



The Special Competitive Studies Project (SCSP) is a bipartisan, nonprofit project with a clear mission: to make recommendations to strengthen America's long-term competitiveness where artificial intelligence (AI) and other emerging technologies are reshaping our national security, economy, and society. NATIONAL ACTION PLAN FOR UNITED STATES LEADERSHIP IN **BIOTECHNOLOGY**

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This report benefited greatly from insights and expertise by a number of individuals to whom we are deeply grateful. It aims to reflect many, though not all, of those insights. Vinny Beranek Toby Blackburn Luciana Borio Jim Brase August Cole Rebecca Doerge Drew Endy Dan Kaufman Ben Kline Milo Medin Ryan Morhard Richard Murray Steve Rosen Jonathan Rosenberg Daniela Rus Marc Salit Reshma Shetty Christina Smolke Brian Spears

A Letter from the Chairman & the CEO

SCSP is developing a series of National Action Plans to establish U.S. leadership in key technology areas. This action plan addresses biotechnology, a sector that will transform industries as diverse as agriculture, health, industrials, materials, and energy in ways that today we can only begin to foresee.

The national security imperative that the United States and its allies and partners lead the world in this critical technology sector cannot be overstated. From the pathogen risks demonstrated so starkly by COVID-19, to the security of individuals' biodata, to the ability to bioengineer solutions to our most vexing challenges, we are entering an era that presents both considerable risks and immense opportunities to transform our world at both the molecular and global scale. For its part, an increasingly powerful People's Republic of China (PRC) is determined to lead the world in biotechnology and is investing heavily in this sector, seeing such investments as key to addressing demographic and healthcare challenges and the potential to convert biotech innovations into military advantage.

The U.S. Government (USG) has taken a number of important steps to set the course for biotechnology leadership. Yet, China still looms large in the rearview mirror as it accelerates its efforts to secure biotech advantage at the expense of U.S. industry and often in ways that do not align with our democratic values and data security norms. Winning this competition will require sustained focus by the government, greater public-private collaboration, and a willingness to make strategic bets on our biofuture.

Drawing on expertise from academia, the private sector, and government, this biotechnology action plan combines bold technology "moonshots" with recommended changes to the innovation ecosystem along with policies to position the U.S. for durable advantage. Rather than address every aspect of this vast sector, our action plan focuses on solving for U.S. advantage from a national security perspective. We invite you to join us in this effort to ensure that America is positioned and organized to win the techno-economic competition between now and 2030, the critical window for shaping the future.

Eric Schmidt, Chairman, SCSP

Ylli Bajraktari, 🖉 President & CEO, SCSP

Introduction

Biotechnology is a multi-trillion dollar general-purpose sector. It will transform industries as diverse as agriculture, health, industrials, materials, and energy,¹ and converge with disciplines like chemistry, artificial intelligence, computer science, data science, physics, and nanotechnology in ways that today we can only begin to foresee. Offering the ability to manipulate the very essence of life as we know it, biotechnology today is understandably attended with a conflicted psychology of awe at the opportunities, caution over the dangers, and fear of the worst possible outcomes that this technology could unleash. These sentiments are heightened by an international competition between democratic and authoritarian nations that approach biotechnology with different norms and values. The national security imperative of biotech leadership cannot be overstated. From the pathogen risks that COVID-19 has made us all too familiar with, to the security of individuals' biodata, to the ability to bioengineer solutions to our most vexing challenges, biotechnology's general purpose era presages considerable risks and even more immense opportunities to reshape our world at both molecular and global scale. This action plan is focused in both intent and the recommendations provided. It provides a biotechnology policy roadmap for a coordinated effort among academia, the private sector, and government to establish U.S. leadership in this critical technology through 2030, alongside our allies and partners, from a national security perspective.²

Desired Endstate

The United States maintains its position as a global driver of advanced biotechnology innovation and is the leader, alongside allies and partners, in catalyzing research, development, and commercialization of breakthrough biotechnologies, as well as setting global biotech standards, in 2030 and beyond. We believe that winning the biotechnology future would include the following qualities:

- A **global "Bionet"** built with data privacy guardrails detects pathogens anywhere on Earth and enables the rapid manufacturing of tailored vaccines, testing equipment, rapid therapeutics, and other treatments at the source of the outbreak within days.
- Biotech solutions like nutrient-dense, drought-resistant crops and genetically engineered algae have increased food and water security, while advancements in energy-dense biofuels – one piece of a renewable energy mosaic – have helped the world accelerate toward shared decarbonization goals.
- **Biomined critical minerals** and **bioengineered materials** enable more efficient, robust, and secure supply chains that over time will be able to be grown anywhere on Earth.
- A **vibrant biomanufacturing ecosystem** has transformed how we produce everything from clothing to buildings, spawning a thriving U.S. "Biobelt" of domestic industries such

as manufactured spider silk, mycelium (mushroom leather), self-healing and carbonnegative construction materials, and more.

- **Reliable and routine bioengineering** enables middle schoolers, doctoral candidates, and every student between to "design, build, and work" on biotech solutions for nearly any challenge.
- An **agile**, **rapidly-scalable**, **distributed biomanufacturing base** that efficiently produces the majority of essential medicines³ and makes affordable medicines available to everyone who needs them. This modernization of pharmaceutical supply chains drives more equitable health outcomes globally.

Central Policy

Treat biotechnology leadership with urgency as a general purpose technology that will define the next period of human history, leveraging public-private partnerships to secure a "biofuture" that neither government nor industry could achieve alone.

Action Plan Overview

1: Launch Biotechnology "Moonshots" to Advance Fundamental Science & Technology (S&T)

1.1: Unlock Nature As a Code Base: The Annotated Non-Human Genome Project 1.2: Biosecurity at Scale: Field a True 24/7 National Medshield

1.3: The Long Game: The Synthetic Cell

2: Align Incentives for Biotechnology Commercialization, Diffusion, and Scale

- 2.1: Biomanufacture Medicines Locally
- 2.2: Invest in the Infrastructure to Enable Domestic Biomanufacturing at Scale
- 2.3: Align the Vast Standards Ecosystem for a General Purpose Era

3: Empower the Entire Innovation Ecosystem

- 3.1: Establish University Centers of Excellence
- 3.2: Augment the National Labs
- 3.3: Expand Biomanufacturing Institutes

4: Build the Infrastructure That Will Allow Us to Tap Into Biotech's Full Potential

4.1: Build Out the Global Bionet4.2: Treat Genomic Data as a Strategic Resource4.3: Fundamentally Change the Way Life Sciences Are Done

5: Cultivate, Attract, and Retain Biotech Talent

5.1: Grow and Train the Biotech Workforce 5.2: Attract and Retain Global Biotech Talent

