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Regenerate

Biotechnology and U.S. Industrial Policy

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About the Author

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About the Technology and National Security Program

Technology is changing our lives. Rapid developments in artificial intelligence, autonomy and unmanned systems, digital infrastructure, networking and social media, and disinformation are profoundly altering the national security landscape. Nation-states have new tools at their disposal for political influence as well as new vulnerabilities to attacks. Authoritarian governments are empowered by high-tech tools of oppression and exploit radical transparency. Artificial intelligence and automation raise profound questions about the role of humans in conflict and war. CNAS' Technology and National Security program explores the policy challenges associated with these and other emerging technologies. A key focus of the program is bringing together the technology and policy communities to better understand these challenges and together develop solutions.

About the Report

This report is published as part of the U.S. National Industrial Policy Strategy project at CNAS. The project is developing an intellectual framework for industrial policy in the American context, in an era of strategic competition with technology at its center. The goal of the project is to pave the way for enhanced and sustained American economic competitiveness and technological leadership. This report was made possible with the generous support of the U.S. Air Force Office of Commercial and Economic Analysis.

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—STEVE JOBS[1]

Executive Summary

A revolution in biotechnology is dawning at the precise moment the world needs it most. Amid an ongoing climate crisis, fast-paced technological maturation, and a global pandemic, humans must find new ways to reduce greenhouse gas emissions, improve food security, develop new vaccines and therapeutics, recycle waste, synthesize new materials, and adapt to a changing world. But incentive structures in the U.S. private sector are generally biased against risk, and therefore constrain development in ways that do not have the same effect on firms in China and other U.S. competitors. This puts the United States at a relative disadvantage and risks ceding American leadership over one of the most powerful and transformative fields of technology in recent memory.

The United States needs some form of industrial policy to promote its bioeconomy—one that is enshrined in democratic values and focused on improving access to four key drivers of bioeconomic growth: equipment, personnel, information, and capital. This report attempts to measure the health and outlook of the U.S. synthetic biology industry and broader bioeconomy by examining U.S. access to each of these four resources. It concludes that the United States still possesses an advantage in each of these fields—but that, absent a proactive strategy to ensure resource access, and without a significant infusion of capital, the U.S. bioeconomy risks languishing behind competitors such as China in the decades ahead.

Summary of Recommendations

This report arrives at nearly two dozen policy recommendations for the United States to undertake in support of a more robust industrial policy. Each is focused on improving access to four resources at the heart of technological progress: equipment, personnel, information, and capital.

Equipment

A U.S. strategy to promote the bioeconomy should focus on improving access to equipment at the core of the bio revolution: computing and data sources used in genomics, and hard infrastructure used in DNA synthesis and fermentation.

- *Congress should pass the America COMPETES Act of 2022*, which authorizes the creation of a National Engineering Biology Initiative. The initiative should pool and subsequently distribute access to data used in biotechnology discovery applications for investigators and biotechnology startups.
- *The National AI Research Resource Task Force should formalize a National Research Cloud* for distributing access to cloud computing power for researchers and enterprises.
- *The White House should launch a bioeconomy opportunity tax credit*. Biotechnology startups should not have to worry about affording crucial resources like cloud-based computing, one-time gene sequencing fees, or expensive licenses for industrial control software.
- *The National Institute of Standards and Technology should establish and update clear definitions, interoperability parameters, and technical specifications for fermentation units* used in the large-scale cultivation of microorganisms, as well as novel, genetically engineered materials and devices for medical use, to ensure that these products remain safe and interoperable with one another.

Personnel

A diverse and well-trained workforce is undoubtedly the United States' single largest bioeconomic strength relative to any other country. There are several tools at the U.S. government's disposal to grow and enhance its pool of human talent in conjunction with allies and partners.

- *The White House Office of Personnel Management and Budget should establish a BioCorps Scholarship for Service* program modeled after the CyberCorps Scholarship for Service, which would support stipends, tuition, and allowances for PhD students in the general area of biotechnology.
- *Congress should pass the America's College Promise Act*, the proposal to fully fund associate degrees for low-income students at community colleges across the United States.[22] Supporting community college education and laboratory certification programs can create alternative career pathways that support the U.S. bioeconomy.
- *The Department of Education's Office of Elementary and Secondary Education should establish a Bio-Competition Grant Program* to cover the cost of after-school training, materials, and travel for teams participating in the International Genetically Engineered Machine competition and other regionally and nationally recognized biotechnology competitions.
- *The Department of State should replicate or otherwise institutionalize the Quad STEM Fellowship* run by Schmidt Futures, which grants PhD funding to 100 students from Quad countries each year.
- *The Department of State's Lower Mekong Initiative should fund Agricultural Centers of Excellence across Southeast Asia*. By working with regional groupings like the Indian Ocean Rim Association and the Bay of Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation, the United States can fund a network of research centers that solve regional challenges and contribute to environmental resilience and socioeconomic mobility.
- *Congress should vote to codify the recent expansion of the STEM Optional Practical Training program* (STEM-OPT) led by the Departments of State and Homeland Security. Expanding STEM-OPT and supporting longer-term immigration pathways will support continued U.S. leadership in biotechnology.
- *Congress should double the H-1B visa cap* from 65,000 to 130,000 visas each year. Amid global crises from climate change, the COVID-19 pandemic, and the Russian invasion of Ukraine, the world's best and brightest talent is increasingly mobile and willing to work in the United States. Bold action is necessary to transform these crises into opportunities.

Information

Expanding access to genetic data, harmonizing intellectual property protections, and upholding a flexible and transparent regulatory environment are crucial to sustain growth in the bioeconomy.

- *The National Institutes of Health (NIH) should establish a National Gene Bank equipped for 21st-century genomic research.* Creating a system that is updated in real time, with authorities and incentives to motivate private- and public-sector participation, is necessary to sustain U.S. progress in biotechnology research.
- *The Food and Drug Administration (FDA) should establish a process to share its existing research data with scientists at universities and trusted research institutions.* The FDA's expansive collection of data, from both clinical trials for pharmaceuticals and diagnostic research, could spur innovation in basic research if provided to public research centers.
- *Congress should broadly aim to preserve the U.S. system of intellectual property protection as it relates to biotechnology.*
- *Congress should scale up funding for the U.S. Patent and Trademark Office.* The patent office needs to examine and issue patents faster. To do so, it needs to retain and improve training for existing patent examiners who have a history of being hired away by intellectual property firms as soon as they learn their trade.
- *The U.S. Trade Representative and Department of Commerce should encourage U.S. allies and partners to relax protections of naturally occurring human genes* to promote further innovation in the global biotechnology industry.
- *The FDA, Environmental Protection Agency (EPA), and U.S. Department of Agriculture (USDA) should overhaul their implementation of the Coordinated Framework for the Regulation of Biotechnology.* An updated approach should give weight to the expected safety impact of providing a given product or service—irrespective of the technical method used to derive it.
- *The Small Business Administration (SBA) should enlist the support of the Federal Bureau of Investigation (FBI) and Defense Counterintelligence and Security Agency (DCSA) in offering security guidance to Small Business Innovation Research (SBIR) and Small Business Technology Transfer (SBTR) funding recipients.* The SBA should collect survey information about awardees' experiences with attempted economic espionage, which should be shared with the DCSA and FBI.

Capital

While private-sector investments have paid the largest dividends, government can play a much more active role in allocating capital and helping early-stage companies bridge the valley of death.

- *Congress should authorize significant increases in the budgets of several biotechnology industry incubators,* including a 50 percent increase in the SBIR and STTR programs run by the USDA, FDA, and EPA; research grants issued by the NIH; funding for Defense Advanced Research Projects Agency's Biological Technologies Office, and In-Q-Tel's biotechnology research portfolio.
- *The Department of Defense should request to expand the remit and budget of BioMADE,* and the Office of the Undersecretary of Defense for Research and Engineering should create redundant initiatives for specific biotechnologies, including novel sources of bioenergy and biomaterials.
- *Congress should establish the Industrial Finance Corporation of the United States,* a new investment mechanism for public-private partnerships, which will act as a magnet for capital in strategic industries.
- *The White House should work with state and local governments to establish a network of Biotechnology Industrial Opportunity Parks.* These special economic zones would include favorable federal and local tax structures, modeled after the oil industry's Foreign Trade Zones along the Texas coast, but for biorefineries across middle America.
- *The U.S. Trade Representative and Department of Commerce should advocate for relaxed restrictions on U.S. genetically modified agricultural exports* at the EU-U.S. Trade and Technology Council and amid negotiations over the Indo-Pacific Economic Framework.

