Additional Considerations

The National Security Commission on Emerging Biotechnology offers the following considerations for policymakers to prioritize biotechnology at the national level, mobilize the private sector to get U.S. products to scale, maximize the benefits of biotechnology for defense, build the biotechnology workforce of the future, and mobilize the collective strengths of our allies and partners.

1

Congress should designate new biotechnology leadership roles at the Department of Defense (DOD), including a new Deputy Assistant Secretary of Defense in the Office of the Secretary of Defense, and three new Deputy Assistant Secretary positions in the Departments of the Army, Navy, and Air Force.

The DOD recognizes biotechnology as one of its 14 critical technologies.

[1]The first Trump Administration created the position of principal director for biotechnology in the Office of the Under Secretary of Defense for Research and Engineering (R&E).[2] However, the position does not have counterparts in the military services, who have a majority of the funding, are most aware of their specific mission needs, and are tasked with integrating new technologies. This limits the principal director for biotechnology's ability to drive necessary change across the DOD.

To address this, Congress should designate new positions at the DOD related to biotechnology, elevating the principal director for biotechnology at the DOD to a deputy assistant secretary of defense (DASD) and designating three new deputy assistant secretary positions dedicated to biotechnology within the Army, Navy, and Air Force.

This new structure would improve coordination between the elevated DASD in the Office of the Secretary of Defense (OSD) and the new senior leaders in the military services, allowing the DOD to more effectively:

- develop, coordinate, assess, and oversee implementation of service-specific biotechnology capabilities across the services;
- ensure that biotechnology efforts are aligned with overarching national security objectives;
- lead R&E efforts to advance military capabilities through biotechnology innovation and maintain a competitive advantage in biotechnology;
- develop specific guidance on biotechnology private sector outreach, engagement, and agreements; and
- monitor biotechnology-relevant workforce recruitment and retention programs.

2

Congress should make biotechnology a higher priority at the Department of Energy (DOE) by codifying and appropriating the Office of Critical and Emerging Technology (OCET), elevating the Bioenergy Technologies Office (BETO), and funding research and development (R&D) at the intersection of national security and biotechnology within DOE labs.

The DOE has several programs dedicated to using biotechnology for its mission. These programs are dispersed throughout the DOE National Laboratories and draw on funding from a variety of offices. Elevating the appropriate offices will be key to continuing and expanding the DOE's focus on biotechnology. These proposals complement NSCEB recommendations related to the creation of new Centers for Biotechnology at the DOE National Laboratories.

Office of Critical and Emerging Technologies

DOE launched the Office of Critical and Emerging Technology (OCET) to harmonize the numerous efforts on emerging technologies, such as biotechnology, which are dispersed throughout the department. The aim of OCET is to centrally unite and coordinate these capabilities to solve critical science, energy, and national security challenges. But the office is not yet fully authorized in statute nor does it receive regular appropriations.[3]

To prioritize biotechnology at the DOE, Congress should codify and appropriate consistent funds for the OCET to give it greater authority to coordinate biotechnology work across the department.

Bioenergy Technologies Office

Congress should also elevate the Bioenergy Technologies Office (BETO). BETO is housed within the DOE's transportation fuels section of the Office of Energy Efficiency & Renewable Energy (EERE), which unnecessarily restricts its efforts to developing biotechnology for fuels. However, biotechnology can improve U.S. energy production through a wider range of applications beyond just fuel. For example, developing biomanufacturing processes to produce critical components of the industrial supply chain, such as chemicals and materials, could be more energy efficient than incumbent manufacturing processes. Allowing BETO to use the full force of its existing biotechnology expertise and infrastructure for energy production beyond fuel will help it meet the DOE's mission by lowering production costs, increasing efficiency, and addressing associated national security concerns.

To address these deficiencies, Congress should elevate the BETO, making it a standalone office under the Assistant Secretary for Energy Efficiency & Renewable Energy.