5.3: Reinvent the Library to Include the Era of Atoms, Bits, and Cells

6: Secure the Inputs for a Thriving Domestic Bioeconomy

6.1: Promote Supply Chain Security for Biotechnology Equipment

7: Unite Democratic Ally and Partner Competitive Advantages

7.1: Establish a Biomanufacturing Alliance Among Like-Minded Nations 7.2: Define America's Baseline for Global Biotechnology Cooperation

8: Run Faster with Guardrails

8.1: Regulate and Govern to "Run Faster" Than Rival Ecosystems

- 8.2: Conduct a Comprehensive Security Review of the Biotech Sector
- 8.3: Limit the Expansion of PRC Global Biotech Platforms
- 8.4: Hardwire Security Into U.S. Biotechnology Platforms

Background

The United States is today the global leader in genetic engineering and molecular biology.⁴ It has the opportunity to unleash an entire "bioeconomy" that is estimated to eventually be worth anywhere between \$4-30 trillion, capable of producing up to 60 percent of the physical inputs to the global economy.⁵ Yet the United States risks squandering its early lead if it fails to lay the groundwork for this emergent general purpose technology that will pervade most aspects of society. For one, biotechnology straddles a *vast* array of disciplines — from health to manufacturing to energy — that are not fully integrated within or across academia, industry, and government. Biotechnology advances, perhaps more so than most other technology sectors, are diffuse across nations given the interconnectedness of the global scientific community. Additionally, transformative biotechnology breakthroughs risk being "stranded in the lab" or outsourced to rival ecosystems if their inventors fail to raise the capital needed for scale and to navigate the legal and regulatory path towards commercialization. Like other "deep technologies" on the decadal horizon, the market alone is unlikely to guarantee sector leadership, and strategic public-private partnerships will be central to solving for U.S. advantage.

U.S allies and partners are also making strides in the biotechnology space. Europe leads the world in health-related biotech patents, producing more than 40,000 over the past five years,⁶ and outperforms the United States in patenting other aspects of biotech like environmental technology.⁷ Nations including Switzerland, Sweden, Israel, and Singapore have accrued leading biotech roles through high volumes of public biotech companies, investment, and research.⁸ Institutions like French DNAScript and United Kingdom (UK)-based Nuclear are leaders in producing "desktop" DNA synthesizers that can produce proteins and DNA on demand.⁹ Finally, nations like the UK and Canada have established meaningful national biotechnology strategies dating back to 2017.¹⁰

The PRC for its part, is determined to lead the world in biotechnology. PRC public and private entities are investing heavily in its relatively nascent biotechnology sector, seeing such investments as key to addressing looming domestic demographic and healthcare challenges and even potentially converting its biotech innovations into military advantages.¹¹ Although total PRC investments in biotechnology are only a fraction of U.S. investments, the number of PRC biotech companies listed in the Forbes Global 2000 is now second only to the United States.¹² Furthermore, the PRC may now be the lead producer of synthetic biology and biological manufacturing research.¹³ Collaboration and linkages between the U.S. and PRC life science ecosystems means that U.S. advances in the sector could also accelerate China's biotech development, potentially at the expense of U.S. national security interests.¹⁴¹⁵ The rise of PRC genomics firm Beijing Genomics Institute (BGI) as the world's largest genetic research

organization, for example, was enabled in part by its access to U.S. intellectual property (IP) and markets.¹⁶

The U.S. Government has taken key steps, particularly within the past year, to set the course for biotechnology leadership. Strategy documents like Executive Order 14081 on the Bioeconomy¹⁷ and the subsequent Bold Goals for U.S. Biotechnology and Biomanufacturing report,¹⁸ as well as the National Biodefense Strategy and Implementation Plan,¹⁹ articulate both the enormous opportunities and the potential vulnerabilities that the biofuture will bring. Entities such as the National Security Commission on Emerging Biotechnology²⁰ and the Advanced Research Projects Agency for Health (ARPA-H)²¹ are coming online to develop and execute bold biotechnology missions including a Cancer Moonshot. Ongoing programming at various government agencies like DARPA²² and the National Science Foundation (NSF),²³ as well as initiatives like the Manufacturing USA Institutes,²⁴ are helping to advance fundamental biotechnology research and development (R&D) and develop novel biotechnology capabilities and applications.

However, looking out toward 2030 in the context of an international competition, enduring leadership in this general purpose technology cannot be left to chance. It will require sustained focus by the government, greater public-private collaboration, and a willingness to make strategic bets on our biofuture.

First Principles

The following first principles frame the national security and economic theory of the case for strengthening U.S. leadership in biotechnology:

- Like Electricity and Artificial Intelligence, Biotechnology Will Drive a General Purpose Leap in Tech History: Properly harnessed, biotechnology will be a general purpose technology that will pervade most aspects of society and shape an era of technological progress in ways that are not fully known today.
- Advanced Technology Makes a Vast Domain Even More So: From how the human mind works to what it takes to biomanufacture something like lithium, fuel, or wood, biotechnology is a *vast* sector involving whole sub-divisions that often do not intersect, such as health and the manufacturing of commodities.
- **Biology Can Manufacture Many Surprising Things:** As much as 60 percent of everything manufactured in the world today could one day be biomanufactured, making this sector a multi-trillion dollar game.²⁵

- **Biotechnology Is Converging with Other General Purpose Technologies:** Biotechnology innovation is being accelerated by other technologies like AI and high-performance compute (HPC) and will also be a key input to technologies like manufacturing and energy. Innovation will occur at the intersection of "atoms, bits, and cells," and the United States has competitive advantages at this intersection.
- All Atoms Are Local: The building blocks of biotechnology are inherently both local and distributed, making it "capable of both atomic precision and enormous scale."²⁶ This makes biotechnology more diffuse, accessible, and interconnected than other technologies and creates distinct benefits and risks in the context of global tech competition.
- Advantage Will Derive from Biotech Platforms: Harnessing nature's inherent distribution will be driven by platform technologies that allow us to compile data, replicate experiments, connect tools, apply AI, and rapidly biomanufacture everything from materials to fuel to medicines. The nation(s) that build these platforms will be best positioned to shape the trajectory of the sector and the rules and standards surrounding the use of such platforms.
- The United States and Our Allies Possess Competitive Advantages to "Run Faster" Than Rivals: With the right incentives, competitive advantages of private sector competition, leadership in convergent technologies, and networked operations will allow the United States — and democracies more broadly — to use a stratagem of "running faster" to outcompete authoritarian rivals.
- **"Running Faster" Will Require Common Sense Guardrails:** While many biotechnology advances should be global public goods, certain national security "corner cases" will need an air gap between our advancements and those of our rivals as well as security protocols to protect our people from biological attacks and accidents.

