and other evidentiary requirements as established, communicated, and required by the FBI and other federal agencies; (6) rapid electronic reporting, exchange, and transmission of data; and (7) evaluation requirements for emergency preparedness, detection, response, attribution, and recovery.
- c. **Authorize the national laboratories collaborative initiative for biodefense research in the virtual environment.** Congress should amend the Energy Policy Act of 2005 (P.L. 109-58) to authorize the BRaVE Initiative. Congress should authorize the Initiative to leverage the physical, computational, and life sciences facilities and capabilities of the national laboratories (under the auspices of the National Nuclear Security Administration) to help support preparedness for, and response to, pandemics and other biological threats. The Secretary of Energy should develop and issue guidance to facilitate this access and coordination across the national laboratories.
- d. **Eliminate the risk of accidental release during hazardous biological material transport by constructing and maintaining an incinerator for Fort Detrick, MD.** Congress should amend the National Defense Authorization Act to direct the Secretary of the Army to direct USAMRIID to manage the operations of any incinerator constructed on the Fort Detrick campus for use by military and other federal laboratories resident there. The Secretary of the Army should submit to Congress a proposed plan for the operation of all incinerators at the Fort Detrick campus, and include funding needs for their operations and maintenance in future Presidential Budget Requests. Congress should appropriate funds for ongoing operations of these incinerators at the requested levels, and should require the Secretary of the Army to send annual reports on the construction status of all incinerators at the Fort Detrick campus, as well as a final report detailing the transition of incinerator operations to Fort Detrick and management of incinerator operations to USAMRIID and any contracted entities upon completion of construction.
- e. **Reduce the risk of funding shortfalls at military laboratories that conduct biodefense research.** Congress should amend the National Defense Authorization Act to direct the Secretary of Defense to reduce the risk of funding shortfalls throughout a given fiscal year. The Secretary should (1) provide adequate overhead; and (2) address the misalignment of research funding and laboratory stewardship (i.e., laboratory infrastructure, operations, safety, security maintenance, and personnel).

- f. **Review adequacy of laboratory biosafety and biosecurity standards, practices, and oversight.** The Secretary of Health and Human Services, in partnership with the DOD and DOE, should direct the NSABB to assess (1) the potential for innovation in laboratory biosafety; (2) potential outcomes of those innovations; and (3) current goals for next-generation technology in laboratory biosafety. The Secretary should take no longer than 180 days to complete this assessment.
- g. **Review laboratory biosafety and biosecurity capabilities and challenges.** The Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, should conduct an annual review of laboratory biosafety capabilities and challenges. The Secretaries should direct the Director of the Centers for Disease Control and Prevention to (1) conduct this review in coordination with at least one representative from each BSL-4 laboratory in the country; (2) identify potential innovations and policies to improve laboratory biosafety; (3) articulate ongoing challenges in laboratory biosafety, especially with regard to accident prevention, reporting; and (4) provide a plan for implementing improvements. The Secretary of Health and Human Services should complete the first review within 180 days.

NATIONAL DECONTAMINATION AND REMEDIATION OF THE ENVIRONMENT AFTER BIOLOGICAL EVENTS

After a biological crisis ends, reduction and elimination of pathogens in areas contaminated with organisms require long-term environmental monitoring in order to avoid further illness, re-exposure, and the development of pathogen reservoirs. While some long-term health monitoring occurs (e.g., those exposed to contaminants during September 11, 2001, response and recovery operations are monitored), the government did not offer those exposed (and possibly exposed) to anthrax in 2001 the opportunity to participate in similar studies. If any low-level immunological responses to anthrax occurred, they were likely missed because no one was looking for them. The DOD monitors some military personnel exposed to a variety of contaminants. Other agencies (e.g., USDA, DOI, HHS) also monitor personnel exposed to pathogens during the course of their work, but only when the need seems dire. Exposed individuals deserve better.

Monitoring the environment for contamination is similarly deficient. The EPA often inspects areas contaminated by the accidental release of biological agents and those affected often ask the agency to conduct environmental decontamination and remediation following these events. The EPA uses a lengthy process to determine whether it should take responsibility for remediating an environment contaminated with biological agents. The Agency's history of holding companies responsible for having released contaminants into the environment (e.g., Superfund activities) does not transfer

well to addressing the impacts of biological releases that can spread far from initial impact sites (if those sites can even be identified). The EPA sometimes decides it should not remediate an area itself, opting instead for others (e.g., non-federal governmental agencies, academia, industry) to do so. Those areas remain contaminated and unsafe during the time it takes to make such a decision and remediate.

EPA statutory authority also needs clarification. The 2017 Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans developed by FEMA designates the EPA as the lead federal entity for environmental cleanup and remediation following a biological event.¹²⁷ The 2022 National Biodefense Strategy and Implementation Plan also lists the EPA as the lead federal entity for developing a “national environmental countermeasures capability to enable rapid containment and remediation of environmental contamination.”¹²⁸ Unfortunately, the process for executing this responsibility remains unclear and ill-defined, plans and responsibilities remain untested by real world events, and duties lack congressional authorization.

Recommendation 35: Increase national environmental decontamination and remediation capacity.

