NATIONAL BIODEFENSE STRATEGY AND IMPLEMENTATION PLAN

FOR COUNTERING BIOLOGICAL THREATS, ENHANCING PANDEMIC PREPAREDNESS, AND ACHIEVING GLOBAL HEALTH SECURITY

OCTOBER 2022

FOREWORD

It is a vital interest of the United States to manage the risk of biological incidents, whether naturally occurring, accidental, or deliberate. This *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* updates the 2018 *National Biodefense Strategy* and serves as a foundational component of the President's vision to create a world free from catastrophic biological incidents, laying out a set of objectives to effectively counter the spectrum of biological threats. It defines biodefense as actions to counter biological threats, reduce biological risks, and prepare for, respond to, and recover from biological incidents, whether naturally occurring, accidental, or deliberate in origin and whether impacting human, animal, plant, or environmental health. It is broader than a Federal Government strategy; it is a call to action for state, local, tribal, and territorial (SLTT) entities, practitioners, physicians, scientists, educators, industry, and the international community to work together to elevate biological preparedness and response.

Biological threats can impact human, animal (domestic and wildlife), plant, and environmental health. They require an integrated approach that ensures the United States will address not only deliberate biological incidents as top national security priorities, but also epidemic and pandemic preparedness and global health security. The inclusion of naturally occurring and accidental biological threats underscores that our understanding of biodefense must be broader than only the threats posed by terrorist groups or adversaries seeking to use biological weapons. In today's interconnected world, biological incidents anywhere can potentially have profound effects on physical and mental health and well-being in the United States and globally, cause significant morbidity and mortality, and disrupt livelihoods and economies, including domestic and international trade and travel. Throughout the Coronavirus Disease 2019 (COVID-19) pandemic, every individual, community, and nation has experienced firsthand the health, social, and economic crises biological incidents can cause and the severe impact they can have on lives and livelihoods. The COVID-19 response has illuminated both longstanding and newly discovered limitations in local, national, and international biodefense capabilities. It has also resulted in the unparalleled mobilization of citizens, nations, and diverse sectors, and galvanized innovation to address a global biological threat. The pandemic has demonstrated the urgent need for sustained investment and coordination across the U.S. Government, private and nonprofit sectors, SLTT entities, our international partners and organizations, and our communities to assess, prevent, prepare for, respond to, and recover from future biological incidents.

Biological threats—whether naturally occurring, accidental, or deliberate in origin—are among the most serious threats facing the United States and the international community. As we have seen with the COVID-19 pandemic, biological incidents can cause extreme harm to the United States, including death, hospitalizations, disabilities, psychological trauma, and economic and social disruption on a massive scale. Biological incidents, whether naturally occurring, accidental, or deliberate, can originate in one country and spread to many others, with potentially far-reaching international consequences.

Advances in life sciences and biotechnology promise better and faster cures, economic advances, a cleaner environment, and improved quality of life, but they also bring new security risks that must be managed. In this rapidly changing landscape, the United States must be prepared to manage the risks posed by natural outbreaks of disease, accidents with high-consequence pathogens, or adversaries who wish to do harm with biological agents.

The health, prosperity, and security of the American people depend on our ability to stop infectious disease outbreaks at their source and rapidly and effectively contain biological incidents wherever they occur. The significant viral, bacterial, fungal, and other infectious disease outbreaks and toxin-related illnesses of recent decades impacting human, animal, and agricultural health, including COVID-19, continue to reveal that the financing cycle of panic and neglect must end. There is significant and urgent need to achieve sustained investments and transformative improvements in the ability of both the U.S. Government and the international community to assess, prevent, prepare for, respond to, and recover from the next biological incident. Our capabilities must address the range of biological threats: emerging and reemerging infectious diseases affecting humans, animals, plants, and the environment; risk of intentional misuse of advances in biotechnology; accidental release of biological agents; and threats posed by terrorist groups or adversaries seeking to use biological weapons.

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VISION

The United States actively and effectively assesses, prevents, prepares for, responds to, and recovers from naturally occurring, accidental, and deliberate biological threats impacting humans, animals, plants, and the environment and creates a world free from catastrophic biological incidents.

PURPOSE

This National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (Strategy) brings together a single coordinated effort to orchestrate the full range of activity that is carried out across the U.S. Government to protect the American people and its global interests from biological threats, regardless of origin. With National Security Memorandum-15 (NSM-15), this Strategy explains how the U.S. Government will manage its activities to more effectively assess, prevent, prepare for, respond to, and recover from biological threats, coordinating its biodefense efforts with those of SLTT entities, international partners, industry, academia, nongovernmental entities, and the private sector.

The mission of the Federal Government during a biological incident is to save lives; reduce human and animal suffering; protect property and the environment; control the spread of disease; support community efforts to overcome the physical, emotional, environmental, and economic impact of the incident; and determine the cause and source of the incident. This federal mission is contingent upon coordination with and the response of SLTT entities, international partners, industry, academia, nongovernmental entities, and the private sector. This *Strategy* describes the goals and objectives that will guide the United States in assessing biological risks and developing risk-mitigation measures, as well as assessing, preventing, preparing for, responding to, and recovering from a biological incident, consistent with its international obligations, including those identified in the World Health Organization's International Health Regulations (2005).

Enhancing the national biodefense enterprise will help protect the United States and its partners abroad from biological incidents, whether naturally occurring, accidental, or deliberate in origin. It will simultaneously build the U.S. innovation base for cutting-edge countermeasures, biosensors, diagnostics, and biosurveillance information technologies, and advance the biomedical and agricultural industries' biodefense capabilities.

THREATS AND CONSEQUENCES

Naturally Occurring Biological Threats. Biological threats can affect humans, animals, plants, and the environment, resulting in significant health, economic, social, and national security impacts. It is therefore important to address biological threats using a One Health approach that recognizes the interconnections among people, animals (domestic and wildlife), plants, and the environment. Infectious disease threats do not respect borders. Urbanization, climate change, habitat encroachment, economic interdependence, and increased travel, coupled with weak health systems, increase the ability of infectious diseases to spread rapidly across the globe. Novel infectious diseases, the resurgence and spread of once geographically limited infectious diseases, zoonotic diseases, and antimicrobial resistance can overwhelm response capacities and make outbreaks harder to control. As we have seen with the COVID 19 pandemic, an infectious disease outbreak—even in the most remote places of the world—could spread rapidly across oceans and continents, directly affecting the U.S. population and its health, security, and prosperity.

Accidental Biological Threats. The risk of laboratory accidents may be increasing with the rise in the number of laboratories around the world conducting high-risk life sciences research and research with potential pandemic pathogens without appropriate oversight. While this research is important for developing countermeasures and understanding and predicting future outbreaks, laboratories with insufficient biocontainment or biosafety protocols and practices exacerbate the risk of an outbreak through laboratory-acquired infections or accidental release of a pathogen into the environment. Even with state-of-the-art equipment and standard biosafety protocols, laboratory accidents are possible due to human error or mechanical failures.

Deliberate Biological Threats. The use of biological weapons or their proliferation by state or nonstate actors presents a significant challenge to our national security, our people, our agriculture, and the environment. Multiple nations have pursued clandestine biological weapons programs, and a number of terrorist groups have sought to acquire biological weapons. In addition, advances in biotechnology, including synthetic biology, are making it easier to develop and use biological agents as weapons. In many countries around the world, pathogens are stored in laboratories that lack appropriate biosecurity measures and could be diverted by actors who wish to do harm. Further, thousands of clinical samples generated during an epidemic can pose a biosecurity vulnerability if handled without appropriate security considerations, potentially facilitating access to materials and information that could be used in the development of a biological weapon.

BIOLOGICAL RISK MANAGEMENT

Biological risk management requires understanding and assessing biological risks and taking steps to mitigate those risks, regardless of whether they originate in the United States or abroad. It also requires shared international recognition that the risk is global to empower effective, collective mitigation. The COVID-19 pandemic reminds us that the issue is not if, but when, the next biological incident will occur.

As the biological threat landscape continues to evolve, so must our biodefense capabilities. If all countries could assess, prevent, prepare for, respond to, and recover from biological incidents at the local level, we could minimize the risk of nationally or internationally significant biological incidents, saving both lives and resources. Preventing acquisition of dangerous pathogens, equipment, and expertise for nefarious purposes, and maintaining the capability to rapidly control outbreaks in the event of a biological attack, are strategic interests of the United States. These must be strategic interests for our partners around the world as well. The United States cannot carry the burden alone, as an outbreak anywhere in the world can pose a threat to all. Finally, as we reap the benefits from biotechnologies and state-of-the-art research, we must also understand and consider the risks they pose. Accordingly, the United States will support an efficient and coordinated biodefense enterprise to protect the American people and its global interests.

Domestic action alone is insufficient to protect America's health and security. The rapid globalization of science and technology and the increased interconnectedness through travel and trade necessitate a strong biodefense enterprise that has global reach to effectively assess, prevent, prepare for, respond to, and recover from biological incidents. The U.S. Government works domestically and globally to ensure that the United States and its partners are protected from naturally occurring, accidental, or deliberate biological threats. While the desired outcomes domestically and globally are the same, the conditions and avenues available to achieve these outcomes can be very different. Internationally, our efforts to protect the United States and our partners include direct investment in sustainable, context-appropriate capacity building, and continued performance assessment and improvement, with the goal of achieving effective, country-led, and financed health security systems. We will work with multilateral organizations, partner nations, private donors, and civil society to prevent and control biological threats at their source by supporting the development and implementation of transparent biodefense and health security capabilities, policies, and standards.

The United States has long been an innovation leader. To meet the biodefense goals in this *Strategy* requires significant advances at the convergence of multiple disciplines, including biological, chemical, physical, and computational sciences. Whether augmenting our ability to provide healthcare and safeguard the environment or expanding our capacity for energy and agricultural production toward global sustainability, continued research and development is essential for a brighter future for the American people. To ensure that the United States is poised to meet the evolving biological risk landscape, at a time when unparalleled advancement and innovation in the life sciences and technology globally continue to transform our way of life, we are committed to promoting innovation throughout the national biodefense enterprise. We will promote innovative technologies and systems; encourage technology communities and industry leaders to meet our targeted biodefense and health capacity needs; link stakeholders with new

ideas, tools, and products; enhance biosafety and biosecurity practices to minimize the risk of accidental or deliberate misuse of biological research and biotechnologies; and pursue innovative approaches and partnerships to achieve, domestically and globally, the goals articulated in Strategy.

Through the Strategy, the United States will use all appropriate means to assess, prevent, prepare for, respond to, and recover from biological incidents—whatever their origin—that threaten health and national or economic security. The Strategy recognizes that a collaborative, multisectoral, and transdisciplinary One Health approach to the national biodefense enterprise is necessary to counter biological threats effectively and efficiently.

ASSUMPTIONS

The evolving biological threat landscape requires a comprehensive approach, and the United States recognizes the following principles:

- **Biological Threats Are Persistent.** Pathogens have emerged and spread throughout history, and the risk from these pathogens grows more acute as the world becomes more urbanized, travel increases, and climate and habitats change. Separately, nation-states and terrorist groups have found value in pursuing biological weapons, and there can be no confidence that will change in the future. Advances in the life sciences will both reduce the technological hurdles to acquiring such weapons and expand the number of individuals with relevant skills to effectuate threats.
- **Biological Threats Originate from Multiple Sources.** Within the scope of biodefense, the United States includes countering both deliberate biological threats and threats that stem from naturally occurring and accidental outbreaks. This approach allows the U.S. Government to fully utilize, integrate, and coordinate the biodefense enterprise and ensure the most efficient use of all biodefense assets.
- **Infectious Diseases Do Not Respect Borders.** An interconnected world increases the opportunity for pathogens to emerge, reemerge, and spread such that a disease threat anywhere is a disease threat everywhere. Infectious diseases cross borders indiscriminately, whether via the movement of humans, animals, plants, or through the environment. The U.S. Government will mitigate biological incidents domestically and globally by working with our partners abroad, because the United States cannot counter biological threats domestically without addressing them globally. We will also seek to improve our ability to prevent the spread of infectious diseases to the United States—including those that affect humans, animals, plants, and the environment—through inbound travelers and goods. The ongoing COVID-19 pandemic, African Swine Fever and Ug99 Stem Rust outbreaks, and the 2014, 2018, and 2021 Ebola outbreaks demonstrate that the U.S. Government must be prepared to act swiftly when outbreaks occur. A swift response necessitates engaging at the local, national, and international levels to galvanize support for and implement context-relevant interventions for the duration of the response. Furthermore, the United States must continue to exhibit catalytic global leadership by working with multilateral institutions, foreign governments, public and private sector partners, and communities for coordinated, whole-of-society action to strengthen health security systems throughout the world.