Introduction

Ask any industrial biochemist to define a "biorefinery," and they will point you to the Bazancourt-Pomacle facility in Champagne, France.[3] This gleaming array of chrome and beige juts out of the French countryside nine miles northwest of Reims. First established in 1985, the facility has evolved to host hundreds of companies and thousands of jobs, each involved in one or more processes of engineering, cultivating, harvesting, and repurposing one crop: sugar beets. Bazancourt-Pomacle converts three million tons of biomass into various products for the food, chemical, cosmetics, and biofuel industries each year.[4] It is the blueprint for what biotechnology optimists call a "circular bioeconomy."[5]

Beets might seem an odd choice for the backbone of a supposedly future-defining industry, but they are a perfect example of the far-reaching impacts ushered in by the global revolution in biotechnology. Beets are harvested worldwide for their sugar, which can be used in cooking or converted into ethanol for fuel.[6] Beet pulp contains a high density of lignins, organic polymers that support cell wall structures and can be used to make products like animal feed, dust-controlling chemicals, and concrete admixtures.[7] Lignins can be further refined into adipic acids, which are staples in the production of nylon and other materials found in products ranging from clothing to building insulation. Beet seeds can be harvested and replanted for the next yield. The beets themselves can be genetically engineered to maximize each of these attributes. Still other companies at Bazancourt-Pomacle specialize in preparing soil, fertilizer, and water treatment and consumption. This diverse suite of applications has produced 2,000 direct and indirect jobs, and propelled a small, ultramodern metropolis to emerge from an otherwise run-of-the-mill farming community.[8]

A strong U.S. bioeconomy should encourage codependent relationships between parts of supply chains involved with engineering, cultivating, and refining products that are complementary with one another.

Policymakers in the United States can draw important lessons from Bazancourt-Pomacle and biorefineries like it. In his keynote speech at the 2022 Built with Biology conference, Eric Schmidt outlined how a circular bioeconomy could "turn scarcity into abundance," and highlighted the stakes for U.S. leadership in what he hopes will be a multitrillion-dollar industry.[9] Despite their unlikely harmony, there are at least three parallels between Schmidt's speech and the wisdom of French sugar beet farmers: First, when it comes to biotechnology, policymakers should not try to eschew the complexity of supply chains, but localize them. A strong U.S. bioeconomy should encourage codependent relationships between parts of supply chains involved with engineering, cultivating, and refining products that are complementary with one another.

Second, the United States does not have to "go it alone" in biotechnology competition with China but may draw on the strength of its allies and partners. Companies of more than a dozen nationalities are represented at Bazancourt-Pomacle. Given how broad biotechnology is as a research field, and the need for such diverse and bespoke applications for designing, growing, harvesting, and delivering its products, it will be important for the United States to uphold seamless integration and specialization in a bioeconomy that is increasingly global in scope.

Finally, and most significantly, the U.S. government has ample tools at its disposal to craft a comprehensive industrial policy that proactively shapes the bioeconomy. Governments can wield some forms of industrial policy, such as corporate tax incentives and research subsidies, to bring together diverse sets of actors like industrial manufacturers, private research organizations, and farmers' cooperatives to form effective partnerships.[10] The resulting biorefinery, itself a microcosm of bioeconomic growth, can take on a life of its own.

Setting Objectives for a U.S. National Biotech Strategy

The 2012 discovery of the CRISPR/Cas9 system—a flexible, high-precision gene editing technique—has propelled what many scientists and practitioners refer to as a revolution in biotechnology.[11] U.S. companies are developing innovative applications ranging from cultured meats to biofuels, which are poised to solve some of the world's toughest challenges.[12] To sustain U.S. leadership in biotechnologies, policymakers in Washington must reimagine their role in shaping the national and global bioeconomy.

Often, the first impulse when drafting any technology strategy is to ask what the technology-specific priorities ought to be. But it is a mistake to think in this way—to divorce the needs of the emerging bioeconomy from broader U.S. economic and security interests. An industrial policy for the bio revolution ought to have a laser-like focus on solving the wicked problem sets that are already top-of-mind for the Biden administration: galvanizing sustainable economic growth, addressing existential threats posed by climate change, and crafting an industrial policy that works in support of, not against, rural states and the American middle class.[13]

A successful U.S. biotechnology strategy will not be about biotechnology on its own; it will connect growth in the biotech industry to broader U.S. strategic objectives: building an economy that is resilient to supply chain disruptions, creating well-paying jobs in geographically diverse areas, informing the U.S. response to the COVID-19 pandemic, and promoting sustainable sources of clean

The discovery of the CRISPR/Cas9 system enabled rapid and precise modification of DNA. It is the foundation for innovative gene editing techniques and marks a biotechnology revolution. Here, a lab technician performs genomic research via the CRISPR/Cas9 technique. (Bill Oxford/Getty Images)

energy. It also should acknowledge, and seek to avoid, the failures of past efforts to cultivate a vibrant biotechnology industry: namely, consolidation in the biopharmaceutical and seed industries, and government's narrow focus on bioterrorism and pandemic preparedness.[14]

Three principles should guide U.S. policies to promote the bioeconomy: urgency, opportunity, and equity.

Urgency. The United States has relied on its significant lead in biotechnology to coast on sustained innovation in the field. But, as explored in this report, the share of resources available to the biotech industry is unevenly distributed, and in some cases, falls short of competitors like China. The returns from federal postwar land grants and science and technology investments diminish each day. Said one subject matter expert, "Second place in the bio revolution might as well be last place if you care about norms, values, access, equality, safety, and security of technology," especially considering that this next phase of biotechnology is shaping up to be "more powerful and important than any of the technologies that came before it."[15] The United States must recognize the urgency of this problem.

Opportunity. The conversation about biotechnology in Washington has long been dominated by risk avoidance. For much of the early Cold War, the United States failed to pay sufficient attention to the *risk* of new biotechnologies. But now the opposite is shaping up to be true: fear of the unknown risks clouding U.S. leadership in a future-defining industry. The National Academies of Science estimate that the current bioeconomy contributes more than 5 percent of U.S. gross domestic product.[16] Consulting groups estimate that the future bioeconomy will be worth somewhere between $4 trillion and $30 trillion by 2040, and that it will touch nearly every corner of society.[17] It is incumbent upon elected officials to sustain U.S. leadership in this industry. Washington should focus less on risks and more on opportunity costs.

Equity. The past 40 years of technological advances have propelled the United States to become the world's most advanced digital economy, at the cost of an emaciated manufacturing industry. While internet services and smart devices brought a higher standard of living and quality of life to many U.S. households,[18] the hollowing out of America's manufacturing industry left middle-class and blue-collar workers in the dust. The bio revolution can offer a course correction. Fields such as synthetic biology promise a new kind of economic development model—one that is innovation driven and high tech in outlook, *and* complementary with America's historical leadership in agricultural supply chains, manufacturing, and localized services such as health care.[19] The United States should harness biotechnology to arrive at more equitable solutions to America's toughest problems.

When asked what the U.S. government could do differently to better support the bioeconomy, several subject matter experts interviewed for this study replied that the government has not done a good enough job of "connecting biotech to people who don't realize that they rely on and use it."[20] Biotechnology is not just for pharmaceutical companies or next-generation fuel products; it is the underappreciated bedrock of American industry.[21] Moreover, new biotechnologies have the potential to reorganize American society in profoundly constructive ways.

Breaking Down the Bioeconomy

The bioeconomy is notoriously large and difficult to define. Other researchers have examined biotechnology's varying goals, techniques, sectors, and enabling technologies.[22] Too often, analysts shoehorn dozens of industries and sectors into a handful of specific use cases. Looking narrowly at a particular goal, technique, or sector allows only a narrow view of the bioeconomy.[23]

The following taxonomy of biotechnology processes offers a starting point from which policymakers can imagine the theoretical and real benefits of biotechnologies now and in the future. It offers policymakers an adaptable and forward-looking vision of the bioeconomy: one that is not defined by end products, but which seeks to enhance the United States' position across eight essential steps of biological processing.