ACTION ITEMS:

- a. **Make the Environmental Protection Agency responsible for environmental decontamination and remediation after biological incidents.** Congress should amend the National Environmental Policy Act of 1969 (P.L. 91-190) to place the Administrator of the Environmental Protection Agency in charge of environmental decontamination and remediation after accidental releases of organisms (from facilities that house them) and biological attacks.¹²⁹ Congress should also direct the Agency, in accordance with the *National Biodefense Strategy and Implementation Plan*, to develop (1) national environmental countermeasures capability; and (2) strategy and implementation plan for the environmental remediation responsibilities assigned to it. The agency should assume operational responsibility and coordinate with other agencies, nonfederal governments, academia, and private sector organizations for environmental decontamination and remediation after accidental releases and biological attacks.
- b. **Exercise environmental remediation plans.** The Administrator of FEMA should regularly exercise the *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* with the EPA and HHS regarding environmental remediation and include the DOI to prevent or control the establishment of new wildlife reservoirs of disease agents introduced into the United States.

- c. **Conduct studies of those exposed to biological agents.** The Secretary of State, Secretary of Agriculture, Secretary of Defense, Secretary of Energy, Secretary of Health and Human Services, Secretary of Homeland Security, Secretary of the Interior, Secretary of Veterans Affairs, Attorney General, and Administrator of EPA, Administrator of the General Services Administration, Administrator of NASA, Director of National Intelligence, and Postmaster General should (1) monitor those that come under their purview (including the public where applicable) when they have, or could have, been exposed during or as a result of natural occurrences, accidental releases, or biological attacks; (2) lead studies analyzing long-term effects on those exposed; and (3) coordinate research with the private sector. They should conduct longitudinal prospective and retrospective studies of those exposed to anthrax on Capitol Hill and elsewhere during the events of 2001, and prospective studies of those suffering from long COVID, and other pathogens (including novel biological agents) known or suspected to cause long-term impacts on health.

GLOBAL PUBLIC HEALTH RESPONSE TO BIOLOGICAL EVENTS

Our Nation cannot afford to ignore global public health security concerns. As the world experienced with COVID-19, an emerging infectious disease in one location (China in that case) poses an existential threat to the entire world. The fragility of the human-animal disease boundary is more pronounced in developing nations where resources, public health, and animal health infrastructure are particularly limited. Urban areas become nucleation points for infectious disease risk as their populations grow. The United States must proactively engage with other countries and international bodies to strengthen our collective public health response capabilities.

Multilateral bodies like the World Health Organization (WHO) and World Organization for Animal Health (WOAH) support the development of in-country activities and capabilities to (1) meet international standards for disease control and reporting; (2) prevent cross-border spread of disease; and (3) reduce the risk of accidental and intentional biological threats. However, response capacity does not come from WHO, it comes from nations who agree to make it a priority. As a voting member of and major donor to both WHO and WOAH, and as a resource-rich nation with enormous public health expertise, the United States should be a major player in these efforts.

Through the Global Health Security Agenda (GHSA), the United States and its international partners collaborate to reduce biological risk and promote global health security. Launched in 2014 and currently composed of 70 countries, as well as international organizations, non-government organizations, and private sector

companies, the GHSA works to prevent, detect, and respond to global public health security threats. US activities include establishing emergency operations centers, strengthening laboratory biosecurity in developing nations, partnering with international health authorities to rapidly detect and manage animal diseases, and implementing and strengthening the International Health Regulations and WOAHA reporting.

The US government's commitment to the GHSA still lacks congressional authorization and dedicated appropriation. Without authorization, the program cannot ensure long-term engagement and runs the risk of discontinuation if not included in the President's Budget Request.

The United States should harness its considerable diplomatic influence to forge the development of a response system with partner nations and the private sector that can meet the need for public health preparedness and rapid response. The Department of State must prioritize global health diplomacy and work with the international community to develop a multilateral Global Public Health Response Strategy and implementation plan. The USAID Office of Foreign Disaster Assistance (OFDA) must plan, and determine how, to provide assistance, training, and resources to their Disaster Assistance Response Teams (DART) to respond to escalating biological events.

Established in 1933, the Commodity Credit Corporation serves as a powerful tool that USDA utilizes to stabilize, support, and protect agriculture income and prices. The Department relies on the Corporation and its \$30 billion in borrowing authority to respond to agricultural emergencies, including biological events and outbreaks of infectious diseases like Highly Pathogenic Avian Influenza. However, current statute restricts USDA from borrowing funding through the Corporation to support animal and plant health activities outside of the United States. As many animal pathogens with pandemic potential—including avian influenza and African Swine Fever—originate abroad, such limitations on the main source of government funding to address animal disease threats hinders national biodefense.

Recommendation 36: Lead the establishment of a functional and agile global public health emergency response apparatus.

