October 2024

Report on Biotechnology in the People's Republic of China's Military-Civil Fusion Strategy

DEPARTMENT OF STATE

International Security Advisory Board

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United States Department of State
Washington DC 20520

November 12, 2024

MEMORANDUM FOR UNDER SECRETARY BONNIE D. JENKINS

SUBJECT: Final Report of the International Security Advisory Board (ISAB) on Biotechnology in the People's Republic of China's Military-Civil Fusion Strategy

This report responds to your request of March 12, 2024, that the Board undertake a study of the biotechnology components of the People's Republic of China's (PRC) Military-Civil Fusion (MCF) Strategy, with a focus on biotechnology development objectives, implementation, and implications for international biosecurity. The report was drafted by members of a study group chaired by Admiral (ret.) Cecil Haney. It was reviewed by all ISAB members and unanimously approved by all the members present at the ISAB plenary meeting on October 30, 2024.

The PRC has identified biotechnology as one of the fields that could allow a country to dominate the next Revolution in Military Affairs (RMA). MCF – the PRC's strategy to apply modern technologies to the RMA by developing the People's Liberation Army (PLA) into a "world class military" by 2049 – has identified biology as a research and development priority. The ISAB's goal is to advise the State Department and other federal agencies on how the United States can adapt to the changing global biotech landscape, particularly in the context of strategic competition with PRC.

The report proposes that the Department of State and other U.S. government agencies take steps to develop a global biotech system in which a broad range of partners cooperates on

scientific research and trade. This requires a long-term strategic approach, and the leadership of the Department of State, to build this global environment that aligns with U.S. interests.

My ISAB colleagues and I stand ready to discuss our report with you.

Honorable Edwin Dorn
Chair
International Security Advisory Board

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I. Introduction

Biotechnology is entering a new, transformative era. While biotechnologies are not new to the fields of medicine and agriculture - the first synthetic insulin became available over 40 years ago,[1] and 30 years ago the first genetically modified "Flavr Savr" tomato could be found on grocery shelves[2] – a growing suite of biologically driven technologies and tools is poised to upend a wide range of traditional methods and industries. Biotechnology approaches are enabling new possibilities for products and services for health, agriculture, food production, energy needs, environmental challenges, manufacturing, sustainable building, and more.

The expansion of biotechnology techniques and knowledge affects a myriad U.S. national security and economic interests, and the potential strategic uses of biotechnology are multiplying rapidly. Advances in biotechnology are being used to reduce biological threats through improvements in diagnostic testing, treatment, and mitigation of diseases affecting people, livestock, and plants, and to advance biosurveillance capabilities to provide early warning of public health threats and aid potential attribution of deliberate use. Replacement of petrochemical synthesis pathways with biosynthesis pathways will speed production of medicines, fuel, and materials (e.g., textiles, plastics, concrete) for civilian and military uses, reducing costs and environmental impact and allowing for self-sufficiency even in remote or less-permissive environments.

In the 1970s, breakthroughs in genetic engineering by U.S. scientists – and financing from private investors to advance commercial applications of their discoveries – gave rise to the modern biotechnology industry.[3] Ever since, the United States has led the global biotechnology sector, outpacing all other countries in biotechnology-related patents, private sector research and development (R&D) investments, and a number of active biotech firms.[4] Continued pre-eminence is not guaranteed, however. Eyeing the potential economic and strategic benefits of biotechnology and biomanufacturing investments, many other governments have intensified support for their biotech sectors in the past decade, including Belgium, Denmark, France, the Republic of Korea, Spain, Switzerland, and the United Kingdom.[5] Nowhere has the impact of government focus on biotechnology been more marked than in China, where the estimated

market value of biotech firms grew to more than $300 billion between 2016 and 2021 – an 100-fold increase.[6]

Like the United States and many other nations, the People's Republic of China (PRC) has identified biotechnology as a driver of economic growth and innovations for health, food, environmental, and energy security as well as sustainable manufacturing. However, the PRC strategic focus on developing its biotechnology sector goes far beyond the traditional industrial policies employed by other global biotech leaders. Under a series of national plans and policies that have been building for decades, the PRC has designated biotechnology a strategic emerging industry, calling for a whole-of-nation, top-down effort using expertise, financing, subsidies, and diplomatic support to mobilize biotechnology innovation as an element of "comprehensive national power."[7]

The PRC has also identified biotechnology as one of the fields that could allow a country to dominate the next Revolution in Military Affairs (RMA). Military-Civil Fusion (MCF) - the national development strategy under which the PRC seeks to adapt and apply modern technologies to the RMA by developing the People's Liberation Army (PLA) into a "world class military" by 2049[8] - has identified biology as an R&D priority**.** Together, the PRC's national biotechnology strategies blur the lines between public and private sector (creating competitive advantages for favored PRC-backed companies) and civilian and military programs, leveraging joint ventures and commercial power to support military objectives and enhance the capabilities of the PLA. The PRC's vision of a biotechnology future in which most nations and industries depend upon PRC-controlled pipelines for everything from pharmaceutical precursors to data needed for innovations in medicine, agriculture, and biosynthesis pathways for manufacturing runs counter to U.S. goals to establish sustainable, diversified and resilient supply chains for critical medicines and chemicals through domestic and international biotechnology partnerships.[9] The race to harness the potential benefits of artificial intelligence (AI) for biotech discovery is driving demand for access to high-quality biological data, especially genomic data from humans, animals, plants and microorganisms. The PRC's strategic investments in industry-dominating genetic sequencing services and a government-owned repository for storing genetic data have raised concerns about a genetic data "arms race," with

the winner controlling not only the currency of future biotechnology discovery but the uniquely personal information of millions of people worldwide.[10]

Advances in biotechnology create new markets and medical possibilities. They can also give rise to concerns about economic competitiveness, technological competitiveness, and national security. U.S. policymakers have increasingly sought avenues to promote robust domestic and global bioeconomies, while protecting the global biotechnology and biomanufacturing enterprise against emerging biotechnology-related risks. The October *2022 National Security Strategy* describes the need to prepare for and prevent misuse of biology, as well as the imperative of implementing a modern industrial and innovation strategy for biotechnology.[11] The September 2022 *Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy* aims to expand U.S. domestic biomanufacturing, build the U.S. biotechnology workforce, protect the U.S. biotech ecosystem (including access to biological and genomic data), and enhance productive cooperation with partners and allies.[12,13] The March 2023 *Bold Goals for U.S. Biotechnology and Biomanufacturing* compiled by the White House Office of Science and Technology Policy builds on this order, directing federal departments and agencies to advance biotechnologies to further societal goals and catalyze cross-cutting advances that could transform approaches to climate change, food and agriculture innovation, supply chain resilience, human health, and other industries.[14] The June 2023 interagency plan for *Building the Bioworkforce of the Future* outlines a plan for expanding education and training opportunities for biotechnology and biomanufacturing in the United States.[15] The October 2022 *National Biodefense Strategy and Implementation Plan*, an update to the 2018 *National Biodefense Strategy*, presents a whole-of-government approach to protect against biothreats, whether natural or man-made.[16] The National Science and Technology Council's *Critical and Emerging Technologies List Update for 2024* features biotechnologies, including novel synthetic biology tools such as nucleic acid synthesis and design tools, bioinformatics, cell-free systems, and biomanufacturing and bioprocessing technologies.[17] At the time of this report, Congress appears poised to pass the BIOSECURE Act, which prohibits contracting with certain Chinese biotechnology "companies of concern."[18]

The United States benefits from a global biotechnology ecosystem where international cooperation supports data-driven, multidisciplinary R&D and trade in innovations that enhance shared resilience to threats from emerging diseases, climate change, and resource scarcity. Domestically, the United States enjoys a well-developed innovation economy which fosters creativity through competition, bolstered by dynamic private sector investment, strong public and private sector research institutions, and robust intellectual property (IP) protections and regulatory frameworks that favor commercialization of discoveries. This strong and open biotechnology ecosystem allows the United States to attract talent and incentivize innovation. It also creates vulnerabilities, from the dependence of the bioeconomy on fluctuating private sector investment trends[19] to potential loss of control over intellectual property and genomic data with inherently dual-use applications through lawful or illicit acquisition by foreign students and researchers, investors, or institutions.[20]

How the United States will adapt to the changing global biotech landscape, particularly in the context of strategic competition with China, is the focus of this report. This report proposes steps for the Department of State and more broadly for the U.S. government to take toward a global biotech ecosystem in which the United States sustains and leverages its leadership to develop rules of the road with a broad range of partners to support scientific cooperation and trade. In this future end state, no country (including the PRC) would exert singular control over data or supply chains for critical pharmaceuticals, but instead would contribute within a competitive global bioeconomy in alignment with practices and values shared by the United States and its partners and allies. This requires a long-term strategic approach, and the leadership of the Department of State to build this global environment that aligns with U.S. interests.

How is the PRC's Approach to Biotech Different and Why Does this Matter?

The PRC's approach in biotechnology is consistent with its objectives in a wide range of areas that it values as part of its overall approach to strategic competition. Given the whole-of-nation

strategic approach and the major role of the Chinese Communist Party (CCP) within the PRC's industrial base, we should not be surprised that the MCF program would be a part of this effort.

China's Military-Civil Fusion (MCF) Strategy

MCF efforts build on the PRC's previous Civil-Military Integration (CMI) programs. From the earliest days of the PRC, successive CCP leaders have sought to strengthen links between civilian society and the military to achieve national security and economic development goals. Iterations of the CMI concept in the 1980s and 1990s focused on integrating civilian expertise and resources into the defense industrial base to develop dual-use technologies with commercial potential while advancing the PRC's military technological capabilities.[21] By the early 2000s, the CMI concept had evolved to emphasize joint civil-military technology cooperation. A series of PRC policy initiatives and defense plans called for measures aimed at leveraging civilian technological advances to support military modernization while commercializing defense technological developments to achieve national economic development goals, making use of both indigenous innovation and foreign technology transfer.[22]

These initiatives progressed unevenly in the face of many structural barriers to collaboration between civilian and military entities, and efforts to enact a law institutionalizing MCF under the National People's Congress have been continuously delayed since 2012.[23] However, President Xi Jinping has instituted a number of organizational, management, legal, and policy initiatives aimed at making MCF more effective. In 2015, Xi called for a transition from "early-state fusion" to "deep fusion;" in March 2016, he called MCF "a grand strategy that benefits the nation, the military and the people;" and in 2017 he reinforced his MCF role by establishing the CCP Central Commission for Military-Civil Fusion Development (CCMCFD), which he chairs. Also in 2017, MCF was included in the updated CCP Constitution in a list of a few strategies that "it is necessary to implement."[24] Xi has embraced MCF as a strategic approach to more rapidly develop and build military capability, while also enhancing the Chinese economy and addressing China's health needs. As Xi stated in June 2017 to the CCMCFD, "We must accelerate the formation of a full-element, multi-domain, and high-return military-civil fusion deep development pattern, and gradually build up China's unified military-civil system of

strategies and strategic capability," with a primary goal of the integrated development of economic and national defense innovation and improvements.[25] To ensure success in these pursuits, MCF seeks to:

> 1) Eliminate barriers between the civilian and defense sectors to facilitate the direct flow of technology, talent, and capital between them;
>
> 2) Exploit civilian access to international technology, investments, R&D, and partnerships to develop the PRC's military and intelligence capabilities; and
>
> 3) Systematically divert technology to ensure the PLA wins the race to develop and integrate a range of critical and emerging technologies for military application, including AI, biotechnology, and quantum computing.