- **Biological Incidents Impact Critical Infrastructure and Supply Chains.** COVID 19 has demonstrated the severe impact biological incidents can have on critical infrastructure and supply chains. Depending on the biological incident, a wide array of sectors may be vulnerable to disruption. The U.S. Government must work across sectors to improve the resiliency of critical infrastructure and supply chains, especially those most needed to mount an effective response.
- **Multisectoral and Multilateral Cooperation Is Critical for Effective Biodefense.** This Strategy calls for whole-of-government and whole-of-society engagement in biodefense, domestically and globally. Assessment, prevention, preparedness, response, and recovery involves diverse sectors, including medical; human, animal, and plant health; emergency response; scientific and technical; law enforcement; industrial; academic; diplomatic; defense and security; intelligence; social and behavioral sciences; strategic risk communications; transportation; travel and tourism; and nonproliferation and counterproliferation sectors, among others. Engagement with SLTT entities, international organizations, nongovernmental organizations, communities, the private sector, and the general public is critical to prevent a biological event and respond to the next one. Transparency in communications, data sharing, surveillance, and response efforts by and with domestic and international partners is vital for success.
- **A One Health Approach Reduces the Occurrence and Impact of Bioincidents.** The health of people, animals, plants, and the environment are linked. One Health is a collaborative, multisectoral, and transdisciplinary approach at the local, regional, national, and global levels, with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals (domestic and wildlife), plants, and our environment. Approximately 75 percent of new or emerging infectious disease threats to human health are of animal origin. Biological threats affecting humans, animals, or plants can cause physical harm to health and well-being and economic and supply chain disruption. Implementing a coordinated One Health approach is a best practice for understanding, communicating, and mitigating biological threats swiftly and efficiently. Such an approach is necessary to rapidly and effectively assess, prevent, prepare for, respond to, and recover from biothreats, mitigating potential nationally or internationally significant biological incidents.
- **Science and Technology Will Continue to Advance Globally.** The ongoing revolution in the life sciences and biotechnology will continue at an ever-increasing rate, offering solutions to many of the challenges of ensuring the health, prosperity, and security of a growing global population. No longer confined to sophisticated research laboratories, these technologies are being developed and utilized all over the world, and the necessary expertise, materials, and equipment are widely available. Advances in science and technology bring revolutionary cures and progress, but they also have the potential for intentional misuse. The United States has a responsibility to ensure our technology, development, and assistance programs do not exacerbate this risk unintentionally.

GOALS AND OBJECTIVES

The *Strategy* has five goals with associated objectives for strengthening the biodefense enterprise, establishing a layered risk management approach to countering biological threats and incidents.

GOAL 1: Enable risk awareness and detection to inform decision-making across the biodefense enterprise.

The United States will build risk awareness at the strategic level through analyses and coordinated research efforts to characterize naturally occurring, accidental, and deliberate biological risks; and at the operational level through One Health surveillance and detection activities to detect and identify biological threats and anticipate biological incidents.

Objectives:

1. Ensure decision-making is informed by intelligence, forecasting, and risk assessment.
2. Ensure that domestic and global biothreat detection, biosurveillance, and information systems are coordinated, integrated, and capable of enabling timely bioincident prevention, detection, reporting, assessment, response, and recovery.

GOAL 2: Ensure biodefense enterprise capabilities to prevent bioincidents.

The United States will work to prevent the outbreak and spread of naturally occurring infectious diseases and minimize the risk of laboratory accidents both domestically and globally. The United States will also strengthen biosecurity to prevent both state and non-state actors from obtaining or using biological material, equipment, and expertise for nefarious purposes, consistent with the U.S. Government's approach to countering weapons of mass destruction. Implementing Goal 2 will ensure we have the capabilities necessary to disrupt plots, degrade technical capabilities, and deter support for state and non-state actors seeking to use biological weapons. This goal also recognizes the dual-use nature of the life sciences and biotechnology, in which the same science and technology base that improves health, promotes innovation, and protects the environment can also be misused for harmful purposes. Domestically and internationally, the United States seeks to prevent the misuse of science and technology while promoting and enhancing its legitimate use and innovation.

Objectives:

1. Promote measures to prevent or reduce the spread of infectious diseases.
2. Strengthen global health security capacities internationally to prevent local bioincidents from becoming epidemics.

3. Deter, detect, degrade, disrupt, deny, or otherwise prevent nation-state and non-state actors' attempts to pursue, acquire, or use biological weapons, related materials, or their means of delivery.
4. Strengthen biosafety and biosecurity practices and oversight to prevent bioincidents and reduce biological risks associated with life sciences research and development and advances in biotechnology.

GOAL 3: Ensure biodefense enterprise preparedness to reduce the impacts of bioincidents.

The United States will take measures to reduce the impacts of bioincidents, including maintaining a vibrant national science and technology base to support biodefense; promoting a strong domestic and international public, veterinary, and plant health infrastructure; developing, updating, and exercising response and recovery capabilities; establishing risk communications; developing and effectively distributing and dispensing countermeasures; and collaborating across the country and internationally to support biodefense.

Objectives:

1. Promote a vibrant, safe, and secure domestic and international science and technology base, including in biotechnology and biomanufacturing, to support biodefense.
2. Ensure a strong public, veterinary, and plant health infrastructure.
3. Develop, exercise, and update prevention, response, and recovery plans and capabilities, including efforts to secure critical supply chains.
4. Develop, exercise, and update risk communication plans and promote consistent, plain language messaging to inform key audiences, expedite desired response actions, and address public uncertainty and fear.
5. Enhance preparedness to save lives through development, testing, evaluation, manufacturing, regulatory approval, distribution, and administration of countermeasures.
6. Enhance preparedness to limit the spread of disease through community mitigation measures.
7. Enhance preparedness to support decontamination, waste management, environmental controls, and other methods of suppressing pathogens during a biological event.
8. Strengthen preparedness to operate and collaborate across the United States, including the U.S. territories.
9. Strengthen international preparedness to support international response and recovery capabilities.

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GOAL 4: Rapidly respond to limit the impacts of bioincidents.

The United States will respond rapidly to limit the impacts of bioincidents through information sharing and networking; evidence-driven, coordinated response operations and investigations; effective public messaging; and research.

Objectives:

1. Compile and share biothreat, bioincident, and response information to enable appropriate decision-making and response operations across all levels of government and with nongovernmental, private sector, and international entities, as appropriate.
2. Conduct evidence-driven federal response operations and activities and implement a federal research agenda in coordination with relevant nongovernmental, private sector, and international partners where appropriate to contain, control, and rapidly mitigate impacts of biothreats or bioincidents.
3. Conduct operations and investigations, and use all available tools to hold perpetrators accountable.
4. Execute risk-informed, accurate, timely, and actionable science-driven risk communications and community engagement.

GOAL 5: Facilitate recovery to restore the community, the economy, and the environment after a bioincident.

The United States will take actions to restore critical infrastructure services and capability; coordinate recovery activities; provide recovery support and long-term mitigation; and minimize cascading effects elsewhere in the world.

Objectives:

1. Promote restoration of critical infrastructure capability and capacity to enable the resumption of vital U.S. activities.
2. Ensure coordination of recovery activities across all levels of government and with nongovernmental, private sector, and international entities, as appropriate, to enable effective and efficient recovery operations.
3. Provide recovery support and conduct long-term mitigation actions to promote resilience.
4. Reduce the cascading effects of international biological incidents on the global economy, health, and security.

CONCLUSION

COVID-19 has demonstrated the enormous dangers posed by biological threats, impacting virtually every community in the world. Mitigating these risks remains an urgent domestic and global imperative. Decisive action is required to build on the investments made for, and the lessons learned from, the COVID-19 response to protect the Nation and our partners from the full range of biological threats to humans, plants, animals, and the environment. Through this Strategy, the U.S. Government will optimize its own efforts and harness the work of essential partners—inside and outside government, domestically and internationally – to assess, prevent, prepare for, respond to, and recover from biological events, whether naturally occurring, accidental, or deliberate, that can harm the American people and the global community.

ANNEX I: DEFINITIONS

The terminology used throughout the Strategy is consistent with the following definitions:

Biodefense: Actions to counter biological threats, reduce biological risks, and prepare for, respond to, and recover from bioincidents, whether naturally occurring, accidental, or deliberate in origin and whether impacting human, animal, plant, or environmental health.

Biodefense enterprise: Stakeholders with a role in the prevention, preparedness, detection, response, and recovery from bioincidents (e.g., Federal and SLTT governments, nongovernmental and private sector entities, and international partners).

Biological hazard (biohazard): A biological agent or biologically active substance—excluding toxic chemical substances that are considered solely as chemical weapons agents, regardless of origin (e.g., naturally occurring or bioengineered)—that represents an actual or potential danger to humans, animals, plants, or the environment.

Biological incident (bioincident):

- Any natural or accidental occurrence in which a biothreat harms humans, animals, plants, or the environment consistent with the scope of this *Strategy*;
- A crime involving a biothreat consistent with the scope of this *Strategy*; or
- Any act of biological warfare or terrorism.

Biological threat (biothreat): An entity involved with, or a situation involving, a biohazard that can potentially cause a bioincident.

Biosurveillance: The process of gathering, integrating, interpreting, and communicating essential information and indications related to all-hazard threats or disease activity affecting human, animal, plant, and environmental health to achieve early detection and provide early warning, contribute to overall situational awareness of the health aspects of the incident, and enable better decision-making at all levels.

Community Mitigation Measures: Behaviors or actions that people and communities can take to help slow the spread of a biological threat, to include threat-appropriate travel and border health measures, contact tracing, isolation, quarantine, social distancing, handwashing, use of personal protective equipment (PPE), and other non-pharmaceutical interventions.

Countermeasures: Medical countermeasures, veterinary, or plant health pharmaceutical products, such as vaccines, antimicrobials, and antitoxins, as well as non-pharmaceutical products, such as ventilators, diagnostic tests, PPE, and patient decontamination materials, that may be used to prevent, mitigate, or treat the adverse health effects from a bioincident.

Dual use: Intended for legitimate purposes but having the potential for both benevolent and malevolent applications.

One Health: A collaborative, multisectoral, and transdisciplinary approach working at the local, regional, national, and global levels, with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals, plants, and the environment.

Nationally or Internationally Significant Biological Incident: A biological threat or incident with present or potential scale, timing, severity, complexity, or unpredictability to: cause harm to the United States or across international borders; overwhelm existing resources, countermeasures, and personnel; and threaten U.S. or global health, national, economic, or food security.

ANNEX II: IMPLEMENTATION PLAN FOR THE NATIONAL BIODEFENSE STRATEGY

OVERVIEW

Coronavirus Disease 2019 (COVID-19) continues to take a tremendous toll on lives and livelihoods around the world, disrupting national and global security and affecting the national, health, and economic security of every nation. The United States must now chart a new vision for biodefense. The COVID-19 pandemic illuminated both longstanding and newly discovered limitations in local, national, and international biodefense capabilities, starkly demonstrating that continual investment in, and innovations toward, a biodefense enterprise must be a top priority for the United States. The United States will take actions to achieve and sustain epidemic and pandemic preparedness, counter biological weapons, and improve health security and global health in collaboration with our international partners.

The Biden-Harris Administration is setting our Nation on a course that is designed to provide all Americans a safe place to live and prosper. Through this implementation plan, we are setting forth a new moonshot, a set of bold outcomes for biodefense, which prioritize transformational technical and measurable targets. Achieving this vision will require not only the technical advancements but also necessitate sociological achievements, such as enhancing trust in science and overcoming a growing hesitancy towards safe and effective medical countermeasures. Domestic action alone is insufficient; achieving this vision necessitates working with multilateral organizations, partner nations, the private sector, and civil society to support and strengthen capacity to prevent and effectively control biological threats at their source.

The outcomes prioritized in this implementation plan include the integration of the critical needed capabilities described in this Administration's *American Pandemic Preparedness: Transforming Our Capabilities*. Departments and agencies will implement these efforts, commensurate with available resources and subject to the availability of appropriations, in support of the *National Biodefense Strategy for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (Strategy)*. The prioritized bold outcomes found here, mapped to the overarching Strategy, are intended to realize the unified vision across U.S. departments and agencies that the United States must actively and effectively detect, prevent, prepare for, respond to, and recover from naturally occurring, accidental, and deliberate biological threats impacting humans, domestic and wildlife animals, plants, and the environment to create a world free from catastrophic biological incidents.

IMPLEMENTING THE STRATEGY

To fulfill its vision for biodefense, the Administration identified the following transformational bold outcomes for countering biological threats, enhancing pandemic preparedness, and achieving global health security. Under each Goal of the Strategy, the following actions will be implemented to achieve these priorities and advance the Strategy. Some activities may contribute to multiple Goals but are listed only under one for simplicity. The conditions and avenues to achieve the international elements of these priorities differ from those available for U.S. domestic capacities; they rely on direct and catalytic engagement through partnership with multilateral organizations, partner nations, the private sector, and civil society to encourage prioritization of biodefense. Implementation of this plan is subject to the annual President's Budget process and the availability of appropriations. Nothing in this Implementation Plan shall be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

The U.S. Government will lead and drive towards the historic goals laid out within this Implementation Plan. The U.S. Government can advance many of the actions described below, but we cannot do everything on our own. We will seek to advance these goals in partnership and collaboration with international organizations, foreign governments, and state, local, tribal, and territorial authorities—as well as other private sector, academic, and civil society stakeholders—that in many cases have primary responsibility and/or legal authority.

For each priority (#.#.), a set of targets (#.#.#.), and corresponding actions (I) have been identified. The priorities and selected targets and actions listed below provide direction as well as a concrete method for tracking and measuring progress towards the achievement of the outcome, with lead and supporting departments and agencies listed for each target. Implementation of this plan is a priority for the Administration and progress on implementation will be tracked internally through the regular updates to the Global Health Security and Biodefense Directorate of the National Security Council as tasked in National Security Memorandum-15 (NSM-15).

In addition to the activities laid out in this section, agencies will implement all of the Strategy through existing policies, plans, and frameworks and consistent with existing statutory authorities. A demonstrative list of policies, plans, frameworks, and statutory authorities can be found in Annex IV.

GOAL 1. Enable Risk Awareness and Detection to Inform Decision-Making across the Biodefense Enterprise

The United States will build risk awareness at the strategic level through analyses and coordinated research efforts to characterize naturally occurring, accidental, and deliberate biological risks; and at the operational level through One Health surveillance and detection activities to detect and identify biological threats and anticipate biological incidents.