Biotechnology Research and the National Nuclear Security Administration

The National Laboratories, particularly those overseen by the National Nuclear Security Administration (NNSA), bring a unique capability to national defense through their state-of-the-art infrastructure and large-scale computational modeling. Many of these unique capabilities were originally built to study, assess, and mitigate risks associated with nuclear weapons of mass destruction (WMDs). However, with the types of potential WMDs expanding with advances in biology and chemistry, this same laboratory infrastructure has become critically important for keeping Americans safe from all types of WMDs. Currently, the NNSA National Laboratories anticipate, assess, detect, and mitigate risks from biotechnology, but such programs are incidental and inadequately empowered to face emerging biological WMDs.

Congress should empower and resource the NNSA to bolster its ability to support national security missions around emerging biotechnology. This includes ongoing successful efforts at the National Labs, such as the Generative Unconstrained Intelligent Drug Engineering (GUIDE) program at Lawrence Livermore National Laboratory (LLNL), which models and develops important medical countermeasures.[4]

3

Congress should pass the bipartisan Agriculture Biotechnology Coordination Act and Agriculture and National Security Act.

Within the United States Department of Agriculture (USDA), biotechnology policies and activities span multiple agencies, including research and development (R&D), extension and education, regulatory oversight, labeling, and trade. Currently, the USDA has one person to coordinate biotechnology across the department, which is not adequate given the many USDA activities that involve biotechnology.

To solve this problem, the Commission's Congressional members introduced the Agriculture Biotechnology Coordination Act in the House and the Senate during the 118th Congress.[5] The bill proposed a USDA Office of Biotechnology Policy which would be responsible for coordinating agricultural biotechnology activities within the USDA and across the U.S. government, similar to how the USDA Office of Pest Management Policy coordinates agricultural pest management activities.[6] This office would also serve as a point of contact for agricultural biotechnology developers, agricultural producers, and other entities that may be affected by biotechnology policies at the local, state, federal, or international level.

Food security is national security. Yet, even though the USDA has an Office of Homeland Security, which supports emergency prevention and response, the department lacks strong connections to national security agencies. In response, the Commission's Congressional members also introduced the Agriculture and National Security Act in the House and Senate during the 118th Congress.[7] This act instructs the Secretary of Agriculture to appoint a senior advisor for national security in the Office of the Secretary within USDA. This senior advisor would elevate the intersection of agriculture and national security, including for emerging technologies. The bill also requires the USDA to identify gaps or limitations related to food and agriculture in existing federal national security efforts.

4

Congress should authorize the National Institute of Standards and Technology (NIST) to establish the Biotechnology Convergence Consortium, a public-private economic development consortium to promote and coordinate companies that work at the intersection of biotechnology and other critical and emerging technologies (CETs).

The convergence of biotechnology and other CETs, or "bioconvergence," has led to a highly varied and multifaceted biotechnology industry landscape that presents great economic potential but also challenges for potential collaborations: Federal agencies often struggle to connect with the biotechnology industry, especially startups and small- and medium-sized enterprises, because of both how wide-ranging the industry is and how a company uses biotechnology may not be obvious. Meanwhile, biotechnology startups often struggle to identify and leverage appropriate federal resources, causing them to miss out on funding sources, government acquisition opportunities, or other chances to work directly with the federal government.

To fully mobilize the strength of its biotechnology sector, the United States needs a streamlined mechanism through which companies, government agencies, and academia can connect, share information, and collaborate. In doing so, biotechnology companies can better understand the full landscape of government resources to help the companies bring their biotechnologies to market. Additionally, biotechnology companies and researchers can better inform government policies. Such a mechanism is especially important for lowering the barriers to collaboration and growth for biotechnology startups as well as small- and medium-sized businesses.

The United States has taken some promising steps to address these concerns for other CETs, including the National Quantum Initiative Act, which called on the field of quantum technology to establish the Quantum Economic Development Consortium (QED-C).[8] This Consortium has been a successful model of public-private partnership connecting industry and government.

