U.S. Department *of* Defense

2023

BIODEFENSE POSTURE REVIEW

2023

BIODEFENSE POSTURE REVIEW

This page left intentionally blank

DEPUTY SECRETARY OF DEFENSE
1010 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-1010

In his National Security Strategy, President Biden made clear that we are at an inflection point, with the United States entering a decisive decade amid a rapidly-changing security environment. In the National Biodefense Strategy and Implementation Plan, the Biden-Harris Administration laid out a vision of a world free from catastrophic biological incidents, setting forth "bold outcomes" for countering biological threats, enhancing pandemic preparedness, and achieving global health security. In support of this strategic direction, the Department of Defense (DoD) must be prepared to operate in a biological threat environment and to support the national biodefense enterprise, at home and abroad.

The Secretary of Defense directed DoD to conduct a comprehensive Biodefense Posture Review to establish our approach to advance this biodefense vision and incorporate lessons learned from the response to the COVID-19 pandemic. This first-of-its-kind review synchronizes our biodefense planning with the 2022 National Defense Strategy (NDS), the National Biodefense Strategy, and, as appropriate, allies and partners, to support their biodefense efforts in alignment with national goals and strategies.

The NDS recognizes that expanding biological threats, enabled by advances in life sciences and biotechnology, are among the many growing threats to U.S. national security that the U.S. military must address. And, as we implement the NDS – by acting urgently to sustain and strengthen U.S. integrated deterrence, campaign day-to-day to gain and sustain military advantages, and build enduring advantages for the future Joint Force – we must prepare to do this all within a biological threat environment, including transboundary challenges like pandemics.

The National Biodefense Strategy makes clear that it is a vital interest of the United States to manage the risk of biological incidents, whether naturally occurring, accidental, or deliberate. DoD plays an important role in helping the national biodefense enterprise prepare for, prevent, deter, detect, rapidly respond to, and recover from biological threats at home and abroad.

This report from the inaugural Biodefense Posture Review outlines strategic guidance, findings, and reforms necessary to posture DoD to meet the present and future challenges posed by biological threats. We will do this through an empowered, collaborative approach that optimizes our capabilities, capacity, resilience, and readiness to address biological threats.

We cannot prevent or anticipate every biological threat in these turbulent times, but I am confident that DoD, along with our counterparts throughout the U.S. government and our allies and partners around the world, will continue to act boldly to meet the biological threats and pandemic challenges of this decisive decade.

This page left intentionally blank

TABLE OF CONTENTS

This page left intentionally blank

EXECUTIVE SUMMARY

Introduction. The Department of Defense (DoD) is at a pivotal moment in biodefense as it faces an unprecedented number of complex biological threats (biothreats). This inaugural DoD Biodefense Posture Review (BPR) initiates key reforms—built on the foundations of the 2022 National Defense Strategy (NDS), the October 2022 National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (NBS); and lessons learned from the coronavirus disease 2019 (COVID-19) pandemic response—to posture DoD to counter biothreats through 2035. Developments in biological technology (biotechnology) are driving an increase in the scope and diversity of biothreats that DoD could face in the next decade. Additionally, as the planet's climate continues to change and its population grows, emerging infectious diseases are expected to develop and spread more frequently and potentially threaten DoD's readiness to achieve and maintain its national defense goals. The COVID-19 pandemic response presented opportunities for DoD to both improve its overall preparedness and posture, as well as to reinforce and reimagine its role in support of the broader U.S. Government and our allies and partners.

Biological incidents (bioincidents) risk undermining DoD's ability to successfully achieve NDS objectives. In November 2021, the Secretary of Defense issued a memorandum, *Biodefense Vision,* providing direction for the Department to ensure DoD's preparedness to operate in a biothreat environment and to support the national biodefense enterprise at home and abroad. In that memorandum, the Secretary of Defense directed a comprehensive review of DoD's biodefense posture to bolster the Department's overall defense posture and maintain readiness and resilience against burgeoning threats, whether they are naturally occurring, accidental, or deliberate in origin The BPR's reforms aim to posture DoD to fight and win in the face of any future biothreat and to incorporate lessons learned from the COVID-19 pandemic response to operate more effectively during bioincidents, consistent with the four NDS priorities to:

- Defend the homeland, paced to the growing multi-domain threat posed by the People's Republic of China (PRC);
- Deter strategic attacks against the United States and its allies and partners;
- Deter aggression, while being prepared to prevail in conflict when necessary – prioritizing the PRC challenge in the Indo-Pacific region, then the Russia challenge in Europe; and
- Build a resilient Joint Force and defense ecosystem.

BPR Purpose. The 2023 BPR priorities align with the overarching objectives of the NDS and aim to support DoD and Total Force, acknowledging the potential impact and risk of biothreats on achieving the four NDS priorities. The 2023 BPR also serves to clarify and delineate DoD's unique role in biodefense across DoD, within the context of broader defense missions, and in support of broader U.S. Government efforts, including activities with allies and partners. This BPR and its priorities support NBS goals and DoD's assigned roles and responsibilities in achieving them. The top priorities of the BPR are to:

- Fully assess the biothreat landscape through 2035.
- Clarify biodefense missions, priorities, roles, responsibilities, authorities, and the capabilities needed to enable biodefense.
- Position DoD to address future biothreats in alignment with the NDS.
- Examine DoD's role in the NBS and provide appropriate support to other departments and agencies.
- Align policies; authorities; research, development, and acquisition (RDA) responsibilities; investments; and force structure to meet DoD's biodefense requirements.
- Ensure biodefense is routinely included in DoD training, exercises, and doctrine.

The BPR was a whole-of-DoD effort involving components, including Combatant Commands (CCMDs) and Military Departments and Services, that have distinct roles and authorities for deterring, responding to, and protecting the force from bioincidents. The outcomes of this review are a result of the analysis of strategies, partnerships, authorities, capabilities, capacities, the defense industrial base and supply chain, and Total Force readiness. This review is informed by the application of lessons learned from the COVID-19 response, along with a comprehensive and contemporaneous assessment of intelligence regarding the biothreat landscape. It is further informed by limited and focused engagements with interagency, intergovernmental, industry, and other biodefense thought leaders.[1] Additionally, this review considers opportunities for improvements to DoD's current posture; addresses the need to balance DoD's biodefense efforts in support of NDS priorities with potential support to civil authorities during other bioincidents; and examines requirements, opportunities, and challenges in working with allies and partners.

Defining Biodefense. Biodefense plays an important role in supporting NDS priorities, namely building a Joint Force and defense ecosystem that is resilient to biothreats and bioincidents. DoD's activities in integrated deterrence also extend to its biodefense posture, supporting warfighting domains and theaters across the full spectrum of conflict and/or instruments of U.S. national power.

Through the BPR, DoD validated biodefense definitions that broadly align with those in the NBS and capture the full spectrum of potential biothreat origins (deliberate, accidental, and naturally occurring); this allows for consistent understanding within DoD and with interagency partners.

The DoD-validated definitions focus on the Total Force other than for areas outside of DoD control (e.g., agriculture) and broader public health/medical care for beneficiaries. DoD plays a significant role in deterring the pursuit, acquisition, or use of biological weapons (bioweapons) and their delivery systems—a key aspect of the NBS goal to ensure that biodefense enterprise capabilities are able to prevent or mitigate bioincidents. Further, DoD has unique responsibilities for biodefense to protect the Total Force and enable defense missions that are not explicitly referenced in the NBS.

---

[1] DoD appreciates the many external perspectives that contributed to the BPR, including the following two externally prepared reports, which provided critical and significant insights:

- Massachusetts Institute of Technology, Lincoln Laboratory. "Biodefense Posture Review Industry Roundtable," March 2022
- Johns Hopkins Center for Health Security. "Summary of Expert Insights for the U.S. Department of Defense Biodefense Posture Review Meeting," June 9, 2022.

BPR Reforms. Although DoD possesses the appropriate authorities for biodefense, the BPR revealed DoD's need for a more collective and unified approach to coordinating its biodefense roles and responsibilities due to the decentralized nature of the biodefense enterprise, limited situational awareness of biothreats, shortfalls in readiness and preparedness, and a lack of integrated portfolio priorities to guide RDA efforts. The BPR identified opportunities to engage the CCMDs and Military Departments and Services to improve biodefense readiness and modernize operations.

(U) DEFINING BIODEFENSE

DoD adopts the following definitions, based on several definitions in the National Biodefense Strategy:

- **Biological defense (biodefense).** Actions to counter biothreats, reduce risks, and prepare for, respond to, and recover from bioincidents.
- **Biological incident (bioincident).** Any act of biological warfare or terrorism; a crime involving a biohazard consistent with the scope of the National Biodefense Strategy; or any natural or accidental occurrence in which a biohazard harms the Total Force.
- **Biological threat (biothreat).** An entity involved with, or a situation involving, a biohazard that can potentially cause a bioincident.
- **Biological hazard (biohazard).** A biological agent or biologically active substance, regardless of origin (e.g., naturally occurring or biologically engineered), that represents an actual or potential danger to humans, animals, plants, or the environment.

This 2023 BPR establishes broad reform initiatives, including a strategic approach to biodefense that:

- Enhances early warning and understanding to counter biothreats.
- Improves preparedness for a resilient Total Force.
- Speeds response to mitigate the impact on DoD missions and the Total Force.
- Improves strategic coordination and collaboration to enhance biodefense.

The BPR details specific initiatives and organizational efforts that are necessary to implement these reforms. These initiatives are undertaken in accordance with the NDS and DoD's responsibilities under the NBS and will posture DoD to address current and future biothreats across the spectrum of naturally occurring, accidental, and deliberate bioincidents.

DoD must take the threat and risk from bioincidents seriously and implement the significant reforms outlined in this review to lay the foundation for a resilient Total Force that deters the use of bioweapons, rapidly responds to natural outbreaks, and minimizes the global risk of laboratory accidents. This must be done with stronger collaboration with U.S. interagency partners and abroad with allies and partners working collectively to understand the threat, prepare and protect the force, and quickly respond to and mitigate the effects of bioincidents.

This inaugural BPR brings DoD's biodefense posture into a clearer, more contemporary stance and serves as a dynamic framework for future assessments to align with national strategies and the biothreat landscape as they evolve.

FIGURE 1. BPR REFORM INITIATIVES

CHAPTER I: THE THREAT AND SECURITY ENVIRONMENT

Biothreat Environment. The National Defense Strategy directs the Department to act urgently to sustain and strengthen U.S. deterrence, with the PRC as the pacing challenge for the Department, while accounting for the acute threat posed by Russia and remaining vigilant in the face of persistent threats posed by North Korea, Iran, and violent extremist organizations (VEOs). The NDS notes that business as usual at the Department is not acceptable and provides a vision for focusing the DoD on our pacing challenge, even as we manage the other threats of a swiftly changing world. Among these threats are traditional and advanced biological weapons, and destabilizing, potentially catastrophic transboundary challenges such as pandemics.

The threats and consequences outlined in the National Biodefense Strategy guide the Department's biodefense considerations:

- *Naturally Occurring Biological Threats*. Biological threats can affect humans, animals, plants, and the environment, resulting in significant health, economic, social, and national security impacts. Infectious disease threats do not respect borders. 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 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. Although 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 and biosecurity 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, could make 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.

The PRC, Russia, North Korea, and Iran, probably maintain the knowledge and capability to produce and employ traditional pathogens and toxins. These countries historically pursued, and at least one country (North Korea) continues to pursue, pathogens that cause highly infectious or contagious diseases, such as anthrax, plague, and toxins, including botulinum toxin. These nations probably also retain the knowledge and ability to employ these agents if necessary.

Adversaries could also use advances in peptide synthesis technology and metabolic engineering to develop and produce toxins in quantities suitable for a range of employment options. Advances in both synthetic biology and peptide synthesis could enable states to develop a wide range of novel toxins with both incapacitating and lethal effects that are not on a select agent list. These toxins could include animal toxins, marine toxins, or plant toxins. Peptide synthesis technologies developed in the last decade could allow toxins, including engineered variants, to be synthesized in quantities that are more militarily relevant, raising the concern that they are no longer just suitable for targeted killings.

The United States assesses that North Korea and Russia maintain offensive biological weapons programs in violation of Biological Weapons and Toxins Convention (BWC) obligations and identifies concerns with Iran's activities and its compliance with the BWC. Russia has provided an incomplete acknowledgement of the former Soviet program, has not furnished evidence of the dismantlement or cessation of key activities, and continues secrecy efforts to protect Russia's potentially dual-use biological research and development efforts. Additionally, the most recent *Compliance and Adherence Report with Arms Control, Nonproliferation, and Disarmament Agreements and Commitments* raises concerns with PRC compliance with the BWC, based on research and activities with potential dual-use applications. The United States has compliance concerns with respect to PRC military medical institutions' toxin research and development given their potential as a biothreat. The PRC has also released plans to make China the global leader in technologies like genetic engineering, precision medicine, and brain sciences. These Chinese publications have called biology a new domain of war.