1.1. Early Warning

Develop the ability to rapidly detect, characterize, report, forecast, and share relevant information (including genetic sequence data), as appropriate, on pathogens that pose a biological threat of national or international significance soon after they emerge in humans, animals†, and plants. Early warning will inform and enable (a) early assessment and identification of the origin of biological incidents and (b) effective decision-making and interventions at local, national, and international levels.

1.1.1. Detection and Reporting of Biological Threats

Develop domestic, and support the development of global, capacities and capabilities to detect and report disease outbreaks in humans, animals†, and plants anywhere in the world and collect and rapidly share information, data, and samples including internationally and across sectors, with appropriate safety and security controls, to prevent or limit nationally or internationally significant biological incidents.

I. Work domestically and with international partner countries to support and implement the development and integration of international systems and operating procedures to rapidly, safely, and securely share technical and analytical information, data, and samples supporting surveillance and mitigation to prevent or limit nationally or internationally significant biological incidents including a Public Health Emergency of International Concern. (Lead: United States Department of State (DOS), United States Department of Health and Human Services (HHS); Support: United States Department of Defense (DoD), United States Department of the Interior (DOI), United States Department of Agriculture (USDA), United States Department of Commerce (DOC), United States Department of Energy (DOE), United States Department of Homeland Security (DHS), United States Agency for International Development (USAID), National Institutes of Health (NIH), Federal Bureau of Investigation (FBI), Centers for Disease Control and Prevention (CDC))

II. Demonstrate the sustained domestic and international capacity of surveillance and monitoring systems, including syndromic, pathogen, and events-based systems, needed to detect and regularly report known and new infectious diseases threats in humans, plants,

† Including wildlife and domestic

and animals†. (Lead: DOS, USAID, CDC; Support: DoD, DOI, USDA, HHS, DOE, DHS, United States Environmental Protection Agency (EPA), NIH, FBI)

III. Accelerate domestic and international basic and applied research and innovation across disciplines to implement advanced biosurveillance and biodetection capabilities for clinical and environmental early warning and enable large-scale, affordable, and routine biological hazard agnostic and/or specific biosurveillance and biodetection, for animal, human‡, plant, and environmental surveillance. (Lead: USDA, DHS, EPA, CDC; Support: DOS, DoD, DOI, DOC, HHS, DOE, USAID, FBI)

1.1.2. Biological Threat Sequencing and Analytical Data Sharing

After acquiring a suitable sample, generate and disseminate domestically, and internationally consistent with international norms and standards and in accordance with applicable laws and policies, pathogen genome sequence data and other analytical information, with appropriate safety and security controls, to support the surveillance and mitigation of nationally or internationally significant biological incidents.

I. Develop domestically, and support internationally, the capacities, policies, and capabilities needed to perform and share rapid genomic sequencing and analysis. (Lead: HHS; Support: DOS, DOI, USDA, DOC, DOE, United States Department of Veterans Affairs (VA), DHS, NIH, FBI, CDC)

1.1.3. Data Integration for Early Warning

After receiving relevant information and data, share domestically and internationally, with appropriate safety and security controls, through identifying, integrating, and improving existing effective global early warning systems, across all sectors, that are tightly integrated with existing state, local, tribal, and territorial (SLTT), national, and international surveillance and monitoring systems for public health, animal health†, plant health, and water infrastructure.

I. Develop a U.S. Government early warning joint capabilities plan to: 1) advance early warning technologies and capabilities for more rapid identification of pathogens; and 2) rapidly and securely aggregate and share surveillance, biological threat information, and additional information needed for early warning and containment of any pathogen with pandemic potential among the federal government, SLTT governments, health providers, international partners, and other key stakeholders. This joint capabilities plan will focus on areas including, but not limited to, data platforms and sharing, real-world evidence based infectious disease modeling, reportable disease lists, improved integration of laboratory response, and wastewater and environmental surveillance, as well as insights gleaned from outreach and partnerships described herein. (Lead: United States National Security Council (NSC), Office of Science and Technology Policy (OSTP); Support: DOS, DoD, DOI, USDA, DOC, HHS, United States Department of Transportation (DOT), DOE, VA, DHS, EPA, USAID, NIH, FBI, CDC, IC)

II. Enhance capacity for rapid analysis, modeling, baselining, forecasting, and reporting to monitor and evaluate the health threat landscape, through a One Health lens, and improve early warning capabilities. (Lead: DHS, CDC; Support: DoD, USDA, HHS, DOT, DOE, FBI)

‡ Including clinical and wastewater

III. Establish multi-sectoral groups of federal, SLTT, and private sector partners, and with international partners, to address policy issues that may limit the interchange of biosurveillance data by addressing issues, such as data provenance; privacy; information security, including but not limited to classification or status as controlled unclassified information, conditions of disclosure, and other applicable safeguarding measures; standard data use agreements and memoranda of understanding; civil liberties; and civil rights. (Lead: DOI, USDA, HHS, DHS; Support: DOS, DoD, DOT, DOE, EPA, USAID, NIH, CDC)

1.1.4. Biological Threat Assessment and Characterization Capabilities

Develop enhanced capabilities and capacities, with appropriate safety and security controls, to initially assess and characterize biological threats to humans, animals, and plants within one week of acquiring a suitable sample, including by developing characterization capabilities for novel pathogens; timely and effective biological material characterization to support investigations, origin determination, and attribution; and functional characterization to support response and recovery decisions.

I. Develop and implement a domestic characterization research and development agenda for collaboration between the federal government, academia, and the private sector and work with foreign partner countries and international organizations to develop internationally recognized standards for safe and secure characterization of novel pathogens to support response and recovery decisions, meeting high standards for biosecurity and biosafety. (Lead: DOI, USDA, DHS, NIH, FBI; Support: DOS, DoD, DOC, HHS, DOE, EPA, CDC)

II. In collaboration with diverse stakeholders and partners, continue existing efforts to leverage strategic risk assessment capabilities to provide data-driven risk-based decision support for resource allocation to measures that protect the United States from a range of biological attacks as required by Homeland Security Presidential Directive-18. (Lead: DHS; Support: USDA, HHS, EPA, NSC, FBI, IC)

III. Enhance and sustain U.S. Government characterization capabilities for forensics and attribution, serving the U.S. human, animal, plant, and environmental health and national security communities. (Lead: HHS, FBI; Support: DOI, USDA, DOE, DHS, EPA, CDC, IC)

1.2. Additional Actions

I. Revise, implement, and exercise operational plans for early warning to enable rapid response, including clarifying roles and responsibilities for integrating biosurveillance information; managing early warning across federal government and participating international partners; and institutionalizing and exercising the Biological Incident Notification and Assessment (BINA) Protocol. (Lead: NSC; Support: DOS, DoD, DOI, USDA, HHS, DOT, DOE, VA, DHS, EPA, USAID, FBI, CDC, IC)

II. Maintain and enhance an enduring domestic all-hazards hospital[§] data collection capability, including data reporting and management systems, governance processes, and

[§] Including other appropriate healthcare facilities and systems

user guidance, to enable comprehensive data reporting for biosurveillance, situational awareness, and emergency response operations at the federal and SLTT levels. (Lead: CDC; Support: DoD, HHS, VA, DHS)

III. Support the capacity of the United Nations system to investigate outbreaks of unknown origin. (Lead: DOS, HHS)

GOAL 2. Ensure Biodefense Enterprise Capabilities to Prevent Bioincidents

The United States will work to prevent the outbreak and spread of naturally occurring infectious diseases and minimize the risk of laboratory accidents both domestically and globally. The United States will also strengthen biosecurity to prevent both state and non-state actors from obtaining or using biological material, equipment, and expertise for nefarious purposes, consistent with the U.S. Government's approach to countering weapons of mass destruction.

2.1. Global Health Security

Advance the development, enhancement, and maintenance of effective global health security capacities through sustained political, financial, and technical support, leveraging catalytic U.S. leadership and support, including in support of the multilateral Global Health Security Agenda (GHSA).

2.1.1. Strengthen Country Capacities

Provide direct support to at least 50 countries and use catalytic leadership to work with key donors and partners to support at least 50 additional countries, to achieve "Demonstrated Capacity" or comparable level (depending on country context) in at least five technical areas critical to the country, by 2025, as measured by relevant health security assessments, such as those conducted within the World Health Organization (WHO) IHR Monitoring and Evaluation Framework, such as the JEE, SPAR, and/or other relevant health security assessments.

I. Review and revise recommendations for the annual expansion of global health security partner countries, considering factors listed in the Global Health Security Strategy, status of country progress towards the GHSA 2024 targets, foreign policy priorities, and existing footprints of departments and agencies, building on U.S. Government COVID-19 response activities. (Lead: NSC)

II. Work with country governments and other partners in United States Government-supported countries to address identified gaps and improve capacities in key technical areas for global health security. (Lead: DOS, USDA, HHS, DOT, USAID; Support: DoD, DHS)

III. In addition to providing direct support to partners, encourage countries to prioritize their domestic health security capabilities and invest in building and sustaining these capacities, including through domestic resource mobilization, and work with donor countries, international financial institutions, and regional organizations to coordinate plans and generate new commitments. (Lead: DOS, HHS)

IV. Catalyze political leadership and attention for biological crisis in order to act more quickly in future emergencies, including at the leaders' level. (Lead: DOS, HHS)

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2.1.2. Establish and Maintain Sustainable Global Financing for Health Security and Pandemic Preparedness

Support and help lead the establishment of a reliably financed international mechanism to catalyze and provide sustainable financing for global health security, pandemic preparedness, and response capabilities.

I. Work with international partners, including the members of the Group of 7 (G7) and the Group of 20 (G20), to develop and establish a Financial Intermediary Fund at the World Bank for global health security and pandemic preparedness. (Lead: DOS, United States Department of Treasury (Treasury), HHS, USAID)

2.2. Prevention

Prevent nationally or internationally significant biological incidents by (a) minimizing the chances of laboratory accidents; (b) reducing the likelihood of deliberate use or accidental misuse; (c) ensuring effective biosafety and biosecurity practices and oversight; (d) promoting responsible research and innovation; and (e) reducing the likelihood of animal to human spillover of zoonotic pathogens.

2.2.1. Promote Safe and Secure Biological Laboratories and Practices

Ensure all facilities in the United States or funded by the U.S. Government that conduct life sciences research, development, manufacturing, or diagnostic activities with especially dangerous biological materials—or which conduct work reasonably anticipated to result in such materials—are implementing and maintaining effective, transparent, rigorous, and comprehensive oversight, training, and monitoring programs for biosafety, biosecurity, and responsible and ethical conduct in science. Ensure the workforce at these facilities is trained to recognize, respond to, and report unsafe practices and threats.

I. Complete an interagency review and provide recommendations for U.S. policy, guidance, and practices to improve laboratory biosafety and biosecurity policy. (Lead: NSC, OSTP; Support: DOS, Treasury, DoD, DOI, USDA, DOC, United States Department of Labor (DOL), HHS, DOT, DOE, VA, DHS, EPA, National Science Foundation (NSF), USAID, NIH, FBI, United States Food and Drug Administration (FDA), CDC, IC)

II. Support the development of a domestic and international cohort of biosafety and biosecurity experts to champion responsible research and cultivate measurably improved biosafety and biosecurity practices globally. (Lead: DOS, USDA, HHS, FBI; Support: NIH, CDC)

III. Strengthen the scientific evidence base of laboratory biological risk management. (Lead: DOS, USDA, NIH; Support: DoD, HHS, DHS, EPA, FBI, CDC)

IV. Strengthen partner countries' ability to have in place a whole-of-government national biosafety and biosecurity system, including at sub-national levels, helping to ensure that especially dangerous biological materials are identified, held, secured, cultured, processed, transferred, and monitored in a minimal number of facilities according to best practices and regulations to prevent proliferation risks. (Lead: DOS, HHS; Support: DoD, USAID, FBI, CDC)

V. Galvanize support for multilateral biosafety and biosecurity commitments and the establishment of regional and global mechanisms to raise the global bar for biosafety and

biosecurity norms and practices, including through effective partnerships with the private sector and existing international organizations and other international forums. (Lead: DOS; Support: DoD, HHS, DHS, EPA, FBI, CDC)

2.2.2. Strengthen Responsible Conduct for Biological Research

Establish or identify domestic or international forums, mechanisms, or entities to focus on supporting efforts to develop and provide guidance for implementable, effective, and rigorous life sciences research biosafety and biosecurity norms and oversight and monitoring programs in all sectors worldwide.

I. Complete an interagency review of efforts to strengthen responsible conduct for biological research and develop and operationalize interagency plans. (Lead: NSC, OSTP; Support: DOS, Treasury, DoD, DOI, USDA, DOC, DOL, HHS, DOT, DOE, VA, DHS, EPA, NSF, USAID, NIH, FBI, CDC)

II. Enhance screening of domestic biotechnology research, nucleic acid and biologics synthesis orders, and systems for identification and reporting suspicious orders, in consultation with relevant private sector partners. (Lead: USDA, DOC, HHS, EPA, OSTP; Support: DOS, DOE, DHS, NIH, FBI, FDA, CDC)

III. Support domestic forums and mechanisms to encourage routine peer-to-peer sharing regarding best practices in responsible conduct of biological sciences research. (Lead: USDA, HHS; Support: EPA, NIH, FBI, CDC)

IV. Work with foreign partners to strengthen responsible research best practices, promote research security, and support the development of systems for research oversight. (Lead: DOS, HHS; Support: USDA, DOE, FBI, CDC)

2.2.3. Accelerate biosafety and biosecurity innovation

Accelerate laboratory biosafety and biosecurity innovation by supporting efforts to identify and address the research gaps needed to improve evidence-based laboratory biological risk management, both in the United States and globally, and share with international partners.

