NSCEB
National Security Commission on Emerging Biotechnology

APRIL 2025

REPORT SUMMARY

Charting the Future of Biotechnology

An action plan for American security and prosperity

Table of Contents

Message from the Chair and Vice Chair

We stand at the edge of a new industrial revolution, one that depends on our ability to engineer biology. Emerging biotechnology, coupled with artificial intelligence, will transform everything from the way we defend and build our nation to how we nourish and provide care for Americans.

In 2022, Congress charged the National Security Commission on Emerging Biotechnology (NSCEB) with developing recommendations to advance U.S. leadership in biotechnology for national security and economic resilience. What follows this letter is an action plan that, if executed now, will unleash private sector job creation in every corner of our country, reshore manufacturing, and free us from supply chain dependencies on China. It will ensure the United States—not China—endures as the best place for biotechnology discovery, invention, and entrepreneurship. And it will help keep our adversaries from using this powerful technology to gain battlefield advantage or geopolitical leverage.

In 1903, a bronze plaque was placed on the pedestal of the Statue of Liberty describing "A mighty woman with a torch, whose flame is the imprisoned lightning." The task before us is to unlock the unparalleled power and potential of American creativity and innovation—our nation's imprisoned lightning—to achieve enduring global technological leadership.

America has led in biotechnology since the 1970s, but the landscape is rapidly changing. A little over a year ago, we asserted that the United States was still ahead, despite considerable efforts by the People's Republic of China to surpass us. We now believe the United States is falling behind in key areas of emerging biotechnology as China surges ahead.

Congress wisely created our group ahead of biotechnology's coming inflection point. There is time to act, but no time to wait.

It is a privilege to lead our fellow Commissioners and talented staff in this work. We extend our deepest thanks to all who contributed to the development of these recommendations and to those who will help us achieve this vision for the American people.

Senator Todd Young
Chair

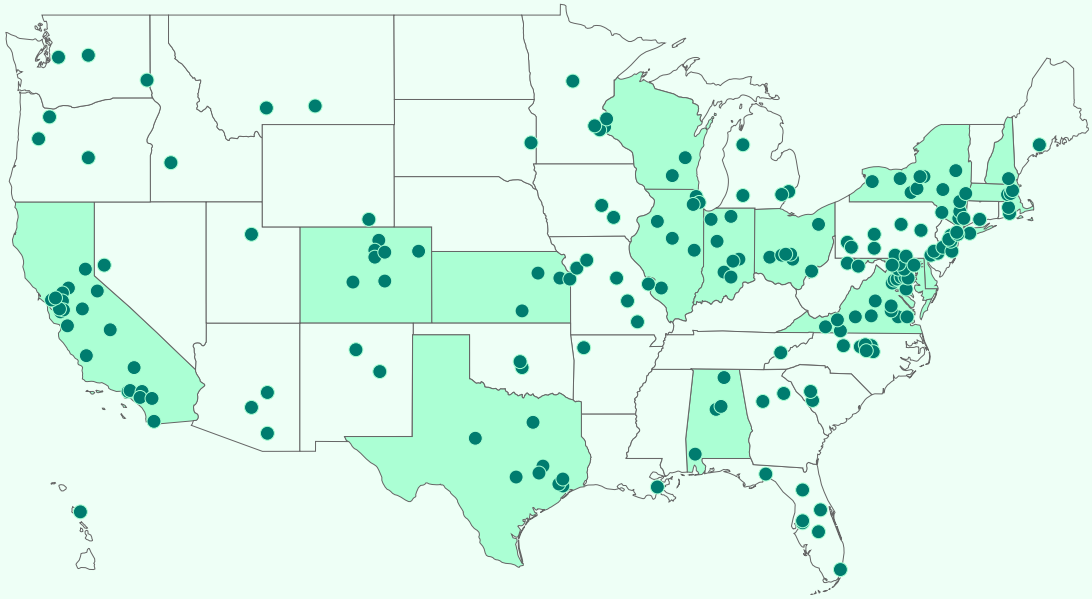
Dr. Michelle Rozo
Vice Chair

Outreach Map: Biotechnology is Everywhere

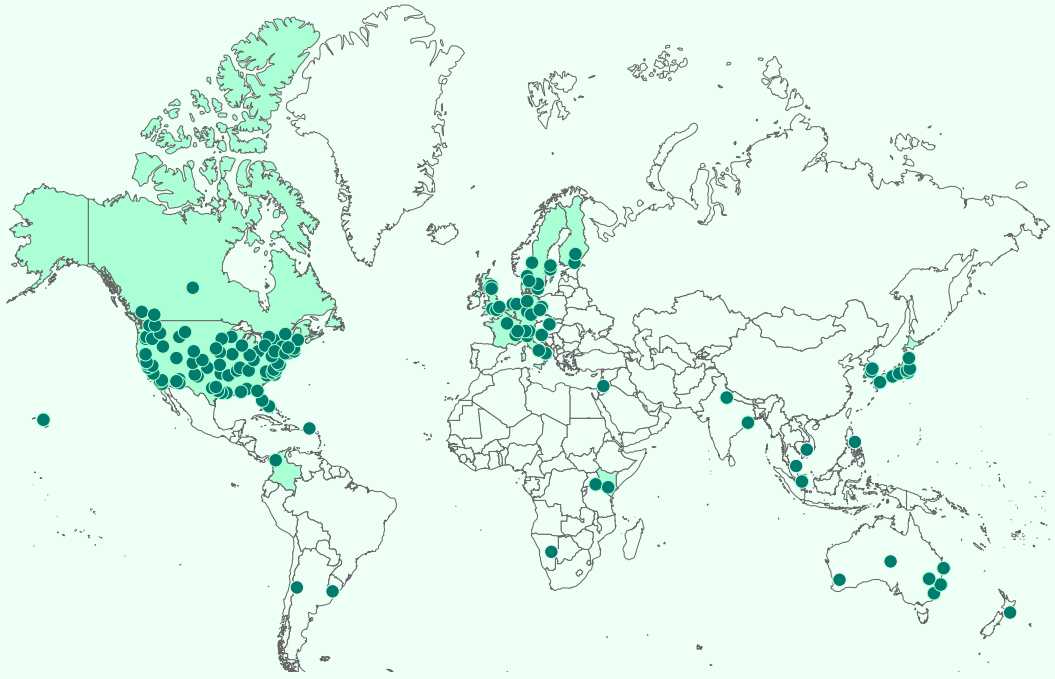
Once clustered on the coasts, American biotechnology is becoming a national industry of international importance. To assess emerging biotechnology, we met with thousands of experts and stakeholders across nearly every state and continent. We spoke with farmers, scientists, entrepreneurs, engineers, generals, scholars, and regulators. We've visited labs, factories, fields, hospitals, and bases. All of these perspectives have contributed to our recommendations.

● Outreach ○ Visit

National



Global



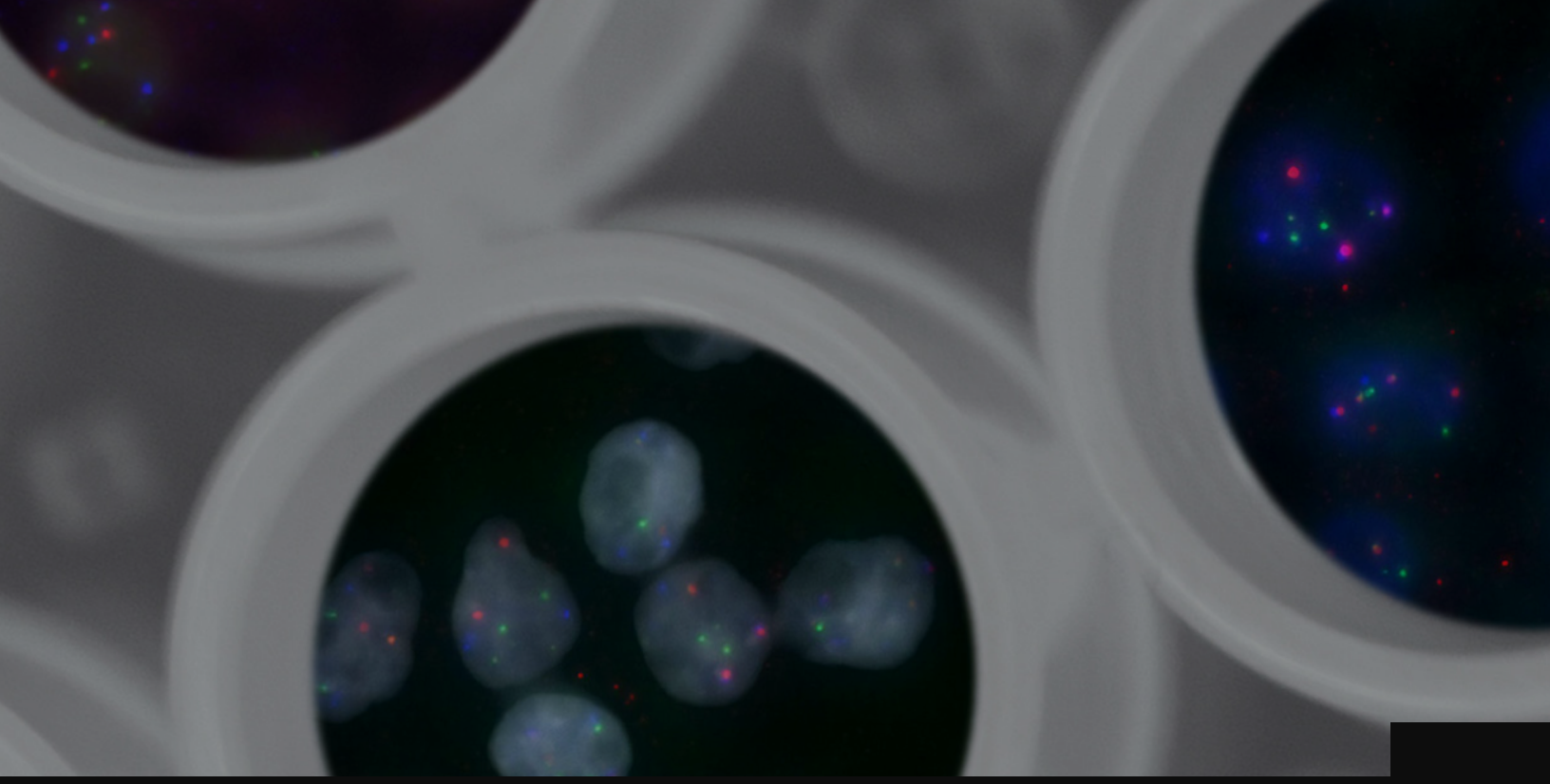
Executive Summary

Americans are already familiar with how the Chinese government conducts economic warfare with crucial technologies such as semiconductors: corner the supply chain, then choke it to weaken the United States. But this is not the last time Beijing will run this play, and it is not even the most dangerous version of it.

Imagine a not-so-distant future where researchers in Shanghai develop a breakthrough drug that can eliminate malignant cells, effectively ending cancer as we know it. But when tensions over Taiwan reach a breaking point, the Chinese Communist Party (CCP), the strategic apparatus of the Chinese government, hoards the treatment under the guise of national security, cutting off supply to the United States. After years of access, this lifesaving drug is immediately in shortage, requiring doctors to ration it while American biotechnology companies scramble to reconstitute production in the United States. The streets and social media overflow with people demanding that the United States abandon Taiwan. The Administration faces an agonizing choice between geopolitical priorities and public health.

This scenario is fiction. But something like it could soon become reality as biotechnology takes center stage in the unfolding strategic competition between the United States and People's Republic of China (China).

Based on two years of research and consultation with private and public experts, this report comes to a sobering, even frightening, conclusion: China is quickly ascending to biotechnology dominance, having made biotechnology a strategic priority for 20 years.[1] To remain competitive, the United States must take swift action in the next three years. Otherwise, we risk falling behind, a setback from which we may never recover.



Biology has been a well-defined scientific discipline for more than 200 years. But thanks to breakthroughs in artificial intelligence (AI), engineering, and automation, biology is becoming more than just a field of discovery; it is becoming a field of design. Chemistry made this leap in the 1880s when chemical engineering unlocked rubber, plastic, and synthetic fibers, materials that transformed society.[2] Physics followed in the 1940s, when academic theory led to the atomic bomb, semiconductors, and computers. Now for the first time in recent history, the United States finds itself competing with a rival over a new form of engineering that will create tremendous wealth, but, in the wrong hands, could be used to develop powerful weapons. **Countries that win the innovation race tend to win actual wars, too.**

We are entering the age of biotechnology, a time when biology is the basis of innovation. From more productive seeds and targeted cancer therapies to the possibility of genetically enhanced soldiers, biotechnology's reach extends far beyond the laboratory. Every strategic sector—including defense, healthcare, agriculture, energy, and manufacturing—can be advanced by biotechnology, but also breached by it, too. These are not just matters of scientific achievement; they are questions of national security, economic power, and global influence.

Falling further behind would signal a global power shift toward China and create an array of new strategic challenges for the U.S. government:

- **What would it mean for world order if China developed biological means for dramatically extending human life or enhancing cognitive capabilities?**
- **Who will control the biological intellectual property (IP), from sustainable energy to advanced agriculture, that may prove as vital in the 21st century as fossil fuels were in the 20th?**
- **What would the implications be for global security if an adversary engineered pathogens and used them against us?**

China's recent success across core biotechnology capabilities, including AI-driven drug discovery platforms and biomanufacturing, signals that they may soon eclipse us. And if that happens, the United States may never be able to catch up. In previous generations, we might have had decades to maintain our lead, but now, the window to act is just years.

AI is accelerating us toward this inflection point. Using tools such as AlphaFold from Google's DeepMind, scientists have predicted hundreds of millions of intricate 3D protein structures, providing a deeper understanding of biology.[3] What once took months or even years can now be done in a weekend. With AI, along with gene editing tools like CRISPR, scientists will soon be able to create materials from scratch, prevent illnesses at the level of genetic code, and develop more resilient crops and livestock.

Though the United States' advantage was once thought unassailable, China has emerged as a powerhouse in AI-enabled biotechnology. For example, the CEO of Chinese technology giant Baidu also established BioMap, a life sciences and AI firm with offices in Beijing, Suzhou, Hong Kong, and Palo Alto.[4] BioMap announced the first life science AI foundation model to hit 100+ billion parameters, which it calls the largest of its kind.[5] In 2024, BioMap signed an agreement with the Hong Kong Investment Corporation, a government-owned fund, to launch a bio-computing innovation accelerator program in Hong Kong to develop the biotechnology ecosystem there.[6] It and other biotechnology companies use AI to design biological products. Companies like these then work with China's leading biomanufacturer, WuXi AppTec, to produce them at scale in its global network of facilities. WuXi AppTec, which has transferred American IP to the Chinese government, manufactures essential ingredients for widely used medications that treat leukemia, lymphoma, obesity, and Human Immunodeficiency Virus (HIV).[7]

China has long been proficient at acquiring IP from abroad—through both legal channels (such as mergers and acquisitions) and illegal channels (such as theft). Now it knows how to put that IP to work through state-backed entities. A multinational company invents a key drug, a national champion like WuXi AppTec scales it up, and then the CCP can control a global supply chain. China has accomplished this feat through massive investments in its domestic biotechnology sector, including a 400-fold increase in biopharma R&D spending, over the past decade.[8] National champions like WuXi AppTec have benefited greatly from such government support.[313] Now with 38,000 employees and almost $6 billion in revenue in 2023, WuXi AppTec has become the Huawei equivalent for biotechnology.[9] In 2024, an industry trade group surveyed U.S. biopharmaceutical companies and found that 79 percent of those companies depend on WuXi AppTec and other China-based companies for at least some component of their manufacturing.[10] As precision medicine advances, it is likely that such dependence will only grow.

This situation is exactly what the CCP wants. The Commission's research indicates that China is likely to follow the same playbook with biotechnology as it has with other strategic technologies. **First, they steal. Then, they scale. Once they have cornered the market, they strangle.**

In late 2024, China cut off U.S. access to gallium and germanium, jeopardizing U.S. semiconductor production.[11] According to the U.S. Geological Survey (USGS), a complete restriction of these minerals by China could slash U.S. GDP by $3.4 billion.[12] But the economic danger of losing the biotechnology competition is much greater.

What would it mean for the United States and the world if the CCP gained control of foundational technologies in key sectors, from agriculture to medicine to energy and defense?

The Commission has every reason to believe that the CCP will weaponize biotechnology. China already deploys genomic surveillance to identify, track, and control Uyghur Muslims, part of an extensive system of technology enabled genocide.[13] In 2018, an ostensibly rogue Chinese scientist produced genetically modified babies and though briefly imprisoned, is already back in the lab.[14] Now, with its Military-Civil Fusion (MCF) strategy, the CCP aims to use biotechnology-powered troops (it calls this human-machine teaming "intelligent warfare") to make the People's Liberation Army (PLA) a "world-class military" by 2049.[15] Drone warfare will seem quaint if we are faced with genetically enhanced PLA super-soldiers with fused human and artificial intelligence.

At the outset of World War I, the United States did not yet fully appreciate how airplanes would rapidly change the nature of war. But once we understood the significance of aviation for force projection, reconnaissance, logistical support, and beyond, we dominated the skies. Similarly, the full impact of the biotechnology revolution will not be clear until it arrives. But one thing is certain: it is coming. There will be a ChatGPT moment for biotechnology, and if China gets there first, no matter how fast we run, we will never catch up.

Our window to act is closing. We need a two-track strategy: make America innovate faster, and slow China down.

On the home front, biotechnology holds immense potential for improving the lives of everyday Americans. After two years of assessing the landscape, we estimate that by 2030, most people on the planet will have consumed, used, worn, or been treated by a product of emerging biotechnology. By 2035, biomanufacturing will be used to onshore the production of critical chemicals, securing supply chains and supporting new jobs. By the 2040s, we will have highly accurate biosensors that can monitor personal health, fitness, and nutrition, and enable personalized treatment plans to dramatically improve health. By 2045, fewer people will die from heart disease, thanks to cell therapy and the 3D printing of organs for transplant. By the 2050s, we will be able to collect rare minerals from the moon and Mars, using robotic missions to biomine in space.

An American-led future of biotechnology can bring all of this home. So how do we realize this future?

The United States should not try to out-China China; that is a losing strategy. Instead, we must lean into our inherent strengths. Our open innovation ecosystem attracts top talent from across the globe, and America's capital markets remain four times larger than China's. We understand that innovation need not come at the cost of safety, security, and responsibility. We are home to many of the world's leading public and private research institutions, with more biotechnology patents, companies, and Nobel Prize winners than any other country.[16] Modern biotechnology is an American innovation.

This is not about our ability to run fast; it is about us tripping over our own shoelaces. While the United States innovates better than any other country in the world, we also make it unnecessarily difficult to commercialize and scale our best ideas. We need a "private-public" partnership for biotechnology, driven by industry in collaboration with government. By coupling supply-side incentives to drive R&D and initial growth with targeted demand-side signals to reduce investment risks, the federal government can unleash private sector capital to drive a world-class biotechnology industry.

Slowing China's progress requires ending our own willful blindness to its biotechnology ambitions. We must defend our biotechnology IP and data against Chinese state-sponsored corporate espionage, even if it means rejecting an attractive investment. We must not treat Chinese state-run companies as ordinary competitors in our market, even if it means using more expensive alternatives. China does not have a right to American research—period.

> The choice is stark: do nothing and accept defeat, or act swiftly and give America a fighting chance.

The Commission's main recommendation is this: the U.S. government should dedicate a minimum of $15 billion over the next five years to unleash more private capital into our national biotechnology sector.

Any smaller amount risks hamstringing U.S. innovation and product development. The advancement of U.S. biotechnology requires a balanced approach, fostering competition without picking winners, while also leveling the playing field by blunting China's non-market actions. While ingenuity thrives on free enterprise, the pressures of quarterly earnings can discourage companies from making bold technological leaps. The government's role is not to create a sluggish bureaucracy, but rather to unlock private capital and streamline regulation, empowering American engineers and entrepreneurs to do what they do best: win.

Principles for Action

01

Promote U.S. biotechnology innovation.

Throughout our history, the United States has had an outsized impact on the world because of our innovation ecosystem, from medicines to the internal combustion engine to space. If we want humanity to benefit from progress in biotechnology, we want our democratic values to lead the way.

02

Be the biotechnology partner of choice for the world.

While we have led in the past, we have not done so alone. We need to work together with our partners and allies to deliver on the benefits of biotechnology while also preventing misuse.

03

Use national security tools to protect our innovation and industrial base in biotechnology.

This means preventing the loss of our technological leadership while also preventing risky supply chain dependencies.

04

Work with the international community, including China where prudent, to develop best practices and standards for biosafety and biosecurity to prevent against misuse, whether deliberate or accidental.

Advances in emerging biotechnology pose risks. Updating protocols and strengthening international standards for biosafety and biosecurity alongside biotechnology development could help prevent or mitigate future biological threats regardless of their origin.

Recommendation Overview

After an extensive study, including more than 1,800 stakeholder consultations, a holistic review of unclassified and classified material, site visits across the United States, and meetings with foreign government and technology leaders, the Commission has developed a set of top-priority recommendations that, taken together, will ensure that we outrun and slow down Beijing in the biotechnology race.

Pillar 1

Prioritize Biotechnology at the National Level

Twenty years ago, the CCP made biotechnology a strategic priority. The U.S. government's approach has been piecemeal and uncoordinated, and we still lack the high-level departmental and agency leadership we need to execute a national biotechnology strategy. The United States must remedy this strategic weakness by adopting a more proactive posture.

1.1a Congress must **establish a National Biotechnology Coordination Office** (NBCO) within the Executive Office of the President with a director, appointed by the President, who would coordinate interagency actions on biotechnology competition and regulation.

Pillar 2

Mobilize the Private Sector to Get U.S. Products to Scale

While China provides its leading companies with cheap capital through government subsidies and investments, America's strong private markets remain our core advantage. We must leverage our capital markets to advance national biotechnology priorities. Complex regulations, underutilized capital, limited domestic scale-up capacity, and insufficient protections all prevent our biotechnology sector from reaching its full potential. By enabling our companies to compete on fair footing, the United States can build a resilient biotechnology ecosystem.

2.1a Congress must direct federal regulatory agencies to **create simple pathways to market and exempt familiar products from unnecessary regulation.**

2.2a Congress must **establish and fund an Independence Investment Fund**, led by a non-governmental manager, that would invest in technology startups that strengthen U.S. national and economic security.

2.3a Congress must authorize and fund the Department of Energy and the Department of Commerce to **develop a network of manufacturing facilities across the country** for precommercial bioindustrial product scale-up.

2.4a Congress must direct the Department of Homeland Security to **ensure that biotechnology infrastructure and data are covered under "critical infrastructure."**

2.5a Congress must **require public companies to disclose single points of supply chain vulnerability** located in foreign countries of concern.

2.5b Congress must **prohibit companies that work with U.S. national security agencies and the Department of Health and Human Services from using certain Chinese biotechnology suppliers** deemed to pose a national security threat.

Pillar 3

Maximize the Benefits of Biotechnology for Defense

While biology represents a paradigm shift in warfare, the Department of Defense (DOD) is not deploying biotechnology-enabled capabilities, leaving our military vulnerable. We must develop these technologies in line with American values before the CCP advances them without ethical constraints.

3.1a Congress must direct the Department of Defense to consult with stakeholders to **define principles for ethical use of biotechnology for the U.S. military.**

3.2a Congress must direct the Department of Defense to work with private companies to **build commercial facilities** across the country to biomanufacture products that are critical for Department of Defense needs.

3.3a Congress must require outbound investment rules to **ensure that U.S. capital does not support Chinese development of certain biotechnologies** that could pose a national security risk.

Pillar 4

Out-Innovate Our Strategic Competitors

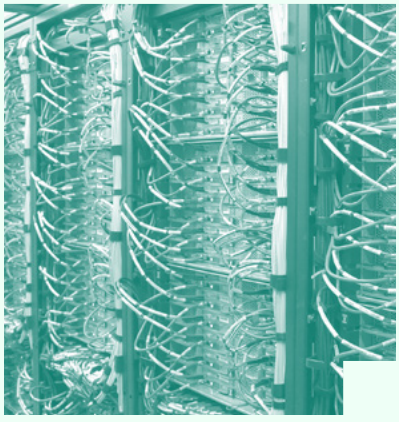
Harnessing our innovative strength will require prioritization. We must treat biological data as geopolitically important, as China already does. We must ensure that researchers have the tools they need to continue conducting the best research in the United States. And we must emphasize safety, security, and responsibility—so that the norms and standards of innovation align with American values and interests.

4.1a Congress must authorize the Department of Energy to **create a Web of Biological Data (WOBD)**, a single point of entry for researchers to access high-quality data.

4.2a Congress must conduct oversight of existing policies, and add new ones where warranted, to **ensure that China cannot obtain bulk and sensitive biological data from the United States.**

4.3a Congress must **establish Centers for Biotechnology within the existing National Laboratory network** to support grand research challenges.

4.4a Congress must direct the executive branch to advance **safe, secure, and responsible biotechnology research and innovation.**



Pillar 5

Build the Biotechnology Workforce of the Future

America's greatest strength has always been its people, yet the United States currently lacks a bioliterate workforce. Federal departments and agencies must ensure that their employees are appropriately skilled and trained to advance and secure biotechnology. We must also strengthen our domestic biotechnology workforce and sustain the pipeline of talent, both at home and from abroad.

5.1a Congress must direct the Office of Personnel Management to **provide workforce training in biotechnology across the interagency.**

5.1b Congress must **ensure that federal agencies have the necessary expertise across national security and emerging biotechnology issues.**

5.2a Congress must **maximize the impact of domestic biomanufacturing workforce training programs.**

Pillar 6

Mobilize the Collective Strengths of our Allies and Partners

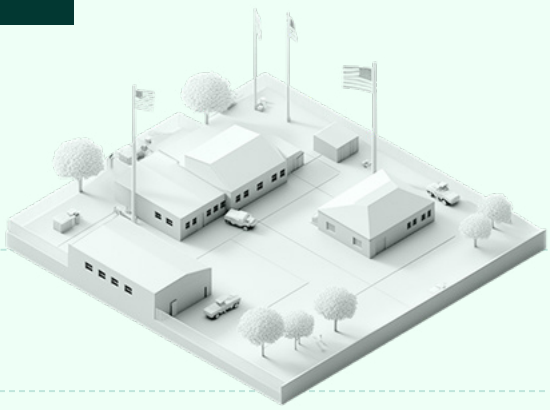
Our allies and partners are already looking to implement their own policies to promote and safeguard biotechnology. The United States should coordinate with likeminded countries on research, talent, and commercialization to harness the power of biotechnology to solve our shared problems.

6.1a Congress must **include biotechnology in the scope of the Department of State's International Technology Security and Innovation Fund** to appropriately fund international biotechnology policy, research and development (R&D), and secure supply chains.

If the United States seizes this moment,

The Future of Biotechnology Has Immense Potential

Defend



The United States military produces what it needs, when it needs it, where it is needed.

The U.S. defense industrial base is deteriorating, which leaves America and our allies vulnerable on the battlefield. Today, it takes more than a month to produce the same number of artillery shells that Ukraine uses in just three days. If war broke out with China, the U.S. military would run out of preferred munitions within days. Biotechnology gives us the tools to reshore the production of chemicals used in munitions, increasing the speed and efficiency with which we can resupply.

The same technology will be used in the future by forward operators. With biotechnology, platoons will be able to synthesize food, munitions, and therapeutics directly on the front lines using technologies that could fit in a backpack, instead of relying on materials produced thousands of miles away at home. Biotechnology will save lives on the battlefield and prevent the need for costly or dangerous refuel or resupply missions.

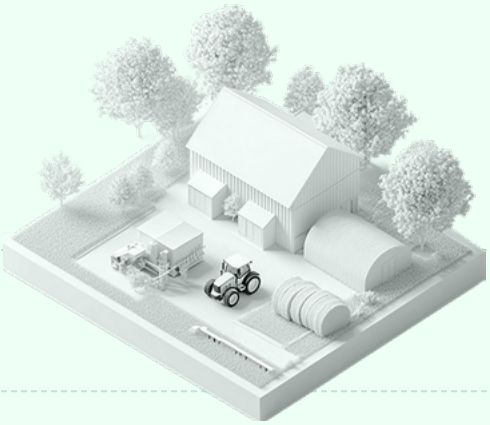
Build

American manufacturers power our economy with resources produced here at home.

The United States is dangerously reliant on other countries, including our adversaries, for our supply of the critical minerals used in essential consumer products, like laptops and cellphones, as well as defense and weapons systems. The United States and many of our partners do possess substantial quantities of rare earth metals—but in many cases, they are mixed with vast amounts of toxic waste and are therefore considered unusable.

Biotechnology will enable American miners and manufacturers to unlock these deposits. Using custom-designed proteins that act like microscopic robots, biotechnology allows us to separate high-purity rare earth elements and other critical minerals from toxic waste with unprecedented selectivity and cost-effectiveness. Biotechnology solutions like these will lower costs, increase domestic production of critical minerals, and reduce our dependence on countries like China.

Nourish



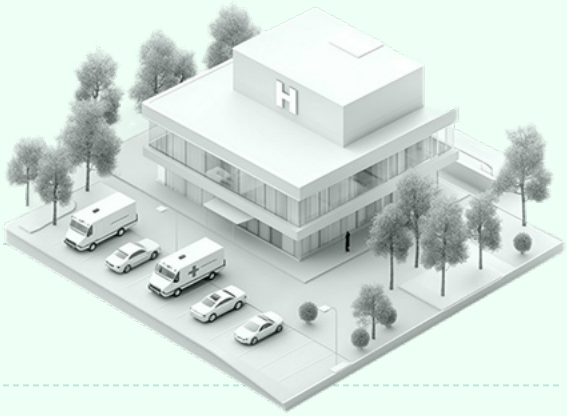
Farmers grow more food using less land, water, fertilizer, and pesticides.

Droughts, wildfires, floods, pests, and diseases cost farmers billions every year. Invasive pests alone cost the United States economy more than $1.2 trillion over the last 60 years.

Using biotechnology, farmers are already growing crops that require less water and are more resistant to pests. We are already well on our way to developing nitrogen-producing microbes that reduce or eliminate the need for expensive fertilizer. These adaptations are game-changers: U.S. farmers who invest in drought- and pest-resistant crops earn approximately three times more revenue compared to conventional crops.

Future biotechnologies will generate more revenue for American farmers, making our agriculture sector stronger and more sustainable, while increasing the supply of affordable and nutritious food for families across the country.

Heal



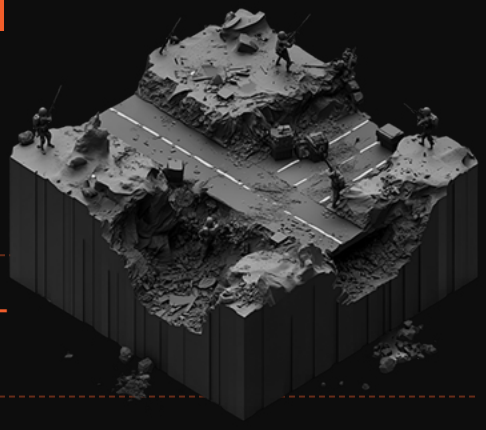
Doctors treat—and beat—disease.

In the case of too many diseases, we only know how to treat their symptoms, not the underlying issue. For example, the standard of care for patients with sickle cell anemia (SCA) is to receive regular blood transfusions to manage, but not eliminate, their disease. Sickle cell disease affects 100,000 Americans, causing life-threatening disabilities and early death.

Gene therapies for SCA can replace the diseased blood cells with healthy ones, providing a true cure. The first gene therapies for SCA were approved in 2023, and in the coming years, similar cures could be developed for a wide range of diseases such as muscular dystrophy, cystic fibrosis, diabetes, and cancer.

But if the United States fails to act,

The Future of Biotechnology Could Be Catastrophic



Attack

Adversaries exploit human enhancements to outmaneuver and overwhelm the American warfighter.

Military forces are inherently limited by human capabilities in physicality, strategy, weaponry, and logistics. Biotechnology could erase these limitations.

Our adversaries could engineer "super soldiers" with genetically enhanced physical capabilities, such as greater intelligence and endurance and the ability to make decisions quicker and more accurately. Paired with new technologies like implanted brain-computer interfaces that tap directly into a soldier's brain chemistry, these super soldiers could attack our military —before our leaders can even act.

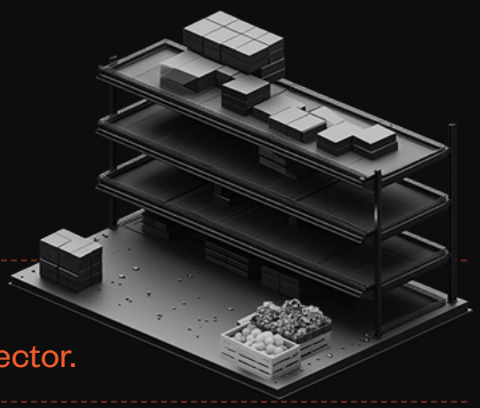
Destroy

Enemies silently attack American infrastructure, disrupting transportation and trade.

It's easy to imagine a future where our enemies stealthily deploy microbes engineered to degrade wood and concrete to weaken our roads, buildings, and bridges. Picture the Francis Scott Key Bridge collapse in Baltimore, which cost the economy an estimated $15 million each day it was closed and up to $4 billion in total losses—but carried out silently, so that our leaders cannot detect or prevent this catastrophe.

Converging technologies—biotechnology supercharged by AI, for example—could arm adversaries with the tools to create quiet and unstoppable chaos, making us fight an invisible enemy.

Starve



Grocery shelves are empty, families go hungry, and farmers suffer when adversaries attack our agriculture sector.

Livestock diseases cost farmers $358.4 billion each year globally in lost production, driving up food costs for Americans. Modify a plant pathogen so that it specifically targets crops grown in the United States, and those existing diseases will become superspreaders that decimate livestock, cripple farmers' livelihoods, skyrocket costs at the grocery store, and make Americans go hungry.

Harm

Americans get sick and die because they don't have access to the medicines they need.

The United States is overly and dangerously reliant on foreign sources for our medicines and therapeutics. We import up to 90% of our most commonly used medicine such as ibuprofen, hydrocortisone, and acetaminophen from China.