The PRC and Russia have also proven adept at manipulating the information space to inhibit attribution, to reduce trust and confidence in countermeasure effectiveness, and potentially to slow decision-making following deliberate use.

The U.S. military has been involved in conflict operations during every declared pandemic of the 20th and 21st centuries. None of these events were a result of bioweapon use, but they all challenged the military's operational capabilities. The most likely infectious disease threats to deployed U.S. forces come from endemic diseases (i.e., diseases that regularly occur in a particular population or area). Respiratory diseases (e.g., tuberculosis, seasonal influenza), food and waterborne diseases (e.g., typhoid, cholera), and vector-borne diseases (e.g., malaria, dengue fever) may cause local or regional epidemics. While force health protection (FHP) measures are usually effective in countering these threats, some emerging infectious disease threats (e.g., multiple-drug resistant bacteria, malaria organisms resistant to anti-malarial medications) risk rendering MCMs ineffective. And COVID-19 demonstrated that some of the most challenging infectious diseases are pandemic-capable novel respiratory pathogens that are either unsuspectingly introduced or arise in areas with limited surveillance and laboratory capabilities. Delays in detection and warning, coupled with global travel, now allow such organisms to rapidly spread around the globe.

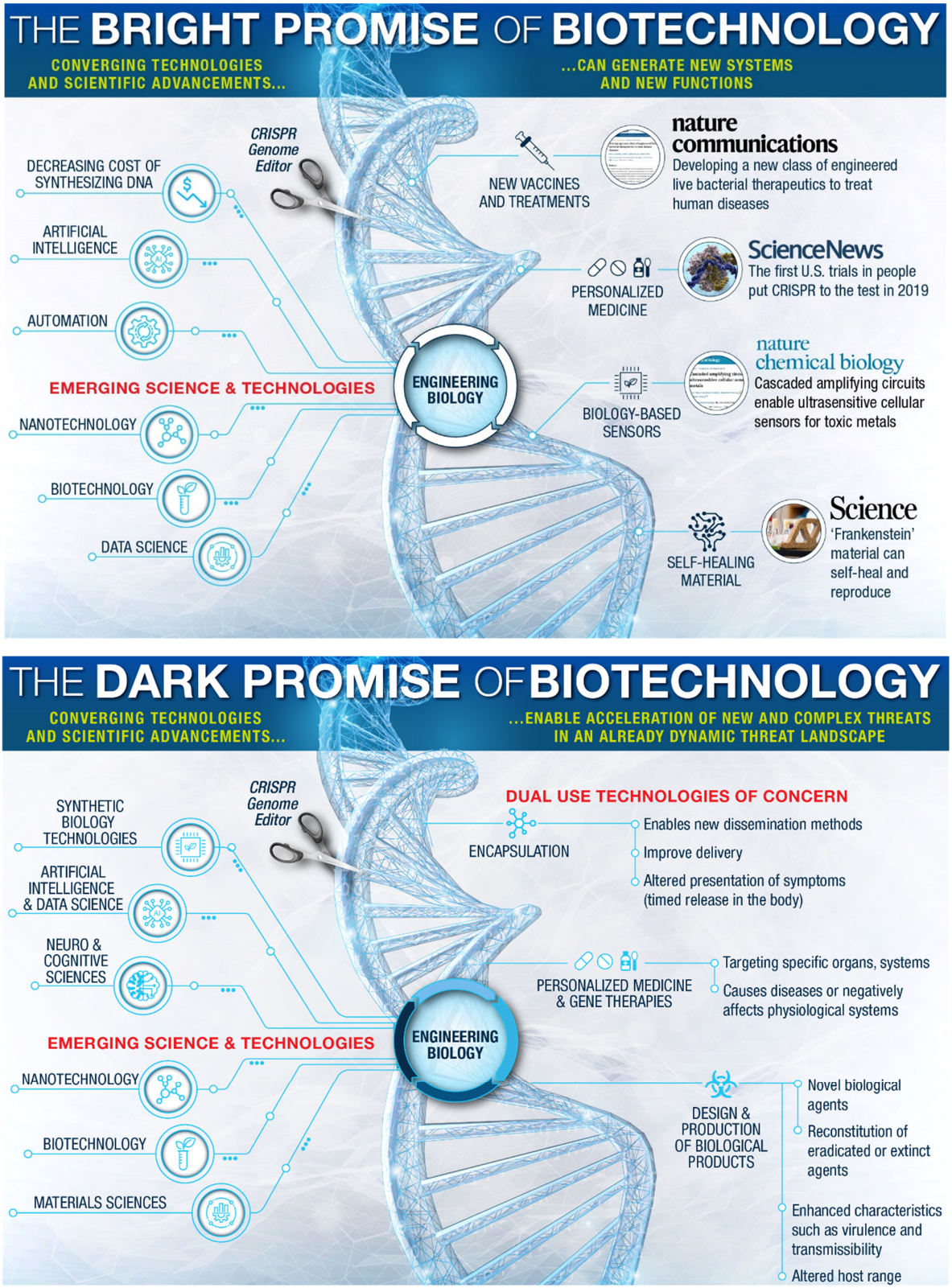
As the biothreat landscape evolves, there is an increased potential for a biological safety (biosafety) event resulting in the unintentional release of pathogens. Growing research in infectious diseases enables the development of testing, pharmaceutical treatments, and vaccines to support public health and the global community. As research in the field of biology and biotechnology expands, so does the increased potential of accidental bioincidents. The increase in accidental biothreats challenge biosafety, biological security (biosecurity), physical security, and other biological containment (biocontainment) considerations, and creates the concern of unintended and dangerous consequences resulting from inconsistent or incomplete review and oversight mechanisms.

Biotechnology Advancements.

Emerging and Disruptive Technologies. New technologies, such as big data, artificial intelligence, and genomic modification, have the potential to significantly influence the chemical, biological, radiological, and nuclear (CBRN) environment. Such technologies simultaneously offer the prospect for more effective, resilient, and cost-efficient military and civilian solutions while also representing potential new threats from state and non-state actors. The same biological and chemical science advancements created to develop life-saving medical countermeasures could also be used by potential adversaries to develop new or enhanced agents. Technologies intended to reduce testing and production inefficiencies, such as biofoundaries and additive manufacturing, create opportunities to reduce the development footprint and increase the number of proliferation pathways available to malign actors. In this way, emerging and disruptive technologies present both risks and opportunities to the United States, its allies, and partners.

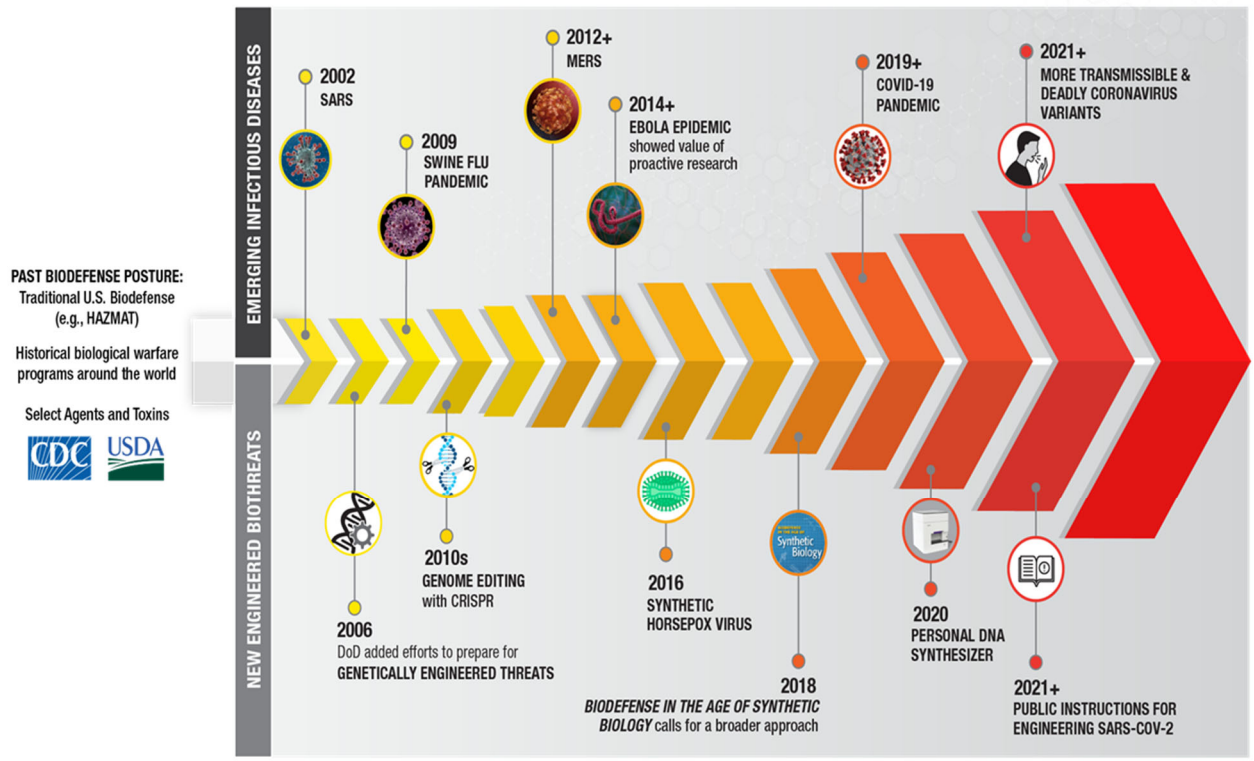
Risks from Bioincidents. The ability to determine a deliberate biological weapons attack is complicated by the potential for an accidental laboratory release and the growing risks from naturally occurring diseases due to climate change. Additionally, reservoirs of naturally occurring pathogens of high consequence are potential avenues for biological weapons research. Adversaries can also leverage this more complex operating environment to constrain U.S. strategic choices by masking an attack, augmenting other activities, or conducting an opportunistic disinformation campaign. Furthermore, outbreaks are likely to lead to an increase in requests for Defense Support of Civil Authorities, which adds a competing activity to the Joint Force mission of fighting and winning the nation's wars.

FIGURE 2. BIOTECHNOLOGY ENABLES COMPLEX BIOTHREATS



As the biological threat landscape continues to evolve, so must our biodefense capabilities. It is critically important that the Total Force can fight and win in a CBRN-contaminated environment. This importance stretches across the costs and risks of future biological threats, whether natural or human-made, for the Department and the Joint Force.

FIGURE 3. EVOLVING BIOTHREAT LANDSCAPE



CHAPTER II: STRATEGIC APPROACH

The Secretary of Defense provided clear direction and guidance that DoD must be prepared to operate in a biothreat environment and support the national biodefense enterprise at home and abroad. Improving the Total Force's ability to assess, prevent, prepare for, respond to, and recover from the full spectrum of biothreats is a key aspect of building a combat credible force that serves as the basis for a strategic approach to address biological threats. DoD must be able to address the full spectrum of biothreats—including deliberate use, accidental release, and naturally occurring diseases—that hinder mission effectiveness. The NDS acknowledges new challenges to the Total Force, including the acute threat of biological weapons by our adversaries and rapidly evolving biotechnology that enables more advanced biological weapons. The biothreat also includes naturally occurring diseases and accidental releases that require increased awareness of the potential impact to DoD both at home and abroad and the potentially serious harm to the Total Force and associated missions.

In validating a definition of biodefense that spans naturally occurring, accidental, and deliberate threats, and in focusing its application on the Total Force, the BPR brings clarity to and begins to integrate existing, but disparate, biodefense efforts into a DoD-wide strategic approach. In support of the NDS, the priorities of the BPR establish the necessary biodefense posture to enable mission effectiveness of the Total Force to support integrated deterrence, campaigning, and prevailing in conflict in biologically threatened environments.

STRATEGIC GOALS

Three strategic goals guide DoD-wide biodefense efforts and the key reform initiatives identified by this review:

- DoD is resilient to biological threats and hazards and able to project force and maneuver freely in a biological hazard and threat environment;
- DoD manages risk to global mission requirements while appropriately supporting civil authorities as a part of a whole of government response to bioincidents; and
- DoD provides continued support to its allies and partners, competes to prevent adversary advantage, and responds to crises.