Congress should authorize NIST to establish the Biotechnology Convergence Consortium, a public-private economic development consortium dedicated to bringing together companies, labs, and government agencies that work at the intersection of biotechnology and other CETs. This Consortium would serve as a clearinghouse for collaboration and information sharing between those in and outside of the government. Key duties of the Consortium would include:

- convening and connecting stakeholders in academia and industry, especially small- and medium-sized enterprises, with Federal agencies to share opportunities for collaboration or funding;
- gathering insights on the needs from the bioconvergence community to better inform government investments and policies;
- facilitating industry participation in national and international standard-setting efforts; and
- creating workforce development programs and community outreach to local communities related to bioconvergence.

The Consortium should initially focus on the convergence of artificial intelligence (AI) and biotechnology. In the future, the Consortium could consider expanding its scope to the convergence of biotechnology with other CETs, such as quantum or high-performance computing.

5

Congress and the Executive Branch should expand and improve the BioPreferred Program.

The industrial biotechnology sector is scaling new technology while competing in a market crowded with companies making the same products more cheaply and abundantly with incumbent means of production. Government can help by aggregating and signaling demand for biotechnology products, enabling early commercial-scale companies to demonstrate to investors that there is government demand for their products.

As discussed in the main report, the Commission heard from American biotechnology companies that are eager to develop and manufacture products that are important for national security, but do not know what is needed when and by whom. As a result, companies gravitate toward products for which there is an attractive commercial market. For example, many industrial biotechnology companies are developing chemicals or materials for personal care, cosmetics, or related consumer applications because they can achieve higher margins in these sectors. These same biomanufacturing processes could be used to make chemicals with defense or energy applications.

Current federal programs to signal demand for technology products are insufficient to help the biotechnology industry effectively scale. The BioPreferred program, for example, promotes the procurement of biobased products, but it lacks relevant and clear definitions, effective procurement practices, and prioritization of domestic biobased products. In fact, many of the 10,000 or more biobased products in BioPreferred are imported, making the $489 billion U.S. biobased products industry vulnerable to supply chain disruptions.[9] Enhancing government procurement efforts could provide a critically needed market pull to catalyze the scaling of the U.S. biotechnology industry.[10] Additionally, strengthening incentives for domestic production could create jobs, boost the economy, and enhance national security.

To maximize the impact of BioPreferred procurement, the U.S. government should reauthorize the program with amendments to expand and improve procurement and tracking of biobased products made by American companies. First, Congress should update the statutory definition for biobased products to include products produced with biomanufacturing to reflect technological advancements and national security needs. For example, definitions can be updated by integrating the bioeconomy lexicon developed by the National Institute of Standards and Technology (NIST).[11] In addition, the Office of Management and Budget (OMB) should implement the recommendations set forth by the Interagency Technical Working Group's (ITWG) for the North American Industry Classification System (NAICS) and North American Product Classification System (NAPCS) revisions.[12]

Second, to send strong and consistent demand signals, the Executive Branch must strengthen procurement practices to effectively reach the biotechnology industry. This would include lowering procurement thresholds for biobased products from $10,000 to $5,000, streamlining biobased product procurement pathways, setting timetables for biobased-only contracts, and mandating staff training on biobased acquisitions. Moreover, strengthening oversight to the program with required reporting and Government Accountability Office reviews will ensure the Federal agencies are held accountable to biobased procurement goals.

Lastly, although the BioPreferred Program promotes the procurement of biobased products, it lacks preferences for American-made biobased products. Many of the 10,000+ items rely on imports, making the $489 billion U.S. biobased industry vulnerable to supply chain disruptions.[13] Prioritizing biobased products made in the United States and Allied countries within the BioPreferred program could create new markets for agricultural byproducts and excess biomass, maximizing the use of surplus production and helping to reduce waste.[14] This approach would capitalize on the United States' abundant resources and open avenues for exporting America's position in the global market. It would also enhance U.S. national security by ensuring that more of the products used for U.S. national defense are American- or ally-made and possess more resilient supply chains.

6

Congress should pass the bipartisan Food Supply Chain Capacity and Resiliency Act.