ACTION ITEMS:

- a. **Sustain US contributions to international global health security and security-related programs.** The Administration and Congress must sustain US financial commitments to international programs that contribute to global health security and federal implementing bodies like USDA, DOD, DOS, CDC, and USAID. The Administration and Congress must also support international institutions such as WHO, WOA, and World Bank, as well as public-private partnerships like the Coalition for Epidemic Preparedness Innovations.
- b. **Develop a global public health response strategy for biological events.** The Secretary of State should (1) convene human, animal, food, plant, and environmental health leaders from throughout the world every four years to evaluate current mechanisms and develop a strategy and implementation plan for global public health response to biological events; and (2) establish bilateral, multilateral, and other agreements needed to help execute this strategy.
- c. **Strengthen the role of the Office of Foreign Disaster Assistance.** Congress should amend the Foreign Assistance Act of 1961 (P.L. 87-195) to direct the Secretary of State to develop a strategy to strengthen the role of OFDA during biological events. The strategy should describe (1) responsibilities of the office during a biological event; (2) protocols for Disaster Assistance Response Teams; (3) how to work with local officials, the international community, and relief and humanitarian assistance agencies; (4) needed stocks of emergency supplies for response to biological events and logistical and operational capabilities to deliver them quickly; and (5) how the Office will ensure equitable distribution and access to these supplies.
- d. **Allow use of Commodity Credit Corporation funding to protect against global biological threats to food and agriculture.** Congress should amend the Commodity Credit Corporation Charter Act (15 U.S.C. 714) to direct the Secretary of Agriculture to utilize the borrowing authority of the Commodity Credit Corporation for animal and plant health activities outside of the United States on a limited basis if the USDA can demonstrate these activities will immediately and directly protect US food and agriculture from African Swine Fever, Foot and Mouth Disease, Bovine Spongiform Encephalitis, and other biological threats. The Secretary of Agriculture should coordinate with the Administrator of the US Agency for International Development and other federal departments and agencies in executing these authorized animal and plant health activities. Congress should direct the Secretary of Agriculture to report annually about the use of the Commodity Credit Corporation to protect US food and agriculture from international biological threats.

CONCLUSION

The 2024 *National Blueprint for Biodefense* contains 37 recommendations and 186 associated action items. Some readers may feel that there are too many...others will insist that there are not enough. We included those we thought most important at this time, while recognizing there are always more recommendations to make.

While this *Blueprint* contains many recommendations and action items, it is not a comprehensive overview of all the challenges to biodefense we need to address. There are other important topics that require additional examination and analysis for the Commission to develop thoughtful and actionable recommendations. For example, public trust is paramount to biodefense but remains a challenging topic to address and requires thorough analysis. Additional complex topics include the biodefense aspects of immigration, climate change, effective communications, and future risks on the horizon that have yet to materialize. We still have more work to do.

The world stands in a partial state of vigilance, reeling from COVID-19, struggling with Mpox, fighting malaria and other seemingly old diseases, discovering new emerging diseases only after illnesses occur, and acknowledging the possibility of biological terrorism and warfare, while simultaneously wanting nothing more than to rest as a result. While there is no rest for the weary in this arena, there is hope. By implementing this *National Blueprint for Biodefense*, America can once again rise to the challenge and save lives. It's not over.

APPENDIX A:

ACRONYMS

ADM	Advanced development and manufacturing
AI	Artificial Intelligence
ASPR	Administration for Strategic Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
BRaVE	Biopreparedness Research Virtual Environment
BSL-4	Biosafety Level Four
BWC	Biological and Toxin Weapons Convention
CDC	The Centers for Disease Control and Prevention
CIA	Central Intelligence Agency
CISA	Critical Infrastructure Security and Resilience
CMS	Centers for Medicare and Medicaid Services
CWC	Chemical Weapons Convention
DARPA	Defense Advanced Research Projects Agency
DHS	Department of Homeland Security
DOD	Department of Defense
DOE	Department of Energy
DOEd	Department of Education
DOI	Department of the Interior
DOS	Department of State
DPC	Domestic Policy Council
DTRA	Defense Threat Reduction Agency
DURC	Dual-Use Research of Concern
EMS	Emergency Medical Services
EPA	Environmental Protection Agency
ePPP	enhanced potential pandemic pathogens
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FRN	Federal Register Notice
FSAP	Federal Select Agent Program
GAO	Government Accountability Office
GHSA	Global Health Security Agenda
GPRA	Government Performance and Results Act
HHS	Department of Health and Human Services

HSC	Homeland Security Council
ISIL	Islamic State of Iraq and the Levant
JPEO-CBRND	Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense
LRN	Laboratory Response Network
MCM	Medical Countermeasures
MRDC	Medical Research and Development Command
NASA	National Aeronautics and Space Administration
NBACC	National Biodefense Analysis and Countermeasures Center
NBFAC	National Bioforensic Analysis Center
NEC	National Economic Council
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NSABB	National Science Advisory Board for Biosecurity
NSC	National Security Council
NSF	National Science Foundation
NVBL	National Virtual Biotechnology Laboratory
NVS	National Veterinary Stockpile
OFDA	Office of Foreign Disaster Assistance
OMB	Office of Management and Budget
OPPRP	Office of Pandemic Preparedness and Response Policy
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
OVP	Office of the Vice President
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHEP	Public Health and Emergency Preparedness
PPE	Personal Protective Equipment
RADx	Rapid Acceleration of Diagnostics
SLTT	States, Localities, Tribes, and Territories
SNS	Strategic National Stockpile
USAID	United States Agency for International Development
USAMRIID	United States Army Medical Research Institute of Infectious Diseases
USDA	United States Department of Agriculture
USPHS	United States Public Health Service
USPIS	United States Postal Inspection Service
WHO	World Health Organization
WMD	Weapons of Mass Destruction
WOAH	World Organization for Animal Health

APPENDIX B: METHODOLOGY

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

RESEARCH QUESTIONS

To address the gaps in the biodefense enterprise and the biodefense body of knowledge, the Commission developed the following research questions:

1. Are US priorities correct?
2. Are US investments commensurate with the challenge?
3. Can the US benefit by rebalancing investments or is new funding required?
4. What has the US done that has brought a significant return on investment?
5. What else should the US be doing that we are not?