Biodefense in National and Military Strategies. The Secretary of Defense's Biodefense Vision memorandum directs DoD to synchronize biodefense planning with the NDS and NBS to establish and maintain a resilient force ready to operate in a biothreat environment. Biodefense provides an increasingly important function that enables implementation of the NDS and postures DoD to address biothreats, whether naturally occurring or human-made. National Security Memorandum-15/NSM-15, *Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security*, October 18, 2022, implements the NBS and establishes policy to clarify coordination and governance of U.S. biodefense efforts and direct near-term tasks to assess, report, and exercise biodefense improvements. The NBS establishes the following clear goals for responding to all bioincidents (naturally occurring, accidental, or deliberate):

- Enable risk awareness and detection to inform decision-making across the biodefense enterprise (risk awareness and detection).
- Ensure biodefense enterprise capabilities to prevent bioincidents (prevention).
- Ensure biodefense enterprise preparedness to reduce the impacts of bioincidents (preparedness).
- Rapidly respond to limit the impacts of bioincidents (response).
- Facilitate recovery to restore the community, the economy, and the environment after a bioincident (recovery).

The NBS establishes the deterrence of bioweapons and deliberate attack as the singular, lead role for DoD and acknowledges where DoD may uniquely contribute to efforts led by other departments and agencies. To achieve this objective, DoD must consider biodefense within the overall strategy of integrated deterrence and anchored with allies and partners to campaign against adversaries and threats posed by bioweapons.

A Total Force resilient to biothreats and biological hazards (biohazards) provides the first step to deter the use of bioweapons and deliberate attack. Such resilience, properly messaged and demonstrated, bolsters integrated deterrence. DoD's extensive biodefense capabilities can be leveraged to deny or greatly minimize the benefit of using bioweapons and further deter the development or proliferation of bioweapons. Should deterrence fail, this resilience will enable the Total Force to operate through contaminated environments and further diminish adversary benefits of deliberate biological attacks.

In concert with improved Total Force resilience, collaborative biodefense engagement with our allies and partners improves our mutual biodefense, strengthens our alliances, improves interoperability, and promotes burden-sharing. These partnerships maximize effectiveness and minimize risk to the Total Force. Reinforcement of international norms, the Committee on Foreign Investment in the United States (CFIUS) process, export controls, information security, and cybersecurity (protection against loss of critical data, capabilities, or intellectual property) will all work to slow and obstruct adversary bioweapon programs. A similarly wide range of response actions could help hold perpetrators accountable for the use of bioweapons and support identification and attribution of naturally occurring diseases or sources of accidental bioincidents.

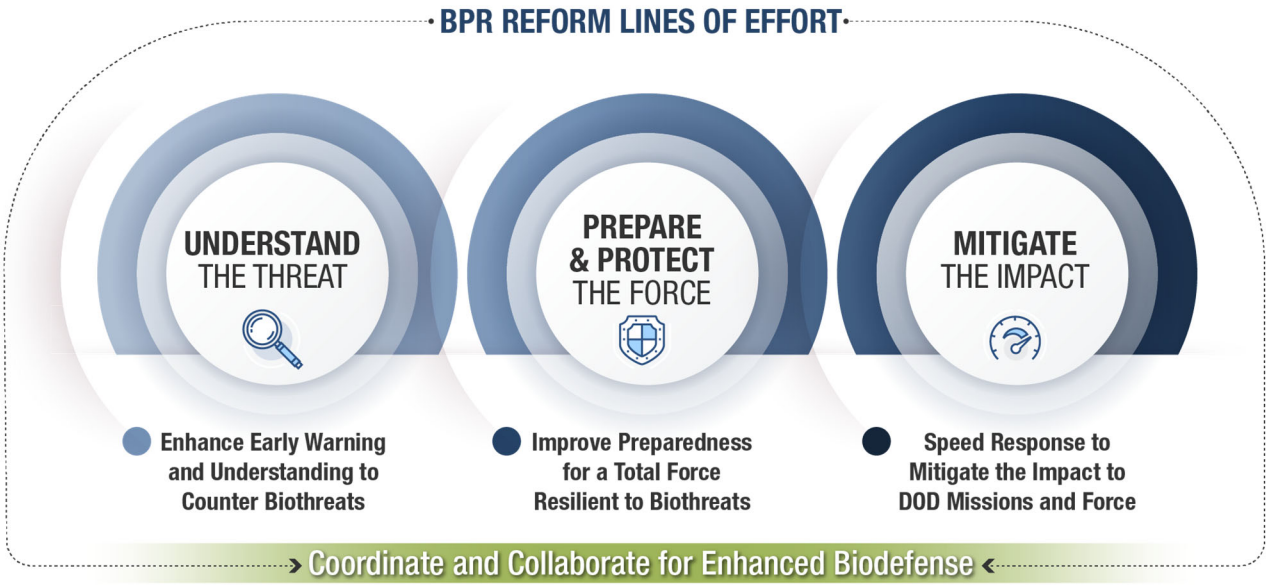
Given that naturally occurring disease cannot be deterred, DoD requires a resilient force enabled by capabilities that also address emerging disease threats. The ability and capabilities to deter deliberate biological attacks also improve the Total Force's overall resilience to emerging, naturally occurring, infectious diseases of operational significance.

The threat of bioincidents caused by laboratory accidents requires proactive actions domestically and internationally. Proper safety and security through further development and implementation of standards and non-proliferation norms throughout the global biological science community is necessary to significantly reduce the likelihood of accidental release.

BPR Reform Lines of Effort. Four BPR reform lines of effort drive biodefense actions supporting the NDS and address the potential costs and risks posed by future biothreats, regardless of origin, to DoD missions and the Total Force. Each line of effort is briefly summarized below, illustrated in Figure 3, and discussed in greater detail in the following chapters of this report.

- *Coordinate and Collaborate for Enhanced Biodefense.* This line of effort and associated reforms enable DoD to maximize its existing authorities; clarify the roles and responsibilities of biodefense stakeholders (both internal and external to DoD); implement biodefense reforms in an integrated manner; and deliver the empowered, collaborative, and integrated approach directed in the Secretary of Defense's Biodefense Vision memorandum.
- *Enhance Early Warning and Understanding to Counter Biothreats.* This line of effort and associated reforms drive DoD to consistently, fully, and accurately understand and recognize the biothreat. DoD will develop a more thorough understanding of the threat through biosurveillance as well as intelligence collection and analysis by the Defense Intelligence Enterprise (DIE) . A shared characterization of the threat is critical for improved risk awareness and enhanced, rapid decision-making.
- *Improve Preparedness for a Total Force Resilient to Biothreats.* This line of effort and associated reforms enable DoD to protect Military Service Members, DoD civilian employees, contractor personnel, and other members of the DoD community from bioincidents. DoD will prepare and protect the Total Force by improving its capabilities, prioritizing high-level biodefense training and exercises, strengthening biodefense requirements processes, speeding RDA responsiveness to emerging threats, and strengthening biological risk (biorisk) management.
- *Speed Response to Mitigate the Impact to DoD Missions and Forces.* This line of effort and associated reforms enable DoD to rapidly mitigate the impacts of bioincidents and sustain DoD capabilities through improved material readiness, associated situational awareness, and enhancements to the industrial base. DoD will work to mitigate impacts of a bioincident through a response that is rapid, resilient, and balanced.

FIGURE 3. BPR REFORM LINES OF EFFORT



CHAPTER III: ESTABLISHING BIODEFENSE GOVERNANCE

The BPR identified that DoD has extensive statutory authorities for biodefense, and capabilities established pursuant to those authorities and implemented through DoD issuances. DoD was also assessed to possess significant authorities to protect the Total Force and support both domestic and international preparedness and response. However, the BPR found that these authorities span a wide range of stakeholders across the biodefense enterprise that are loosely connected and divided between naturally occurring, accidental, and deliberate threats.

The BPR revealed that, although DoD possesses the necessary authorities for biodefense, it could benefit from a more collective and unified approach to coordinating its biodefense roles and responsibilities due to the decentralized nature of the biodefense enterprise with responsibilities that converge at the Deputy Secretary of Defense (DepSecDef)-level. This enterprise is made up of multiple Office of the Secretary of Defense (OSD) Components, led by designated Principal Staff Assistants (PSA) with diverse responsibilities for policy, planning, resourcing, and capability development; along with the CCMDs, Military Departments and Services, and various Defense Agencies and Field Activities that execute biodefense preparedness and response.

Although biodefense roles, responsibilities, and authorities are memorialized across OSD components there is no DoD official below the DepSecDef level who has overarching responsibility to direct internal coordination and provide oversight of biodefense capabilities and prioritization of threats, and to coordinate DoD efforts with the rest of the U.S. Government. The BPR's analysis found that the DoD biodefense enterprise could improve unity of effort to strengthen integration mechanisms for situational awareness of biothreats, priorities, or biodefense readiness and preparedness in a manner that will maximize existing PSA authorities below the DepSecDef-level. This lack of coordination, integration, and understanding compromises DoD's ability to rapidly detect, characterize, and respond to biothreats, potentially leaving the Total Force vulnerable to those threats.

The BPR proposes a governance structure to enable DoD to maximize use of its existing authorities, clarify the roles and responsibilities of biodefense stakeholders (both internal and external to DoD), implement biodefense reforms in an integrated manner, and provide coordinated response to deliver the empowered, collaborative, and integrated approach directed in the Secretary of Defense's Biodefense Vision memorandum.

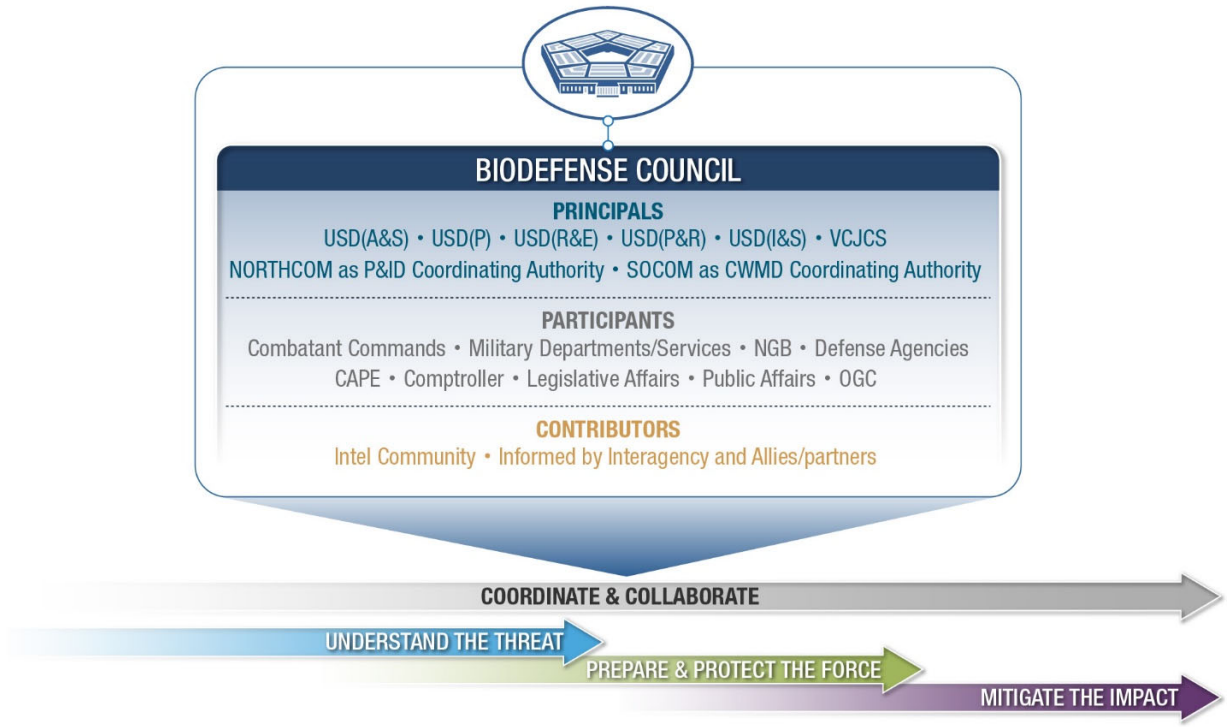
Biodefense Council. DepSecDef established the Biodefense Council to synchronize, coordinate, and integrate existing DoD Component authorities and responsibilities to achieve an empowered, collaborative approach to biodefense in DoD.

The Biodefense Council will serve as the principal forum to advise the Secretary of Defense, the DepSecDefand other DoD leadership on biodefense issues and address the challenges identified in the BPR and beyond. The Biodefense Council will not supplant individual missions in biodefense but will facilitate integration and information flow; enable collective decisions; convene the biodefense enterprise to review topics on a recurring basis; and empower the heads of DoD Components to address tough or acute challenges, when necessary.

The Biodefense Council will convene to delineate primary functions to enhance collaboration, prioritize threats, and create an efficient approach to address the prioritized threats. Additionally, the Biodefense Council will advance the execution of responses to significant bioincidents and enhance the ability of DoD to mitigate biothreats and biohazards.