Recent supply shocks and high food prices have hurt American families and exposed the need for resilient, varied Food Supply Chain Capacity and Resiliency Act offers flexible government-backed loans to companies that start or expand manufacturing projects that can help alleviate food supply chain shocks.[15] Biomanufacturing companies can use this financing to de-risk their investments while offering innovative solution to supply chain challenges leading to direct positive effects on Americans' pocketbooks.

Passage of this bill would catalyze biomanufacturing projects that can ultimately lower food prices, create jobs in rural America, and reshore critical food supply chains. This increased capital is particularly attractive for biomanufacturing developments because it offers flexibility that can account for the wide range of commercial scale bioprocessing projects. If passed, this bill would also bolster the production and adoption of biobased products. Food products are particularly attractive bioproducts because they have comparatively high consumer demand.

7

Congress should establish a biosurveillance program at the Department of Defense (DOD) to detect harmful pathogens.

Biosurveillance is the capability to systematically survey, detect, and identify viruses or other biological entities in the environment that might cause disease in people, animals, or plants.[16] Biosurveillance improves situational awareness by scanning for outbreaks before they become pandemics, generating valuable data in the process, and laying the groundwork for a rapid response to any emerging biological threats.[17] A robust biosurveillance capability ensures a prepared and strong U.S. biotechnology sector.

Approaches such as untargeted metagenomic sequencing, which enable the detection of all pathogens in a given sample, differ from targeted approaches that look only for sequences of specific pathogens. An untargeted system would lower the time between outbreak and identification, making deployment of other countermeasures more effective, mitigating the undetected spread of a stealth virus (such as a future version of HIV) through populations, and providing valuable scientific data. While some of the technology to accomplish untargeted metagenomic sequencing is in early development, a clear roadmap with phased implementation milestones would support private-sector innovation and capitalize on significant reductions in sequencing costs.

Despite rapid advancements and cost reductions in emerging biotechnology, the U.S. government continues to rely almost entirely on the list-based detection of known pathogens. Such a system breaks down when it comes to detecting asymptomatic or novel viruses, or biosurveillance in places where individuals lack access to health infrastructure. Additionally, current biosurveillance work is siloed across the U.S. government, and transparency levels mandated by public health agencies make it difficult to work with the private sector. Although significant progress has been made, these limitations continue to pose a particular challenge for the DOD, which has limited operational capability to meet its mission of protecting the American warfighter while operating in contested and contaminated environments.[18]

The DOD needs a pathogen-agnostic, scalable, and global biosurveillance infrastructure.[19] This infrastructure should be capable of detecting a wide range of new and emerging potential pathogens, regardless of origin. Many technologies must converge to develop and scale such a broad-spectrum biosurveillance capability. In addition to sharpening U.S. government threat awareness, implementing this infrastructure could drive advancements across other technologies and enable innovations well beyond biosurveillance. Similar to how CRISPR was first discovered by sequencing microbial genomes, gaining a better understanding of biological systems through sequencing undiscovered organisms, such as bacteria and viruses, could catalyze an adjacent innovation ecosystem and yield far-reaching benefits.[20]

Other potential advancements include generating more accurate long reads of genetic material, paired with a stronger capability to identify microbes, which would enhance the ability to accurately construct complete genomes of various microorganisms, streamline sample-processing, and improve bioinformatic analyses.[21] Such advancements would elevate America's readiness to detect and confront a broader range of biological threats, while stimulating a wider innovation ecosystem.

This potential merits an expansion of the United States' pathogen-agnostic biosurveillance capabilities. Accordingly, Congress should establish a biosurveillance program at the DOD to detect pathogens that threaten national security. To do so, the DOD should define and implement strategic requirements for a scalable, global, pathogen-agnostic detection capability and the accompanying required analytical tools.

Within one year of creating the program, the DOD should submit a detailed plan for leveraging functional and risk-based methodologies, including untargeted metagenomic sequencing, to achieve a pathogen-agnostic detection capability that meets the DOD's needs. This capability should be fully implemented within two years of taking on this proposal.

The DOD Biodefense Council should coordinate this effort and interface with stakeholders across the department in drafting this plan. The effort should be implemented at select DOD overseas installations to ensure a global detection capability. Furthermore, the Secretary of Defense should brief all Congressional Committees with relevant jurisdiction on the results of the analysis and the resulting plan.