PRELIMINARY RESEARCH

The Commission reviewed previous research efforts; scientific studies; reports by congressional and presidential commissions; presidential directives; statute and proposed legislation; GAO reports; and federal strategies, plans, budgets, organizational constructs, and programs related to defense against 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; 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.

FORMAL COMMISSION MEETINGS

Along with twenty nine other formal meetings, the Commission held four specific meetings to inform this report. These meetings focused on the activities that comprise biodefense: threat awareness, prevention, deterrence, preparedness, detection and surveillance, response, attribution, recovery, and mitigation. During each of these day-long meetings, Commissioners, ex officio members, and staff received 1) information regarding current relevant national policy, legislative issues, and governmental activities; and 2) statements from current and former

Members of Congress; current and former federal officials; state, local, tribal, and territorial representatives; thought leaders, and subject matter experts. Commission staff summarized and analyzed major insights, areas for improvement, and recommendations articulated by meeting speakers, and conducted preliminary high-level analysis of each day-long meeting.

INTERVIEWS OF EXPERTS

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

ANALYSIS

The Commission used qualitative methods to analyze this information. Staff examined the oral and written statements provided by meeting speakers. Staff further evaluated each finding and recommendation by various means, including additional policy research and interviews with subject matter experts and former high-level officials. Throughout the process, the five questions defined previously provided the basis for assessment. This approach allowed the Commission, ex officio members, and staff to identify continuing organizational, legal, policy, and programmatic issues, and recommend specific solutions. The Commission did not use statistical or other quantitative methods.

STUDY LIMITATIONS

A number of biodefense programs and policies; intelligence, raw data, and documents; appropriations and budget documents; and other sensitive pieces of information are sensitive, classified, or otherwise unavailable.

CONTENT UNCLASSIFIED

No classified information is discussed in this report. 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.

APPENDIX C: PUBLIC MEETINGS AND SPEAKERS

Since its inception in 2014, the Commission has held 33 public meetings to inform our reports and activities. These meetings focused on the activities that comprise biodefense: threat awareness, prevention, deterrence, preparedness, detection and surveillance, response, attribution, recovery, and mitigation.

- **Threat Awareness (December 4, 2014)**
Potential risks and opportunities to address vulnerabilities posed by biological threats that can inflict potentially catastrophic consequences.
- **Prevention & Protection (January 14, 2015)**
National efforts to prevent and protect against biological threats.
- **Surveillance & Detection (March 12, 2015)**
Requirements for effective surveillance and detection of biological threats that can inflict potentially catastrophic consequences.
- **Response & Recovery (April 1, 2015)**
Biodefense requirements for effective preparedness, response and recovery from biological threats that can inflict potentially catastrophic consequences.
- **Agrodefense: Challenges and Solutions (January 26, 2017)**
Agricultural threats, as well as agro-biodefense requirements, key issues and questions concerning the current state of biodefense, and the extent to which it includes agrodefense.
- **Budget Reform for Biodefense: Leadership and Coordination (May 1, 2017)**
Leadership, interagency coordination, and risk challenges to biodefense budgeting.
- **Attribution of Biological Crime, Terrorism, and Warfare: Challenges and Solutions (October 3, 2017)**
Ability of the United States to (1) identify pathogens and their sources correctly; (2) attribute biological crimes, terrorism, proliferation, and warfare to their perpetrators, using scientific and other forms of evidence and information; and (3) explore the processes used for investigative, legal, policy, and political decisions involving biological attribution.

- **National Biodefense Strategy: Implementation and Implications (November 2, 2017)**

Implementation of the National Biodefense Strategy and its implications for the Office of Management and Budget, congressional authorization and appropriation, leadership, coordination, collaboration, and innovation.

- **SLTT Ability to Respond to Large Scale Biological Events: Challenges and Solutions (January 17, 2018)**

Ability of the state, local, tribal, and territorial governments to (1) respond to large-scale biological events; (2) identify and utilize state, local, tribal, and territorial assets and resources for immediate response (prior to a declaration of a state, local, tribal, and territorial biological emergency or disaster; (3) operate before federal assistance arrives and after federal resources are exhausted; and (4) shift to population management when a biological event overcomes pre-hospital and hospital response protocols.

- **Transnational Biological Threats and Global Security (April 25, 2018)**

Current transnational biological threats and global security and global health security efforts to combat them.

- **The Cost of Resilience: Impact of Large-Scale Biological Events on Business, Finance, and the Economy (July 31, 2018)**

Private sector views on (1) financial impacts of large-scale biological incidents; (2) public-private partnerships and collaboration in advance of such incidents; and (3) what/how the private sector can contribute to biodefense, especially before federal assets are mobilized and after federal resources are exhausted.

- **Fits and Starts: Reactionary Biodefense (October 9, 2018)**

How far the Nation has come in addressing biological threats and how much work remains.

- **Biodefense Indicators: Progress in Implementing Key Elements of the National Blueprint for Biodefense (November 14, 2018)**

How far the Executive Branch has come in implementing the National Blueprint for Biodefense.