- *Chair.* The Biodefense Council is chaired by the Under Secretary of Defense for Acquisition and Sustainment (USD(A&S)). The Biodefense Council has a single chair to better organize DoD-wide biodefense responsibilities.
- *Membership.* The Biodefense Council, as noted in Figure 4 below, will consist of Council Principals and Council Participants. The Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ASD(NCB)) will serve as the Council's Executive Secretary.
- *Council Activities.* The Biodefense Council's activities include:
  - Coordinating informed reporting across the DoD biodefense enterprise and appropriately elevating issues to DepSecDef.
  - Providing guidance and oversight for the biodefense posture to achieve high confidence in DoD's ability to assess, prevent, prepare for, respond to, and recover from bioincidents as necessary to support the NDS and NBS.
  - Synthesizing intelligence products, biosurveillance, early warning, and attribution information in order to warn DoD leadership of potential impacts on posture and missions.
  - Reviewing biodefense integrated portfolio priorities and coordinating investment strategy to address readiness shortfalls and modernization needs.
  - Supporting DoD Components' efforts to increase biodefense readiness and modernize Total Force capabilities to meet evolving threats, deter adversaries, and execute the NDS.
  - Providing analysis and options to DoD leaders to address readiness, preparedness, or deterrence challenges that have significant bearing on DoD's biodefense posture.
  - Serving as a standing body to facilitate DoD-wide collaboration on biodefense response activities, as needed, to address bioincidents of national or international significance.
  - Addressing key or priority biodefense issues as requested by Council members and/or as determined by the Secretary of Defense, DepSecDef, or the Biodefense Council Chair, including interagency synchronization on biodefense-related issues and response.
  - Tracking and assuring NBS Implementation Plan compliance.
  - Developing a BPR Implementation Plan and overseeing BPR reforms.

FIGURE 4. BIODEFENSE COUNCIL GOVERNANCE STRUCTURE



CHAPTER IV: ENHANCING EARLY WARNING AND UNDERSTANDING TO COUNTER BIOTHREATS

The NBS establishes a prioritized need for early warning and development of the ability to rapidly detect, characterize, report, forecast, and share relevant information (including sequence data), as appropriate, on pathogens that pose a biothreat of national or international significance soon after they emerge. Consistent with the NBS, DoD must strive for early warning to inform and enable early assessment and identification of biothreats and facilitate effective decision-making and interventions to maintain a ready, resilient Total Force to execute the NDS.

This line of effort and associated reforms enable DoD to consistently, fully, and accurately recognize and understand the biothreat situation and risks. DoD will develop a more thorough understanding of the threat through intelligence collection and analysis by the DIE, biosurveillance, and characterization to achieve the early warning and risk awareness needed to inform rapid decision-making to counter biothreats.

Improve Biothreat Intelligence Collection, Analysis, and Sharing. The rapidly evolving threat landscape warrants bolstering the Department's intelligence collection and analytic capabilities to better detect emerging threats of potential operational significance or pandemic potential that may impact our ability to achieve our defense strategy. These improvements will enhance capabilities to collect, analyze, and make reporting readily available to more quickly identify emerging biothreats, increase early warning, and speed threat characterization to understand the potential impact of biothreats on DoD missions, capabilities, and people. The BPR, consistent with NDS direction, also identified greater opportunities for intelligence, information sharing, and combined planning for shared deterrence challenges with allies and partners. Robust intelligence collection, in concert with the work of other departments and agencies, will seek to provide early indication and warning to help manage risk.

In summary, the BPR recommends the following to expand and prioritize biothreat intelligence collection, analysis, and sharing:

- Through the Biodefense Council, identify and develop appropriate and regular mechanisms to maximize the sharing of intelligence across DoD, within the U.S. Government, and with allies and partners to support DoD biodefense activities and identify additional DoD intelligence requirements and priorities.

Increase Biothreat Situational Awareness Through Biosurveillance. The NDS requires prioritizing early warning of naturally occurring biothreats that may disrupt or prevent the execution of military operations. Biosurveillance is a key enabler to gather, integrate, interpret, and communicate essential information and indications of biohazards or disease activity affecting DoD missions or forces. The BPR identified opportunities to improve and refine the programmatic strategy for biosurveillance to build DoD's capabilities for early warning, risk awareness, and monitoring for bioincidents. DoD requires a coordinated, resourced Biosurveillance Program Strategy to:

- Prioritize early warning to detect biothreats and inform decisions.
- Operationalize a biosurveillance information platform to organize, assess, and communicate risks to CCMDs and allies and partners.
- Align milestones with NBS implementation goals to capitalize on whole-of-government efforts and advancements.
- Include clearly defined and ambitious milestones to transform biosurveillance data into actionable, decision-focused information at the tactical, operational, and strategic levels

The Biosurveillance Program, established by DoD Directive (DoDD) 6420.02, under the direction of the Under Secretary for Defense of Personnel and Readiness (USD(P&R)), is an effort to support biodefense, CWMD, and health surveillance to improve risk-based decision-making at all levels.

The BPR found that, despite more than 30 months of pandemic response associated with COVID-19, areas remain where DoD can create a more comprehensive information-collection system capable of integrating enterprise-level data streams and leveraging data analytics to create a common understanding across the whole of DoD. Related surveillance, detection, and analytic information currently resides in stove-piped data repositories and systems that do not share data or easily support decision-making. The needed information system should provide information on adversary capabilities and intent, on friendly vulnerabilities, on detection results, from environmental surveillance, and from local nationals, syndromic and medical surveillance, and civilian medical surveillance.

The Department will pursue a forward-leaning program strategy with clearly defined and ambitious milestones to transform biosurveillance data into actionable, decision-focused information at the tactical, operational, and strategic levels. The Biosurveillance Program Strategy and its responsible actors should prioritize efforts to integrate broader sources of biosurveillance information, make use of wearable technologies, increase sequencing capabilities, and field new capabilities (e.g., wastewater surveillance against unknown threats) to enhance biosurveillance efforts already underway.

The BPR recommends key initiatives to develop and fully integrate the Biosurveillance Hub and Portal with increased

***A Biodefense Enabler Example*:**
BIOSURVEILLANCE PROGRAM

The Biosurveillance Program covers all CBRN health surveillance and seeks to inform decision makers with early warning of health concerns to enhance protection of the force.

Current program efforts include development of a concept of operations for a Hub- and Portal-based approach and conduct of a capability based assessment to address burgeoning threats and prioritize early warning.

Early warning outlined in the NBS presents opportunities to advance and align DoD's efforts with interagency partners to facilitate rapid sharing of samples and sequence data, enhance biosurveillance, and enable rapid response in advance of a nationally or internationally significant bioincident.

DoD is developing a Biosurveillance Program Strategy to enable reforms recommended by the BPR.

analytical capabilities, to expand direct support to CCMDs with assigned areas of responsibility, and to establish mechanisms to improve access to early warning data and communicate common situational awareness to enable more rapid and informed operational decision at all echelons. The goal is to achieve data integration and management capabilities across multiple classifications and communities of interest. Existing domestic and global early warning biosurveillance systems should promote interoperability and data sharing with the interagency and with allies and partners. These systems should coordinate a centrally accessible data repository in support of the Total Force without costly duplication of efforts. This data could then be merged into a senior leader dashboard, providing actionable data to support decision-making and Total Force readiness and augmenting the previously funded initiatives to create and deploy biosurveillance algorithms in DoD electronic health records.

Combined efforts to enable rapid identification of emerging biothreats (days to weeks earlier than significant outbreaks) and support rapid attribution of attacks will facilitate appropriate FHP, military response, and Total Force resilience. Likewise, the bold outcomes for biosurveillance and early warning outlined in the NBS present opportunities to advance and align DoD's efforts with broader progress with interagency partners to facilitate and elevate norms around the rapid sharing of samples and sequence data, enhancing biosurveillance, and enabling rapid response in advance of a nationally or internationally significant bioincident.

To prioritize early warning and biothreat detection and inform decision-making, the BPR recommends the following:

- The Biodefense Council will oversee the Biosurveillance Program Strategy to ensure a forward-leaning program with the necessary, clearly defined, ambitious milestones to transform biosurveillance data into actionable, decision-focused information at the tactical, operational, and strategic levels.
- The Biosurveillance Hub and Portal should be integrated with diverse information streams, interoperable with classified systems, and available to CCMDs.
- DoD should align milestones for biosurveillance with NBS implementation goals coordinating with lead agencies to address known gaps.
- DoD should maximize existing surveillance capabilities within overseas laboratories and expand information-sharing agreements with allies and partners.

Expedite Characterization of Emerging Threats. To remain agile and responsive to emerging threats, DoD must rapidly identify and understand biothreats to characterize impacts on the Total Force and national defense missions. The NBS identifies bold objectives to develop enhanced capabilities and capacities with appropriate safety and security controls to initially assess and characterize biothreats within one week of acquiring a suitable sample. These capabilities and capacities include 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. For DoD, threat characterization includes critical analyses to assess operational and tactical impacts and the effectiveness of existing or developmental capabilities to detect, protect against, and mitigate the impacts of these threats.

DoD must be prepared to rapidly develop and deliver capabilities against any potential threat, including currently unknown or novel ones. To be prepared, DoD requires enabling capabilities and analytical capacity to quickly characterize the potential risks posed by emerging or re-emerging biothreats, and an assessment of existing and developing capabilities against those threats. This threat characterization must be closely linked to intelligence and biosurveillance improvements that drive early warning.

The future threat landscape requires moving beyond the historical "threat list" approach for capability development to more effectively and rapidly respond to biothreats (naturally occurring, accidental, or deliberate). The rapid evolution of technology continues to drive the expansion of potential threats and, as the COVID-19 pandemic demonstrated, the threat landscape includes the emergence of novel infectious disease pathogens.

To better prepare the Total Force against future and unknown threats, including naturally occurring emerging pathogens, DoD will pivot away from viewing the threat landscape as a defined list of known biological and chemical agents towards removing or reducing the impact of agents' effects. DoD's enhanced biodefense and pandemic preparedness will enable the Chemical and Biological Defense Program (CBDP) to expand efforts to characterize biothreat agents and support more rapid development and delivery of biodefense products and capabilities.

The BPR recommends continued efforts and investments in studies that generate data and information to support and increase the speed of capability development, including:

- Expand threat-agent, disease, and host characterization studies to understand the risk to DoD missions and the Total Force.
- Develop an adaptable process that allows for testing of existing MCMs against threats and drives the development of novel MCMs.
- Develop appropriate animal models or novel alternatives to support new drug application and biologics license application submissions, including label expansion, to speed development of countermeasures against novel pathogens.
- Speed validation of existing capabilities against emerging threats or rapidly delivering new physical countermeasures (e.g., improved mask filtration, updated detector modalities).
- Utilize data analytics to inform updates to DoD concepts of operation (CONOPs), training, and exercises.
- Consider additional investments to utilize agnostic methodology capable of detecting multiple pathogens simultaneously and directly from a biological sample.

CHAPTER V: IMPROVE PREPAREDNESS FOR A TOTAL FORCE RESILIENT TO BIOTHREATS

The Secretary of Defense's Biodefense Vision memorandum seeks to modernize DoD operations to optimize capabilities, capacity, resilience, and readiness to counter biothreats. Without a driving prioritization, plans and exercises were not challenged by a bioincident of operational significance to elucidate potential shortfalls in plans and readiness to address information awareness, prevention, preparedness, and response.

This BPR line of effort and associated reforms enable DoD to prepare for and to protect Military Service Members, DoD civilian employees, contractor personnel, and other members of the DoD community from biothreats and biohazards. To ensure a Total Force resilient to biothreats and able to project force and maneuver freely in a biohazard environment, DoD must build on increased threat understanding to target key reforms that better prepare and protect the Total Force against biothreats and biohazards. These reforms include prioritizing high-level biodefense training and exercises, focusing biodefense requirements processes, speeding RDA responsiveness to emerging threats, and strengthening biological risk (biorisk) management.

The BPR found that DoD can improve integrated portfolio management to prioritize RDA efforts to enhance capabilities and capacity. Programs use different processes for capability development with no required interaction between the processes, resulting in gaps, seams, and overlaps. The BPR recommends a variety of actions to improve threat-to-risk operational analysis and exercises to inform CCMD demand signals and increase oversight of processes that result in validated requirements to deliver the capabilities to address NDS priorities and the 2035 threat.

Elevate Biodefense Training, Exercises, and Readiness Assessments to Posture the Total Force for 2035 Biothreats. The BPR recommends a focused effort to increase CCMD understanding of the risks posed by biothreats relative to other risks to inform requirements and assessments. Earlier discussion of reforms to improve intelligence collection, analysis, and information sharing should better inform CCMD plans, training, exercises, and readiness assessments. Informed by increased biothreat awareness, exercises can improve integrated risk assessments, identify shortfalls, develop mitigation efforts, and drive capability improvement. Exercise scenarios should incorporate biothreats to enhance readiness and explore opportunities for enhancing force development and protection.