Collection involves procuring genetic resources and material to serve as the basis of experimentation, as well as data and genetic information derived from that material. The United States has a complex web of genetic privacy laws designed to protect individuals' data from government misuse, some of which help and some of which may hinder innovation. A National Cancer Institute study from 2004 found that states had drastically different approaches to regulating the collection of human tissue specimens and associated data for research.[24] Relatedly, the Supreme Court's 2013 ruling in *Association for Molecular Pathology v. Myriad Genetics* held that "naturally occurring" human genes cannot be patented because they are a "product of nature," closing the door to some forms of biotechnology commercialization while keeping costs low for consumers.[25] Further challenges lie in the United States' highly fragmented and mostly proprietary medical records collection and outdated infrastructure for collecting and disseminating genomic data—as well as international laws and treaties aimed at giving developing countries a fairer share of the fruits of exploitation of genetic material sourced within their boundaries.

Sequencing involves understanding the nucleic acid sequence of DNA—"reading" the "code of life." Sequencing costs have plummeted in recent years.[26] The next frontier of sequencing-related challenges now lies in designing algorithms, especially those based on machine learning, which can optimally extract information and identify patterns endogenous to extremely long DNA sequences—sometimes millions of base pairs long.

Storage involves using DNA to encode and store information. Using innovative techniques, the 74 million bytes of information stored by the Library of Congress "could be crammed into a DNA archive the size of a poppy seed—6,000 times over."[27] DNA storage involves genomics, a field dedicated to understanding the structure, function, evolution, mapping, and editing of genomes, the complete set of an organism's DNA. Progress in gene storage and related applications will rely not just on access to genetic information, but also computational power and huge quantities of synthetic nucleic acids with which to write, and later read, data.

Synthesis is an application intimately connected with storage—manufacturing DNA and mRNA at scale. Whether a laboratory or company chooses to purchase hardware or synthesis-as-a-service (SynaaS), sequencing remains a crucial component of several processes at the core of the bio revolution.[28] Synthetic DNA can be inserted into organisms, changing their genetic composition and ultimately physical properties, or used for storage and other genomic applications.

Discovery involves finding new patterns in gene expression interactions, and novel molecules to produce biomaterials, pathogens, and therapeutics. Discovery-based elements of the bioeconomy face some of the same barriers as those engaged in DNA sequencing, synthesis, and storage. High synthesis and cloud computing costs are, in turn, inhibiting discovery of new chemical and biological interactions that could be used to drive progress in the bioeconomy.[29]

Editing involves manipulating genotypes to produce desirable changes in organism phenotypes, as in the CRISPR/Cas9 gene editing system. Since its discovery in 2012, CRISPR/Cas9 has been used for a wide variety of tasks beyond editing, to include establishing cancer models, investigating the mechanisms behind drug resistance, and understanding the function of gene non-coding regions.[30] The size of the global CRISPR genome editing market is estimated to exceed $4 billion by the mid-2020s.[31]

Growth involves incubating and scaling the in-vitro cultivation of new cells, tissues, and even whole organisms. Here, space and equipment are potential barriers to biotechnology commercialization. These include fermentation units for large-scale production of microorganisms, clean-rooms for growing cell tissue, and massive tracts of land on which to build cultivators for carbon-dense microalgae.[32] Land use is particularly important to agricultural elements of the U.S. bioeconomy, but the precise costs are not standardized, and poorly understood. A 2014 Harvard study estimated that, "For a scenario in which algae-based biofuels provide 3.5 percent of the transportation fuels in the European Union in 2030, the system with the highest land productivity needs 17,000 sq km to produce 850 PJ/yr"—a land mass approximately the size of Connecticut.[33] Growth segments of the bioeconomy therefore should focus on developing fuels that are more efficient, or developing alternative or repurposed spaces for cultivation.

Conversion, also called "back-end processing," involves extracting and harvesting food, fuel, materials, and medicine from organisms that were engineered to produce them. It includes, for example, the extraction and purification of reagents used in biopharmaceuticals. New technologies and processes are designed to minimize waste and repurpose every component of a living organism—a "circular bioeconomy."

As policymakers grapple with the changing shape and nature of the bioeconomy, they will be well served conceiving of a particular enterprise or technological breakthrough as belonging to one or more of these eight categories. But the tools, techniques, and procedures driving growth in the U.S. bioeconomy today are slightly different in shape and form, and no less important to understand.

Drivers of the Bio Revolution

At its most basic, the "bio revolution" is about increasing mankind's ability to read, write, and edit RNA and DNA. Many separate capabilities have contributed to this effort, including the DNA sequencing, editing, and synthesis steps outlined above; as well as the fields of synthetic biology—the ability to understand, create, and manipulate biological parts to create new organisms and functions; the "resolution revolution"—the development of new instruments that enable measurement and visualization at nanometer scales; and "big data biology"—the computational capacity to deal with huge amounts of data, especially genomic and ecosystem data.

Each of these fields promises to fundamentally change the way humans produce food, medicines, materials, and energy—none more so than synthetic biology, itself a plethora of activities and industries ranging from data science to cell engineering and fabrication.[34] The building blocks of synthetic biology applications include technical components that may read as foreign to the layperson—like oligonucleotides, synthetic DNA, enzymes, cloning technology kits, synthetic cells, chassis organisms, and Xeno nucleic acids. But scientists, academic institutions, and enterprises interact with these components to generate new products like foods, biomedical applications, materials, and energy.

- *Foods* include agricultural products themselves, but also biomarkers and other tools used in food safety and inspection. Existing government funding opportunities regularly extend to agricultural elements of the bioeconomy, but the U.S. approach to supporting plant-based biofuels has not been impactful. Researchers in China have been far more active in publishing academic research that makes use of CRISPR for agricultural applications. Between 2014 and 2017, China accounted for 42 percent of CRISPR-based plant genome editing studies worldwide, to the United States' 19 percent.[35]
- *Biomedical applications* include synthetic organs, tissues, and blood for therapeutic applications, but also medical devices, lubricants, and sanitizing agents. Biomedical textiles such as heart valves, sling implants, stents, and mesh are another promising category of synthetic biotechnologies that may greatly enhance the speed and efficiency with which people heal from traumatic accidents or disease.[36]
- *Materials* include synthetic materials with novel properties—like biofilms intended to stave off infection, and mycelium, a self-propagating fungus for building construction—but also scalable production of age-old products like concrete.[37]
- *Energy* is focused primarily on accelerating growth of organic matter (biomass), which can be converted to ethanol and burned as fuel. Ethanol and biodiesel accounted for 11 percent of gasoline consumed in the United States in 2019.[38] But the pricing model for biofuels is not yet aligned with market incentives: The United States has heavily subsidized the production of corn-based ethanol in the Midwest, but its share of gas consumption has been slow to grow.[39] Alternative forms of biomass, like microalgae, could prove more energy-efficient and cheaper to produce. However, for at least the past decade, biofuel prices have remained relatively stable, and innovation appears to have slowed.[40]

A U.S. industrial policy for biotechnology cannot be so narrow in scope as to support only a few steps of biological processing, or a handful of synthetic biology products. Its principal aim should be to support U.S. biotechnology researchers and enterprises across diverse specializations, techniques, fields, and levels of technological maturity. Success rests on improving access to resources.

Measuring Success in U.S. Biotechnology Development

A previous CNAS report argued that U.S. policymakers would need to build the capacity to monitor and evaluate the inputs and processes relevant to technology strategy and industrial policy—such as research and development (R&D) spending needs, workforce issues, barriers to innovation, infrastructure shortfalls, and supply chain constraints, among other issues.[41] This report attempts to measure the health and outlook of the U.S. synthetic biology industry and broader bioeconomy by examining U.S. access to four resources crucial to technological growth in any context: equipment, personnel, information, and capital. It concludes that the United States still possesses an advantage in each of these fields—but that the U.S. government still has ample opportunities to unleash the full potential of its biotechnology industry.

Equipment

While not as pronounced as in fields such as semiconductors or green technology, access to equipment is a potential bottleneck in U.S. biotechnology development—though its precise impact depends on the activity and industry in question. This study identifies a handful of potential U.S. biotechnology equipment access issues through subject matter expert interviews and literature review, including steel fermentation units for microorganisms, industrial control software used in large-scale agricultural cultivation, and DNA synthesis—both in the form of synthetic nucleic acid sequences and "desktop" synthesizers capable of making it.