I. Develop a U.S. Government joint capabilities plan to accelerate biosafety and biosecurity innovation. (Lead: NSC, OSTP; Support: DOS, DoD, USDA, HHS, DOT, DOE, VA, DHS, EPA, USAID, NIH, CDC)

2.2.4. Deter Biological Weapons

Strengthen (1) the international norms against biological weapons (BW) and (2) the mechanisms and tools needed to hold state and non-state actors accountable for BW development, proliferation, use, or the deliberate misuse of biological research, technologies, and knowledge.

I. Work with foreign partners to strengthen the international security communities' capabilities to recognize, interdict, disable, and destroy biological weapons and weapons-related equipment, material, means of delivery, and facilities, as well as to attribute responsibility for their use. (Lead: DOS, DoD; Support: DHS, FBI)

II. Strengthen the implementation of the Biological Weapons Convention and United Nations Security Council Resolution 1540 in order to prevent nation-state or non-state development, acquisition, or use of biological weapons, related materials, or means of delivery. (Lead: DOS, DoD; Support: DOT, DOE, FBI)

III. Strengthen the capability of the UN Secretary-General's Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons (UNSGM) to determine the facts, including attribution, regarding the alleged use of biological or toxin weapons. (Lead: DOS, DoD, FBI)

2.2.5. Reduce Zoonotic Pathogen Spillover

Use a One Health approach to understand the greatest drivers of risk for pathogen spillover, with appropriate safety and security controls, and implement sustainable, evidence-based, infectious disease prevention, detection, identification, control, mitigation interventions, and risk reduction activities at the local, community, tribal, national, and regional levels, and support implementation internationally.

I. Enable a common U.S. federal operating picture of spillover events. (Lead: DOI, USDA, DHS, EPA, CDC; Support: DOS, HHS, DOT, USAID, NIH, FBI)

II. Work with domestic public health, animal and plant health, and environmental health stakeholders to increase agricultural biosafety, biosecurity, and bio-surveillance for activities associated with pathogen spillover, and reduce activities found to be drivers of pathogen spillover. (Lead: DOI, USDA, DHS, CDC; Support: HHS, EPA, NIH, FBI)

III. Support partner countries to develop, implement, and scale-up evidence-informed interventions at the community level to reduce zoonotic pathogen spillover informed by risk assessment and other critical information (i.e., understanding of viral and ecological factors), engagement of traditional and non-traditional partners, and targeted research to prioritize, implement, and validate interventions. (Lead: DOS, USDA, USAID, CDC; Support: HHS, NIH, FBI)

GOAL 3. Ensure Biodefense Enterprise Preparedness to Reduce the Impacts of Bioincidents

The United States will take measures to reduce the impacts of bioincidents, including maintaining a vibrant national science and technology base to support biodefense; promoting a strong domestic and international public, veterinary, and plant health infrastructure; developing, updating, and exercising response and recovery capabilities; establishing risk communications; developing and effectively distributing and dispensing countermeasures; and collaborating across the country and internationally to support biodefense.

3.1 Domestic Health Capacity

Enhance U.S. ability to respond swiftly to biological incidents by modernizing and expanding the footprint of domestic health infrastructure and by restoring public trust in health, science, and medicine, in part by countering misinformation and disinformation.

3.1.1. Invest in Domestic Public Health Capacities

Ensure all levels of government, including SLTTs, the largest population centers, and rural and frontier jurisdictions, are operationally ready to assess, prevent, prepare for, respond to, and recover from nationally or internationally significant biological incidents affecting public health.

I. Update federal SLTT operational plans and upgrade national and SLTT capabilities for contact tracing, including digital technologies to facilitate contact tracing, and exposure notification to enable containment of infectious pathogens during future biological incidents. (Lead: CDC; Support: DHS)

II. Develop SLTT capability to preserve healthcare and public health delivery capacity during public health outbreaks and emergencies to enhance and preserve timeliness and continuity and quality of care. (Lead: CDC)

III. Recruit, train, and sustain a robust, flexible, permanent cadre of essential critical health infrastructure workers, public health laboratory scientists, technicians, and data quality managers to support surveillance and response testing and reporting and support the recruitment of One Health experts and dedicated animal disease epidemiologists, who are critical frontline workers for animal disease control at relevant state and territorial agencies and departments, in all 50 states. (Lead: USDA, CDC)

IV. Provide technical assistance on border health security to support domestic capacity to detect, report, and respond to diseases affecting travelers and mobile populations arriving in, transitioning through, and departing from the United States. (Lead: CDC; Support: DOT, DHS)

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3.1.2. Strengthen Capacities to Combat Emerging and Zoonotic Disease

Ensure governments at all levels, federal and SLTT, can implement, using a One Health approach, enhanced emerging and zoonotic surveillance, prevention, and control programs, including for vector-borne diseases.

I. Enhance and expand domestic capacity to advance a One Health approach for the surveillance, prevention, and control of emerging and zoonotic infectious diseases in animals, human populations, and the environment with all SLTT health departments using a data-driven approach in decision making around both vector control and surveillance efforts. (Lead: DOI, USDA, EPA, CDC; Support: DOE, DHS, FBI)

II. Increase domestic surveillance and sampling of potential sources of zoonotic spillover of existing and emerging diseases. (Lead: DOI, USDA, HHS; Support: DHS, EPA, NIH, FBI, CDC)

3.1.3. Promote Evidence-Based Health Communication to the Public

Increase (1) vaccine uptake rates for all recommended vaccines to over 85% of American population and (2) public information campaigns reaching 80% of American population related to health, science, innovation, medicine, and biodefense by empowering the public and SLTT officials to keep themselves and their communities safe from biological incidents through evidence-based public messaging and education campaigns, while also countering and mitigating the spread of disinformation and misinformation.

I. Improve federal messaging coordination for biothreats and bioincidents by developing a government-wide strategy that creates an enabling environment for coordination of information, institutionalizes the use of risk communication principles, and provides clear, consistent, and coordinated information. (Lead: HHS; Support: USDA, DOT, DHS, NSC, OSTP, United States Domestic Policy Council (DPC), NIH, FBI, CDC)

II. Enhance messaging partnerships in advance of a bioincident. (Lead: USDA, HHS; Support: DOT, NSC, OSTP, DPC, CDC)

III. Create evidence-based public information campaigns to prepare the public for potential adverse events, handle messaging during response, and prepare, educate, and inform the public of appropriate steps to take. This work would incorporate learning from past responses, in particular COVID-19. (Lead: USDA, HHS; Support: DHS, NSC, OSTP, DPC, NIH, CDC)

3.1.4. Strengthen Healthcare-Associated Infections (HAI) and Antibiotic Resistant (AR) Pathogens Capacities

Ensure states, localities, tribes, and territories can implement comprehensive programs to detect, respond to, and prevent the transmission of healthcare-associated infections (HAI) and antibiotic resistant (AR) pathogens.

I. Through E.O. 13676 and the National Action Plan for Combating Antibiotic Resistant Bacteria (CARB), 2020-2025, strengthen U.S. federal and SLTT capacity to slow the emergence of resistant bacteria, prevent the spread of resistant infections, promote the responsible use of antibiotics, and conduct surveillance of antibiotic resistant pathogens. (Lead: DoD, USDA, HHS, VA; Support: CARB Task Force agencies as identified in the CARB National Action Plan)

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3.2. Rapidly and Widely Available Diagnostics

Develop, validate, manufacture, authorize, and deploy widely available, affordable, and highly sensitive and both specific and broadly reactive tests domestically for biological hazards assayed from any human-, animal-, agriculturally-, or environmentally derived specimen, at timescales and sensitivities necessary to respond, contain, and control a potential nationally or internationally significant biological incident.

Targets 3.2.1 through 3.2.3 will be covered in a diagnostics joint capabilities plan, described below.

3.2.1. Pathogen Agnostic Tests

Enable the capability and capacity, including pre- and post-analytical capabilities and capacities, to deploy and utilize, including clinical utilization, at least one authorized pathogen agnostic test, such as sequencing, for use in epidemiologically relevant locations, or for deployment within twelve hours, for thousands of samples on the first day, and tens of thousands of samples per day within seven days, after determination of a potential nationally or internationally significant biological incident, to support response, containment, and control.

3.2.2. Pathogen Specific Tests

Develop, validate, and produce authorized pathogen-specific tests, for human-, animal-, agriculturally-, or environmentally derived specimens, that can be deployed rapidly within thirty days of determination of a potential nationally or internationally significant biological incident, in sufficient quantities domestically to support the response to, and containment and control of, a potential nationally or internationally significant biological incident.

3.2.3. Rapid, Low Cost, Point-of-Need Tests

Develop, validate, and produce affordable authorized pathogen-specific tests, for human, animal, agriculturally, or environmentally derived specimens, with necessary sensitivity and specificity for wider clinical and non-clinical use domestically, such as point-of-need testing (i.e., near-patient use, field use, or pen-side use), including low-resource settings, with a test run time between five and thirty minutes within ninety days of determination of a potential nationally or internationally significant biological incident.

I. Develop a U.S. Government diagnostics joint capabilities plan. (Lead: NSC, OSTP; Support: DOS, DoD, USDA, DOC, HHS, DOE, DOT, VA, DHS, EPA, NIH, FDA, CDC)

3.3. Resilient and Scalable Supply of Personal Protective Equipment (PPE)

Establish resilient and scalable supply and manufacturing capabilities for PPE in the United States that can: (a) enable a containment response for; and (b) meet U.S. peak projected demand for healthcare and other essential critical infrastructure workers during a nationally or internationally significant biological incident.

3.3.1. PPE Capacity

Maintain a sustainable and continuously improving federal stockpile of PPE systems and enhance capacities and capabilities that, including through the implementation of Executive Order 14017 of February 24, 2021 (America's Supply Chains): (1) provides a domestic

minimum ninety-day surge capability; (2) can accommodate commercial distribution channels as well as replenish federal, state, and local PPE stockpiles and provides (a) steady-state market supply, (b) manufacturing surge capacity, and (c) storage and inventory capacity, including monitoring of PPE stockpiles and user inventories; and (3) contributes domestically to the response to, and containment and control of, a potential nationally or internationally significant biological incident.

I. Conduct an analysis to determine the quantities of PPE needed to protect the healthcare and other essential critical infrastructure workforce in any catastrophic biological incident or pandemic, to set requirements for the Strategic National Stockpile and domestic surge manufacturing capacity. Analysis will cover equipment needed in the event of highly virulent and transmissible pathogens or other biological hazards, including N95 masks, gowns, gloves, reusable respirators (half-face and full-face), reusable full body suits, fully encapsulated Occupational Safety and Health (OSHA) Level A or B boots, Powered Air Purifying Respirators, and sterilization chemicals. Analysis will also assess PPE capacity needs to cover vulnerable populations and a diversity of body types, including children. (Lead: HHS; Support: DOT, VA, DHS, EPA, CDC)

II. Safeguard PPE supply chain diversity for public and animal health through policy, incentives, regulation, and other tools to reduce dependence on a single region, source, or product. Diversity in this context includes a diverse set of products (e.g., N95 filtering facepiece respirators and elastomeric half mask respirators) and domestic sources/suppliers (e.g., components and end products) for these products. (Lead: USDA, HHS; Support: DOS, DoD, DOL, DOT, VA, DHS, FBI, CDC)

III. Reinforce PPE supply chain agility to ensure that supply chain partners can better respond to supply chain disruptions and increased demand. (Lead: HHS; Support: DOS, USDA, DOL, DOT, CDC)

IV. Enhance the PPE supply chain at the SLTT level through partnership, policy, procurement, guidance, and regulation. (Lead: DOL, HHS; Support: DOT, CDC)

3.3.2. PPE Innovation

Invest in and incentivize innovations in PPE design, novel material development, advanced manufacturing, and reusable technology capabilities that result in steady state and surge capacities for domestic production of PPE with resilient supply chains and enhanced effectiveness, usability, comfort, affordability, reusability, and fit capabilities to protect against various routes of pathogen transmission, including for use by the general population.

I. Develop a U.S. Government PPE joint capabilities plan. (Lead: NSC, OSTP; Support: DOS, DoD, USDA, DOL, HHS, DOT, DOE, DHS, EPA, FDA, CDC)

3.4. Vaccines

Rapidly make and equitably deploy safe and effective vaccines against any pathogen family, at timescales and quantities necessary to contain and control a potential nationally or internationally significant biological incident.

Targets 3.4.1 through 3.4.4 will be covered in a vaccines joint capabilities plan, described below.

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3.4.1. Vaccine Design, Testing, and Authorization

Establish and maintain domestic, and catalyze international, capacity and capabilities in vaccine design, testing, and review of safe and effective vaccines against (1) any human or animal viral threat for which a candidate vaccine has been developed within one hundred days after determination of a potential nationally or internationally significant biological incident, and (2) any other human or animal pathogen threat.

3.4.2. Vaccine Production

Establish and maintain domestic capability and capacity to produce sufficient quantities of regimens of safe and effective vaccines to vaccinate the United States population or for impacted animal species to control a nationally or internationally significant biological incident, within one hundred thirty days of the determination of a potential nationally or internationally significant biological incident, and work with international partners to catalyze international capability to produce sufficient quantities to vaccinate high-risk populations within two hundred days.

3.4.3. Vaccine Distribution

Support capabilities and capacities to distribute vaccines rapidly and equitably to anywhere in the world, by eliminating challenging requirements for transportation and storage, and supporting distributed manufacturing.

3.4.4. Vaccine Administration and Allocation

Establish and maintain the domestic capability and capacity, and support international capabilities and capacities, to safely, securely, and equitably allocate and flexibly administer to at-risk human and impacted animal populations the necessary vaccine quantities to control a nationally or internationally significant biological incident, within one hundred days following authorization or approval.