In a major global conflict, our adversaries could weaponize this dependence by cutting off our access to basic medicines or to life-saving therapeutics such as chemotherapies, either as retribution or as a preemptive move. The United States would face the impossible situation of defending our sovereignty and security, while trying to source treatments for millions of Americans.

Introduction

What Is Biotechnology, and How Will It Shape America's Future?

The United States is locked in a great-power competition with China that will define the coming century. This contest will shape the security of our nation, the strength of our economy, and the well-being of our people. Unlike the great-power struggles of the past, this one is playing out less through arms races, land grabs, and proxy warfare than through the quest to dominate cutting-edge technology.

Biotechnology, the design and engineering of biological systems, is the next battlefield of this great-power competition. Biotechnology starts with the cell and provides the tools to reprogram it. It allows scientists to grow everything from medicines to crops to materials, enabling "biology by design," in the words of one pioneering U.S. company.[17] In short, biotechnology allows humans to program life itself.

Emerging biotechnology holds exhilarating potential for the United States. If a product is too expensive to make or an industrial process too difficult to carry out, biotechnology allows us to grow an alternative. The applications reach into every sector: biotechnologies that already exist today have the power to transform America's military capabilities, end our dangerous supply chain dependencies, strengthen food security and agricultural resilience, and cure life-threatening diseases. And developments in this sector are advancing at blistering speed.

Biotechnology Represents the Next Transformative Leap for Human Potential

Human development has always been driven forward by technological revolutions. The prehistoric Agricultural Revolution saw the domestication of plants and animals that radically transformed civilizations.[18] The Industrial Revolution of the eighteenth and nineteenth centuries brought about mechanization that vastly increased economic output.[19] And in our own time, the Information Age has revolutionized the way we live and work.[20]

Now, the biotechnology revolution is here. And its transformative power is nearly unlimited. Although biotechnology has not yet reached its inflection point, it is coming, faster now than even two years ago when the Commission began its work.

Biological systems are uniquely powerful because they have adapted to perform complex chemistry naturally. But biology's complexity can also limit scientists' ability to harness its full potential. For example, there are 20,000 individual genes in the human genome, which contains the code that instructs cells to produce proteins, most of which perform multiple jobs within a cell. The same DNA code produces distinct functions across hundreds of cell types, each of which fulfill specialized roles and work in concert with one another. Biology is not yet fully engineerable because of this complexity.

Enter artificial intelligence (AI). Today, AI is beginning to decipher the patterns that govern the behavior of biological systems. Thanks to AI's tremendous modeling power, in the future we will no longer need

to know (or expend the human effort and time determining) exactly how a biological system works in order to harness it. Instead, we will be able to program cells as we program computers, accurately and precisely engineering biology in order to achieve desired results.

Take the problem of figuring out what shapes proteins fold into, which was a "grand challenge" for biology for more than 50 years until researchers from DeepMind released the AI system AlphaFold in 2021. By human calculations alone it would take longer than the age of the known universe to enumerate all 10^300 possible shapes of a single protein.[21] AlphaFold can accurately predict most protein structures to within the width of an atom, a feat that earned the team behind it the 2024 Nobel Prize in Chemistry.[22]

AI is well-suited for biology; once models can become as fluent in DNA and other biological molecules as they now are in human language, the results will be profound. Soon, decades of biotechnology breakthroughs will happen in mere years. Already, there are glimpses of the improvements that AI-enabled biotechnology will unlock. In 2023, for example, Insilico Medicine, whose R&D facilities are located in Hong Kong, announced that it had produced the first fully AI-generated drug, a treatment for idiopathic pulmonary fibrosis, a deadly lung disease.[23]

Just as people today can freely leverage the power of computers, which once required specialized coding skills, soon they will be able to engineer biology just as easily.

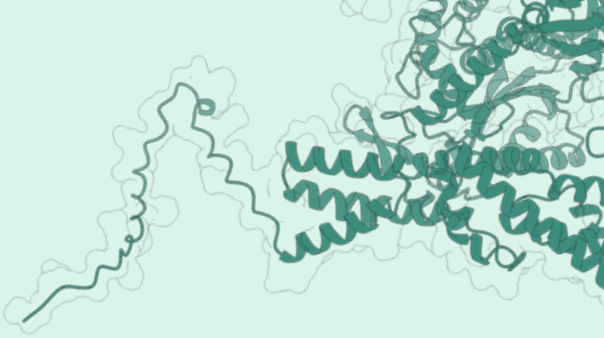
Already, the cost of sequencing a human genome has plummeted from the hundreds of millions of dollars it took in the early 2000s to less than $1,000 today.[24] DNA synthesizers, which allow researchers to print bespoke strands of DNA to make everything from heat-tolerant crops to vaccines, cost just tens of thousands of dollars.[25] As costs come down, more people will be able to solve more problems more cheaply and quickly than ever. Soon emerging biotechnology will change nearly every sector of our economy and touch every aspect of our daily lives, with profound implications for economic competitiveness and national security.

If the United States Wins the Biotechnology Race, Our Nation Will Be Stronger, Safer, Richer, and Healthier

We are in a race to win the biotechnology future. Countries that master the AI-biotechnology convergence will gain tremendous strength and prosperity. They will also get to shape how these technologies are used for decades, if not centuries, to come.

For the United States, achieving global biotechnology superiority is an imperative. If America secures its position as the greatest biotechnology power in the world, we will see major gains in five critical areas: defense, supply chains, agriculture, healthcare, and computing.

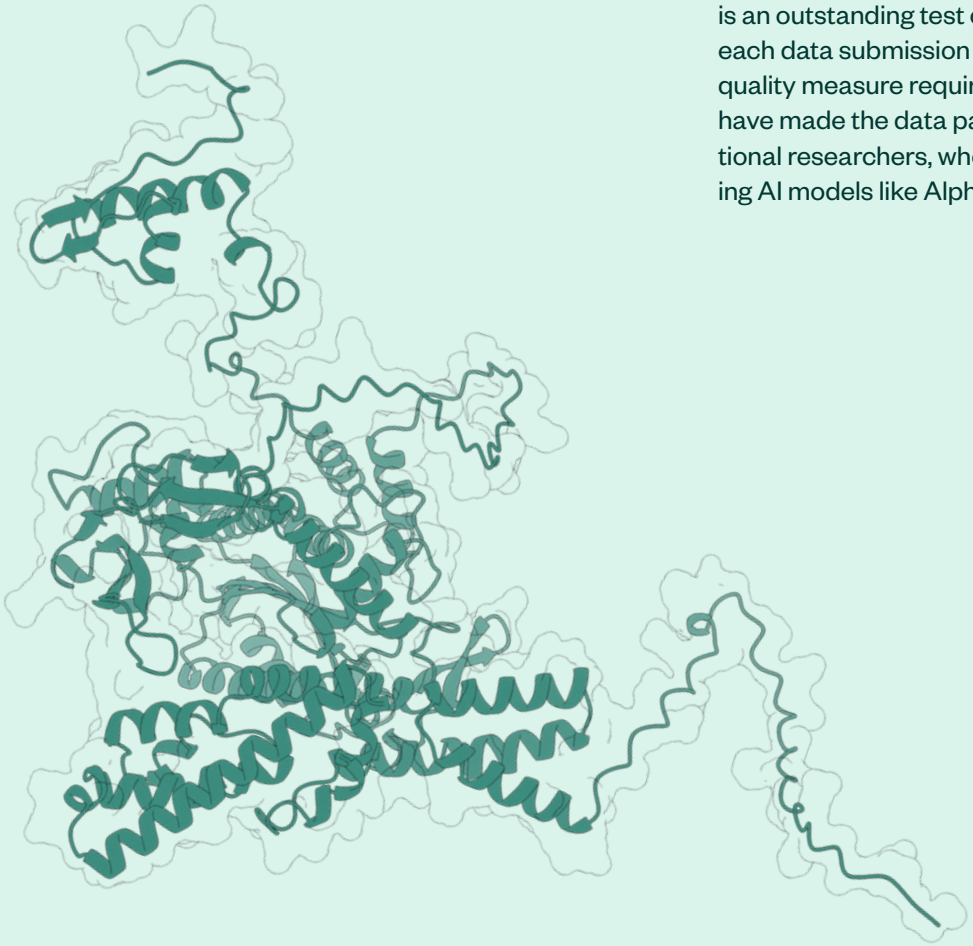
Nobel-Worthy Biological Data: An AlphaFold Case Study



The 2024 Nobel Prize in Chemistry is a testament to the potential of artificial intelligence and biotechnology (AIxBio) innovation.[i] One recipient, the American scientist David Baker, used computational resources to design novel proteins with new functions. The other two recipients, the British scientist and entrepreneur Demis Hassabis and the American scientist John Jumper, worked at Google DeepMind on AlphaFold, an AI model that predicts with high accuracy the three-dimensional shape of proteins, one of the hardest and most important problems in biological research.[ii]

Most medicines are designed to interact with the specific shape of a protein, like a key in a lock. Many antibiotics, for example, target and deactivate proteins that bacteria need to live and kill the bacteria by binding to those necessary proteins. Determining the 3D shapes of proteins accurately and rapidly can aid in quickly designing new antibiotics or vaccines for emerging diseases.[iii]

The computational efforts that earned these Nobel Prizes would not be possible without the decades of work done to build meticulous datasets. One database, the Protein Data Bank (PDB), is filled with 3D protein structures, primarily determined one at a time in low-throughput labs, which helped researchers understand the logic of protein structures and how those structures relate to their functions.[iv] The PDB is an outstanding test case in AI-ready data, because each data submission has rigorous metadata and quality measure requirements.[v] These requirements have made the data particularly useful to computational researchers, who can use it to develop pioneering AI models like AlphaFold.

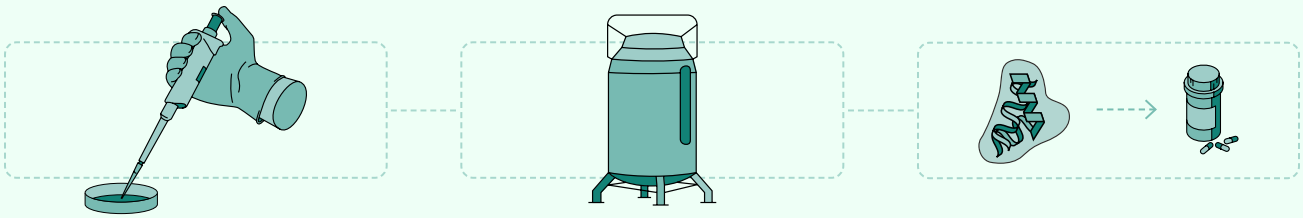


Biotechnology Innovation of Today

Years to decades

$$$

Billions of dollars



Manual Experimentation → Scale-up → Commercialization

Biotechnology Innovation of Tomorrow

Days to months

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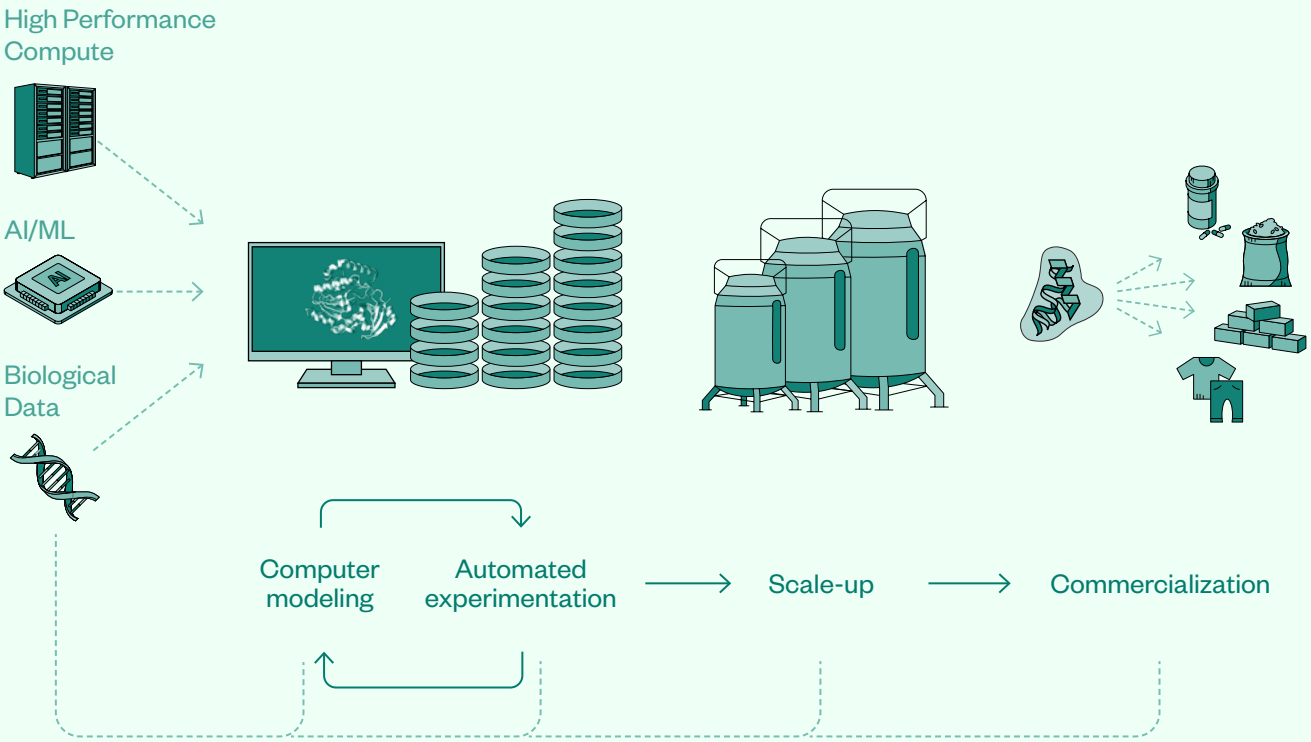
Thousands of dollars



Defense

Emerging biotechnologies will help America maintain U.S. military superiority.

Advances in biotechnology represent a paradigm shift in how conflicts can be fought and won. The countries that seize the moment will retain or achieve superpower status. Those that fail to do so will not only fall behind but also become vulnerable to the use of biotechnology against them.

In the 1900s, the United States was the first to take flight but fell behind in the military development of airpower going into World War I.[26] Nevertheless, once it recognized that airplanes could become central to military doctrine, from force projection to reconnaissance to logistical support, the U.S. military prioritized airpower in time to reap its enormous advantages in World War II.

Just as aviation fundamentally changed the nature of military operations, so too can biotechnology.

For example, biotechnology could revolutionize logistics by linking strategic objectives with tactical flexibility. Where planes shortened resupply times and extended operational reach, synthetic biology could enable on-demand production of essential resources such as fuel, food, and medicine, reducing reliance on vulnerable supply chains. Imagine a battlefield where shelf-stable synthetic blood removes the need to refrigerate and transport multiple blood types. Such advancements could simplify logistics, allow warfighters to safely extend their operational range, and enhance battlefield survivability.

Biotechnology is also the best defense against bioweapons. The United States does not and will not have an offensive bioweapons program. Other countries do.[27] The best deterrent is to master biotechnology so that the United States can prevent, detect, and respond to any biological event.

Fielding biotechnology for defense requires a mindset shift. Instead of viewing this technology as a collection of separate tools, we need to see it as a comprehensive framework that transforms the military's approach to logistics, surveillance, operations, and, ultimately, deterrence.

Supply Chains

Biotechnologies can rebuild global supply chains for the critical components powering our economy.

By the end of the decade, according to one estimate, biomanufacturing will be used extensively in more than a third of traditional manufacturing industries, representing nearly $30 trillion in global value.[28] Plastics, cement, metals, and textiles could someday all be grown rather than produced. In addition to providing new and safe domestic methods of production, biomanufacturing also offers good, high-skilled jobs.

One area with especially promising biotechnology applications is the mining and processing of rare earth elements, which are essential components of everything from cars to computers to cell phones.[29] Today, China produces about 60 percent of these minerals and processes as much as 90 percent of them.[30] Some of these minerals sit unused in the United States because they are too hard to separate out from mining waste.[31] Companies are now using biotechnology to create enzymes that can specifically target and extract minerals from deposits that are currently impossible to separate.[32] At scale, this new method of sourcing critical minerals could help meet demand from semiconductor and advanced weapons manufacturers, while insulating our economy from the CCP's exploitation of this critical industry.

Agriculture

Biotechnology can revolutionize agricultural production in America.

Biotechnology is already the norm in much of American agriculture. Over 90 percent of U.S. soybeans, corn, and cotton are enhanced using biotechnology to help farmers reduce the need for land, water, and chemical inputs.[33] We are already starting to see the benefits of biotechnology for agriculture, with cattle that can stay cooler and continue to produce milk in hot conditions and custom soil microorganisms that can pull nitrogen from the air and reduce fertilizer needs.[34] These technologies will be a game-changer for America's farmers, while giving consumers across the country access to less expensive and more nutritious food.

Healthcare

Biotechnology can transform healthcare in America.

Biomanufacturing will enable better and less invasive treatments that extend and improve lives. In 2023, the Food and Drug Administration (FDA) approved the first CRISPR-based gene therapies for sickle cell disease, a life-threatening condition afflicting some 100,000 Americans.[35] Similar gene therapies could provide targeted and effective treatments for many other diseases. According to one estimate, 45 percent of the total global burden of disease could be treated with existing biotechnologies.[36]

Biomanufacturing could also reduce U.S. dependence on foreign supply chains for pharmaceuticals. Starting in the 1990s, American producers began offshoring drug manufacturing made through the traditional chemical process because it involves toxic chemicals.[37] But as many as half of the drugs on the FDA's list of essential medicines could be produced using biomanufacturing instead.

Biotechnology can also protect Americans from public health threats such as toxic waste.[38] American researchers are developing biomanufactured materials that can break down chemical compounds known as per- and polyfluoroalkyl substances (PFAS), persistent toxic substances that are used in many consumer goods and often end up in the water supply.[39] PFAS is found in drinking water for an estimated 95 million Americans, including a number of military personnel and their families.[40] The Department of Defense has determined that 722 military sites across the country may be contaminated with PFAS.[41] Biotechnology offers a solution, such as sponges that promote natural microbial growth that can soak up and break down PFAS.[42]

Computing

Biotechnology can change the future of computing power.

There are limitations to silicon-based computers. As the world continues to generate massive volumes of data, one major concern is the difficulty of building enough physical storage. Football field-sized data centers are cropping up across the country, taking up vast amounts of land and straining the electrical grid.[43] Biotechnology has the potential to reimagine data storage and computing power by replacing silicon-based parts with DNA. DNA can hold an unbelievable amount of information. The entire Library of Congress holds approximately 24 petabytes of data, a quantity that could fit in a poppy seed-sized amount of DNA.[44]

Biology also holds the potential to tackle computational problems that are challenging for traditional computers, and replace, modify, or create the semiconductors that are so critical to the field of computing.[314]

If America's Adversaries Win the Biotechnology Race, They Will Use These Technologies to Try to Surpass Us or Even Deploy Them Against Us

The United States (our government and our people) is committed to using biotechnology to improve lives and strengthen our country. But not everyone has the same motives. Bad actors, whether state or nonstate, can harness the power of biotechnologies to disrupt societies, destroy economies, and undermine the international order.

Bioweapons have been a part of great-power conflicts for millennia. As early as 1500 BC, the Hittites of Anatolia deliberately drove victims of a plague into enemy lands to set off an epidemic.[45] During the Cold War, the Soviet Union ran an industrial-scale bioweapons program called "Biopreparat," which by 1987 was producing more than 5,000 tons of anthrax a year.[46]

Today, the theoretical bioweapons capabilities of both state and nonstate actors could be orders of magnitude more powerful. Bad actors could exploit biotechnologies to devastating effect. Imagine a world where an adversary engineers new lethal pathogens or toxins, whose origins are impossible to trace.[47] Consider a future where adversaries can edit or select a person for genetic attributes—such as intelligence, speed, and strength—and use brain-computer interface technology to fuse that optimized human intelligence with artificial intelligence. The result would be a seamless human-machine team to outpace our decision making and outperform our forces.

> The future of warfare will no doubt involve biotechnology, whether or not the United States takes the lead in that field. There is no sensible choice but to ensure that America maintains superior and overwhelming capabilities, while maintaining our prohibition on the development and use of bioweapons.

China's Vision for Biotechnology

China has made no secret of its goal for biotechnology: to use it to achieve global economic and military supremacy.

For decades, the CCP has pursued Military-Civil Fusion (MCF), an aggressive strategy that, among other things, governs how it will use biotechnology. By 2049, the CCP aims to use MCF to turn the People's Liberation Army (PLA) into a world-class military that can rival or defeat our own.[48] Biotechnology is a critical component of this strategy, and China is striving to develop and integrate biotechnology into its warfighting capabilities before anyone else.[49]

In 2020, Chinese President Xi Jinping instructed the CCP to "incorporate biosecurity into the national security system."[50] Although President Xi made this statement to push for legislation on biosecurity, the CCP and PLA have taken this message to heart. The CCP has launched an aggressive, whole-of-nation effort to develop the most cutting-edge biotechnologies and use them to advance its military and economic objectives.[51]

China is investing heavily in gene editing, bionic robots, human-machine teaming, and biomanufacturing, and it is targeting these technologies for military applications. To accelerate its progress, it has collapsed the barriers between civilian and defense research. As a result, ostensibly private Chinese companies such as BGI, one of the world's largest genome research organizations, effectively serve to implement the CCP's technology policies.[52] While super soldiers may sound like science fiction today, in reality the CCP has long called for "population improvement," and has backed research into topics like the genetic basis of intelligence.[53] Experts interpret this as willingness to pursue eugenics.[54]

Indeed, some Chinese scientists are already turning to gene editing to achieve population improvement. In 2018, a Chinese biophysicist created the world's first genetically modified babies, shocking the international scientific community, which had called for a pause on this type of genetic modification research.[55] The genetic modifications were intended to produce humans that were more resistant to infections.[56] One can easily imagine a future where embryos are edited for intelligence and other desired traits.

The defense implications of such innovations are alarming. If China wins the military biotechnology race, its forces will gain advantages that ours will lack.

The consequences for human rights are just as troubling, given the CCP's lax attitude toward eugenics and obsession with surveillance. Beijing could wield biotechnology to control its population, intimidate ethnic minorities, and perpetrate genocide. In Xinjiang, Chinese authorities have already collected genomic data on millions of people to identify those who are ethnically Uyghur, contributing to genocide against this group.[57] It is easy to imagine the CCP collecting the DNA of outspoken dissidents in the diaspora to identify and punish their families back in China.

China has also repeatedly failed to honor international commitments—including withholding critical information and samples during the early stages of COVID-19—and engaged in nontransparent, nonreciprocal, and coercive behaviors that undermine meaningful engagement on biotechnology.

The United States is Falling Behind in Key Areas

For most of the twentieth century, the United States dominated the field of biotechnology. American research institutions and scientists unlocked cutting-edge innovations that were the envy of the world.

In the 1940s, the U.S. Department of Agriculture, working with the private sector, discovered how to produce new strains of penicillin and began mass producing the drug, saving untold millions of lives.[58] In the 1970s, American biochemists were the first to learn how to "cut" DNA fragments from one source and join them with another. They founded the world's first biotechnology company, Genentech, which produced the first synthetic insulin and has since created dozens of other medicines to treat everything from cancer to multiple sclerosis.[59] In the 1990s, the United States led the Human Genome Project, a massive international effort that identified and sequenced the full human genome for the first time.[60]

The United States owes these successes to its tremendous underlying strengths. We are home to many of the world's premier biotechnology experts and leading public and private research institutions. Our open innovation ecosystem attracts top talent from across the globe. Both our government and our private sector emphasize funding foundational research and development (R&D), rather than funding only fully realized products. We have more biotechnology patents, companies, and Nobel Prize winners than any other country.[61] Modern biotechnology is an American innovation.

Unfortunately, many of these strengths have begun to atrophy. Above all, biotechnology companies are struggling in today's market environment. At the beginning of the biotechnology boom in the early 2000s, abundant private capital poured into fledgling companies that were pushing the boundaries far beyond traditional biopharmaceutical applications. But when the market recently contracted and lending became more expensive, many biotechnology companies were hit hard.[62] Investors fled to safer investments, returning to biopharmaceuticals with defined return profiles and moving away from cutting-edge biotechnology applications in medicine, agriculture, industrial manufacturing, energy, and defense.

The United States Lacks a Federal Strategy

To win the biotechnology race, we need to start by getting our own house in order. Currently, the U.S. government has no cohesive, intentional biotechnology strategy, while China is gaining ground thanks to its aggressive and carefully coordinated state-led initiatives.[63] Support for biotechnology investment is bipartisan and widely championed across the United States. But our policymaking is fragmented. Coordination between the executive and legislative branches of government and within the executive branch is poor. And the federal government's regulatory system is complex and outdated due to a patchwork of laws and authorities.

Our Federal Funding Has Stagnated

In the 1960s, federal R&D spending reached nearly 2 percent of GDP. Today, it has declined to just 0.6 percent.[64] The problem is not just how little funding there is but also what gets funded. With fewer federal dollars available and funding agencies less tolerant of failure, researchers and their institutions tend to pursue less risky, more incremental research. Far too little federal funding goes toward innovative, disruptive projects whose breakthroughs will shape the future of biotechnology.

The administrative requirements of federal funding—lengthy paperwork, evidence of previous success, and the like—also mean that it is easier for

established researchers and well-resourced institutions to capture these dollars than their less experienced or smaller counterparts. Researchers should be able to spend less time writing grant proposals and filling out paperwork for dwindling pots of federal funds and more time innovating.

We Fail to Sufficiently Commercialize Innovations

While the United States has long excelled at advancing our fundamental understanding of science, it has focused less on converting ideas into products, particularly those with strategic promise. Moreover, poor infrastructure, a lack of long-term capital investment, and confusing market signals all serve to shrink America's share of the global biotechnology market. China, by contrast, picks national champions and aggressively advantages them through CCP policies to ensure that they seize as much global market share as possible.[65]

In addition, American biotechnology companies have to navigate a thicket of slow, unpredictable, and complex regulations to bring products to market while regulatory agencies face repeated legal challenges to their enforcement of outdated rules. Until we fix both these commercialization problems, our innovation edge will continue to erode.

Our Innovation Edge Is Eroding

The future of biotechnology is inextricably linked with that of AI, and the more researchers use AI to power biotechnology discoveries, the more essential high-quality biological data will become. But the United States has failed to amass a large repository of biological data that could be leveraged by researchers, thereby forgoing a game-changing strategic resource.

Federal funds also do not adequately support research infrastructure, such as lab space, equipment, and computing power, which researchers and innovators need to generate the high-quality biological data that lead to discoveries.[66]

The combination of less federal funding for biotechnology research and insufficient data to drive AI-powered discovery puts America's innovation edge at risk, compared to countries such as China that are willing to invest heavily in biotechnology research and data.

America Is No Longer the Premier Destination for Top Talent

As impressive as it has been over the years, the American education and training system is not producing enough skilled workers to meet the demands of the biotechnology industry, particularly outside of the major hubs of Boston and San Francisco.[67] While we remain a leader in attracting international talent, China is quickly catching up. We desperately need a more aggressive strategy to attract, develop, and retain the best minds in the field.

We Fail to Harness the Strengths of Our Allies and Partners

As with many other aspects of technological dominance, the United States cannot win the biotechnology race alone. We must work with other countries to solve hard problems and build an international ecosystem that fills the gaps in our own capabilities. For example, in 2012 American and French scientists worked together to understand and characterize the CRISPR-Cas9 genetic scissor tool, which led to its adaptation into the revolutionary CRISPR technologies available today.[68]

Many U.S. allies and partners offer unique capabilities. Companies in Denmark are driving advances in biomanufactured chemicals, including for use in healthcare.[69] Germany is doing the same for biomass for energy.[70] The United Kingdom is leading efforts in computational biology research.[71] South Korea is establishing itself as a hub for biopharmaceutical manufacturing.[72] Japan is advancing regenerative medicine and biomanufacturing.[73] And India is prioritizing cost-effective biomanufacturing, particularly of vaccines.[74] We must do more to take advantage of our partners' unparalleled strengths, which could include entering into reciprocal data-sharing agreements or pooling demand for biotechnology products.

Currently, the U.S. government has no cohesive, intentional biotechnology strategy, while China is gaining ground thanks to its aggressive and carefully coordinated state-led initiatives.

China Is Closing the Gap

President Xi has made it clear that emerging technologies such as biotechnology will shape the future. And he has moved quickly to seize the advantage. China has long relied on aggressive industrial policies to get ahead in the sectors it considers vital. This track record gives it a clear playbook for how to win the biotechnology race and then translate that victory into military and economic power.[75]

China Emphasizes Biotechnology as a "Strategic Emerging Industry"

For nearly two decades, China has made biotechnology a priority.[76] As early as 2007, the CCP announced plans to "set up high-tech industrial bases for biotechnology," and in 2011, it designated biotechnology as a "strategic emerging industry," unleashing a comprehensive package of financing, subsidies, and diplomatic support for the Chinese biotechnology sector.[77]

In 2014, President Xi declared to the Chinese Academy of Sciences that his country could not become a "technological vassal of other countries" and insisted that it pursue a path of independent scientific innovation.[78] In an April 2020 speech, he elaborated on this vision:

"We must place greater emphasis on basic research in heredity, genetics, virology, epidemiology and immunology, accelerate R&D and technological innovation of related drugs and vaccines, and attach greater importance to applications of information and data technologies in these fields."[79]

Later that year, China enacted a biosecurity law, further enshrining biotechnology, genomics, and other life-sciences research under CCP and state control, including under the PLA.[80]

China Provides Massive State Support for Hand-picked Winners

The CCP lavishes its chosen domestic firms with subsidies and preferential regulatory treatment that advantage them at the expense of foreign competitors. It complements this strategy by helping Chinese firms acquire U.S. companies that are developing promising technologies. In 2012, for example, BGI bought the U.S.-based sequencing company Complete Genomics, bringing American technology under CCP control.[315] Today, BGI is a world leader in sequencing, thanks in no small part to the support that the CCP has given it to undercut the competition with below-market prices.

The Chinese government has made tremendous investments in its domestic biotechnology industry, plowing money into developing talent and building research infrastructure, unlike the United States, which has no strategic vision or coordination for federal biotechnology funding.[81]

In agriculture, the Chinese government uses its regulatory system to delay approval for American-developed seeds and require larger-than-normal samples of seeds. This allows China to develop its own versions of American seed varieties in a fraction of the time it would otherwise take.[82]

China now boasts over 100 biotechnology research parks and 17 industrial clusters where researchers can conduct biological research and use AI in biodiscovery.[83] These sites offer Chinese researchers everything they need to scale up innovations, from the laboratories to test their ideas to the infrastructure to bring their products to market.[84] China's rapid investment into these sites could allow the country to surge more students into its biotechnology workforce, creating a feedback loop that would expand its biotechnology industry faster than we are able to grow ours.

China Deploys Predatory Capital and Acquires Intellectual Property (IP)

China regularly exploits America's open market by funding acquisitions of U.S. biotechnology startups solely for the purpose of acquiring their IP. A telling example is Chinese pharmaceutical company WuXi AppTec, which has purchased a number of U.S. firms, granting it access to the best technology in the world.[85] Thanks to acquired American IP, it now dominates the biomanufacturing of pharmaceuticals and has earned a reputation among biotechnology companies as a critical firm that can solve the hardest manufacturing problems in as little as a week. Because of WuXi AppTec's edge, the American biopharmaceutical industry is now utterly reliant on it. In 2024, an industry group surveyed U.S. biopharmaceutical companies and found that 79 percent of those companies depend on it and other Chinese-based contractors for manufacturing.[86] WuXi AppTec's success was built on the back of U.S. technology.[87] But now it is the United States that is vulnerable. In that sense, WuXi AppTec is the new Huawei.[88]

China Prioritizes Data Control and Security

China understands the importance of genetic data, and its investments in genetic sequencing services have given it vast amounts of genomic information. National champions such as BGI collect data on behalf of (and are functionally indistinguishable from) the Chinese state, granting the CCP access to massive troves of data that power developments in biotechnology.[89] The CCP's 2020 biosecurity law established a national biosecurity information bank with which companies must share all their "biosecurity data and materials." If interpreted broadly, the law would require sharing data for all "human genetics resources" (human tissue, DNA samples, and so on), including all clinical trial data.[90]

China is Working to Win the Competition for Talent

Fewer Chinese students are choosing to pursue higher education abroad now than in previous years. The number of Chinese students studying abroad increased year-by-year from 2013 to 2019; however, that number has steadily declined since the COVID-19 pandemic.[91] More than 80 percent of Chinese PhDs who do study abroad return home after, where they can end up working in Chinese firms or directly for the CCP.[92] In this regard, 20 years of Chinese investment in its domestic biotechnology industry are paying off. Indeed, Americans and Europeans with biotechnology expertise are also studying and working in China, drawn by the vast government resources available to researchers and students.[93]

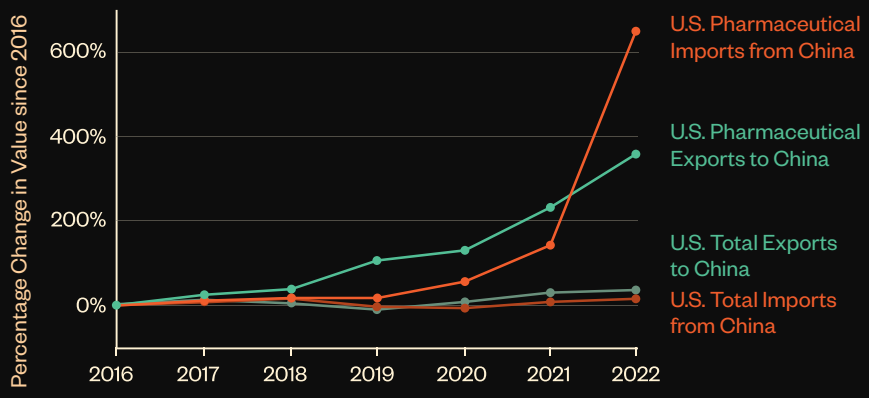
China's Strategy is Working

As part of its strategy, the CCP seeks to dominate the global biotechnology industry so that other countries, including the United States, are dependent on the channels it controls. China is already deeply embedded in the United States' critical biotechnology supply chains, including those for life-saving medicines and agriculture. Every year from 2014 to 2022, the United States sourced up to 28 percent of total active pharmaceutical ingredient imports from China.[94] Chinese state-owned Syngenta is now the world's largest seed and agricultural chemicals conglomerate, with $27 billion of annual sales and unprecedented global influence.[95] These dependencies make us highly vulnerable to Chinese pressure.