Advance Fundamental S&T

ACTION PLAN RECOMMENDATION Launch Biotechnology "Moonshots" to

- Unlock Nature As a Code Base: The Annotated Non-Human 1.1 **Genome Project**
- 1.2 Biosecurity at Scale: Field a True 24/7 National Medshield
- The Long Game: The Synthetic Cell 1.3

Moonshots are audacious goals that can move the entire U.S. innovation ecosystem toward a position of competitive advantage. These proposed goals are beyond "hard," but they are attainable through a whole-of-ecosystem unity of effort like that of the Apollo program, which stretched our sense of what was possible at the time it was conceived. The three proposed moonshots below - two of which are short-term and aimed at the current biotechnology paradigm, and the other a long-term step change — could complement existing programs like the President's Cancer Moonshot.²⁷ The correct number and type of moonshots can ultimately be determined through technology and competitive strategy arguments.

1.1. Unlock Nature As a Code Base: The Annotated Non-Human Genome Project (A-NHGP)

Objective: Create an open-source genetic library for the entire biodiversity (e.g. all eukaryotic and prokaryotic life²⁸) of the United States by 2027 and the world by 2030. This open-source ecosystem²⁹ would turn nature into a code base for biomanufacturing; help shape norms, values, and technical standards surrounding the use of biodata; and provide "hurricane forecasting"-like capabilities for biothreats and pandemic surveillance.

Method: A public-private consortium could populate the genetic library in three main ways. National labs that conduct genetic sequencing could be required to publish a certain portion of their work. Industry labs could get access to the database and a share of IP rights in exchange for their contributions.³⁰ Universities, researchers, and other not-for-profit entities could freely access and contribute to the open-source library like a genomic GitHub. Surplus COVID-19 testing

infrastructure (e.g. physical space, test processing facilities, PCR chemicals, test tubes) could be made available for any participating entity to use, and tax credits offered to institutions that sustain such infrastructure. A specific initial objective, like manufacturing ten carbon negative foods or fuels by 2025, could be incentivized through tax credits.

1.2. Biosecurity at Scale: Field a True 24/7 National Medshield

Objective: Operationalize a national medical shield ("Medshield") that gathers innovations across the public-private spectrum in the Unite States and with allies and partners in tech categories including—but not limited to—rapid vaccines, rapid therapeutics, a global biothreat "radar," advanced AI-enabled modeling to facilitate product development and testing, rapid manufacturing technologies, and an enhanced trial system that speeds up effectiveness and efficiency in the delivery of medical solutions to citizens. Ultimately, the health of our citizens against biological threats must be under someone's 24/7 command to operationalize something that functions like a true shield.

Method: The U.S. Department of Defense (DoD) is most familiar with operationalizing very largescale systems like North American missile defense or global nuclear command and control. Running a NORAD-like 24/7 incident command system to prepare and respond to destabilizing medical emergencies (like COVID-19) requires a full-time interagency effort to gather the numerous biomedical and biomanufacturing innovations across U.S. Health and Human Services (HHS). This includes the National Institutes of Health (NIH), Food and Drug Administration (FDA), Department of Energy (DOE), ARPA-H, NSF, DoD, and most importantly, the private sector. All solutions to medical emergencies depend on the baseline or fabric of supported medical care to improve patient outcomes in general. Thus, a Medshield overseen by DoD would truly operationalize a national defense system of systems across the interagency and private sector that demand a single accountable form of leadership to negate the need for a reactive Operation Warp Speed-like effort with every new medical crisis. The Medshield would also have a "response strategy" function across the interagency to rapidly develop a shared theory of success for each unique medical emergency the nation and world face together. Thus, it is also essential to consult with select allies and partners to learn from their progress and map out how to make these systems interoperable with existing alliance structures and partnerships like NATO and the Quad.

1.3. The Long Game: The Synthetic Cell

Objective: Pursue a step change in fundamental biological understanding by creating a fully synthetic cell. This would drive our understanding of what happens inside the cell at a fundamental level (measuring cell function),³¹ mastering physics at the cellular scale (modeling cell function),³² and figuring out how to purify molecules from many sources (making cell function).³³ This effort would lay the groundwork for new paradigms such as "lab-grown intelligence."³⁴

Method: A network of university Centers of Excellence and DOE national labs with government and private sector access (see recommendation 3 for further explanation) could each tackle a portion of the problem and house the project's work on a single, coordinated, interoperable interface. A **Phase 1** "moonshot" across multiple national labs could focus on achieving the fundamental R&D breakthroughs for "measure, model, and make" by 2028, leveraging national labs' High Performance Computing (HPC) clusters and Modeling and Simulation (MODSIM) and cognitive simulation (COGSIM) capabilities. To incentivize private sector participation, companies that contribute to Phase 1 could be eligible for government funding/incentives for a **Phase 2** "moonshot" of reducing the cost of building a synthetic cell to \$1,000,000 or less by 2030.

ACTION PLAN RECOMMENDATION

2/8

Align Incentives for Biotechnology Commercialization, Diffusion, and Scale

- 2.1 Biomanufacture Medicines Locally
- **2.2** Invest in the Infrastructure to Enable Domestic Biomanufacturing at Scale
- 2.3 Align the Vast Standards Ecosystem for a General Purpose Era

Breakthroughs in biotechnology do not guarantee positional advantage. Misaligned incentives can present barriers to national competitiveness post-breakthrough by way of **1**) unclear pathways to commercialization, **2**) barriers to adoption and the natural diffusion of technological advancements and applications, and **3**) other tensions of scaling breakthroughs that do not already fall under traditional policy levers (like infrastructure and talent). This recommendation is an attempt to align incentives that promote commercialization, diffusion, and scaling.

2.1. Biomanufacture Medicines Locally

Objective: Unlock the scale needed for a thriving bioeconomy through a national medicines biomanufacturing initiative.

Method: For a **Phase 1** goal of 100 domestically biomanufactured essential medicines by 2028, HHS through ARPA-H could make available funding and/or facilities (e.g. national labs, biomanufacturing institutes, cloud labs) to companies in exchange for purchase agreements in the event of a future pandemic or crisis. **Phase 2** could create a new, public-private model of multiple "self-driving labs"³⁵ across the United States that can biomanufacture and widely deliver nearly any medicine on demand by 2043. **Phase 3** could entail building out such facilities in cooperative ventures in allied and partner countries.³⁶

2.2. Invest in the Infrastructure to Enable Domestic Biomanufacturing at Scale

Objective: Solve the fundamental commercialization challenge for U.S. biotech companies by funding and/or incentivizing cost-effective options for long-term, consistent, domestic biomanufacturing at scale.

Method: Provide government subsidies and grants to offset the cost to startups of partnering with contract manufacturing organizations (CMOs) to scale domestic manufacturing capacity of medicines on the U.S. Essential Medicines list. Additionally, provide government loans, grants, and other incentives to enable companies to build their "brownfield" (retrofitted) and "greenfield" (new) domestic biomanufacturing capacity. An initial version of this program for biofuels could be stood up within the Department of Energy's Loan Programs Office, and the DOE model could be considered for a larger standalone office covering a wider array of bioindustrial application areas.³⁷

2.3. Align the Vast Standards Ecosystem for a General Purpose Era

Objective: Work with allies and partners to shape biotech industry and ethical standards toward democratic principles, respect for individual rights, and promotion of a fair economic playing field and deprive strategic rivals of the opportunity to strategically shape the vast and disparate biotech standards ecosystem in their interests.