I. Develop a U.S. Government vaccines joint capabilities plan. (Lead: NSC, OSTP; Support: DOS, DoD, USDA, DOL, HHS, DOT, VA, DHS, USAID, NIH, FDA, CDC)

3.5. Agile Therapeutics Development and Production

Establish innovative and agile domestic therapeutic research, development, manufacturing, and delivery capabilities that yield a range of safe and effective therapeutics, available before or readily created during a nationally or internationally significant biological incident.

Targets 3.5.1 through 3.5.3 will be covered in a therapeutics joint capabilities plan, described below.

3.5.1. Therapeutic Development and Manufacturing

Create and maintain the domestic capability to identify, develop, test, authorize, manufacture, and deploy new and repurposed therapeutics that reduce mortality, morbidity, or transmission by at least fifty percent within ninety days (for repurposed therapeutics) and six months (for new therapeutics) of determination of a potential nationally or internationally significant biological incident.

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3.5.2. Antiviral Development and Manufacturing

Develop antivirals with fifty percent reduction in mortality, morbidity, or transmission, focusing pre-emptive efforts on outbreak-prone virus families, and achieve FDA approval for at least two novel antivirals that will be ready for domestic stockpiling within five years.

3.5.3. Controlling Counterproductive Responses to Infection

Develop pathogen agnostic therapeutics for the treatment of severe disease and achieve regulatory approval of at least two therapeutics that will be ready for domestic stockpiling within five years.

I. Develop a U.S. Government therapeutics joint capabilities plan. (Lead: NSC, OSTP; Support: DOS, DoD, USDA, HHS, DOE, VA, NIH, FDA, CDC)

3.6. Additional Actions

I. Conduct a whole-of-government approach to assessing vulnerabilities in, and strengthening the resilience of, critical supply chains and implement through Executive Order 14017. The White House issued Executive Order on America's Supply Chains (EO 14017) in February of 2021. EO 14017 requires the Secretary of Health and Human Services to develop a report outlining considerations and recommendations for improving the public health industrial base supply chain, describing the current state of the supply chain for each of the following domains: raw materials, PPE, testing and diagnostics, pharmaceuticals and active pharmaceutical ingredients, therapeutics, and vaccines; risks and vulnerabilities for each of the six domains above; how to mitigate those risks and vulnerabilities in each domain; and recommendations for future actions. (Lead: HHS; Support: DOS, FBI)

II. Implement the National Strategy for a Resilient Public Health Supply Chain (the Strategy), which was developed in response to the Executive Order (EO) 14001 on a Sustainable Public Health Supply Chain. The implementation plan supports the nation’s efforts to prepare for and respond to a public health emergency by designing, building, and sustaining a long-term capability in the United States to manufacture supplies for future pandemics and biological threats. To achieve the goals outlined in the Strategy, the implementation plan provides a clear pathway to meet those goals and support objectives articulated within EO 14001 and EO 14017. (Lead: HHS, NSC; Support: DOS, DoD, DHS)

III. Strengthen federal capabilities to effectively mitigate the impact of, and recover from, future bioincidents. (Lead: HHS, DHS; Support: DOT, EPA)

IV. Analyze the effectiveness of community mitigation measures and related public health policies domestically and internationally, based on evidence from the COVID-19 pandemic and other responses; determine gaps in community mitigation preparedness and response to address emerging and deliberate threats; and develop guidelines for updated community mitigation plans for future biological incident response. (Lead: CDC; Support: DOS, HHS, DOT, USAID)

V. Fund basic research, innovation, and the development of tools and technology for suppressing pathogen transmission in the built environment, including antimicrobial and antiviral structures and surfaces, ventilation, filtration, sterilization, and decontamination

technologies. Increase the adoption of these technologies in federal buildings and work with external stakeholders to encourage and incentivize adoption of these technologies in public spaces, public transport, and laboratories. (Lead: HHS, EPA; Support: DoD, DOL, DOT, DOE, DHS, General Services Administration (GSA))

VI. Develop a national environmental countermeasures capability to enable rapid containment and remediation of environmental contamination. (Lead: EPA; Support: DOT, DHS, FBI)

VII. Develop a unified, regional approach to improve national health care readiness and medical surge capacity by better integrating preparedness within the already-existing health care delivery infrastructure and by strengthening public-private partnerships. (Lead: HHS; Support: DOT, DHS)

VIII. Enhance pre-existing capabilities for treatment, biocontainment, and movement of patients infected with high consequence pathogens. (Lead: HHS; Support: DOS, DOT)

GOAL 4. Rapidly Respond to Limit the Impacts of Bioincidents

The United States will respond rapidly to limit the impacts of bioincidents through information sharing and networking; evidence-driven, coordinated response operations and investigations; effective public messaging; and research.

4.1. Whole-of-Society Response

Establish both (a) a unity of effort across governments (federal, SLTT) and local communities and (b) a national environmental countermeasures capability; to limit health, economic, social, and national security impacts and consequences of nationally or internationally significant biological incidents, whether naturally occurring, accidental, or deliberate.

4.1.1. Effective Response to Mitigate Biological Incidents

Develop the capability to, within seven days of the determination of a potential nationally or internationally significant biological incident, (1) trigger and coordinate a domestic One Health evidence-informed response and (2) support an appropriate collaborative One Health evidence-informed international response, to contain and mitigate any significant domestic biological incident.

I. Promptly activate and appropriately scale interagency response coordination mechanisms, centers, and strategic groups described in Presidential policies and federal planning documents (e.g., Homeland Security Presidential Directive 5, as amended; National Prevention and Response Frameworks; Biological Incident Annex), and adapt to the biothreat or bioincident, after notification of a credible biothreat or bioincident. (Lead: (Non-Stafford Human Health Impact) HHS, (Non-Stafford Animal, Plant, or Agricultural Health Impact) DOI, USDA, (International Response Co-Lead) DOS, (Stafford) HHS and DHS; Support: (Non-Stafford Human Health Impact) DOS, DoD, DOI, USDA, DOC, DOL, HHS, DOT, DOE, VA, DHS, EPA, USAID, FBI, Appalachian Regional Commission, GSA, United States Postal Service, (Non-Stafford Animal, Plant, or Agricultural Health Impact) Same as above and Emergency Support Function-13 supporting agencies and organizations)

4.1.2. Limit Environmental Impacts of Biological Incidents

Develop the domestic capability to detect, sample, analyze, and evaluate the extent of environmental contamination of affected areas by a biological hazard to inform and operationalize mitigation, response, remediation, and recovery efforts, within seven days of the determination of a nationally or internationally significant biological incident.

I. Specific to the incident, develop and publish decontamination and waste management plans to address the proper handling, collection, and disposal of waste streams contaminated with a biological hazard(s) as well as to inform re-occupancy after decontamination and established clearance levels achieved. (Lead: EPA)

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4.1.3. Coordinate Real-Time Research for Response

Develop and implement an integrated, adaptive, and flexible federal One Health research agenda that coordinates real-time federal and public and private sector research to support rapid domestic response and mitigation, within fourteen days of the determination of a nationally or internationally significant biological incident.

I. Develop an approved plan and clear processes that allow for developing and implementing a coordinated, transparent, United States Government research response agenda for nationally or internationally significant biological incidents within fourteen days, subject to revision as new evidence becomes available. (Lead: DOI, USDA, HHS, DHS, EPA; Support: VA, NIH, FDA, CDC)

4.1.4. Innovative Clinical-Trial Infrastructure

Maintain and build upon the clinical-trials infrastructure, inclusive of U.S. rural hospitals, and international sites as appropriate, ready to administer candidate countermeasures to participants within 14 days after the identification of a viable countermeasure to expedite the evaluation of safe and effective vaccines, therapeutics, and diagnostics for all segments of the population during a nationally or internationally significant biological incident.

I. Develop a U.S. Government clinical trials infrastructure joint capabilities plan. (Lead: NSC, OSTP; Support: DOS, HHS, VA, NIH)

GOAL 5. Facilitate Recovery to Restore the Community, the Economy, and the Environment after a Bioincident

The United States Will Take Actions to Restore Critical Infrastructure Services and Capability; Coordinate Recovery Activities; Provide Recovery Support and Long-Term Mitigation; and Minimize Cascading Effects Elsewhere in the World.

5.1. Whole-of-Society Recovery

Establish both (a) a unity of effort across governments (federal, SLTT) and local communities and (b) a national environmental countermeasures capability; to limit health, economic, social, and national security impacts and consequences of nationally or internationally significant biological incidents, whether naturally occurring, accidental, or deliberate.

5.1.1. Recovery Planning and Implementation

Develop and initiate a domestic recovery strategy and long-term federal strategic and equitable recovery plan, within seven days of the determination of a potential nationally or internationally significant biological incident.

I. Ensure recovery actions are described in a crisis action plan (CAP), consistent with the Biological Incident Annex and specific to an identified large-scale biological incident, and update the CAP as additional information and science of the large-scale biological incident occurs. (Lead: (Non-Stafford Human Health Impact) HHS, (Non-Stafford Animal, Plant, or Agricultural Health Impact) DOI, USDA, (Stafford) DHS; Support: DOS, DOC, United States Department of Housing and Urban Development, DOT, DOE, EPA, USAID)

II. Update and/or develop additional policy, guidance and practices as necessary to improve future recovery efforts. (Lead: NSC)

ANNEX III: List of Acronyms

AR	Antibiotic Resistance
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease—2019
DHS	United States Department of Homeland Security
DOC	United States Department of Commerce
DoD	United States Department of Defense
DOE	United States Department of Energy
DOI	United States Department of the Interior
DOL	United States Department of Labor
DOS	United States Department of State
DOT	United States Department of Transportation
DPC	United States Domestic Policy Council
EPA	United States Environmental Protection Agency
FAO	Food and Agriculture Organization
FBI	Federal Bureau of Investigation
FDA	United States Food and Drug Administration
FEMA	Federal Emergency Management Agency
GHSA	Global Health Security Agenda
GSA	General Services Administration
HAI	Healthcare-Associated Infections
HHS	United States Department of Health and Human Services
IC	Intelligence Community
IHR	International Health Regulations
JEE	Joint External Evaluation
NHSN	National Health Safety Network
NIH	National Institutes of Health
NSC	United States National Security Council
NSF	National Science Foundation
OSHA	Occupational Safety and Health
OSTP	Office of Science and Technology Policy
PPE	Personal Protective Equipment
PPT	Personal Protective Technology
S&T	Science and Technology
SLTT	State, Local, Tribal, and Territorial
SPAR	State Party Self-Assessment Annual Report (SPAR)
Treasury	United States Department of the Treasury
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
VA	United States Department of Veterans Affairs
WHO	World Health Organization

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ANNEX IV: Legal and Policy Authorities

Departments and Agencies will support the broader implementation of the entirety of the *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* through existing policies, plans, and frameworks and consistent with relevant legal authorities. The policies, plans, frameworks, and legal authorities listed below are examples of many, but not all, of the authorities and guidance documents that the United States Federal Government relies upon to fulfill the United States Federal Government's vision for biodefense, including many important activities not included in the prioritized goals. These relevant policies, plans, frameworks, and legal authorities may change over time and, depending on the circumstances or nature of the biological threat, the United States Federal Government may rely upon other authorities not included herein to enable an appropriate and effective response.

GOAL 1. Enable Risk Awareness and Detection to Inform Decision-Making Across the Biodefense Enterprise

The United States will build risk awareness at the strategic level through analyses and coordinated research efforts to characterize naturally occurring, accidental, and deliberate biological risks; and at the operational level through One Health surveillance and detection activities to detect and identify biological threats and anticipate biological incidents.

Objective 1.1: Ensure Decision-Making is Informed by Intelligence, Forecasting, and Risk Assessment

Agencies will implement Objective 1.1 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 195b, 321q, 591 et seq.
- 7 USC §§ 391, 5921, 5939, 7701 et seq., 8301 et seq., 8401, 8411, 8901, 8912
- 18 USC §§ 175-178
- 22 USC §§ 2151b, 2151b-2, 2151b-3, 2151b-4, 2292
- 42 USC §§ 247d-4, 7139, 7251, 7256
- 50 USC §§ 2370, 2401, 3057
- HSPD-9
- HSPD-18
- HSPD-21
- PPD-21
- NSM-1
- EO 12333
- EO 13676
- EO 13747

- EO 13987
- Global Health Security Strategy
- 2019-2022 National Health Security Strategy Implementation Plan
- National Strategy for Biosurveillance
- National Biosurveillance S&T Roadmap
- National Strategy for Pandemic Influenza
- National Strategy for Combating Antibiotic Resistant Bacteria
- National Action Plan for Combating Antibiotic Resistant Bacteria 2020-25
- National Action Plan for Multidrug Resistant Tuberculosis
- United States President's Emergency Plan for AIDS Relief
- U.S. President's Malaria Initiative Strategy

Objective 1.2: Ensure that domestic and global biothreat detection, biosurveillance, and information systems are coordinated, integrated, and capable of enabling timely bioincident prevention, detection, reporting, assessment, response, and recovery.
Agencies will implement Objective 1.2 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 195b, 321q, 591 et seq.
- 7 USC §§ 391, 5921, 5939, 7701 et seq., 8301 et seq., 8401, 8411, 8901, 8912
- 18 USC §§ 175-178
- 22 USC §§ 2151b, 2151b-2, 2151b-3, 2151b-4, 2292
- 42 USC §§ 247d-4, 300hh-1 as amended (PL 107-296), 300hh-10b, 300jj-17, 300jj-51, 7139, 7251, 7256, 17903
- 50 USC §§ 402-1a-c, 402a, 2370, 2401
- Global Health Security Strategy
- 2019-2022 National Health Security Strategy Implementation Plan
- HSPD-9
- HSPD-21
- PPD-21
- NSM-1
- EO 12333
- EO 13676
- EO 13747
- EO 13987

- National Strategy for Biosurveillance
- National Biosurveillance S&T Roadmap
- National Strategy for the COVID-19 Response and Pandemic Preparedness
- National Strategy for Pandemic Influenza
- National Strategy for Combating Antibiotic Resistant Bacteria
- National Action Plan for Combating Antibiotic Resistant Bacteria 2020-25
- National Action Plan for Multidrug Resistant Tuberculosis
- U.S. President's Malaria Initiative Strategy
- U.S. President's Emergency Plan for AIDS Relief
- U.S. COVID-19 Global Response and Recovery Framework

GOAL 2. Ensure Biodefense Enterprise Capabilities to Prevent Bioincidents

The United States will work to prevent the outbreak and spread of naturally occurring infectious diseases and minimize the risk of laboratory accidents both domestically and globally. The United States will also strengthen biosecurity to prevent both state and nonstate actors from obtaining or using biological material, equipment, and expertise for nefarious purposes, consistent with the U.S. Government's approach to countering weapons of mass destruction. Implementing Goal 2 will ensure we have the capabilities necessary to disrupt plots, degrade technical capabilities, and deter support for state and nonstate actors seeking to use biological weapons. This goal also recognizes the dual-use nature of the life sciences and biotechnology, in which the same science and technology base that improves health, promotes innovation, and protects the environment can also be misused for harmful purposes. Domestically and internationally, the United States seeks to prevent the misuse of science and technology while promoting and enhancing its legitimate use and innovation.