$300 billion increase in market value of Chinese biotechnology firms

From 2016 to 2021, the market value of Chinese biotechnology firms grew 100-fold, to $300 billion.[96] These companies' combined market capitalization is second only to that of U.S. companies, and Chinese firms are on track to catch up quickly.

The U.S. Relies Heavily on Chinese Pharmaceuticals

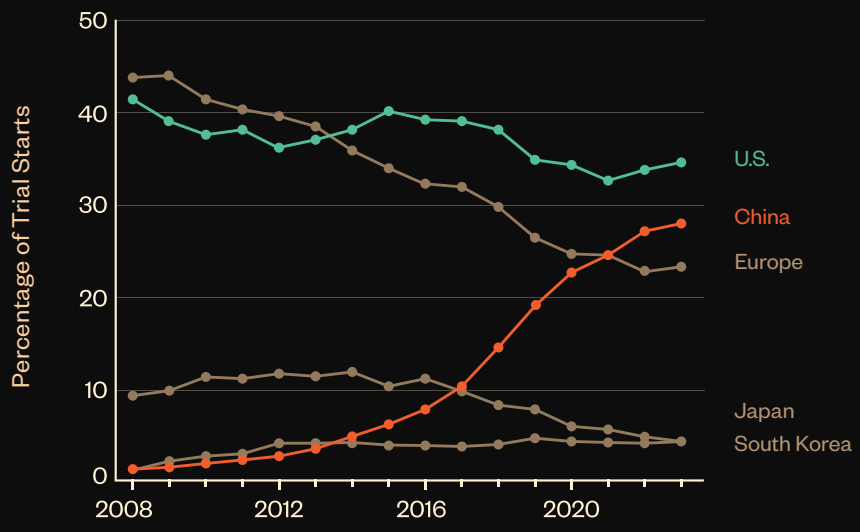


Niels Graham, "The US Is Relying More on China for Pharmaceuticals — and Vice Versa," Atlantic Council (blog), April 20, 2023, https://www.atlanticcouncil.org/blogs/econographics/the-us-is-relying-more-on-china-for-pharmaceuticals-and-vice-versa/.

2x increase in number of Chinese biotechnology deals

The share of clinical trials launched by Chinese-headquartered biopharmaceutical companies rose from just three percent in 2013 to 28 percent in 2023.[97] And the global share of China's pharmaceutical output increased from just over five percent in 2002 to nearly 25 percent in 2019.[98] The number of deals Chinese biotechnology companies struck to license their own IP to others more than doubled from 15 in 2019 to 33 in 2023, mostly in oncological therapeutics.[99] In 2023, the FDA approved three new drugs biomanufactured in China.[100]

Chinese Clinical Trials Increased 25% Within Ten Years



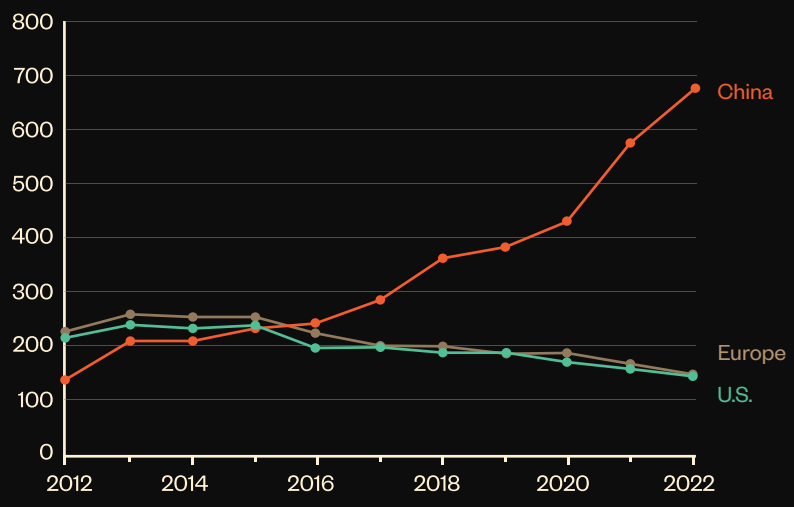
IQVIA Institute for Human Data Science, "Global Trends in R&D 2024," February 2024, https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-trends-in-r-and-d-2024-activity-productivity-and-enablers/iqvia-institute-randd-trends-2024-02-24-forweb.pdf.

22% In 2019, China applied for 22 percent of all international patents, surpassing the United states and the EU.

In recent years, China has become the largest funder of agricultural R&D in the world, surpassing the United States and the EU.[316] In 2019, for the first time in history, China applied for more international patents than the United States.[101] Many of these Chinese applications were for agricultural patents that use CRISPR.[102]

China's advances in R&D are paying out across the biotechnology landscape, most notably in synthetic biology. In 2010, researchers in the United States published 45 percent of the world's most highly cited papers on synthetic biology, with Chinese researchers accounting for just 13 percent. By 2023, that ratio had flipped: Chinese researchers published 60 percent of the most-cited papers while U.S. research accounted for just 7 percent.[103]

China Surpasses the U.S. As the Country With the Most-Cited Biotechnology Research Publications



Niels Graham, "The US Is Relying More on China for Pharmaceuticals — and Vice Versa," Atlantic Council (blog), April 20, 2023, https://www.atlanticcouncil.org/blogs/econographics/the-us-is-relying-more-on-china-for-pharmaceuticals-and-vice-versa/.

"We must place greater emphasis on basic research in heredity, genetics, virology, epidemiology and immunology, accelerate R&D and technological innovation of related drugs and vaccines, and attach greater importance to applications of information and data technologies in these fields."

– President Xi

The United States Must Win the Biotechnology Race

China is using every tool at its disposal to replace the United States as the global leader in biotechnology. The CCP's strategy is to make its firms less dependent on the world, and the world more dependent on them. And it is succeeding.

In the face of this onslaught, no single action will be enough; there is no silver bullet that will singlehandedly delay China's progress by a decade or secure U.S. dominance for a generation. Rather, the U.S. government must aggressively deploy all the tools at its disposal to preserve American biotechnology leadership.

China has run its playbook before with other technologies, and we have lessons to draw on for how to counter it. Consider semiconductors. Chips were originally an American invention, and China had lagged far behind. In recent years, however, China began to close the gap, while the United States itself all but lost the ability to produce leading-edge chips.[104]

In 2022, Congress passed the CHIPS and Science Act, which seeks to stimulate the production of semiconductors on U.S. and allied soil, and the Commerce Department enacted export controls to prevent advanced semiconductor technology from getting into China's hands.[105] As a result, the United States has again become a global hub for advanced chip manufacturing.[106] China's climb up the chip-manufacturing value chain has slowed; it has continued to struggle to produce advanced chips at scale, in part hindering its progress in AI and other dual-use and military applications.[107]

We can still secure our position as the world's biotechnology leader if we act now. If we fail to meet the moment, however, U.S. economic and military leadership will be weakened for generations.

How to Win the Biotechnology Race

To make up for two decades of complacency, we must launch a whole-of-government strategy to promote the U.S. biotechnology industry. We must mobilize our private sector so that American products dominate the global biotechnology market. We must attract private capital through such mechanisms as an Independence Investment Fund and advance purchase commitments from the federal government to smooth out demand. We need to create public-private partnerships so that companies can get the support (such as guidance on navigating the government contracting and regulatory processes) and financial backstop they need to test innovations early and scale what works. We also need to invest in our talent pipeline, make it easier to collect and use standardized biological data, and boost funding for R&D.

We must do all of this in a manner that aligns with American values and prioritizes safety, security, and responsibility. Our values are one of our key enduring advantages; they are what unites us with our allies and differentiates us from our adversaries. Sacrificing our values for short-term gains would only serve to imperil U.S. leadership in the long-term.

The government can be a force multiplier that reinvigorates the United States' historic strengths and helps ensure that the country finishes the biotechnology race in first place. These long-term measures to promote domestic technologies and companies will ensure that we can outrun China in this contest and avoid needing to make a CHIPS Act–sized investment to catch up.[108]

Our strategy must not just promote American technology, but protect it, too. The U.S. government has an array of tools at its disposal to prevent transactions that would harm the United States. Applying them to biotechnology should prevent the transfer of sensitive biological data that could be used against the United States. The government should reform the Committee on Foreign Investment in the United States (CFIUS) so it can better block predatory Chinese investments in the U.S. biotechnology industry. It should impose restrictions on outbound investment to prevent U.S. investments from supporting Chinese biotechnology companies that pose national security risks. It should enact new export controls on specific types of biotechnology equipment that would threaten our national security if they fell into the hands of the PLA. And it should require firms whose supply chains rely on China to publicly disclose their dependencies and prohibit U.S. government contractors and grantees from procuring goods from Chinese biotechnology firms that could create such dependencies.

The U.S. government cannot adopt a one-size-fits-all approach to the biotechnology sector. In devising export controls, for instance, the Administration should remain flexible. It should be willing to deploy them in areas where they could have a strategic benefit, including on a country-wide basis, but also be willing to amend them if they risk ultimately setting back U.S. biotechnology leadership. Biotechnology supply chains are particularly diffuse, with important technologies dispersed across the world, a characteristic that requires export controls to be surgical and nimble to be effective.[109] When it comes to reducing investment and supply chain risks, by contrast, the Administration should pursue wider-ranging protection measures, since these pose fewer downside risks to domestic industry.

Biotechnology is a less consolidated industry than others, such as the semiconductor sector, and technological breakthroughs regularly occur at startups and small firms. But small biotechnology companies often face a tough choice: doing business with China or going out of business. That is why protection must go hand in hand with promotion. A comprehensive strategy should not just restrict transactions with China that could pose national security risks but also open up new market opportunities within the United States and allied and partner nations.

No single step on its own will ensure that the United States can outrun and slow down China in biotechnology. But together, our recommendations offer the best chance of success. There is still time, but the window is rapidly closing.

> The inflection point for biotechnology has not yet arrived. Ultimate leadership of the sector is still up for grabs. With chips and advanced telecommunications we were caught flat-footed. But with biotechnology, fortunately, we can act early and decisively.

About the Commission and Report

Commission Background

In 2021, recognizing the national security implications of emerging biotechnology, Congress came together on a bipartisan basis to create the National Security Commission on Emerging Biotechnology (NSCEB). Established as part of the annual defense authorization bill (FY22 NDAA) the Commission was given a clear and urgent mandate: to conduct a comprehensive review of emerging biotechnology's impact on national security and provide practical recommendations to preserve American dominance in this field.

The NSCEB is an independent commission currently comprised of 11 commissioners appointed by a bipartisan group of Members of the House and Senate. We include four Members of Congress—two from each chamber, and two from each party—and seven prominent industry leaders, academic experts, and former government officials from the defense and intelligence communities.

Our work is short-term in nature. Our directive is to provide recommendations and support their implementation, after which point—specifically, eighteen months after the report's publication, as required by statute—this Commission will dissolve.

NSCEB Commissioners

Senator Todd Young
Chair

Dr. Michelle Rozo Vice
Chair

Senator
Alex Padilla

Congresswoman
Stephanie Bice

Congressman
Ro Khanna

Paul Arcangeli

Dr. Angela Belcher

Dawn Meyerriecks

Dr. Eric Schmidt

Dr. Alexander Titus

Dr. Dov Zakheim

Report Methodology

Our final report is the product of two years of intensive study. Its findings and recommendations reflect input from hundreds of experts and government officials both in the United States and abroad, covering every facet of biotechnology and national security. In total, we met and interviewed more than 1,800 people from over 30 countries on six continents. This report has also undergone a formal review process by all Commissioners and reflects the unanimous consensus of our Commission.

While this report has been submitted to the Congressional defense committees and the President, we have also made it fully available to the American public. This is intentional: to win the biotechnology race, we must mobilize not only policymakers but also the private sector and general public in support of a targeted and aggressive national biotechnology strategy.

Report Scope

This report lays out a set of practical recommendations that, if adopted, will both advance our progress and slow that of our strategic adversaries—particularly China—in the race for biotechnology supremacy.

The Commission conducted research from April 2023 to February 2025 to inform this report. Our research is ongoing, and we anticipate expanding on these recommendations in the coming months as the technology advances and the policy landscape evolves.

Within our scope of emerging biotechnology, we have focused primarily on the design and engineering of biological systems, devices, and parts. Other biotechnology applications that build toward far-future capabilities, such as brain-computer interfaces, are not the primary focus of this report.

We define national security broadly, reflecting today's complex geopolitical realities. We understand national security to encompass traditional defense issues as well as the broader considerations of economic resilience and competitiveness, health security, food security, and energy independence and security.

This report provides recommendations only within the scope of biotechnology. Many related fields, such as biodefense, food security, and energy security, do not exclusively implicate biotechnology. In the case of biodefense, for example, biothreats exist without biotechnology, and remain lethal and prevalent to this day.

Organizations such as the Bipartisan Commission on Biodefense aim to address the full range of biothreats. We do not seek to duplicate this work. Instead, we present recommendations pertaining to biodefense in the context of emerging biotechnology, specifically both the challenges and potential solutions this technology raises. For example, our recommendations—including proposals for a Department of Energy-led Web of Biological Data (WOBD), pilot-scale precommercial manufacturing facilities, and grand research challenges—will, if enacted, enable U.S. researchers to produce medicines that serve as a defense against biothreats. But biotechnology is only part of the solution. The work of the Bipartisan Commission on Biodefense and the inaugural Department of Defense Biodefense Posture Review cover important areas outside the scope of this report.

Similarly, while we address biotechnology applications across many industries, we do not cover the full span of any specific industry sector. Emerging biotechnology will play an increasingly critical role in agriculture, pharmaceuticals, and other key industries, but it will not provide the sole solution to the challenges these industries face. Biotechnology, for example, will supercharge efforts to help the United States domestically produce the active pharmaceutical ingredients (APIs) needed for essential medicines, but it alone cannot solve the major vulnerabilities in our health supply chains. The United States will need to identify ways to onshore today's generic drug manufacturing, including through policy and legislation.

We separately issued a classified annex to this report that provides additional details on how policymakers should prioritize biotechnology for U.S. national security. The annex is available upon request to those with the appropriate clearance and a validated need to know.

However, there is far more that policymakers could do beyond the recommendations presented in these reports to address this expansive and critical set of national and economic security issues.

Next Steps

Over the next 18 months, this Commission will work with Senators, Members of Congress, Congressional staff, and the Administration to support the introduction and passage of the recommended legislation outlined in this report. During this time, we also intend to continue work on select areas to further develop targeted recommendations. We aim to provide, for example, more specific recommendations on regulatory actions tailored to each of the three individual regulatory agencies.

The mission ahead is clear. We stand on the cusp of massive developments in emerging biotechnology. If we act now, the United States can secure its position as the biotechnology leader in the world for decades to come. We look forward to working with our partners in government and industry to bring about this future.

> If we act now, the United States can secure its position as the biotechnology leader in the world for decades to come.

Recommendations

Pillar 1

Prioritize Biotechnology at the National Level

1.1a **Congress must establish a National Biotechnology Coordination Office (NBCO) in the Executive Office of the President with a director, appointed by the President, who would coordinate inter-agency actions on biotechnology competition and regulation.**

1.2a Congress should direct each relevant agency to designate a senior official to lead biotechnology policy.

1.3a Congress should establish the Office of Global Competition Analysis to develop timely data and technology forecasting to inform policymakers' decisions.

Pillar 2

Mobilize the Private Sector to Get U.S. Products to Scale

2.1a **Congress must direct federal regulatory agencies to create simple pathways to market and exempt familiar products from unnecessary regulation.**

2.1b Congress should direct federal regulatory agencies to prepare for novel products to come to market.

2.2a **Congress must establish and fund an Independence Investment Fund, led by a non-governmental manager, that would invest in technology startups that strengthen U.S. national and economic security.**

2.2b Congress should direct the Department of Energy and the Department of Health and Human Services to use existing authorities to smooth out unpredictable and inconsistent demand for biotechnology products through advance market commitments (AMCs) and offtake agreements and provide new authorities where necessary.

2.2c Congress should restore full and immediate expensing of research and development (R&D) expenditures.

2.2d Congress should improve the effectiveness and reach of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs to support early-stage innovation.

2.3a **Congress must authorize and fund the Department of Energy and the Department of Commerce to develop a network of manufacturing facilities across the country for precommercial bioindustrial product scale-up.**

2.3b Congress should direct the Department of Commerce to create a public-private biopharmaceutical manufacturing center of excellence focused on developing and scaling new ways to make medicines.

2.4a **Congress must direct the Department of Homeland Security to ensure that biotechnology infrastructure and data are covered under "critical infrastructure."**

2.5a **Congress must require public companies to disclose single points of supply chain vulnerability located in foreign countries of concern.**

2.5b **Congress must prohibit companies that work with U.S. national security agencies and the Department of Health and Human Services from using certain Chinese biotechnology suppliers deemed to pose a national security threat.**

2.5c Congress should reform the Committee on Foreign Investment in the United States (CFIUS) to better and more nimbly screen the highest-impact, highest-risk types of investment in critical technology sectors in the United States.

2.5d Congress should direct the International Trade Commission to investigate Chinese dumping or oversupply of biotechnology products and services.

Pillar 3

Maximize the Benefits of Biotechnology for Defense

3.1a **Congress must direct the Department of Defense to consult with stakeholders to define principles for ethical use of biotechnology for the U.S. military.**

3.2a **Congress must direct the Department of Defense to work with private companies to build commercial facilities across the country to biomanufacture products that are critical for Department of Defense needs.**

3.2b Congress should continue oversight of and support for BioMADE's efforts to create a network of facilities that precommercial bioindustrial companies across the country can use to meet Department of Defense needs.

3.2c Congress should require changes to military specifications (MIL-SPECs) to enable biotechnology companies to more easily sell their products to the Department of Defense.

3.2d Congress should require the Department of Defense to enter into advance market commitments (AMCs) and offtake agreements for biotechnology products that are needed for defense.

3.2e Congress should require the Department of Defense and other agencies involved in national security to train their workforces to be ready for biotechnology.

3.3a **Congress must require outbound investment rules that ensure U.S. capital does not support Chinese development of certain biotechnologies that could pose a national security risk.**

3.3b Congress should direct the Department of Commerce to consider country-wide export controls blocking the sale of specific, highly sophisticated U.S. biotechnology items to China that would pose a substantial risk to national security if used for military end-uses.

3.3c Congress should require the Department of Defense to incorporate military-relevant applications of emerging biotechnology into wargaming exercises.

3.3d Congress should resource the intelligence community to prioritize understanding adversaries' development of biotechnology and its diverse applications.

Pillar 4

Out-Innovate Our Strategic Competitors

4.1a **Congress must authorize the Department of Energy to create a Web of Biological Data (WOBD), a single point of entry for researchers to access high-quality data.**

4.1b Congress should authorize the National Institute of Standards and Technology to create standards that researchers must meet to ensure that U.S. biological data is ready for use in AI models.

4.1c Congress should authorize and fund the Department of Interior to create a Sequencing Public Lands Initiative to collect new data from U.S. public lands that researchers can use to drive innovation.

4.1d Congress should authorize the National Science Foundation to establish a network of "cloud labs," giving researchers state-of-the-art tools to make data generation easier.

4.2a **Congress must conduct oversight of existing policies, and add new authorities as warranted, to ensure that China cannot obtain bulk and sensitive biological data from the United States.**

4.3a **Congress must establish Centers for Biotechnology within the existing National Laboratory network to support grand research challenges.**

4.3b Congress should initiate a grand research challenge focused on making biotechnology predictably engineerable.

4.3c Congress should initiate a grand research challenge focused on making biomanufacturing scale-up predictable, rapid, and cost-competitive.

4.4a **Congress must direct the executive branch to advance safe, secure, and responsible biotechnology research and innovation.**

Pillar 5

Build the Biotechnology Workforce of the Future

5.1a **Congress must direct the Office of Personnel Management to provide workforce training in biotechnology across the interagency.**

5.1b **Congress must ensure that federal agencies have the necessary expertise across national security and emerging biotechnology issues.**

5.1c Congress should receive accurate, timely, and nonpartisan scientific and technical counsel.

5.2a **Congress must maximize the impact of biomanufacturing workforce training programs.**

5.2b Congress should expand educational efforts in biotechnology for American students.

5.3a Congress should authorize new green cards for biotechnology talent, especially from allied and partner countries.

5.3b Congress should optimize the vetting process for foreign nationals to prevent illicit technology transfer.

Pillar 6

Mobilize the Collective Strengths of Our Allies and Partners

6.1a **Congress must include biotechnology in the scope of the Department of State's International Technology Security and Innovation Fund to appropriately fund international biotechnology policy, research and development (R&D), and secure supply chains.**

6.1b Congress should direct the Department of State and other agencies to promote the U.S. biotechnology industry in foreign markets, including through commercial diplomacy.

6.1c Congress should expand regulatory diplomacy for biotechnology.

6.1d Congress should require the Department of State to form reciprocal biological data-sharing agreements with other countries.

6.1e Congress should direct the Department of State and the Department of Defense to encourage North Atlantic Treaty Organization (NATO) countries to aggregate demand and pool purchasing power for biotechnology products.

6.2a Congress should direct the Department of State, along with the National Institute of Standards and Technology, to support the development of international norms and standards, including defining shared values and interests in biotechnology.

6.2b Congress should require the Department of State to create a strategy for harmonizing multilateral export controls.

Chapter 1

Prioritize Biotechnology at the National Level

Throughout much of its history, the United States has had an outsized impact on the world thanks to its role as an engine of innovation. From automobiles to medicine to nuclear energy to space, researchers in the United States have been at the forefront.

But in biotechnology, America is at risk of losing its edge. The U.S. government has not prioritized biotechnology as a strategic sector like it has semiconductors and artificial intelligence.

Instead, America has taken a piecemeal and uncoordinated approach to biotechnology policy and programs. This decentralized approach to biotechnology research and development (R&D) has its strengths, but it also comes with inherent weaknesses. Federal scientists and program managers pursue a wider range of biotechnology research projects that advance the mission of their specific department or agency, but because their efforts are disaggregated, the result is a confusing landscape of biotechnology research that inhibits potential interagency collaborations.

Moreover, the lack of effective coordination has resulted in a jumble of strategies, investments, and committees scattered across the federal government. Biotechnology research, regulation, manufacturing, workforce development, program management, and policymaking are treated as discrete issues rather than considered together, as they should be. This fragmented system is difficult for biotechnology innovators and policymakers to navigate, utterly opaque to the public, and detrimental to collaboration across the federal government, academia, and private industry.

This piecemeal approach is a strategic weakness.

For now, the United States enjoys the global lead in biotechnology, but it cannot remain complacent. To secure its status, the country must abandon its reactive approach to biotechnology and adopt a proactive one. A new presidential administration in 2025, coupled with a growing sense of urgency among policymakers about technological competition with China, gives the U.S. government the opportunity to adopt a concerted strategy. That strategy should begin with openly and urgently making biotechnology a national priority.

The relationships among industry, academia, and government are critical to leadership in biotechnology. And in the United States, government is the weak link.

Section 1.1

Establish a National Biotechnology Coordination Office

Federal departments and agencies perform a wide range of activities that advance biotechnology, such as conducting research and regulating biotechnology products. While valuable, these efforts are fragmented and lack a common understanding of how the federal government should advance biotechnology to meet national goals. There is an urgent need for lasting coordination that would connect federal agencies, provide a long-term strategy, and de-duplicate redundant investments.

1.1a Recommendation

Congress must establish a National Biotechnology Coordination Office (NBCO) in the Executive Office of the President (EOP) with a director, appointed by the President, who would coordinate interagency actions on biotechnology competition and regulation.

The U.S. government has previously tried to coordinate biotechnology efforts across agencies, but these efforts have generally not kept pace with scientific discovery occurring outside of government.[110] Additionally, none of these efforts designated a senior official to oversee and advocate for biotechnology efforts in the federal government.

To coordinate interagency actions and unify the American effort to retain its lead in biotechnology, Congress must establish a National Biotechnology Coordination Office (NBCO) in the EOP. The NBCO would oversee interagency activities related to promoting, protecting, and regulating biotechnology. The NBCO would be headed by a director, appointed by the President, to serve as the principal advisor on biotechnology. The director would manage a small staff that would be responsible for the operations of the NBCO and an interagency committee. The director should be jointly appointed as a principal assistant director within the Office of Management and Budget (OMB) to oversee biotechnology-related budgets across the federal departments and agencies.

The Director of the NBCO would primarily be responsible for:

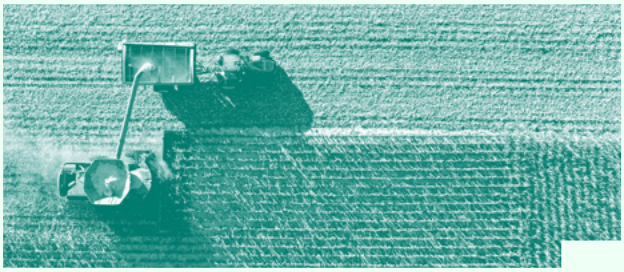
- creating and maintaining a national biotechnology strategy;
- assessing the national security implications of emerging biotechnologies, including any major needs or gaps;
- providing long-term strategic guidance on biotechnology R&D;
- streamlining regulation of biotechnology products in coordination with regulatory agencies (see recommendation 2.1a);
- enabling public-private partnerships with academia and industry through an economic development consortium;
- identifying biotechnology workforce and training gaps across the federal government (see recommendation 5.1a); and
- creating and maintaining a federal website for the biotechnology community (biotech.gov) that would offer information about biotechnology for the public, open opportunities for researchers, guidance on biotechnology regulations for developers, and more.

The NBCO, as a part of its responsibilities, would submit an annual report to relevant Congressional committees with information on federal efforts related to biotechnology, a summary of federal biotechnology spending, and the NBCO's plans for the following year. Congress could authorize the establishment of the director and the NBCO by either amending existing legislation or passing a new bill. The EOP should house the NBCO, and Congress should authorize and appropriate funds to the National Science Foundation (NSF) for its administration. There is precedent for this model, which would provide consistent staffing and resources over time.[111]

National Biotechnology Initiative

A whole-of-nation initiative to advance biotechnology for food, health, economic, and national securities.

The United States Government has numerous biotechnology efforts scattered throughout the federal departments and agencies, but there are no efforts to holistically address coordination.



Because of a lack of coordination, there is no effective way to see the progress of America's full biotechnology landscape, coordinate and maximize research investments, and identify associated national security implications.

To solve this problem, we recommend establishing and funding the National Biotechnology Coordination Office (NBCO).

A National Biotechnology Initiative, led by the National Biotechnology Coordination Office, will help ensure that the United States Government, in collaboration with partners in industry and academia, is prepared to lead the bioindustiral revolution.

National Biotechnology Coordination Office

Interagency Coordination

Support interagency activities related to biotechnology.

National Security

Assess national security implications of biotechnology.

Research & Development

Streamline biotechnology regulations.

Regulation

Promote research and development for biotechnology across the interagency.

Section 1.2

Elevate Biotechnology Across the Executive Branch

1.2a Recommendation

Congress should direct each relevant agency to designate a senior official to lead biotechnology policy.

The National Biotechnology Coordination Office (NBCO) would coordinate biotechnology efforts across the government and provide strategic leadership from the White House. Ultimately, the departments and agencies themselves are responsible for the day-to-day implementation of biotechnology policies and programs. But few have designated senior leaders at a high enough level to guide biotechnology activities within their agency and represent their agency's viewpoints to the White House.

To ensure that each agency has an appropriate champion of biotechnology, Congress should direct relevant departments and agencies to designate a senior leader at the assistant secretary level or equivalent to oversee and steer biotechnology-related work in their departments and agencies. The senior leader should also serve as the department's primary liaison to the director of the NBCO.

The Commission identified several opportunities to elevate biotechnology across the federal government, including at the Department of Defense (DOD), the Department of Energy (DOE), and the Department of Agriculture (USDA).

Section 1.3

Establish the Office of Global Competition Analysis and Include Foresight Capabilities

To safeguard U.S. leadership in critical technologies, the United States needs to assess classified, public, and commercial information to fully understand where the nation stands in relation to strategic competitors such as China. Only then would the United States be able to make informed policy decisions about how to strengthen its technology competitiveness.

1.3a Recommendation

Congress should establish the Office of Global Competition Analysis to develop timely data and technology forecasting to inform policymakers' decisions.

Currently, there is no single federal agency that uses data-backed analyses to evaluate the entire global and domestic landscape of critical technologies such as biotechnology, artificial intelligence, and quantum computing. Yet these technologies are vital to U.S. economic prosperity and national security.

To fix this problem, in 2023, a bipartisan group of Senators introduced the Global Technology Leadership Act (GTLA) (S.1873), which would establish the Office of Global Competition Analysis (OGCA).[112] While this bill has not been signed into law, it provides an important framework for how the United States can undertake a competitive analysis to understand its own current technological vulnerabilities.

In addition to adopting the provisions covered by the GTLA, the government would be well served by actively working to understand what the future of emerging technologies might hold. The United States tends to play catch-up after critical technologies have already become mainstream. Rarely does the government proactively identify emerging technologies so that it can implement policies to ensure the United States takes the lead in developing them.

Policymakers already draw on "foresight capabilities" to explore potential scenarios in the future, so they can make more informed policy decisions in the present.[113] The Food and Drug Administration (FDA), for example, regularly convenes experts to better understand emerging medical devices and biologics (medications derived from living organisms or their cellular components).[114] The FDA then uses the information gathered to prepare its regulators and thereby accelerate the timeline for innovations to go to market.

The government's lack of a centralized foresight office, however, means that foresight practitioners must set up such capabilities from scratch. Each agency has to invest in similar resources and activities, wasting time and effort.

Finally, the federal government fails to sufficiently leverage its vast network of scientists and technical experts across various departments and agencies. Their expertise could offer the United States a distinct advantage in foresight, especially for emerging technologies.

To address these shortcomings, Congress should establish the OGCA, as proposed in the GTLA, with an amendment to include strategic foresight as part of its responsibilities. Doing so would position the United States to take a more informed, future-oriented approach to technological development.

The OGCA would have two primary duties. First, it would conduct continual short- and long-term assessments of the United States' global competitiveness in technology and innovation. To do this, the office would assess the United States' research and commercialization capabilities, its policies toward industry, and its foreign dependencies, and then compare these assets and liabilities to those of America's strategic competitors. To inform its analyses, the office would collect relevant information and data from federal departments and agencies as well as obtain information from companies that may not be publicly available.

Second, the office would host a "strategic foresight library." Similar to how community libraries provide books, databases, journal subscriptions, and research expertise, but do not conduct the research themselves, a strategic foresight library would help federal departments and agencies conduct foresight studies relevant to their specific missions.

This library would:

- acquire and maintain resources (such as proprietary datasets and academic journals) for departments and agencies interested in conducting foresight studies;
- maintain a repository of past foresight exercises to collect and share best practices and references;
- conduct outreach to promote awareness and adoption of foresight among federal departments and agencies, including through a public-facing website; and
- establish a crowdsourced forecasting platform that would tap into the collective knowledge of thousands of scientists and researchers across the federal government who are actively working on critical and emerging technologies.

Intermission

Driving Biotechnology on Capitol Hill

The United States is on the cusp of a new industrial revolution, driven by biology, that will transform manufacturing, energy, agriculture, healthcare, and more.

This moment represents an inflection point for humanity's relationship with the natural world, and by extension how we defend, build, nourish, and heal our country.

The National Security Commission on Emerging Biotechnology was created to explore how emerging biotechnologies can affect our national security and recommend paths forward to Congress. Getting this mandate right—ensuring that we produce good policy that resonates not only with Congress but also builds a bright future for the country—is an audacious task. The catalyzing force for this mission is the four members of Congress who serve as Commissioners.

Our Congressional Commissioners have unique experiences of service to the Commission. They also have unique assessments of American strength in science and technology, what the stakes are in leading in biotechnology, and what is in store for the United States if America gets this right.

The Wisdom in this Design

This bipartisan and bicameral advisory body, one that is time-limited and calibrated for high impact, has a unique advantage. Unlike many prior commissions, this Commission includes two Senators and two Representatives from different parts of the country and across the political spectrum, alongside other Commissioners.

"I knew the Commission and its findings would have a lasting impact on the lives of Americans, and I wanted to be part of that work," Senator Todd Young (R-IN) said of his appointment. Senator Young chairs the Commission and leans on his years of bipartisan work to lead the group.

Senator Alex Padilla (D-CA) was likewise eager to accept the appointment. "I was excited to be selected to serve on the Commission to help position the United States at the forefront of shaping biotechnological advancements," he said. "The next generation of emerging biotechnologies will play a major role in safeguarding our national security interests and in enabling sustainable solutions to global challenges."

Prioritizing American Biotechnology

Our Congressional Commissioners are eager to bring biotechnology to the forefront of Congress and share the belief that the United States is primed to meet this moment and to lead the world in biotechnology.

"Through this Commission, we are seeking to place newfound emphasis on this domain so that we can adequately protect Americans and our interests," said Representative Stephanie Bice (R-OK-05). Such a critical mission requires sharp bipartisan thinking and broad bicameral support.

Starting with the Fundamentals

Representative Ro Khanna (D-CA-17) sees better access to STEM education as a vital piece of the national security puzzle, saying "STEM education, and biology education specifically, is essential for America's future." As biotechnology creates opportunity and highlights new risks, a ready and capable U.S. population will be critical to ensure safety and security.

"A bioliterate public will ensure American leadership in the development and fielding of critical new capabilities and enable us to stay ahead of global threats," Senator Young added. Innovating at the leading edge is what will keep the United States ahead of its adversaries.

Putting Biotechnology to Work for the United States

Prioritizing American leadership in biotechnology is also a savvy economic strategy. "We need to prioritize a new economic patriotism that revitalizes American production and lifts up the working class by embracing emerging biotechnologies," said Representative Khanna.

"I worked hard to be a bridge in the legislative negotiations with my Republican colleagues," he added, highlighting his collaboration with Senator Young to help pass the CHIPS and Science Act of 2022. "That was a fantastic bipartisan moment, and now the Commission is yet another opportunity to look at a greater vision for building America's future."