Although the United States does not yet lag any country in producing any of these kinds of equipment, failing to secure U.S. supply chains for these devices could risk hamstringing biotechnology innovation in the long term.

One rate-limiting factor for the bioeconomy may well become fermentation tanks—huge, stainless steel vats in which to grow microorganisms or otherwise process biological materials. These chambers, typically manufactured using stainless steel, are expensive and resource-intensive to produce.[42] Success in building large-scale biorefineries across the United States will require a huge amount of steel, which has been hit hard in recent years due to the COVID-19 pandemic and the closure of many steel and aluminum plants in the United States.[43] As in other common bioeconomy equipment supply chains, most of the high-end suppliers of clean-room and microbe chamber technologies are based in the United States—though others, like Japan's Airtech and Germany's Octanorm, easily could be integrated into U.S. supply chains.[44] Beyond access to steel, one other issue worth monitoring is that these kinds of fermentation units are prone to failure if seal rings are corroded, for example, by sulfate-producing bacteria—which is a common issue in the oil and gas industry.[45]

A scientist runs insect matter through a machine at the Algenex production plant in Madrid, Spain, on February 8, 2021, to help inform the company's expansion from animal to human vaccine development during the COVID-19 pandemic. The importance of biotechnology equipment emphasizes the United States' need to protect supply chains while securing channels for innovation. (Pablo Blazquez Dominguez/Getty)

One other potential barrier to innovation, particularly for agricultural startups, lies in access to industrial control software. Only a handful of applications exist to operate complex biorefinery facilities, with some of the most well-known brands being Aspen Plus, SuperPro Designer, and CAPCOST, which is used for managing energy and financial services.[46] These systems can cost up to $300,000 for a single commercial license, which is often cost-prohibitive for cash-strapped startups attempting to design products that are interoperable with existing refinery platforms. The U.S. government could better sustain its leadership in the emerging bioeconomy by subsidizing access to these kinds of control systems, funding the creation of competitive applications, or pooling access to licenses via some kind of public-private partnership.

Finally, DNA synthesis is one other area where the United States appears to lead but risks falling behind if companies fail to prepare for potential changes in technological capabilities and market dynamics. Among both the hardware-based synthesizer and SynaaS industries, U.S. companies own significant market share and are considered industry leaders.[47] But European institutions, such as France's DNAScript and UK-based Nuclera, stand as leaders in the emerging trend of "desktop" DNA synthesizers.[48] Their products can fabricate proteins, microfluidics, and DNA on demand, and could drastically expand the impact and availability of synthesized nucleic acid sequences. Ensuring their continued import to the United States will be important to sustain U.S. leadership in biotechnology over the next decade.

Personnel

A growing skills gap threatens to constrain U.S. progress in biotechnology. Having enough well-trained and qualified personnel working at laboratories, agricultural research stations, and medical institutions appears to be the greatest bottleneck throttling explosive growth in the U.S. bioeconomy. Talent is also the resource China has made the most substantial progress in addressing vis-à-vis the United States.

Education is a significant component of the U.S. biotechnology skills gap. As in other countries, most pathbreaking biotechnology research in the United States is conducted by career scientists with PhDs. Subject matter experts say there are few substitutions for the credential, at least when it comes to generating novel and high-impact basic research.[49] Here, the writing on the wall is bleak: Nationwide, universities in the United States produce far fewer STEM PhDs each year (34,000) than universities in China (50,000), and this is particularly true for the biomedical sciences. China currently graduates about 10,000 health sciences PhDs each year, to the United States' 3,000.[50] The gap is expected to widen substantially by 2025.[51] An industrial policy focused on supporting the U.S. bioeconomy would need to significantly scale up educational investments and scholarship opportunities for students pursuing biology-adjacent PhDs.

Even if the United States succeeds in graduating more PhDs, increasing the volume of credentials will not be enough to sustain U.S. leadership in biotechnology. For their part, research institutions also must provide opportunities for credentialed candidates, such as creating and maintaining postdoctoral programs. In the United States, holding a biology-related PhD primes a person to take a position as a principal investigator. A gender gap also undermines the United States' innovative potential: Women are less likely to be appointed to tenure-track research positions at universities and less likely to be promoted to senior leadership roles, and their average mid-career salaries trail those of their male academic counterparts by more than 7 percent.[52] Concluded one subject matter expert, "The route to a doctorate in the life sciences or bioengineering is long, hard, fraught with well-documented discrimination against women and minorities, extremely costly, and in the vast majority of cases, results in much lower incomes than one would earn with a two-year MBA. . . . What the United States needs is a substantive review and upgrade of science education from grade school through postdoctoral work."[53]

> **An industrial policy focused on supporting the U.S. bioeconomy would need to significantly scale up educational investments and scholarship opportunities for students pursuing biology-adjacent PhDs.**

As the bioeconomy continues to evolve, there will be more opportunities for non-PhDs to enter the workforce and take on roles in refinement, process management, business management, and technology transfer. Here, technical and vocational training can be a compelling alternative to a PhD, or even four-year university programs. Johns Hopkins University, for example, offers a certificate in biotechnology enterprise focused on "managing science and business" via biotechnology marketing and business development.[54] Several community colleges offer biotechnology certificates for entry-level bioscience laboratory work, but it is too early to tell whether or when the job market may correct to offer opportunities targeted at people who hold these credentials.[55]

The U.S. government has failed to elevate biotechnology to the same degree it has promoted international physics and robotics competitions for young people. One example of this is in poor U.S. performance at international science competitions like the International Genetically Engineered Machine competition (iGEM) hosted in Boston each year. The competition typically attracts 7,000 students from 40 countries each year, with most teams coming from the United States.[56] But even with the home-field advantage, a U.S. team has not been the top team in any of iGEM's high school, undergraduate, or postgraduate competitions since 2015.[57] By comparison, teams from China have won three out of the past four years' high school divisions. One subject matter expert, a U.S.-based biochemist and former iGEM team leader, advised that "[Chinese and Indian teams] spend months preparing for regional competitions and qualifiers, while in the United States, coaches are trying to raise money just to go to Boston by using car washes and bake sales."[58] In addition to contributing to mankind's' collective understanding of biotechnology, iGEM and programs like it have the added benefit of persuading some students to pursue research careers in the health and life sciences.[59]

A final point on personnel management and training rests in technological literacy. Americans are generally ignorant of the biological processes that contribute so much to their economy—to say nothing of rapidly evolving capabilities—and this is particularly true for elected officials.[60] "We need to have more people," said one subject matter expert, "even if they aren't doing science, who are at least science-literate in political leadership."[61] She emphasized that "COVID-19 is not the same as biology," and that there is a dearth of biotechnology knowledge among senior government leaders, which makes it difficult to discuss different elements of the bioeconomy with any degree of specification.[62]

Information

Information—in the form of data, intellectual property, or implicit know-how—is the third driver of success in the U.S. biotechnology industry. The U.S. government has long relied on utility patents as means to incentivize innovation and protect intellectual property as they relate to biotechnologies. While there are significant limitations to referring to patents generated in a given year as an indicator of a nation's innovative capacity, biotechnology patents cover a wide range of processes, machines, manufacturing knowledge, and material composition.[63]

Today, U.S. companies dominate in international patent production. U.S. companies produced 5,812 biotechnology patents in 2021, far outstripping other leading economies like Japan (1,575) and China (1,539).[64] But growth in Chinese patent filings is cause for concern, as the number of annual biotechnology patents has grown 18 percent annually—eight times faster than the United States.[65] As U.S. leaders reckon with the best way to support the bioeconomy, they must weigh the risks of academic patent spoiling against the rewards of increased innovative output and commercialization. They also must recognize that there are uneven international patent opportunities in the field of biotechnology.