Objective 2.1: Promote measures to prevent or reduce the spread of infectious diseases

Agencies will implement Objective 2.1 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC § 104
- 7 USC §§391, 396, 398, 499n, 5921, 5939, 7701 et seq., 8301 et seq., 8401, 8411
- 22 USC §§ 2151b, 2151b-2, 2151b-3, 2151b-4, 2292
- 42 USC §§ 201 et seq.
- HSPD-9
- NSM-1
- EO 13676
- EO 13747
- EO 13987

- 2019-2022 NHSS-IP
- National Action Plan for Combating Antibiotic Resistant Bacteria, 2020-2025 (CARB)
- National Framework for the Prevention and Control of Vector-Borne Diseases in Humans
- National Strategy for Pandemic Influenza
- National Strategy for the COVID-19 Response and Pandemic Preparedness
- Countering Terrorism and Targeted Violence (PAP and IP)
- National Prevention Framework (FEMA)
- National Strategy for Combating Antibiotic Resistant Bacteria;
- National Action Plan for Multidrug Resistant Tuberculosis
- U.S. President's Malaria Initiative Strategy
- U.S. Global Water Strategy 2022-2027
- U.S. COVID-19 Global Response and Recovery Framework
- USAID Water and Development Plan
- Global Health Security Strategy

Objective 2.2: Strengthen Global Health Security Capacities Internationally to Prevent Local Bioincidents from Becoming Epidemics

Agencies will implement Objective 2.2 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC § 104
- 7 USC §§ 391, 396, 398, 499n, 5921, 5939, 7701 et seq., 8301 et seq., 8401, 8411
- 22 USC §§ 2151b, 2151b-3
- 42 USC § 300hh–1 as amended (PL 107-296)
- HSPD-21
- PPD-21
- NSM-1
- EO 13747
- EO 13987
- Global Health Security Agenda
- Global Health Security Strategy
- National Strategy for the COVID-19 Response and Pandemic Preparedness
- U.S. COVID-19 Global Response and Recovery Framework

- Promoting Global Health Security: Guidance and Principles for U.S. Government Departments and Agencies to Strengthen IHR Core Capacities Internationally (2011)

Objective 2.3: Deter, Detect, Degrade, Disrupt, Deny, or Otherwise Prevent Nation-State and Nonstate Actors' Attempts to Pursue, Acquire, or Use Biological Weapons, Related Materials, or Their Means of Delivery

Agencies will implement Objective 2.3 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC § 104
- 7 USC §§ 391, 396, 398, 499n, 5921, 7701 et seq., 8301 et seq., 8401, 8411
- 18 USC §§ 175-178
- 22 USC §§ 2349bb-1
- 42 USC §§ 300hh–1 as amended (PL 107-296)
- PL 109-347
- HSPD-9
- PPD-21
- Countering Terrorism and Targeted Violence (PAP and IP)
- National Protection Framework (FEMA)

Objective 2.4: Strengthen biosafety and biosecurity practices and oversight to prevent bioincidents and reduce biological risks associated with life sciences research and development and advances in biotechnology

Agencies will implement Objective 2.4 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC § 104
- 7 USC §§ 391, 396, 398, 499n, 3351, 3354, 5921, 5939, 7701 et seq., 8301 et seq., 8401, 8411
- 22 USC §§ 2151a, 2151b
- 42 USC §§ 201 et seq., 300hh–1 as amended (PL 107-296)
- 29 CFR §§ 1910, 1926
- NSM-1
- EO 13747
- EO 13987
- EO 14081
- 2019-2022 NHSS-IP
- Global Health Security Strategy

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GOAL 3. Ensure Biodefense Enterprise Preparedness to Reduce the Impacts of Bioincidents

The United States will take measures to reduce the impacts of bioincidents, including maintaining a vibrant national science and technology base to support biodefense; promoting a strong domestic and international public, veterinary, and plant health infrastructure; developing, updating, and exercising response and recovery capabilities; establishing risk communications; developing and effectively distributing and dispensing countermeasures; and collaborating across the country and internationally to support biodefense.

Objective 3.1: Promote a Vibrant, Safe, and Secure Domestic and International Science and Technology Base, Including in Biotechnology and Biomanufacturing, to Support Biodefense

Agencies will implement Objective 3.1 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 195b, 321q, 591 et seq.
- 7 USC §§ 391, 398, 5841, 5939, 7701 et seq., 8301 et seq., 8901, 8912
- 21 USC §§ 151-158
- 22 USC §§ 2151a, 2151b
- 42 USC §§ 241, 243, 247d-6a, 247d-6b, 247d-7e, 247d-7f, 289c, 289g-4, 300hh-10, 300hh-31, 7139, 7251, 7256
- 50 USC § 2401
- PAHPAIA, Title VI: Advancing Technologies for Medical Countermeasures, Section 605: Review of the Benefits of Genomic Engineering Technologies and Their Potential Role in National Security
- 29 CFR §§ 1910, 1926
- HSPD-9
- HSPD-18
- NSM-1
- EO 13747
- EO 13987
- EO 14081
- PHEMCE SIP
- 2019-2022 NHSS-IP
- Global Health Security Strategy

Objective 3.2: Ensure a Strong Public, Veterinary, and Plant Health Infrastructure

Agencies will implement Objective 3.2 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 195b, 321q, 591 et seq.
- 7 USC §§ 391, 398, 5841, 5939, 7701 et seq., 8301 et seq., 8901, 8912
- 21 USC §§ 511-518
- 22 USC §§ 2151a, 2151b
- 42 USC §§ 204, 204a, 243, 247b-21, 247d-3b, 247d-4, 247d-6, 247d-7b, 264-272, 280g-16, 289g-4, 300hh-1, 300hh-10, 300hh-11, 300hh-15, 300hh-17, 300hh-2, 300hh-31, 2391, 2391-2
- 18 USC §§ 175-178
- 29 CFR §§ 1910, 1936
- PL 115-43
- PL 115-387
- HSPD-9
- HSPD-21
- NSM 1
- EO 13747
- EO 13987
- 2019-2022 NHSS-IP
- Global Health Security Strategy
- National Influenza Vaccine Modernization Strategy

Objective 3.3: Develop, Exercise, and Update Prevention, Response, and Recovery Plans and Capabilities, Including Efforts to Secure Critical Supply Chains

Agencies will implement Objective 3.3 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 591 et seq.
- 7 USC §§ 391, 5841, 5939, 7701 et seq., 8301 et seq., 8901, 8912
- 18 USC §§ 175-178
- 21 USC §§ 151-158
- 22 USC §§ 2292 as extended to include "international disaster rehabilitation and reconstruction" by annual appropriations (e.g., PL 116-260 for FY21)
- 42 USC §§ 204, 204a, 234, 239, 241, 243, 247d, 247d-3a, 247d-3b, 247d-3c, 247d-4, 247d-6, 247d-6a, 247d-6b, 247d-6d, 247d-6e, 247d-7b, 247d-7e, 247d-7f, 247d-91, 280g-16, 281, 282, 289c, 289g-4, 300ff-131, 300hh-1, 300hh-10, 300hh-10a, 300hh-11, 300hh-15, 300hh-16, 300hh-17, 300hh-2, 300hh-31, 2391, 2391-2, 7139, 7251, 7256

- PAHPAIA, Improving Preparedness and Response, Section 210 42 USC 300hh-11 42 USC 300hh-1042 USC 247d-4b
- 50 USC § 2401
- PPD-21
- PPD-40
- HSPD-9
- HSPD-18
- HSPD-21
- PPD-21
- PPD-40
- NSM-1
- EO 12656
- EO 13961
- EO 14001
- EO 14017
- EO 13257
- EO 13747
- EO 13987
- National Prevention Framework
- National Mitigation Framework
- National Response Framework
- National Disaster Recovery Framework
- ESF-11
- Federal Continuity Directive 1 (FCD-1)
- Federal Continuity Directive 2 (FCD-2)
- National Continuity Policy Implementation Plan
- National Strategy for the COVID-19 Response and Pandemic Preparedness
- U.S. COVID-19 Global Response and Recovery Framework
- National Infrastructure Protection Plan
- Global Health Security Strategy
- Annual updates to DOL/OSHA emergency plans

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Objective 3.4: Develop, Exercise, and Update Risk Communication Plans and Promote Consistent, Plain Language Messaging to Inform Key Audiences, Expedite Desired Response Actions, and Address Public Uncertainty and Fear

Agencies will implement Objective 3.4 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 591 et seq.
- 7 USC §§ 398, 5841, 5939, 7701 et seq., 8901, 8912
- 21 USC §§ 151-158
- 22 USC §§ 2151b, 2292
- 42 USC §§ 247d-4, 289c, 300hh-1, 300hh-10
- PPD-40
- HSPD-9
- HSPD-21
- EO 12656
- EO 13961
- Federal Continuity Directive 1 (FCD-1)
- Federal Continuity Directive 2 (FCD-2)
- National Continuity Policy Implementation Plan
- National Response Framework
- National Infrastructure Protection Plan
- National Disaster Recovery Framework
- Annual updates to DOL/OSHA emergency plans; provide information to DOL/OSHA Office of Communications on internal and external messages for response and recovery actions

Objective 3.5: Enhance Preparedness to Save Lives through Development, Testing, Evaluation, Manufacturing, Regulatory Approval, Distribution, and Administration of Countermeasures

Agencies will implement Objective 3.5 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 195b, 591 et seq.
- 7 USC §§ 391, 398, 5841, 5939, 7701 et seq., 8301 et seq., 8901, 8912
- 21 USC §§ 151-158
- 22 USC § 2151b

- 42 USC §§ 241, 247d-4, 247d-6, 247d-6a, 247d-6b, 247d-6d, 247d-7e, 280g-16, 281, 289c, 300hh-1 as amended (PL 107-296), 300hh-10, 300hh-10b, 300hh-13, 300hh-31, 360bbb-4b, 7139, 7251, 7256
- 50 USC § 2401
- PAHPAIA, Title VI: Advancing Technologies for Medical Countermeasures, Section 606: Report on the Development of Vaccines to Prevent Future Epidemics
- HSPD-9
- HSPD-18
- HSPD-21
- 2019-2022 NHSS-IP
- PHEMCE SIP
- National Action Plan for Combating Antibiotic Resistant Bacteria, 2020-2025 (CARB)
- National Response Framework

Objective 3.6: Enhance Preparedness to Limit the Spread of Disease through Community Mitigation Measures

Agencies will implement Objective 3.6 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 921, 945, 1003
- 7 USC §§ 391, 5841, 5939, 7701 et seq., 8301 et seq., 8901, 8912
- 21 USC §§ 151-158
- 22 USC §§ 2292, 9808b
- 42 USC §§ 264-71, 300hh-1, 300hh-10
- 29 CFR §§ 1910, 1926
- 42 CFR §§ 70, 71
- PL 109-347
- HSPD-9
- 2019-2022 NHSS-IP

Objective 3.7: Enhance Preparedness to Support Decontamination, Waste Management, Environmental Controls, and Other Methods of Suppressing Pathogens during a Biological Event

Agencies will implement Objective 3.7 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 921, 945, 1003
- 7 USC §§ 391, 5939, 7701 et seq., 8301 et seq., 8901, 8912

- 21 USC §§ 151-158
- 22 USC §§ 2151a
- 42 USC §§ 241, 243, 247d-6, 247d-6a, 247d-6b, 247d-7e, 281, 289c, 300hh-1, 300hh-10, 300hh-13, 7139, 7251, 7256
- 50 USC § 2401
- PL 109-347
- 29 CFR §§ 1910, 1926
- HSPD-9
- 2019-2022 NHSS-IP

Objective 3.8: Strengthen Preparedness to Operate and Collaborate Across the United States, Including the U.S. Territories

Agencies will implement Objective 3.8 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 591 et seq.
- 7 USC §§ 391, 398, 5841, 5939, 7701 et seq., 8301 et seq., 8901, 8912
- 21 USC §§ 151-158
- 42 USC §§ 204, 243, 282, 247d-3c, 247d-4, 247d-7b, 247d-7e, 280g-16, 300hh-1, 300hh-10, 300hh-11, 300hh-15, 300hh-17, 300hh-2, 300hh-31, 300hh-21
- PAHPAIA, Title VI: Advancing Technologies for Medical Countermeasures, Section 606: Report on the Development of Vaccines to Prevent Future Epidemics
- HSPD-9
- HSPD-21
- PPD-21
- PPD-40
- EO 12656
- EO 13961
- 2019-2022 NHSS-IP
- Federal Continuity Directive 1 (FCD-1)
- Federal Continuity Directive 2 (FCD-2)
- National Continuity Policy Implementation Plan
- National Response Framework
- National Infrastructure Protection Plan
- National Disaster Recovery Framework

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Objective 3.9: Strengthen International Preparedness to Support International Response and Recovery Capabilities

Agencies will implement Objective 3.9 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC § 104
- 7 USC §§ 391, 5841, 5939, 7701 et seq., 8301 et seq.
- 18 USC §§ 175-178
- 21 USC §§ 151-158
- 22 USC §§ 2151b, 2292 as extended to include "international disaster rehabilitation and reconstruction" by annual appropriations (e.g., PL 116-260 for FY21), 9808b
- 42 USC §§ 281, 243, 247d-4, 242l, 300hh-10
- PAHPAIA, Title VI: Advancing Technologies for Medical Countermeasures, Section 606: Report on the Development of Vaccines to Prevent Future Epidemics
- HSPD-9
- HSPD-21
- NSM-1
- EO 13747
- EO 13987
- Global Health Security Agenda
- Global Health Security Strategy
- Building Resilience to Recurrent Crisis—USAID Policy and Program Guidance
- National Strategy for the COVID-19 Response and Pandemic Preparedness
- U.S. COVID-19 Global Response and Recovery Framework
- U.S. Government Global Food Security Strategy (GFSS); Global Food Security Strategy "Refresh" (GFSS-R)
- U.S. Government Global Nutrition Coordination Plan
- U.S. Government Global Water Strategy 2022-2027 and USAID Water and Development Plan

GOAL 4. Rapidly Respond to Limit the Impacts of Bioincidents

The United States will respond rapidly to limit the impacts of bioincidents through information sharing and networking; evidence-driven, coordinated response operations and investigations; effective public messaging; and research.