Method: Liaise diplomatically with allied and partner missions to international standard-setting institutions, such as the International Standards Organization (ISO), Organization for Economic Cooperation and Development (OECD), and other multilateral organizations relevant to biotechnology, in order to create common positions. Efforts also should involve U.S., allied, and private sector actors and civil society in a multi-stakeholder model to help ensure that a range of voices are incorporated and the latest technological expertise is available.

ACTION PLAN RECOMMENDATION

Empower the Entire Innovation Ecosystem

- 3.1 Establish University Centers of Excellence
- 3.2 Augment the National Labs
- **3.3** Expand Biomanufacturing Institutes

A thriving bioeconomy will require a mosaic of organizations across the innovation landscape to serve a variety of roles, from advancing fundamental science, to developing applications, to biomanufacturing goods at scale. Strengthening the ties between public and private actors can help the United States harness the full strength of its innovation ecosystem. A "minimum viable set" of organizational changes include:

3.1. Establish University Centers of Excellence

Objective: Establish a network of university "Centers of Excellence" in the United States and in allied/partner nations to help **1**) advance fundamental science, **2**) develop cutting-edge tooling and techniques to push the frontiers of synthetic biology and applied genomics, **3**) spin out companies, and **4**) plug into government strategy and policy processes.

Method: Professionally-staffed research centers on the combined frontiers of genomics and synthetic biology (i.e., an open "Skunk Works"³⁸ for biotech) could be stood up, at an anticipated cost of \$25-40 million a year,³⁹ at select universities around the country. Existing entities such as the SLAC National Accelerator Laboratory at Stanford⁴⁰ could be an example location for one of the centers.

3.2. Augment the National Labs

Objective: A national network-enabled synthetic biology stack that helps expedite and scale the production of new products like materials and therapeutics in the short term, and continues to break ground in basic science to enable the engineering of more complex biological systems down the road.

Method: Leverage and scale existing initiatives like the Agile BioFoundry⁴¹ and the Livermore Valley Open Campus⁴² and launch new initiatives as needed to provide space and lab resources (e.g. HPC clusters) at National Laboratories for private sector and government actors to collaborate on shared problem sets.⁴³

3.3. Expand Biomanufacturing Institutes

Objective: Leverage public-private partnerships and existing regional innovation ecosystems to build a national industrial base for biomanufacturing, such as a "Biobelt" to renew America's "Rust Belt."

Method: Continue and expand existing programming like HHS's Advanced Regenerative Manufacturing Institute (ARMI),⁴⁴ the Department of Commerce's National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL),⁴⁵ and DoD's Bioindustrial Manufacturing and Design Ecosystem (BioMADE) program.⁴⁶ Measures like the Regional Technology Hubs authorized by the CHIPS and Science Act could further expand such programming.⁴⁷

ACTION PLAN RECOMMENDATION 4/8 Build the Infrastructure That Will Allow Us to Tap Into Biotech's Full Potential 4.1 Build Out the Global Bionet 4.2 Treat Genomic Data as a Strategic Resource 4.3 Fundamentally Change the Way Life Sciences Are Done

Biotechnology infrastructure – like infrastructure in other sectors – is a fundamental pillar in an industrial strategy pillar to national competitiveness. Infrastructure often involves substantial public investment and can be costly. The purpose of this recommendation is to determine the minimum essential infrastructure investments required today to unlock long-term biotechnology advantage tomorrow.

4.1. Build Out the Global Bionet

Objective: As biology knows no borders, bioresponse capabilities must be both global and local. Create a globally accessible information-sharing portal — a "Bionet" — to enable early warning detection systems, increase the speed of bio-solutions to bio-problems, and enable localized responses to bio-related incidents (like the SARS-CoV-2 genetic sequence being passed around the world for forensics and vaccine solutions⁴⁸). Parts and pieces of a Bionet over the Internet were stood up during the COVID-19 pandemic but **1**) should be more systematic and **2**) used for a widerange of problem solving beyond public health (e.g. solutions to biomanufacture lithium locally).

Method: A Bionet coordinated by an organization with global reach⁴⁹ would link biotechnology actors with biotechnical data and infrastructure around the world. On the data side, existing resources like Johns Hopkins University Applied Physics Laboratory's COVID-19 dashboard,⁵⁰ commercial data streams such as wastewater surveillance,⁵¹ and new initiatives such as the A-NHGP (see more information in recommendation 1) could combine into a global early warning detection system. These data streams could support and feed into closed systems such as a national MedShield (see more information in recommendation 1) and international data-sharing arrangements with allies and partners and, as appropriate, with multilateral institutions.⁵² On the infrastructure side, a Bionet Application Portal Interface (API) could accelerate "Open Science"⁵³ and enable local biosolutions at the speed of the Internet. Organizations pursuing Open Science could use the Bionet API as a platform for exchanging data and techniques, and in times of emergencies, governments could promote shared access to instructions, sequences, and other supplies. An initial goal of the Bionet could be to digitally send a microbiome across the United States by 2025.

4.2. Treat Genomic Data as a Strategic Resource

Objective: Drawing inspiration from successful efforts like the UK's Biobank,⁵⁴ policymakers should turn the currently disparate U.S. data ecosystem into a strategic resource that is greater than the sum of its parts. The United States should gather open and proprietary datasets from the government and the private sector in conjunction with allies and partners on human, animal, and plant genomes into a central biobank that is well-curated, interoperable, easy for researchers to access and use, and models strong privacy protections for human genetic data. This biobank would democratize biotechnology innovation, facilitate AI-enabled analysis, and reduce reliance on entities like Chinese company BGI for genomics data that feeds into PRC genomic data advantage.⁵⁵

Method: In line with the recommendations of the National Security Commission on Artificial Intelligence,⁵⁶ the United States should fund and prioritize efforts to build a world-class biobank containing a wide range of high-quality biological and genetic data sets securely accessible by

researchers. The database should be a central repository for data collected through the Annotated Non-Human Genome Project (see recommendation 1). Congress should continue funding the National Institute of Health's "All of Us" Research Program and identify potential bridging mechanisms between that effort and private sector datasets. Additionally, it should consider augmenting the program by signaling interest in a direct-to-consumer effort to build a biobank housed in the private sector, keeping in mind the need to build in data security measures and ways to safeguard personally identifiable information. Finally, the United States should forge biotech data-sharing agreements with allies and partners to foster cooperation, interoperability, and if possible harmonization of regulatory regimes, rules, and norms to enable democracies to operate from a combined position of advantage vis-à-vis data sharing and collaboration.