The United States has Cold War–era intellectual property protections to thank for its booming biotechnology industry. Passed in 1980, the Bayh-Dole Act and the Stevenson-Wydler Act "were instrumental in creating a technology ecosystem conducive for successful partnerships between the federal government and the private sector by providing universities, research labs, small businesses, and nonprofits the rights to any intellectual property resulting from federal research funding."[66] Bayh-Dole "was and is all about establishing the role of universities as stewards of patentable inventions produced with federal funds," establishing that the general public—American manufacturers and small businesses, inventors, scientists, and educators, and the federal government—ought to be the beneficiaries of research supported with federal R&D dollars.[67] It was partially because of Bayh-Dole that, between 1995 and 2005, the United States saw a wave of biotechnology patenting by small- and medium-sized biotech enterprises.[68]

A U.S. industrial policy for the bioeconomy ought to focus on maintaining and strengthening U.S. intellectual property protections, rather than weakening them. At the same time, the U.S. Trade Representative (USTR) and Department of Commerce should make it a priority to harmonize global protections—or lack thereof—on naturally occurring human genes. Some in industry view the Bayh-Dole Act as a relic of the Cold War that hampers rather than helps innovation.[69] They argue that encouraging mass patenting of research conducted at universities is harmful to U.S. innovation in the long term, because, said one participant, it "locks up" new technologies into "the basements of university archives," rendering them unusable by industry for a period of several decades.[70] But this argument misses the fact that U.S. competitors, too, have upheld robust patent frameworks as systems to be emulated, and in some cases have started to weaponize patents against U.S. companies. In 2019, for example, China's National Intellectual Property Administration reformed its Patent Examination Guidelines to permit patenting inventions based on some kinds of human embryonic stem cells.[71] Recognition of the patentability of human stem cell technology likely will fuel innovation and promote its commercialization in China, as has been the case in the European Union. Since 2016, there has been a threefold increase in the number of patent cases brought by Chinese businesses against foreign firms operating inside the country.[72]

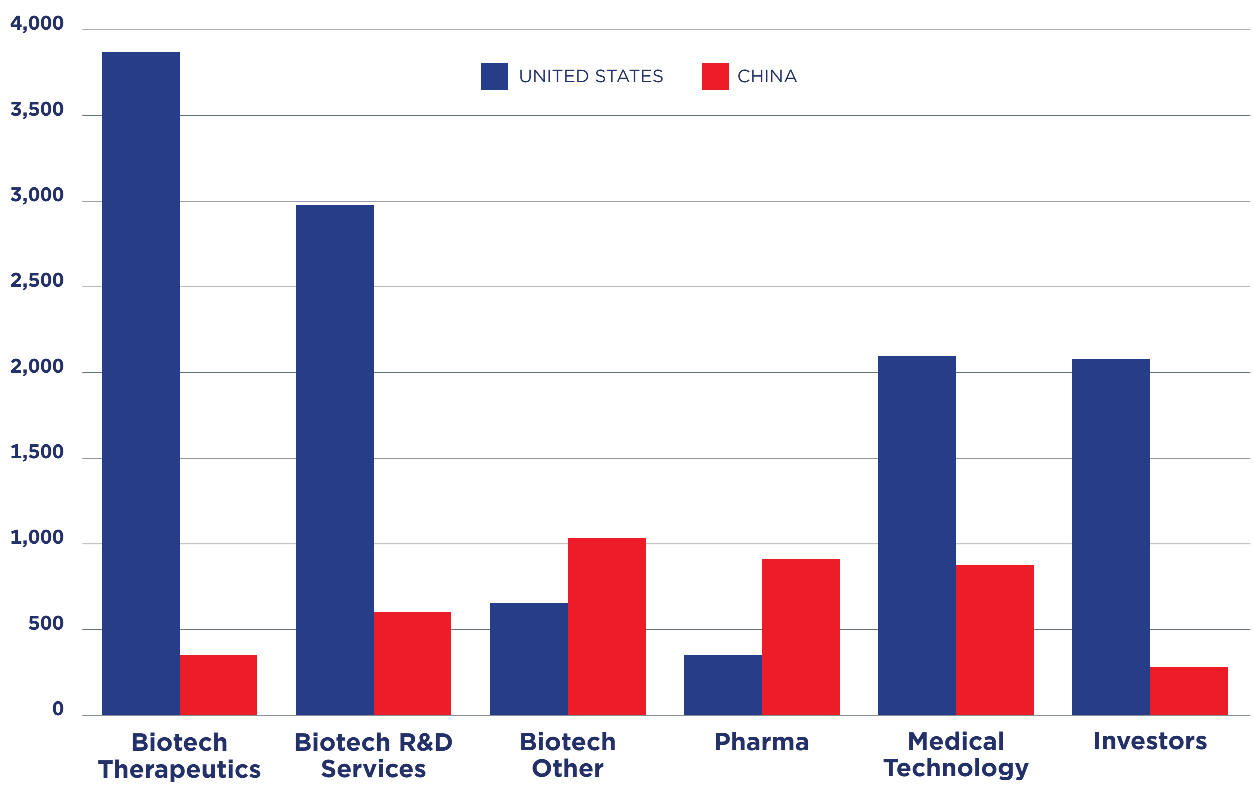
Capital

Finally, sustaining U.S. bioeconomic leadership will require a huge influx of capital at various stages of the technology development cycle. Venture capital is the core driver of U.S. biotechnology financing, especially in early funding rounds. The global synthetic biology industry has attracted approximately $18 billion in investment over the past decade, with total market value in 2021 being reported at $9.5 billion.[73] The focus of a U.S. industrial policy for the bioeconomy should be on enabling industry to capture as much of that market as possible.

One indicator of potential growth lies in opportunities for public funding. The National Institutes of Health (NIH) regularly publish announcements of funding opportunities related to synthetic biology, allocating several million dollars to related projects each year. NIH also operates a Synthetic Biology Consortium, which meets annually to discuss research breakthroughs.[74] Recent projects have included deep dives into synthetic biomarkers, cancer treatment, personalized immunotherapy, and biologically inspired computer circuits.[75]

Further down the technology development cycle are joint ventures, startups, and established biotechnology enterprises. The United States appears to be leaps and bounds ahead of China when it comes to private-sector capital allocated in the name of biotechnologies. By some estimates, the United States occupies 59 percent of global value share in biotechnology to China's 11 percent.[76] As of May 2022, Biotechgate, a database comprising more than 60,000 biotechnology companies, lists the United States as having the largest number of biotech enterprises in the world (12,064), far outstripping China's 4,053. The platform's USA Life Sciences database puts the number of U.S. enterprises significantly higher, at about 18,000.[77]

Number of Active Biotechnology Enterprises in the United States and China



Source: Adapted from Biotechgate.[78]

The relatively open and safe U.S. investment environment appears to be a strong driver of continued investment in the biotechnology industry. Of course, the sheer number of companies operating in the biotech space is a poor marker of quality: It might take just one private or state-owned company to lead the global bio revolution. But so far, in terms of capital, the United States appears to have a significant lead.

Finally, the U.S. government also has shown real progress in amassing and directing private-sector capital in support of biotechnology. Subject matter experts praised the work of the U.S. Department of Defense (DoD) in establishing a Bioindustrial Manufacturing Innovation Institute, BioMADE. The $87 million initiative was designed to act as a magnet for private-sector investment in emerging biotechnologies and met with significant results: $87 million in DoD funding was combined with over $187 million in non-federal cost share from 31 companies, 57 colleges and universities, six nonprofits, and two venture capital groups distributed across 31 states.[79] BioMADE publishes regular calls for biotechnology project applications designed to uphold U.S. norms and values.[80] Clearly, there is demand for additional public-private cost sharing mechanisms to dilute risk for venture capital investors. Discussing BioMADE's initial endowment, one subject matter expert quipped, "You could add a 'zero' to that $87 million, and it would be even better."[81]

Mitigating Risks to the Emerging Bioeconomy

At the same time that a U.S. biotech strategy seeks to promote U.S. economic and security interests, it also should seek to protect the emerging bioeconomy against threats that would hinder its development. The U.S. government's relationship with the biotechnology industry historically has been defined by concern about preventing deliberate or accidental misuse. To succeed in crafting a competitive biotechnology strategy, leaders in Washington will need to rethink their approach to risk management. A U.S. strategy to promote the bioeconomy should focus principally on mitigating risks to sustained innovation, which stem from an unevenly enforced regulatory regime, as well as risks of espionage and intellectual property theft at the behest of foreign governments—namely the People's Republic of China.