"It unlocked investments around the country to help address a national security vulnerability," Senator Young said.

The Congressional Commissioners see this work as vital to get ahead of similar supply chain vulnerabilities in biotechnology, before another investment at the scale of CHIPS and Science is necessary.

"Americans want a modern national security strategy and more investments at home," maintained Representative Khanna.

"That's where this report from the Commission comes in," Senator Padilla said. "Biotechnology is a strategic domain essential for tackling our most pressing challenges and being prepared for what the future will bring."

"We must be better prepared to face future threats," Representative Bice added. "And we must work diligently to protect the American homeland."

Congress can and must take steps to strengthen and prepare the American biotechnology enterprise to meet any challenge.

This report from the Commission may be the culmination of over a year and a half of work, but the work continues beyond its publication. How Congress responds at this critical moment will define how the United States out-innovates strategic competitors, leverages the benefits of biotechnology for our national defense, safeguards our national security, and makes America the leading partner for biotechnology worldwide.

Chapter 2

Mobilize the Private Sector to Get U.S. Products to Scale

The United States' world-leading capital markets have long supported early-stage biotechnology companies, fueling discovery after discovery. The American venture capital investment ecosystem is nearly three times the size of the next biggest: China's.

But the U.S. emerging biotechnology industry faces major headwinds. After a period of significant investment, investors learned the hard way that "hard tech" industries like biotechnology are very different from industries like software, where margins are nearly infinite and scaling is as simple as buying more computers and hiring more people. Hard tech like biotechnology and semiconductors require derisking both design and technology, followed by a capital-intensive process of scaling up manufacturing capabilities. Many biotechnology products must then go through regulatory approvals, adding another step in the process. Finally, customers must buy the product in order to generate revenue and deliver returns to investors. For a biotechnology product, moving from lab to market is long and expensive.

In the current economic landscape, capital has become scarcer and investors have become more risk averse. Investors have become more cautious, in part because interest rates have gone up and in part because many promising biotechnology companies have failed to produce attractive returns. As a result, many biotechnology companies that looked promising as recently as the early 2020s are struggling to secure funding for subsequent investment rounds. Biotechnology company bankruptcies hit a 10-year peak in 2023, leading to numerous company closures, layoffs, and restructurings.

Absent government action, the commercial market will not produce a biotechnology sector that aligns with broader U.S. national security needs. Three problems stand out.

First, there is often a gap in funding as a company seeks the necessary infrastructure to scale up. Venture capitalists are willing to fund biotechnology development and private equity is willing to fund expansion once there is a proven product, but between those two stages capital is harder to come by. In that gap, novel technologies with strategic or national security importance are at risk.

Second, emerging biotechnologies lack confident early customers. For an emerging technology, the first customer not only takes the risk of integrating a new product or service into its supply chains but also the risk that a product or service will not be delivered on time. Many buyers of biotechnology products are other companies within a largely business-to-business (B2B) market, meaning that biotechnology is often used to produce ingredients and components for other downstream products. Thus, the market is extremely sensitive to delays in delivery and buyers are reluctant to commit to meeting their needs with biotechnology

products. This reluctance, in turn, makes investors hesitant to bet on emerging biotechnology companies.

Third, U.S. biotechnology companies face intense competition from China. The Chinese biotechnology sector is expanding its capacity, and in some cases, Chinese firms are exceeding the performance of U.S. firms. As U.S. firms seek to grow and commercialize, they face formidable Chinese competitors that are rapidly expanding and bringing products and services to market at prices that have no floor. This unfair competition makes it even harder for the U.S. firms to establish a foothold in this nascent industry.

The overall picture is of an industry that is extremely strapped for capital, with high costs and slow timelines. That, in turn, makes American biotechnology companies vulnerable.

The Chinese Communist Party (CCP) employs a strategy that experts have called "brute force economics," a set of policies designed to increase China's dominance in strategically important sectors, including biotechnology.[115]

The CCP uses a range of legal and illegal tactics to acquire the necessary technologies and gain market access, including making investments, undertaking mergers and acquisitions, dumping products at below-market rates, coercing companies and talent, and buying or stealing intellectual property and data.[116]

In 2017, for example, two Chinese companies—the private equity fund Asia-Germany Industrial Promotion Capital (AGIC Capital) and the pharmaceutical company Humanwell Healthcare—acquired Ritedose Corporation, a South Carolina biopharmaceutical manufacturer. The sale price was $605 million, a staggering figure some 25 percent more than what alternative buyers offered.[117] In 2022, the Chinese firm Huafon purchased DuPont's biomaterials business and Tennessee manufacturing facility. The Committee on Foreign Investment in the United States (CFIUS), which focuses on national security concerns related to such transactions, reviewed and approved the purchase with qualifications. But even though measures were put in place to limit the transfer of intellectual property from DuPont that had dual-use implications, the Chinese company ended up obtaining the intellectual property anyway.

Other notable CFIUS-cleared transactions include the sale of Syngenta (which has significant control of the global seed market) to ChemChina and the sale of Complete Genomics (which has cutting-edge DNA sequencing technology) to the Beijing Genomics Institute (BGI). Many other questionable transactions were not even reviewed. CFIUS is now waking up to the national security threat of Chinese capital in the U.S. biotechnology sector.

Chinese companies are also amassing control and leverage over large segments of the global biotechnology market. The global biopharmaceutical behemoth Wuxi AppTec, for instance, obtained its position through a staggering number of acquisitions of U.S. and international firms. These include the British firm Oxford Genetics Limited (which specializes in mammalian cell engineering), ResearchPoint Global (a contract research organization based in Texas), HD Biosciences (a California-based company specializing in preclinical drug discovery), and AppTec Laboratory Services (a medical device and biologics testing firm with facilities in Minnesota, Pennsylvania, and Georgia).[118] Wuxi AppTec is so entrenched in American biopharmaceutical supply chains that American firms estimate they would need at least eight years to develop alternative sources for its services.[119]

BGI is another case in point. BGI is less a true private company than an extension of the CCP, having gained its market advantage in part through undisclosed state subsidies.[120] The firm also gained a technological advantage from U.S. sequencing companies—legally, by acquiring Complete Genomics, and illegally, by willfully infringing on patented technology owned by Illumina.[121] BGI's combination of state support and American intellectual property allows the company to undercut market rates for sequencing technologies.[122] As of 2020, BGI said it could sequence a human genome for just $100.

In another move made possible by subsidies from Beijing, the Commission heard from stakeholders that Chinese firms are offering U.S. biotechnology firms, particularly those struggling to access affordable manufacturing plants, free custom facilities if they move their operations to China.

In the face of China's aggressive efforts to dominate the biotechnology industry, the U.S. government must fight back, taking targeted steps to unleash American innovation, capital, and manufacturing capacity. The U.S. government will need to shoulder some of the risk of early-stage financing for biotechnology and encourage private investment through demand-side measures. It should use targeted public support to seed new private investment in critical gaps, mitigating the need for a more expensive approach to claw back U.S. capabilities in the future..

To mobilize the U.S. private sector in support of biotechnology, the United States must:

Simplify regulation for American biotechnology companies.

Streamline regulatory processes to alleviate unnecessary burdens and accelerate the commercialization of innovations.

Attract private capital to support biotechnology.

Enhance incentives and signal demand for private investment to bridge funding gaps and support the commercialization of emerging companies.

Scale up and de-risk manufacturing.

Support pre-commercial manufacturing facilities that enable the scaling up of emerging bioproducts and defray costs for individual firms and investors.

Protect critical biotechnology infrastructure.

Safeguard vital infrastructure against external threats.

Fight back against brute force economics.

Counteract unfair competitive practices employed by China, leveling the playing field for U.S. companies.

By adopting these recommendations, the United States could lean into the strength of its private sector, neutralize the advantages the CCP uses to undermine U.S. national security, and serve all Americans by bringing beneficial biotechnologies to market faster to defend, build, nourish, and heal.

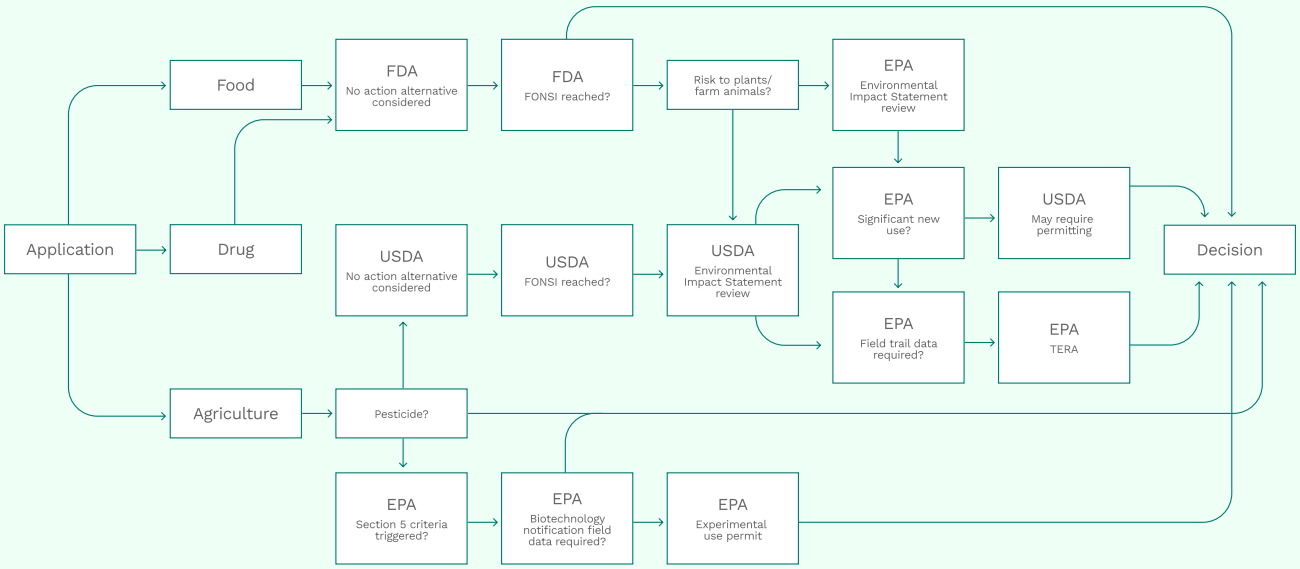
Section 2.1

Simplify Regulation for American Biotechnology Companies

More than 15 federal offices and programs play some part in U.S. biotechnology regulation, with three agencies in leading roles: the Animal and Plant Health Inspection Service (APHIS) within the Department of Agriculture (USDA), the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA).[123] The result is a fragmented regulatory system in which no single federal entity is empowered to standardize redundant processes or adjudicate overlapping jurisdictions.

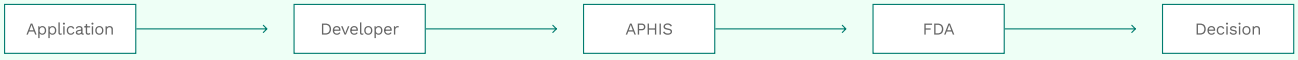
Since the 1980s, the U.S. biotechnology regulatory system has operated as a patchwork because agencies largely rely on statutory authorities that were not intended for biotechnology, resulting in misalignment between their mandates and technological advancements.[124] Agencies are constrained by outdated or overly broad interpretations of statutory mandates. The USDA, for example, took major steps to fast-track reviews and provide exemptions, adopting a new rule for certain genetically engineered organisms in 2020, but this common-sense regulatory improvement was vacated by a federal court in 2024.[125]

The Current Regulatory Maze



A Map for a Clear Regulatory Pathway

This is an example of a clear pathway for one product. Not all products will have the same pathway.



Challenges of the U.S. Biotechnology Regulatory System

Innovators have identified four key challenges within the U.S. biotechnology regulatory system. First, they face uncertainty about which agencies are responsible for regulating their products. Second, they must navigate overlapping processes across multiple agencies. Third, they frequently encounter unnecessary regulatory burdens for products that have already been deemed safe. Fourth, even when they overcome these hurdles, the regulatory agencies' limited capacities result in significant delays.

Because each agency acts independently and there is no coordinated way to enter the regulatory system, innovators can struggle to determine who is responsible for regulating their products. It is often unclear how regulatory agencies work together to review products, and innovators can face lengthy delays as products are bounced between agencies. Engineered insects, for example, may fall under the FDA's animal drug authority, EPA's pesticide authority, and APHIS's plant and animal health authority. Developers of gene-drive mosquitoes, which are engineered to reduce pathogen transmission or fertility in their offspring, were passed off from agency to agency for nearly 10 years.[126] In contrast, similar mosquitoes that are modified without biotechnology are regulated by the EPA and gained approval in just five years.

Even after identifying the appropriate starting point, innovators must navigate a convoluted maze of overlapping processes across multiple agencies. Each agency has its own requirements, timelines, and procedures, resulting in duplicative and asynchronous review. Innovators must contact each regulatory agency separately, and each product must follow a unique path to obtain multiple approvals at different times. Innovators have to repeat themselves, double back, and change course with little predictability, all of which is remarkably inefficient.

These obstacles pose a particular challenge for biotechnology products that are similar to products made with conventional methods or to products that have been repeatedly reviewed. For example, non-browning apples and potatoes have both been approved in the United States, but regulatory agencies are unable to take prior approvals into account to expedite reviews of similar products. As of today, a non-browning avocado, peach, or pear would likely face the same lengthy approval process, even when the non-browning traits are the same.[127]

Finally, after navigating this regulatory maze, innovators must wait their turn in an ever-lengthening queue. Regulatory agencies face persistent understaffing despite a growing backlog of applications. Timelines vary from product to product, but some innovations have been held by agencies for a decade or more.[128] If agencies do not shift their focus onto the most novel and complex products, the backlog will only grow, and more innovations will remain uncommercialized.

Focus Review on Novel Products

Biotechnology is a powerful tool for producing safe and beneficial products. The potential risks stem not from the technology itself but from the novel products it enables.[129] For decades, biotechnology has been safely used to produce life-saving medicines like insulin. But it can also be used to create novel products that have characteristics not found in nature. Some biotechnology products are themselves living organisms, which live on and replicate when introduced into the environment. These products may have effects that require a closer look.

Several other countries are simplifying or have already simplified regulations for certain biotechnology products. Not surprisingly, innovators are increasingly seeking approval in those countries first or even moving their operations there. Without efforts to simplify and clarify U.S. biotechnology regulation, this offshoring trend is likely to continue, and the United States will lose its hard-won leadership in biotechnology development and commercialization.

The recommendations in this section aim to simplify America's biotechnology regulatory system. If taken together, they would result in more straightforward and risk-proportionate regulation that would encourage innovators to bring biotechnology products to market efficiently and transparently, while still protecting human health and the environment.

"American agriculture is vital to our national and economic security, yet it faces a host of challenges, from pests and environmental stressors to the growing threat of cyberattacks on this distributed and diversified sector. Advances in biotechnology and biomanufacturing can enhance our resilience against these threats, but realizing these benefits will require an active effort to keep pace with current challenges, including the PRC's efforts to close the gap in agricultural innovation."

- Commissioner Dawn Meyerriecks

Food Security is National Security

The American agricultural sector encompasses over a third of all U.S. land and almost 3.5 million farmers, ranchers, fishers, and other producers, and faces many potential vulnerabilities.[vi] These vulnerabilities are especially concerning in light of a rapidly evolving threat landscape with profound consequences for our national and economic security.[vii]

Threats to agriculture come in many forms. Diseases and pests cost farmers an estimated $590 billion globally each year.[viii] Moreover, geopolitical conflicts increasingly threaten global supply chains: after Russia's 2022 invasion of Ukraine, global fertilizer prices tripled due to Western sanctions on Russian exports.[ix]

Biotechnology and biomanufacturing offer exciting new opportunities to protect American agriculture from these threats. For instance, advances in these biotechnologies could improve the nutritional quality of foods, boost plant and animal resistance to disease, and reduce the need for fertilizer.[x] Domestically produced bioproducts could support robust supply chains for everything from feedstocks to chemicals, creating new jobs and growing our economy.[xi]

Realizing the full potential of agricultural biotechnology requires addressing the challenges it faces. Total U.S. spending on agricultural research has fallen by a third since peaking in 2002.[xii] By contrast, China is now the largest global funder of agricultural research and development (R&D), and China-based companies are acquiring and consolidating global agricultural companies to bolster their technology portfolio.[xiii] For all of these reasons, it is critical that the United States leverage the opportunities of biotechnology today to build an agricultural sector that is up to the challenges of tomorrow.

2.1a Recommendation

Congress must direct federal regulatory agencies to create simple pathways to market and exempt familiar products from unnecessary regulation.

The U.S. biotechnology regulatory system was intended to regulate products based on their characteristics and risks, rather than the processes used to create them.[130] Unfortunately, this distinction has eroded over time, resulting in unnecessary and burdensome regulation. The current approach is not just unwise; it is also unsustainable, given the growing number of truly novel biotechnology products entering the development pipeline. The default government policy should be that if a biotechnology product is generally understood to be safe and can be made through conventional means, it should be regulated no differently than conventional products. If a biotechnology product is similar to previously reviewed products that are well-understood by regulators, it should be exempt from further review. Regulators should spend their time and energy on understanding the effects of truly novel products made with biotechnology.

To achieve these goals, the National Biotechnology Coordination Office (NBCO) (see recommendation 1.1a) should be empowered to drive simplified biotechnology product regulation. Congress should direct the NBCO to:

- lead and coordinate biotechnology regulation efforts across the interagency through a deputy director for regulation (though regulatory authorities would remain with existing agencies);
- work with regulators to resolve overlaps, gaps, and ambiguities;
- work with regulators to map clear regulatory pathways, including to simplify and ease regulation for familiar products and conduct regulatory trials;
- build and maintain digital infrastructure; and
- communicate clearly and consistently about biotechnology regulation.

To accomplish these goals, the NBCO should be staffed with full-time biotechnology science and regulatory policy experts, as well as experts in human-centered design, software engineering, and science communication. Staffing needs may decrease over time as clear regulatory pathways are successfully established. Additionally, Congress should grant the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) the authority to determine and enforce clear regulatory pathways when the regulators cannot reach consensus.

Create Simple Pathways and Exemptions

To create simple pathways to market, regulators should identify biotechnology products that could have arisen naturally or through conventional methods, as these generally pose no additional risk, and exempt or expedite their regulatory review.[131]

Currently, regulatory agencies lack the statutory authority to apply their expertise to reduce regulation for well-understood products. Instead, they are required to evaluate each product independently, even when similar products have already been reviewed and found to be safe.

Recent judicial actions, such as the Supreme Court decision in Loper Bright Enterprises v. Raimondo and a ruling against the USDA in the Northern District of California, have raised uncertainty about agencies' ability to interpret their authorizing statutes.[132] Regulatory agencies may now face additional legal challenges when using authorities that are not explicitly intended for biotechnology, and it may be harder for agencies to nimbly address novel products. As a result of the decision reversing USDA's policy, developers of biotechnology products are again subject to potentially lengthy and cost-intensive permitting processes.[133]

To address these challenges, Congress should authorize regulators to reduce or remove regulatory hurdles for familiar products based on accumulated evidence, enabling agencies to reallocate resources toward supporting emerging biotechnologies.

Specifically, Congress should amend relevant statutes that give agencies authority to regulate biotechnology products, such as the Plant Protection Act, the Federal Food, Drug, and Cosmetics Act, and the

Toxic Substances Control Act. Amendments should clearly delineate which agencies are responsible for each type of product and authorize the NBCO and the OIRA to resolve any remaining overlaps, gaps, and ambiguities.

Map Clear Regulatory Pathways that Resolve Regulatory Overlaps, Gaps, and Ambiguities

Congress should instruct the NBCO to guide regulatory agencies in creating interagency agreements that map clear regulatory pathways. The NBCO would work with agencies to ensure that such agreements describe expected timelines, data requirements, and decision points for each product type. Each map would show how a developer could advance to each step, with clear handoffs between agencies. Agreements would also facilitate information sharing across agencies, with appropriate safeguards for confidential business information. High-quality maps that delineate all applicable regulatory processes during research and development (R&D) would allow innovators and investors to accurately estimate what it takes to get to market.

Conduct Regulatory Trials to Inform Clear Regulatory Pathways

For products that lack a clear regulatory pathway, Congress should authorize the NBCO to work with regulators to create a regulatory "sandbox," an environment featuring short-term trials of proposed tests so that they can evaluate new regulatory pathways and potential improvements to existing pathways.

Sandboxes can help facilitate dialogue between developers and regulators, informing the development of regulatory processes that facilitate innovation while mitigating risks.[134] Governments are increasingly creating regulatory sandboxes for emerging technologies, as the United Arab Emirates and Spain have done.[135] In 2024, the United Kingdom created the Engineering Biology Sandbox Fund to support regulator-led sandbox projects that accelerate regulatory reforms. [136]

The NBCO-led sandbox would allow innovators to propose new or updated regulatory pathways. For example, an innovator could propose a new testing method to replace a more expensive, older method. Working together, the NBCO, the innovator, and regulators would develop and conduct a short-term trial for the new method, with metrics to determine success. If the proposed method meets established guidelines for safety and efficacy, the NBCO would then work with regulators to update regulatory pathways accordingly.

The NBCO could also use the regulatory sandbox to identify ways to accelerate the approval of crucial products. The FDA provides "emergency use authorization" for medical countermeasures and expedited processes for certain therapies and devices that meet a serious medical need.[137] But there are few expedited processes for agricultural or industrial products, leaving innovations such as disease-resistant citrus trees languishing in review while American farmers are forced to expend resources removing diseased trees.[138]

Verify Voluntary Standards for Biotechnology

Alongside the regulatory process, voluntary standards can boost confidence in new products—for example, helping farmers weigh the value of new agricultural inputs, food manufacturers evaluate the benefits of new ingredients, and insurers consider the risks of introducing new products into existing supply chains.

The USDA's Process Verified Program (PVP) allows companies, trade groups, and others to create custom standards through a fee-for-service model, with audits to ensure that the standards are being followed.[139] The USDA is already authorized to use audits for products in food and agriculture, but is not currently using this authority for biotechnology.[140] Congress should encourage the USDA to advertise the PVP as an option for biotechnology products, thereby helping innovators to determine if the program could provide value for them and their customers.

Build Digital Infrastructure to Simplify Biotechnology Regulation

Each regulatory agency currently has its own submission portal, forms, processes, and data requirements. Even though regulators have taken some steps to coordinate, biotechnology product developers must submit the same information multiple times in different formats, a frustration that has led them to call for a "single door" approach that would streamline submissions, data requirements, and timelines.[141] Moreover, each regulatory agency keeps its own repositories of regulatory decisions, in some cases providing limited or no public information. This lack of transparency presents a challenge for innovators, consumers, and others seeking to identify what paths products have taken through the regulatory system and which products have previously been approved.

Congress should authorize the NBCO to build and maintain a single point of entry for biotechnology innovators at biotech.gov (see recommendation 1.1a).

The NBCO could create easy-to-find repositories of interagency agreements and regulatory decisions, driving toward a "single door" application process for biotechnology products that would minimize the administrative burden on both industry and government.

Communicate Clearly and Consistently about Biotechnology Regulation

It should be easier for industry and the public to find useful information about biotechnology regulations. Researchers and startups need to understand regulatory requirements so that they can gather the necessary data and make sound decisions early in product development, and investors need a better grasp of regulatory pathways to assess market readiness. Consumers should also have easy access to information about biotechnology products and the processes used to ensure their safety.

The NBCO could work across the agencies on:

Regulatory guides

Providing guidance for innovators as they enter and progress through the regulatory system for the first time (the NBCO would build on lessons learned from the FDA's Veterinary Innovation Program (VIP), which gives developers of animal drugs feedback and other assistance during the regulatory process).[142]

Public outreach

Exploring outreach methods to identify concerns and improve public understanding of biotechnology (including collaboration with community leaders such as Master Gardeners, who help provide science-based information to the public).[143]

Developer outreach

Delivering plain-language information about biotechnology regulation for the developer community, including academia and industry.

Regulatory diplomacy

Working toward international alignment of biotechnology product regulations. This could include reviewing applications collaboratively, aligning data requirements, and sharing risk assessments, all of which could shorten regulatory timelines and reduce burden for both developers and regulators. (See Section 6.1 for more detail on regulatory diplomacy).

Rainbow Papaya: A Regulatory Success Story

The historic story of the Rainbow papaya shows the importance of both agricultural biotechnology and streamlined regulation. The papaya ringspot virus devastated the U.S. papaya industry in the 1990s. Scientists detected the virus on commercial papaya farms in 1992, and by 1995, Hawaiian farmers could no longer grow papayas.[xiv]

With support from the Department of Agriculture (USDA), Dr. Dennis Gonsalves led a team of scientists at Cornell University in developing a virus-resistant papaya using a gene from the virus itself, effectively vaccinating the plant.[xv] The team crossbred the resistant plants with commercial varieties, resulting in the Rainbow papaya.[xvi]

The scientists grew Rainbow papayas on a farm that had gone out of business due to the destructive virus, demonstrating that the new papaya was resistant and still had the familiar qualities that had existed for generations.[xvii] Next, the Rainbow papaya underwent a thorough but expedited review by the USDA, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) to ensure it was safe for consumption and the environment. In 1997, the Rainbow papaya was officially approved and made available for widespread cultivation.[xviii]

Biotechnology saved the Hawaiian papaya industry. Less than two years after their livelihoods were wiped out, farmers returned to growing papaya and the threat of the virus waned.[xix] This example shows that biotechnology can promote food security and economic security if regulatory frameworks balance safety reviews with timely access for farmers. Today, U.S. crops and livestock are under constant threat from pests and diseases, including citrus greening, wheat rust, avian influenza, and African swine fever.[xx] Biotechnology can help combat these hazards and ensure continued prosperity of American farmers.

2.1b Recommendation

Congress should direct federal regulatory agencies to prepare for novel products to come to market.

Even if biotechnology product regulation is simplified and coordinated, the U.S. government's low regulatory capacity will continue to delay the commercialization of biotechnology products in the United States. Regulatory agencies cannot keep up with the exponential increase in applications for regulatory review.[144] The APHIS, for example, received and completed an average of 4.5 requests for review each year between 1992 and 2022. In 2023 alone, it received 43 requests.[145] This increase in applications is expected to continue and will quickly overwhelm regulatory agencies.

Congress should prepare regulatory agencies for the products of the future in three ways. First, it should ensure that agencies have the necessary capacity and expertise to review these products. Second, Congress should give regulators access to public-private partnerships through a regulatory foundation. Finally, Congress should establish a regulatory research program that provides the scientific underpinning needed to simplify biotechnology regulation.

Bolster Regulatory Agency Capacity

Staffing at regulatory agencies has remained constant even as applications have more than doubled in recent years. Experts shared with the Commission that the Food and Drug Administration (FDA) has only nine employees working on food safety for plants and microorganisms produced with biotechnology, despite the importance of pre-market oversight for such foods, and the Environmental Protection Agency (EPA) has only six staff reviewing applications for the commercial use of certain microorganisms produced with biotechnology. Senior scientists are stretched particularly thin since they must provide technical reviews, meet with innovators, develop rules, coordinate with domestic and international regulators, and train junior staff, among other responsibilities.

Appropriators should provide small funding increases for all biotechnology regulatory agencies, with additional targeted increases for a subset of these agencies. After years of flat budgets and growing workloads, a modest boost in regulatory capacity would benefit American biotechnology companies and unlock major economic growth by enabling more products to safely enter the market. The NBCO could work with regulatory agencies to quantify staffing and expertise needs, particularly as those needs shift to address novel products.

In addition, the NBCO could coordinate a biotechnology regulatory fellowship program for federal government employees. Such a program would improve the regulatory workforce, help provide continuing education for current federal employees, and encourage cross-functional understanding of biotechnology research and regulation. While the primary participants would be current regulators, the program could also be open to other federal government employees, such as lawyers who work in regulatory agencies, policy advisors in trade agencies, and program officers in research agencies. Fellowships could include a capstone project on regulatory topics, such as clear regulatory pathways, digital infrastructure, or communication strategies.

Establish a Foundation to Enable Biotechnology Innovation

Regulatory agencies need access to external experts in order to improve regulatory processes, scan the horizon for emerging technologies, and engage with the public, among other activities. Government-affiliated foundations provide a flexible and efficient way to supplement federal activities. Examples include the Reagan-Udall Foundation for the FDA and the Foundation for Energy Security and Innovation (affiliated with the Department of Energy (DOE) and established by the CHIPS and Science Act of 2022). A more recent example is the Foundation for Standards and Metrology, which was proposed in Congress in 2024 and would be affiliated with the National Institute of Standards and Technology (NIST).[146] Some government-affiliated foundations focus on R&D and others make policy recommendations, but none focus on biotechnology.

To fill the gap, Congress should establish an independent, non-profit foundation to support U.S. biotechnology product regulation. This foundation

could work with the NBCO and across biotechnology regulatory agencies. Industry stakeholders have expressed interest in partnering with regulatory agencies through a foundation, including by financially supporting it. To protect against potential conflicts of interest, the foundation would have strict accountability requirements in its authorizing language.

While creating a foundation is no substitute for sufficiently funding regulatory agencies, it would significantly increase their capacity by allowing regulators to focus on regulation. A foundation would bring together experts from academia, industry, and government to share information about regulatory challenges, and suggest ways of solving them. It could also make recommendations about how regulation might incentivize innovation—for example, proposing simplified regulations for certain platforms to encourage companies to modernize their manufacturing practices.

The foundation could also help the NBCO and federal agencies with communication and outreach. For example, the foundation could offer a regulatory fellowship for innovators and others involved in biotechnology product development, including a short course on biotechnology regulation. Shadowing experiences and other interactions between developers and regulators would help developers better understand regulatory processes and help regulators understand those processes from the vantage point of developers. External fellows would not handle potentially sensitive developer data, and safeguards would address potential conflicts of interest and protect confidential business information. Eventually, programs could place federal employees in academia, industry, or trade groups for additional learning experiences.

Establish a Federal Biotechnology Regulatory Research Program

U.S. regulatory agencies need scientific information to justify simplifying regulatory pathways. In 1992, Congress established the U.S. Department of Agriculture (USDA) Biotechnology Risk Assessment Research Grants (BRAG) program to fund research that supports biotechnology regulation, but its success has been limited. Funded by withholding two percent of the budget of USDA biotechnology research projects, the program receives only $5-6 million annually.[147] This amount is inadequate to meet regulatory research needs, and BRAG does not support the multi-season, multi-location studies necessary to evaluate the potential environmental impacts of biotechnology products. Furthermore, researchers who study biotechnology products outside of agriculture may not even be aware of the USDA's programs.

Congress should establish a biotechnology regulatory research program at the National Science Foundation (NSF). To make certain that the research is targeted to regulators' needs, the NSF should collaborate with the NBCO and regulatory agencies in designing requests for proposals. In implementing this program, the NSF should use a variety of funding mechanisms, including research grants, cooperative agreements, and temporary research consortia to ensure that researchers produce the information that regulators need to allow others to unlock innovation. If the NSF program is established, Congress should consider rolling BRAG's responsibilities into it.

In addition, Congress should instruct the NSF to contract with the National Academies of Science, Engineering, and Medicine (NASEM) to study the safety and benefits of biotechnology tools and products relative to conventional manufacturing methods and other human activities. NASEM has conducted multiple studies related to biotechnology, but none have provided a consensus on the safety of biotechnology tools.[148] Such a study would yield a public source of high-quality information needed to update regulations for U.S. biotechnology products and identify any gaps in scientific information needed for regulation.

After years of flat budgets and growing workloads, a modest boost in regulatory capacity would benefit American biotechnology companies and unlock major economic growth by enabling more products to safely enter the market.

Section 2.2

Attract and Scale Private Capital to Support Biotechnology

Precise federal action can de-risk investment and unlock the private capital necessary to scale up and commercialize biotechnology innovations.

The U.S. government can achieve this goal through both "push" and "pull" measures, coupling supply-side incentives to drive R&D, innovation, and initial growth with demand-side signals to reduce investment risks, attract private sector support, and ensure the long-term resiliency of domestic production. These steps will be critical to creating a robust commercial biotechnology sector in the United States.

2.2a Recommendation

Congress must establish and fund an Independence Investment Fund, led by a non-governmental manager, that would invest in technology startups that strengthen U.S. national and economic security.

Private capital alone will not carry biotechnologies that are critical to U.S. national security along the path from the laboratory to the market; the technical and business risks are simply too high. While government funding should not singlehandedly propel a company through that stage, it can act as a powerful signal to private investors about the importance and viability of a company or technology.

Several U.S. government efforts have attempted to solve the problem of seeding and attracting capital toward technologies critical to U.S. national security.

Existing financing mechanisms include:

- a partnership among the Department of Health and Human Service's (HHS) Biomedical Advanced Research and Development Authority (BARDA) and the Global Health Investment Corporation (GHIC), a non-profit venture capital entity (GHIC deploys government money to make venture capital style investments in medical countermeasures for health security);[149]
- In-Q-Tel (IQT), a non-profit strategic investor that invests on behalf of the U.S. national security community across a range of technology sectors including space, microelectronics, and biotechnology;[150] and
- the Office of Strategic Capital at the Department of Defense (DOD), which has partnered with the Small Business Administration (SBA) to create the Small Business Investment Company Critical Technology (SBICCT) Initiative.[151] Through the SBICCT, fund managers deploy low-cost, government-guaranteed capital in alignment with DOD's critical technology areas (CTAs), including biotechnology.[152]

Each of these investment vehicles serve to commercialize technologies in the United States, but they all serve different purposes and gaps remain. For example, none of these investment vehicles has in its mandate the responsibility to support and commercialize the type of technologies that would create a competitor to WuXi Apptec. Without an additional investment approach, emerging technologies that are important for U.S. national security will fail.

Congress must establish the Independence Investment Fund at the Department of Commerce (DOC) to support high-priority areas of national security technology that are left unaddressed by current initiatives. These technology areas encompass a broad range of national security concerns, expanding beyond strictly defense and intelligence applications. By making initial investments in high-potential areas, the fund could signal market opportunities and incentivize private investors to follow suit. The investments would lead to a "crowding-in" effect, unlocking private capital to scale up national security technology products. Roughly 30 percent of the fund's capital should be set aside specifically for emerging biotechnology investments.