4.3. Fundamentally Change the Way Life Sciences Are Done

Objective: Identify ways to scale cloud-based lab concepts, using Carnegie Mellon University's distributed Cloud Lab concept as a model.⁵⁷ The Cloud Lab fundamentally changes the way science is performed by moving scientific experimentation into a virtual cloud lab. Cloud labs work by remotely controlling a complete life science and chemistry laboratory from a researcher's computer (versus on a "wet bench" lab) for experimenting. This can **1**) greatly increase the speed of experimentation, **2**) improve the replicability of science, and **3**) improve access to lab resources in under-resourced universities. The distributed cloud lab concept could be scaled for use across the nation and the free world.

Method: The National Science Foundation could help expand the cloud-based lab concept by matching academic and private sector investments to develop three to four labs strategically placed around the United States that universities, the private sector, and government can access. Additionally, NSF and other government funders could incentivize academics to use the cloud-based labs via specific grant streams and government support, and the National Academies could support top-down, nation-wide educational programming to help diffuse the technology faster. Finally, the proposed National Artificial Intelligence Research Resource (NAIRR)⁵⁸ should be accessible to biotechnology researchers and startups for research and development that is compute-intensive and/or could be accelerated by AI.

ACTION PLAN RECOMMENDATION

Cultivate, Attract, and Retain Biotech Talent

- 5.1 Grow and Train the Biotech Workforce
- 5.2 Attract and Retain Global Biotech Talent
- **5.3** Reinvent the Library to Include the Era of Atoms, Bits, and Cells

Talent is a dependent economic variable in a nation's competitiveness in any international technology battleground. Even as human-machine teaming transforms the way science is done over time, human intuition, communication, abstract reasoning, and creativity will always be at the center of how America competes. The United States must set the path today to develop, attract, and retain a world-class workforce fit for biotechnology's general purpose potential.

5.1. Grow and Train the Biotech Workforce

Objective: Develop and train a robust biotechnology and bioengineering workforce with education, recruitment, and training pipelines that match the full range of job opportunities in the bioeconomy. Simultaneously, improve the cross-fluency of scientists and engineers to enable innovation at the convergence of biotechnology and other disciplines.

Method: Scale to every U.S. state the industry movement of partnering with community colleges to train and employ Biotech Associate degrees.⁵⁹ Provide government resources and incentives through the Department of Labor and state governments for workforce training and reeducation programs across the country. Promote cross-disciplinary internship, apprenticeship, and exchange programs across the life sciences and engineering disciplines.

5.2. Attract and Retain Global Biotech Talent

Objective: The United States must also improve our ability to attract and retain global biotech talent, including from the PRC. In addition to maintaining pathways for global talent to work and study in the United States, the U.S. Government should create pathways for top scientists and engineers already here, as well as their families, to stay in the United States.

Method: Leverage existing immigration pathways to their fullest extent. Update relevant employment-based, research, and investor visas to prioritize applicants with expertise in strategic technologies, including biotech, and increase the H-1B cap. Develop a new visa category that allows academic institutions, national labs, and companies to nominate and fast-track prominent researchers and entrepreneurs to live, work, and start businesses in the United States, along with their families.⁶⁰ Support dual-path biotech research fellowships with allies and partners, such as through the Quad (Australia, India, Japan) or Five Eyes (Australia, Canada, New Zealand, and United Kingdom) partners.

5.3. Reinvent the Library to Include the Era of Atoms, Bits, and Cells

Objective: Inspired by the role of local libraries and librarians in driving education, build interactive, publicly accessible human-machine rooms ("LABraries"⁶¹) to foster a culture shift toward interest in advancing STEM in general and the biofuture specifically.

Method: The Department of Education should work with state and local governments to identify, pilot, and scale creative laboratory models such as "Communal Computing"⁶² that could help virtually and safely replicate a lab environment that inspires future generations and becomes a societal public good.

ACTION PLAN RECOMMENDATION

6/8

Secure the Inputs for a Thriving Domestic Bioeconomy

6.1 Promote Supply Chain Security for Biotechnology Equipment

As a general purpose technology, we can expect biotechnology's impact to dwarf the already wide-ranging capabilities and applications in use today. Further, the United States will only be able to unlock "grow anywhere" effects if it can more efficiently utilize existing capacity while rapidly accelerating buildout. The United States must deepen public-private collaboration to monitor biomanufacturing capacity in real time, while utilizing techno-industrial strategy tools to catalyze private investment and help the industry rapidly achieve scale.

6.1. Promote Supply Chain Security for Biotechnology Equipment

Objective: Mitigate existing supply chain bottlenecks and enable capacity buildout for biotechnology equipment.

Method: Biomanufacturing equipment, ranging from fermentation tanks to bioreactors to DNA sequencers, is a potential bottleneck to a large-scale biomanufacturing buildout.⁶³ USG departments and agencies including the Department of Commerce and National Science Foundation should grant targeted incentives to promote cost-competitive domestic options and/or procurement from trusted partners as appropriate for various inputs. For example, the government should incentivize domestic production of modern fermentation tanks needed to support domestic biomanufacturing capacity. Government should similarly incentivize domestic sequencing capacity, as well as explore establishing a "trusted foundry" equivalent for genetic sequencing to prevent such data from accruing to rival platforms.

Unite Democratic Ally and Partner Competitive Advantages				
Со	ompetitive Advantages			
Co 7.1	Establish a Biomanufacturing Alliance Among Like-Minded	Nations		

No nation is secure alone. The power of a general purpose technology behooves democracies to work together in crafting a shared vision that puts our values front and center. The long-standing U.S. principle of uniting our allies in mutually beneficial ways should extend to biotechnology advantage.

7.1. Establish a Biomanufacturing Alliance Among Like-Minded Nations

Objective: Create a network of democratic biomanufacturers to enable "design anywhere, grow everywhere" network effects, secure democracies' supply chains, and enhance geopolitical soft power.

Method: The State Department should develop data-sharing agreements within existing and/or future alliance structures to enable shared access to an early warning system and an interface for local biomanufacturing response capabilities (see more information in recommendation 4).

7.2. Define America's Baseline for Global Biotechnology Cooperation

Objective: On one hand, the 2022 U.S. National Security Strategy establishes guidance that the United States should seek to collaborate with major powers on global issues that can only be resolved together.⁶⁴ On the other hand, the United States must proceed with eyes wide open on how collaboration with competitors like the PRC and Russia could be used against open societies. The U.S. Government should clearly identify and message to the U.S. private sector and allies and partners whether and where opportunities for cooperation may be worth the associated risks.

Method: The United States should continue to openly signal willingness to pursue meaningful, results-oriented cooperation with any country or group of countries committed to advancing shared goals on global public goods, such as in climate and global health. Simultaneously, the United States should emphasize that it will not ignore the importance of pursuing those public goods in alignment with democratic values in both the process and outcome. This baseline should be developed in conjunction with guardrails designed to protect against biotech-specific risks (see more in recommendation 8).