During and since the Cold War, much of the conversation about biotechnology in Washington has centered around risks—mainly as they relate to biosecurity. For personnel in the Departments of Defense and Commerce, some of the most common heuristics with respect to biotechnology today are rooted in memory of the Soviet biological weapons program in the 1960s and 1970s, the Aum Shinrikyo subway attacks in Japan in the 1990s, and the anthrax letters of 2001.[82] Debate about the origin of COVID-19 spurred a similar conversation about laboratory safety protocols in the United States and China, and the Chinese Communist Party has actively sought to foment uncertainty and cast doubt on the safety and reliability of U.S. industrial control processes.[83]

> **To succeed in crafting a competitive biotechnology strategy, leaders in Washington will need to flip the long-standing approach to bio-risk on its head.**

To succeed in crafting a competitive biotechnology strategy, leaders in Washington will need to flip the long-standing approach to bio-risk on its head. What if the world had not developed the polio vaccine, penicillin, or pacemakers?[84] A biotech strategy that obsesses over bio*security* risk is bound to be reactive and slow-moving, and risks missing the reality that institutions in China are moving ahead with developing these technologies—and setting norms around their use.

In their efforts to promote a more competitive bioeconomy, policymakers also must acknowledge the potential for more anodyne yet widespread risks to U.S. biotechnologies, including stifled innovation and the theft of intellectual property, which arise from both the muddled U.S. regulatory environment and the relatively relaxed approach to international scientific collaboration.

A Demanding but Opaque Bureaucratic Straitjacket

The greatest concern for the bioeconomy is that the U.S. innovation engine will simply run out of steam. Although indicators related to equipment, personnel, information, and capital paint a generally rosy outlook for U.S. biotech development, scientists and entrepreneurs point to the U.S. regulatory environment as one that creates uncertainty, imposes high costs, and ultimately stifles innovation in the industry. Nearly all of the subject matter experts consulted in the preparation of this report complained about the U.S. Coordinated Framework for the Regulation of Biotechnology.[85]

The coordinated framework is the guiding authority under which the U.S. government regulates biotechnology products. This mandates various federal agencies to ensure the safety of biotechnology derived products under their purview by applying their authorities as assigned by Congress. These products span agriculture, energy, medicine, and materials. Established in 1986 by the White House Office of Science and Technology Policy (OSTP), it is today implemented by the U.S. Food and Drug Administration (FDA), Department of Agriculture (USDA), and Environmental Protection Agency (EPA).[86] Since its inception the framework has been updated on a handful of occasions, most recently in 2017, to account for changes in biotechnology development. One of the problems with the framework—or at least the way it has been implemented—is that it creates an unpredictable regulatory environment by applying varying levels of scrutiny to different biotechnology products "based not on the degree of hazard they carry or the risk they present but rather primarily on the process used to create them."[87] Significant differences in the coordinated framework's implementation can disincentivize companies from generating new classes of products, or dissuade them from using modern bioprocessing techniques.

The trigger for regulating genetically engineered products and new biotechnologies is so arbitrary and unrelated to hazard or risk that, in some scenarios, its application is often unclear even to regulators. Ironically, this uneven approach to enforcement can lead to less safe practices in the biotechnology industry: Some subject matter experts interviewed said they knew of other stakeholders in their industry who were not acquiring licenses and approvals to sell genetically modified products under the coordinated framework even though they probably should be. Others said they were personally deterred from using some more modern gene editing processes, like CRISPR—which could trigger a costly review process under the coordinated framework—in favor of older, less precise techniques which have essentially been grandfathered out of consideration.[88]

What the current regulatory approach gets right—and what should remain in place even after reform—is the notion that government should not focus on the process by which a given synthetic biology product is created, but on its potential impacts to society, human health, and the environment.[89] A scientifically defensible, more modern regulatory approach would focus regulatory reviews on safety hazards and tailor their mitigation measures to the level of risk exposure, rather than giving rise to limits on whole classes of technological processes. As regulatory agencies are now exercising their authorities under the framework , industry experts complain that they often do not know which tech category most accurately describes their product, or whether it should be reported to the EPA or USDA.[90] On top of sometimes arbitrary definitions of "genetically modified" products, the outdated and uncertain approach to biotechnology regulation creates steep compliance costs and legal fees, adding to the burden of establishing a biotechnology enterprise in the United States.[91]

Challenges with International Collaboration

Given the expanding scope and impact of the global bioeconomy, rates of both international collaboration on academic research and cross-border joint ventures are poised to increase over the next five to ten years. More than 40 countries have created formal strategies for promoting their bioeconomies.[92] Still others have developed separate strategies for promoting biotechnology and biobased production, which relies on the substitution of biological resources for fossil fuels.[93] Subject matter experts also are broadly optimistic that U.S.-China cooperation in biotechnology will yield positive results. One said, "You wouldn't be able to have a world-class science program without collaborating with China."[94] But experts also are clear-eyed that such interactions will create new vulnerabilities for intellectual property theft and industrial espionage.

> **Biotechnology is a rich target set for Chinese technology scouts and intelligence collectors, and policymakers in Washington should expect cases of industrial espionage to increase over the next decade.**

The Chinese government has established its own industrial policies that in some cases compel or incentivize Chinese citizens to engage in acts of espionage, trade secret theft, and visa fraud, among other crimes. In 2019, for example, Zaosong Zheng was convicted of smuggling 19 vials of biological research specimens in a sock through Boston's Logan Airport; the specimens were based on research he had conducted at the Harvard-affiliated Beth Israel Deaconess Medical Center.[95] The incident was far from isolated. In his 2022 speech before the Reagan Presidential Library, Federal Bureau of Investigation (FBI) Director Christopher Wray specified that the Bureau was investigating more than 2,000 active cases of Chinese agents attempting to steal U.S.-origin information and technology.[96] Charging documents reveal that at least some, and probably many, of these cases are related to biotechnologies. A 2021 Center for Security and Emerging Technology report found that 25 percent of tech projects identified by China's science and technology diplomats were related to biopharmaceuticals and medical devices.[97] News reports likewise demonstrate that agriculture has been a major focus of China's state-backed espionage campaigns for a decade or more. Biotechnology is a rich target set for Chinese technology scouts and intelligence collectors, and policymakers in Washington should expect cases of industrial espionage to increase over the next decade.

Without taking appropriate precautions, the United States risks forestalling the progress it has made in novel biotechnology techniques. Subject matter experts agreed that international collaboration on biotechnology had produced outstanding results in responding to the COVID-19 pandemic, and that a U.S. industrial policy for the bioeconomy should seek to maximize scientific engagement with other like-minded and industrious states. "That being said," said one participant, "we need to make sure we aren't allowing companies to be bought out by the Chinese government without recognizing the security risks."[98] Striking this balance has been a perennial struggle for both the Trump and Biden administrations, and it likely will continue to shape the contours of U.S. industrial policy toward the bioeconomy.

Recommendations to Regenerate the U.S. Bioeconomy

To sustain its global leadership in biotechnology development, the United States should embrace an industrial policy tool kit that is focused on improving access to the four key resources at the heart of technology development—equipment, personnel, information, and capital. It also should seek to fix shortcomings in "soft" regulatory infrastructure that risk derailing the U.S.-led bio revolution: Perhaps the most important obstacle to innovations in agriculture, industry, and biomedicine is the existence of regulatory policies that apply the maximal oversight to safe, albeit new innovations, adding years and tens of millions in costs to their development. Streamlining the U.S. approach to biotechnology regulation and maintaining an edge in equipment, personnel, information, and capital will be essential to build and scale a bioeconomy that works for all Americans.

Equipment

Equipment access is a core driver of U.S. progress in biotechnology, but policymakers are faced with difficult choices in whether and how to facilitate greater access to potentially sensitive or dual-use technologies, such as DNA sequencing and synthesis, in the long term. A U.S. strategy to promote the bioeconomy should focus on improving access to equipment at the core of the bio revolution: computing and data sources used in genomics, and hard infrastructure used in DNA synthesis and fermentation.