- **Fighting the Next War: Defense Against Biological Weapons (February 5, 2019)**

Department of Defense concerns about biological weapons, and Department responsibilities and requirements for biodefense.

- **A Manhattan Project for Biodefense: Taking Biological Threats Off the Table (July 11, 2019)**

How best to create a national, public-private research and development undertaking to defend the United States against biological threats.

- **Cyberbio Convergence: Characterizing the Multiplicative Threat (September 17, 2019)**

The convergence of cyber- and biological sciences; the vulnerability of pathogen and biomanufacturing data systems; biological risk mitigation; and the vulnerability of intellectual property and the national and global bioeconomy.

- **Too Great a Thing to Leave Undone: Defense of Agriculture (November 5, 2019)**

Catastrophic biological risks to all components of agriculture; innovative leadership to address these risks; land grant university contributions to national security; public-private partnerships for agrodefense; and challenges to agricultural surveillance, detection, response, and recovery across all levels of government and throughout the private sector.

- **COVID-19: Forewarned, But Not Forearmed (May 8, 2020)**

Ongoing response to novel coronavirus 2019, national readiness to address large-scale spread of the disease in the United States and throughout the world, and implications for strengthening our defense against the next, inevitable, biological threat.

- **COVID Complexities: Converging Threats, Fractured Resources (July 21, 2020)**

Potential for COVID-19's reemergence, the country's efforts to track the spread of the disease, and national readiness to address future biological threats.

- **The Biological Event Horizon: No Return or Total Resilience (September 24, 2020)**

Emerging biological threats and innovative technology for biodefense.

- **A Nation Unprepared: Incomplete Implementation of the National Blueprint for Biodefense (November 30, 2020)**

Federal efforts to enhance national biodefense since the 2015 release of the National Blueprint for Biodefense.

- **Holding the Line on Biodefense: Supporting First Response to Large-Scale Biological Events (March 23, 2021)**

Needs for first responders when addressing large scale biological incidents.

- **Biologia et Machina: Cyberbiosecurity for Today's Hybrid Evolution (June 22, 2021)**

Cyberbiosecurity threats, vulnerabilities, and consequences; opportunities, and solutions arising as the cyber- and biological sciences converge; and the role of the government in safeguarding against current and future cyberbiosecurity threats.

- **Saving Sisyphus: Course Corrections for National Biodetection (November 2, 2021)**

Federal efforts to develop, acquire or otherwise secure proven, effective technology for a nationwide biodetection system; public and private advancements in environmental biodetection technology; and mission requirements for 21st Century biodetection capabilities.

- **The Athena Agenda: Executing The Apollo Program for Biodefense (December 8, 2021)**

Ongoing federal efforts to implement *The Apollo Program for Biodefense*; the role of the private sector in implementing *The Apollo Program for Biodefense*; and how the public and private sectors can fully implement *The Apollo Program for Biodefense* by the end of the decade.

- **The Biological Threat Expanse: Current and Future Challenges to National Biodefense (March 22, 2022)**

The expanding landscape of current and future biological threats; the roles and responsibilities of the federal government in addressing various biological threats; and biological weapons, terrorism, and arms races.

- **When Borders Don't Matter: Defending the Homeland Against Biological Threats (March 22, 2022)**

Biological incidents that affect homeland and national security; roles and responsibilities of the Department of Homeland Security in addressing biological threats; and opportunities to enhance national biodefense.

- **Banding Together: Partnerships for Biodefense (September 22, 2022)**

Recent White House biodefense activities and the value the White House places on partnerships for biodefense; the Congressional perspective on what partnerships are important for biodefense; and how innovative partnerships between the federal government and industry, academia, and nongovernmental organizations contribute to technological defense against biological threats.

- **Afterthoughts: Response, Recovery and Mitigation of Biological Events (December 8, 2022)**

Improvements needed for the national response to biological threats; implications for recovery from largescale biological events like the COVID-19 pandemic; and how the nation can build resilience and mitigate future biological threats.

- **Informing Blueprint 2.0: Please, Look Up! (March 21, 2023)**

National preparedness needs and efforts; biosurveillance solutions; and real-time data capture and analysis improvements. This is the third Commission meeting to inform our refresh of the *National Blueprint for Biodefense*.

- **Informing Blueprint 2.0: Know the Enemy (May 9, 2023)**

Prevention; deterrence; and attribution of biological threats. This is the fourth Commission meeting to inform our refresh of the *National Blueprint for Biodefense*.

- **Solving the Puzzle: Biological Intelligence and Information Sharing (July 27, 2023)**

The expanding nature of the biological threat; the federal biological intelligence enterprise; and information sharing with non-federal governments.

- **No Checkered Flag: The Perpetual Race Against Biological Threats (September 27, 2023)**

State and local efforts to strengthen public health and biodefense; special security management of biological threats to mass gatherings; and efforts to understand and mitigate the agricultural impact of biological threats to plants and animals.

- **Meeting the Moment: Biodefense Policy, Procurement, and Public Health (December 5, 2023)**

Biodefense policies and activities at the Department of Defense; federal stockpile evaluation and decision-making for smallpox medical countermeasures; and biodefense leadership and needed authorities of the Department of Health and Human Services, including the Centers for Disease Control and Prevention.

