



UNDER SECRETARY OF DEFENSE
3030 DEFENSE PENTAGON
WASHINGTON, DC 20301-3030

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MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
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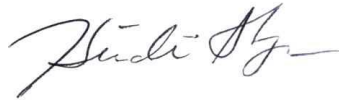
SUBJECT: Department of Defense Biomanufacturing Strategy

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

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

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

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

A handwritten signature in black ink, appearing to read "Heidi Shyu", with a stylized flourish at the end.

Heidi Shyu

U.S. Department of Defense Biomanufacturing Strategy



Office of the Under Secretary of Defense for Research and Engineering

21 March 2023

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

1. Background

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

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

¹ Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)) Industrial Policy, “Fiscal Year 2020 Industrial Capabilities Report To Congress,” January 2021, p. 117.

² McKinsey Global Institute (MGI), “The Bio Revolution: Innovations transforming economies, societies, and our lives,” p. 65.

³ MGI, 2020, p. 57.

⁴ Executive Office, Public Meeting of the President’s Council of Advisors on Science and Technology, November 2021, p. 6.

⁵ Executive Office, November 2021, p. 6-7.

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

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

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

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

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

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

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

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

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

Executive Order (E.O.) 14081¹⁰, among other prior legislation, E.O.s and memoranda, and DoD strategies, the DoD Biomanufacturing Strategy will meet the Department's capability needs in current and future missions by developing and fielding biotechnology-derived solutions. Consistent with U.S. Government initiatives to strategically leverage biomanufacturing for economic, military, and technological advantage,¹¹ implementation of the DoD Biomanufacturing Strategy will protect and promote a self-sustaining domestic biomanufacturing ecosystem. A self-sustaining domestic biomanufacturing ecosystem will be poised to provide an enduring source of biologically-based solutions while ensuring the U.S. military maintains an enduring advantage to deter conflict and secure the Nation. In addition, DoD's priorities in supporting biomanufacturing will fill capability gaps in critical military supply chains; solve challenges in logistics, especially in contested regions; and provide materials with novel properties, some of which we can only create through biology.

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

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

2. Guiding principles of the DoD Biomanufacturing Strategy

¹⁰ E.O. 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," September 12, 2022.

¹¹ Department of Defense, "New Biotechnology Executive Order Will Advance DoD Biotechnology Initiatives for America's Economic and National Security," September 2022.

¹² Department of Defense, "National Defense Strategy," October 27, 2022, pp. 19-20.

¹³ Department of Defense, "Executive Summary: DoD Data Strategy Unleashing Data to Advance the National Defense Strategy," September 2020; and Deputy Secretary of Defense, "Creating Data Advantage," May, 2020.

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

- (1) The Department will establish transition partners for early-stage innovations (e.g., at Technology Readiness Levels 1-5);
- (2) The Department will develop the field of biomanufacturing through innovations in practice and application; and
- (3) The Department will map the domestic biomanufacturing ecosystem and the changes that occur over time for identification and tracking of metrics to support future implementation and refinement of the DoD Biomanufacturing Strategy.

a. Establish DoD transition partners for biotechnology

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

b. Innovate in biomanufacturing

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

¹⁴ Chairman of the Joint Chiefs of Staff Instruction (CJCSI) 5023.011, "Charter of the Joint Requirements Oversight Council and Implementation of the Joint Capabilities Integration and Development System," October 30, 2021.

¹⁵ The CHIPS and Science Act of 2022 specifically assigned DoD to "(3) Assess risks of potential national security and economic security threats" from biotechnology. See Title IV, Section 10406(d)(3).

thrive,”¹⁶ and the CHIPS and Science Act of 2022.¹⁷ While it has been well-established by numerous start-ups, academics, and DoD laboratories that biology can generate products at the bench scale that could *potentially* fill capability gaps, research is required in scaling-up biomanufacturing to produce at a scale sufficient to prototype these products. While this is the second hurdle in adopting biotechnology-based solutions to DoD mission needs, it is also an incredible opportunity to develop biomanufacturing at home and with allies and partners¹⁸ to create a self-sustaining domestic biomanufacturing ecosystem. Furthermore, it will contribute to the United States remaining the world leader in innovation, guarantee DoD interests are protected, and ensure that U.S. global competitiveness in biotechnology is maintained.

c. Map and measure the biomanufacturing ecosystem

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

3. Conclusion

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

¹⁶ E.O. 14005, “Ensuring the Future is Made in All of America by All of America’s Workers,” January 25, 2001.

¹⁷ See TITLE IV, Section 10402(a)(2), National Engineering Biology Research and Development Initiative, Public Law 117-167, August 9, 2022.

¹⁸ See Executive Office of the President, “National Security Strategy,” 2022, p. 33; 2022 NDS, p. 19-20; and E.O. 14017.

¹⁹ DoD Directive 5137.02, “Under Secretary of Defense for Research and Engineering (USD(R&E)),” July 15, 2020, Distro A; CJCSI 5123.011, “Charter of the Joint Requirements Oversight Council and Implementation of the Joint Capabilities Integration and Development System,” Enclosure C, October 30, 2021, Distro A.

²⁰ 2022 NDS, p. 19, 22.

²¹ See TITLE IV, Section 10402 (b) (6).

²² 2022 NDS, p. 22.

²³ 2022 NDS, p. 19.

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

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

Appendix A: Acronym List

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