The BPR acknowledged the value of table-top exercises as key contributors to integrated risk assessments across the biodefense space. Biodefense portfolio operational risk assessments allow DoD to better understand risks, vulnerabilities, trade space, and opportunities to address gaps over the coming 5-15 years. Exercise scenarios should consider not just traditional bioweapons threats, but response to emerging threats that include emerging and re-emerging infectious diseases.

The Military Departments and Services must prioritize plans and training to improve readiness to meet the mission requirements in a biologically challenged environment. Currently, readiness reporting may not sufficiently capture biodefense requirements. If scenario analyses indicate insufficient capabilities or capacities, these readiness shortfalls should be identified to prioritize

capabilities that maximize mission success and protect the Total Force.

The BPR recommends the following reforms to elevate biodefense training, exercises, and readiness assessments:

- The Biodefense Council should initiate a DoD-wide effort to develop and exercise scenarios that incorporate biothreats into relevant continuity of operations, operational, interagency, and international exercises to stress plans and identify capability and capacity gaps when responding to bioincidents or operating in a biothreat environment.
- DoD should direct and elevate the visibility and frequency of biodefense exercises to improve integrated risk assessments, increase biothreat awareness, identify shortfalls, develop mitigation efforts, and drive capability improvement.
- The CCMDs and Military Departments and Services should expand exercise opportunities with RDA programs to receive warfighter feedback; identify material and non-material integration challenges and requirements; and improve tactics, techniques, and procedures with novel capability delivery.
- DoD will initiate a review of biodefense readiness to identify readiness challenges and recommend reporting improvements to the Biodefense Council.
- The Biodefense Council should coordinate threat-to-risk and operational analysis across DoD to deliver relevant, analytically sound recommendations to drive capability improvements to support NDS priorities and to support DoD's roles in the NBS.

Strengthen the Delivery of Modernized Biodefense Capabilities to Combatant Commands and Military Departments and Services. The BPR identified opportunities to better align the requirements process and improve demand signals.

DoD currently manages biodefense requirements across several major RDA programs—the CBDP, the Defense Health Program (DHP), the Defense Advanced Research Projects Agency (DARPA), and the newly established Biosurveillance Program.

- The CBDP is responsible for the chemical and biological weapons (CBW) defense program to counter weapons of mass destruction; it primarily addresses deliberate threats and is transforming its approaches to more-rapidly respond to emerging threats.
- The DHP provides all medical needs, health care, and public health across DoD and conducts associated research, development, test, and evaluation (RDT&E), which primarily addresses naturally occurring threats.
- DARPA conducts fundamental, basic research and technology development and plays a key role in encouraging industry to develop innovative approaches to address biothreats broadly.

Like other parts of the DoD biodefense enterprise, the requirements capability development processes have employed a federated approach to address deliberate, accidental, and naturally occurring biothreats. The distribution of authorities, responsibilities, and processes across RDA programs creates silos that impact DoD's ability to provide integrated solutions to the full range

of biothreats and may result in programmatic gaps that impair ability to anticipate and mitigate emerging threats.

The Joint Capabilities Integration and Development System (JCIDS) supports the development, validation, and approval of joint requirements through the assessment of military capabilities and the identification, approval, and prioritization of gaps in these capabilities. Within this system, efforts dedicated to address deliberate biothreats and naturally occurring biothreats have been implemented through different functional capability boards (FCBs). The Joint Staff routes CBDP medical and non-medical bioweapon-related requirements through the Protection FCB, while DHP's requirements for naturally occurring diseases are routed to the Logistics FCB. Although the JCIDS process includes integrating fora at all levels, the integration between fora is largely informal. This complicates achieving an integrated DoD biodefense portfolio that is sufficiently prioritized and balanced to mitigate military and strategic risk aligned to NDS priorities.

***A Biodefense Enabler Example*:**
IMPROVED JCIDS INTEGRATION

The Joint Staff is taking proactive measures to address potential gaps and seams in requirements development for the biodefense portfolio.

The Protection FCB processes CBDP requirements for understanding, protecting, and mitigating biological warfare agents, while the Logistics FCB manages DHP requirements for protecting and treating naturally occurring diseases.

The Joint Staff is implementing changes to process all future biodefense requirements through the Protection FCB to improve requirements integration, enhance overall program effectiveness, and increase DoD resilience to bioincidents.

As a result of the BPR, the Joint Staff is centralizing biodefense requirements development oversight within the Protection FCB so that, eventually, a single FCB will address all biodefense-related joint military capabilities, gaps, and performance requirements, including prioritizing and monitoring the development of next-generation vaccines and updating requirement documents and timelines to more effectively address the rapidly evolving threat space. This key reform will drive a more-holistic and integrated view of the biodefense portfolio across the spectrum of prioritized threats.

In summary, the BPR recommends the following reforms to strengthen the requirements pipeline to deliver modernized biodefense capabilities to CCMDs and the Military Departments and Services:

- The Joint Staff will address alignment across JCIDS to increase integration and more holistically manage biodefense requirements.
- Biodefense stakeholders will pursue improved integration of joint requirements across the JCIDS process using the NDS, approved Joint Requirements Oversight Council memoranda, and operational scenarios to prioritize gaps in DoD's capabilities and capacity.
- The Biodefense Council should leverage existing joint assessments to identify potential

CCMD and Military Department and Service shortfalls against biodefense posture needs.

- The Biodefense Council should oversee recommended improvements to increase readiness and modernize Total Force biodefense capabilities to meet evolving threats, deter adversaries, and implement the NDS.

Improve RDA Responsiveness and Alignment to Address Emerging Biothreats. The NBS outlines targets to reduce the impacts of bioincidents through the development of rapidly and widely available diagnostics, resilient and scalable supplies of PPE, and rapid development and delivery of vaccines and therapeutics. Part of these targets (or "bold outcomes") is the aim to develop safe and effective vaccines and new or repurposed therapeutics in 100 days or less after a bioincident of national or international significance. Likewise, DoD strives to meet these accelerated timelines to develop capabilities for DoD missions in support of the NDS.

DoD's contributions to Operation Warp Speed, in partnership with the Department of Health and Human Services (HHS) and combined with the addition of billions of dollars invested, led to the unprecedented and historic delivery of two Food and Drug Administration (FDA)-authorized antibody treatments, two FDA-authorized vaccines, and 20 million first vaccine doses allocated by the end of 2020. The COVID-19 pandemic demonstrated the need to alter how we approach and resource RDA of defensive countermeasures and capabilities. DoD must capitalize on innovative approaches and rapid response capabilities pioneered in the COVID-19 response to deliver flexible platforms against a range of threats to enhance preparedness of the Total Force.

The innovation advancements made during the COVID-19 response, combined with the bold outcomes outlined in the NBS Implementation Plan, provide significant opportunities to transform DoD's RDA approaches to more rapidly respond to emerging threats and expedite capability delivery to the Total Force. The BPR found that the distribution of authorities, responsibilities, and processes across RDA programs, particularly CBDP and DHP, creates silos that impact the ability to establish integrated portfolio priorities to best meet the requirements of DoD, particularly the CCMDs and the Military Departments and Services, if not properly managed and coordinated[2]. The overlapping authorities and responsibilities between the programs, and lack of established coordination mechanisms, leads to potential overlaps, gaps, and seams as both the CBDP and the Defense Health Agency (DHA) conduct RDA to counter infectious diseases and toxins to enable emerging infectious disease preparedness and response. The BPR found that the CBDP and DHP have sufficiently unique missions, partners, and processes that drive a "spirit of competition" and innovation that argue against consolidating authorities and responsibilities into a single program.

Before the BPR, DoD clarified the CBDP's role in enhanced biodefense and pandemic preparedness, setting conditions to transform the program's RDA approaches. This decision was made to better align the mission of the CBDP with greater NDS requirements. As noted earlier, DoD's enhanced resources for biodefense and pandemic preparedness in DoD's FY 2023 appropriations enable the CBDP to expand efforts to better prepare the Total Force against future and unknown threats, including naturally occurring emerging pathogens. With these resources,

[2] (U) For the purpose of anticipating biothreats, this review broadly considered emerging areas of biological research, the bioeconomy, and dual-use biotechnology. However, the review only considered those DoD RDA programs that fall squarely within biodefense.

the CBDP is making vital investments in novel and advanced biodefense capabilities against additional NBS/American Pandemic Preparedness Plan targets including improved diagnostics and detection capabilities to expedite surveillance and pathogen characterization, expanded protection and hazard mitigation capabilities, and increased critical technical expertise to enhance biodefense, biosecurity, and supply chain resilience activities. These strategic investments focus on technologies that enable a more agile and resilient Total Force while addressing the dynamic and evolving biothreat landscape.

The CBDP efforts include accelerating characterization and situational awareness of emerging biothreats and accelerating delivery of improved protection from and mitigation of biothreats, including the rapid repurposing of available therapeutics and the development of new vaccines, diagnostics, and therapeutics. Additional efforts include improved decontamination and disinfection technologies, prototyping and delivery of low-burden biothreat respiratory protection, air purification enhancements, portable biocontainment patient transport capabilities, and forward-deployable collective protection/isolation systems. The CBDP is leaning forward to address the current and future threat landscape while building an agile and adaptable portfolio to execute DoD priorities for modernized capabilities to understand the threat, protect the force, and mitigate the effects of biothreats.

***A Biodefense Enabler*: CBDP**

DoD validated the CBDP role in addressing emerging biothreats, whether naturally occurring, accidental, or deliberate. Validating this mission allows the CBDP to transform its approaches to speed capability development to understand, protect against, and mitigate biothreats to the Total Force.

The CBDP is maximizing lessons and opportunities from the COVID-19 response, as well as interagency initiatives to support NBS implementation, to speed development of pathogen-agnostic capabilities, capitalize on AI/machine-learning and repurposing to optimize MCM development, and more rapidly deliver capabilities to the Total Force.

The BPR recommends that the ongoing transformation of the Military Health System and DHP supports a similar review of investments in medical research and development against infectious diseases to ensure an appropriate focus on response to novel or emerging biothreats. This presents opportunities to review DHP and DHA efforts to enable far-forward care, speed clinical trials and research within the Military Health System, inform optimal clinical care strategies, and support development of MCM specific to the military population.

DoD, through the oversight of the Biodefense Council, will effectively coordinate defense RDA activities and investments within DoD. The innovative approaches of the CBDP and DHP will enable DoD's biodefense RDA efforts to more immediately address exposure to an unknown agent or novel pathogen to build resilience in the Total Force across the full spectrum of biothreats. To maximize investments and gain efficiencies, DoD must pursue opportunities to better coordinate RDA activities internal to DoD and better identify when to collaborate with or defer activities to other Federal departments or agencies—particularly to HHS, including the National Institutes of Health, Centers for Disease Control and Prevention (CDC), and Biomedical Advanced Research and Development Authority. Ultimately, this approach will posture DoD to quickly detect

emerging biothreats; reduce risks; and prepare for, respond to, and recover from any type of bioincident.

In summary, to improve RDA responsiveness and alignment to address emerging biothreats, the BPR recommends the following:

- The Biodefense Council should ensure alignment across DoD's RDA activities and portfolio priorities across the entire biothreat spectrum.
- DoD should continue transformation of RDA approaches to address priority emerging threats and rapidly deliver capabilities to the Total Force focused on the NDS, building on bold outcomes and opportunities driven by NBS implementation.
- The Biodefense Council serves as the guiding oversight mechanism to focus and align CBDP and DHP collaboration with interagency programs and projects.

Reinforce Biorisk Management to Ensure Safe and Secure Research. As DoD pursues R&D to address emerging threats, it must minimize the chances of laboratory incidents, reduce the likelihood of deliberate or accidental misuse of biological agents, ensure effective biorisk (biosafety and biosecurity) practices and oversight, and promote responsible research and innovation.

The BPR recommends further review for opportunities to strengthen biorisk management within DoD to ensure a coordinated and integrated effort, better posturing DoD's laboratories and performer partners to safely and securely conduct research into prioritized, emerging threats. As NBS implementation drives U.S. Government review of national and international standards and interagency efforts to govern biological select agents and toxins (BSAT), infectious agents and toxins, dual-use research of concern, and other evolving technologies, the BPR identified opportunities to better coordinate and standardize DoD's approach. DoD could more fully integrate and better invest in biorisk (biosafety and biosecurity) management to contribute to the prevention of bioincidents of national or international significance. The BPR identified opportunities to decrease the risk of accident and improve biorisk management through increased coordination, clarification of responsibilities, and the potential to leverage the oversight activities and expertise of other Federal departments and agencies. DoD must also evaluate biorisk management requirements to ensure the necessary standards and protocols to safely and securely conduct research into emerging threats into 2035.