Where does biotechnology fit in this MCF strategic approach?

The MCF construct specifically addresses biotechnology in a multi-domain approach that includes six traditional domains (identified as fundamental domains, manufacturing, science and technology, education resources, social service, and emergency and public safety); three major security domains (maritime, space, and cyberspace) and three nascent technological areas (biotechnology, new energy, and AI). Biotechnology and related capabilities have emerged in various Chinese strategic documents, including an article from the Deputy Director of the CCMCFD General Office that lists the following tasks:

- "Strengthen military-civil coordinated work mechanisms in biosecurity;
- Strengthen coordination in the prevention and control of infectious disease outbreaks;
- Promote joint constructions of infrastructure and platforms related to biosecurity, examination, and treatment; and
- Strengthen the biosecurity monitoring and early warning network systems and improve national defense capabilities."[26]

While the details are sparse regarding specific national defense capabilities, other policies are consistent in the emphasis of both military modernization and biotechnology innovation. The 13th Five Year Plan (2016-2020) addresses "the development of the biotech industry with

imperatives to move faster in the wide application of genomics and other biotechnologies….to stimulate the large-scale development of personalized medical treatment, new drugs, bio-breeding, and other next-gen biotech products and services." The 14th Five Year Plan (2021-2025) for National Economic and Social Development and Vision 2035 of the PRC set goals "focusing on independent and original innovation in defense related science and technology, as well as the development of strategic, innovative and disruptive technologies" to "strengthen national defense in tandem with economic growth," which specifies "boosting military-civilian collaborative innovation in science and technology; advance both military and civilian development in the fields of ocean, aerospace, cyberspace, biology, new energy, AI and quantum science and technology."[27] Clearly, there is an emphasis on both military and civilian application of biotech developments.

This should be of concern to policy makers due to the dual-use technology risk as the PRC seeks to implement fully a strategy coupling civil and military biotech research and development to improve their efforts in military modernization and enhancements. Some analysts have gone further in warning about the applications of PRC's investments in becoming a leading player in biotechnology, noting that PRC "sponsorship of research on gene editing, human performance enhancement, and other biotechnological applications for military purposes has raised concerns about the potential for biological warfare and the ethical implications of human enhancement in a military context."[28]

Various articles and publications have noted the PLA's specific interest in biological and biotechnology applications. For example, analysis from the Center for a New American Security (CNAS) describes a growing body of publications by PRC military strategists (including a retired general and former president of PLA's National Defense University) that focus on biology and biotechnology as a new domain of warfare, including statements on "modern biotechnology development…showing strong signs characteristic of an offensive capability," the possibility of "specific ethnic genetic attacks," and "biology as a domain of military struggle."[29] While these writings may be considered thought pieces by PLA scientists and scholars, their connections to reputable institutions such as the National Defense University, Academy of Military Medical Sciences, and Third Military Medical University imply broad consideration by PLA actors of how biotech advances could be exploited for offensive capabilities as well as to achieve economic

competition ambitions. The same CNAS publication notes that "Since 2016, the Central Military Commission has funded projects on military brain science, advanced biomimetic systems, biological and biomimetic materials, human performance enhancement, and 'new concept' biotechnology."[30]

Leveraging industries and individuals to achieve national biotechnology objectives

As seen in the past, the PRC is willing to make long-term investments in infrastructure, using the Belt and Road approach, to open new markets for PRC-backed firms while at the same time gaining access to foreign technology, knowledge, and data through both legal and illicit means.

In the closely related biopharmaceutical sector, the PRC has historically complemented innovation policies considered fair by most global norms (e.g., investing in basic research, R&D infrastructure, and a skilled workforce) with unfair and illegitimate practices, including:

- Subsidies and regulations that strongly advantage domestic firms (including discriminatory review and approval processes, price controls, export financing, and procurement policies), distorting markets and pressuring foreign companies to enter into joint ventures if they wish to access China's domestic consumer markets;
- Leveraging such pressured joint ventures to force technology transfer from the foreign partners, allowing PRC state enterprises to gain their assets, data, and IP;
- Investing in U.S. companies to procure and export their valuable biological and genetic data while strictly constraining access to PRC-controlled genetic data; and
- Supporting IP theft, from stealing data via espionage, cybertheft, or hacking to recruiting PRC citizens conducting research in U.S. universities or companies to return to China with their skills, knowledge, and, at least in some cases, stolen data or materials.[31]

In a February 2023 speech delivered at the third study session of the politburo, Xi emphasized that basic scientific research is key to achieving "high-level scientific and technological self-reliance" to sustain global competitiveness, building on a 2022 announcement by the PRC's

Ministry of Education to move China's universities (which account for about half of China's basic research funding) toward "organized scientific research" aimed at increasing "strategic scientific and technological strength."[32]

Despite Beijing's rhetoric regarding the obligation of its citizens and private companies to support national security, it is difficult to find cases of biotechnology firms being forced to cooperate with the state. But the scale of the resources that the PRC can bring to bear to incentivize and support biotech companies in targeted sectors is truly impressive. An example of this is the development of the national gene sequencing capacity (identified as a target in the 13th Five Year Plan) and the explosive growth of the BGI Group, which includes MGI Technology, BGI Genomics and Complete Genomics, among others.[33] BGI (formerly Beijing Genomics Institute) grew out of the Chinese Academy of Sciences group that participated in the Human Genome Project 25 years ago. The China Development Bank, a state institution, funded its purchase of 128 DNA sequencers from Illumina, a major U.S. manufacturer of specialized equipment for "next-generation" genetic sequencing.[34] When BGI went public, it received another $30 million in government funds. Since 2011, BGI has had the government role of running the China National GeneBank DataBase. In 2013, BGI acquired Complete Genomics, a U.S.-based competitor to Illumina. The Key Lab Project in Shenzhen, a state entity that promotes China's high-tech industry, funded BGI's development of the NIFTY pre-natal test for genetic abnormalities. Subsequent government subsidies have enabled BGI to offer the test at extremely low prices, undercutting other international firms in the world market -- and, not incidentally, providing PRC's R&D sector with genomic data from over 11 million tests in roughly 100 countries.[35]

A recent study found that at least 75 percent of BGI Genomics was owned by government entities or by people affiliated with them. The comparable figure for MGI Technology was at least 85 percent. And a major source of funding for BGI Group operations appears to be pledges of future shares by the current, largely governmental, shareholders.[36] The firms have yet to be profitable, but government entities are able to make very long-term investments.

The PRC also invested an estimated $3.8 billion in agricultural biotechnologies between 2008-2020 and overhauled its regulatory regime for genetically engineered crops in 2022 as part of

its strategy to leverage biotechnology advances to achieve food security. Although investments in biofuels have lagged, the PRC has initiated an increasingly comprehensive national policy framework to replace petroleum products with bio-based fuels.[37,38,39]

The growth of China's biotechnology sector is intertwined with U.S. growth. The United States currently depends upon Chinese firms for supplies and equipment used in R&D and for biopharmaceutical manufacturing, while China depends on U.S. investments in basic research and in research-based training by U.S. institutions to develop its own workforce.[40] For more than two decades, Chinese nationals have comprised the largest share of U.S.-based foreign scientists, contributing to the overall innovation ecosystem in the United States.[41] The issue of intellectual property theft or theft/diversion/misuse of technologies becomes a national security concern when the technologies themselves pose dual-use risks or when there is an adversarial relationship between the United States and the researchers' countries of origin, which has increasingly been the case regarding PRC-born scholars and researchers.

Given that the PRC has prioritized global leadership in biotechnology to benefit its economy, establish its reputation as a global leader, and support its goal of warfighting dominance, Beijing has strong motivations to recruit individuals who have studied and worked in the United States in relevant technical fields to work in PRC state-operated or state-supported institutions, bringing their knowledge and skills with them. Although biotech firms and large R&D companies are often reluctant to disclose the details of IP thefts, court documents and other public records describe large-scale IP thefts in the biotechnology sector (biopharmaceutical and agricultural applications), including individual cases that have led to criminal prosecutions. Well-publicized legal cases include the theft of mRNA research data by Chinese nationals working for Pfizer, institutional data transfer from Chinese firms in the United States or U.S. firms in China, and trade secret theft from pharmaceutical companies.[42,43,44,45] Still, the intertwined nature of PRC and U.S. R&D has made rooting out IP theft murky and difficult; the U.S. Department of Justice has been accused of targeting scientists of Chinese descent through investigations of "research integrity" absent evidence of economic espionage or national security impact, leading to talent loss and other negative consequences for U.S. innovation.[46,47]

Concerns about the PRC's leveraging of overseas PRC-born scholars in STEM (Science, Technology, Engineering, and Mathematics) fields for economic espionage and national security applications go back at least two generations. The case of Qian Xuesen illustrates the complexity of the globalized STEM workforce for U.S. national security interests, and how the reactive measures of an earlier age produced unintended consequences. Qian, who was born in China, came to the United States in 1935 to study engineering, first at MIT and then at Caltech (where he received his Ph.D.). He became renowned in aircraft and rocket technology, rose to the rank of full colonel in the U.S. Army during and after World War II, helped found the Jet Propulsion Laboratory at Caltech, and held chairs at both MIT and Caltech. In 1950, at the height of the "Red Scare," Qian had just begun the process of becoming a U.S. citizen when he was accused of being a former member of the Communist Party. Over the next five years, he remained under partial house arrest as immigration officials worked to deport him (despite a lack of evidence of intentional wrongdoing) while security officials prevented him from leaving the country due to his technical knowledge. He was finally allowed to return to China in an exchange for U.S. prisoners of war. Once in China, he founded aerospace institutes, personally trained a generation of Chinese engineers, and led development of PRC's missile program, providing not only the technical expertise but organizational knowledge needed to catapult PRC military capabilities forward.[48]

II. Vulnerabilities

The PRC whole-of-nation, top-down focus on developing biotechnology as a strategic emerging industry has precipitated a challenge for the United States: how to engage in a continuously evolving global biotechnology ecosystem in which its major strategic competitor has embraced an approach that runs counter to accepted practices. The scope of the PRC's success is difficult to measure – there are few tools to assess biotechnology and biomanufacturing activities outside of the heavily regulated and monitored pharmaceutical industry, and the PRC under Xi has become less transparent about its industrial and technological capabilities. The United States still objectively leads China in most measures of biotechnology innovation. Nonetheless, the rapid growth of the PRC's international biotech footprint has raised concerns among decision makers that the U.S. government's less comprehensive, mission-stratified approach to

biotechnology breeds creativity through competition, but also creates vulnerabilities through dependence on a global R&D workforce and international collaborations that can be exploited, and on markets that can be distorted, affecting access to biotechnology knowledge, materials, services, and other resources that are critical to U.S. abilities to respond to crises such as potential pandemics.