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Objective 4.1: Compile and Share Biothreat, Bioincident, and Response Information to Enable Appropriate Decision-Making and Response Operations across All Levels of Government and With Nongovernmental, Private Sector, and International Entities, as Appropriate

Agencies will implement Objective 4.1 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 195b, 467 321g, 591, 592, 596, 597,
- 7 USC §§ 499n, 7701 et seq., 8301 et seq.
- 22 USC §§ 2151b, 2292, 9808b
- 42 USC §§ 103, 247d, 247d-4, 280g-16, 300ff-138, 300hh-1 as amended (PL 107-296), 300hh-10, 300hh-11, 7545c-4c(ii)
- 50 USC § 4501
- 54 USC §§ 100101 et seq.
- HSPD-9
- PPD-8
- PPD-21
- NSM-1
- 2019-2022 NHSS-IP
- National Response Framework
- Response Federal Interagency Operational Plan (Response FIOP)
- Biological Incident Annex (BIA)
- National Disaster Recovery Framework

Objective 4.2: Conduct Evidence-Driven Federal Response Operations and Activities and Implement a Federal Research Agenda in Coordination with Relevant Nongovernmental, Private Sector, and International Partners Where Appropriate to Contain, Control, and Rapidly Mitigate Impacts of Biothreats or Bioincidents

Agencies will implement Objective 4.2 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 195b, 591 et seq., 592, 596, 7545c-4c(ii)
- 7 USC §§ 499n, 3351, 3354, 7701 et seq., 8301 et seq., 8401
- 22 USC §§ 2151b, 2292, 9808b
- 42 USC §§ 103, 204, 204a, 243, 247d, 247d-4, 247d-4b, 247d-6d, 247d-6e, 247d-7b, 280g-16, 300hh, 300hh-1 as amended (PL 107-296), 300hh-10, 300hh-10a, 300hh-11, 300hh-15, 300hh-16, 300ff-131, 7139, 7251, 7256
- PAHPAIA, Title VI: Advancing Technologies for Medical Countermeasures, Section 606: Report on the Development of Vaccines to Prevent Future Epidemics

- 50 USC §§ 2401, 4501 et seq.
- 54 USC §§ 100101 et seq.
- HSPD-9
- PPD-8
- PPD-21
- 2019-2022 NHSS-IP
- National Response Framework
- Response Federal Interagency Operational Plan (Response FIOP)
- Biological Incident Annex (BIA)
- National Disaster Recovery Framework

Objective 4.3: Conduct Operations and Investigations, and Use All Available Tools to Hold Perpetrators Accountable

Agencies will implement Objective 4.3 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 195b, 591, 592, 596, 597
- 7 USC §§ 499n, 8401
- 18 USC §§ 175-178, 2332a, 2332b(f)
- 42 USC §§ 103, 247d, 280g-16, 300hh-1 as amended (PL 107-296), 300hh-11, 7545c-4c(ii)
- 50 USC §§ 4501 et seq.
- 54 USC §§ 100101 et seq.
- 28 CFR § 0.85(1)
- 42 CFR § 73
- HSPD-5
- HSPD-9
- PPD-8
- PPD-21
- 2019-2022 NHSS-IP
- National Response Framework
- National Prevention Framework
- Prevention Federal Interagency Operational Plan (Prevention FIOP)
- Response Federal Interagency Operational Plan (Response FIOP)

- Biological Incident Annex (BIA)

Objective 4.4: Execute Risk-Informed, Accurate, Timely, and Actionable Science-Driven Risk Communications and Community Engagement

Agencies will implement Objective 4.4 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 195b, 591, 592, 596, 597
- 7 USC §§ 499n, 7701 et seq., 8301 et seq., 8401
- 42 USC §§ 103, 247d-6e, 300hh-1 as amended (PL 107-296), 300hh-11, 300hh-16, 7545c-4c(ii)
- 50 USC §§ 4501 et seq.
- 54 USC §§ 100101 et seq.
- HSPD-5
- HSPD-9
- PPD-8
- PPD-21
- 2019-2022 NHSS-IP
- National Response Framework
- Response Federal Interagency Operational Plan (Response FIOP)
- Biological Incident Annex (BIA)
- National Disaster Recovery Framework

GOAL 5. Facilitate Recovery to Restore the Community, the Economy, and the Environment after a Bioincident.

The United States will take actions to restore critical infrastructure services and capability; coordinate recovery activities; provide recovery support and long-term mitigation; and minimize cascading effects elsewhere in the world.

Objective 5.1: Promote Restoration of Critical Infrastructure Capability and Capacity to Enable the Resumption of Vital U.S. Activities

Agencies will implement Objective 5.1 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 195b, 591, 592, 296, 597
- 22 USC §§ 2292 as extended to include "international disaster rehabilitation and reconstruction" by annual appropriations (e.g., PL 116-260 for FY21), 9808b
- 42 USC §§ 300h-1 as amended (PL 107-296), 300hh-11, 7545c-4c(ii)
- 50 USC §§ 4501 et seq.

- 54 USC §§ 100101 et seq.
- HSPD-9
- PPD-21
- NSM-1
- EO 13987
- 2019-2022 NHSS-IP
- National Response Framework
- National Disaster Recovery Framework
- National Strategy for the COVID-19 Response and Pandemic Preparedness
- U.S. COVID-19 Global Response and Recovery Framework

Objective 5.2: Ensure Coordination of Recovery Activities across All Levels of Government and With Nongovernmental, Private Sector, and International Entities, As Appropriate, to Enable Effective and Efficient Recovery Operations

Agencies will implement Objective 5.2 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 6 USC §§ 104, 195b, 591, 592, 596, 597
- 22 USC §§ 2292 as extended to include "international disaster rehabilitation and reconstruction" by annual appropriations (e.g., PL 116-260 for FY21), 9808b
- 42 USC §§ 300hh-1 as amended (PL 107-296), 7545c-4c(ii)
- HSPD-9
- PPD-21
- NSM-1
- EO 13987
- National Disaster Recovery Framework
- National Strategy for the COVID-19 Response and Pandemic Preparedness
- U.S. COVID-19 Global Response and Recovery Framework

Objective 5.3: Provide Recovery Support and Conduct Long-Term Mitigation Actions to Promote Resilience

Agencies will implement Objective 5.3 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 42 USC §§ 247d-6d, 300hh-11, 300hh-16
- HSPD-9
- PPD-21

- Biological Incident Annex
- Response and Recovery Federal Interagency Operational Plans
- 2016 National Mitigation Framework
- U.S. Government Global Water Strategy 2022-2027
- National Disaster Recovery Framework

Objective 5.4: Reduce the Cascading Effects of International Biological Incidents on the Global Economy, Health, and Security

Agencies will implement Objective 5.4 through existing policies, plans, and frameworks and consistent with existing legal authorities, including:

- 22 USC §§ 2151a, 2292, 9808b
- PPD-21
- NSM-1
- EO 13987
- Building Resilience to Recurrent Crisis—USAID Policy and Program Guidance,
- U.S. Government Global Food Security Strategy (GFSS); Global Food Security Strategy "Refresh" (GFSS-R)
- U.S. Government Global Nutrition Coordination Plan
- U.S. Government Global Water Strategy 2022-2027
- National Response Framework
- National Disaster Recovery Framework
- National Strategy for the COVID-19 Response and Pandemic Preparedness
- U.S. COVID-19 Global Response and Recovery Framework
- National Mitigation Framework

UNDER SECRETARY OF DEFENSE
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RESEARCH
AND ENGINEERING

21 March 2023

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
CHIEF OF THE NATIONAL GUARD BUREAU
GENERAL COUNSEL OF THE DEPARTMENT OF DEFENSE
DIRECTOR OF COST ASSESSMENT AND PROGRAM EVALUATION
INSPECTOR GENERAL OF THE DEPARTMENT OF DEFENSE
DIRECTOR OF OPERATIONAL TEST AND EVALUATION
CHIEF INFORMATION OFFICER OF THE DEPARTMENT OF DEFENSE
ASSISTANT SECRETARY OF DEFENSE FOR LEGISLATIVE AFFAIRS
ASSISTANT SECRETARY OF DEFENSE FOR SPECIAL OPERATIONS AND LOW INTENSITY CONFLICT
ASSISTANT TO THE SECRETARY OF DEFENSE FOR PRIVACY, CIVIL LIBERTIES, AND TRANSPARENCY
ASSISTANT TO THE SECRETARY OF DEFENSE FOR PUBLIC AFFAIRS
CHIEF DIGITAL AND ARTIFICIAL INTELLIGENCE OFFICER
DIRECTOR OF ADMINISTRATION AND MANAGEMENT
DIRECTOR OF NET ASSESSMENT

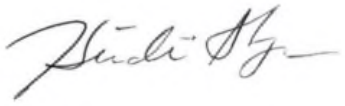
SUBJECT: Department of Defense Biomanufacturing Strategy

The Office of the Under Secretary of Defense for Research and Engineering, informed by the 2022 National Defense Strategy and Executive Order (E.O.) 14081 (*Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy*), spearheaded development of the official Department of Defense (DoD) Biomanufacturing Strategy. The United States faces a foundational gap in the ability to scale up bioindustrial manufacturing from laboratory research and development to commercial-scale production due to the insufficient network of pilot-scale biomanufacturing infrastructure to validate a technology or product. As a purpose-built pilot production facility costs $100-200 million, the return on investment for private industry does not exist. The biomanufacturing strategy is structured around three core principles—establish DoD transition partners for biotechnology, innovate in biomanufacturing, and map and measure the biomanufacturing ecosystem—to incentivize the establishment of the infrastructure required to close the gap.

The Department will make substantial investments in support of the strategy, including $1 billion over five years to catalyze the establishment of a domestic biomanufacturing industrial base, $270 million over five years for the Tri-Service Biotechnology for a Resilient Supply Chain program, and $200 million to support biosecurity- and cybersecurity-related efforts

associated with the biomanufacturing industrial base. The highlighted investments in biotechnology and biomanufacturing technologies support the bioindustrial manufacturing base to ensure the Department has access to domestic products and materials and strengthen U.S. technological superiority amidst a global race for technological advantage. A detailed implementation plan for Department review is under development.

The cross-cutting nature of building the domestic biomanufacturing ecosystem poses potential challenges, including harmonizing investments, priorities, and policies across the Department and with the National Biotechnology and Biomanufacturing Initiative created by E.O. 14081. Therefore, the attached strategy will be shared with the executive branch, the Federal agencies, and the public to foster the public-private partnerships required to position the United States as the global leader in transitioning biotechnology research to commercial-scale production. DoD's strategy provides the framework to develop critical biotechnologies, rapidly prototype them, scale production, and deliver capabilities that support the Warfighter. Innovating the domestic biomanufacturing ecosystem today enables the industrial base to deliver military dominance tomorrow in an ever-shifting and fast-moving global environment.



Heidi Shyu

U.S. Department of Defense
Biomanufacturing Strategy

Office of the Under Secretary of Defense for Research and Engineering

21 March 2023

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"Political leaders in the U.S., Europe, and Japan hadn't thought much about semiconductors in decades. Like the rest of us, they thought tech meant search engines or social media, not silicon wafers." –Chris Miller in *Chip War: The Fight for the World's Most Critical Technology*, 2022.

1. Background

Biomanufacturing, defined as the use of biological mechanisms in manufacturing, is a rapidly maturing technology.[1] While the origins of biomanufacturing are rooted in medicine and agriculture, today, biotechnology is used to manufacture an increasing range of materials that are of significant interest to the Department of Defense (DoD). One estimate suggests that "more than half of the impact from the visible pipeline of [biotechnology] applications is outside of healthcare—in agriculture, consumer, and other areas."[2] If resources are strategically placed, biotechnology can support the U.S. military and the militaries of our allies and partners. The strategy described herein builds on initial investments in biomanufacturing to accelerate its maturation and use. A key aspect of this strategy is ensuring that DoD investments focus on addressing critical shortfalls in military capability and building an enduring advantage in biomanufacturing by retaining a domestic capability.