SPEAKERS

Elected Officials

- Governor Eric Holcomb (R-IN)
- Senator Lamar Alexander (R-TN)
- Senator Richard Burr (R-NC)
- Senator Robert P. Casey Jr. (D-PA)
- Senator Ron Johnson (R-WI)
- Senator Sheldon Whitehouse (D-RI)
- Representative Susan Brooks (R-IN)
- Representative Tom Cole (R-OK)
- Representative Jason Crow (D-CO)
- Representative Andy Harris (R-MD)
- Representative Chrissy Houlahan (D-PA)
- Representative James Langevin (D-RI)
- Representative Roger Marshall (R-KS)
- Representative Joe Neguse (D-CO)
- Representative Dutch Ruppersberger (D-MD)
- Representative Donna Shalala (D-FL)
- Representative David Trone (D-MD)

Keynotes

- The Honorable Tom Bossert
- Max Brooks
- The Honorable Richard Danzig
- Peter Daszak, PhD
- Anthony S. Fauci, MD
- Sheri Fink, MD, PhD
- Julio Frenk, MD, PhD, MPH
- Paul Friedrichs, MD
- The Honorable Andrea Hall
- Paul S. Keim, PhD
- Eric S. Lander, DPhil
- Jason G. Matheny, PhD
- Tim Morrison, JD
- The Honorable Andrew S. Natsios
- Michael T. Osterholm, PhD, MPH
- The Honorable Rajesh R. Panjabi
- Former Representative Mike J. Rogers (R-MI)
- The Honorable Deborah G. Rosenblum
- Richard Serino
- Former Senator James M. Talent (R-MO)
- Governor Thomas J. Vilsack
- The Honorable Kenneth L. Wainstein
- The Honorable Tim Ziemer
(Rear Admiral, US Navy – Retired)
- Howard A. Zucker, MD

Experts

- Labeeb Abboud, JD
- Daniel J. Abdun-Nabi, JD
- Yonah Alexander, PhD
- Donald Alway, MS
- Douglas L. Anders, PhD
- John Ball
- Gilda Barabino, PhD
- Cherie Bartram, MA
- Bruce Batten, PhD
- Ann M. Beauchesne
- Tammy R. Beckham, DVM
- Casey Barton Behraves, DVM, DrPH
(Captain, US Public Health Service)
- Paul Benda, MS
- Shumeane L. Benford, MA
- Kavita M. Berger, PhD
- Alison Berke, PhD
- Kenneth Bernard, MD, (Rear Admiral,
US Public Health Service – Retired)
- Thierry Bernard, MS
- Blake Bextine, PhD, MA
- Henrik Birk, MBA
- Jason Blumenauer, MBA
- Luciana Borio, MD
- Kristina Box, MD
- The Honorable Reginald Brothers
- Rob Brown, MA
- Sergeant Robert Brown Jr.
- G. Keith Bryant
- William T. “Thom” Burnett, MD
(Colonel, US Army Reserves)
- Joshua Bushweller
- Charles “Chuck” Call, PhD
- Virginia A. Caine, MD
- Elizabeth E. Cameron, PhD
- Andrew C. Cannons, PhD
- Hillary Carter, PhD
- W. Seth Carus, PhD
- Mike Casey, PhD
- Tory Castor, JD
- Paul Chaplin, PhD
- Mike Chervenik, MBA
- Jane Christopher-Hennings, DVM, MS
- May Chu, PhD
- Cornelius J. Clancy, MD
- John M. Clerici, JD
- Nancy D. Connell, PhD
- Joe Coomer
- Maria Croyle, RPh, PhD
- Paul Dean, JD
- Ann DeGroot, MD
- Amy Delgado, PhD, DVM, MS
- Dan Desmond
- Malick Diara, MD, MBA, MPH
- Dan Didier, MD, PhD
- Diane DiEuliis, PhD
- James Diggans, PhD
- Scott F. Dowell, MD, MPH
- Nicolas Dunaway
- Susan E. Duncan, PhD
- Paul Ebner, PhD
- Peter Edge, MPA
- Esther Ellis, PhD
- Alan Embry, PhD
- Kevin English, PhD
- Kevin M. Esvelt, PhD
- Patricia Falcone, PhD
- Special Agent Casey P. Farrell
- Julie E. Fischer, PhD