The United States leads the world in biotechnology R&D, but the PRC is narrowing the innovation gap

The U.S. biotechnology sector benefits from a mature domestic innovation ecosystem. Decades of public funding for basic and applied research have established strong academic and public research institutions where experts in the life sciences, data sciences, engineering, and other disciplines collaborate to advance fundamental knowledge and train the next generation of research talent. Robust IP protections coupled with a legal and regulatory environment favorable to technology transfer (via licensing or other agreements) incentivizes the commercialization of scientific discoveries. The potential pay-off for successful products attracts private sector financing, ranging from venture capital and private equity for small start-up ventures to self-financing of R&D portfolios by large established companies.

In 2021, more than 2800 active biotech firms and more than $100 billion in private sector R&D expenditures supported biotech innovation in the United States.[49] The U.S. biotech industry employed 2.1 million workers in 2021.[50] Many of these workers clustered in established and emerging regional biotech hubs, where networks and agreements connecting co-located universities and research institutions, small biotech firms, large companies, and government partners promote sharing of knowledge, resources, and expertise.[51,52] Biotech incubators and accelerators connect start-up biotech ventures to mentorship and resources, using primarily private sector financing to allow innovations to be developed and scaled.[53]

For at least two decades, this highly competitive ecosystem has allowed the United States to lead the global biotechnology sector by key measures of market share and impact. The United States produced more than one-third of the world's biotechnology-related patents each year from 2000-2021,[54] and accounted for almost 60 percent of the value of the $1.1 trillion global

biotech market in 2021.[55] Beyond economic activity, biotech played a critical role in national and global health security in 2020-21, as public-private partnerships between the federal government, small biotech firms, and large biopharmaceutical companies catalyzed successful testing, production, and rapid deployment of novel mRNA-based vaccines to protect against COVID-19.

Given the potential economic and innovation benefits, numerous governments – including France, Japan,[56] the Republic of Korea,[57] Switzerland,[58] and the United Kingdom[59] – have established plans and policies to increase the global competitiveness of their own biotech sectors. Various initiatives among these leaders (and by other governments in Southeast and South Asia and the Americas) focus on investing public funds in infrastructure to support biotech R&D and strategic collaborations aimed at attracting top talent, while creating commercialization-friendly regulatory environments (plus additional incentives such as tax breaks) to attract international private sector partnerships and financing.

The steady rise of China's biotech sector overshadows these efforts. The national biotechnology strategy shaped under the 13th Five-Year Plan (2016–2020) focused on developing the capabilities and infrastructure needed to jump-start a mature biotechnology ecosystem, including talent development and public financing to establish high-tech science parks with the research facilities to support start-ups and serve as nuclei for regional biotech hubs. Under the 14th Five-Year Plan (2021-2025), the PRC government developed milestones and goals for a whole-of-nation effort to accelerate biotech innovation, supported by a national program of subsidies, financial incentives, and reimbursement for activities that lead to innovative therapies and investment in shared resources for R&D, from research and biomanufacturing infrastructure to national cell and gene banks (i.e., large genetic databases). Strategies prioritize development of novel therapeutics for noncommunicable chronic diseases, such as cardiovascular disease and cancers, that represent a growing burden in China's aging population.[60]

Early indicators suggest that the PRC's strategies are yielding fruit. In 2021, China held more than 11 percent of global biotech market value - well behind the United States, but ahead of every other country.[61] From 2017-2021, clinical trial activity in China more than doubled. More

than 2,500 trials for cancer therapeutics took place in China in 2021, outpacing all other countries. In 2023, the PRC's National Medical Products Administration (NMPA) approved five first-in-class drugs developed domestically. Deals to out-license Chinese biotech products to multinational corporations more than doubled from 15 in 2019 to 33 in 2023, demonstrating growing international trust in the PRC's domestic regulatory regime.[62] Between 2012 and 2022, the number of Chinese-authored biotech articles published in the top 10 percent of most-cited scientific publications rose from 139 to 671 per year (an increase of nearly 400 percent).[63] Four major regional biotech clusters within China now host over 8,500 biotech and biopharma companies. By 2022, nine of the top ten PRC biotech firms had established overseas operations,[64] including R&D facilities and full value chains located in major U.S. biotech hubs.[65]

Non-transparent investment in biotech skews the playing field

Much of the U.S. R&D ecosystem lies outside the federal government, which is both a strength and a vulnerability. While the PRC has invested state funds strategically in biotechnology as an arena for economic and military dominance, the ability to advance, scale and deploy biotechnology innovations in the United States depends on the ability of innovators to compete for public and private sector funding.

U.S. government leadership in biotechnology-relevant fields is shared across multiple federal agencies with different missions.[66] With a few exceptions to address market or innovation failures – or for time-limited coordinated portfolio funding initiatives such as the Human Genome Project or Operation Warp Speed – U.S. government support for biotechnology innovation generally focuses on financing early discovery research, procuring finished products and technologies, and tax incentives that can reduce the cost of cost of R&D spending by private sector firms (by an average of about 5 percent).[67]

U.S. government agencies fund the largest share (40 percent) of basic research in the United States, primarily through competitive awards to universities and other institutions or via intramural R&D, just under 30 percent of applied research, and about 10 percent of development efforts. In contrast, the business sector funds about 37 percent of basic research, more than 60 percent of applied research, and nearly 90 percent of development. The business

sector is both the largest funder and performer of R&D activities in the United States, accounting for more than 75 percent of total U.S. R&D.[68] Biotech companies, from start-ups to established firms, depend on equity financing (private investments), debt financing, and net profits realized from product sales and other transactions to fund R&D activities. Broader market trends affect the availability of this private sector funding, which can fluctuate wildly. For example, following "pandemic exuberance" in 2020 that saw record investment in biotech firms and products, changing economic trends affected the availability of venture financing that smaller biotech firms depend upon to finance discovery and early translation research, the costs of debt financing, and investments by larger R&D companies in advancing biotechnologies through mergers and acquisitions.[69] By the time the private sector funding environment began to improve in 2024, many biotech firms had cut their workforces, shelved products, or closed altogether.[70,71] That is not an aberration: two-thirds of new companies fail in this competitive ecosystem. When U.S. firms bring biotechnologies or bio-based products to market, they need to recover the costs of innovation risks (e.g., failed approaches) as well as covering the costs of inputs, operating expenses, interest payments, and taxes, before they can reinvest funding into R&D.

While private firms in the PRC may also seek venture financing, financing of favored companies through governance guidance funds (hybrid public-private investments anchored by a government sponsor that aim both at producing financial returns and achieving national goals for strategic and emerging technologies) and other subsidies and reimbursements support later-stage R&D and translational research. As a result, favored domestic companies enter global markets unencumbered by debt, and cushioned against innovation risk. Practices that tie access to China's consumer market by foreign companies to specific actions such as joint ventures and technology transfer allow PRC entities to "obtain foreign technology without paying market rates for it… and foreign-company acquisition not based on market prices and terms."[72] The PRC's comprehensive state funding support for its biotech innovation economy has been characterized as "an alternative blueprint for the development of emerging technologies and industries" that "creates market distortions and undermines the global norms of science by using researchers, and academic and commercial entities to further the goals of

the state, not open collaborations that benefit both parties or fair commercial competition free from market distorting subsidies and market restrictions."[73]

Such practices have implications not only for U.S. economic competitiveness but for the global biotechnology ecosystem: if any company successfully gains a customer base for its biotechnologies or bio-based products because state subsidies permit market entry at low costs, the trade-off is loss of market share and revenue to invest in new innovations by global actors playing by fair-market rules.

Biased market practices create risks for PRC dominance of supply chain chokepoints

The United States depends on shared global supply chains, workforce, and resources to support its innovation economy. The U.S. R&D enterprise and broader national preparedness for disruptive events such as infectious disease outbreaks presuppose a certain level of responsible, ethical, and intelligent management of the interdependency of global supply chains and collaborations (including with the PRC), from chokepoints in supply chains for pharmaceutical precursors and biotech services to talent management of the international R&D workforce. Practices that skew market competition in favor of PRC-backed companies in areas such as gene sequencing could erode incentives for other international firms to enter markets, ultimately leaving the United States and its partners and allies dependent upon supply chains for critical building blocks in biotechnology and biomanufacturing that are not resilient, and that are controlled directly by PRC interests.

Should the PRC's strategic support for its biotechnology sector (and particularly the gene sequencing industry) create such chokepoints in key building blocks for innovation, the consequences could go beyond market implications. Lessons from the COVID-19 pandemic illustrate some of the risks in uncritical dependence on Chinese biotech supply chains.