CLOUD COMPUTING AND DATA SOURCES

Broadly speaking, small biotech and pharmaceutical companies find cloud computing very attractive with only minor drawbacks, which can be mitigated with adequate planning and proper implementation.[99] In the biomedical field, cloud usage has varied due to varying levels of security and other features required for operation. One way to accelerate cloud use is to expand the number of federally funded scientific data sets being made available in public clouds. For example, Human Microbiome Project data funded by NIH is already available on Amazon Web Services simple storage service.[100]

- *Congress should pass the America COMPETES Act of 2022*, which authorizes the creation of a National Engineering Biology Initiative.[101] The initiative should pool and subsequently distribute access to data used in biotechnology discovery applications for investigators and biotechnology startups.
- *The National AI Research Resource Task Force should formalize a National Research Cloud (NRC)* for distributing access to cloud computing power for researchers and enterprises. Once operational, biotechnology researchers and enterprises, in addition to artificial intelligence researchers, should be provided access to the NRC.[102]

EQUIPMENT SUBSIDIES AND TAX BREAKS

Short of directly controlling the price of goods and services, the United States could accelerate bioeconomic growth by subsidizing the costs of DNA sequencing and synthesis for innovative, cash-strapped startups. A simple format for such an incentive could be to make the cost of DNA synthesis tax-deductible up to a given value for businesses that earn less than $1 million in revenue, or to permit DNA sequencing to be eligible for a new form of biotechnology innovation tax credit.

- *The White House should launch a bioeconomy opportunity tax credit*. Biotechnology startups should not have to worry about affording crucial resources like cloud-based computing, one-time gene sequencing fees, or expensive licenses for industrial control software. Businesses earning less than $1 million in revenue should be eligible to write off at least $50,000 in biotechnology-related equipment and software expenses—and the ceiling should be doubled for businesses established within three years of its enactment.

DEFINITIONS AND STANDARDS

It is time for the National Institute of Standards and Technology (NIST) to harmonize definitions for classes of biotechnologies expected to manifest in the next decade. Although it may be too early to stipulate and regulate their technical features, the U.S. government can offer to discuss interoperability and set standards for domestic markets.

- *The NIST should establish and update clear definitions, interoperability parameters, and technical specifications for fermentation units* used in the large-scale cultivation of microorganisms, as well as novel, genetically engineered materials and devices for medical use, to ensure that these products remain safe and interoperable with one another. To do so, NIST should convene public-private advisory bodies that include members of industry and academia at the forefront of biotechnology applications. Soliciting input from the public and private sectors will help NIST adopt flexible approaches to update rulemaking notices to adapt to changes in technology.

Personnel

A diverse and well-trained workforce is undoubtedly the United States' single largest bioeconomic strength relative to any other country. U.S. universities sport high-quality research programs with ample prestige to sustain international collaboration with like-minded partners. But there are several other tools at the United States' disposal, which it also could bolster with the help of allies and partners.

EDUCATION FUNDING

Since PhDs are likely to continue to be required credentials to make meaningful impact at the basic research level, the United States should fund significantly more of them. The U.S. government also should plan to fund vocational and technical education programs, including biotechnology licenses and certifications, to aid in the generational transition from a fossil fuel–led energy mix to one based on biofuels and clean sources of energy.

- *The White House Office of Personnel Management and Budget should establish a BioCorps Scholarship for Service* program modeled after the CyberCorps Scholarship for Service, which would support stipends, tuition, and allowances for PhD students in the general area of biotechnology. The service component of the scholarship should be led by the National Institutes of Health and Centers for Disease Control and Prevention. The service obligation could be reduced to two years, and candidates should be allowed to delay their service obligation to immediately pursue further research or commercialize innovations derived from their years of study.

Then–U.S. Vice President Joe Biden addresses a biotechnology class at Miami Dade College on September 2, 2015. To curate a highly skilled and diverse workforce for biotechnology, educational institutions and organizations must collaborate and invest in equal opportunities and partnerships. (Joe Raedle/Getty)

- *Congress should pass the America's College Promise Act*, the proposal to fully fund associate degrees for low-income students at community colleges across the United States.[103] Supporting community college education and laboratory certification programs can create alternative career pathways that support the U.S. bioeconomy.

YOUTH TALENT DEVELOPMENT AND UPSKILLING

The United States should embrace the power of competitive prize competitions. It should seek to create regional iterations of iGEM and set aside need-based financial aid to help students participate.

- *The Department of Education's Office of Elementary and Secondary Education should establish a Bio-Competition Grant Program* to cover the cost of after-school training, materials, and travel for teams participating in iGEM and other regionally and nationally recognized biotechnology competitions.

INTERNATIONAL TALENT EXCHANGE PROGRAMS

Policymakers should recognize that the United States and China are not the only two states involved in high-stakes competition in biotechnology. U.S. allies including South Korea, Japan, Singapore, and partners throughout Europe and Southeast Asia all are developing workforces capable of shaping the bioeconomy. For example, the U.S.–Republic of Korea joint statement issued by the Yoon and Biden administrations in 2022 called for high-level talent exchange programs in emerging tech fields like biotechnology.[104] Institutionalizing those forms of talent exchange will be essential to cross-pollenate innovative ideas and grow a workforce that thinks about interoperability from the get-go.

- *The Department of State should replicate or otherwise institutionalize the Quad STEM Fellowship* run by Schmidt Futures, which grants PhD funding to 100 students from Quad countries each year.[105] Governments can run a similar program at a much greater scale. This project should be endowed through shared funding from the governments of the United States, Japan, India, and possibly other like-minded allies like South Korea and Vietnam. A certain quota of PhD scholarships should be reserved for students pursuing a degree in biotechnology-related applications.
- *The Department of State's Lower Mekong Initiative should fund Agricultural Centers of Excellence across Southeast Asia.* Southeast Asian partners will be some of the hardest hit by climate change, and each remain central nodes in local and global food security. The State Department should offer technical assistance to regional groupings like the Indian Ocean Rim Association and the Bay of Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation. The United States can fund a network of research centers that solve regional challenges and contribute to environmental resilience and socioeconomic mobility.

IMMIGRATION REFORM

Many in Washington would prefer to eschew the topic for its political complications, but it is difficult to overstate the role immigration plays in sustaining U.S. innovation. Multiple subject matter experts interviewed in the course of this study argued that immigration is essential to U.S. leadership in the bioeconomy. Said one participant, "At some point the rate-limiting step in the growth of the bioeconomy is going to be people. That's a problem that can be fixed."[106] For decades, the American Dream has been enough to attract the world's best and brightest scientists, as well as hard-working aspirants looking to make an impact on the world. Academic literature on U.S. immigration policy illustrates its impact on the proliferation of knowledge clusters in the United States. For biotechnology, that includes places such as Boston (Charles River), San Diego, Piedmont (Research Triangle Park), the Bay Area, and Washington, D.C.[107] But these trends are starting to change as U.S. allies like Canada become more attractive alternatives for high-end STEM talent.[108] The path forward is clear: Congress needs to raise H-1B visa cap and hire more immigration officers. But mustering the political will to achieve even the most basic gains—like keeping the STEM Optional Practical Training program (STEM-OPT)—has proven increasingly difficult in the past decade.

- *Congress should vote to codify the recent expansion of the STEM-OPT* led by the Departments of State and Homeland Security. A February 2022 rulemaking notice by the Office of Personnel Management and Budget expanded STEM-OPT eligibility from two years to three, and greatly increases the number of fields eligible for the program.[109] Making this change permanent, and supporting longer-term immigration pathways, will support continued U.S. leadership in biotechnology.

- *Congress should double the H-1B visa cap* from 65,000 to 130,000 visas each year.[110] Amid global crises from climate change, the COVID-19 pandemic, and the Russian invasion of Ukraine, the world's best and brightest talent is increasingly mobile and willing to work in the United States. Bold action is necessary to transform these crises into opportunities.

Information

Information for and about biological processes and proposed regulations is crucial for sustained progress in the bioeconomy. From the perspective of the U.S. government, relevant informational assets include troves of genomic data collected by various federal agencies, the strong U.S. intellectual property protection regime, a flexible and transparent regulatory environment, and opportunities for expanded in-house data resources made possible by survey research.

GENOMIC DATA AND RECORDS SHARING

Various elements of the U.S. government collect large troves of medical records, drug trial outcomes, and genomic data, only some of which are released for public consumption. In addition to expanding the amount of data made available to university-affiliated researchers, the U.S. government should strive to build a world-leading gene bank competitive with similar efforts in China and Japan.