Government-Backed, Private-Run

The DOC would set overarching strategic priorities for the fund. The fund would be operated by a non-governmental investment partner, with experienced fund managers making investment decisions without day-to-day government oversight. The DOC could suggest technology startups for consideration by the fund managers, but the fund would have the final say on those specific investment decisions. The fund would be established with the support of a strategic advisory board, including venture capital investors, large equity investors, and a designated representative from the National Biotechnology Coordination Office (NBCO) (see recommendation 1.1a).

Strategic funding would allow for longer time horizons and accommodate the uncertainty inherent in scaling innovative technologies, particularly in sectors such as biotechnology that face extended commercialization timelines and entrenched market competition.

Maximizing Impact

The goal of the fund would be to earn returns through continuous access to private market investments that enable self-sustainment after initial appropriations from Congress. There is a possibility that a second, smaller allocation will be necessary roughly 10 years after establishment of the fund, depending on investment returns and how long the fund needs to become self-sustaining.

The fund's operational model is designed to maximize efficiency and impact. By delegating investment decisions to an experienced investment partner and establishing a strategic advisory board, the fund ensures a balance between government oversight and private sector agility. Additionally, its structure would drive toward long-term self-sustainment, reducing its dependence on continuous government appropriations while attracting significant private capital. These features would make the fund adaptable and scalable, so that it is best positioned to support a wide array of national security technology investments, particularly in high-risk areas such as biotechnology where existing models fall short.

Partners

The fund would be directed to invest in American companies but could possess the authority to make limited investments in companies in allied countries where appropriate, and over time, seek to partner with allied funds, such as the NATO Innovation Fund and the UK National Security Strategic Investment Fund.

> Without an additional investment approach, emerging technologies that are important for U.S. national security will fail.

Financing a Biotech Startup

Whiteboard to Vision

$50K – $500K
Pre-Seed

This initial capital can help a biotechnology founder pursue key scientific discovery steps, such as conducting preliminary lab research to conceptualize a product idea and hiring a founding team to form a company.

Private Funding Sources

Family and friends, crowdfunding, incubators, loans

Analogous Government Funding Sources

Grants (e.g., Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR)), loans, cooperative agreements, some equity investments (e.g., In-Q-Tel (IQT), Biomedical Advanced Research and Development Authority-Global Health Investment Corporation (BARDA-GHIC))

Vision to Prototype

$500K – $2M
Seed

The first official equity investment round can allow a biotechnology company to purchase lab infrastructure, undertake proof-of-concept experiments, and conduct market research to ensure that it has a viable product with a clear path to market.

Private Funding Sources

Angel investments, venture capital, crowdfunding

Analogous Government Funding Sources

Grants (e.g., SBIR/STTR), loans, cooperative agreements, some equity investments (e.g., IQT, BARDA-GHIC)

Prototype to Initial Production

$2M – $10M
Series A

Next, a biotechnology company must secure funding to continue product development with technology maturation infrastructure, conduct pre-clinical trials (if applicable), and navigate the regulatory process.

Private Funding Sources

Venture capital, private equity

Analogous Government Funding Sources

Grants, loans (e.g., Department of Defense Office of Strategic Capital (DOD OSC)), cooperative agreements, prototype contracts (e.g., Defense Innovation Unit (DIU))

Initial Production to Scaled up Production

$10M – $30M
Series B

$30M – $200M
Series C

Growth capital is typically provided for a biotechnology company with a proven track record of stable growth. This capital can then enable the company to scale up its product with technology maturation and commercial infrastructure, conduct clinical trials (if applicable), secure regulatory approvals, and pursue product and/or market expansion.

Private Funding Sources

Venture capital, private equity

Analogous Government Funding Sources

Grants, loans (e.g., DOD OSC), cooperative agreements, prototype contracts (e.g., DIU)

Scaled Up Production to Sustained Commercial Product

Maturity, Acquisition, Exit

Biotechnology companies can use mature stage funding to establish a dominant market position, explore international markets, and consider options such as mergers, acquisitions, or going public.

Private Funding Sources

Private equity, hedge funds, investment banks, initial public offerings (IPOs)

Analogous Government Funding Sources

Production contracts, procurement

2.2b Recommendation

Congress should direct the Department of Energy (DOE) and the Department of Health and Human Services (HHS) to use existing authorities to smooth out unpredictable and inconsistent demand for biotechnology products through advance market commitments (AMCs) and offtake agreements and provide new authorities where necessary.

Biotechnology products that meet existing U.S. government needs struggle to attract private sector investment and scale up. These difficulties arise in part because the government is not clearly signaling consistent demand for biotechnology.

Biotechnology can satisfy the technical needs of various agencies. Consider the DOE's efforts to develop nontoxic lubricants for hydropower equipment, some of which could be manufactured with cost-competitive and scalable biomanufacturing.[153] The problem, however, is that biotechnology companies do not always know what is needed, when, and by which part of the government. Furthermore, current government procurement mechanisms generate inconsistent demand. The challenges are familiar to anyone contracting with the government: single year appropriations, abrupt policy shifts, and crises can all drive volatility in demand. Companies producing antibody drugs, for example, encountered a spike and sudden drop in government demand during the COVID-19 pandemic.[154] It is critical to clearly define and smooth out demand for biotechnology products that can fulfill government needs. Companies and investors, especially those in private equity, look for steady market demand as evidence that they should pursue scale-up.

To signal consistent demand, governments can use advance market commitments (AMCs) and offtake agreements. AMCs are a promise to purchase a product that does not yet exist, if a developer can make it at scale. They help companies de-risk the costs of new product development by positioning the U.S. government as the first, but not only, buyer. Offtake agreements are promises to purchase an existing product in multiple orders over a given period. They help companies demonstrate to private investors that there is steady demand within government markets for their products.[155] Government AMCs and offtake agreements intend not to create artificial demand but rather to formalize a commitment to purchase products that fulfill existing needs and standards.[156]

Congress should direct the DOE and the HHS to leverage other transaction authorities (OTAs)—a flexible procurement mechanism authorized by Congress—to establish AMCs for biotechnology products that meet existing technical needs, signaling demand to pull these products through development. The DOE should also establish offtake agreements, signaling demand to pull developed biotechnologies through scale-up.

The DOE and the HHS should each define which of their existing technical needs can be met with biotechnology. The DOE, for example, might need biobased lubricants for hydropower equipment, while HHS might want new vaccine platforms for U.S. public health. Once those needs are defined, the DOE and the HHS should determine which biotechnologies would most benefit from AMCs (such as those that have not yet scaled up) and which would benefit from offtake agreements.

AMCs and offtake agreements should be meticulously designed in consultation with technical and market experts from both inside and outside the government. Each AMC or offtake agreement should detail agreed-on prices, specifications, delivery timelines, and frameworks for evaluation. Finally, for Congressional oversight purposes, the DOE and the HHS should report annually to Congress on their AMCs and offtake agreements. This oversight mechanism would ensure that the agreements are meeting their objectives and timelines so that the government is not locked into expensive or unneeded pledges.

2.2c Recommendation

Congress should restore full and immediate expensing of research and development (R&D) expenditures.

Recent changes to the Internal Revenue Code have reduced the amount of R&D costs that businesses can deduct annually. Previously, a company could fully deduct its domestic R&D expenditures in the year in which those expenditures were incurred, but companies must now spread those deductions across five years.

For biotechnology startups, the amortization of R&D expensing can make it harder to stay afloat. R&D accounts for about a quarter of the overall spending by biotechnology companies.[157]

Congress should restore full and immediate expensing of domestic R&D expenditures under Section 174 of the Internal Revenue Code. A return to this prior treatment of R&D expensing would provide some financial cushion for small businesses as they develop their technologies.[158]

2.2d Recommendation

Congress should improve the effectiveness and reach of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs to support early-stage innovation.

The Small Business Administration's (SBA) Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are mechanisms for the U.S. government to strategically invest in early-stage technologies, including biotechnologies. Powered by a network of federal agencies, "America's seed fund" is intended to provide non-dilutive funding—that is, investment that does not require owners to give up equity—to help emerging technologies move toward commercialization.[159] Eleven federal agencies participate in the programs, and each agency with a R&D budget of over $100 million sets aside 3.2 percent of its budget for its own SBIR/STRR programs, with early research award amounts limited to $306,000 and pre-commercialization award amounts limited to $1.5 million.[160]

The SBIR/STTR programs comprise one of the largest hard tech seed funds in the world. Yet there is no overarching, coherent strategy for deploying its over $3 billion of annual funding. Each federal agency allocates grants in accordance with its respective mission without any broader considerations. For biotechnology in particular, funding is fragmented across the DOD, the NSF, the EPA, the DOC, the USDA, and the Department of Homeland Security (DHS). SBIR/STTR grant applications can be cumbersome. Some early-stage companies find the size of early research grants (which range from $100,000 to $306,000, depending on the agency) not worth the effort to apply.

The programs would be better if they more easily reached companies whose technology have high potential for commercialization. Federal SBIR/STTR program administrators may have no experience investing in the industry, and even though federal agencies have the legal authority to grant SBIR/STTR funds to businesses owned by hedge funds or private equity firms, they are inappropriately excluding these businesses from participating in their SBIR programs.[161] Critics have accused the SBIR/STTR programs of fostering "SBIR mills," whereby firms obtain multiple early-stage SBIR grants for

An SBIR Success Story

As "America's Seed Fund," the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs aim to stimulate technological innovation, foster small businesses in meeting federal research and development (R&D) needs, encourage participation from socially and economically disadvantaged individuals in technology innovation, and increase private sector commercialization of federal R&D through early-stage, high-risk funding.[xxi]

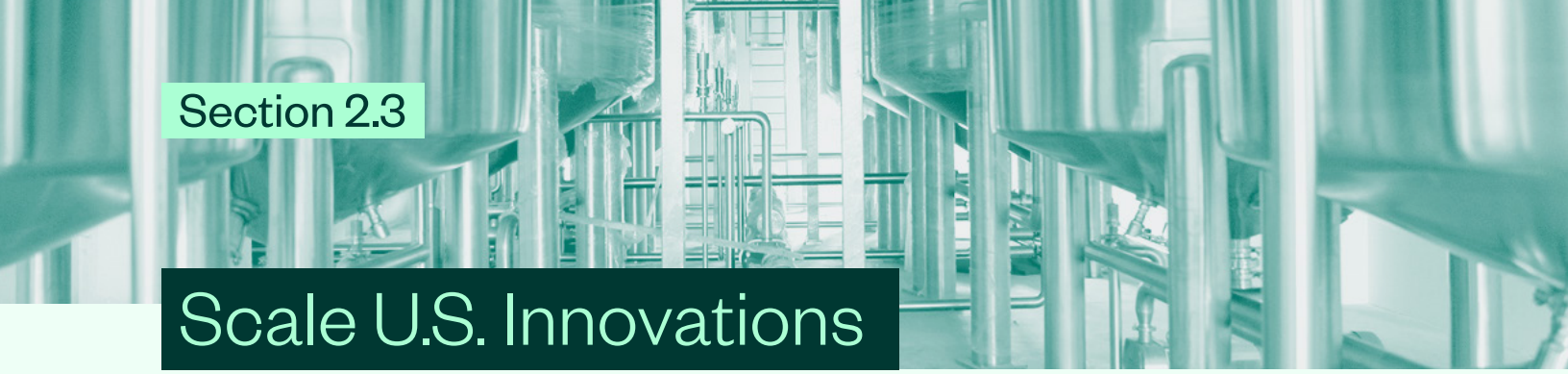
Geno, a San Diego-based biotechnology company that has received SBIR/STTR grants, provides an illuminating example of how such funding in early-stage research can translate into technological innovation and economic growth in an emerging industry. Founded in 1998, Geno was awarded multiple SBIR/STTR grants in support of various research efforts between 2000 and 2007.[xxii] Since then, Geno has commercialized GENO Bio-BDO, a process technology that harnesses plant sugars to produce the widely used industrial chemical 1,4-butanediol. Geno has grown the company's portfolio to include plant-based nylon production and has secured partnerships with brands including Lululemon and L'Oreal.[xxiii] In August 2024, Geno received $1.51 million from the Department of Defense's (DOD) Distributed Bioindustrial Manufacturing Program (DBIMP) to plan a multiproduct biorefinery for polymer precursors that have applications in the aviation and automobile markets.[xxiv]

short-term revenue without ever commercializing a product.[162]

Lastly, even if SBIR/STTR grants reach high-potential companies, they remain vulnerable to China's brute force economic tactics. A 2021 DOD report found that Chinese state-sponsored firms target SBIR-funded companies for intellectual property acquisition and theft.[163] In 2023, the SBA issued due diligence guidelines to manage the risk of intellectual property theft from foreign governments, but they applied only to current recipients and new applicants.[164]

Given the large annual budget, it is critical that policymakers ensure that the SBIR/STTR programs have the direction needed to catalyze emerging biotechnology startups.

Congress should ensure that funding reaches biotechnology companies that have high commercialization potential and are critical to U.S. national security interests. To ensure that grants are strategically allocated, Congress should provide direction, resources, and guardrails. It should convey the importance of funding in critical technology areas alongside an overall increase of the set-aside percentage for the SBIR/STTR programs. The programs should be reformed to better incorporate industry expertise and commercialization potential when reviewing grants. Congress should also consider ways of solving the problem of companies that repeatedly consume SBIR/STTR resources without ever reaching commercialization. The SBIR/STTR programs should also be streamlined so that they allocate grants more quickly and efficiently. Lastly, Congress should expand the recent measures that mitigate risks of foreign intellectual property theft and require the reporting of foreign acquisitions of past grant recipients.



Section 2.3

Scale U.S. Innovations

For U.S. biotechnology innovators, the biggest roadblock to commercialization is proving that their products and processes can scale, thus showing investors a path to financial return. The breadth of products that biotechnology can make translates into a broad range of infrastructure needed to make them, including facilities, equipment, and manufacturing processes. The United States faces two main challenges to securing this infrastructure.

First, the United States lacks biomanufacturing capacity.[165] Researchers are generating new products faster than manufacturing capacity is increasing. Building new facilities is expensive and time-consuming. Precommercial facilities can cost $100-200 million—while facilities for commercial scale can take two to five years to build and prepare and cost up to $2 billion.[166]

As a result, American companies, particularly early-stage ones, mainly use overseas manufacturing capacity to scale processes for commercialization during the initial stage of bringing a product to market, and a number of foreign governments are investing billions to create even more biomanufacturing infrastructure.[167]

Second, biomanufacturing technologies of the future have yet to mature into routine commercial applications. Today's biomanufacturing facilities are generally optimized for one type of product and are usually not compatible with other products.[168] A facility designed to make vaccines, for example, cannot easily pivot to making chemicals without a major retrofit. Building more of this bespoke, traditional capacity will not translate into making a wider range of products under one roof.

Manufacturing innovations that are under development, such as greater automation and continuous manufacturing (a process by which inputs are continuously fed into a system, as opposed to made in batches), could change the paradigm for biomanufacturing. These innovations could lead to smaller, less expensive facilities that use modular equipment and cleanrooms to manufacture products at lower cost while using less energy. Despite early signs of promise, both the bioindustrial and biopharmaceutical sectors have been slow to develop and adopt these technologies, primarily because of concerns that they might pose regulatory risk and not recoup their capital investments.

To create the biomanufacturing infrastructure of the future in the United States, Congress should invest in the science of biomanufacturing scale-up, undertake biomanufacturing grand challenges (see Section 4.3b and Appendix D for more detail), create data-sharing platforms and artificial intelligence/machine learning (AI/ML) tools to accelerate biomanufacturing design (see 4.1a and 4.3c), and support domestic precommercial facilities that integrate expanding state-of-the-art infrastructure to help innovators mature their technologies. In addition, there are other government entities responsible for supporting commercial-scale manufacturing capacity, such as the DOE's Loan Programs Office and the Administration for Strategic Preparedness and Response (ASPR) BioMap Consortium.

Taken together, these actions would advance American leadership and bolster local economies, all while minimizing long-term federal spending.

Biomanufacturing 101: An Introduction to Fermentation

Like traditional manufacturing, biomanufacturing allows the United States to use what it has to make what it needs. The most widespread form of biomanufacturing, called fermentation, uses living microorganisms to transform inputs into products. These products include everything from beer to immunotherapies to fuel. A simplified process is outlined below.

Step 1

Infrastructure

Biomanufacturers first select two key ingredients: a feedstock, which acts as the "food" to be transformed, and the chassis organism, which "eats" the feedstock to produce the product. Critical enablers, such as water, energy, and natural chemicals, are also essential inputs.

What are Feedstocks?

Feedstocks are bulk raw materials used as an input for an industrial process. For biomanufacturing today, a common feedstock is sugar derived from biomass sources like corn and sugarcane. Less common biomass sources include corn stalks and husks, forest debris, and waste gas from steel mills. Advancements in the conversion technologies that turn biomass sources into feedstocks could make many sources easier to use.

What are Chassis?

Much like how a chassis in a car is a standard structural frame that can be used with different engine sizes, seats, and colors, a chassis in biomanufacturing is a biological frame that allows for customization. In biomanufacturing, scientists customize chassis with specific genetic sequences to produce desired products. Most chassis used in biomanufacturing today are microorganisms, such as yeast, that have sufficient genetic information and molecular tools available. Researchers are studying many other cell types, such as algae and plant cells, as potential novel chassis to produce future products.

Process Design

Biomanufacturers can now design the entire process. They determine how much of each input is needed to yield the desired amount and form of the product, whether the feedstocks need processing to be more "edible" for the chassis, and what packaging is needed to distribute the final product.

Infrastructure

Biomanufacturing needs a range of specific equipment and facilities, from glass beakers to giant bioreactor tanks. As biotechnologies mature from lab scale discoveries to commercial products, innovators must change their equipment and facilities to match each development stage.

Step 2

Fermentation

The chassis "eats" and transforms the feedstock into the desired product through fermentation in bioreactors. Bioreactors, software, and sensors help to create a controlled environment (setting the right temperature, humidity, and oxygen levels, for example) to make the process as efficient and effective as possible.

Step 3

Downstream Processing

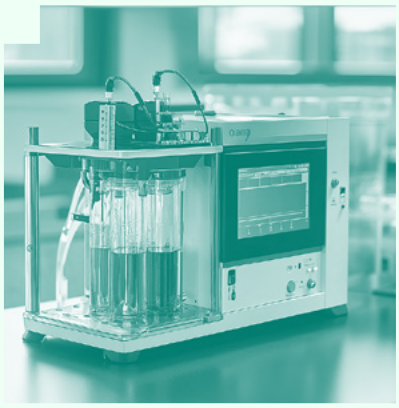
Fermentation results in a mixture that includes both the target product and waste products. Manufacturers need to isolate the target product through purification and recovery methods that remove waste.

Step 4

Final Steps

Manufacturers package and transfer the end product to consumers who will use it as-is or as an ingredient for other products.

Infrastructure Across Stages to Scale Biomanufacturing



Laboratory & Bench → Technology Maturation → Commercial

Initial discover and prototyping phase for bioproduction.

Iterative process of maturing technology and processes to reach quantity and cost for the market.

Commercial production where optimized processes consistently meet market demand.

2.3a Recommendation

Congress must authorize and fund the Department of Energy (DOE) and the Department of Commerce (DOC) to develop a network of manufacturing facilities across the country for precommercial bioindustrial product scale-up.

The United States has many favorable conditions for scaling industrial biotechnology, including its abundant feedstocks, reliable utilities, extensive transportation infrastructure, and proximity to consumers. But even so, companies tend to do their scale-up abroad.[169]

Congress must authorize the DOC and the DOE to create facilities that companies and researchers can use to prove that their lab inventions work at pilot and demonstration scale before moving to full commercial scale production. This effort should include expanding existing DOE facilities and building new facilities. (See Section 3.2 for recommendations to address biomanufacturing for the Department of Defense (DOD).)

Congress should require the DOE and the DOC, in collaboration with the NBCO (see recommendation 1.1a), to lay out a strategy to create a network of new precommercial facilities across the country for scaling up bioindustrial products. This network should integrate next-generation techniques (see Section 4.3c) and data-sharing platforms (see Section 4.1a).

These precommercial facilities should be designed as user facilities. Their operating models and capabilities should align with the needs of their customers, whether they be from industry or from other government entities such as a National Lab. Charging fees for certain users would also ensure financial viability through cost-sharing with the private sector, prevent operational dependence on a single company's success, and provide regular feedback regarding the effectiveness of these scale-up facilities. If the facilities are not meeting their needs, companies would not pay for access and the facility would be forced to adjust. This setup would ensure the government does not finance large-scale biomanufacturing facilities that no one uses.

As a promising example, policymakers should look to the Bio Based Europe Pilot Plant (BBEPP) in Ghent, Belgium, a user facility that was capitalized with

contributions from the European Union and the local government but whose operations are funded principally by user fees.[170] Its non-profit model ensures that the facility's financial health is not directly tied to the success or failure of the individual companies that use it.

Within six months, the DOC and the DOE should jointly submit a plan to Congress outlining concrete steps to finance and construct these facilities. They should coordinate their steps with other agencies that finance scale-up facilities and should describe how the plans address a gap not filled by other agencies. The departments should include specifics such as the process for site selection, design specifications, and construction timelines as well as specifics about how, once the sites are selected, the departments would engage with community stakeholders, local industry, and nearby academic institutions.

Congress should evaluate the departments' plans to ensure that the proposed facilities are distributed across the country, make the most of existing infrastructure, and are located near skilled workers, feedstocks, and feedstock processing facilities.

Congress should conduct regular oversight of the progress the departments are making on constructing the facilities and, once built, collect metrics about their operation, usage, and financial health. Congress should require the executive branch to meet ambitious timelines and quality metrics before continuing to appropriate funds for this effort. Additional facilities should not be built unless there is demand for them.

Department of Commerce Facilities

The specific focuses of each facility may vary based on local resources, expertise, and needs, but the DOC should consider the following infrastructure and capabilities for all facilities:

- a wide range of products, including dedicated Current Good Manufacturing Practice (CGMP) compliant equipment to scale-up food- and agricultural-related products and processes;[171]
- a variety of fermentation methods, including gas, solid state, and continuous fermentation;
- infrastructure to support a variety of non-fermentation biomanufacturing, such as cell-free systems;
- biomass processing equipment that supports biological conversion and other conversion methods;
- numerous downstream processing capabilities, including product recovery and purification equipment;
- fermentation capacity that ranges from pre-pilot to intermediate, including at least a 75,000-liter tank, with additional capacity as feasible; and
- data infrastructure that integrates with a Web of Biological Data (WOBD) (see recommendation 4.1a).

New Department of Energy Facilities

Under this strategy, the DOE should propose new facilities that would each:

- upgrades to equipment and an expansion of fermentation capacity;
- cutting-edge infrastructure driven by industry needs, including automated bioreactors, gas fermentation equipment, processing equipment for emerging feedstocks, and equipment for bioprocessing critical materials such as rare earth elements;
- application and tool development, equipment and algorithm testing, and process improvement; and
- a pilot program to establish digital infrastructure for collecting biomanufacturing and bioprocessing data.

Increase Support for Existing Department of Energy Facilities

The DOE's current user facilities include the Advanced Biofuels and Bioproducts Process Development Unit (ABPDU) at Lawrence Berkeley National Laboratory and the Integrated Biorefinery Research Facility (IBRF) at the National Renewable Energy Laboratory (NREL). These not-for-profit facilities offer strategic partnerships, joint research projects, technology licensing, and a variety of other avenues for academics to partner with National Laboratory groups, all in an effort to de-risk the scale-up of biotechnology products and processes within the DOE mandate.

The ABPDU has successfully worked with numerous companies to help mature a variety of biotechnology products.[172] But it also has long wait times and is constrained by its current funding and equipment, preventing it from meeting the substantial needs of industry and government. The IBRF, which boasts a larger biomanufacturing fermentation capacity and has been used extensively for many cross-sector collaborations, faces the same constraints.[173]

Congress should increase support for existing DOE facilities, which would allow them to increase the number and speed of their collaborations with private industry and academia, upgrade their equipment, work on novel bioprocessing technologies, and drive next-generation advancements in biomanufacturing that could be spurred by grand research challenges for biotechnology (see Section 4.3).

Expansion of existing ABPDU and IBRF facilities should include:

- upgrades to equipment and an expansion of fermentation capacity;
- cutting-edge infrastructure driven by industry needs, including automated bioreactors, gas fermentation equipment, processing equipment for emerging feedstocks, and equipment for bioprocessing critical materials such as rare earth elements;
- application and tool development, equipment and algorithm testing, and process improvement; and
- a pilot program to establish digital infrastructure for collecting biomanufacturing and bioprocessing data.

Creating new facilities with a similar partnership structure, along with expanding and capitalizing on existing ABPDU and NREL facilities, would allow the DOE to expand its precommercial development infrastructure across the country and support more companies at all stages of commercialization.

"Biomanufacturing is rapidly becoming a core pillar of the American economy. By investing in the full development pipeline for emerging biotechnologies—from technology maturation infrastructure to AI research for production at scale—these proposals advance our position as a global leader while building a strong and innovative American biotechnology sector."

• Commissioner Eric Schmidt

2.3b Recommendation

Congress should direct the Department of Commerce (DOC) to create a public-private biopharmaceutical manufacturing center of excellence focused on developing and scaling new ways to make medicines.

Biopharmaceutical manufacturing requires flexible and affordable development infrastructure to ensure that innovative products can rapidly move from the lab to commercial-scale production. It is important that such infrastructure complies with regulatory requirements and is commercially relevant since when a biopharmaceutical company takes a product through FDA review, regulators evaluate how the product is made. Methods that incorporate CGMP, Quality by Design (QbD), and Chemistry, Manufacturing, and Controls (CMC) guidance are particularly vital for ensuring efficient and effective manufacturing and subsequent regulatory approval.[174]

Once a company chooses a manufacturing method that is approved by regulators, the incentive to iterate on that manufacturing method decreases, since a change could require additional regulatory scrutiny. As a result, companies may not pursue manufacturing innovations, even ones that are faster or more cost efficient.[175] The biopharmaceutical sector needs manufacturing innovations, given how expensive and difficult biopharmaceuticals are to produce. The sector needs to advance their manufacturing processes and catalyze full-scale production in the United States especially to solve future technical challenges. Once completed, such a center would bring together companies, academics, and government scientists to advance innovative biopharmaceutical manufacturing.

Congress should appropriate $120 million to the DOC to create a biopharmaceutical manufacturing center of excellence that would:

- innovate and advance the science of biopharmaceutical manufacturing, especially for products important to U.S. national security, health security, and economic security (such as gene therapies and antibodies);
- support CGMP, QbD, CMC, and similar guidance to ensure effective and efficient manufacturing and improve regulatory understanding of innovative manufacturing methods; and
- focus on workforce training and development by working with educational and community partners to bolster biotechnology talent.

The DOC should competitively bid the contract to run the facility. For example, the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), a DOC Manufacturing USA Institute, is one organization focused on advancing biopharmaceutical manufacturing that could be involved with the center.

Section 2.4

Protect Critical Biotechnology Infrastructure

2.4a Recommendation

Congress must direct the Department of Homeland Security (DHS) to ensure that biotechnology infrastructure and data are covered under "critical infrastructure."

The Cybersecurity and Infrastructure Security Agency (CISA), within the DHS, is the operational lead for federal cybersecurity policy and operations and the national coordinator for critical infrastructure security and resilience.[176] Its activities are guided by a list of 16 Critical Infrastructure Sectors that Presidential Policy Directive (PPD) 21 established in 2013.[177]

CISA is responsible for engaging with stakeholders in these Critical Infrastructure Sectors, including for the purpose of revising the National Infrastructure Protection Plan (NIPP).[178] Biotechnology infrastructure cuts across a number of these designated Critical Infrastructure Sectors, including the health, agricultural, and industrial sectors.

Indeed, PPD-21 designates as critical a number of sectors relevant to biotechnology: chemicals, critical manufacturing, the defense industrial base, energy, food and agriculture, and healthcare and public health.[179] But these areas are neither specific to biotechnology nor are they reflective of the full breadth of the biotechnology sector.[180] Currently, the federal government does not adequately protect either physical biotechnology infrastructure or sensitive biological data, despite their major ramifications for the economy, public health, and national security. [181]

> Adversaries and malicious actors will increasingly target the biotechnology sector's infrastructure and data.[182]

Already, they have carried out numerous attempted and successful cyberattacks on critical infrastructure in biotechnology, including against hospitals and agricultural facilities.[183]

Biological data, which are critical to discovery and frequently contain sensitive personal information, face specific vulnerabilities. Some federal government efforts underway aim to protect sensitive types of biological data, including the National Institute of Standards and Technology (NIST) framework for genomic cybersecurity and the National Institute of Health's (NIH) Genomic Data Sharing policy.[184] But these piecemeal efforts do not holistically address the changing landscape of genomic and biometric cybersecurity.

The DHS has existing authorities to help the private sector protect its most valuable and national security-relevant physical and digital assets, but its sector-based approach means there are currently no clearly-designated, biotechnology-specific critical infrastructure protections. The DHS needs to treat biological data, along with the entire biotechnology sector, as critical infrastructure for cybersecurity purposes.[185]

To this end, Congress must direct the DHS to ensure that the biotechnology sector is covered by the list of Critical Infrastructure Sectors and require CISA to integrate the protection of genomic and other sensitive biometric data into its national strategy. Together, these actions should ensure that biotechnology infrastructure and data is covered under "critical infrastructure" and duly protected as such.

Given the urgent need to address this gap, once this recommendation is passed into law, the DHS should submit a work plan within 45 days. Since some biotechnology-specific infrastructure is already covered, this work plan should ensure that biotechnology is covered under the existing sectors, rather than adding it as a new one.

The DHS should consider including in the work plan:

- a preliminary list of biotechnology infrastructure stakeholders, such as the Bioeconomy Information Sharing and Analysis Center (BIO-ISAC);
- an outreach plan to ensure that stakeholders are aware that they are covered under existing Critical Infrastructure Sectors (and which ones);
- an action plan to ensure that biotechnology stakeholders are represented at their appropriate consortia and Coordinating Councils; and
- an action plan to update the National Infrastructure Protection Plan (NIPP) by 2026, with input from the biotechnology sector.

Following the submission of this plan, DHS would execute it and submit a final report to Congress based on its findings. This entire process should take less than a year.

Additionally, Congress should amend the Cybersecurity and Infrastructure Security Agency Act of 2018 to:

- categorize genetic data systems that involve genomic sequences and other sensitive biometric data as critical infrastructure;
- require CISA and biotechnology sector stakeholders, including the government agencies responsible for biosecurity (see Section 4.4a), to together develop security protocols for genetic data, including joint exercises and data sharing;
- increase the staff at CISA as necessary to implement security policies and protocols related to the new responsibilities regarding genomic and other sensitive biometric data;
- implement training for federal personnel on protecting genetic and other sensitive biometric data, addressing unique security challenges and ethical considerations;
- incorporate genetic and biometric data security into the national cybersecurity strategy, thereby ensuring an ongoing focus on and adaptation to new threats; and
- collaborate with entities working on biosecurity (see Section 4.4a) to ensure that security concerns are synchronized (for example, coordinating when these data connect with systems that convert them into physical genetic sequences).

No later than two years after the NIPP is updated, Congress should direct the DHS to conduct a follow-up evaluation. If there are additional critical biotechnology areas that do not fit under the current sectors, that finding should be explicitly stated in the DHS's report to Congress.

Section 2.5

Fight Back Against China's Brute Force Economic Tactics

China devotes billions of dollars in state subsidies to prop up companies that would not withstand normal market forces. Its goal is not only to support Chinese biotechnology companies but also to court fledgling foreign firms that are struggling to commercialize their innovations. The CCP is even willing to subsidize national champions beyond the point of market viability, just to undercut companies based in the United States and allied countries.

China is taking advantage of the barriers to commercialization in the United States so it can enter and, in some cases, dominate markets. The U.S. government must therefore both remove those barriers and prevent China from using adversarial capital and non-market practices to undermine U.S. companies and gain control of strategic markets.

2.5a Recommendation

Congress must require public companies to disclose single points of supply chain vulnerability located in foreign countries of concern.

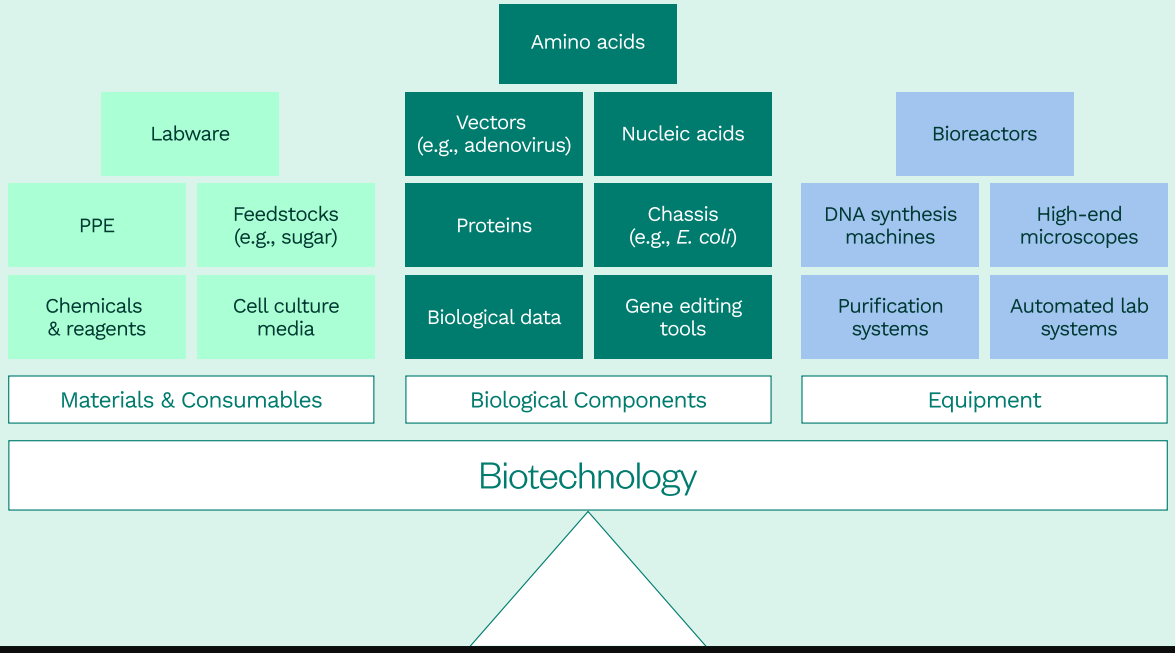
For companies seeking to maximize profits and minimize costs, relying on single-source suppliers has long been an attractive strategy. This approach often leads to short-term savings by concentrating orders with a limited number of vendors, resulting in lower operational and logistics costs. Many of these single-source suppliers are headquartered or have manufacturing facilities in China.[186] These dependencies can cause problems for a company in times of global instability and conflict.