The United States has been pivotal in developing nearly all modern technological industries. Spurred by its unique role in national security, DoD often provides crucial early investment in research and development (R&D), pioneers novel applications of technology, supports industrial manufacturing of these applications, and spurs the commercial adoption of new technologies. As a result, the entry of technologies into the into the commercial market for civilian use often follows military advances. As commercial use of these technologies expands and if the United States fails to invest in its domestic manufacturing capabilities, market forces can drive manufacturing to overseas sites, often at the expense of the national economy and potentially creating vulnerabilities in the DoD supply of these products. Semiconductor manufacturing is a prime example. Biotechnology is now expanding similarly; in 10 to 20 years, the current biotechnology pipeline is expected to have a significant impact,[3] accompanied by a commensurate expansion to other nations. Currently, strategic competitors are investing in flexible "multi-product and multi-organism" biomanufacturing facilities that enable the production of different products at a single facility in response to product demand.[4] As a result, many U.S. companies go to the European Union for their biomanufacturing needs, and it is only a matter of time before U.S. companies also go to China for biomanufacturing.[5] To prevent the continued economic loss of U.S.-developed biotechnology innovations to overseas

[1] Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)) Industrial Policy, "Fiscal Year 2020 Industrial Capabilities Report To Congress," January 2021, p. 117.
[2] McKinsey Global Institute (MGI), "The Bio Revolution: Innovations transforming economies, societies, and our lives," p. 65.
[3] MGI, 2020, p. 57.
[4] Executive Office, Public Meeting of the President's Council of Advisors on Science and Technology, November 2021, p. 6.
[5] Executive Office, November 2021, p. 6-7.

manufacturing, it is critical that the U.S. Government become more involved in the race for the industrialization of biotechnology.

However, the United States can implement lessons learns from the semiconductor industry—loss of high-end manufacturing to Taiwan—to help shape a potentially different fate for biomanufacturing than semiconductor manufacturing.[6] Moreover, because of the range of potential defense capabilities that could arise from biomanufacturing (e.g., mitigating military supply chain vulnerabilities, solving logistics challenges with point-of-need biomanufacturing, and adopting materials with novel characteristics into the joint forces), DoD has a stake in investing in and retaining a domestic capability to build an enduring advantage in biomanufacturing.

Biologically-derived products, such as the chemicals in paints, are already a part of the DoD supply chain and are poised to continue to increase in significance going forward. As a result, DoD cannot wait until there is a supply chain crisis in any critical biomanufactured component to reveal the Department's already growing dependence on biomanufacturing in adversary nations.[7] The supply chain crisis of 2020-2022 revealed our significant vulnerability, the importance of microelectronics, and the disproportionate contribution of the humble integrated circuit to modern technology. In order to adapt and fortify our defense ecosystem against similar vulnerabilities in the future, DoD must look at biotechnology beyond a means to improve medical care and vaccines and must capitalize on the biomanufacturing revolution to meet its capability gaps. By doing so, the Department will be able to help ensure that domestic biomanufacturing capabilities do not erode and adversaries do not overtake the United States in biomanufacturing. For example, the People's Republic of China (PRC) publicly declares its intention to win on the "main economic battlefields" and become a "manufacturing powerhouse" in the field of biotechnology,[8] without respect for protocols, conventions, or human rights.[9]

The biomanufacturing revolution is happening now, and the United States will continue to lead the way in biotechnology, as it did in semiconductors. However, the Nation must act swiftly and deliberately to maintain its competitive advantage. Because biomanufacturing is a nascent industry, DoD's efforts will catalyze domestic biomanufacturing, protect biomanufacturing at home and with our allies and partners, and secure biotechnology and biosafety.

In alignment with the strategic priorities defined in 2022 under the National Security Strategy (NSS) and the National Defense Strategy (NDS), the Joint Warfighting Concept (JWC), the Creating Helpful Incentives to Produce Semiconductors (CHIPS) and Science Act of 2022, and

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[6] See E.O. 14083, September 15, 2022; E.O. 14017, February 24, 2021; E.O. 14081, September 12, 2022; E.O. 14005, January 25, 2021; National Science and Technology Council, "National Strategy for Advanced Manufacturing," October 2022.

[7] This loss is noted in E.O. 13806, "Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States," July 21, 2017.

[8] See part two of the PRC's 14th 5-year plan describing its modernization, science and technology self-reliance and self-improvement (科技自立自强), and its aim toward becoming a manufacturing powerhouse (制造强国).

[9] OUSD(A&S) Industrial Policy, 2021, p. 117

Executive Order (E.O.) 14081[10], among other prior legislation, E.O.s and memoranda, and DoD strategies, the DoD Biomanufacturing Strategy will meet the Department's capability needs in current and future missions by developing and fielding biotechnology-derived solutions. Consistent with U.S. Government initiatives to strategically leverage biomanufacturing for economic, military, and technological advantage,[11] implementation of the DoD Biomanufacturing Strategy will protect and promote a self-sustaining domestic biomanufacturing ecosystem. A self-sustaining domestic biomanufacturing ecosystem will be poised to provide an enduring source of biologically-based solutions while ensuring the U.S. military maintains an enduring advantage to deter conflict and secure the Nation. In addition, DoD's priorities in supporting biomanufacturing will fill capability gaps in critical military supply chains; solve challenges in logistics, especially in contested regions; and provide materials with novel properties, some of which we can only create through biology.

As directed by Congress in the James M. Inhofe National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2023 (Public Law 117-263), DoD will invest in biomanufacturing thru to 2035, consistent with the strategy delineated here, which aligns with the NSS, the NDS, the JWC, and the roles and responsibilities of the Under Secretary of Defense for Research and Engineering (USD(R&E)). When implemented, this strategy will fulfill direction in the NDAA for FY 2023, the CHIPS and Science Act of 2022, and numerous E.O.s.

Ensuring that DoD is making the right technology investments will be central to implementing the DoD Biomanufacturing Strategy. The NDS strives to "seed opportunities in biotechnology" to support the broader innovation ecosystem, providing military advantage through a technological edge. In addition, DoD seeks to strengthen the industrial base within the United States and with allies and partners,[12] focusing its resourcing toward establishing transition partners for early-stage innovations, developing the field of biomanufacturing through R&D innovations within this nascent field, and continuing to support efforts to map the biomanufacturing ecosystem and how it evolves over time. The latter will provide DoD the necessary data to adjust its resourcing and priorities in the future to accommodate and account for changes in the biomanufacturing ecosystem that result from DoD's actions or other exigent events in alignment with DoD's prioritization of creating data advantage by treating data as a strategic asset.[13]

2. Guiding principles of the DoD Biomanufacturing Strategy

[10] E.O. 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," September 12, 2022.
[11] Department of Defense, "New Biotechnology Executive Order Will Advance DoD Biotechnology Initiatives for America's Economic and National Security," September 2022.
[12] Department of Defense, "National Defense Strategy," October 27, 2022, pp. 19-20.
[13] Department of Defense, "Executive Summary: DoD Data Strategy Unleashing Data to Advance the National Defense Strategy," September 2020; and Deputy Secretary of Defense, "Creating Data Advantage," May, 2020.

The DoD Biomanufacturing Strategy supports a self-sustaining domestic biomanufacturing ecosystem that will mitigate the risk of losing newfound capabilities DoD adopts, thus preventing new supply chain vulnerabilities. Three principles guide this strategy:

(1) The Department will establish transition partners for early-stage innovations (e.g., at Technology Readiness Levels 1-5);

(2) The Department will develop the field of biomanufacturing through innovations in practice and application; and

(3) The Department will map the domestic biomanufacturing ecosystem and the changes that occur over time for identification and tracking of metrics to support future implementation and refinement of the DoD Biomanufacturing Strategy.

a. Establish DoD transition partners for biotechnology

The expanding field of biomanufacturing provides a plethora of possible new capabilities. Key to the DoD Biomanufacturing Strategy is investing in approaches that provide technology solutions that fill specific capability gaps and have identifiable DoD customers for resultant products. The Joint Capabilities Integration and Development System process is one of DoD's methods to assist in linking technologies to programs of record.[14] However, there are a number of other formal and informal approaches to match the required capabilities of specific systems to emerging technology solutions, such as biomanufactured technology solutions. Establishing DoD customers for biomanufactured capabilities will guide DoD technology investments. The core of the DoD Biomanufacturing Strategy is a culture shift throughout the Department that both recognizes and prioritizes, where applicable, biotechnology-based solutions to prevent strategic surprise. When the Department looks to biotechnology as a strategic pathway to create novel solutions to adopt into military applications, such investment will contribute significantly toward securing the domestic biomanufacturing industry for the Department and the Nation.[15]

b. Innovate in biomanufacturing

The processes for biomanufacturing scale-up require new R&D. DoD has the opportunity to support the United States in its leadership in innovating and establishing the field of biomanufacturing. Domestically producing technology solutions for the U.S. military is consistent with E.O. 14005, which directs the U.S. Government to procure goods "from sources that will help American businesses compete in strategic industries and help America's workers

[14] Chairman of the Joint Chiefs of Staff Instruction (CJCSI) 5023.01I, "Charter of the Joint Requirements Oversight Council and Implementation of the Joint Capabilities Integration and Development System," October 30, 2021.
[15] The CHIPS and Science Act of 2022 specifically assigned DoD to "(3) Assess risks of potential national security and economic security threats" from biotechnology. See Title IV, Section 10406(d)(3).

thrive,"[16] and the CHIPS and Science Act of 2022.[17] While it has been well-established by numerous start-ups, academics, and DoD laboratories that biology can generate products at the bench scale that could *potentially* fill capability gaps, research is required in scaling-up biomanufacturing to produce at a scale sufficient to prototype these products. While this is the second hurdle in adopting biotechnology-based solutions to DoD mission needs, it is also an incredible opportunity to develop biomanufacturing at home and with allies and partners[18] to create a self-sustaining domestic biomanufacturing ecosystem. Furthermore, it will contribute to the United States remaining the world leader in innovation, guarantee DoD interests are protected, and ensure that U.S. global competitiveness in biotechnology is maintained.

c. Map and measure the biomanufacturing ecosystem

The USD(R&E) sets technology development and manufacturing policies for DoD, including technology prioritization informed by the NDS and allocation of resources.[19] The NDS requires that the Department make the right technology investments and also reduce implementation risk by "consistent attention to monitoring implementation in line with clear metrics to enable assessment and course correction."[20] In order for DoD to build enduring advantage through the implementation of the DoD Biomanufacturing Strategy, the Department needs to address implementation risk in this context. However, the biomanufacturing ecosystem is poorly defined, primarily because it is nascent. The CHIPS and Science Act of 2022 recognizes this and directs the development of "robust mechanisms for documenting and quantifying the outputs and economic benefits" associated with biotechnology..[21] Concurrent with the Department's need to prioritize where it places its resources in biomanufacturing, DoD will support an upfront assessment of the biomanufacturing ecosystem, along with continued evaluation during and following early investments, allowing for more precise tailoring of DoD resource allocation as the biomanufacturing ecosystem develops. Mapping the biomanufacturing ecosystem and establishing metrics to evaluate the bioeconomy is central to mitigating implementation risk.[22]

3. Conclusion

Biotechnology and biomanufacturing can contribute to the Department's priority for a future force that is sustainable, resilient, survivable, agile, and responsive.[23] Furthermore, investment in biomanufacturing is consistent with the NDS's framework for strategic readiness aligned with

[16] E.O. 14005, "Ensuring the Future is Made in All of America by All of America's Workers," January 25, 2001.
[17] See TITLE IV, Section 10402(a)(2), National Engineering Biology Research and Development Initiative, Public Law 117-167, August 9, 2022.
[18] See Executive Office of the President, "National Security Strategy," 2022, p. 33; 2022 NDS, p. 19-20; and E.O. 14017.
[19] DoD Directive 5137.02, "Under Secretary of Defense for Research and Engineering (USD(R&E))," July 15, 2020, Distro A; CJCSI 5123.01I, "Charter of the Joint Requirements Oversight Council and Implementation of the Joint Capabilities Integration and Development System," Enclosure C, October 30, 2021, Distro A.
[20] 2022 NDS, p. 19, 22.
[21] See TITLE IV, Section 10402 (b) (6).
[22] 2022 NDS, p. 22.
[23] 2022 NDS, p. 19.

the Department's priorities. Manufacturing products using biology will contribute to supply chain resiliency; enhance logistics; and create materials with novel, mission-required properties, which enhance the U.S. military's ability to provide integrated deterrence. The DoD Biomanufacturing Strategy supports the U.S. Government and DoD as they strive to establish a stable and open international system in emerging technologies and secure the United States and its partners through the development and support of the domestic and allied biomanufacturing ecosystem.[24]

[24] See E.O. 14083, 2022 NSS, 2022 NDS, and JWC.

Appendix A: Acronym List

CHIPS	Creating Helpful Incentives to Produce Semiconductors
CJCSI	Chairman of the Joint Chiefs of Staff Instruction
DoD	Department of Defense
E.O.	Executive Order
FY	Fiscal Year
JWC	Joint Warfighting Concept
MGI	McKinsey Global Institute
NDAA	National Defense Authorization Act
NDS	National Defense Strategy
NSS	National Security Strategy
OUSD(A&S)	Office of the Under Secretary of Defense for Acquisition and Sustainment
PRC	People's Republic of China
R&D	Research and Development
USD(R&E)	Under Secretary of Defense for Research and Engineering