- *The NIH should establish a National Gene Bank equipped for 21st-century genomic research.* NIH's existing GenBank, an annotated collection of all publicly available DNA sequences, was founded in 2013. Updates to its public data holdings are only released every two months.[111] Creating a system that is updated in real time, with authorities and incentives to motivate private- and public-sector participation, is necessary to sustain U.S. progress in biotechnology research.
- *The FDA should establish a process to share its existing research data with scientists at universities and trusted research institutions.* The FDA's expansive collection of data, from both clinical trials for pharmaceuticals and diagnostic research, could spur innovation in basic research if provided to public research centers.

PATENTS AND INTELLECTUAL PROPERTY

The United States continues to support strong intellectual property protections for biotechnology processes and products. Cold War–era legislation, namely the Bayh-Dole Act, provides incentives for university researchers to innovate, and opportunities for them to commercialize and progress with technology transfer. These forms of patent protection are feats to be celebrated, not maligned.

- *Congress should broadly aim to preserve the U.S. system of intellectual property protection as it relates to biotechnology.* While contentious, the 2013 *Association for Molecular Pathology v. Myriad Genetics* case democratized access to genetic products at a time when nearly 20 percent of the human genome previously had been patented.[112] The result has been an open and competitive environment characterized by innovation in synthetic-biological products.
- *Congress should scale up funding for the U.S. Patent and Trademark Office.* The patent office needs to examine and issue patents faster. To do so, it needs to retain and improve training for existing patent examiners who have a history of being hired away by intellectual property firms as soon as they learn their trade.
- *The USTR and Department of Commerce should encourage U.S. allies and partners to relax protections of naturally occurring human genes* to promote further innovation in the global biotechnology industry. European laboratories are less likely to offer genetic tests to patients for fear of running afoul of patent restrictions, hampering innovation, and reducing opportunities for international collaboration.[113]

FLEXIBLE AND TRANSPARENT REGULATORY ENVIRONMENT

One of the United States' greatest economic strengths, across industries, is its transparent and relatively fair regulatory environment. Unlike in closed-door, autocratic systems, there are rarely snap changes to regulations of U.S.-produced goods and services. Agencies publish requests for public comment and take this input into account when making rule changes. Promoting growth in the bioeconomy will require an even tighter-knit, cooperative relationship between the agricultural, medical, materials science, and energy industries and government.

- *The FDA, EPA, and USDA should overhaul their implementation of the Coordinated Framework for the Regulation of Biotechnology.* To bring it in line with foundational principles, that regulation should focus on hazard identification and risk assessment/management/mitigation driven by data and experience, and the regulation should be proportional to the hazard involved. An updated approach should give weight to the expected safety impact of providing a given product or service—irrespective of the technical method used to derive it.

DATA COLLECTION TIED TO FEDERAL FUNDING

Data is one of the most powerful tools the U.S. government has at its disposal, and it can be materialized easily by attaching a compulsory survey to various funding mechanisms. Individuals and institutions that receive funding from the federal government can provide additional information about instances when they may have felt coerced by foreign trade partners or encouraged to share intellectual property under duress.

- *The Small Business Administration (SBA) should enlist the support of the FBI and Defense Counterintelligence and Security Agency (DCSA) in offering security guidance to Small Business Innovation Research (SBIR) and Small Business Technology Transfer (SBTR) funding recipients.* The SBA should collect survey information about awardees' experiences with attempted economic espionage, which should be shared with the DCSA and FBI. The U.S. government should shine a light on coercive economic practices, but it can do so only if it has ample information about when such activities are occurring behind closed doors.

Capital

Capital has been a major driver of the U.S.-led bio revolution. While private-sector investments have paid the largest dividends, government can play a much more active role in allocating capital and helping early-stage companies bridge the valley of death.

DIRECT FINANCIAL SUPPORT

The United States already provides significant public R&D funding for synthetic biology projects, though it is difficult to quantify exactly how much. By 2026, Defense Advanced Research Projects Agency (DARPA) and In-Q-Tel aim to help more than 150 laboratory research teams transition to full-fledged commercialization.[114] DARPA's early investments in mRNA-based vaccines also helped propel Moderna into the COVID-19 vaccination juggernaut that it is today.[115]

- *Congress should authorize significant increases in the budgets of several biotechnology industry incubators,* including a 50 percent increase in the SBIR and STTR programs run by the USDA, FDA, and EPA; research grants issued by the National Institutes of Health; funding for DARPA's Biological Technologies Office, and In-Q-Tel's biotechnology research portfolio.

PUBLIC-PRIVATE PARTNERSHIPS

In recent years the United States, like China, has attempted to consolidate and amplify private-sector investment in strategic emerging industries. The DoD's BioMADE initiative is a prime example of this kind of government-sponsored risk dilution in practice. But opportunities abound for democratic governments to more actively shape their biotechnology investment portfolios—for example, by extending loans to technology startups; or consolidating access to resources like cloud computing for firms who may not be able to afford it on their own.[116]

- *The DoD should request to expand the remit and budget of BioMADE*, and the Office of the Undersecretary of Defense for Research and Engineering should create redundant initiatives for specific biotechnologies, including novel sources of bioenergy and biomaterials.

Members of the U.S. House of Representatives leave the House chambers after voting on the Senate-passed bipartisan infrastructure bill on October 28, 2021. A key factor in the biotechnology revolution is securing strategic capital that can help promote U.S. leadership. (Samuel Corum/Getty)

- *Congress should establish the Industrial Finance Corporation of the United States (IFCUS)*, a new investment mechanism for public-private partnerships, which will act as a magnet for capital in strategic industries. IFCUS would support the U.S. biotechnology industry by providing low-interest loans for projects that might otherwise be deemed too risky by banks and venture capital firms. IFCUS is already designed and ready to see the light of day; Congress need only pass the Industrial Finance Corporation Act.[117]

CORPORATE TAX INCENTIVES

The United States has long subsidized some forms of bioeconomic output—namely corn-based methanol and ethanol production—but there are more productive, efficient, and sustainable options to drive growth in the U.S. bioeconomy in support of middle America.

- *The White House should work with state and local governments to establish a network of Biotechnology Industrial Opportunity Parks.* These special economic zones would include favorable federal and local tax structures, modeled after the oil industry's Foreign Trade Zones along the Texas coast, but for biorefineries across middle America.

INTERNATIONAL MARKET ACCESS

The United States should encourage European partners to relax their restrictions and end the stigma around genetically modified crops, thereby expanding U.S. market access and potentially driving an influx of foreign capital to U.S. biotechnology enterprises. Multiple subject matter experts called EU approaches to genetically modified products antiquated and argued that a Union-wide panic about genetically modified organisms in the 2000s seriously inhibited opportunities for international collaboration with the United States.

- *The USTR and Department of Commerce should advocate for relaxed restrictions on U.S. genetically modified agricultural exports* at the EU-U.S. Trade and Technology Council and amid negotiations over the Indo-Pacific Economic Framework. Antidumping and countervailing duties risk throttling the market for a major source of U.S. bioeconomic growth. Specifically, USTR should support indigenous developments in the EU that are increasing pressures to relax constraints first on gene edited products, and should hold World Trade Organization members accountable for anticompetitive market practices.[118]

Conclusion

To sustain its global leadership in the life sciences, the United States must adopt a more muscular approach to industrial policy. The urgency of the moment, the opportunity it provides, and the equity it promises to bring all portend a revolution driven by biotechnology.

But just as the United States has a unique opportunity to shape the trajectory of the bio revolution, so too should policymakers expect biotechnology to alter the socioeconomic fabric of the United States. New technologies, particularly those at the intersection of synthetic biology and agriculture, promise to regenerate the American economic growth engine.

Appendix: Structured Interview Questions

1. What do you feel are the primary drivers and barriers in the field of synthetic biology today? These could be related to investment, regulation, intellectual property rights, technical difficulty, or any number of issues.
2. If the United States were to undertake a "Manhattan Project" –like effort to promote its synthetic biology industry, what do you think that program would entail? What should it avoid?
3. What do you consider to be strengths of the U.S. biotechnology industry, relative to biotechnology enterprises in other countries?
4. In your opinion, has the United States done a good job of balancing between promoting and protecting its emerging bioeconomy? What could the U.S. government do to strike a better balance between these objectives?
5. In general, how much interaction does your industry have with companies and researchers based in China? Are you optimistic about the future of international collaboration in the field of synthetic biology?
6. How do you assess the maturity of the biotechnology sector in the United States, whether it's fragmented or very consolidated? Are there subsets of the biotech sector that have consolidated more than others, and if so, why?

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