- Charles Fracchia, MS
- Philip Francisco
- David R. Franz, DVM, PhD,
(Colonel, US Army – Retired)
- Michael Fraser, PhD
- Dia Gainor, MPA
- Bruce Gellin, MD, MPH
- Michael Gemelli
- Nicholas Generous, MS, MPH
- Julie L. Gerberding, MD, MPH
- Daniel M. Gerstein, PhD, MS, MMAS,
MSOR (Colonel, US Army – Retired)
- Kathryn Godfrey
- Tracy Goldstein, PhD
- Lisa E. Gordon-Hagerty, MPH
- J. Nadine Gracia, MD, MSCE
- Laura J. Gross
- The Honorable Stephen M. Hahn
- Dan Hanfling, MD
- John M. Hardham, PhD
- Brooke Harmon, PhD
- Kevin C. Harriger
- Terrell Harris, JD
- Judith Harrison
- D. Christian Hassell, PhD
- Joseph M. Henderson, MPA
- Jack Herrmann, MSED
- Melissa Hersh, PhD
- Tina Batra Hershey, JD, MPH
- Stephen Higgs, PhD
- Alice C. Hill, JD
- Brey Hopkins (Colonel, US Army)
- Michael Hopmeier, MS
- Corey Hudson, PhD
- D. Charles Hunt, MPH
- Alexander P. Isakov, MD, MPH
- Dean Jamison, PhD
- Franca R. Jones, PhD, MS
- William Jones
- The Honorable Robert P. Kadlec
- Norm Kahn, PhD
- Daniel Kaniewski, PhD, MA
- William B. Karesh, DVM
- Lawrence D. Kerr, PhD
- Ali S. Khan, MD, MPH
- Amy Kircher, PhD
- Ron Klain, JD
- Gregory D. Koblentz, PhD
- Kristin Korte, MS
- Akhila Kosaraju, MD
- Thomas G. Ksiazek, DVM, PhD
- Sergeant Mark R. Landahl, PhD
- Randy Larsen (Colonel, US Air Force
– Retired)
- James Lawler, MD, MPH (Commander,
US Navy – Retired)
- Jennifer Layden, MD, PhD
- Lee Leachman
- Kelly F. Lechtenberg, DVM, PhD
- Kelvin H. Lee, PhD
- Jeffrey Levi, PhD
- Rachel Levinson, MA
- Scott R. Lillibridge, MD
- Geoffrey Ling, MD, PhD
- Marc Lipsitch, PhD
- Nicolette A. Louissaint, PhD
- Timothy Lu, MD, PhD
- Daniel Lucey, MD, MPH
- Kenneth N. Luongo, MA
- Syra Madad, DHSc
- Nita Madhav, MSPH
- Alexis Madrigal

- The Honorable Curt J. Mann
- Monique K. Mansoura, PhD, MBA
- Lou Marciani, PhD, Director, National Center for Spectator Sports Safety and Security, University of Southern Mississippi
- David E. Marcozzi, MD
- Bret D. Marsh, DVM
- Derek (Dirk) Maurer, JD (US Marine Corps Reserves – Retired)
- Marina Mayo
- Jackie McClaskey, PhD
- The Honorable Mark McClellan
- James F. McDonnell, MA
- Duncan E. McGill, PhD (Lieutenant Colonel, US Army – Retired)
- Suzet McKinney, DrPH
- Carter Mecher, MD
- Janine Medina, MSc
- Bruce E. Miller, OE, MS
- Kathryn Millett, Director, Biosecu.re
- Piers Millett, PhD
- Warren Mino, PhD
- Matthew Minson, MD
- David Mitchell
- Prasant Mohapatra, PhD
- The Honorable Michael Moodie
- Beth Maldin Morgenthau, MPH
- Jared Moskowitz, JD
- Harshini Mukundan, PhD
- Colin Mulloy
- Randall S. Murch, PhD
- Jimmy Mynatt, AAE
- The Honorable Ali Nouri
- John O’Connell
- The Honorable Dawn O’Connell
- Linda Rouse O’Neill, MLA
- The Honorable Tara O’Toole
- Vayl Oxford, MS
- Gerald W. Parker Jr., DVM, PhD
- Steve Parker, MBA, MSCM
- Christine Parthemore, MA
- Sandeep Patel, PhD
- Eléonore Pauwels
- Denise Pettit, PhD
- Eric Pevzner, PhD
- Celeste Philip, MD, MPH
- Jude Plessas
- Robert S. Pope, PhD
- Elizabeth Posillico, PhD
- George Poste, DVM, PhD, DSci
- Connie Savor Price, MD
- Sohini Ramachandran, PhD
- Jay Rappaport, PhD
- William F. Raub, PhD
- Jeff Reczek, MPA
- Stephen C. Redd, MD (Rear Admiral, US Public Health Service – Retired)
- Irwin Redlener, MD
- Kathleen Reilly (Chief, US Navy – Retired)
- Robin Robinson, PhD
- James Robinson
- Chris Rodriguez, PhD
- Keith A. Roehr, DVM
- Robert J. Roller
- Peter J. Roman, PhD
- Jason W. Roos, PhD
- Deborah Rosenblum, MA
- Sara Roszak, MPH
- Brittney M. Roy
- Alan Rudolph, PhD, MBA
- The Honorable Jeffrey W. Runge

- Justin Sanchez, PhD, ME
- Mauricio Santillana, PhD
- Brent C. Satterfield, PhD
- Sterling Sawaya, PhD
- Abel J. Schall
- Jeff Schlegelmilch, MPH, MBA
- Debra D. Schnelle, MS (Lieutenant Colonel, US Army – Retired)
- Anne Schuchat, MD (Rear Admiral, US Public Health Service – Retired)
- Caroline Schuerger, PhD
- Suzanne Schwartz, MD, MBA
- Mike Sena
- Umair A. Shah, MD, PhD
- Erica S. Shenoy, MD, PhD
- Anup Singh, PhD
- Stu Solomon
- James P. Stack, PhD
- Ken Staley, MD
- David Starr
- Tim Stephens
- David Stoltzfus, MBA
- Jennifer Stone, MA
- Michael A. Stoto, PhD
- Ren Sun, PhD
- Jacob L. Swett
- Terrance Taylor (Colonel, British Army – Retired)
- Darcy E. P. Telenko, PhD
- James Terbush, MD, MPH
- Deydre S. Teyhen, PhD, DPT, OCS (Colonel, US Army)
- The Honorable Tevi D. Troy, President
- Julia Vaizer, MD
- Eric Van Geison, PhD
- The Honorable W. Craig Vanderwagen
- Robert VanDine
- Brandi C. Vann, PhD
- Jay K. Varma, MD
- The Honorable Rajeev Venkayya
- Bryan S. Ware
- Ian Watson, MS, MA
- Dan Wattendorf, MD
- The Honorable Andrew Weber
- Keith H. Wells, PhD
- Todd Wiemers (Rear Admiral, US Coast Guard)
- Brian Wiley
- Paul Williams
- Michelle Woods, MPA
- Robert Wyllie, MD
- Jaime Yassif, PhD
- Edward H. You, MS
- David Zambrana, PhDc, DNP
- Scott J. Zimmerman, DrPH