ACTION PLAN RECOMMENDATION	8 / 8
Run Faster with Guardrails	

- 8.1 Regulate and Govern to "Run Faster" Than Rival Ecosystems
- 8.2 Conduct a Comprehensive Security Review of the Biotech Sector
- **8.3** Limit the Expansion of PRC Global Biotech Platforms
- 8.4 Hardwire Security Into U.S. Biotechnology Platforms

Anticipatory governance in any technology is the attempt to foresee how regulation can prevent accidents and misapplications of technology breakthroughs without irrationally limiting the power of innovation and stifling U.S. competitive advantages.⁶⁵ Additionally, while biotech innovation in rival ecosystems has acceptable uses such as addressing domestic challenges like health and food security, proactive measures are required to prevent rival dominance in global biotechnology

platforms and to safeguard science against unacceptable risks or uses in a way that does not slow down our own innovation.

8.1. Regulate and Govern to "Run Faster" Than Rival Ecosystems

Objective: Prime our ecosystem to safely "run faster" and lead with our values in an inherently distributed sector via the right combination of investment, regulatory clarity, and guardrails for national security corner cases that risk ceding platform advantage to rivals or would violate democratic norms and values.

Method: Align and update existing regulations and identify new models as necessary to develop a regulatory regime that accounts for risks, reflects our values, and incentivizes market competition through jurisdictional clarity and creative investment structures. For example, create a mechanism for expedited FDA approval of domestically manufactured medicines.

8.2. Conduct a Comprehensive Security Review of the Biotech Sector

Objective: Guardrails should be informed by an examination of the potential harm to U.S. interests and the global community that excessively broad or stringent boundaries could cause weighed against the risks of ceding additional biotechnology market segments⁶⁶ and other advantages to rival nations – like the PRC – through inaction. No sufficiently comprehensive assessment weighing the tradeoffs of U.S.-China entanglement across the life sciences ecosystem has been conducted to date.

Method: The White House, informed by the private sector and academia, should lead an interagency net assessment of the costs and benefits of potential guardrails across all disciplines biotechnology touches, including pharmaceuticals, manufacturing, and energy.⁶⁷ Even as this comprehensive review is underway, other common sense guardrails⁶⁸ should be adopted without delay to mitigate known and growing risks while the United States retains a lead.

8.3. Limit the Expansion of PRC Global Biotech Platforms

Objective: Looking across the decade, citizens around the world need fair warning about how their genomic data — a key input to PRC biotech platforms — may be used by PRC national champion firms that are subject to the national security laws of the Chinese Communist Party (CCP). The U.S. Government has placed a few subsidiaries of BGI on the "entity list" for links to the PRC's military and repression of ethnic minorities, but it should take additional steps to displace and prevent U.S. reliance on BGI and other existing or potential PRC biotech platforms.⁶⁹

Method: The United States must treat genomic data as a strategic resource that enables biotech advantage in the form of global platforms, rather than a commodity to be outsourced to the lowest bidder. Starting with the federal government, U.S. institutions should not award contracts to or form partnerships with PRC genomics conglomerate BGI, and the government should use additional entity listings, as well as other export controls, sanctions, content requirements, and

other tools to limit firms like BGI's⁷⁰ ability to gain market share at U.S. and other trusted firms' expense. Additionally, the U.S. Government should commission an updated assessment of emerging and potential PRC biotech platforms to inform a more proactive approach moving forward.⁷¹

8.4. Hardwire Security Into U.S. Biotechnology Platforms

Objective: As more and more science becomes virtualized, hardware and platform-derived security protocols should provide a base layer of security against unacceptable risks.

Method: Industry, in collaboration with the government, should develop security solutions that are "hardwired" into biotechnology platforms, such as end-to-end encryption and the development of protocols that prevent unauthorized printing of dangerous DNA codes and/or perform automatic audits of downloads of sensitive data.⁷² Such collaborations should also focus on developing a comprehensive list of hazardous sequences to enable automated screening,⁷³ potentially informed by AI models for predicting molecule structures⁷⁴ and functions.⁷⁵

Endnotes

¹ See <u>The U.S. Bioeconomy: Charting a Course for a Resilient and Competitive Future</u>, Schmidt Futures (2022); Christopher A. Voigt, <u>Synthetic Biology 2020-2030</u>: <u>Six Commercially-Available Products That Are Changing Our World</u>, Nature Communications (2020).
² Further implementation details such as science and technology appendices for the moonshots could be developed to the degree they foster implementation.

³ Such as the U.S. and the World Health Organization's Essential Medicines Lists. See <u>Executive Order 13944 List of Essential</u> <u>Medicines. Medical Countermeasures, and Critical Inputs</u>, U.S. Food and Drug Administration (2020); <u>WHO Model List of Essential</u> <u>Medicines - 22nd List</u>, World Health Organization (2021).

⁴ The U.S. Bioeconomy: Charting a Course for a Resilient and Competitive Future, Schmidt Futures (2022).

⁵ Michael Chui, et al., <u>The Bio Revolution: Innovations Transforming Economies, Societies, and Our Lives</u>, McKinsey & Company (2020); <u>Remarks by NSC Senior Director for Technology and National Security Tarun Chhabra at the Brookings Institution</u>, Brookings (2022) (at 19:19 minutes).

⁶ Matthias Evers, et al., Europe's Bio Revolution: Biological Innovations for Complex Problems, McKinsey & Company (2023).

⁷ Matthias Evers, et al., <u>Europe's Bio Revolution: Biological Innovations for Complex Problems</u>, McKinsey & Company (2023).

⁸ John Hodgson & Deanna Schreiber-Gregory, <u>The Worldview National Ranking of Health Biotech Sectors</u>, Nature (2022); <u>Key</u> <u>Biotechnology Indicators</u>, Organization for Economic Cooperation and Development (2022).

 ⁹ Ryan Fedasiuk, <u>Regenerate: Biotechnology and U.S. Industrial Policy</u>, Center for a New American Security at 9 (2022).
 ¹⁰ Matthias Evers, et al., <u>Europe's Bio Revolution: Biological Innovations for Complex Problems</u>, McKinsey & Company (2023); <u>Canada's Biotechnology Strategy</u>, Government of Canada (2017).

¹¹ Scott Moore, <u>China's Role in the Global Biotechnology Sector and Implications for U.S. Policy</u>, Brookings Institution (2020).
 ¹² PRC biotech firms grew from one to 14 between 2010 and 2021, ranking second to the United States, which had the most biotech firms (31) included on the list. Gail Dutton, <u>Why China's Biotech Sector Thrives Despite a Global Recession</u>, BioSpace (2022).
 ¹³ Brian Gromley, <u>Tales From the 2022 Biotech VC Fundraising Trail</u>, Wall Street Journal (2022); <u>Critical Technology Tracker</u>, Australian Strategic Policy Institute (2023).