To de-risk future investments, the U.S. government must require companies to report their supply chain vulnerabilities. Greater transparency into potential supply chain vulnerabilities will help investors better assess risk and incentivize diversification, if needed.

Congress should direct the U.S. Securities and Exchange Commission (SEC) to require publicly held securities and companies of a certain size to file annual reports with the SEC disclosing the existence of single-source suppliers located in foreign countries of concern. This requirement would apply only to publicly held securities and companies involved in the production of technologies critical to U.S. economic and national security, including biotechnology.

The Wide Range of Biotechnology Critical Enablers

While the AI boom has dramatically increased demand for resources directly linked to AI, such as training data and computing power, the boom has also put major strains on other common resources such as land, water, and electricity Similarly, biotechnology relies on a wide range of critical enablers with complex supply chains. As the sector grows, these critical enablers may become chokepoints or bottlenecks that could jeopardize or stunt the entire biotechnology industry.



2.5b Recommendation

Congress must prohibit companies that work with U.S. national security agencies and the Department of Health and Human Services (HHS) from using certain Chinese biotechnology suppliers deemed to pose a national security threat.

U.S. companies rely too much on firms located in China for the production and supply of critical biotechnologies. This reliance presents two vulnerabilities. First, sensitive business and biological data may be collected and shared with the Chinese government to support its military biotechnology ambitions. Second, the Chinese Communist Party (CCP) could instruct its state champion biotechnology companies to sever ties with their American customers, leaving the U.S. biotechnology industry without suppliers of key products and services.

Congress must pass legislation that prohibits companies that work with the DOD, the DOE, the intelligence community (IC), and the HHS from using Chinese biotechnology suppliers that are deemed to pose a national security threat.

These agencies are likely to have the most biotechnology-related transactions with the greatest national security impact. Chinese biotechnology companies that should be covered by this prohibition include those on the "Chinese military companies" list maintained by the DOD under Section 1260H of the 2021 National Defense Authorization Act (NDAA), those on the DOC's Entity List, and any other company of "national security concern," as designated by the President (with authority delegable to a cabinet secretary).

Companies would have an appropriate amount of time to wind down long-term contracts and move to less risky alternative suppliers, such as those based in the United States and allied countries.

2.5c Recommendation

Congress should reform the Committee on Foreign Investment in the United States (CFIUS) to better and more nimbly screen the highest-impact, highest-risk types of investment in critical technology sectors in the United States.

CFIUS is an interagency committee that reviews the national security implications of foreign investments in U.S. companies or operations. Its jurisdiction includes the review of mergers, acquisitions, and takeovers that result in foreign control of a U.S. business, along with non-controlling investments in U.S. businesses related to critical technologies, critical infrastructure, sensitive personal data, and certain real estate transactions.

Adversarial investments are a critical vector of vulnerability in the U.S. biotechnology industry. Before the 2018 Foreign Investment Risk Review Modernization Act (FIRRMA) expanded CFIUS's purview, the committee failed to recognize the strategic importance of biotechnology and allowed Chinese companies to acquire strategic technologies and capabilities through foreign direct investments.

After FIRRMA, CFIUS has tried to prioritize strategic sectors such as biotechnology. But in practice, its mandate and resources are insufficient to protect against adversarial investment in emerging technologies.

The Commission's analysis of past biotechnology-related CFIUS cases and the way FIRRMA has been applied have revealed four key vulnerabilities in current authorities.

First, current definitions for "critical technology" constrain the scope of CFIUS's review. These definitions rely on static lists, such as the DOD's U.S. Munitions List, the DOC's Commerce Control List (CCL), and the DOC's Section 1758 list of emerging and foundational technologies.[187] CFIUS relies on the DOC's Section 1758 list, but this list is updated infrequently.

Second, CFIUS does not currently have jurisdiction over "greenfield investments,"—whereby a company creates a completely new business operation in a foreign country via the establishment of new physical facilities—and has jurisdiction only over joint ventures that result in control of an existing U.S. business. Yet both types of transactions pose security risks. In 2022, CFIUS cleared the Chinese company Fufeng Group's purchase of 370 acres of agricultural land in North Dakota, near the Grand Forks Air Force Base, because it deemed the transaction to be outside of its jurisdiction.[188] Joint ventures, for their part, pose risks of intellectual property theft and technology transfer, even when a foreign company has a non-controlling interest.

Third, CFIUS is not mandated by law to analyze the control of strategic supply chains and markets in the course of its review process. Under the current statute, CFIUS may take into account "the cumulative control of, or pattern of recent transactions involving any one type of critical technology by a foreign government or foreign person" when considering national security risks, but it is not explicitly required to do so.[189] Thus, the CFIUS review process can sometimes fail to prevent foreign adversaries from "slicing and dicing" market control of critical technology sectors through multiple transactions.

And finally, CFIUS has blanket review for covered transactions involving allied countries, in addition to countries of concern. Although there are exemptions for certain foreign states from CFIUS jurisdiction of nonpassive minority investments and real estate transactions (also known as the Excepted Foreign State and Excepted Real Estate Foreign States lists), the CFIUS review process does not differentiate between foreign adversaries and allies when assessing transactions related to critical technologies. As a result, CFIUS's finite time and resources are spread across cases with differing levels of security risk when reviewing for certain covered transactions.[190]

The 2022 CFIUS Executive Order on Evolving National Security Risks and CFIUS enforcement guidelines (EO 14083) attempted to address some of these issues in investment screening for emerging technologies, including biotechnology.[191] A February 2025 National Security Presidential Memorandum signaled further executive interest from the Trump Administration to improve CFIUS review and outbound investment screening for strategic technologies, such as biotechnology.[192] However, there are limits to what can be accomplished solely through executive branch action without legislative changes.[193]

Congress should reform CFIUS to better and more

nimbly screen the highest-impact, highest-risk types of investment into critical technology sectors in the United States. To ensure this, Congress should amend the FIRRMA to:

- Expand definitions of "critical technology" for CFIUS review. The legal definition of "critical technology" should be expanded in order to give CFIUS greater flexibility when screening investments by foreign adversaries in critical technology areas. Congress should direct the Secretary of the Treasury to review cases involving technologies of "national security concern," and to enumerate any such technologies that meet this definition that are not covered by existing lists of critical technologies.
- Reform CFIUS review to no longer be "country-agnostic" for certain covered transactions. Congress should direct the Department of Treasury (Treasury) to generate an "excepted foreign state" list of allied countries that have investment security practices that are harmonized with those of the United States and whose transactions would go through an expedited review process. The Secretary of the Treasury would be given the authority to scrutinize investments originating in these countries only when there is evidence of undisclosed interests or control of a firm by a third country or when the Secretary of the Treasury (whose authority in this case would be non-delegable) determines that there is a significant national security risk in the proposed transaction.
- Expand CFIUS's jurisdiction to include non-controlling joint ventures and greenfield investments when a country of concern is involved.
- Mandate that CFIUS analyze the control of strategic supply chains and markets as part of its review process.

Lastly, to effectively carry out its legislative mandate, Congress should provide Treasury with the resources it needs to modernize the digital systems that underpin CFIUS's analysis and expand its analysts' access to up-to-date business and other data.

2.5d Recommendation

Congress should direct the International Trade Commission (ITC) to investigate Chinese dumping or oversupply of biotechnology products and services.

China's top-down strategies, subsidies, and anticompetitive practices often distort global markets. Without normal price floors or the economic pressure to maintain production in proportion to demand, Chinese firms have been able to flood global markets with cheap goods and acquire control of critical industries.

There is emerging evidence that China is distorting biotechnology markets in particular. Beijing Genomics Institute (BGI) and MGI Tech have financed their growth in an atypical manner that indicates undisclosed state involvement and subsidization, undermining their foreign competitors in the genomic sequencing market.[194] China's ability to manufacture active pharmaceutical ingredients (APIs) at disproportionately low prices led India to impose a unilateral anti-dumping duty on certain APIs from China in 2022 to protect its domestic manufacturing industry.[195]

If the ITC receives a petition or a Congressional directive, it has the authority and resources to investigate the material impact of foreign subsidies and market dumping on U.S. industry. The results of that investigation would inform executive branch action on any remedy (such as a tariff or a countervailing duty) that might level the playing field. Congress should direct the ITC to speedily investigate Chinese subsidization and production overcapacity in biotechnology that could economically harm the United States. If the ITC's investigation confirms Chinese dumping and oversupply in the biotechnology industry, then the DOC's International Trade Administration (ITA) can use this information to inform subsequent executive branch action. For example, for anti-dumping cases, the ITA can issue additional duties on imported items to offset the below-cost pricing. Similarly, for countervailing duties (CVD) cases, the ITA can issue duties equivalent to the subsidy amounts on the imported items.

Biomanufacturing Critical Products

Acetaminophen (pain reliever, brand name Tylenol)

Traditional Manufacturing

The United States sources 70% of its acetaminophen from China, leaving America vulnerable to Chinese supplier disruptions,during the COVID-19 pandemic.[xxvi]

Biomanufacturing

Researchers at the Great Lakes Bioenergy Research Center have patented a method to convert lignin, a complex molecule derived from plants sourced directly in the United States, into acetaminophen. This process not only presents an alternative production process for products like Tylenol but also serves as a secondary source of revenue from a bioproduction process, improving the economic viability.[xxvii]

Sunscreens, Anti-Aging Creams, and Facial Cleansers

Traditional Manufacturing

Squalene, used in many sunscreens, anti-aging creams, and facial cleansers, is a naturally produced compound that hydrates and detoxifies the skin. But most squalene comes from the livers of sharks found throughout the Northeast and Central Atlantic, Asia, and the Southwest Pacific Ocean.[xxviii] An estimated 2.7 million sharks have been harvested each year to meet the squalene demand for the cosmetic industry alone, increasing the risk of shark extinction and creating an unstable supply.

Biomanufacturing

Biomanufacturers are using engineered yeast, sugarcane, and precision fermentation to produce an alternative version for squalene, called "squalane," at commercial scale without the need for sharks.[xxix]

Not only is squalane more stable and effective than squalene,[xxx] but domestic production of squalane will also make U.S. supply chains more resilient without harming shark populations.

Rubber Tires

Traditional Manufacturing

U.S. dependence on foreign sources of rubber dates back to World War II, when the United States was cut off from 95% of the global rubber supply in 1942. Today, the United States continues to source its rubber from abroad, primarily from Asia. This leaves the United States vulnerable to volatile supply chain disruptions and price spikes, such as when a drought in Thailand caused global natural rubber prices to reach record highs.[xxxi]

Biomanufacturing

Several organizations are using genetic modification and selective plant breeding to turn rubber-containing plants, like dandelions, into commercially viable alternative sources of rubber.[xxxii]

For example, a research partnership between the U.S. Department of Agriculture (USDA), Bridgestone, and the University of Arizona is working to increase rubber production in a shrub called guayule.[xxxiii] The teams aim to increase domestic production of natural rubber using biotechnology, while reducing pollution and waste compared to traditional rubber manufacturing.

Naloxone (opioid overdose medication, brand name Narcan)

Traditional Manufacturing

Thebaine, a precursor to naloxone, is sourced directly from poppy plants, which take years to grow. Once harvested, manufacturers use chemical processing to convert the thebaine into naloxone.[xxxiv] But only a few countries, including India, Turkey, and Australia, can legally grow poppy plants.[xxxv]

Biomanufacturing

One company commercially produces thebaine through precision fermentation, removing the need for poppy plants entirely. This process uses genetically engineered yeast that can produce thebaine, reducing the production time from years to weeks.[xxxvi] This fermentation process could be one way to increase U.S. domestic supply of this critical precursor, reduce the overall production timeline, and reduce reliance on other nations.

Military Uniforms

Traditional Manufacturing

The U.S. military relies on textiles that are durable and adaptable to different environments for uniforms and equipment. There is constant demand for uniforms and equipment that are stronger, more resilient, and can perform in austere environments.

Biomanufacturing

Supported by the Department of Defense (DOD), one company is creating synthetic textiles derived from proteins that mimic those originally found in squid tentacles. These new textiles are stronger and more durable than traditional synthetic fibers and present an alternative method for the military to source their uniforms.[xxxvii]

To-Go Food Containers

Traditional Manufacturing

Traditional single-use plastic packaging, such as to-go food containers, accounts for approximately one third of plastic waste. Almost all manufacturers use significant inputs to produce single-use packaging.[xxxviii]

Biomanufacturing

By combining agricultural feedstocks with a compound typically found in mushroom roots called mycelium, one biotechnology company is essentially growing single-use packaging. The packaging is thermally insulative, water resistant, shelf stable, and compostable, presenting a less wasteful option.[xxxix]

Laundry Detergent

Traditional Manufacturing

Existing laundry detergents contain a mixture of enzymes, sourced from living organisms, and surfactants, chemicals responsible for the cleaning action that are primarily synthesized through chemical processes, as well as a variety of other chemicals.[xl]

Biomanufacturing

Biotechnology companies are producing better enzymes through protein engineering and microbial fermentation.[xli] For example, cold-tolerant enzymes allow consumers to switch from hot to cold water washing without affecting cleaning ability, which can reduce energy use by as much as 90% and save the average American household roughly $150 per year.[xlii]

Baby Formula

Traditional Manufacturing

In 2022, the temporary closure of a major baby formula manufacturing facility, combined with already-stretched supply chains, roiled the country as parents scrambled to get their hands on baby formula for their children. At the peak of the shortage, more than 40% of formula products were out of stock across the country, and one in four parents reported having to travel more than 20 milesto purchase formula.[xliii]

Biomanufacturing

Several U.S. biotechnology companies are working to fill these critical supply gaps. Using precision fermentation, companies are using modified yeast and algae to biomanufacture the complex nutrients and proteins typically found in human breastmilk for use in baby formula.[xliv] Having new ways to produce baby formula will not only ensure that infants receive more nutrients but also give parents more peace of mind in terms of ensuring a more dependable supply.

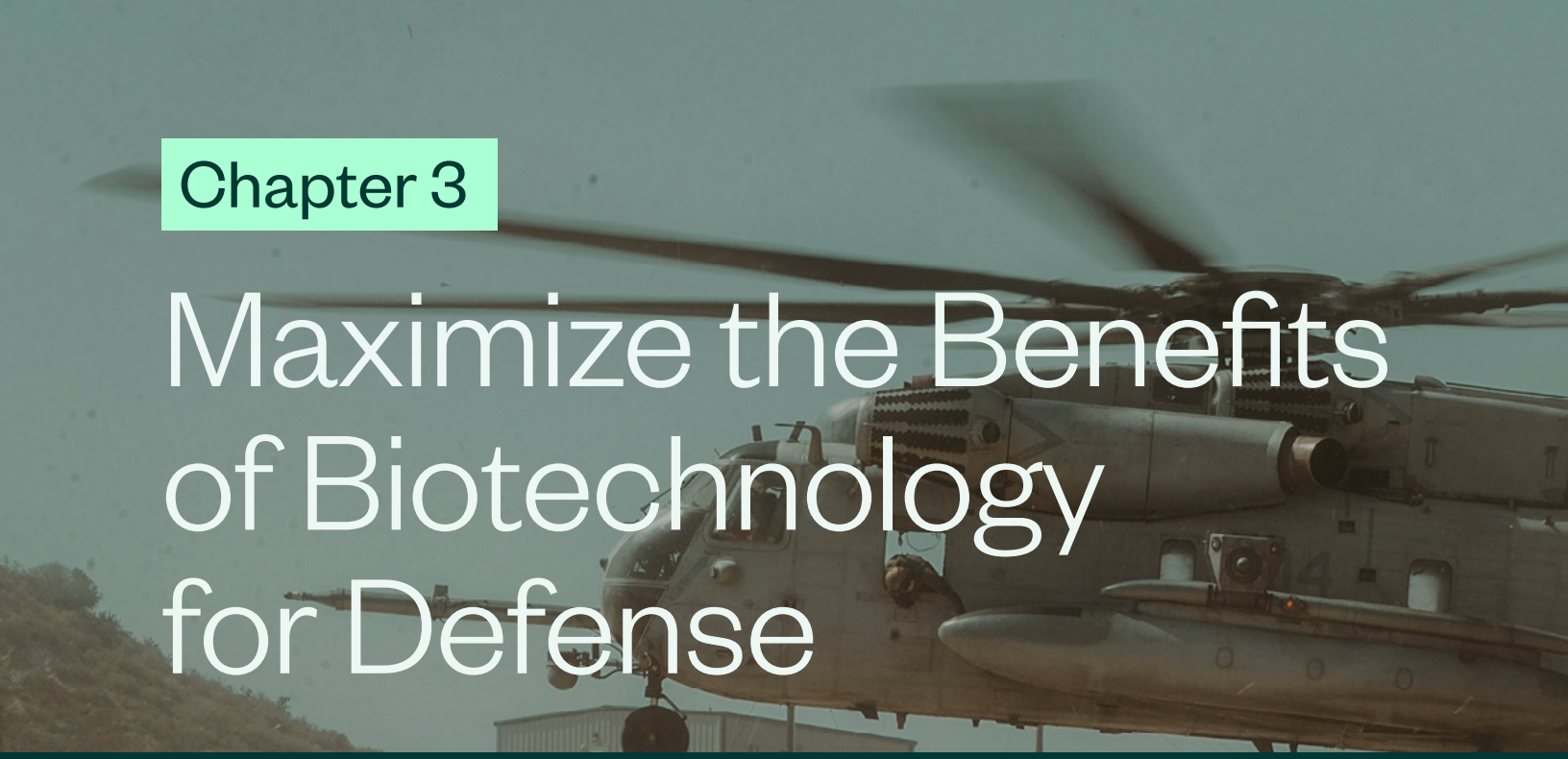
Cell Phones and Laptops

Traditional Manufacturing

Critical minerals such as germanium, antimony, and gallium are used in a wide range of products, from the cell phones in everyone's pockets to semiconductors used in high performance computers. But the United States is almost entirely reliant on China for many of these critical minerals, including over half of its annual consumption for 31 of 35 critical minerals.[xlv] However, China is taking aggressive actions to restrict these shipments to the United States.[xlvi]

Biomanufacturing

Biomining could increase extraction of critical minerals here in the United States to support domestic production, including for 14 of the 35 critical minerals that currently lack a domestic production source. Genetically engineered microbes and plants can help extract critical minerals from both deposits and recycled materials that already exist in the United States.



Chapter 3

Maximize the Benefits of Biotechnology for Defense

Biology represents the next paradigm shift in how wars can be fought and won. At the dawn of the twentieth century, the United States fell behind in airpower despite being the birthplace of aviation because it failed to see how airplanes changed the nature of war. Once the U.S. military started recognizing airplanes as central to all military doctrine, it reorganized itself to unlock the technology's potential. For the military, biology could prove equally transformative.

Just as the invention of flight forever changed force projection, surveillance, and logistics, so could biotechnology redefine what is possible in military operations.

Biology's ability to grow and adapt could revolutionize logistics. Just as aviation shortened resupply times and expanded forces' operational reach, emerging biotechnology could enable the on-demand production of essential resources such as fuel, food, and medicine, reducing the military's reliance on vulnerable supply chains. Such advances could simplify logistics, extend the operational range of forward units, and enhance battlefield survivability.

Biotechnology's impact on surveillance could be similarly transformative. Biological sensors could detect pathogens or chemical threats in real time, creating a dynamic and resilient system for battlefield awareness. As a result, warfighters would be able to make faster, more informed decisions in complex environments.

Biotechnology also promises new advantages in stealth and mobility. Dynamic biological camouflage, for instance, could shield warfighters from thermal detection, while wearable biosensors could adjust mission parameters based on real-time physiological data.[196]

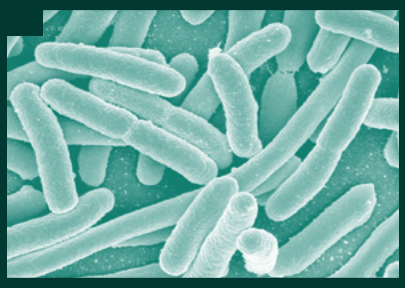
Taken together, these advances demand a fundamental rethinking of how biology supports sustained, agile military operations, revolutionizing what it means to defend the United States, including building for, nourishing, and healing forces in the field. Like aviation before it, biotechnology requires a mindset shift—from viewing the technology as a collection of separate tools to understanding it as a comprehensive framework that should transform the military's approach to logistics, surveillance, and operations.

Several Department of Defense (DOD) entities are already working to advance biotechnology. This includes the important work carried out by the DOD's Office of Strategic Capital (which works to attract and scale investment in biotechnologies), the Defense Advanced Research Projects Agency's (DARPA) Biological Technology Office (which simulates the warfighter's biological systems, optimizes combat casualty care, and

improves logistics through distributed manufacturing), and the DOD's Tri-Service Biotechnology for a Resilient Supply Chain (T-BRSC) (which is scaling biomanufactured products so that the DOD will have alternative supply chains for critical products).[197]

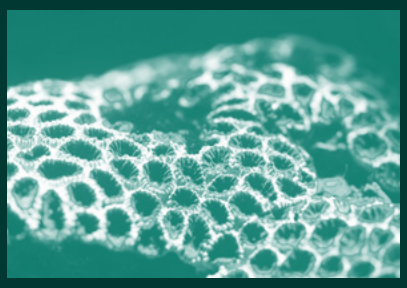
The Commission identified several key steps that the United States must take to build on this work and realize the full military potential of biotechnology to give the nation vital lead time against its adversaries. These include defining DOD principles for ethical use of biotechnology, fielding biotechnology at scale across the U.S. military, and preventing adversaries, especially China, from using or developing U.S. biotechnology in ways that threaten the United States and its allies.

Examples of Biotechnology Research in the Army, Navy, and Air Force



Air Force

The Air Force Research Laboratory is studying the gut microbiome to look for indicators of stress or fatigue. This information can be used to develop probiotics to decrease warfighter stress and increase alertness.[xlvii]



Army

The Army Research Office is developing genetically engineered bacteria that glow when exposed to chemicals associated with landmines, enabling safe and remote detection of buried explosives.[xlviii]

Navy

The Naval Research Laboratory is creating entirely new types of batteries made from biology. These bio-batteries have the potential to be more portable and less of a fire hazard than traditional lithium-ion batteries.[xlix]

Section 3.1

Define Department of Defense Principles for Ethical Use of Biotechnology

Maintaining a military advantage with cutting-edge technology is imperative to deterring adversaries and protecting U.S. national security. But the DOD must accomplish that task while maintaining a strong commitment to America's values.

3.1a Recommendation

Congress must direct the Department of Defense (DOD) to consult with stakeholders to define principles for ethical use of biotechnology for the U.S. military.

A mark of the U.S. military's professionalism is its commitment to American values. The DOD takes corrective action in response to public oversight of its development and use of emerging technology. When emerging AI capabilities began to enter battlefield applications in 2018, for example, the first Trump Administration released a DOD strategy that laid the groundwork for the lawful and ethical application of this emerging technology, culminating in the Defense Innovation Board's (DIB) publication of five ethical principles for the department.[198] These principles are a source of American strength, promoting trust, providing guidance, and encouraging accountability.

Emerging biotechnology has reached an analogous point in its development. The United States does not and will never maintain an offensive biological weapons capability, in line with commitments to the UN Biological Weapons Convention.[199] But this critical red line no longer sufficiently captures the wide variety of ways in which this technology could be used to cause harm, including by non-state actors and U.S. adversaries.

By more clearly defining its principles for the development and deployment of biotechnology, the DOD would better support critical innovations within these boundaries while allowing the United States to lead by example through strengthened norms surrounding this evolving technology.

Defining principles for ethical use of biotechnology will require the DOD to consult with a wide range of stakeholders, spanning industry, academia, civil society, and local communities.

As part of this effort, the DOD should consider:

- biotechnologies for warfighter performance optimization, including policies on informed consent, reversibility, and heritable treatments; and
- biotechnologies that could affect the environment.

Section 3.2

Field Biotechnology at Scale across the Force

The Department of Defense (DOD) must deploy and incorporate biotechnology into next-generation warfighting capabilities before the United States' adversaries do. Winning this race will require de-risking the domestic production of defense-related biotechnology products, efficiently connecting those outputs to customers within the U.S. government, and training the relevant workforce.

3.2a Recommendation

Congress must direct the Department of Defense (DOD) to work with private companies to build commercial facilities across the country to biomanufacture products that are critical for DOD needs.

The private sector will not build commercial-scale biomanufacturing infrastructure for defense-related products without direction from the DOD. To address this concern, the DOD launched the Distributed Bioindustrial Manufacturing Program (DBIMP) in 2024, which supports private industry and develops commercial scale facilities that fortify defense supply chains.[200]

DBIMP targets high-risk components of the military supply chain that could be alternatively produced through biomanufacturing, such as rocket propellant, jet fuel, chemicals used for coatings on ships, and textiles for military uniforms.[201] During the program's first phase, the DOD awarded planning grants totaling over $60 million to 34 companies. Located across the country—including in California, Nebraska, Ohio, Pennsylvania, Tennessee, and Utah—these companies are developing business and technical plans for their bioindustrial manufacturing facilities.[202] Importantly, through these awards, DBIMP has integrated novel companies into the nation's defense industrial base. In the second phase, the DOD intends to award up to $100 million per company.[203]

DBIMP is currently funded through appropriations to Defense Production Act (DPA) Purchases, and biomanufacturing is but one of many uses of these funds.[204] The FY25 President's Budget requested $125 million for the "biomanufacturing of critical chemicals," but as of December 2024, neither the House nor the Senate appropriations bills included a line item in the DPA for DBIMP.[205] Without Congressional action, the DOD could divert DPA funds to other priorities, a move that would hollow out of the DBIMP program before it can fund full-scale biomanufacturing facilities.

Without adequate and reliable funding, DBIMP will not be able to continue de-risking projects through early-stage demonstrations nor will it be able to fund sufficient infrastructure projects. As a result, the DOD may also lose valuable partnerships. Greater risk and longer project timelines may further discourage small companies with innovative technologies from participating in these programs in the future.

Congress must support the commercialization of national security related biotechnologies by appropriating at least $762 million over the next five years to fund DBIMP. For DBIMP to succeed in the long run, the DOD must also be clear about its requirements and timelines, its communication with industry partners, and its plans for aligning industry outputs with the needs of defense purchasers. Sustained funding is critical if this program is to continue supporting and de-risking some of the nation's most innovative companies, firms that are fielding mission-critical products and processes at the intersection of national security and emerging biotechnology.

3.2b Recommendation

Congress should continue oversight of and support for BioMADE's efforts to create a network of facilities that precommercial bioindustrial companies across the country can use to meet Department of Defense (DOD) needs.

The Bioindustrial Manufacturing and Development Ecosystem (BioMADE), the DOD's Manufacturing Innovation Institute for bioindustrial manufacturing, is a public-private partnership with nearly 300 members across 37 states, including industry leaders, academic institutions, and government officials. BioMADE's mission is to enable domestic bioindustrial manufacturing scale-up and commercialization, develop and deploy technologies to enhance U.S. bioindustrial competitiveness, de-risk infrastructure investments, and expand the U.S. biomanufacturing workforce.[206]

BioMADE provides a promising model for supporting biotechnology companies that make up America's defense industrial base. Its status as a public-private partnership facilitates collaboration and information sharing among industry, academia, and government. The program also works with local communities to educate and train the next generation of biomanufacturers.[207]

To support these objectives, Congress appropriated a total of $400 million in fiscal years8 2023 and 2024 for BioMADE to develop a network of open-access, precommercial bioindustrial facilities across the country.[208] In response to Congressional appropriations, BioMADE announced several efforts to establish these facilities.[209] As of December 2024, however, an issue of statutory interpretation is preventing BioMADE from building its first facility in Minnesota.[210] Congress—through oversight and, if necessary, statutory language—should ensure that BioMADE has the authority to spend funds on construction and that it is using those funds to construct facilities consistent with Section 215 of the FY23 National Defense Authorization Act (NDAA).[211]

Congress should work with the DOD to ensure that BioMADE is using previously appropriated funds effectively and quickly to establish facilities as a part of the network of precommercial facilities. It should also ensure that the DOD, the Department of Energy (DOE), and the Department of Commerce (DOC) have clear mechanisms for collaboration so that they can leverage infrastructure across agencies. If these objectives are met, Congress should consider additional appropriations in the future.

To that end, Congress should require the DOD to submit annual reports that include (at a minimum):

- the average time that it takes BioMADE to execute contracts, from the time the organization closes solicitations for a grant or contract to the time that the decision and associated funding are received;
- a list of current BioMADE awardees;
- all BioMADE grant amounts, grant purposes, execution timelines, and budgets over time; and
- an assessment of any statutory or policy hurdles to using Congressionally appropriated funds.

Congressional oversight for this initiative should include:

- site selection decisions, criteria, processes, and timelines (criteria should include discussions of operational models and completion timelines, and approval should be peer-reviewed);
- grant award decisions, criteria, processes, timelines, and communication processes for members (this selection process should also be peer-reviewed for technical feasibility by external experts);
- membership in BioMADE, what membership provides, and how membership affects usage or payment for use of the infrastructure network;
- the time it takes to add new members to the network; and
- the establishment of mechanisms for interagency participation, especially regarding DOE National Laboratories and current precommercial infrastructure.

3.2c Recommendation

Congress should require changes to military specifications (MIL-SPECs) to enable biotechnology companies to more easily sell their products to the Department of Defense (DOD).

Companies selling biotechnology products may not be able to sell to the DOD, as the products do not meet military specifications (MIL-SPECs), which serve as a common language that ensure military products produced by different stakeholders are functionally the same.[212] MIL-SPECs are not intended to favor one manufacturing process over the other, but in practice, many of the specifications can be met only with traditional manufacturing. As a result, biotechnology products may be unintentionally excluded from consideration, and the DOD risks missing out on critical technologies.

To maintain its edge, the United States should make it easier for the DOD to:

- purchase biotechnology-derived products;
- adopt biotechnology-derived products; and
- maintain its technological advantage while helping the DOD fulfill its mission.

The Secretary of Defense—in consultation with the military services, the Undersecretary of Defense for Research and Engineering, the Undersecretary of Defense for Acquisition and Sustainment—should release public guidance on how nongovernment entities can prove the merit of biotechnologies and materials in meeting MIL-SPEC requirements.

To ensure that this guidance is linked to an efficient and impartial process, Congress should also task the Government Accountability Office (GAO) with conducting a comprehensive analysis of intentional or unintentional preconceptions against biotechnology and biomaterials in the MIL-SPEC process.

Lastly, standards have the greatest utility when they are adopted and applied by many stakeholders. To that end, the DOD should partner with U.S. allies to explore broader international harmonization of military specifications.

3.2d Recommendation

Congress should require the Department of Defense (DOD) to enter into advance market commitments (AMCs) and offtake agreements for biotechnology products that are needed for defense.

The DOD has not signaled clear and consistent demand for biotechnology products with defense applications that meet its existing needs, hindering the scale-up of these products. Instead, current DOD procurements result in fluctuating demand for emerging technologies such as biotechnology.[213] If companies and investors continue to doubt that there will be an end-use market in the DOD, they will not scale biotechnology products needed for defense.

Advance market commitments (AMCs) and offtake agreements would send a strong DOD demand signal for biotechnology products, overcoming the uncertainty in year-to-year demand that results from differences in the DOD's annual appropriations. There are a number of biotechnology products that could meet the DOD's needs. For example, the DOD could use biobased concrete to build runways or landing pads or bioremediation technologies to break down PFAS in water or soil on military instillations.[214] Already, the DOD has identified a list of critical chemicals that may require domestic production due to vulnerabilities in the supply chain, many of which could be biomanufactured domestically.[215]

Congress should direct the DOD to use its other transaction authorities (OTAs) to establish AMCs for biotechnology products that would be produced at scale in the United States, meet the DOD's technical needs, and are competitive on cost, schedule, and performance. Congress should also direct the DOD to establish a pilot program to award offtake agreements to biotechnology companies.

For AMCs, the Undersecretary of Defense for Acquisition and Sustainment should:

- first define which DOD technical needs can be met with biotechnologies such as biobased concrete, bioremediation products, and biobased chemicals;
- design AMCs to include agreed-on product prices, specifications, delivery timelines, and criteria for evaluation;
- design AMCs in consultation with technical and market experts from inside and outside the DOD;
- exercise OTAs to establish and implement AMCs;
- report to Congress annually on the progress and success of AMCs; and
- use lessons learned to develop and report to Congress a strategy for how AMCs and other innovative financial tools could be used to procure biotechnology products that meet U.S. national security needs.

For offtake agreements, the Undersecretary of Defense for Acquisition and Sustainment should:

- exercise OTAs to create a pilot Biotechnology Purchase Incentive Program to award prizes in the form of offtake agreements to biotechnology companies for products that meet the DOD's technical needs, laying out agreed-on prices, specifications, delivery timelines, and criteria of evaluation; and
- report annually to Congress on the progress and success of the program for oversight purposes and for its possible extension.

The DOD has not signaled clear and consistent demand for biobased products with defense applications that meet existing DOD needs, hindering the scale-up of these products.

3.2e Recommendation

Congress should require the Department of Defense (DOD) and other agencies involved in national security to train their workforces to be ready for biotechnology.

New technologies and concepts in biotechnology are constantly emerging, and biotechnology is increasingly converging with other emerging technologies, including AI and quantum. The DOD and intelligence community (IC) workforce must maintain an up-to-date understanding of critical and emerging technologies to effectively execute national security policy. To maximize effectiveness, these efforts should reach into the military services and include the Joint Staff and combatant commands.

Keeping the government's biotechnology training up-to-date is especially critical given the fast pace of advances. (For more recommendations on equipping the U.S. government with necessary biotechnology resources and expertise, see Section 5.1.) Currently, however, there are limited opportunities for federal employees working on national security to upskill in biotechnology.