The BPR recognizes that, since the 2015 biosafety lapses at Dugway Proving Ground, Utah, DoD has made significant changes to improve biorisk programs at DoD laboratories conducting RDT&E with BSAT. The creation of the DoD BSAT Biorisk Program, with the USD(A&S) as the PSA and the Secretary of the Army designated as the DoD Executive Agent, has made progress in improving the oversight, technical review, inspection, and synchronization of biorisk programs across DoD BSAT laboratories. To oversee the possession, use, and transfer of BSAT—which have the potential to pose a severe threat to public, animal, or plant health—all DoD BSAT laboratories must comply with Federal Select Agent Program regulations, which are jointly managed by the CDC and the U.S. Department of Agriculture. The DoD BSAT Biorisk Program oversees compliance with Federal regulations, coordinates necessary inspections and reviews, and is responsible for ensuring that DoD reports any BSAT releases to the congressional defense committees within 15 days of release. The BSAT Biorisk Program includes a scientific review panel that conducts technical and periodic assessment of biorisk protocols and funds projects to promote responsible research, to close scientific knowledge gaps, and to base DoD protocols on sound scientific data to mitigate risk.

***A Biodefense Enabler*:**
BSAT BIORISK PROGRAM

DoD is pursuing initiatives to strengthen biorisk management through the BSAT Biorisk Program.

To develop DoD's biorisk workforce and reduce the potential for conflicts of interest between lab safety and research outputs, the CBDP is centrally funding the Biosafety Officers supporting DoD BSAT laboratories, beginning in FY 2023.

DoD continues to elevate biorisk training, education and opportunities, support development and manufacturing of biosafety level-4 PPE with interagency partners, and expand sharing of approved DoD biorisk protocols with the interagency, allies, and partners.

The BPR recommends a more thorough review of opportunities to improve internal biorisk management policies and processes. This thorough review should consider the appropriate alignment of responsibilities across the PSAs, and evaluate whether a broader biorisk program, beyond the scope of BSAT risk management, is required to appropriately mitigate biosafety and biosecurity risks and ensure DoD laboratory compliance with national and international standards. This would also present opportunities to leverage interagency initiatives and expertise to increase both oversight and transparency and counter disinformation about DoD research capabilities.

To minimize the risk of overseas accidents, DoD should improve coordination with allies and partners to identify and capitalize on critical defense-specific capabilities. These partnership activities present opportunities to strengthen DoD transparency and compliance with international standards and norms and serve to counter disinformation asserting DoD biodefense activities support an offensive weapons program.

To reinforce biorisk management to ensure safe and secure research, the BPR's recommendations include the following:

- Conduct further review of biorisk management roles and responsibilities within DoD, and identify opportunities to nest oversight more directly under laboratory authorities.

- Engage other Federal departments and agencies and review opportunities to improve and increase efficiencies in oversight, compliance, and transparency measures.
- Engage allies and partners on improvements to mitigate laboratory accident threats.
- Strengthen biorisk oversight and promulgation of standards and protocols both within DoD laboratories and its performer base.
- Evaluate biorisk management requirements to establish standards and protocols to safely and securely conduct research into emerging threats.
- More proactively shape rhetoric around biodefense activities and counter adversary mis/dis-information campaigns that attempt to undermine peaceful efforts.

CHAPTER VI: SPEED RESPONSE TO MITIGATE IMPACTS TO DOD MISSIONS AND FORCES

In response to a bioincident, DoD must demonstrate the ability to deny or greatly minimize the effects of biohazards, including deliberate biological attacks, and remained postured to address NDS priorities The COVID-19 response highlighted shortfalls in both the Nation's and DoD's preparedness to respond to bioincidents. Despite DoD's ability to maintain operational readiness throughout the COVID-19 pandemic, the BPR identified concerns with:

- The ability to track locations, amounts, and availability of critical biodefense supplies.
- Shortcomings in capabilities to forecast future needs based on use, shelf life, or other factors.
- A lack of clear responsibilities and resources to sustain and manage non-medical and non-warfighting biodefense capabilities, such as Service requirements for non-medical PPE.

This line of effort and associated reforms enable DoD to rapidly mitigate the impacts of biothreats and biohazards and reconstitute DoD capabilities. DoD will work to mitigate impacts of a bioincident through a response that is rapid, resilient, and balanced. The BPR advocates for improvements in the following areas:

- Increase visibility of biodefense materiel readiness.
- Enhance Military Service stockpiles.
- Address vulnerabilities in the industrial base and supply chains.
- Optimize manufacturing capabilities.

Improvement in these areas, combined with the other reforms in the BPR, will aid in posturing DoD to rapidly mitigate the impacts of biothreats and biohazards and reconstitute DoD capabilities.

Gain Situational Awareness of Biodefense Materiel Readiness. DoD made significant strides since the early days of the COVID-19 response to improve the availability of products and supplies required to support the pandemic response. The COVID-19 Task Force (CVTF) took key steps to address problems like requirements determination, supply availability, logistics, and data management. The CVTF, with support from the Under Secretary of Defense (Comptroller)/Chief Financial Officer, initiated efforts to leverage Advana—a large DoD data platform for analytics—to support COVID-19 response data. Despite this, shortfalls in data collection and asset visibility for biodefense logistics still persist now.

To enable a more rapid response to biothreats, DoD must:

- Achieve enterprise-level visibility of biodefense materiel readiness.
- Increase situational awareness of indicators like PPE stockpile locations, key supply levels, and utilization rates.

- Initiate efforts to create a biodefense logistics common operating picture (COP).

An identified model for this solution is the Munitions Readiness Initiative (MRI), which provides near real-time situational awareness of the DoD-wide munitions enterprise across the entire lifecycle for operational and readiness assessments. The MRI provides decision makers with the ability to identify future courses of action and optimize available resources. In creating the biodefense COP, DoD should seek to leverage analogous capabilities and, where possible, pull from existing data sources and processes to establish a COP that provides users with a dynamic, near-real-time, evolving picture of global biodefense preparedness. This COP will enable the biodefense enterprise to monitor assets and acquisition programs to consolidate data streams into executive dashboards and working-level planning tools to provide materiel readiness status, and provide supply chain visibility. Situational awareness of required biodefense materiel capabilities, including medical and non-medical PPE, will enable leaders to track and manage the necessary capabilities to protect the Total Force and mitigate the effects of bioincidents.

In summation, to gain situational awareness of biodefense materiel readiness, DoD must:

- Develop a system that enables the biodefense enterprise to monitor assets and provide working-level planning tools for materiel readiness status and supply chain visibility.
- Assess existing Military Department and Service and Defense-wide processes and data sources to provide a foundational data layer that the COP would be built upon.

Bolster Military Department and Service Stockpiles to Protect the Total Force. The BPR advocates for improvements to close gaps in Military Department and Service requirements for non-medical biodefense PPE (e.g., N-95 industrial masks, barrier masks, and hand sanitizer). The COVID-19 pandemic response demonstrated the need to improve stockpile availability and supply levels to meet the Services' operational requirements.

In addition to the CVTF's efforts to address requirements determination, supply availability, logistics, and data management; DoD initiated significant work to address stockpile requirements during the COVID-19 response. A combined operational planning team (OPT) formed by the Joint Staff/J4, OUSD(P&R), Office of the USD(A&S) (OUSD(A&S)), and the Defense Logistics Agency (DLA) analyzed and established DoD's supply requirements and readiness levels for medical PPE to meet potential pandemic needs. The OPT was chartered to provide oversight and recommendations to ensure policy alignment, clearly defined authorities, procedures, and data standardization for this critical planning task. The OPT determined Military Department and Service stockpile requirements and successfully procured adequate supplies and materiel to meet DoD's initial needs. The BPR recommends increasing non-medical PPE stockpiles to meet the Military Departments' and Services' 90-day supply requirements and to prepare DoD more fully to respond to significant bioincidents, a recommendation that received support in the President's Budget request for FY 2024.

Within OUSD(P&R), the Assistant Secretary of Defense for Health Affairs is responsible for providing guidance and planning factors for medical PPE and, in collaboration with the Military Departments and Services, maintains a stockpile of critical items needed to support medical operations in a biothreat environment (e.g., facemasks, N-95 respirators, gowns). However, this

planning did not encompass other critical front-line professionals within the Total Force (e.g., security forces, fire and other installation emergency response personnel, operators, aircrews) who require PPE to continue operations that are critical to maintaining readiness and the generating force. Similarly, within OUSD(A&S), the ASD(NCB) plans, programs, and procures warfighter PPE and capabilities that address biothreats within the CBRN/CWMD mission space. Although many joint capabilities are managed through the same logistics channels, there are opportunities to improve synchronization on materiel requirements to meet the needs of the Total Force at home or abroad during peacetime or during conflict.

The BPR recommends the following reforms to improve the status, oversight, and management of stockpiles to ensure overall biothreat preparedness:

- The Biodefense Council will develop and recommend biodefense medical and non-medical stockpile strategies and options, including a review of responsibilities for materiel preparedness.
- The Biodefense Council will provide coordination mechanisms to ensure alignment of existing responsibilities and assess the sufficiency of resources to maintain and manage critical stockpiles.
- DoD will invest, maintain, and monitor required stockpiles for Military Department and Service biopreparedness.
- DoD will assess and invest in the required manpower to maintain these stockpiles.

***A Biodefense Enabler Example*: OPTIMIZED MANUFACTURING**

DoD is partnering and investing in efforts to optimize manufacturing processes and strength industrial base partnerships to more rapidly deliver capabilities to mitigate emerging biothreats.

Building off of lessons learned and opportunities from the COVID-19 response, the CBDP is partnering with the Office of the Assistant Secretary of Defense for Industrial Base Policy, interagency partners, and academic/commercial partners to use computational models and tools to optimize MCM development. This development includes efforts to proactively design fully optimized manufacturing processes based on desired product characteristics; and efforts to improve biologics production approaches, process controls, and small-molecule manufacturing toward "real-time release" capabilities.

DoD is also exploring opportunities for continuous, on-demand manufacturing of active pharmaceutical agents critical to MCM production.

Address Vulnerabilities within the Industrial Base to Ensure Secure and Consistent Supply Chains and Optimize Manufacturing Capabilities. The industrial base and supply chain supporting biodefense is a key enabler to DoD's biodefense posture. DoD requires a resilient, secure, and robust industrial base that can develop, manufacture at scale, and deliver biodefense capabilities when and where they are needed. DoD has authorities that enable procuring from a variety of providers—including the biotechnology innovation ecosystem, industry, universities, laboratories, and allies and partners—to maximize DoD's asymmetric advantages over adversaries.

DoD's biodefense industrial base faces significant challenges similar to other critical sectors (e.g., semiconductors). For example, the bulk of production, especially for key precursor materials, has moved overseas (especially to China). Subsequently, in many cases, domestic production has dwindled to a single supplier. Resultantly, investors increasingly find investing in the domestic biodefense sector unattractive, which further erodes the infrastructure needed to support DoD requirements. Additionally, the production workforce has shifted, leaving a dearth of talent in the United States. Compared to the global market, DoD's unique biodefense demands are small and not commercially competitive.

The COVID-19 pandemic demonstrated a need to produce key biodefense capabilities domestically to reduce U.S. vulnerabilities to global and regional supply chain shocks and reduce exposure to geopolitical interference. The myriad challenges to accomplishing this goal include reliance on overseas manufacturing and supply chains, inadequate domestic infrastructure and inconsistent demand from DoD, and competing demands to attract and retain workforce across a variety of biodefense skill sets.

To effectively posture the biodefense industrial base and supply chain, DoD must identify and prioritize critical missions and functions to develop strategies that mitigate the aforementioned challenges. DoD can accomplish this by partnering across the Office of the Assistant Secretary of Defense for Industrial Base Policy, CBDP, and DHP to prioritize on-shoring of production and distribution of key chemicals critical to produce DoD-unique biodefense MCMs. Increased use of computational tools and manufacturing controls can reduce the cost burden of small batch and continuous advanced manufacturing methods. These methods also enhance FDA regulatory compliance for DoD-specific biothreats. Likewise, DoD must strengthen its supply chain and industrial base for PPE, suit and filter components, and technologies to enable biological detection.

On-shoring of production and other efforts to strengthen the biodefense industrial base and supply chain can be achieved through two primary mechanisms: the Defense Production Act (DPA) and Manufacturing Innovation Institutes (MII).

- *DPA.* When authorized by the President, Title III of the DPA provides various financial measures (e.g., loans, loan guarantees, purchases, and purchase commitments) to improve, expand, and maintain domestic production capabilities needed to support national defense and homeland security procurement requirements. The DPA can be (and has been) readily applied in urgent biodefense scenarios like the COVID-19 pandemic.
- *MII.* The nine MII aim to revitalize domestic manufacturing capability through domestic, public-private partnerships; several of these are specifically for broader biotechnology needs and have some relevance to biodefense needs. Development of a long-term strategic relationship between DoD and the industrial base will allow for formation of an integrated and collaborative framework for protecting the Total Force from biothreats. This focus will enable leaders across DoD and the industrial base to develop, integrate, and synchronize policies, plans, programs, and resource investments in ways that more proactively link strategic mitigation decisions to operational requirements and critical functionality.