¹⁴ Sharing and benefits have in many cases been non-reciprocal, with China gaining and the United States and other nations losing in terms of access to markets, technology, data, samples, and research. On the effects of PRC mercantilist policies in

biopharmaceuticals, see Rob Atkinson, China's Biopharmaceutical Strategy: Challenge or Complement to U.S. Industry

<u>Competitiveness?</u>, Information Technology and Innovation Foundation (2019). On China withholding sharing of virus samples, see Emily Baumgaertner, <u>China Has Withheld Samples of a Dangerous Flu Virus</u>, New York Times (2018).

¹⁵ For example, the PRC government has collected biometric data including DNA samples, fingerprints, iris scans, and blood types from all Xinjiang residents ages 12 to 65. This biometric data is linked to individuals' identification numbers and centralized in a searchable database used by PRC authorities. See <u>China's Collection of Genomic and Other Healthcare Data from America: Risks to</u> <u>Privacy and U.S. Economic and National Security</u>, National Counterintelligence and Security Center, Office of the Director of National Intelligence (2021).

¹⁶ See Kirsty Needham, <u>Special Report: COVID Opens New Doors for China's Gene Giant</u>, Reuters (2020); Antonio Regalado, <u>China's</u> <u>BGI Says It Can Sequence a Genome for Just \$100</u>, MIT Tech Review (2020).

¹⁷ Executive Order 14081, <u>Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American</u> <u>Bioeconomy</u>, The White House (2022).

¹⁸ Bold Goals for U.S. Biotechnology and Biomanufacturing, The White House (2023).

¹⁹ <u>National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and</u> <u>Achieving Global Health Security</u>, The White House (2022).

²⁰ Congress, through the National Defense Authorization Act for Fiscal Year 2022, created the National Security Commission on Emerging Biotechnology as a strong positive and initial step to harness biotechnology. Pub. L. 117-81, <u>National Defense Authorization</u> <u>Act for Fiscal Year 2022</u> (2021).

²¹ Proposed by President Biden and enacted by Congress through Public Law 117-103 in March 2022, the Advanced Research Projects Agency for Health (ARPA-H) was established to improve the U.S. Government's ability to speed up biomedical and health research. See 87 Fed. Reg. 32174, <u>Establishment of the Advanced Research Projects Agency for Health</u>, U.S. Department of Health and Human Services (2022).

²² See Amy Jenkins, <u>Pandemic Prevention Platform (P3)</u>, Defense Advanced Research Projects Agency (last accessed 2023).

²³ <u>American Leadership in Biotechnology</u>, National Science Foundation (last accessed 2023).

²⁴ See for example the Department of Defense's BioMADE program, <u>DoD Approves \$87 Million for Newest Bioindustrial</u> <u>Manufacturing Innovation Institute</u>, U.S. Department of Defense (2020); see also the Advanced Regenerative Manufacturing Institute (ARMI), <u>DoD Announces Award of New Advanced Tissue Biofabrication Manufacturing Innovation Hub in Manchester, New</u> <u>Hampshire</u>, U.S. Department of Defense (2016).

²⁵ Michael Chui, et al., <u>The Bio Revolution: Innovations Transforming Economies, Societies, and Our Lives</u>, McKinsey & Company (2020).

²⁶ Elliot Hershberg, <u>Atoms Are Local</u>, The Century of Biology (2022).

²⁷ Fact Sheet: President Biden Reignites Cancer Moonshot to End Cancer as We Know It, The White House (2022).

²⁸ The <u>Earth Biogenome Project</u> and other similar initiatives provide a "proof-of-concept" that such an undertaking is possible. However, no previous effort has been sufficiently ambitious. A "national moonshot" with government resources and incentives could rally private actors and build upon work that has already been done, expanding it to the scale needed to supercharge the bioeconomy.

²⁹ Cultivating an open-source ecosystem would help democratize access to these tools and would deprive rival ecosystems of an ability to have a closed-source data advantage in this space.

³⁰ In the short-term, pre-competitive contractual agreements could be a mechanism for industry participation. However, larger changes to the intellectual property landscape will be required over the longer term to truly unlock biotechnology's general purpose potential. As noted by the National Security Commission on Artificial Intelligence, an emblematic example of the current paradigm's limitations is that inventors, facing uncertainty in obtaining and retaining patent protection, often pursue trade secret protection rather than patents, thereby not contributing accessible technical knowledge to the public domain. See <u>Final Report</u>, National Security Commission on Artificial Intelligence at 201 (2021).

³¹ Measuring could include understanding all 92 of the cell's essential functions and developing a real-time, run-time video recorder to study what happens inside of cells. SCSP discussion with a bioengineering expert.

³² Modeling could include developing a "real-time, run-time, physically fateful whole-time cell simulation," potentially via colloidal hydrodynamics and high-performance computing. SCSP discussion with a bioengineering expert.

³³ "Making" could build upon the insights of the PURE mixture developed in Japan 20 years ago that can read out DNA added to a tube, serving as a coordination tool to understand what is missing from something. SCSP discussion with a bioengineering expert. See also <u>His-Tag</u> | <u>Definition & Data</u>, Cube Biotech (last accessed 2023).

³⁴ <u>'Organoid Intelligence' Could Create Brain Cell-Led Computers</u>, CNN (2023).

³⁵ Hector G. Martin, et al., Perspectives for Self-Driving Labs in Synthetic Biology, Current Opinion in Biotechnology (2023).

³⁶ Given its leading role in producing generic pharmaceuticals, India would be a natural partner for joint efforts at biomanufacturing of medicines. See Ravi Buddhavarapu, <u>India Wants to Be the 'Pharmacy of the World.' But First, it Must Ween Itself from China</u>, CNBC (2022).

³⁷ <u>Products & Services</u>, U.S. Department of Energy, Loan Programs Office (last accessed 2023).

³⁸ <u>Skunk Works</u>, Lockheed Martin (last accessed 2023).

³⁹ Notional figure suggested in SCSP engagement with a bioengineering expert.

⁴⁰ <u>SLAC National Accelerator Laboratory</u>, Stanford University (last accessed 2023).

⁴¹ <u>About Us</u>, Agile BioFoundry (last accessed 2023).

⁴² Livermore Valley Open Campus, Lawrence Livermore National Laboratory (last accessed 2023).

⁴³ This effort could also expand the footprint of cooperation to select, tech-capable allies and partners, including in the Global South,

to strengthen alliance partnerships in biotech areas of importance to local partners.

⁴⁴ <u>ARMI</u>, Advanced Regenerative Manufacturing Institute (last accessed 2023).

⁴⁵ <u>NIIMBL</u>, The National Institute for Innovation in Manufacturing Biopharmaceuticals (last accessed 2023).

⁴⁶ See <u>The Bioeconomy: A Primer</u>, Congressional Research Service (2022).

⁴⁷ Tim Clancy, <u>Regional Innovation Provisions in the CHIPS and Science Act</u>, American Institute of Physics (2022).

⁴⁸ Priya Joi, <u>Data-Sharing in a Pandemic: Even Though Scientists Shared More than Ever, It Still Wasn't Enough</u>, Gavi (2022).