Lastly, the president should submit to Congress a report detailing how interagency cooperation on biosurveillance is to be conducted to ensure adequate threat awareness, timely response, and streamlined efforts. All parts of this proposal should comply with Privacy Act provisions and existing DOD regulations.

8

Congress should direct the National Science Foundation (NSF) to establish a federal grant program for a national system of community biology labs that would engage Americans in informal learning.

The federal government should enable more Americans to learn about and innovate with biology directly in their local communities. Community biology labs (CBLs), which are research, education, and innovation spaces open to the public, create a natural pathway to working in biotechnology. Such labs can expose people to the wonders of biology and inspire curiosity. But community labs are rare, tend to be small, and operate on meager local budgets. Federal support would enhance and expand access to these informal learning spaces across the country.

CBLs are a relatively small effort by the federal government that could have an outsized impact on advancing bioliteracy among the public. Expanding CBLs would be a natural step toward increasing public trust and understanding of biotechnology, empowering citizens to make informed decisions about how they engage with biotechnology and driving more people to contribute ideas and innovations.

Congress should direct the NSF to establish a federal grant program for a national system of community biology labs that would be open to the public and would engage Americans in informal learning. The program would offer grants to create community biology programming at existing public spaces such as libraries, museums, and nature centers, and to build new infrastructure. Grants would also provide funding for communities to convene local stakeholders, academic institutions, and businesses for information sharing and bioliteracy development.

As community labs grow, there would be a need for certified technicians to teach the public about biotechnology, biosafety and responsible innovation. Technicians could be trained through an accredited certification program that would cover topics such as biology and biotechnology, biosafety, bioethics, and community outreach and engagement. Under the guidance of trained technicians and the NSF Office of the Chief of Research Security Strategy and Policy, and in collaboration with the FBI WMD Directorate, these CBLs will adhere to strict biosafety protocols and federal, state, and local regulations, fostering an appreciation for biology while undertaking low-risk research for public participation, as existing CBLs have done for more than a decade.

References

1 Office of Strategic Capital, "DoD Critical Technology Areas," Department of Defense, Under Secretary of Defense for Research & Engineering, accessed March 4, 2025, https://www.cto.mil/osc/critical-technologies.

2 U.S. Department of Defense, "Critical Technology Areas," Office of the Under Secretary of Defense for Research and Engineering, accessed January 28, 2025, https://dod-critical-technology-area-roadmaps.zoiclabs.io/.;
U.S. Department of Defense, "R&E Leadership," Office of the Under Secretary of Defense for Research and Engineering, accessed March 7, 2025, https://www.cto.mil/leadership/.;
Alexander J. Titus, Edward van Opstal, and Michelle Rozo, "Biotechnology in Defense of Economic and National Security," *Health Security* 18, no. 4 (August 19, 2020): 310–12, https://doi.org/10.1089/hs.2020.0007.

3 Department of Energy AI Act, S.4664, 118th Cong. (2024).

4 GUIDE Program Office, "Generative Unconstrained Intelligence Drug Engineering," Lawrence Livermore National Laboratory, accessed March 4, 2025, https://guide.llnl.gov/.

5 Agricultural Biotechnology Coordination Act, S.4421, 118th Cong. (2024).;
Farm, Food, and National Security Act, H.R. 8467, 118th Cong. (2024).

6 U.S. Department of Agriculture, "About OPMP," U.S. Department of Agriculture, accessed March 4, 2025, https://www.usda.gov/about-usda/general-information/staff-offices/office-chief-economist/office-pest-management-policy-opmp/about-opmp.

7 Agriculture and National Security Act, S.4420, 118th Cong. (2024).;
Agriculture and National Security Act, H.R.8522, 118th Cong. (2024).

8 National Quantum Initiative Act, Pub. L. No. 115-368 (2018), https://www.govinfo.gov/app/details/PLAW-115publ368.; "The Quantum Consortium," QED-C, accessed March 4, 2025, https://quantumconsortium.org/.