To reduce national security concerns in the biodefense industrial base, DoD could improve assessment of CFIUS cases to more effectively communicate the risks posed by specific foreign

investments. CFIUS, an interagency process, is a regulatory regime with nine executive agency members. CFIUS conducts national security reviews of foreign direct investment into U.S. companies falling under its jurisdiction. CFIUS reviews foreign mergers and acquisitions of U.S. companies to ensure that the foreign ownership of a U.S. company does not impair national security. CFIUS also has the authority to enter into national security mitigation agreements with the companies it reviews; these agreements allow CFIUS to reduce specific national security risk on a case-by-case basis. Additionally, CFIUS may prevent the investment or acquisition of a company through a referral process to the President. CFIUS presents a key avenue to share national security concerns with interagency partners and to solidify protection of domestic industries and the broader bioeconomy.

The BPR identified these additional actions that DoD can take to ensure the robustness of the biodefense industrial base and supply chain:

- Coordinate with the Industrial Base Council to strengthen the biodefense industrial base and direct staff to include biodefense considerations, including the potential use of DPA Title III authorities, to enable industry partnerships on DoD requirements.
- Conduct a deep dive into the supply chain for critical biodefense products to identify areas of risk (e.g., sole sources or foreign suppliers) and establish ongoing supply chain visibility for decision-making and prioritization.
- Effectively conduct relevant CFIUS case reviews involving the biodefense and biotechnology sectors;
- Maintain engagement with interagency partners, the National Security Council staff, the Office of Science and Technology Policy, and other key stakeholders to enable cross- U.S. Government understanding of biodefense- and biotechnology-related risks to national security.
- Continue to support interagency activities to improve biodefense protection mechanisms to identify and mitigate threats to the U.S. industrial base.
- DoD should consider opportunities to establish priority agreements with key manufacturers to support surge demand.
- Leverage the United Kingdom-U.S. Biotechnology Working Group to identify opportunities to optimize cooperation and collaboration.
- DoD should establish a biodefense community of interest to guide research, development, and exploration of transition efforts.

Provide Responsive FHP Guidance and Messaging to Maintain a Ready Force and Mitigate Bioincident Impacts. During the COVID-19 response, DoD implemented substantial improvements to processes to develop, distribute, and enforce FHP guidance. The COVID-19 Comprehensive Assessment identified lessons learned; made recommendations to consolidate FHP guidance; and provided a follow-up on the implementation of directives to better prepare, communicate, and execute guidance to best protect the Total Force. Trustworthy information needs to flow effectively and efficiently to provide the globally distributed force the guidance to execute the mission and allow for command flexibility.

Disinformation about public health was evident throughout the COVID-19 pandemic and has continued following Russia's brutal and unprovoked 2022 invasion of Ukraine. It represents a potential vulnerability for overall biodefense for the Total Force. Health-related misinformation or disinformation may threaten Total Force readiness by affecting force protection measures, readiness, retention, and recruitment. Mis-/dis-information regarding COVID-19 etiology and effective infection prevention and control measures reduced the acceptance of disease mitigation efforts by some DoD personnel and adversely impacted readiness.

DoD must provide clear, actionable, and enforceable FHP guidance to counter and correct competing information that threatens Total Force readiness and exacerbates the impacts of bioincidents. FHP also requires training staff on how to better recognize mis-/dis-information related to biodefense and public health issues and conveys awareness training and best practices to separate the truth from fiction. DoD leadership and management should seek to recognize where mis- and dis-information is taking hold and take active steps (e.g., consultations, brown bag learning sessions, mandatory training) to dispel it.

Mitigating the effects of a bioincident relies heavily on preparedness efforts to collaborate, understand, prepare, and protect the force from potential threats. Once an incident occurs, rapid activation of effective and efficient communication channels provides the foundation for the force to continue operations to meet NDS priorities with minimal degradation. The effective production and trust in FHP guidance will guard against mis-/dis-information campaigns that can undermine force readiness. The following should be pursued in terms of public health and medical messaging with the full engagement of DoD's public affairs offices:

- The dissemination of biodefense messaging should be addressed at the OSD level and communicated via command channels, including via official social media accounts.
- A common information campaign to communicate FHP guidance should be considered. This should be done in collaboration with DoD's public affairs offices to develop and provide detailed information.
- The Office of the Joint Staff Surgeon and the Military Department Surgeons General should collaborate to develop messaging efforts to counter mis-/dis-information and maintain readiness.

CHAPTER VII: COORDINATE AND COLLABORATE FOR ENHANCED BIODEFENSE

DoD has effective, established processes, in DoD policy and consistent with the *National Response Framework* (NRF), to coordinate whether and how to support civil authorities. However, the BPR revealed that DoD has a disorganized and diffused approach to supporting broader interagency and international biodefense activities. DoD is not sufficiently engaging with interagency partners and allies and partners to build global biodefense capabilities, enhance posture, maximize interoperability, and strengthen campaigning. A lack of shared understanding of biothreats across the U.S. Government and with global partners, further complicated by restricted information and data sharing, interferes with greater collaboration and coordination.

The BPR validated the unique role that DoD plays to dissuade, deter, and defeat actors of concern and their networks that seek to harm or coerce U.S. citizens, military capabilities, and allies and partners through the use or threat of use of biological warfare or the exploitation of naturally occurring or accidental disease outbreaks. This unique role requires DoD to clarify its position and commitments to the national biodefense enterprise and strengthen engagement with Allies and partners to maximize interoperability and improve campaigning to achieve biodefense goals.

Supporting the National Biodefense Enterprise at Home and Abroad. The COVID-19 response illuminated limitations in local, State, national, and international biodefense capabilities; and demonstrated the power of unparalleled mobilization, investment, and innovation by the U.S. Government, our international and industry partners, and citizens and communities around the world. DoD made many significant contributions to the pandemic response, which benefited the Nation, the world, and the resilience and readiness of the Total Force; however, the future biothreats that DoD faces might not elicit the same degree of unified national or global response. Therefore, DoD must prioritize biodefense activities and needs to implement the NDS and provide capabilities for the Total Force.

Although DoD directly supports many of the goals, outcomes, and targets in the NBS[3]; its leading responsibility, in partnership with the Department of State (DOS), is to deter bioweapons use. DoD must capitalize on this increased clarity of purpose to decrease focus on competing NBS demands and accept risk when and where other departments or agencies have primary responsibility. The NDS highlights that substantial DoD resources have been used to support civil authorities and international partners because of insufficient capability elsewhere, and emphasizes the need to anchor our strategy in an holistic response that includes other U.S. Government departments and agencies and international allies and partners; minimizes bureaucratic challenges to information sharing, and increases interoperability.

A key aspect to mitigating the impacts of a bioincident is interaction with interagency partners. In addition to laws governing interagency support and reimbursement, the NRF and other Federal and DoD policies outline the process for requesting such support. These processes have generally performed well and are used repeatedly for natural disasters and other national emergencies. In

[3] See Annex III for a complete list of DoD's lead and support roles and responsibilities in alignment with accomplishing NBS goals.

the event of a deliberate biological attack or naturally occurring outbreak of pandemic potential, requests for DoD support may far exceed these routine processes and require additional collaboration to coordinate and balance mission needs, similar to what was seen with the CVTF. If another significant and long-spanning response event occurs, DoD must work with interagency partners to balance support of domestic and international responses to limit risk to DoD primary missions (military contingencies), operations, activities, and investment(s) overseas. (See Annex III for a summary of DoD's lead and supporting roles and responsibilities aligned to NBS goals.) The governance proposed through the BPR will provide the integration of DoD capabilities and capacity to meet the demands of incidents of operational, national, and/or international significance in accordance with the NBS. Through the Office of the Under Secretary of Defense for Policy (OUSD(P)), requests for external support (domestic or international) should be coordinated across stakeholders to achieve a synchronized DoD position and appropriate commitment of resources and activities.

To improve interagency engagement, the USD(P) will utilize existing National Security Council interagency policy fora and the National Level Exercise Program to advance collaboration. Plans and exercises should include simultaneous military contingencies and homeland defense requirements, but should keep DoD's NDS responsibilities in the forefront; this will inform Federal and individual departments and agencies' domestic response planning, capabilities development, and force strength.

Although DoD must primarily focus on the NDS and the unique DoD responsibilities in the NBS, key opportunities remain to partner with HHS, the Department of Homeland Security, and DOS to provide capabilities for the Total Force and advance the achievement of national biodefense goals. This includes previously discussed reforms to expand early warning and biosurveillance capabilities and leverage partnership opportunities to speed research, improve RDA, and deliver coordinated and rapid response.

DoD will conduct the following activities to clarify DoD's role in the national biodefense enterprise, integrate incident response activities, and manage partner expectations on the availability of Defense Support of Civil Authorities to support response efforts:

- Focus on DoD's lead responsibilities in the NBS and prioritize biodefense needs to execute the NDS and provide capabilities for the Total Force.
- Establish a unified, coordinated DoD position to support NBS implementation and potential bioincident response requirements.
- Advocate for interagency exercises that include biothreats, their probability, potential severity, and security implications, and the impacts of the current global security environment in realistic scenarios that stress interagency coordination.
- Advocate for interagency exercises (conducted over Classified and Unclassified modes of communication) that utilize a broader range of content and more engaging and immersive technology.
- Work with interagency partners to identify and define agency-specific response and surge capabilities and capacity to manage expectations of potential DoD assistance.

- Coordinate with DOS, including specific biodefense lines of efforts within country plans (i.e., building partner civil and military capacity) and collaborate with individual countries ministries of health or other governmental bodies responsible for public health measures.

Strengthening Biodefense Collaboration with Allies and Partners. Collaborative biodefense engagement with our allies and partners improves our mutual biodefense, strengthens our alliances and partnerships, improves interoperability, and increases potential for burden-sharing. These collaborations maximize effectiveness and minimize risk to the Total Force.

As the NDS outlines, close collaboration with allies and partners is foundational for U.S. national security interests and for collective ability to address the challenges that the PRC and Russia present, while responsibly managing the array of other threats we face. Similarly, the NBS Implementation Plan highlights the importance of collaboration with the international community to counter the full spectrum of biothreats (e.g., natural, accidental, and deliberate), enhance pandemic preparedness, and achieve global health security.

DoD has significant international connections to further deter bioweapon use through arms control implementation, reinforcing international norms, and establishing processes to protect critical infrastructure and intellectual property. However, the BPR identified that DoD must strengthen common understanding of international, intergovernmental, multinational, and Ally and partner biodefense capabilities. Understanding capabilities and risk tolerance underpins a coordinated approach for interoperable preparation and response to crisis.

Ongoing challenges with classification of CBRN-related intelligence, along with data sharing concerns regarding medical information, limits meaningful and consistent information sharing with key allies and partners. In addition, the rapidly evolving nature of biothreats, combined with broader public health and national response commitments, complicates shared understanding of partner capabilities and their potential willingness to support a combined military response if/when local populations are impacted.

Existing programs and partnerships, such as the DoD Cooperative Threat Reduction (CTR) Program and overseas DoD medical laboratories, provide opportunities to strengthen collaboration and burden-sharing, but require prioritization and development of specific, measurable, achievable, and realistic objectives. Currently, DoD's biodefense-related foreign capacity and security assistance programs largely operate independently of each other. Opportunities exist for mutually reinforcing efforts to better support partnership capacity-building efforts.

DoD has done substantial work to collaborate with some key allies and partners to improve biodefense, laboratory safety and security, biosurveillance, and global health security. Furthermore, the North Atlantic Treaty Organization (NATO) has agreed to enhance its CBRN defense posture to, among other things, increase the range of capabilities to detect and analyze the use of biological agents. To identify further opportunities for sharing detection, protection, and mitigation capabilities and to solidify the ability to fight and win in biologically challenged environments, DoD must continue efforts to build understanding among allies and partners' for interoperability with U.S. capabilities. DoD will cooperate with allies and partners to increase resilience to coercion and improve allied and partner interoperability with the Joint Force. allies and partners are essential to DoD's ability to improve cooperative planning, intelligence sharing, and capability development to potentially reduce the shared vulnerability of accidental bioincidents, improve response to deliberate use, and counter disinformation campaigns.

***A Biodefense Enabler Example*:**
DOD CTR PROGRAM

The DoD CTR Program will expand focus to address the growing threats emanating from state actors and seek to expand investments in pandemic defense with allies and partners. The Program will continue working to improve global biosafety and biosecurity to reduce the likelihood of accidental release or deliberate misuse of biological agents. The Program will also support U.S. Government efforts to make the United States the partner of choice for preventing, detecting, and reporting infectious disease outbreaks of national or international significance, regardless of origin.