⁴⁹ For example, the Centers for Disease Control and Prevention or the State Department's Office of the Special Envoy for Critical and Emerging Technologies could potentially coordinate this effort.

⁵⁰ Justyna Surowiec, <u>"We Had to Get This Right:" How Johns Hopkins Built the Coronavirus Tracking Global Dashboard: An Oral</u>

<u>History</u>, Johns Hopkins University Applied Physics Laboratory (2021).

⁵¹ See, for example, <u>Biobot Analytics</u>.

⁵² See, for example, the World Health Organization's Biohub system. <u>WHO BioHub</u>, World Health Organization (last accessed 2023).

⁵³ Ruben Vicente-Saez & Clara Martinez-Fuentes, <u>Open Science is a Research Accelerator</u>, Journal of Business Research (2018).

⁵⁴ <u>UK Biobank</u>, UK Biobank (last accessed 2023).

⁵⁵ Emile Dirks & James Leibold, <u>Genomic Surveillance</u>, Australia Strategic Policy Institute (2020).

⁵⁶ <u>Final Report</u>, National Security Commission on Artificial Intelligence at 261 (2021).

⁵⁷ Carnegie Mellon University and Emerald Cloud Lab to Build World's First University Cloud Lab, Carnegie Mellon University (2021).

⁵⁸ <u>Strengthening and Democratizing the U.S. Artificial Intelligence Innovation Ecosystem</u>, National Artificial Intelligence Research Resource Task Force (2023).

⁵⁹ BFIT, Ginkgo Bioworks to Launch Biotechnology Manufacturing Associates Degree, Franklin Cummings Tech (2021).

⁶⁰ For example, the Military Accessions Vital To National Interest (MAVNI) visa category or a similar STEM talent nomination system could be created to offer visas to top-tier scientists and technologists who wish to stay in the United States, as well as their families, who are already working at U.S. Government agencies and national labs. See <u>Military Accessions Vital to National Interest (MAVNI)</u> <u>Recruitment Pilot Program</u>, U.S. Department of Defense (last accessed March 2023).

⁶¹ Name inspired by an SCSP conversation with a bioengineering expert.

⁶² See, for example, <u>Dynamicland</u>.

⁶³ Ryan Fedasiuk, <u>Regenerate: Biotechnology and U.S. Industrial Policy</u>, Center for a New American Security at 8 (2022); Matt Blois, <u>The US Aims to Close its Fermentation Capacity Gap</u>, Chemical & Engineering News (2023).

⁶⁴ <u>National Security Strategy</u>, The White House (2022).

⁶⁵ For example, in fusion energy, if commercial fusion facilities are regulated like fission reactors instead of low-hazard systems like modern MRI machines, U.S. companies are likely to go offshore due to a mismatch between the regulatory environment and fusion's technical merits. Anticipatory governance is also important because companies need to know what regulatory world they will be living in to develop and execute long-term plans for commercialization and scale. See <u>Harnessing the New Geometry of Innovation</u>, Special Competitive Studies Project at 109 (2022).

⁶⁶ PRC genomics firm BGI is now the world's largest genetic research organization; access to U.S. IP and markets enabled its rise. In 2013, it acquired California-based Complete Genomics, which had developed the fastest and most cost-effective gene mapping technology in the world. The U.S. Government reviewed the transaction and allowed it to proceed, despite security concerns raised during the investigation. BGI is seeking to expand its foothold in the U.S. market and is gaining contracts and FDA approvals in the United States. See BGI entry <u>here</u>, and Steve Friess, <u>Concerns Over Chinese Genomics Bid</u>, Politico (2012); Alison Snyder, <u>There's New</u> <u>Competition for Faster, Cheaper DNA Sequencing</u>, Axios (2022).

⁶⁷ The review should assess the complex, interconnected nature of global biotechnology supply chains, including U.S. and PRC advantages and dependencies in instrumentation, equipment, and reagents. For a starting point, see <u>China's Biotechnology</u> <u>Development: The Role of US and Other Foreign Engagement</u>, Gryphon Scientific & Rhodium Group (2019). A review should also build the principles in the <u>Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and</u> <u>Secure American Bioeconomy</u> published by the White House in 2022, which directs the Office of the Director of National Intelligence

to work with the DoD to develop an assessment of the "technical applications of biotechnology and biomanufacturing that could be misused by a foreign adversary for military purposes or that could otherwise pose a risk to the United States."

⁶⁸ See, for example, recommendations on research security (at 45), investment screening (at 53), and other guardrails (at 76) in <u>Restoring the Sources of Techno-Economic Advantage</u>, Special Competitive Studies Project (2022).

⁶⁹ As of March 2023, five BGI units have been added to the Department of Commerce Entity List (EL) – which requires U.S. firms to obtain a license before exporting to BGI – due to the firm's links to China's military and state-sponsored repression of ethnic minorities. See 88 Fed. Reg. 13673, <u>Additions and Revisions of Entities to the Entity List</u>, U.S. Bureau of Industry and Security (2023). But BGI has more than 200 entities, most of which are not on the EL. See Anna Puglisi, <u>Anna Puglisi's Testimony Before the U.S.-China Economic and Security Review Commission</u>, Center for Security and Emerging Technology (2023).

⁷⁰ Such as pharmaceutical manufacturing and research services giant WuXi Biologics and the family of firms related to corporate parent WuXi Apptec. See <u>WuXi AppTec Group</u>, Australian Strategic Policy Institute (last accessed 2023).

⁷¹ Previous such reports exist, but should be updated. See <u>China's Biotechnology Development: The Role of U.S. and Other Foreign</u> <u>Engagement</u>, U.S.-China Economic and Security Review Commission (2019).

⁷² See the <u>International Gene Synthesis Consortium</u>, a group of 30 gene synthesis companies and organizations that designs and applies a common protocol to screen both the sequences of synthetic gene orders and potential customers, for an example of such an effort. However, BGI's involvement in the IGSC warrants evaluation of whether those protocols sufficiently guard against manipulation and/or misuse by countries of concern. See <u>International Gene Synthesis Consortium Adds New Global Members to Advance</u> <u>Biosecurity Objectives</u>, PR Newswire (2017).

⁷³ James Diggans, Ensuring the Responsible Use of Synthetic DNA, Chemical Engineering Progress (2021).

⁷⁴ John Jumper, et al., <u>Highly Accurate Protein Structure Prediction with AlphaFold</u>, Nature Communications (2021); Melissa Heikkilä, <u>DeepMind has Predicted the Structure of Almost Every Protein Known to Science</u>, MIT Technology Review (2022).

⁷⁵ See Žiga Avsec, et al., <u>Effective Gene Expression Prediction from Sequence by Integrating Long-Range Interactions</u>, Nature Communications (2021); Natasha Latysheva, <u>Deep Learning and Genomics: Predicting Gene Expression from DNA Sequence</u>, Federation of European Biochemical Societies Network (2022).



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