Under pressure to lower their prices, biopharmaceutical companies in the United States, Europe, and Japan have increasingly turned over the past two decades to imports from China and India to source the active pharmaceutical ingredients (API) needed to produce antibiotics and medications for noncommunicable chronic diseases. In the early 2000s, the PRC adopted

national policies, from funding to favorable regulations, to support its growing API industry with an aim of increasing the competitiveness of China's pharmaceutical sector. This included incentives for international companies to enter into joint ventures in which they transferred API manufacturing processes (which include chemical and biotech approaches) to local firms in exchange for access to China's domestic market. Disruptions early in the COVID-19 pandemic revealed that global API supply chains that appeared diversified and resilient ultimately depended on key starting materials produced by a limited number of geographically concentrated Chinese manufacturing facilities, affecting the availability of APIs for pharmaceutical production worldwide – including from India – when local lockdowns interrupted production.[74]

From 2014-2022, the United States sourced between 12 percent and 28 percent of its total global API imports from China annually, part of the growing two-way trade in pharmaceuticals between the United States and the PRC (driven in part by increased demand for therapeutics for cancer and cardiovascular disease produced by the PRC's biotech industry). While this remains a fraction of overall United States drug imports, a Chinese economist raised concerns in 2019 by suggesting that the PRC could exert strategic control over pharmaceutical exports to the United States as part of its overall competition strategies.[75] The additional vulnerabilities identified during the COVID-19 pandemic prompted inclusion of API and pharmaceutical supply chains in White House strategies to secure supplies as part of the U.S. critical infrastructure.[76]

Academic researchers, biotech and biopharmaceutical firms, clinical researchers, and healthcare providers use genetic sequencing as a basic tool for discovery, applied research, and clinical medicine. High-throughput sequencing requires access to highly specialized and costly equipment and supplies; consumers must choose between procuring, maintaining, and operating sequencing platforms in-house or outsourcing to commercial gene sequencing services. BGI Genomics, which provides genetic and genomic testing services for research and clinical applications, is now among the top ten companies in the global genetic sequencing market (valued at $12.4 billion in 2023).[77] From 2017-2022, MGI Technology increased its share of the global market for gene sequencing equipment and related services from zero percent to five percent (in addition to reaching 40 percent of China's domestic market).[78]

Currently, these companies have claimed only a share of a market still dominated by more established U.S. and European companies, but the ability to offer lower-cost products in an industry where cost control is a major driver is helping that share grow. As stated by analysis from Georgetown University's Center for Security and Emerging Technology,

> *"When the rest of the world's research institutions rely on Chinese companies for sequencing, it gives Chinese entities—and the Chinese government—access to not only worldwide genomic data, but also the world's biotech research ideas, putting the foundation of global biotech research at risk of IP theft, exploitation, and manipulation."*[79]

Over reliance on PRC companies for data, processes, and products that are critical to the U.S. bioeconomy could affect the ability to develop, scale and deploy a range of biotech-related products, including:

- Pharmaceutical products and precursor materials;
- Manufacturing equipment and technologies;
- Nucleic acid sequencing/synthesis and genomic data;
- Agricultural products and agrobiotechnologies; and
- Synthetic processes and industrial chemicals/products.

Ultimately, dependence on PRC entities for gene sequencing services and access to biological data sets could lead to unequal access to critical materials and technologies across the global biotechnology ecosystem. Bottlenecks for services and products could result in the loss of capacities to mitigate threats to health and economic security, particularly during an acute crisis such as a rapidly emerging human, animal, or plant disease.

The U.S. biotech sector depends on an international workforce and on international collaborations

In contrast to historical precedents from past peer economic competitions, the U.S. and PRC biotech R&D sectors are entwined and interdependent at the level of global workforce, markets, and services.

Innovation thrives on collaboration across disciplines, sectors, and borders, and open sharing of data and information through publications and peer review is the backbone of scientific discovery. Collaborations range from joint ventures under formal agreements to less structured short- or long-term exchanges of expertise, tools, and resources. Over the past two decades, established biotechnology companies have scaled back their in-house budgets for discovery R&D in favor of technology transfer; as a result, academic-industry collaborations have become more common. This includes collaborations between leading universities in the United States and Europe and international R&D companies – including companies based in China.[80] Similarly, partnerships between small biotech firms and established companies (industry-industry collaborations) are fundamental to the U.S. and global biotech ecosystems, providing innovators with resources needed to validate, scale, and market new technologies or products.[81] In a 2024 survey, 79 percent of 124 participating small biotech firms in the United States reported having at least one agreement with a Chinese-owned or China-based manufacturer.[82] In 2022, U.S. researchers collaborated with international partners on 40 percent of their published articles in technical journals, with the largest share of internationally co-authored papers (about 24 percent) having at least one PRC national co-author. (In contrast, about 19 percent of articles published by PRC-based researchers had an international co-author.)[83] With the exception of formal joint ventures, most of these collaborations are neither structured nor documented by U.S. government authorities.

The PRC has been the top producer of doctorates in the natural sciences fields and engineering since 2007, and remains the most common country of origin for all students on temporary visas seeking doctoral degrees in science and engineering at U.S. institutions. In 2020, foreign students from the PRC earned 17 percent of all U.S. doctoral degrees in science and engineering. Over the last decade, 81 percent of students with PRC citizenship remained in the

United States for at least ten years after earning their doctoral degrees from U.S. institutions. For more than two decades, China has been the most important source of U.S.-based foreign scientists.[84] Efforts to address national security concerns and prevent economic espionage must balance the risks posed by the loss of specific IP to PRC-based institutions against the risks of perpetuating and amplifying general anti-Asian biases that, through consequences for individuals, their families, and their institutions could drive top research talent away from the United States and curtail the opportunities for collaboration that are at the heart of innovation.

China's business practices and the MCF policy together raise concerns about potential weaponization of biotechnologies.

The U.S. State Department's 2024 annual assessment of Adherence to and Compliance with Arms Control, Nonproliferation, and Disarmament Agreements and Commitments concluded that "The PRC continued to engage in biological activities with potential BW applications, including possible development of toxins for military purposes, which raise concerns regarding its compliance with Article I of the BWC." In this context, PRC policies that encourage the use of biotechnology tools, skills, and knowledge and biological data sets obtained through civilian R&D to benefit the PLA have raised concerns about potential military applications of biotechnology-enabled or bio-based weapons capable of harming humans or causing economic damage to the agricultural sector.[85]

Chinese researchers have published mapping studies that leverage genetic data derived from prenatal testing and other sources to characterize genetic variations specific to Uyghurs and other ethnic minority populations within China in peer-reviewed international journals – in some cases in collaboration with U.S. or European counterparts. Scientists and human rights groups have raised concerns that such data could be used to support state surveillance strategies.[86,87] Beyond direct weaponization, leveraging of forced technology transfer and stolen IP within the PRC's growing biotechnology innovation ecosystem could advantage the PLA in military innovations, such as the use of biosynthesis pathways to develop fast-drying concrete for in site, bio-based runway repair, or to develop energetic materials. These examples illustrate the risk that international researchers – through collaborative partnerships

initiated in good faith – might unwittingly accelerate military adaptation of dual-use technologies, or support coercive security practices.

Risk and threat perceptions vary among stakeholders in the U.S. biotech sector

Many of the equities and risks for protecting biotech innovations and resources lie with the academic and private sectors, which comprise a diverse set of actors with different drivers, sensitivities, and understanding of the risk environment (as well as differing degrees of non-responsibility for risk management). For example, large R&D companies and small biotech firms have vastly different levels of capital, resources, infrastructure, and relationships with government partners.[88]

While the PRC formally protects all genetic data collected through research conducted in China or with PRC-based institutions, both the collection and the protection of data related to biotech and genetic data by private sector and academic actors in the United States are protected through a patchwork of behavioral, cyber hygiene and cybersecurity practices. This leaves biological data and genetic data sets generated in the United States – the "new oil" that fuels biotechnology advances and that can be used to train AI – potentially vulnerable to theft, even as U.S. researchers enjoy less access to centralized, large data sets for R&D advances than their Chinese counterparts.

III. Current Regulations, Policies, and Plans

The landscape of U.S. biotechnology is shaped by a complex interplay of legal and regulatory frameworks, policies, and guidance that aim to enhance innovation while addressing security concerns.

The *National Biotechnology and Biomanufacturing Initiative*[89] lays the groundwork for advancing biotechnological applications across various industries, emphasizing the need for increased investment in research and development. This initiative advocates for streamlined

regulatory processes and the establishment of public-private partnerships to drive innovation. However, the lack of a well-resourced strategy to implement risk management cohesively across agencies and programs, particularly concerning dual-use technologies that could be exploited for malicious purposes, remains a significant gap.

Complementing this initiative, the *National Biodefense Strategy and Implementation Plan*[90] addresses the critical intersection of biotechnology and national security. This strategy underscores the need for a coordinated response to biological threats, emphasizing preparedness, prevention, and rapid response capabilities. The plan highlights the necessity for continuous risk assessment and collaboration among federal agencies, private sector stakeholders, and international partners. The challenge lies in coordinating efforts among diverse stakeholders, including private sector actors who may operate under different regulatory expectations.

Recent legislative proposals highlight the growing concerns regarding the integrity of biotechnology providers and the risks associated with foreign partnerships. While these legislative efforts reflect a necessary shift toward greater scrutiny, they may inadvertently stifle innovation by creating an environment of fear and distrust.

Additionally, the *Vision, Needs, and Proposed Actions for the Data for the Bioeconomy Initiative*[91] underscores the importance of data in driving innovation, yet it does not fully address data governance and security concerns that accompany increased data sharing among stakeholders. The absence of robust data protection measures may exacerbate vulnerabilities, particularly in an age where data breaches can have widespread implications.

Protecting the United States and global biotechnology ecosystems requires careful long-term planning

In examining the current landscape of U.S. policy, it becomes evident that merely addressing immediate gaps with short-term fixes is insufficient for fostering sustainable progress. While reactive measures may offer temporary relief, they often overlook the deeper systemic issues that require comprehensive solutions. This lack of strategic foresight can leave critical gaps in the policy architecture, making it difficult for the United States to effectively respond to

emerging challenges in two rapidly evolving ecosystems – biotechnology and global competitiveness.

Moreover, the reliance on piecemeal approaches can erode the United States standing as a global leader. As other nations develop more cohesive and long-term strategies, the United States risks falling behind in competitiveness. The absence of a cohesive policy framework not only hampers domestic growth but also diminishes the country's influence on the world stage. In a landscape where international cooperation and strategic partnerships are vital, short-sighted measures can lead to a perception of instability and inconsistency, undermining trust and collaboration.

Ultimately, addressing these gaps requires a commitment to strategic, forward-thinking policies that prioritize long-term resilience to the risks and vulnerabilities associated with a growing biotechnology and biomanufacturing enterprise. Emphasizing collaboration across sectors and aligning short-term actions with a broader vision will not only strengthen the nation’s internal framework but also enhance its competitive edge in the international landscape.

For instance, taking actions focusing exclusively on the PRC in discussions about global biotechnology can create a skewed perspective that reduces a complex ecosystem to a binary competition between great powers. This approach risks painting the PRC as the singular antagonist, overshadowing the multifaceted challenges and opportunities that exist within the global landscape. It is important to frame any measures focused on the PRC as part of a larger strategy that accounts for interdependencies of our global partners. By framing the biotechnology ecosystem as a zero-sum game, policymakers may inadvertently stifle collaboration and innovation, limiting the potential for diverse partnerships that could drive progress for all partners.