The DOD, the IC, and other agencies with national security mandates should upskill their workforces in biotechnology and biosecurity through tailored training. Such training would help the U.S. government maintain improved threat awareness and give employees the up-to-date knowledge they need to make informed decisions about funding and using biotechnology.

Specifically, Congress should require that:

- relevant parts of the DOD and the IC define core competencies for their biotechnology and biodefense personnel, including outlining requirements for refresher training on the latest advances in biotechnology science, laboratory work, equipment, and software (these requirements should be informed by core competencies defined by relevant agencies, such as the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) (see Section 5.1b));
- the DOD develop workforce education and training on biotechnology for both uniformed and civilian personnel whose duties involve analyzing, preparing for, or responding to biological threats;
- the Office of the Director of National Intelligence (ODNI) provide educational courses at the National Intelligence University (NIU) or other venues to ensure that intelligence professionals covering biotechnology have a functional understanding of how the field is advancing; and
- the Department of Homeland Security (DHS)—including Customs and Border Protection (CBP), Homeland Security Investigations (HSI), and the Transportation Security Administration (TSA)—as well as the Federal Bureau of Investigation (FBI), develop workforce education and training on biotechnology issues, particularly for personnel who might encounter inbound and outbound biological samples or who focus on issues related to illicit technology transfer.

Intermission

NASEM Report on Research and Development in Biotechnology for Defense Innovation

In addition to the extensive outreach that the Commission conducted with external stakeholders, the Commission contracted with the National Academies of Sciences, Engineering, and Medicine (NASEM) to assess the risks and rewards of biotechnology research and development (R&D), with particular focus on its convergence with artificial intelligence (AI) and automation.[i]

Through a series of workshops and a final report, this work emphasized the promise of biotechnology converging with other technology areas, including recent breakthroughs and future innovations.[ii] The NASEM report lays out a strategic vision for optimizing research and innovation at the intersection of AI, automation, and biotechnology by connecting and coordinating key elements of these technologies, including robotics, data, compute, and algorithms.

Many of their conclusions and recommendations are reflected in the recommendations throughout the Commission's own report, showing important alignment of priorities between stakeholders in different sectors.

In their main recommendation, NASEM calls for the creation of the Biotechnology Coupled with Artificial Intelligence and Transformative Automation for Laboratory Yielding Strategic Technologies (BioCATALYST) network. Led by the Department of Defense (DOD) and the Office of the Director of National Intelligence (ODNI), this network would leverage academic institutions, industry, and government to use emerging technologies to address national security challenges. This network would involve generating AI-ready datasets, establishing pilot test beds for technology demonstration, identifying technology transition partners in industry, establishing a research program on ethical and societal questions, and creating a program for robust risk assessments.

The NASEM and Commission reports share the common thread of recognizing the great potential of biotechnology for national security and the importance of taking action now to turn this potential into reality. The NASEM's report is available here.

Section 3.3

Prevent Adversaries, Especially China, from Using or Developing U.S. Biotechnology for Purposes that Undermine U.S. and Allied National Security

In 1969, the United States took the important step of unilaterally banning biological weapons (or bioweapons), stopping the offensive development of these capabilities and, shortly thereafter, destroying its bioweapons stockpile.[216] The United States subsequently led the negotiations that resulted in the worldwide ban on this entire class of weapons under the UN Biological Weapons Convention (BWC), signed in 1972.[217]

Unfortunately, the evidence shows that some parties to that treaty are actively pursuing bioweapons, despite their commitment not to. The Department of State (DOS) has publicly assessed that both Russia and North Korea maintain offensive biological weapons programs that violate the BWC.[218] The department has also assessed that the Chinese Communist Party (CCP)—whose strategy of Military-Civil Fusion (MCF) blurs the line between commercial and military applications of many technologies—is conducting dual-use research activities that may also violate the BWC.[219]

While non-state actors have fewer resources and operational capabilities than governments, their potential to exploit biology to cause harm remains deeply concerning, underscoring the need for the United States to develop defensive technologies.[220]

To protect against adversaries' misuse of biotechnology, the United States must be able to detect and characterize the widest possible array of biological threats and do so early. Only then can the U.S. government respond effectively to a biological incident, whether that means developing vaccines against the pathogen or shifting the manufacturing of other countermeasures into high gear. To attain this ability, the DOD should deploy a detection capability that is scalable and pathogen-agnostic, coordinating this effort across government agencies.

To complement these efforts, the U.S. government must use all the technology protection tools it has to block transactions that could harm U.S. national security, including through foreign direct investments (see recommendation 2.5c). At the same time, it must recognize that there is no one-size-fits-all approach.

Regulating at the frontier of technology is difficult, particularly in biotechnology, given the nascent nature of many of its subfields. The Administration must legislate outbound investment rules to ensure that U.S. capital does not contribute to Chinese biotechnology developments that could pose a national security risk. It must also adopt a flexible approach to biotechnology export controls and be willing to deploy them in areas where they could have a strategic effect, including on a country-wide basis, but also closely scrutinize their efficacy.

> To protect against adversaries' misuse of biotechnology, the United States must be able to detect and characterize the widest possible array of biological threats—and do so early.

3.3a Recommendation

Congress must require outbound investment rules that ensure U.S. capital does not support Chinese development of certain biotechnologies that could pose a national security risk.

The U.S. government currently lacks a clear understanding of U.S. investments in the Chinese biotechnology sector and thus is in a poor position to make informed policy decisions in this area. Experts shared with the Commission that approximately 20 percent of transactions involving U.S. investment in China do not report financial values. This is a missed opportunity to limit flows of American capital into Chinese biotechnology companies in areas that pose strategic risks. Moreover, recipients of U.S. capital also reap intangible benefits such as access to talent networks, management support, markets, and additional financing, bolstering their ability to outcompete U.S. firms.

In Congress, various bills have sought to establish outbound investment notifications. If passed, the Outbound Investment Transparency Act of 2023 would require U.S. investors to notify the Department of Treasury (Treasury) of certain outbound U.S. investments in "covered sectors" (i.e., semiconductors, AI, quantum, hypersonics, satellite communications, and networked laser scanning systems with dual-use applications) to "countries of concern."[221] Another bill, the Preventing Adversaries from Developing Critical Capabilities Act, would require the President to identify categories of technologies and products in "covered sectors" that may pose a threat to the national security of the United States.[222]

The executive branch has also tried to address this problem. In August 2023, the Biden Administration issued Executive Order 14105 on "Addressing United States Investments in Certain National Security Technologies and Products in Countries of Concern," which directs the Treasury to establish a program to prohibit or require notification of certain types of outbound investments for three categories of national security technologies: semiconductors and microelectronics, quantum information technologies, and artificial intelligence.[223]

None of these efforts have included biotechnology, however. Congress should legislate outbound investments rules, including the mandatory notification of outbound U.S. investments in relevant categories of biotechnologies and products to countries of concern, and include biotechnology as a covered sector for mandatory notification. These requirements would ensure that U.S. capital does not support Chinese biotechnology development in areas that pose significant national security risks, including those that would create or exacerbate supply chain dependencies.

One year after enactment, the Secretary of the Treasury should provide a report to Congress that includes information collected from the mandatory notification requirement to inform potential future measures to screen and/or prohibit future outbound biotechnology investments.

3.3b Recommendation

Congress should direct the Department of Commerce (DOC) to consider country-wide export controls blocking the sale of specific, highly sophisticated U.S. biotechnology items to China that would pose a substantial risk to national security if used for military end-uses.

Export controls are an important tool for restricting the misuse of technologies. Controls on biotechnology-related items have largely been harmonized internationally through the Australia Group, an association of 42 like-minded countries focused on monitoring the global flow of goods and technologies related to chemical and biological weapons.

These controls work best when goods and technologies flow through a vulnerable chokepoint and when there is a window of time wherein restricting that chokepoint provides a strategic advantage to the United States and its allies and partners. These controls also work best when there is a small, well-defined group of countries and companies that can develop a technology and when they all agree not to provide that capability to countries that cannot develop it. But the current export control system relies heavily on case-by-case and actor-by-actor assessments that focus on end uses and end users of concern. This approach makes it extremely challenging to prevent the flow of sensitive items because state and non-state actors can obfuscate the intended end use or divert goods to end users of concern.[224] Export controls are an essential part of the U.S. technology protection strategy, but they can be, and are being, circumvented.

The United States took a significant step in rethinking export controls in the current geopolitical environment with its October 2022 limits on the sale of certain semiconductor technology to China. Many of these controls were enacted on a country-wide basis, meaning it did not matter which particular entity within China was requesting the items. In light of the CCP's MCF strategy, the Biden Administration updated these controls in October 2023 to also apply to any China-headquartered entity, no matter where in the world it is operating. These broadly applied but tightly scoped controls were designed to provide a window of time to slow China from militarizing semiconductor technology. And because chip production relies on access to extremely specialized equipment—produced only by a small number of allied countries—it is very difficult for China to indigenize. Because of this, the United States can still respond.

Biotechnology is very different. Much of its value resides in things that are not easily contained by export controls, such as human capital, biological data, intellectual property, and industrial processes. Aspects that are controllable, like specific equipment, will likely not give the United States as much time respond as in the case of semiconductors. At the same time, the DOC needs to develop agile export controls to mitigate the threat of adversaries using emerging biotechnology to do harm. Therefore, the DOC will need to be not just more aggressive in employing export controls for emerging technologies like biotechnology but also nimbler in removing controls that are no longer effective. Going forward, the DOC should consider country-wide export controls that block the sale of specific, highly sophisticated U.S. biotechnology items to China.

To be effective, such controls should be:

- specific in the items it governs;
- able to give the United States and key partners the windows they need to secure advantages; and
- coordinated with promotion measures, such as enabling domestic firms to tap into the proposed Independence Investment Fund (see section 2.2a), to ensure that domestic companies, particularly small and medium enterprises, can maintain viability while controls are in place.

Making country-wide export controls more agile will require a new type of relationship between the government and industry, especially with smaller enterprises. It will require the private sector to work proactively and in good faith with the government and share information about the leading edge of technology in order to assist with crafting meaningful controls. It will also require that the government ensure that the controls are in place only as long as they are strategically helpful.

Additionally, given the global nature of the biotechnology industry, allies and partners will need to consider the threat of China's diversion and misuse of dual-use biotechnology equipment. They will need to implement controls in partnership with the United States, thereby collectively controlling equipment of concern on a country-wide basis.

3.3c Recommendation

Congress should require the Department of Defense (DOD) to incorporate military-relevant applications of emerging biotechnology into wargaming exercises.

Biotechnological advancements have the power to fundamentally alter the way future wars are fought and won, leaving the United States vulnerable to strategic surprise as adversaries' use of biotechnology rapidly evolves. To ensure that the U.S. military remains ready for all eventualities, the DOD should ensure that wargaming exercises incorporate the effects of emerging biotechnologies.

U.S. Joint Staff wargaming efforts, such as the annual Globally Integrated Wargames, focus on testing multi-domain operations and explore how different military forces can be synchronized to counter emerging threats.[225] Incorporating biotechnology into such wargames, the Joint Staff and combatant commands could simulate scenarios where, for example, biotechnology-enabled enhancements improved warfighter performance. Doing so would help the U.S. military better anticipate both the strategic challenges and opportunities posed by advancements in biotechnology and ensure that it is considered alongside other critical and emerging technologies such as cyber and AI when shaping military doctrine and operations.

By incorporating biotechnology into wargames, the military and DOD civilians could better understand how the latest biotechnological advances might influence tactics, logistics, and force structures, as well as how to counteract bio-based threats. This proactive approach would help the U.S. military stay ahead of adversaries in an era when biological innovations could play a central role in strategic operations, ensuring a more resilient and adaptive force.

These efforts should be undertaken in coordination with the Office of Global Competition Analysis (OGCA) (see recommendation 1.3a) to couple wargaming exercises with outside analysis and other available foresight tools.

3.3d Recommendation

Congress should resource the intelligence community (IC) to prioritize understanding adversaries' development of biotechnology and its diverse applications.

Ensuring that the United States' threat awareness keeps up with biotechnological advancements starts with equipping agencies at the front lines of evaluating these developments with the right tools and resources. In practice, that means making certain that Congressional oversight committees are informed on the IC's evolving needs. Congress should require the Central Intelligence Agency (CIA), the Defense Intelligence Agency (DIA), the FBI, the National Security Agency (NSA), and the ODNI to periodically brief relevant Congressional committees about the resources they need to analyze potential threats from biotechnology. This brief would include a discussion of the tradeoffs that may occur if resources are diverted from competing priorities to address threats related to biotechnology. Already, Congress has undertaken some efforts on this front, including passing a provision in the 2025 NDAA requiring the IC to develop a strategy for countering the ways foreign adversaries use biotechnology.[226] The Commission encourages the IC to develop and implement this strategy expediently.

Intermission

Biotechnology Tech Hubs: Driving Economic Growth Across the Country

Technology hubs are a proven way to drive local economic development and forge partnerships across government, industry, and educational organizations. For example, the North Carolina Biotechnology Center has catalyzed investment for 40 years, growing a local industry that directly employs 75,000 people. Building on this model, the Department of Commerce (DOC) launched the Regional Technology and Innovation Hubs (Tech Hubs) program in 2023, authorized by the CHIPS and Science Act.[lii] Tech Hubs invest in American communities, funding programs that target critical technology areas. They aim to scale American technology and discoveries locally, build globally competitive manufacturing centers, and create well-paying jobs.

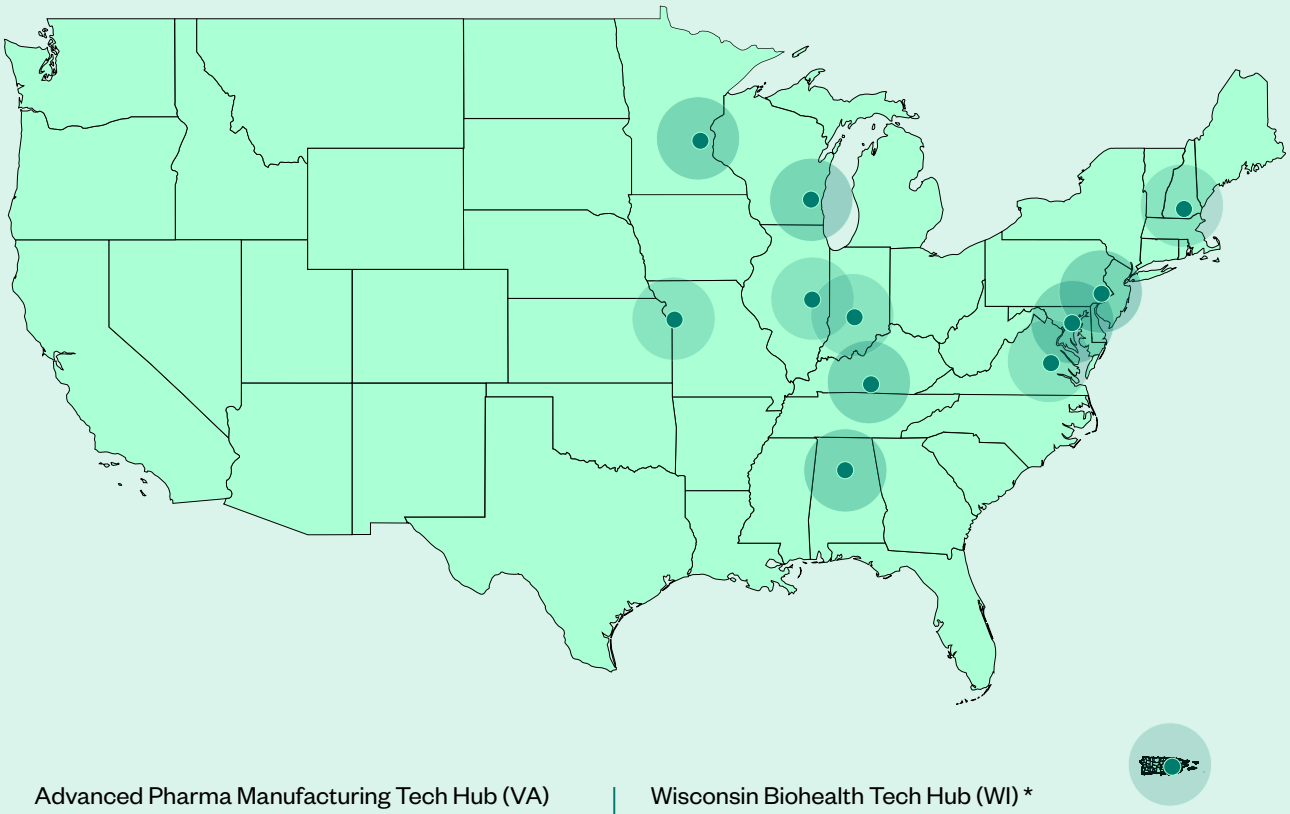
The Tech Hubs program is a recognition that local communities best understand what they need to grow. That is why Tech Hubs are public-private partnerships, bringing together academia, state and local governments, and private industry to most effectively use federal funding to discover, mature, and commercialize groundbreaking technologies.

The 31 Tech Hubs, representing communities across America, will lead a new era of technological innovation. 11 tech hubs focus on biotechnology, such as converting corn into chemicals, advancing biologics in medicine, and developing artificial intelligence (AI) applications for biotechnology.

In 2024, the DOC announced over $500 million in grants for Tech Hubs. Each Tech Hub provides funding ranging from $20-55 million for regional consortia to spend on infrastructure, workforce, and commercialization efforts. This initial funding jumpstarts regional growth while promoting an organization that reduces the need for continuous federal funding.

If the United States is going to capture the opportunities that biotechnology and biomanufacturing present, Tech Hubs across the country will lead the way. The future of biotechnology is local, but the impact will be global.

Biotechnology Tech Hubs: Driving Economic Growth Across the Country (continued)



- Advanced Pharma Manufacturing Tech Hub (VA)
- ReGen Valley Tech Hub (NH) *
- iFab Tech Hub (IL) *
- Kansas City Inclusive Biologics and Biomanufacturing Tech Hub (MO and KS)
- Heartland BioWorks (IN) *
- PRBio Tech Hub (Puerto Rico)
- Wisconsin Biohealth Tech Hub (WI) *
- Baltimore Tech Hub (MD)
- Birmingham Biotechnology Hub (AL)
- Greater Philadelphia Region Precision Medicine Tech Hub (PA, DE, MD, and NJ)
- Minnesota MedTech 3.0 (MN and WI)

Tech Hub Highlights

Alabama

Birmingham Biotechnology Hub

Mission

Enhance drug discovery, vaccine development, and diagnostics with artificial intelligence-driven biotechnology. Improve the efficacy of biotechnology products by increasing the diversity of genetic data and clinical trials.

Investment

Eligible for future funding. Proposals include a life sciences incubator, venture partnerships, secure biobank data sharing, and Alabama's first Innovation District.

Impact

Proposed plans would advance precision medicine technologies, with initiatives to create jobs and boost the regional economy.

Illinois

Illinois Fermentation and Agriculture Biomanufacturing Tech Hub (iFAB)

Mission

Biomanufacturing & Precision Fermentation – Turn corn feedstocks into valuable products like chemicals, materials, proteins, and food ingredients using existing agricultural infrastructure.

Investment

$51 million to upgrade and expand existing infrastructure, attract partners, and develop the critical workforce.

Impact

Over the next five years, estimated to create thousands of new jobs.

Indiana

Heartland BioWorks

Mission

Strengthening domestic biotech manufacturing by developing and commercializing health-related bioproducts.

Investment

$51 million for workforce development, and for early-stage innovators, among other investments.

Impact

Create thousands of new jobs and $2.6 billion in additional annual economic output. Part of the funding will be reinvested in the region, with workforce development initiatives to support startups.

New Hampshire

The ReGen Valley Tech Hub

Mission

Develop cost-effective regenerative therapies that address chronic diseases and organ failure. Because this Tech Hub is led by the Advanced Regenerative Manufacturing Institute (ARMI), a Department of Defense (DOD) Manufacturing Innovation Institute, there will be a closer link between private sector and DOD for needs in regenerative therapies to be clearly communicated to the community.

Investment

$44 million to advance biofabrication infrastructure, raise awareness of regenerative therapies, and train the critical workforce.

Impact

Projected to create thousands of jobs, increase regional economic production by 5% by 2032, and reduce healthcare costs with the use of regenerative therapies.

Chapter 4

Out-Innovate Our Strategic Competitors

To ensure that the best research in the world continues to happen in the United States, the nation needs to reinvigorate its historic strengths in innovation. America's technology sector has a rich history of ambitious research ideas turning into pathbreaking discoveries. The U.S.-led Human Genome Project, for example, was fueled by ambitious public investment and led to entirely new markets, starting a cascade of innovation that continues to shape biotechnology today.[227]

The following sections include recommendations to guarantee that the United States outpaces its strategic competitors while ensuring safety, security, and responsibility in biotechnology innovation both at home and abroad. This chapter explains why and how the United States must treat biological data as a strategic resource, solve challenging research problems before its competitors, and protect against the misuse of biotechnology.

While the United States currently leads in biotechnology research and development (R&D), that lead is slipping. The United States is not meeting the moment for biotechnology because it lacks a mechanism for prioritizing high-quality data collection, sufficient support for innovative research ideas, and adequate instrumentation, facilities, and capabilities.

Section 4.1

Treat Biological Data as a Strategic Resource

Biological data lie at the heart of emerging biotechnologies and are defined by the National Institute of Standards and Technology (NIST) as "the information, including associated descriptors, derived from the structure, function, or process of a biological system(s) that is either measured, collected, or aggregated for analysis."[228]

Biological data include a wide variety of human data as well as data from animals, plants, fungi, bacteria, and viruses that comprise the rich biological landscape of the United States. These biological data enable scientists to discover, design, and optimize everything from individual components of cells to the behavior of whole groups of organisms to the inputs and outputs of biomanufacturing processes.

Biological data are especially important for unlocking AI's potential. Just as large language model (LLM) chatbots such as ChatGPT are trained on vast amounts of text from the internet, biological design tools and scientific language models are trained on troves of biological data from research efforts.

If the United States is to cement its global lead in biotechnology, it must do more to develop high-quality data. The country has failed to provide high-quality data in a usable way, address gaps in data holdings, invest in automated biological data collection, or build the infrastructure needed to ensure that the United States fully leverages its wealth of biological data. The federal government has even failed to maximize the scientific discoveries and innovations already held in its existing collections of biological specimens. U.S. natural history collections alone house an estimated 800 million to 1 billion biological specimens, ripe for opportunities to collect different types of biological data, including genomic data, but the samples are mostly untouched by researchers.[229]

China's approach to biological data involves accessing and exploiting publicly available data from around the world, including from the United States, while harvesting its own domestic datasets and closing them off to the rest of the world.[230] This approach gives China an asymmetric advantage in exploiting biological data and highlights its lack of data-sharing reciprocity. Many Chinese Communist Party (CCP) policies explicitly state that the government intends to prioritize the collection and use of biological data, as do statements from China's medical AI industry.[231] Accordingly, the U.S. government must ensure that China cannot obtain bulk and sensitive biological data from the United States.

U.S. natural history collections alone house an estimated 800 million to 1 billion specimens, ripe for research and discovery but mostly untouched by researchers.

Biological Data Definition

Biological data are "the information, including associated descriptors, derived from the structure, function, or process of a biological system(s) that is either measured, collected, or aggregated for analysis."[lxiii] Biological data and associated metadata illuminate how biology behaves, from individual components of cells to the behavior of whole groups of organisms and their ecosystems. Biological data also describe the necessary conditions for production of medications such as vaccines and antibodies, materials such as those derived from mushroom leather or spider silks, and chemicals that are produced from microbes.

Biological source	Biological data types	Example of derived data	Example insights from data
Humans, animals, plants, and microbes	DNA	Genome sequences	• Understanding an organism's evolution • Improving the characteristics of crops and animals in agriculture • Diagnosing genetic disorders • Determining the identity of microbes
	RNA	RNA expression levels	• Identifying when and where genes are active • Understanding an organism's response to stress or changes in its environment
	Proteins	Protein structure	• Understanding how proteins interact • Developing drugs more effectively
	Image data	CT scans	• Understanding the structure and function of biological systems • Detecting and characterizing diseases
	Cell dynamics	Cellular growth and downstream bioprocessing data	• Understanding the requirements for cellular growth, such as nutrient availability, growth factors • Understanding the environmental conditions essential for enhancing biomanufacturing and biopharmaceuticals, especially for the science of scale-up

4.1a Recommendation

Congress must authorize the Department of Energy (DOE) to create a Web of Biological Data (WOBD), a single point of entry for researchers to access high-quality data.

Currently, U.S. biological data is generated from a wide variety of sources and organized with different purposes in mind. These data are organized differently across organizations in academia, government, and industry, and even across individual labs within the same organization.[232]

This uncoordinated approach makes collating large datasets a burdensome process for researchers, slowing potential discoveries. It might take months to answer a single question, assuming the information exists in the first place.

There are several noteworthy examples of biological databases created by federal departments and agencies, but each is incomplete for a future that requires data for new AI models. For example, the National Center for Biotechnology Information (NCBI) at the National Institutes of Health (NIH) is one of the most comprehensive genomic databases in the world.[233] But its datasets are in reality spread over different databases and data types and are not designed to be used comprehensively, a key requirement for training AI models. Targeted programs to make biological data more compatible would help to ensure that efforts such as the NCBI drive the future of biotechnology. The Joint Genome Institute at Lawrence Berkeley National Laboratory leads an exemplary data program on microbial sequences and ecosystems, but the program is focused on a small subset of microbiome data.[234] Expanding efforts like this to include a larger class of organisms and other types of biological information, such as protein data, would add valuable tools needed for the future of biotechnology.

Having the ability to standardize, combine, and analyze biological data generated from different places, organisms, or experiments is critical to advancing research and training AI models. In many cases, the combination of different datasets is more valuable than the individual parts.

The creation of a resource that combines biological datasets in a usable way would allow researchers to spend less time curating biological data and more time testing hypotheses, training models, and designing novel biological functions. Such a resource would:

- serve as a single point of entry for researchers to access different sources of biological data, all of which would be standardized, usable, and interoperable;
- enable discovery with advanced computational methods; and
- protect and control access to U.S. biological data.

To create these resources, Congress must authorize the Department of Energy (DOE) to create the Web of Biological Data (WOBD), a comprehensive central biological data infrastructure that would serve as single point of entry for accessing biological data, have built-in security and access controls, and provide opportunities for advanced computation and analysis. The WOBD would start with data collected from federally funded efforts and have the potential to expand to collect other sources of data.

A Web of Biological Data would:

- serve as an access point for high-quality biological data from different locations;
- host new biological data;
- develop and maintain tools for using these biological data such as bioinformatics pipelines, models, and ontologies (i.e., the categories, properties, and relationships between concepts and conventions that define a field); and
- have a requirement that any datasets included on the platform must be standardized.

This centralized resource would have the added benefit of incorporating cybersecurity and access controls into the earliest stages of its design and development. There are many considerations when designing security and access controls for biological data. For example, plant genome sequences from basic research projects would need different access controls and cybersecurity protocols than sensitive medical records or human genomic data. The WOBD

would be meant to encompass many different types of biological data, and as it expands, it would need to carefully build in security and take into account all appropriate privacy laws.

Implementation for the WOBD within its first two years would include:

- assigning a National Laboratory to serve as the manager of the WOBD;
- having that National Laboratory work with existing datasets and collaborate with the NIST to stress-test the digital infrastructure and develop frameworks for interoperability; and
- requiring the DOE to report to Congress on the progress it has made on these tasks.

After the first two years, the WOBD should start establishing connections to all existing biological data from federally funded sources. The ultimate goal is for the WOBD to connect as many sources of biological data as possible through a single point of entry.

The WOBD would also have a R&D arm that would support human-centered design and ensure that its interface is user-friendly. As researchers and other users begin incorporating the WOBD into daily research life, it would grow and evolve with the field.

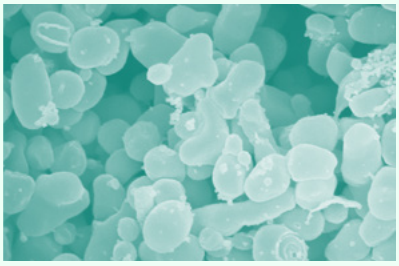
Security Considerations for Biological Data

Security considerations are not the same for different types of biological data. Safeguards implemented on the Web of Biological Data (WOBD) should be proportionate to the sensitivity of the data, ensuring access is appropriately managed, while encouraging scientific collaboration.

While much of the security and access control implemented through the WOBD would be decided on a case-by-case basis, there are some basic distinctions in the types of biological data that exist. While not an exhaustive list, these include:

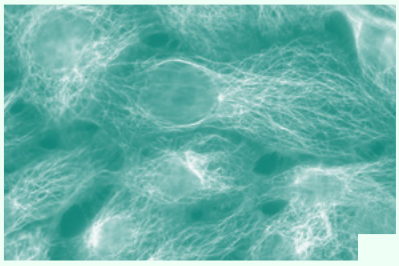
Molecular data versus functional data

Molecular data provide information about what a biological system is (such as DNA sequences and protein structure), while functional data provide information about what a biological system does (such as physical characteristics and enzymatic production). While the security concerns for these two types of data are fairly similar, special consideration should be given to functional data that provide key insights into biology.



Human data versus non-human data

While most non-human data, including that from plants, animals, microbes, and fungi, are available in open-source databases, access restrictions and security must be applied appropriately to human-related data. Biological data for non-human organisms may also be sensitive. For example, biomanufacturing conditions or farm yields may be considered proprietary information that mayneed to be secured.



Human health data versus non-health human data

Human health data is governed by specific laws and typically requires controlled access and additional security measures. Non-health human data, such as location or demographic information, could be more open to the public, unless used to identify individuals, in which case the data become sensitive and require stricter controls.

Current State of Biodata

01

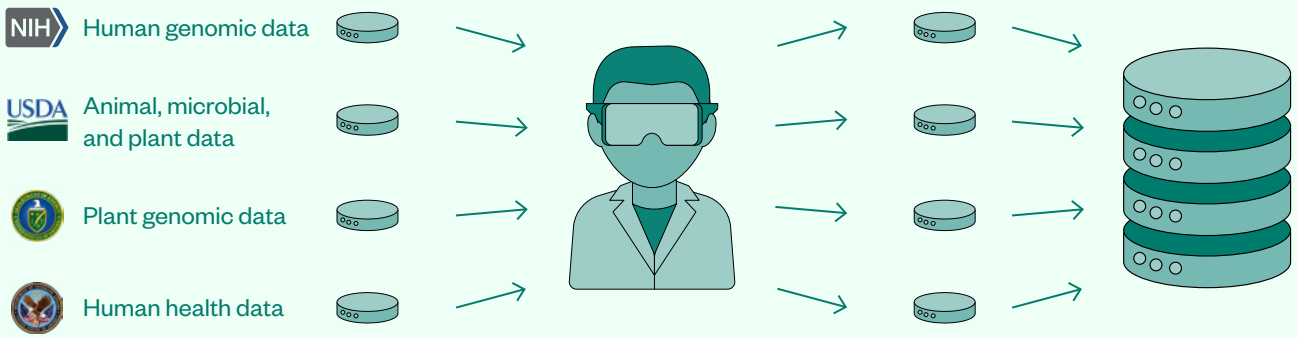
Researcher manually searches and recalls data.

02

Researcher manually cleans each dataset.

03

Researcher manually combines datasets.



Recommendation: AI-Ready Biodata + Web of Biodata

01

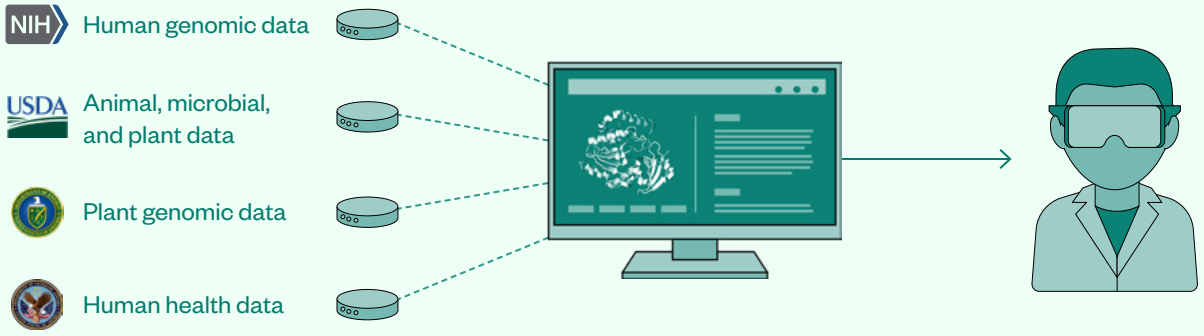
Agencies generate data in-line with NIST standards for AI-ready biodata.

02

Agencies connect data to DOE Web of Biodata.

03

Researcher pulls AI-ready data from Web of Biodata.



4.1b Recommendation

Congress should authorize the National Institute of Standards and Technology (NIST) to create standards that researchers must meet to ensure that U.S. biological data is ready for use in AI models.

National infrastructure, metrology (the study of metrics), and standards for biological data are critical to advancing the field and maintaining American leadership, especially when it comes to AI-ready data. But the lack of universal standards, centralized access systems, or even a common language for biological data has exacerbated the current disconnected approach.

The federal government can fix this problem by building national infrastructure and frameworks for biological data that maximize the ability to combine biological datasets that are greater than the sum of their parts. Creating standards and frameworks for data would also require the NIST to expand its portfolio of work related to biometrology, which is the study of metrics and standards related to biotechnology. Taken together, these steps would help create usable biological datasets that would reduce the amount of time and effort researchers spend curating biological data. The resulting datasets could be used to train advanced AI models that could provide novel biological insights at unprecedented levels of performance.

An expanded biotechnology portfolio at the NIST should include expanded capabilities for biometrology. These should include additional instrumentation and research that would translate into usable frameworks, metrics, and units, all built in collaboration with the biotechnology industry. These capabilities would support the building of AI-ready requirements. (For more details on biometrology and the expanded NIST portfolio, see Appendix C.) The NIST is well positioned to take on this mission because it leads the establishment of national standards for critical and emerging technologies such as AI and semiconductors. Indeed, it has already undertaken some efforts to standardize biological data, such as hosting the Genome in a Bottle Consortium, which seeks to characterize human genome data.[235] While such efforts are helpful, there is still a need for a concentrated focus on developing AI-ready data. In particular, there is a need to maximize the potential of biological research by requiring that recipients of federal funding collect AI-ready data.