9 Jay S. Golden et al., "An Economic Impact Analysis of the U.S. Biobased Products Industry: 2023 Update," March 8, 2024, https://www.rd.usda.gov/media/file/download/usda-rd-economic-impact-analysis-us-biobased-products-industry-2023-508.pdf.

10 U.S. Department of Agriculture, "Latest Economic Impact Report Shows a Thriving and Resilient Bioeconomy Despite Impacts of the Global Pandemic," March 2024, https://www.biopreferred.gov/BPResources/files/BiobasedProductsEconomicAnalysis2023FS.pdf.

11 National Institute of Standards and Technology, "NIST Bioeconomy Lexicon," December 9, 2022, https://www.nist.gov/bioscience/nist-bioeconomy-lexicon.

12 Interagency Technical Working Group, "Measuring the Bioeconomy: Recommended Revisions to the NAICS and NAPCS," September 12, 2023, https://www.usda.gov/sites/default/files/documents/OCE-Measuring-the-Bioeconomy.pdf.

13 Institute Jay S. Golden et al., "An Economic Impact Analysis of the U.S. Biobased Products Industry: 2023 Update," March 8, 2024, https://www.rd.usda.gov/media/file/download/usda-rd-economic-impact-analysis-us-biobased-products-industry-2023-508.pdf.

14 Rafael Rodrigues Philippini et al., "Agroindustrial Byproducts for the Generation of Biobased Products: Alternatives for Sustainable Biorefineries," *Frontiers in Energy Research* 8, no. 152 (July 28, 2020), https://doi.org/10.3389/fenrg.2020.00152.

15 Food Supply Chain Capacity and Resiliency Act, S.4099, 118th Cong. (2024).

16 National Institute of Standards and Technology, "Biosurveillance and Pathogen Detection," August 19, 2024, https://www.nist.gov/programs-projects/biosurveillance-and-pathogen-detection.

17 Simon N. Jarman, Oliver Berry, and Michael Bunce, "The Value of Environmental DNA Biobanking for Long-Term Biomonitoring," *Nature Ecology & Evolution* 2, no. 8 (July 2, 2018): 1192–93, https://doi.org/10.1038/s41559-018-0614-3.; U.S. Government Accountability Office, "Biodefense: National Biosurveillance Integration Center Has Taken Steps to Address Challenges, but Could Better Assess Results," November 29, 2023, https://www.gao.gov/products/gao-24-106142.

18 Thomas Cullison and J. Stephen Morrison, "The Time Is Now for the DOD to Expedite Action on Biosurveillance," Center for Strategic and International Studies, August 15, 2024, https://www.csis.org/analysis/time-now-dod-expedite-action-biosurveillance.; U.S. Department of Defense, "2023 Biodefense Posture Review," August 17, 2023, https://media.defense.gov/2023/Aug/17/2003282337/-1/-1/1/2023_biodefense_posture_review.pdf.; Defense Innovation Unit, "DIU Demonstrates Capability To Find Novel Threats in High Complexity Wastewater Data," U.S. Department of Defense, January 22, 2025, https://www.diu.mil/latest/diu-demonstrates-capability-to-find-novel-threats-in-high-complexity?utm_source=LinkedIn&utm_medium=Social.

19 Rhys Dubin et al., "Pathogen Early Warning: A Progress Report & Path Forward" (Council on Strategic Risks, Janne E. Nolan Center, December 2022), https://councilonstrategicrisks.org/wp-content/uploads/2022/12/ImprovePathogenEW-2022.pdf.

20 Irina Gostimskaya, "CRISPR–Cas9: A History of Its Discovery and Ethical Considerations of Its Use in Genome Editing," Biochemistry (Moscow) 87, no. 8 (August 15, 2022): 777–88, https://doi.org/10.1134/S0006297922080090.

21 Karrie K. K. Ko, Kern Rei Chng, and Niranjan Nagarajan, "Metagenomics-Enabled Microbial Surveillance," Nature Microbiology 7, no. 4 (April 1, 2022): 486–96, https://doi.org/10.1038/s41564-022-01089-w.