Engagements must nest closely with broader CBRN and medical engagements to maximize effect. allies' and partners' capabilities and DoD's standing with those partnerships need regular assessment to appropriately prioritize engagements to focus on the most productive and greatest impact. To accomplish the greatest impact, engagements should be looked at in two main categories:

- Focusing on burden-sharing and collaboration across biodefense.
- Increasing U.S. capability in addition to that of our partners.

Working with like-minded countries on campaigning creates a stronger foundation for interoperability in global response to bioincidents. Focusing on the security development of countries at highest risk and facilitating those countries' abilities should improve partner capabilities to save lives, reduce unnecessary suffering, and help prevent deterioration of security conditions without dependence on external response.

Furthermore, DoD should encourage the development and acquisition of interoperable capabilities through bilateral and multilateral engagements with allies and partners to strengthen deterrence and response capabilities globally. Engagements should extend beyond countering bioweapons to span broader capabilities and interoperability to respond to naturally occurring or accidental threats. DoD should explore and conduct low-cost, high-impact engagements to promote partner connectivity with DoD, the U.S. Government writ large, and trusted health organizations with the goal of incentivizing closer cooperation with the United States to counter biothreats.

Resource limitations require prioritization of countries that are most at-risk of bioincidents and have willingness to partner to enhance capabilities to understand, protect against, and mitigate bioincidents. These partnerships must share information bi-directionally to enhance biodefense intelligence and early warning. To deepen collaboration and coordination, DoD should conduct exercises and experimentation to project DoD requirements in support of designated allies and partners that are critical throughout the execution of theater campaign and contingency plans, across the biodefense mission areas, and against the full range of biothreats; this will require senior leader guidance as to which global and regional exercises may benefit from exclusive focus on, or incorporation of, biothreat and biohazard environments.

Adding a greater focus on a set of priorities and improved sharing across DoD will improve the interoperability of the unmatched network of allies and partners to address biodefense problems globally. These efforts will also help to address adversary mis-/dis-information campaigns by demonstrating the transparency of defensive programs and capabilities.

In summary, to strengthen biodefense collaboration with allies and partners, DoD will:

- Enhance support/resources for overseas DoD medical laboratories that integrate biosurveillance, tests of MCMs, and similar key activities (e.g., Naval Area Medical Research Units, Armed Forces Research Institute of Medical Sciences) to expand integrated, cooperative, and routine, regional Military-to-Military and Military-to-Civilian engagements.
- Conduct exercises with allies and partners that demonstrate the ability to operate in and recover from bioincidents.
- Prioritize engagements with countries that can achieve cooperation and campaigning activities to advance biodefense globally; this includes solidifying norms against bioweapons, biosurveillance and early warning, and response interoperability to mitigate the effects of bioincidents.
- Focus on security development of nations that are most at-risk from bioincidents and willing to partner with the United States to enhance capabilities to understand, protect against, and mitigate biothreats, including through efforts such as the DoD CTR Program.
- Support coordination with interagency partners to strengthen global biosurveillance networks to identify outbreaks and threats sooner.
- Build allies and partners' capability and capacity to detect, report, and respond to bioincidents that include laboratory accidents or other attempts to illicitly acquire valuable information (e.g., via DoD CTR assistance).

CHAPTER VIII: CONCLUSION

Implementation Plan and Priorities. The 2023 BPR outlines significant reforms to address shortfalls in biodefense and requires implementation of these reforms as soon as possible to execute the NDS in the face of growing biothreats. The Department's most important activities to improve biodefense include:

- Expanding threat understanding and biothreat awareness.
- Innovating and modernizing biodefense capabilities against the threats DoD will face through 2035 to maintain a ready and resilient force in support of the NDS.
- Improving readiness through training and exercising to identify and report shortfalls aiding the prioritization of modernization efforts.
- Establishing the Biodefense Council to synchronize, coordinate, and integrate authorities and responsibilities to provide an empowered and collaborative approach to sustained biodefense.

The proposed BPR reforms, when implemented, will strengthen the posture necessary to address the evolving biothreat landscape, prepare DoD to operate in a biothreat environment, and support the national biodefense enterprise at home and abroad. This established biodefense posture supports the NDS and the key responsibilities outlined in the NBS to enhance and sustain a resilient force prepared for bioincidents that can arise from natural, accidental, and/or deliberate origins.

ANNEX I: DEFINITIONS

Biodefense: Actions to counter biological threats, reduce risks, and prepare for, respond to, and recover from bioincidents.

Biodefense Enterprise: Stakeholders with a role in the prevention, preparedness, detection of, response to, and recovery from bioincidents of national significance.

Bioeconomy: Economic activity derived from biotechnology and biomanufacturing. (E.O. 14081)

Biological Incident (bioincident): Any act of biological warfare or terrorism; a crime involving a biohazard consistent with the scope of this strategy, or any natural or accidental occurrence in which a biohazard harms the Total Force, consistent with the National Defense Strategy and the National Biodefense Strategy

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

Biological hazard (biohazard): A biological agent or biologically active substance, regardless of origin (e.g., naturally occurring or bioengineered), that represents an actual or potential danger to humans, animals, plants, or the environment.

Biosurveillance: The process of gathering, integrating, interpreting, and communicating essential information and indications related to all-hazard threats or disease activity affecting human, animal, or plant health to achieve early detection and warning, contribute to overall situational awareness of the health aspects of an incident, and enable better decision-making at all levels (DoDD 6420.02, *DoD Biosurveillance*, September 17, 2020)

Early Warning: Ability to rapidly detect, characterize, report, forecast, and share relevant information, as appropriate, on pathogens that pose a threat of national or international significance soon after they emerge in humans, animals, and plants. (NBS)

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, economic well-being, or food security (2022 NBS).

Total Force: The organizations, units, and manpower used to meet the requirements associated with DoD missions. It includes Active Component and Reserve Component military personnel, DoD civilian employees (including foreign national direct- and indirect-hires), as well as non-appropriated fund employees, host nation support personnel, and contracted services. (DoDD 5124.11, *Assistant Secretary of Defense for Readiness (ASD(R))*, September 6, 2019)

ANNEX II: DISPOSITION OF COVID-19 LESSONS LEARNED

DepSecDef directed the BPR to address lessons learned from the Department's response to the COVID-19 pandemic. Recommendations for BPR consideration were drawn from source documents summarized below.

The initial work of the BPR analyzed 179 recommendations from three reports, combining similar findings (whether overlapping, synonymous, or interdependent), for a consolidated list of recommendations referred to the BPR for evaluation. Throughout the review process, these recommendations shaped analysis and findings of the BPR recommendations, while the Department continued to implement those actions most directly linked to the continued pandemic response. Overall, these reports and their associated recommendations assisted the BPR in learning from the COVID-19 response while considering the reforms necessary to execute the National Defense Strategy and support the National Biodefense Strategy.

Department of Defense COVID-19 Response: Comprehensive Assessment: The Comprehensive Assessment evaluated DoD's accomplishments and challenges in responding to COVID-19 between December 2019 and June 2021. Compiled by the DoD COVID-19 Task Force and the RAND Corporation, the report drew on hundreds of DoD documents, media reports, and interviews with DoD and interagency officials to chronicle DoD's activities, and offer observations and recommendations. The Comprehensive Assessment focused on DoD's success rate in achieving three objectives: protecting DoD's people, maintaining readiness, and supporting the whole-of-government interagency response. The Comprehensive Assessment made over 100 recommendations, some focused on the next phase of the pandemic and others for future bioevent scenarios.

COVID-19 Military Response In-Stride Review: The Chairman of the Joint Chiefs of Staff[4] directed a review of findings, insights, and recommended actions of the military response to COVID-19, which are consolidated in the Joint Staff's classified In-Stride Review. Many of its recommendations are similar to those in the Comprehensive Assessment, including ones focused on strategic planning, biosurveillance, data and information sharing, medical capacity, and medical readiness. This study highlights the need for DoD to better align with the National Response Framework, as well as with the pillars and implementation goals of the National Biodefense Strategy. The majority of these recommendations were managed through the Joint Lessons Learned process and are tracked and implemented by the Joint Staff or Joint Force. The Joint Staff-led Joint Force Lessons Learned Working Group for OSD Component level implementation or consideration within the BPR.

USNORTHCOM COVID-19 Strategic Lessons Learned: The Commander, U.S. Northern Command (CDRUSNORTHCOM) memorandum for the Secretary of Defense provides observations and recommendations regarding the Department's response to the COVID-19

[4] The Chairman, Joint Chiefs of Staff, is required by Title 10, U.S. Code, section 153(a)(6)(E), to formulate policy for gathering, developing, and disseminating joint lessons learned for the Armed Forces. The Joint Lessons Learned Program, administered by the Joint Staff (J-7), fulfills that requirement. See CJCSI 3150.25H for more information. The Joint Staff assisted BPR leadership with applying JLLP principles and terms of reference to the review process.

pandemic, based on USNORTHCOM's dual mission of homeland defense and civil support and CDRUSNORTHCOM's Unified Command Plan-assigned responsibility for planning of DoD efforts in support of the U.S. Government response to P&ID. The classified memorandum's observations focus on readiness and identifies opportunities for improving homeland defense and preparing to respond to potential actions by our adversaries.

The BPR considered the three reports and the contained recommendations to aid the development of the reforms presented throughout this report. The Biodefense Council can address any outstanding recommendations or additional lessons learned for future biodefense efforts to iteratively improve DoD's posture.

ANNEX III: NBS GOALS AND DOD ROLES

NBS GOAL	DOD LEAD ROLE	DOD SUPPORT ROLE
1 **Enable Risk Awareness and Detection to Inform Decision-Making Across the Biodefense Enterprise**	Work domestically and with international partner countries for sharing to enhance early warning.	Demonstrate sustained capacity of surveillance and monitoring systems
		Accelerate domestic and international research and innovation for clinical and environmental early warning.
		Enhance capacity for rapid analysis, modeling, baselining, forecasting, and reporting to improve early warning
		Address policy issues that may limit interchange of biosurveillance data.
		Develop and implement domestic characterization research and development agenda to develop recognized standards for safe and secure characterization of novel pathogens to support decisions.
		Revise, implement, and exercise operational plans for early warning.
		Maintain and enhance an enduring domestic all-hazards "hospital" data collection capability to enable comprehensive data reporting for biosurveillance.
2 **Ensure Biodefense Enterprise Capabilities to Prevent Bioincidents**	Work with foreign partners to strengthen 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.	Work with U.S. Government -supported countries to address identified gaps and improve capacities in key technical areas for global health security
		Complete interagency review and provide recommendations for U.S. policy, guidance, and practices to improve laboratory biosafety and biosecurity policy.
		Strengthen the scientific evidence base of laboratory biological risk management.
	Strengthen the implementation of the BWC and UNSC Resolution 1540 in order to prevent development, acquisition, or use of biological weapons, related materials, or means of delivery.	Strengthen partner countries' ability to have national biosafety and biosecurity system operating according to best practices and regulations to prevent proliferation risks.
		Galvanize support for biosafety and biosecurity commitments and the establishment of mechanisms to raise the bar for norms and practices.
	Strengthen the capability of the UN Secretary-General's Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons to determine the facts, including attribution, regarding the alleged use of biological or toxin weapons.	Complete interagency review of efforts to strengthen responsible conduct of biological research to develop and operationalize plans.
		Develop a U.S. Government joint capabilities plan to accelerate biosafety and biosecurity innovation.

3 **Ensure Biodefense Enterprise Preparedness to Reduce the Impacts of Bioincidents**	With other interagency partners, strengthen U.S. Federal, State, local, tribal, and territorial capacity to slow the emergence of resistant bacteria, prevent the spread of resistant infections, promote the responsible use of antibiotics, and surveillance of antibiotic resistant pathogens.	Develop a U.S. Government diagnostics joint capabilities plan.
		Safeguard PPE supply chain diversity through policy, incentive, regulation, and other tools to reduce dependence on a single region, source, or product.
		Develop a U.S. Government PPE joint capabilities plan.
		Develop a U.S. Government vaccines joint capabilities plan.
		Develop a U.S. Government therapeutics joint capabilities plan.
		Prepare for and respond to a public health emergency by designing, building, and sustaining a long-term capability in the U.S. to manufacture supplies for future pandemics and biological threats.
		Fund basic research, innovation, and the development of tools and technology for suppressing pathogen transmission in the built environment.
4 **Rapidly Respond to Limit the Impacts of Bioincidents**		Implement appropriate use of atmospheric, water and surface-type dispersion models with good predictive analysis on open-air release to identify potential contaminated areas and areas for sampling and analysis.

This page left intentionally blank


DEPARTMENT OF DEFENSE
UNITED STATES OF AMERICA