Moreover, this adversarial framing pressures other nation-states and private sector entities to take sides, potentially fragmenting an already intricate global network. Such polarization could inhibit cooperation in addressing pressing global challenges, like public health crises or environmental sustainability, which require collective action rather than divisive competition. A more nuanced understanding of the global biotechnology ecosystem—one that recognizes the contributions and roles of various players—would promote a collaborative environment,

fostering advancements that benefit all rather than perpetuating a dichotomy that ultimately hinders progress.

Pursuing a strategy of exclusion towards the PRC not only risks creating two closed ecosystems but also elevates the potential for harm on a global scale. By isolating the PRC, the United States may inadvertently push it into closer alliances with other nations, particularly those with divergent interests, such as Russia. This could facilitate collaborations in critical areas like biotechnology and innovation, where both nations could exchange knowledge, technologies, and strategies. Such partnerships could lead to advancements that may not only be beneficial for their own national interests but could also raise significant ethical and security concerns, especially if these innovations are repurposed for military applications.

The implications of this polarization extend beyond the U.S.-PRC dynamic; they also affect third-party countries caught in the middle. As nations face pressure to choose sides, many may gravitate toward exclusive partnerships with the PRC to ensure access to resources and technological advancements. This shift can create a divide in the global innovation landscape, where countries aligned with the PRC miss out on collaborative opportunities with U.S. partners. Such exclusion can stifle innovation in these nations, limiting their potential for growth and technological progress while also reinforcing dependency on a single bloc.

Moreover, the erosion of U.S. standing as a promoter of standards and norms can have lasting repercussions on international cooperation. Countries look to the United States as a benchmark for best practices and ethical governance; thus, a reactive policy stance could diminish this trust. Ultimately, the strategy of exclusion not only undermines U.S. interests but also threatens the collaborative spirit necessary for addressing global challenges. A more inclusive approach that encourages dialogue and partnership across nations could foster an environment of shared innovation and responsibility. By focusing on collaboration rather than division, the United States can reinforce its leadership role while also promoting a stable and cooperative international system that addresses the complex realities of today's technological and geopolitical landscape.

Establishing a shared understanding of the risks facing the U.S. bioeconomy is essential for formulating effective responses to emerging challenges

The interconnected nature of global markets means that threats to one nation can have cascading effects on others, particularly in sectors like biotechnology, which are vital for health, agriculture, and technology. By fostering continuous risk assessment practices among international partners, the United States can build a collaborative framework that enhances situational awareness and enables proactive measures.

This shared commitment not only strengthens national security but also promotes a resilient global bioeconomy that can better withstand disruptions. Ultimately, fostering a culture of shared risk awareness among international partners will enhance the resilience of the bioeconomy, allowing it to thrive in the face of uncertainty while promoting stability and cooperation on a global scale.

IV. Desired End States and Recommendations

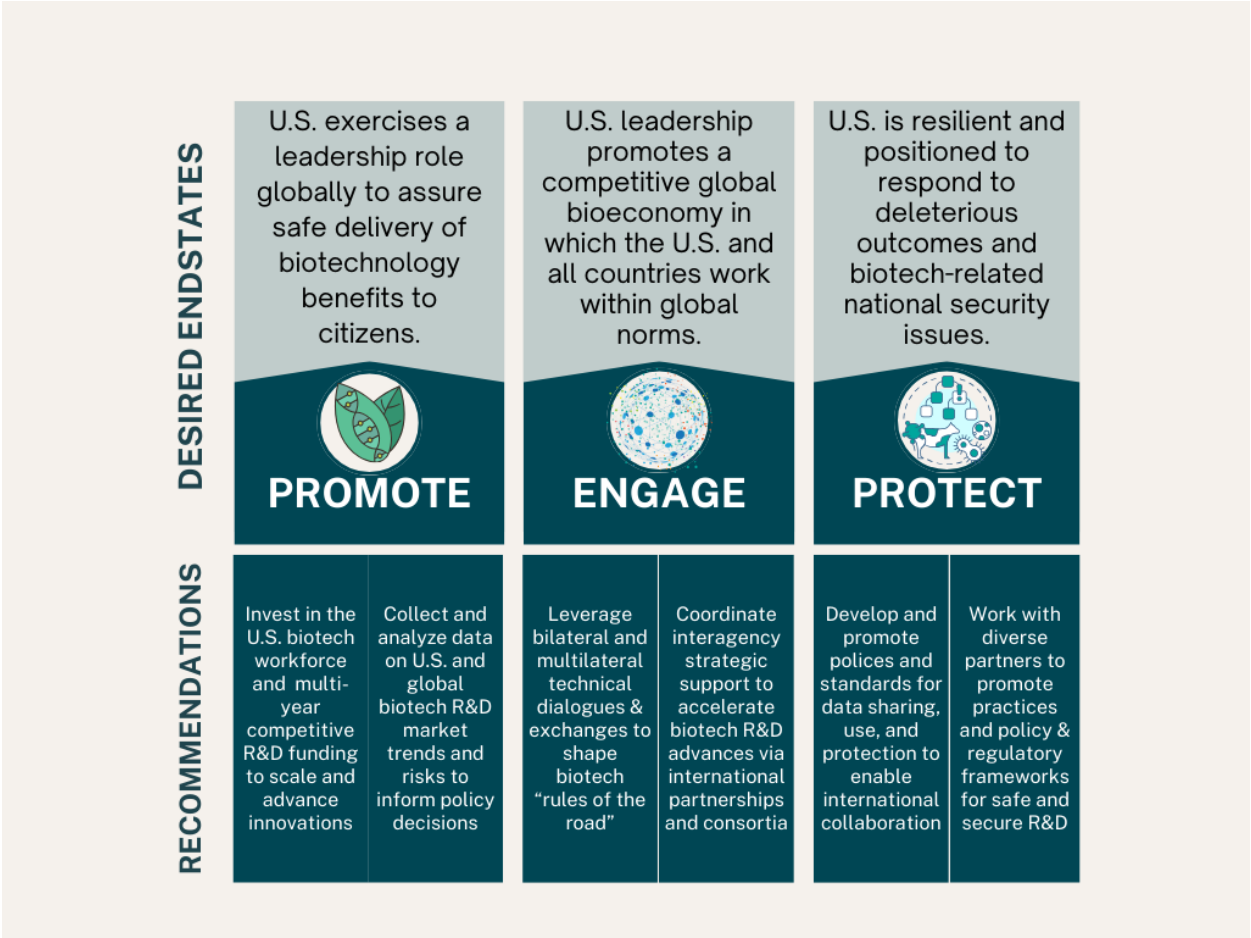
End states

The myriad issues described above – the import and promise of biotechnology together with concerns about a global biotechnology ecosystem negatively impacted by actions of the PRC and its MCF policies – call for a disciplined approach to achieve a set of desired end states. These desired end states are highlighted in Figure 1 and include these items:

- The United States continues to exercise a leadership role globally to assure safe delivery of biotechnology benefits to citizens.
- U.S. leadership promotes a competitive global bioeconomy in which the United States and all countries work within global norms and where dependence on any one country for critical products is avoided.

- The United States is more resilient and better positioned to respond to deleterious outcomes and national security issues related to biotechnologies.

Figure 1. Desired end states and recommended approaches to promote and protect biotechnologies.



Recommendations

New efforts throughout the U.S. government, in engagement with the private sector and the broader research enterprise, are required to achieve these three desired end states. Recommendations fit into four broad categories of actions and top-level goals:

1) Maintain and enhance the strength of the U.S. biotechnology enterprise through workforce development (including a modern National Defense Education Act) and multi-year competitive funding to advance biotechnology and biomanufacturing advances.

2) Anticipate, prevent and mitigate risks to the biotechnology enterprise through thoughtful engagement of scientists in the global scientific ecosystem, prudent management of data assets, and appropriate controls over transfers of hardware, compute, and process knowledge across state borders.

3) Secure trust of partners and publics by using bilateral and multilateral engagements and dialogue with academic and private sector stakeholders to constructively influence international governance norms and "rules of the road."

4) Build partner capacities to participate in the global bioeconomy in alignment with U.S. values and global norms by taking deliberate, data-informed steps to strengthen research, development, and deployment partnerships with a broader range of nations and to develop shared practices to managing research enterprises in biotechnology.

Maintain and Enhance the Strength of the U.S. Biotechnology Enterprise

Maintaining the strength of the U.S. biotechnology enterprise requires a multi-component approach that prioritizes the quality of the workforce, the adequacy of resources, and a robust policy toolset for innovation, partnering arrangements, and intellectual property.

A talented and trained workforce that is diverse with respect to the disparate needs within the biotech ecosystem is essential for sustaining a strong biotechnology enterprise. The United

States must invest in tailored education and training programs that recruit and prepare the next generation of scientists, engineers, and technicians for careers in biotechnology. This includes enhancing STEM curricula at all educational levels, from K-12 through higher education. Collaborations between educational institutions and biotechnology companies can provide hands-on training opportunities, internships, and mentorship programs. By developing a skilled workforce, the United States can ensure that its biotechnology sector has the human capital necessary to drive innovation and maintain its competitive edge.

Beijing has prioritized investment in the life sciences and biotechnology for decades. As a result, the challenge that the PRC now poses to U.S. and global advancements in biotechnology has reached the point of sounding alarms. The rapid pace by which U.S. advances are unwittingly benefitting the PRC's progress is significant. While the details of this competitive but also interdependent relationship are as novel as the biotechnology advances spurring them, it is important to remember that the contours of this problem are familiar. The United States has been in this situation before. In multiple technology areas, over the course of many decades, there have been times of increased technology and security competition when the fruits of U.S. science were deliberately plucked by adversaries to advance their economies and militaries. The United States succeeded in those past examples not only by guarding U.S. advances to limit opportunities for them to be used for other nations' benefit (though that has been a component), but by adopting a U.S. policy to "run faster," to advance both the technology and the workforce that makes use of it, and to invest in the U.S. research enterprise. This strategy should be undertaken now in response to the PRC's rise in biotechnology.