ENDNOTES

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³ 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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¹⁰ For example, Russia buried an estimated 100-200 tons of weaponized anthrax 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*. Retrieved from: <https://www.ph.ucla.edu/epi/bioter/anthraxburied.html>.

¹¹ 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.

¹² 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.

¹³ J. Gordon & J. Bellamy van Aalst. (2013). The Dangers of Syria's Bio-Warfare Complex Should Assad Fall: An Interview with Dr. Jill Bellamy van Aalst. *Israel Behind the News*. Retrieved from: <https://israelbehindthenews.com/2013/01/11/the-dangers-of-syriaes-bio-warfare-complex-should-assad-fall-an-interview-with-dr-jill-bellamy-van-aalst-2/>.

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¹⁷ 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.

¹⁸ Alexander, Y. & Swetnam, M. (2012). Al-Qa'ida: Ten Years After 9/11 and Beyond. Arlington, VA: Potomac Institute for Policy Studies.

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²⁰ 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, US citizens who sympathize with ISIL and likeminded groups may present an equal or even greater danger than terrorist groups.

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- ²⁹ 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.
- ³⁰ 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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- ⁹⁶ World Organisation for Animal Health. (2023). Chapter 1.1.10. Vaccine Banks. Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, twelfth edition 2023. World Organisation for Animal Health. Retrieved from: <https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-manual-online-access/>.
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- ¹⁰⁴ The DOI Bureau of Indian Education (BIE) funds 183 elementary and secondary schools and residential programs on 64 reservations in 23 states; supports 126 tribally administered BIE-funded schools, 27 tribal colleges and universities, and 2 technical colleges; "BIE is responsible for ensuring the implementation of federal education laws, including the No Child Left Behind Act, in 183 BIE-funded elementary and secondary schools and residential programs on 64 reservations in 23 states, provides resources and technical assistance to 126 tribally administered BIE-funded schools, 27 tribal colleges and universities, and 2 technical colleges. For more information, see: <https://www.bie.edu>.
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- ¹¹⁶ Colorado State University. "Coalition for Epi Response, Engagement and Science." Retrieved from: <https://www.research.colostate.edu/ceres-agricultural-biosecurity/>.
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¹²² Section 206, Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22).

¹²³ Though Congress appropriated more than \$600 million for the CDC Infectious Diseases Rapid Response Reserve Fund at the beginning of the COVID-19 pandemic, most annual appropriations for the Fund since 2019 have been less than \$200 million, far short of HHS needs to respond to biological threats.

¹²⁴ Disaster Assistance Directorate, Federal Emergency Management Agency. (2009). Fact Sheet 9580.106: Pandemic Influenza. Washington, DC: Federal Emergency Management Agency. Retrieved from: https://www.fema.gov/pdf/emergency/pandemic_influenza_fact_sheet.pdf; Disaster Assistance Directorate, Federal Emergency Management Agency. (2009). Disaster Assistance Policy (DAP9523.17). Washington, DC: Federal Emergency Management Agency. See: <https://www.hsd.org/?view&did=13921>; Disaster Assistance Directorate, Federal Emergency Management Agency. (2009). Fact Sheet 9580.105: H1N1 Influenza Frequently Asked Questions (FAQs). Washington, DC: Federal Emergency Management Agency. See: https://www.fema.gov/media-library-data/20130726-1824-25045-5518/h1n1_influenza_frequently_asked_questions_faqs_.pdf; and Office of Response and Recovery, Federal Emergency Management Agency. (2016). Fact Sheet FP 104-009- 001: Infectious Disease Event. Washington, DC: Federal Emergency Management Agency. See: <https://www.fema.gov/media-library-data/1464717519589-ba4712cb1e-ab5dfb47636b8a2a108676/InfectiousDiseaseFactSheetORR05132016.pdf>.

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¹²⁶ Of the 49 federally recognized tribes, three received Major Disaster Declarations: The Navajo Nation, the Poarch Band of Creek Indians, and the Seminole Tribe of Florida. All other tribes received an Emergency Declaration. See also: Federal Emergency Management Agency. (2020). COVID-19 Emergency Declaration. Washington, DC: Department of Homeland Security. Retrieved from: <https://www.fema.gov/press-release/20210318/covid-19-emergency-declaration>.

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¹²⁸ The White House (2022). National Biodefense Strategy and Implementation Plan. Washington DC: The White House. p. 17. Retrieved from: <https://www.whitehouse.gov/wp-content/uploads/2022/10/National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf>.

¹²⁹ Environmental Policy Act of 1969, P.L. 91–90, 42 U.S.C. §4321 et seq. (2006).



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