When the Soviet Union launched the first artificial satellite, Sputnik, in 1957, the United States responded with the National Defense Education Act of 1958 (P.L. 85-864), signed by President Dwight Eisenhower. This legislation aimed to improve the U.S. education system and vastly increase the numbers of scientists and engineers in the United States; U.S. shortages of mathematicians and other specialties were recognized as a national security issue for years, but Sputnik spurred the United States to take action. The Act provided low-cost student loans for studying STEM and foreign languages, increased teacher training, funded research, and increased public awareness and understanding of science and technology. It is now seen as a

landmark achievement not only for U.S. education but also for U.S. national security in providing the essential workforce to compete. **A modern National Defense Education Act (NDEA) is needed now.** These targeted workforce talent programs will be important to achieve the "maintain and enhance" goal. The need for a New National Defense Education Act is also a recommendation of a 2023 Defense Science Board report entitled "Balancing Openness and Security Across the DoD Academic Research Enterprise";[92] proposals for updated programs are a current focus of the National Academies' Board on Higher Education;[93] and the National Science Board Chair has called for an NDEA 2.0 to inspire and recruit the STEM workforce needed in the future.[94]

The *Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy*[95] has directed the Department of State to produce a plan to promote and protect the US and global bioeconomies. The objectives for the plan include enhancing cooperation and expert exchanges on biotechnology R&D; cooperating on regulatory approaches; promoting the open sharing of data; engaging allies and partners to address shared national security threats; developing shared approaches for biosafety and biosecurity; and executing workforce initiatives to further strengthen the talent pools.

To achieve these objectives, the Department of State must focus on increasing the capabilities of its own talent pool in biotechnology and related scientific fields to better enable it to lead these efforts. Ideas for attracting more scientists to the Department of State workforce, partnering with other agencies, and creating new rotational programs are consistent with the recommendations for personnel in the 2023 ISAB report on AI and Associated Technologies, and are described there.[96]

Beyond developing its domestic talent pool for biotechnology through efforts such as the NDEA, the United States should focus on providing continuity in key areas of research, including the biotech disciplines. The 2023 Defense Science Board report recommended complementing a modernized NDEA with multi-year research funding for R&D in priority areas, and through scholarships and fellowships to support research-based training.[97] Resources are critical to supporting both the workforce development programs described above and fundamental and applied research led by government agencies. Federally funded research and development

totaled about $170 billion in 2022, and over the last 70 years has fallen to about three quarters of one percent of the annual Gross Domestic Product (GDP). Total U.S. R&D spending reaches a more globally competitive rate of close to 3.5 percent of national GDP, driven principally by private sector businesses, and, to a lesser extent, from philanthropic sources and state governments.

The U.S. government can play a pivotal role by increasing federal funding for domestic biotechnology initiatives, particularly in areas with high potential for innovation and economic growth. Federal funding for biological science and engineering is directed to virtually all of the science and technology agencies, including DoD, HHS, DOE, NASA, NSF, and Commerce. Going forward, each should have larger appropriations for biotech and related convergent technologies such as AI. Increased funding offered by these agencies could be directed toward public research institutions, universities, and private companies engaged in cutting-edge biotechnological R&D. By fostering a competitive environment through grants, tax incentives, and subsidies, the United States can stimulate innovation and ensure that its biotechnology sector remains at the forefront of global advancements. The Department of State does not receive significant funding for scientific research programs; more resources are needed for the Department to play a leadership role in facilitating 21st Century strategic and sustained partnerships between U.S. scientists and engineers and their counterparts in key nations in competitive technology areas such as bioscience.

Fostering innovation ecosystems via policies and incentives is another key strategy for enhancing the strength of the biotechnology enterprise. This involves creating collaborative environments that bring together universities, research institutions, startup companies, and established biotech firms. Innovation hubs, such as biotechnology incubators or accelerators, can provide resources, mentorship, and networking opportunities for emerging companies. By promoting interdisciplinary collaboration and knowledge sharing, these ecosystems can accelerate the commercialization of new technologies and foster a culture of innovation.

Finally, a key element of enhancing and maintaining the strength of the U.S. biotechnology enterprise is a program of rigorous assessment and, when warranted, reconfiguration of the programs supported to provide resources, to build talent, and to encourage synergies within

the overall enterprise. Long-term investments will often be required, and setbacks must be expected. But there must also be a willingness to cut one's losses when lines of inquiry or commercial ventures prove to be unfruitful. The purpose of "run faster" programs should be to promote, not undermine, a competitive biotech economy.

It is also important to improve the capture of experimental and research data to better understand trends and to evaluate the impact of interventions on the biotech ecosystem globally. Recently, participants in the National Security Council's interagency process have proposed an enhanced government-sponsored program called Global Competitive Analysis (GCA) to collect data and perform analyses regarding how R&D sectors are working globally and how the U.S. innovation ecosystem stacks up. These analyses require collection and use of better metrics for understanding competitiveness, and their effectiveness will depend upon links to domestic decision making on priorities and investments.

Anticipate, Prevent and Mitigate Risks to the Biotechnology Enterprise

Threats and vulnerabilities affecting the biotechnology enterprise arise from concerns that the PRC's capture and harnessing of advances in biotechnology through MCF could enable civilian advances to be readily adapted for military applications, enhance and power unfair business practices and disadvantage U.S. companies, and give the PRC an edge in military and strategic capacities that could affect the global balance of power. Additionally, there is a fear that military interests could overshadow ethical considerations in research, pose risks to global biosecurity, and enable genetic data collection and manipulation to strengthen Beijing's state control over its citizens, impacting privacy and personal freedoms.

These concerns underscore the importance of monitoring the PRC's biotechnology developments and continuously assessing the implications of MCF and the PRC's comprehensive national biotechnology plan. Given the broad scope and potential impacts of the burgeoning biotechnology field, the United States must consider and implement a set of countermeasures to meet these challenges and reduce U.S. vulnerabilities. The United States seeks to harness the benefits of the new biotechnology for its citizens and for global citizens, to

capture economic opportunities in new biotechnology businesses and jobs, and to forestall theft and malignant applications.

Overall, the most effective approach is for the United States to achieve "security by accomplishment" and make significant investments in the U.S. biotechnology ecosystem as described above. But that alone is not adequate.

Lessons learned from nonproliferation efforts can inform thinking about some protective measures the United States can undertake. The first need is to sensitize scientists and entrepreneurs, both overseas and at home, to the nature and relevance of the security challenges they may face – in this case, in their use of PRC researchers, partner companies, and funding. Professional and technical societies could be enlisted or funded to help craft or sponsor thoughtful presentations of the real risks that must be mitigated as researchers and companies navigate the complex ecosystem of international biotechnology. Restrictions on engagement among scientists and entrepreneurs, knowledge transfer, and access to critical items have proven to be generally effective at slowing proliferant behaviors. The Department of State has led the development and overseen the execution of many of these practices. A strategic and clear approach to controls on people, knowledge and ideas, materials, processes, and products in this domain is needed.

Purposeful Engagements and Capable People

Science and invention benefit from a community and ecosystem of partners who contribute to a fierce competition for ideas and urgency for productive applications. Historically, there have been a shared set of norms for scientific exploration and discovery in all scientific domains including integrity, responsibility, openness, and respect for intellectual property processes. However, there are concerns about PRC state-sponsored efforts that involve dishonesty and theft, fabrication, falsification, and plagiarism. Alarms have also been raised about scientists, in the United States and beyond, who have conflicts of interest and conflicts of commitment.

Personal engagement and sharing of scientific hypotheses and results are central in a discovery and innovation ecosystem. Promoting and protecting biotechnology innovation while also benefiting from the valuable contributions of the U.S. foreign-born STEM workforce requires a

nuanced approach that balances national security concerns with the need for collaboration and innovation.

American scientists and research partners in other nations must approach scientific collaboration today armed with the knowledge that not all potential new collaborators share the same approaches to science or are willing to operate in accordance with these desirable shared norms for science and technology. Awareness is needed and, while engagement is important for the quality of science and the advancement of science and technology, it must be carried out purposefully and wittingly.

There have been many discussions about how best to raise awareness of this tension between "open science" norms and the abrogation of those norms by some members of the global scientific community. This tension has been addressed in the United States for several years, notably in the Research Security Roundtable of the National Academies of Science, Engineering and Medicine,[98] and in national policy documents including the January 2021 *National Security Presidential Memorandum (NSPM) 33*,[99] the January 2022 *Implementation Guidance for NSPM 33*,[100] and the July 2024 *Memorandum from the Director of the Office of Science and Technology Policy*.[101]

In addition to these efforts to raise awareness of threats to U.S. science and to motivate "aware" behavior, there have been continuing efforts to develop and deploy a strategic approach to attracting and retaining international scholars and including research communities from other countries in our biotechnology ecosystem. More needs to be done in this area. The U.S. biotechnology enterprise must actively engage in international collaboration to maintain its leadership role globally. Establishing partnerships with foreign research institutions, biotech firms, and governments can facilitate knowledge exchange, joint research initiatives, and access to new markets. Participating in international forums and initiatives focused on biotechnology can also help the United States shape global standards and regulations, ensuring that its values and interests are considered in global discussions. By fostering a collaborative global network, the United States can enhance its biotechnology enterprise while also contributing to the development of secure and ethical practices worldwide.

Appropriate Access to Knowledge and Data

Scientific data are ever more important for deeper scientific understanding, to address national missions, and as a constituent part of employing the new capabilities of artificial intelligence. Data increasingly underpin both current and new business enterprises. U.S. policies for data protection are in a nascent stage. Openness with data has long been a desirable scientific attribute, one that is necessary to address scientific discourse and enable reproducibility assessments. Curated and accurate data sets with good provenance have increasing economic value which can be best harvested through clear use and ownership rules.

Going forward, there must be efforts to ensure awareness among stakeholders throughout the biotechnology enterprise about the importance of practical and beneficial data controls. There are concerns that current fears about vulnerabilities may lead to an excessively baroque data protection architecture that could undermine U.S. engagement in the global community. It is important that policies for publication of federally supported research, intellectual property protection, export controls, and classification are all made in a manner that promotes a free and open society without government dominance of research, development, and innovation and that protection approaches for data and tacit knowledge are enhanced.

The government and other sectors in the economy must work together to examine, select, and implement updated data policies. These policies may also include updated approaches for protection of intellectual property. Not all innovative communities embrace patent processes (for protecting trade secrets and proprietary information), and biotech is increasingly seeing a convergence of communities with different types of sensitive data and differing current use approaches.

The United States must work to develop a clear approach to data policies and standards for data privacy that align with U.S. policies and other nations' regulations (e.g., the EU's General Data Protection Regulation) to allow sharing of biomedical/biological data so that the United States is not excluded from collaborations and from the discussions of global standards and norm setting.

Control of Advanced Materials, Products, and Equipment

Implementation of controls can mitigate the risks associated with the misuse of advanced biotechnological tools and materials while ensuring safety, security, and compliance with regulations. Currently, two types of export controls, ITAR (International Traffic in Arms Regulations) and EAR (Export Administration Regulations**)** help prevent sensitive technologies from being exported to adversarial nations, thus protecting U.S. military and technological superiority.

ITAR regulates the export and import of defense-related articles and services. Items covered include military equipment, technical data, and services related to defense. Export licenses are required for any transfer of controlled items to foreign persons or entities. ITAR is administered by the Department of State and companies must register with them. Export license applications are reviewed based on national security, foreign policy, and economic interests.

EAR governs the export of dual-use items (commercial items that can have military applications). EAR is administered by the U.S. Department of Commerce and items are classified under the Commerce Control List (CCL). Depending on the classification, different levels of export control apply. Exporters must determine the classification of their items. Depending on the classification, they may need to apply for an export license.

Another process, CFIUS (Committee on Foreign Investment in the United States)**,** reviews foreign investments in U.S. companies to assess their impact on national security. CFIUS ensures that foreign investments do not compromise critical technologies or infrastructure, safeguarding U.S. innovation and economic interests. CFIUS is an interagency committee chaired by the Secretary of the Treasury. CFIUS can review transactions that may result in foreign control of a U.S. business. Transactions can be voluntarily submitted for review. CIFIUS can block transactions or impose conditions to mitigate risks. CFIUS has a 30-day review period, which can be extended for a more in-depth investigation. CFIUS has become increasingly proactive in addressing national security concerns related to foreign investments, especially from countries like the PRC.

These regulations play a crucial role in maintaining U.S. technological leadership and national security. For example, for technologies important for semiconductors and computing, in October 2022, the United States enacted a new set of export controls on advanced semiconductor technology and equipment for making chips smaller than 14 nanometers (nm), restricting U.S. companies from exporting advanced semiconductors to China, along with restrictions on the engagement of subject matter experts in those technologies who are not U.S. citizens. Other nations, including the Netherlands, and Japan, followed with related restrictions on technology.[102,103]

It is also true that ITAR, EAR, and CFIUS create challenges for American suppliers of science and technology, can be difficult to implement, and do not always achieve their intended outcome. Continuous improvement and policy innovation are critical to enable suppliers to thrive in a competitive global landscape, and to balance regulatory compliance with business growth. The evolving landscape requires the need to balance national security concerns in a fast-moving industry sector; biotechnology companies need to invest in expensive compliance programs to keep up, or risk incurring heavy penalties and/or expensive legal costs. Smaller biotech companies may be unable to have such compliance programs. ITAR and EAR also slow the ability of biotechnology companies to introduce products into foreign markets, and they make recruiting foreign workforce talent difficult, both of which can slow innovation. Further, the science advances much faster than EAR or ITAR can keep up with, and as many biotechnologies are at least theoretically dual-use, this creates uncertainty about whether new technologies will be addressed under the regulations. The CFIUS “clock”, which requires action within a certain time and multi-agency input, may be helpful for ITAR and EAR evaluation of biotech exports.

Efforts to affirmatively support thoughtful engagement of scientists in the global scientific ecosystem, to prudently manage data assets, and to be watchful over transfers of hardware, compute and process knowledge across state borders, will better prepare the United States to protect its biotechnology innovations and enterprises from PRC efforts to steal intellectual property and to enhance its overall security posture in this critical area. The United States must adopt a comprehensive approach that includes legal and technological measures, as well as guidance for the governed community that takes into account the complexity of R&D collaborations, to safeguard American ingenuity in biotechnology.

Secure Trust of Partners and Publics

The United States must continue to be a global biotechnology leader to reap the benefits of the new biotechnology for its citizens, to prevent deleterious impacts, and to constructively influence international governance norms and "rules of the road." Leaders in other nations and citizens globally must become partners in creating and benefitting from this new global biotechnology enterprise. The processes to achieve the goal of shared trust among citizens and partner nations include the development of shared norms and operating approaches established through strong multi-lateral dialogues informed by citizen perspectives.

The Department of State should take the lead, with the right tools and flexibilities, to convene diverse allies and partners to define the strong standards and norms to which all nations should adhere in support of a robust international biotechnology ecosystem. The Department of State can work with U.S. science and technology (S&T) agencies, professional societies, and nonprofits to establish, "test-drive," and promote workable norms and standards around biotechnology that can be adopted at the international level.

Multilateral diplomatic dialogues have an important role in addressing national security risks related to the PRC's MCF plans related to biotechnology. The MCF strategy blurs the lines between civilian and military research, raising concerns among global powers about the potential dual-use applications of biotechnological advancements. Through multilateral engagements, countries can collaboratively monitor and evaluate the implications of these technologies, ensuring they are not weaponized or used to disadvantage other nations in access to critical supplies, knowledge, and technologies. Such dialogues provide a platform for international stakeholders to voice their concerns and propose frameworks that maintain transparency and limit the proliferation of dangerous biotechnologies.

One of the key values of these dialogues is the establishment of norms and agreements regarding the ethical use of biotechnology. Multilateral diplomatic efforts will be crucial in forming global standards that prevent the misuse of such innovations while promoting cooperation in peaceful research. Diplomatic dialogues can be used to establish verification

protocols, confidence-building measures, or cooperative research programs that foster mutual trust.

In addition, multilateral dialogues promote the inclusion of diverse perspectives, enabling countries to address the broader global implications of the PRC's MCF strategy. Smaller nations and developing countries, which might not have the same level of technological or military power, stand to gain a voice in shaping the global regulatory landscape. Their participation ensures that the policies and regulations developed through these discussions reflect a balanced and equitable approach to biotechnological advancements and their potential military application. This inclusiveness is vital for creating a cooperative international security environment where no single nation creates choke points.

The value of these diplomatic dialogues extends to crisis management and prevention of unintended consequences. The rapid pace of biotechnological innovation, combined with its dual-use nature, presents numerous risks, such as the accidental release of dangerous pathogens or the weaponization of bio-engineered organisms. Multilateral platforms offer a means for the international community to collaboratively identify, respond to, and mitigate potential security threats posed by the PRC's MCF-driven biotechnological progress. Early warning systems, joint research initiatives, and rapid response mechanisms can be developed through such dialogues to prevent crises before they escalate, contributing to global stability and security.

There is no single international authority that provides norm setting or global governance for all of biotechnology, but there are multiple institutions and organizations that form an imperfect web of global governance. In emerging technical areas, such as at the intersection of biotechnology and AI, the fast pace of discovery and development may require that norms surrounding biosafety, biosecurity, transparency, data reporting, and other concerns are shaped amidst uncertainty in how the technical details will unfold, and the role that external forces, especially private sector investments, will play in driving the pace of change. Even for biotechnology products that are already highly regulated by national authorities, such as medicines and food, there are international organizations that work to harmonize national approaches. Harmonized approaches include how regulatory agencies will specifically measure

characteristics such as toxicity or carcinogenicity. In all cases of norm development, whether for emerging technology areas or for longstanding products, there are implications for economic development as well as shaping the future of biotechnology to align with positive values and uses.

Norms for biotechnology have been developed by different international organizations, including the World Health Organization (WHO), the Biological Weapons Convention Implementation Support Unit, the Organization for Economic Cooperation and Development (OECD), the G7, and others, aided by the involvement of private sector companies, research institutions, and nonprofit organizations. **For U.S. interests, the Department of State should have the flexibility to work across these organizations to accelerate the development of workable norms that benefit the productive, positive uses of biotechnology.**

There are several areas where these norm development efforts should focus; one framework for biotechnology is organized around what have been termed the "4 S's"[104] – safety, security, sustainability, and social responsibility:

- *Safety:* A shared approach to biosafety would help the workplace, consumers, and the general public. Specific concerns for biosafety range from making sure that a worker in a poorly funded clinical laboratory receives training and personal protective equipment, to developing the appropriate testing regimen before releasing a gene drive intended to reduce malaria transmission, or agreements on appropriate levels of containment for handling specific pathogens.

- *Security*: Potential biosecurity threats and loss due to theft, misuse, diversion, unauthorized possession of property, loss of intellectual property, and intentional use of a biological agent or product as a weapon are all biosecurity concerns that require shared approaches to deter, detect, and attribute.

- *Sustainability:* Nations have opportunities to maintain or improve the long-term viability of the environment and economy, including the impacts of biotechnology products and processes on the environment, supply chains, and consumer practices.

- *Social Responsibility:* The significant impact of biotechnology on stakeholders' benefits, risks, and consequences, makes it a priority to maximize positive social outcomes and adherence to ethical standards. Outcomes may include shared perspectives on the importance for researchers to disclose conflicts via transparency measures, to understand research security guidelines, and to take training on scientific norms integrity.

There have also been efforts to develop international norms around biosecurity, such as the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists[105] developed by an international group of scientists, supported by the Department of State, and endorsed by the InterAcademy Partnership.[106]

Build Partner Capacities to Participate in the Global Bioeconomy in Alignment with U.S. Values and Global Norms

Building partnerships internationally allows for knowledge sharing, collaboration on research and development, and a coordinated approach to address global challenges in biotechnology. Partnerships and broad capabilities can insulate the United States and partner nations from a forced dependency on the PRC as a provider of knowledge, tools, workforce, and resources. Successful capacity-building partnerships will contribute to a mutually beneficial global biotechnology ecosystem with diverse, robust, and high value supply chains for pharmaceutical precursors, bio-manufactured products, and other key commodities.

The United States should take deliberate steps to strengthen research, development, and deployment partnerships with a broader range of nations and to develop shared practices to managing research enterprises in biotechnology. Overall, the goal is to have an enabling environment for innovation both on our shores and with like-minded partners. The Department of State should pilot and scale talent exchanges to foster these connections as part of a broader strategy to build partner nation capacities, focusing on opportunities to strengthen the regulatory workforce as well as research expertise. Establishment of an international task force (or similar structure) to build relationships and help define technical capacities needed

across the global biotechnology workforce may help to operationalize approaches to biotechnology collaboration among partner countries.

Deployment models from the World Bank and the Department of Defense may be good examples for the support of promising biotech industry partnerships. These models can be paired with the Department of State's perspectives on specific opportunities for building partner nation capacities including workforce development, education, and research facilities.

Biotech collaboration and cooperation with other countries can also support the development and promotion of norms and standards for research and for deployment applications. Partner countries should be supported to develop capacities and systems for regulatory oversight to facilitate technology development and deployment partnerships.

The Department of State must engage partner nations in bilateral/multilateral agreements about data transparency and reasonable controls for biosecurity. Together, nations should work to establish shared norms for governments, for research enterprises, and for research records such as archives and journals, etc.

Partner nations, and the United States should also develop joint strategies for protecting intellectual property and combating industrial espionage. Partner nations should negotiate multi-country agreements focused on establishing agreed-upon IP protection standards, sharing intelligence about threats, and implementing coordinated counter-espionage tactics.

Other topics must be addressed as well. In the field of biotechnology there is not yet a comprehensive understanding of economic value. In the bio domain, there are security partnerships and preferred partners for trade in technologies and bio-based materials, but it is just the beginning of developing parallel approaches and mechanisms for prioritizing preferred partnerships related to biotech innovation and S&T investments that include value propositions for multinational organizations and companies. Additional discussions and policy analyses are needed to develop a shared view on the role of government or multi-governmental institutions on industrial policy.

These discussions about market structure and the roles of government and the private sector are important to enable approaches to the hard problems of working together in crises, such

as, for example, merging supply chains during a pandemic. It will also be important to have a broad perspective on the development of biotech programs in many nations, to prioritize adequately resourced, reciprocal programs that promote continuing collaboration instead of "one-and-done" efforts with the countries that already have capacities similar to those of the United States.

These key elements are needed to meet the challenge presented by China's military-civil fusion scheme in biotechnology and the bright promise of 21st Century biotechnology. The Department of State has a set of important responsibilities to help meet this challenge. Its most immediate task is to develop the budget, personnel and funding that will be needed for the Department to fulfill those responsibilities.

V. Endnotes

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VI. Appendix A – Terms of Reference

UNDER SECRETARY OF STATE FOR
ARMS CONTROL AND INTERNATIONAL SECURITY
WASHINGTON

March 12, 2024

MEMORANDUM FOR THE CHAIRMAN, INTERNATIONAL SECURITY ADVISORY BOARD (ISAB)

SUBJECT: Terms of Reference – ISAB Study on Biotechnology in the People's Republic of China's Military-Civil Fusion Strategy

The International Security Advisory Board (ISAB) is requested to undertake a brief study of the People's Republic of China's (PRC) Military-Civil Fusion (MCF) Strategy's biotechnology development objectives, implementation, and implications for international biosecurity.

Biotechnology promises to revolutionize everyday life through rapid advances in medical treatment, genetic engineering in agriculture, and novel biomaterials. Because of its potential, biotechnology has emerged as a key domain in U.S.-PRC competition and a new focus area for the protection of dual-use technologies. The PRC views biotechnology as a component of the next industrial revolution and key to future economic development and comprehensive national power. U.S. policymakers are increasingly focused on the national security implications of biotechnology and the challenge of protecting and promoting this emerging technology.

PRC military scientists and strategists have consistently emphasized that biotechnology advancements are one of the fields that could allow a country to dominate the next Revolution in Military Affairs (RMA). MCF, the national development strategy under which the PRC is working to adapt modern technologies to apply to the RMA, has identified biology as a research and development priority and key field for developing dual-use technologies. As the PRC targets advances in biotechnology, it has emphasized the importance of actively exploring new frontiers of biological cross-disciplinary technologies with potential military application,

including prominent developments in CRISPR to bionic robotics, human enhancement technologies such as intelligent control exoskeletons, and techniques for human-machine collaboration. The PRC has demonstrated its commitment to advancing biotechnology capabilities for the military by funding projects on military brain science, advanced biomimetic systems, biological and biomimetic material, using biosynthesis for military production, and human performance enhancement. The People's Liberation Army (PLA) has further identified brain-machine interfaces and the resulting human-machine integration as a potential game changer for future combat platforms.

The PRC's approach to advancing its military and commercial capabilities in biotechnology embodies the MCF development strategy – it integrates developments among industry, academic institutions, and military programs via research collaborations and the procurement of dual-use technologies, in some cases leveraging collaboration with international universities, research institutions, and pharmaceutical companies. As a national strategy, MCF uses all levers of state and commercial power to strengthen and support the PLA. MCF posits that eliminating barriers between the civilian and defense sectors facilitates the direct flow of technology, talent, and capital between them thereby speeding technology development in both domains. As MCF seeks to ensure the PLA wins the race to develop and integrate a range of critical and emerging technologies for military applications, including biotechnology, the United States and partner nations must work to protect access to these technologies for national security purposes while continuing to promote their research and development.

The PRC's current high level of integration in global biotechnology and biomanufacturing supply chains and its key role in biotechnology research and development initiatives, combined with Beijing's efforts to systematically divert biotechnology advancements to military end uses creates daunting challenges. Accordingly, it would be of great assistance if the ISAB study on biotechnology challenges from the PRC's Military-Civil Fusion development strategy could examine and assess:

- The PRC's policy objectives for the development of biotechnology, bioeconomies, and biomanufacturing, as well as the policies and implementation measures Beijing is utilizing to realize them;

- The MCF strategy's biotechnology-related initiatives, especially how the PRC is integrating these technologies into its military state security apparatus;
- Vulnerabilities from existing global biotechnology supply chains, research collaborations, procurements of dual-purpose commercial technologies, and other proliferation and diversion risks; and

- Potential mitigation measures to protect and promote the development of biotechnology.

In the conduct of its study, as it deems necessary, the ISAB may expand upon the tasks listed above. I request that you submit a completed study to the ISAB Executive Directorate no later than September 30, 2024.

The Under Secretary of State of State for Arms Control and International Security will sponsor the study. The Assistant Secretary for International Security and Nonproliferation will support the study. Frederic Vellucci and Audrey Fritz will serve as the Executive Secretary for the study and Michelle Dover and Scott Bohn will represent the ISAB Executive Directorate.

The study will be conducted in accordance with the provisions of P.L. 92-463, the "Federal Advisory Board Committee Act." If the ISAB establishes a working group to assist in its study, the working group must present its report or findings to the full ISAB for consideration in a formal meeting, prior to presenting the report or findings to the Department.

Bonnie D. Jenkins

[Updated October 2024 to reflect additional Executive Secretary]

VII. Appendix B – Members and Project Staff

Board Members

- Hon. Edwin Dorn (Chair)
- Ms. Sherri Goodman (Vice Chair)
- Dr. Daniel Byman
- Hon. Patricia Falcone
- Dr. Julie Fischer
- Dr. James Goldgeier
- Dr. Gigi Kwik Gronvall
- Dr. Gregory Hall
- ADM Cecil Haney, USN (ret.)
- Dr. Eboni Haynes
- Ms. Julie Herr
- Dr. Michael Horowitz
- Ms. Heather Hurlburt
- Hon. Shirley Ann Jackson
- Amb. (ret.) Laura Kennedy
- Dr. Susan Koch
- Dr. Edward Levine
- Dr. Jeffrey Lewis
- Hon. Jamie Morin
- Hon. Eric Rosenbach
- Dr. Ian Simon
- Ms. Lyric Thompson
- Dr. Paul Walker
- Dr. Heather Williams
- Mr. Jon Wolfsthal

Study Group Members

- Chair: ADM (ret) Cecil Haney
- Dr. Patrica Falcone
- Dr. Julie Fischer
- Dr. Gigi Kwik Gronvall
- Dr. Michael Horowitz
- Hon. Shirley Ann Jackson
- Dr. Edward Levine
- Dr. Ian Simon

Project Staff

- Mr. Frederic Vellucci, Executive Secretary, ISAB
- Ms. Audrey Fritz, Executive Secretary, ISAB
- Ms. Michelle Dover, Executive Director, ISAB
- Mr. Scott Bohn, Deputy Executive Director, ISAB
- Ms. Thelma Jenkins-Anthony, Senior Advisor, ISAB

VIII. Appendix C – Individuals Consulted by the Study Group

April 22, 2024

Dr. Kelly Seagraves	Senior Advisor, Office of the Special Envoy for Critical and Emerging Technology, U.S. Department of State

April 29, 2024

Halley Smith	Unit Chief for Technology, Office of China Coordination, Bureau of East Asian and Pacific Affairs, U.S. Department of State

May 6, 2024

Peter Mattis	President, Jamestown Foundation

May 20, 2024

Dr. Anne Cheever	Director for Technology and National Security Council, National Security Council, The White House
Dr. Robert Fisher	Director for Biodefense and Biotechnology Risk, National Security Council, The White House
Dr. Chandresh Harjivan	Special Assistant to the President, Domestic Preparedness and Response to Biological Threats, Office of Pandemic Preparedness and Response Policy, The White House
Dr. Shankar Sundaram	Special Assistant to the President and Senior Director, Global Health Security and Biodefense, National Security Council, The White House

Stephen Welby	Special Assistant to the President and Deputy Director, National Security, Office of Science and Technology Policy, The White House
Rhys Dubin	Policy Advisor, Office of the Special Envoy for Critical and Emerging Technology, Department of State
Shaun Hayeslip	Deputy Director, Office of Policy Coordination, Bureau of International Security and Nonproliferation, Department of State
Halley Smith	Unit Chief, Office of China Coordination, Bureau of East Asian and Pacific Affairs, Department of State
Dr. Christine Payne	Jefferson Science Fellow, Office of Critical Technology Protection, Bureau of International Security and Nonproliferation, Department of State
Briefer	Office of the Biological Policy Staff, Bureau of International Security and Nonproliferation, Department of State
Andrew Souza	Foreign Affairs Officer, Office of Missile, Biological, and Chemical Nonproliferation, Bureau of International Security and Nonproliferation, Department of State
Dr. Benedict Wolf	Foreign Affairs Officer, Office of Missile, Biological, and Chemical Nonproliferation, Bureau of International Security and Nonproliferation, Department of State
Dr. Kathleen Stevens	Foreign Affairs Officer, Office of Science and Technology Cooperation, Bureau of Oceans, International Environment, and Scientific Affairs
Dr. Kirsten Weand	Head of Strategy, Office of Strategy, Communication, and Health Equity, Bureau of Global Health Security and Diplomacy, Department of State

Dr. Arik Shams	Biotechnology Advisor, Office of Agricultural Policy, Bureau of Economic and Business Affairs, Division for Trade Policy and Negotiations
Dr. Alexander Weiss	Analyst, Office of Cyber Security and Emerging Technology, Bureau of Intelligence and Research
Briefer	Bureau of Intelligence and Research

June 10, 2024

Dr. Steph Batalis	Research Fellow, Georgetown Center for Security and Emerging Technology (CSET)
Vikram Venkatram	Research Analyst, Georgetown Center for Security and Emerging Technology (CSET)

June 24, 2024

Dr. Luciana Borio	Venture Partner, ARCH Venture Partners
Dr. Megan Palmer	Independent

August 15, 2024

Dr. Michelle Rozo	Vice Chair, National Security Commission on Emerging Biotechnology (NSCEB)