Congress should authorize the NIST to develop standards and frameworks for biological data, prioritizing the establishment of a definition of, and parameters for, AI-ready biological data. The NIST should design standards that support interoperability between new and existing U.S. biological datasets and that support the use of biological data in AI models.

To develop the AI-ready biological data definitions and frameworks, there should be a two-phased approach that would complement other work on standards as part of an expanded biotechnology portfolio at the NIST.

A phased approach is critical because developing a definition of AI-ready biological data is a complicated process due to the sheer number and breadth of biological data types. Accordingly, it is important to establish initial evaluation criteria before fully implementing an AI-ready biological data requirement.

Phase I: Define AI-Ready Biological Data and Pressure-Test Frameworks

Phase I would occur over the first two years, during which the NIST would define AI-ready data and pressure-test the definition to ensure it does not impose an undue burden on the research community. The NIST should create a definition in consultation with key federal, academic, and industry stakeholders. The definition, at a minimum, should specify that AI-ready biological data:

- are compatible with the WOBD (see recommendation 4.1a);
- are accessible via an application programming interface (API) within one year of collection;
- include machine-readable metadata that enables reusability;
- can be normalized to support aggregation with other biological datasets;
- include all data controls and outputs; and
- are available in a raw, unprocessed format.

Phase II: Fully Implement AI-Ready Data Requirement

In Phase II of the program, which would take place over the next three years, the NIST would expand its work to provide data management resources for biological data, build complete cybersecurity frameworks, hire a dedicated staff, and coordinate with relevant federal funding agencies on AI-ready data requirements. In this phase, the NIST would fully implement the requirements.

In parallel with developing these guidelines, the NIST should work with departments that are members of the Federal Acquisition Regulation (FAR) Council to update the FAR to incorporate a base-level requirement that federal funders produce AI-ready biological data. This requirement should be applicable to large biological datasets, with thresholds defined by the NIST. Updates to the FAR should apply to all relevant agencies, while allowing for authorized exemptions on a case-by-case basis. The NIST should serve as a hub for helping recipients of federal funding that are subject to AI-ready provisions ensure that their data are indeed AI-ready.

4.1c Recommendation

Congress should authorize and fund the Department of Interior (DOI) to create a Sequencing Public Lands Initiative to collect new data from U.S. public lands that researchers can use to drive innovation.

Efforts to collect biological data in the United States are not strategically planned and executed, leaving gaps in biological data holdings and preventing researchers from understanding what data is needed. The United States would benefit from data collection in a number of different sectors, including healthcare, agriculture, and biomanufacturing. While the Commission identified many gaps in U.S. biological data collection, there is a particular need for non-human biological data, including data from animals, plants, microbes, and fungi, in order to better understand the breadth of America's biological landscape.

> The United States has one of the most extensive and varied public lands systems in the world, encompassing enormous distributions of preserved ecology and biological organisms. The National Parks alone cover 85 million acres, including extreme landscapes such as Death Valley, with its record-breaking heat, and Gates of the Arctic, with its glacial wilderness.[236]

The national parks are home to unique organisms and ecosystems, including the coral formations at Dry Tortugas National Park in Florida, many different species of salamanders at Great Smokey Mountain National Park in North Carolina and Tennessee, and the gypsum dune fields and endemic moth species of White Sands National Park in New Mexico.[237]

Genomic data from plants, fungi, animals, and microorganisms are essential resources for research in genetics, evolution, and biochemistry, as well as for applied purposes such as medicine, food, and conservation. Genomic data collected from organisms living in extreme environments, such as the hydrothermal sites in Yellowstone National Park, could provide insights into how organisms adapt to live in these extreme environments. Similar to how penicillin was discovered by studying a fungus that produced the antibiotic for its own survival, studying a wide range of different organisms from public lands could contribute to biotechnology innovations.[238]

There is no coordinated federal effort to catalog the genomic landscape of U.S. federal lands. While there are efforts to collect genomic sequence data, these are tailored to the missions of specific departments and agencies, and they lack interoperability, collaboration, overarching data standards, and shared interagency goals.

Congress should authorize and fund the Department of the Interior (DOI) to create a Sequencing Public Lands Initiative to collect data from U.S. public lands that researchers can use to drive innovation. This major initiative would seek to sequence and catalogue the genomes of animals, plants, fungi, and bacteria across the United States.

The biological data collected from this initiative, which would be made available through the WOBD (see recommendation 4.1a), would help protect National Park lands, allow researchers to learn from nature to develop innovations, and enhance broad educational opportunities.

The Sequencing Public Lands Initiative should proceed in three phases, so that the project is carefully executed and gradually expanded, culminating in an opportunity to sequence a wide variety of organisms from different federally managed lands.

Phase I: Selecting Five National Parks :

The Sequencing Public Lands Initiative should start with a two-year initial phase in which five national parks are selected through a competitive process based on four criteria, including:

- **Biological Resources:** Each park should conduct an inventory of its own biological resources, including information on the breadth of known species and the rarity of present species.
- **Implementation Plan:** Each park should devise an implementation plan that includes input from experts on regional organisms, genomic sequencing, and taxonomy. These experts would coordinate sampling and collection logistics, as well as a proposed sequencing timeline.
- **Education and Outreach Plans:** Each park should have plans to establish partnerships with local public universities to provide opportunities for recent graduates to work on sample collection and processing. Furthermore, parks should have plans for outreach and public education efforts.
- **Specific Research Questions:** Each park should feature scientist-generated research questions particular to that park and its unique biome

A newly established office in the DOI would work with the selected national parks to establish how to safely and appropriately collect samples, who would perform the collection, what training would be necessary, and how to work with the NIST to establish data standards. The DOI would also work with the U.S. Department of Agriculture (USDA) and the Smithsonian Institution to establish best practices for storing samples. Phase I would require that the DOI report to Congress with an implementation plan for the entire initiative and give an annual update on progress. It is critical to set up the systems that make up Phase I before moving on to Phase II.

Phase II: Sequencing Twenty National Parks

The DOI would expand the initiative to 20 additional national parks. Each additional park should be required to conduct a survey of the breadth of biological organisms within its boundaries and create implementation and education and outreach plans, as well as scientist-led research questions.

Phase III: Sequencing Public Lands

The final phase would entail the full realization of the program, which would expand to more federal lands, and seek to capture a holistic picture of the biological landscape of the United States. Land managed by the DOI's Bureau of Land Management, its Fish and Wildlife Service, and the USDA's U.S. Forest Service would be included, and genome sequencing would fit into the previously established infrastructure and pipelines. The outcome of this initiative would consist of biological data, such as whole genome sequences, and necessary metadata to ensure the data are AI-ready. These data would comprise a database within an established data storage system—namely, the proposed WOBD (see recommendation 4.1a).

The Sequencing Public Lands Initiative would require close collaboration with local communities and landowners. At every step, program coordinators would have to consult with the Assistant Secretary for Indian Affairs and other relevant partners to incorporate their views and expertise into the project.

Education and outreach would be key components of the Sequencing Public Lands Initiative. The initiative would provide an opportunity to engage with scientists, students, and broader communities on the environment and its inhabitants, as well as on the importance of basic science and genomic data. This initiative would also offer opportunities for students, recent graduates, and postdoctoral fellows to gain

technical experience in the research pipeline, from collecting samples to assembling and annotating genomes. The Sequencing Public Lands Initiative could serve as a springboard for bioliteracy across the country. National parks could develop curricula for local students from elementary through high school to learn about topics such as ecology, molecular biology, and computer science, all while working on projects that feature real biological systems in their area. While these genomic data would become a valuable resource for scientists, the discoveries from these biological data could also be incorporated into education and outreach materials that the parks could use to generate further interest in the United States' rich ecosystems.

Intermission

What can the U.S. National Parks tell us about biology?

A grand proposal for the Department of the Interior to collect, read, and archive the wealth of non-human biological information in U.S. public lands through genomic sequencing.

Photos courtesy of NSCEB staff, friends, and family.

4.1d Recommendation

Congress should authorize the National Science Foundation (NSF) to establish a network of "cloud labs," giving researchers state-of-the-art tools to make data generation easier.

To gain an advantage in AI capabilities related to biotechnology, the United States needs more high-quality training data for AI models. Currently, however, there are limited research opportunities for biological data collection using robotics and automation. Robotics and automation are redefining what is possible for large-scale, high-throughput biotechnology research and data collection.

The costs to build a highly automated laboratory are significant, as are the costs of sustaining a highly specialized workforce to keep the laboratory operational. There are examples of several commercial automated laboratory facilities, called "cloud labs" that provide such resources, but there are significant barriers to entry for both building and using a cloud lab, mostly related to cost.[239]

Given these costs and the benefits that come from the massive quantity of high-quality data that a cloud lab can generate, automated laboratories should be viewed as an opportunity to invest in economies of scale. The United States could create an opportunity for researchers to generate large amounts of high-quality biological data through new and existing automated instrumentation infrastructure. The resulting data would be critical for the future of biological AI models.[240]

Next-Generation Laboratory Definitions

Laboratory automation

refers to processes that involve robotics, computers, liquid handling, and other advanced technologies to complete biological experimentation.[liv]

Autonomous laboratories

are fully automated and guided by artificial intelligence and machine learning software to plan, execute, learn, improve, and repeat experiments based on a desired outcome. Autonomous laboratories are sometimes called self-driving labs because a human does not define each step of the experimental protocol or perform any experiments.

Cloud laboratories

are physical laboratories that are equipped with lab automation that can be programmed and controlled remotely by scientists to conduct biological experiments. Cloud laboratories are typically semi-automated and often operate on a fee-for-service basis.[lv]

Congress should authorize the National Science Foundation (NSF) to establish a network of cloud labs. To give researchers access to state-of-the-art automated instrumentation for biotechnology data collection and experimentation, the NSF would coordinate the different capabilities of existing cloud lab facilities in addition to establishing new cloud lab infrastructure.

This program should be executed in three phases, including a careful initial planning phase.

Phase I: Assessment and Planning

The NSF, in consultation with the National Biotechnology Coordination Office (NBCO) (see recommendation 1.1a), the DOE, and the NIST, would assess the state of existing cloud lab infrastructure in the United States. The NSF would also develop an implementation plan for the program, in consultation with relevant public and private sector stakeholders, including a plan for creating new cloud lab facilities in the United States.

Phase II: Initial Awards for New Cloud Laboratories

The NSF would award grants on a competitive basis to develop and operate at least two new cloud labs, while continuing to update and maintain its network of existing cloud labs.

Phase III: Additional Awards for New Cloud Laboratories

The NSF would award grants to develop and operate at least three additional cloud labs.

"Biotechnology has held promise for decades as the revolutionary frontier of tomorrow, but I firmly believe we are at the most critical inflection point. We are barreling toward never-before-seen capabilities: AI and related cutting-edge technologies are supercharging our ability to discover biobased products. The need is clear: Emerging national security threats, such as supply chain insecurity, the strengthening of adversaries, and public health threats require innovative, world-leading solutions. The biotechnology mindset is shifting: Our companies, universities, and leaders are increasingly realizing biotechnology product-market fit which will impact all Americans, whether it be service members, farmers, or families.

All of this is happening right now at an unprecedented pace, and it's happening around the world. I'm excited that our recommendations will make it easy for the United States to run the fastest and win this race at home. We can't afford to let up."

- Commissioner Alexander Titus

Section 4.2

Block China from Obtaining Sensitive U.S. Biological Data

While the United States has not prioritized biological data, China has emphasized its importance to biotechnology innovation, raising concerns about an arms race in genetic data. Beijing harvests and protects its own biological data while taking advantage of unprotected data from abroad.[243] With all this data, the Chinese government can link individuals to their genetic information, track their susceptibility to particular health problems, or learn about their ancestry.[244]

Data also offers military advantages. In the hands of researchers backed by the People's Liberation Army (PLA) and supercharged with advanced AI, high-quality biological data could enable Chinese advances in using biotechnology to fight wars and to enhance human performance.[245] Overall, China's strategic investments in biological data enhance its global position in biotechnology, contrary to U.S. values and interests.

4.2a Recommendation

Congress must conduct oversight of existing policies, and add new authorities as warranted, to ensure that China cannot obtain bulk and sensitive biological data from the United States.

In some cases, the current federal framework for biological data protection enables foreign and domestic entities to acquire sensitive biological data about U.S. persons through legally permitted bulk data transfers. Recent laws and executive orders have tried to address this concern.

> "Sensitive biological data" are data that have the potential to be used to personally identify an individual or group of individuals.

They include but are not limited to human genomic data, other -omics data, and biometric data.

The March 2024 Executive Order (EO) 14117 on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern is intended to restrict transactions for types of data, including biological data, and to protect that data as sensitive and personal. But there are limitations to relying on this kind of executive branch action, which can be overturned and face legal challenges.[246]

In 2024, Congress passed the Protecting Americans' Data from Foreign Adversaries (PADFA) Act, which complements EO 14117's focus on types of data by preventing a range of sensitive data brokerage transactions.[247] Future assessments may be necessary to evaluate whether the Department of Justice's (DOJ) efforts, combined with the PADFA, strike the right balance between national security and the needs of academia and industry.

Congress must conduct oversight of PADFA and EO 14117 implementation (through a DOJ rulemaking) to ensure that China cannot obtain bulk and sensitive biological data from the United States. Such oversight would require hearings from appropriate officials at the DOJ and the Federal Trade Commission (FTC), in which these officials would report on progress made on the data protection mechanisms they are responsible for. Congress should specifically inquire about protections related to bulk and sensitive biological data. Relatedly, Congress should continually assess what new authorities might be needed and necessary to ensure bulk data protections, adding new authorities as needed.

In particular, Congress should assess what biological data types may be sensitive, since new advances and technologies can change biological data types. For example, data related to the microbes that live in the gut were previously considered harmless, but after large-scale efforts of collection and analysis, the same information was shown to carry unique forensic signatures that can be used to identify individuals.[248]

Section 4.3

Launch Grand Research Challenges to Unlock Leap-Ahead Capabilities

Dedicated funding and infrastructure would inspire American innovators to pursue once-impossible goals and solve the most challenging research problems.

4.3a Recommendation

Congress must establish Centers for Biotechnology within the existing National Laboratory network to support grand research challenges.

The United States needs specialized and coordinated federal research infrastructure for biotechnology. Innovation in this sector requires interdisciplinary connections and access to key equipment.

The federal government has cutting-edge R&D facilities, including four Bioenergy Research Centers, two of which are led by DOE National Laboratories (i.e., Lawrence Berkeley National Laboratory and Oak Ridge National Laboratory). But these research centers tend to focus narrowly on early-stage R&D related to a specific mission and place less emphasis on translating research into products.[249] Moreover, the United States lacks some R&D infrastructure that is critical for emerging biotechnologies, including:

- risk-assessment testbeds;
- data collection and computing power for biotechnology;
- advanced measurement development and instrumentation;
- chemical and material production using biology; and
- biotechnology scale-up innovation and infrastructure that span basic and applied research.

To achieve breakthroughs in biotechnology discovery akin to what Lawrence Livermore National Laboratory has done with fusion research or what Los Alamos National Laboratory has done with nuclear research, Congress must establish six Centers of Biotechnology within the 17 existing National Laboratories, each center with its own area of focus.[250]

The main purposes of these biotechnology centers would be to:

- provide facilities for interdisciplinary biotechnology research, discovery, and development;
- encourage large-scale research projects that have some risk of failure but could lead to huge leaps in the study, development, or adoption of biotechnology; and
- provide biotechnology practitioners access to expensive resources and instrumentation, such as supercomputers and advanced measurement capabilities.

These new Centers for Biotechnology would complement existing research efforts and enable biotechnology progress across the National Laboratory system, in collaboration with partners from academia and industry. They would also provide an opportunity for researchers across government, academia, and

industry to access state-of-the-art equipment and instrumentation, similar to what the five Nanoscale Science Research Centers at the DOE have accomplished.[251] By providing instrumentation and interdisciplinary collaboration, these hubs would also enable progress on the grand research challenges proposed in this section.

The appropriate DOE office should manage each center. The DOE's Office of Critical and Emerging Technologies (OCET) should facilitate the coordination of biotechnology efforts across the DOE, including the activities of all six biotechnology centers and other biotechnology capabilities at the National Laboratories. The OCET should help to lead a biotechnology group within the DOE that would develop a strategic plan for establishing and selecting the Centers for Biotechnology. The centers would be selected through a competitive process among the existing 17 National Labs.

4.3b Recommendation

Congress should initiate a grand research challenge focused on making biotechnology predictably engineerable.

While the United States has led the world in biotechnology innovation for many decades, that lead is at risk. This is largely owed to a lack of federal funding and prioritization for biotechnology research to unlock "leap-ahead capabilities," or disruptive technologies that offer unprecedented new functionalities, in the United States. The U.S. research enterprise is either stagnant or falling behind in some key areas.

Funding for biotechnology research typically goes to ideas that represent incremental progress, and it is difficult to find funding for risky and innovative ideas. Some funding mechanisms, such as those at the Defense Advanced Research Project Agency (DARPA) or at Advanced Research Project Agencies (ARPA) within other departments, have long funded high-risk research, but they represent only a small portion of all government research funding.[252] New programs such as the National Science Foundation's (NSF) Catalyzing Across Sectors to Advance the Bioeconomy (CASA-Bio) use interagency goals and interdisciplinary teams to seek common priority areas in biotechnology.[253] But while CASA-Bio is a helpful mechanism through which an interagency group coalesced around important biotechnology goals, it is not a funding program.

To build on these programs, the United States needs to act boldly, inspiring its innovation base and encouraging a range of projects, small and large, across the country by initiating grand research challenges.

> One of biotechnology's most important quests is to make biology predictably engineerable.

While the biotechnology community has worked toward this goal for decades, it has yet to reach the maturity of many engineering fields, including electrical engineering, computer engineering, and mechanical engineering, which have all reached a point where building end products is routine. Biotechnology is still in an earlier stage. Challenging the sector to harness nature in transformative ways that could benefit all would bring biological engineering to a similar maturity. Breakthroughs related to this goal could be applied to all different types of living organisms, including animals, plants, microbes, and fungi, and would subsequently enable advances in biotechnology and biomanufacturing.

Currently, however, broader funding by the federal government related to such a goal is sparse and diffuse, preventing breakthroughs.

To inspire more biotechnology breakthroughs, Congress should initiate and fund a grand research challenge to make biology predictably engineerable. That grand challenge should be:

- an inspiring goal that captures the public imagination;
- a mission the private sector is unlikely to pursue on its own;
- a challenge requiring an interdisciplinary approach;
- a project that fosters innovation and progress beyond the primary goal of the grand challenge; and
- a goal that is broad and ambitious enough to be pursued across the research community and advanced by both incremental discoveries and major breakthroughs.

The U.S. government should appropriate a minimum of $5 billion over five years to achieve this goal. Any lesser investment would risk being too small to enable future biotechnology invention and product development in the United States.[254]

A portion of this new funding should be designed to reward success in solving hard, ambitious scientific challenges that unlock important leap-ahead capabilities. Structuring the funding in such a way would imbue grand research challenges with a spirit of constructive competition, while only deploying taxpayer dollars when ambitious goals are met. (For more detail on this grand challenge, including a potential funding structure, see Appendix D.)

This grand challenge would require bolstering the engineering paradigm of "make, model, and measure" for biological systems. Therefore, government funders should develop component challenges that break down predictable engineering into individual tasks. Some other key steps to implement this grand research challenge include:

- creating an interagency program and establishing a lead agency that would work with other departments and agencies toward this goal;
- consulting with the Director of the NBCO (see recommendation 1.1a) at the White House; and
- working with philanthropic funders to get buy-in on research areas and to increase the pool of money for funding research projects.

4.3c Recommendation

Congress should initiate a grand research challenge focused on making biomanufacturing scale-up predictable, rapid, and cost-competitive.

Biotechnology processes and production must also scale predictably—another challenge involving interdisciplinary science, technology, and engineering.

After decades of outsourcing the manufacturing of both legacy and next-generation biotechnology products, the United States has woefully deprioritized research that would reduce the complexity and costs of scaling biological processes.

Even with the U.S. biotechnology sectors' tools and expertise, transitioning from small-scale research to large-scale production is inefficient, slow, and expensive.[255] Expanding the United States' number of physical facilities, while critical, is not sufficient on its own. Innovations in the science of biomanufacturing scale-up, in tandem with increased physical capacity, lie at the crux of ensuring that American biotechnology products make it to market. Advances in U.S. biomanufacturing spurred by solving scale-up questions in early-stage research—as well as equipment and technologies that span the bioprocessing chain—promise to unlock new ways of creating biomanufactured products.[256] Prioritizing the science of scale-up would help create distributed, diversified, and flexible biomanufacturing across the United States.

To accomplish this, Congress should fund a grand research challenge to develop novel biomanufacturing technologies that make scale-up predictable, rapid, and cost-competitive. This grand challenge should prioritize interdisciplinary research focusing across four key research areas:

- chassis;
- feedstocks;
- process technology and equipment; and
- critical inputs.

Advancements in the first three research areas (chassis, feedstocks, and process technology and equipment) would expand the number of bioproducts that could be created with biomanufacturing, ensure that biomanufacturing is location-agnostic, and draw on plentiful raw material inputs such as location-specific agricultural biomass. Moreover, uniting and simplifying scale-up processes would decrease the money and expertise needed to transition bioproducts to the market.

Advancements in the fourth area (critical inputs) would diversify and secure the supply chain of low-margin chemicals and biological materials such as amino acids that are necessary to sustain scaled biomanufacturing. Demand for these materials is expected to greatly increase as the United States expands its biomanufacturing sector, but for the most part, these inputs are sourced abroad and often have market prices that are so low that they disincentivize innovations to cost-effectively produce them domestically.[257]

Other key implementation details for this grand research challenge include:

- congressional designation of a federal agency to lead efforts for each research area, based on considerations such as current or past agency efforts and mission spaces;
- collaboration among lead agencies and across the interagency to ensure that this multidisciplinary grand challenge draws on all relevant expertise within the federal government;
- coordination through the Director of the NBCO (see recommendation 1.1a) at the White House, to ensure collaboration, prevent duplicative research, and have a technical advisor to assess progress; and
- milestone-based funding, contingent on annual progress reports submitted by lead agencies to Congress. Congress could authorize incrementally larger funding amounts each additional year to ensure that funding is given in proportion to demonstrated progress. (Further further guiding detail on this scale-up grand research challenge, including suggested funding amounts and examples of lead agencies, see Appendix D.)

The four identified areas of scale-up research—chassis, feedstocks, process technology and equipment, and critical inputs—have implications for a wide range of biomanufacturing areas and can be applied broadly to biomanufacturing for chemicals, medicines, fuels, materials, and other biotechnology products. These areas also touch on biopharmaceuticals, especially when it comes to rapid vaccine production and new vaccine types.

Section 4.4

Protect Against the Harms of Biotechnology

U.S.-led biotechnology revolution requires American innovators to do what they do best: create new technologies to solve hard problems. The Commission has seen and heard firsthand U.S. innovators' commitment to ensuring that their work is safe, secure, and responsible. And people working on biotechnology in both industry and academia have long called for government to improve the way it makes policy and enforces biotechnology safety, security, and responsibility. The current system places undue burden on researchers and innovators to navigate unwieldy bureaucratic processes while enduring market and academic pressures.

> Just as the United States should be the place where the world's most innovative scientific discoveries come to market, so too should America. be home to the most innovative work to develop the sciences of biosafety and biosecurity.

This is where the U.S. government has an important role. It can operate outside of market pressures, funding and incentivizing innovations that the market will not necessarily produce on its own. Right now, however, government imposes safety, security, and responsibility requirements and yet does not work alongside researchers to build the tools and capabilities to meet those requirements.

Current Tools are Blunt and Reactive

The United States relies on a limited set of tools to ensure safety, security, and responsibility in biotechnology.

The first of these is the moratorium—essentially a stop-work order on innovation. Academia, industry, and government alike reach for this tool when research moves beyond existing oversight systems and governance cannot adapt. In the early days of genetic engineering, for example, researchers called for a pause on their own work and spent years collaborating with the government on a set of safety and ethical oversight systems.[258]

Similar calls followed OpenAI's release of ChatGPT in the fall of 2022. Many industry leaders raised the alarm and demanded a pause on large AI experiments to mitigate, as an open letter put it, "profound risks to society and humanity."[259] Despite the unprecedented popularity of ChatGPT, it took a year for the government to create the AI Safety Institute, which is part of the NIST.[260] Lawmakers are still grappling with the right way to legislate on AI safety. But the U.S. government's reactive approach lowered confidence in its ability to oversee transformational technology.

Every time innovators have to hit the brakes unexpectedly, they lose time, money, and public trust. Biotechnology has not yet reached its ChatGPT moment. In the face of rapid advancements originating in China, the United States cannot afford for innovation in biosecurity and biosafety governance to happen in stops and starts.

Another oversight tool the United States uses is lists of biological hazards, such as organisms with destructive potential. List-based systems, such as the Federal Select Agent Program (FSAP), are most appropriate when researchers and innovators know how concerned they should be about a particular organism or type of experiment. List-based systems work less well for emerging or poorly understood risks.[261]

While these tools are good starting points, the government fails to routinely evaluate their effectiveness.[262] The United States, therefore, does not know how much innovation is lost or how much safety and security is gained through these approaches.

Government Leadership is Fragmented

Despite the United States' historic leadership in biosecurity and biosafety, existing government policies are fragmented across federal agencies, leading to

redundancies, gaps, and inefficiencies. These policies include the FSAP, Biosafety Levels (BSL) designation and laboratory biosecurity and biosafety guidance, and gene synthesis screening guidance.

For example, a multitude of agencies and offices conduct inspections and require reporting for laboratory oversight. Inspections look at the same things and ask the same questions, but operate on different timelines, imposing a frustrating compliance burden on laboratory staff.

Another example of fragmentation concerns the security of gene synthesis. The process of creating physical genes based on digital sequence data, called gene synthesis, is critical for the growth of the biotechnology industry. While industry is united in calling for a measured, enforceable, and standardized approach, the U.S. government is unable to respond to such requests with the needed agility. Policies regarding gene synthesis security are distributed across multiple federal agencies and offices, including the Department of Health and Human Services (HHS), the Federal Bureau of Investigation (FBI), and the Executive Office of the President (EOP) or Office of Science and Technology Policy (OSTP). As of February 2025, these are voluntary standards, not mandatory ones.

Furthermore, the Commission found that many of the agencies designated to address different aspects of biosecurity and biosafety see this work as peripheral to their core missions and mandates and lack the incentive to tackle these issues.

Policies are Quickly Outdated as Technology Advances

Biosecurity practices and policies have traditionally revolved around preventing the misuse of biological pathogens, primarily through controlling access to them. However, as researchers develop novel biodesign capabilities, such as gene editors, gene synthesis capabilities, and AI-powered protein design, these practices and policies must evolve.

The U.S. government is not modernizing policies quickly enough to keep up with biotechnology development. It took 13 years to update guidance on gene synthesis screening, and the resulting frameworks remain limited to federal research.[263] It took 10 years to modernize oversight of Dual Use Research of Concern (DURC) and research involving Pathogens with Enhanced Pandemic Potential (PEPP).[264] Calls for a foundational reassessment of the FSAP have still not resulted in the necessary changes.[265] List-based policies are particularly likely to lag behind the leading edge of biotechnology.[266]

Going Forward

The United States needs a sharper set of tools. The government body that develops those tools must itself be at the leading edge of technology, not just in biotechnology innovation but also in developing the science of biosecurity, biosafety, and responsibility.

Governance must keep pace with innovation. To do so, the government must streamline policies and develop a proactive culture, cultivate dedicated expertise, and secure a resource stream for advancing governance capabilities. Policies should not stifle innovation. Rather, they should ensure risk awareness and mitigation while maximizing benefit.

The United States should lead by example in building biosecurity and biosafety into research and innovation processes. International collaboration will be essential to realizing the full benefits of advances in biosecurity, biosafety, and responsible innovation.

Fixing the U.S. government's outdated approach in these areas would secure America's technological lead by giving the nation's industry and academia the confidence to do what they do best: out-innovate the world.

The U.S. government could continue to have each agency with a hand in biotechnology innovation perform its own biosecurity and biosafety measures. For example, in December 2024, the HHS and the Department of Homeland Security (DHS) announced the Biosafety and Biosecurity Innovation Initiative Plan for the Bioeconomy, a suite of recommendations for each biotechnology agency to implement on their own.[267] But this approach does not adequately address the problems described above.

Instead, the United States could take a new approach: create a consolidated, dedicated capability to protect against harms from biotechnology in a way that integrates leading-edge science and evidence-based policymaking into enforcement and regulation, allowing policies and enforcement to continuously adapt.

4.4a Recommendation

Congress must direct the executive branch to advance safe, secure, and responsible biotechnology research and innovation.

After 20 years of trying and failing to protect against harms without stifling innovation, Congress must pursue a different approach. One solution is for Congress to create a new entity that both serves as a resource to innovators at the forefront of technology development and modernizes legacy safety and security policymaking and enforcement.[268]

The Department of Commerce (DOC) is the logical place to house such an entity: it has a culture of promoting innovation and economic development across the country, experience with metrology and standards-setting through the NIST, and a focus on security. It could work closely with the NBCO (see recommendation 1.1a), the Centers for Biotechnology (see recommendation 4.3a), and implementers of the proposed grand research challenges for biotechnology (see recommendations 4.3b and 4.3c).

This entity would have five main responsibilities:

1. Identify emerging risks and vulnerabilities with biotechnology and existing oversight.

To do so, it would:

- perform continual evaluation and assessment of vulnerabilities, weaknesses, and threats, including lab testing of equipment and advanced tools;
- analyze inputs from regular disclosures (which already exist) and a no-fault reporting system (which should be developed) from industry and academia on potential concerns; and
- run a whistleblower mechanism and host regular forums for industry and academia to identify gaps in technical capabilities and concerns with existing oversight.

2. Fund basic and applied biosecurity, biosafety, and responsibility innovation and tool development.

Taking an ARPA-style approach to solving hard problems quickly, the entity could fund projects addressing:

- technical advances on biosecurity and biosafety by design capabilities;
- the use of machine learning to assess the level of concern of novel sequences or organisms;
- methodologies for biosafety officers to handle concerns about specific research projects that do not fit neatly into existing policies;
- methods and organizational designs for safe, secure, and responsible biotechnology; and
- systematic and streamlined risk assessments to inform biotechnology innovation pathways.[269]

The entity could also pilot, test, and refine new technological and organizational abilities in a controlled sandbox with key stakeholders.

3. Develop and incentivize the adoption of best practices.

This would include:

- standardizing best practices for biosecurity, biosafety, and responsibility across funding agencies;
- promoting the adoption of innovations that arise from the entity's research; and
- collaborating with industry and academia to train and develop the workforce for biosecurity, biosafety, and responsibility.

4. Consolidate and oversee biosecurity, biosafety, and responsibility policies.

This would entail:

- immediately modernizing and overseeing the FSAP and enforcing gene synthesis screening procedures;
- over time, updating and adapting other biosecurity and biosafety policies;
- helping other agencies adapt policies affecting biotechnology where it converges with other technology areas (for example, working with the DHS and the Cybersecurity and Infrastructure Security Agency (CISA) on cybersecurity policies that involve biological algorithms and data);
- establishing a comprehensive licensing system for BSL-3/4 facilities and accreditation for relevant biosecurity and biosafety personnel; and
- maintaining strong connections with law enforcement agencies, including the FBI and the DHS, to enable effective enforcement of relevant criminal statutes.

5. Work with the international community.

This would include improving best practices and standards and sharing information and technical advances to prevent misuse and encourage trust in emerging biotechnology.

Advancing Safe, Secure, and Responsible Biotechnology Research and Innovation

HHS Administration for Strategic Preparedness and Response

Synthetic nucleic acid screening guidelines

Digital-physical cyber protection issues

HHS National Institutes of Health

Lab oversight

National Science Advisory Board on Biosecurity

Recombinant DNA research guidelines

Novel and Exceptional Technology and Research Advisory Committee

DHS Cybersecurity and Infrastructure Security Agency

Bio-specific cybersecurity protection

Gene synthesis security stress testing

Executive Office of the President

Executive Order on Safe and Secure AI

Frameworks for Nucleic Acid Synthesis Screening

Dual Use Research for Concern – Pathogens with Enhanced Pandemic Potential (DURC-PEPP)

USDA Animal and Plant Health Inspection Service and HHS Centers for Disease Control and Prevention

Select Agent Program, Lab oversight

Additonal activities not currently addressed by any agency

No-fault reporting system

Biosecurity and Biosafety training

Others...

A Consolidated Approach

Identify emerging risks and vulnerabilities.	Incentivize the adoption of best practices.	Collaborate with the international community.	Fund applied innovation and tool development.

Intermission

How Will You Participate In The Biorevolution?

From students to workers to citizens all over the United States, everyone has the potential to contribute their talents, ideas, and innovations to biotechnology. The Commission encourages all Americans to seek out biotechnology in action in their local communities—often, it is closer than you think!

Consumers may not realize that biotechnology is already available on store shelves, from sweaters to food containers, while new products like biomanufactured fragrances or computers that use DNA as storage could one day be found in local stores.

Students can try out biomanufacturing courses at local community colleges, which will help them enter the workforce or continue to four-year universities and beyond.

Teachers attend teacher education workshops and bring hands-on activities in bioengineering to their students.

Community scientists are everyday citizens who encounter biotechnology labs in local settings, such as the library, and feel inspired to innovate.

Healthcare specialists are actively using biotechnology to treat diseases with biologics and antibodies, and emerging biotechnologies are enabling even more effective, personalized treatments.

Farmers are already using biotechnology in their day-to-day operations, and new products can further help their farms increase yields, withstand pests, and endure weather extremes.

Nature lovers who engage in gardening, hunting, fishing, and foraging can better understand how biotechnology might benefit the environment.

Citizens who cook and ferment in their kitchens at home already interact with biotechnology as a part of their daily routines.

Mid-career workers from other sectors learn through local workforce development programs that many of their existing skills can be transferred to the field of biotechnology.

Entrepreneurs can use local feedstocks and resources to create new products that are healthier for society, employing local workers to drive their ventures forward.

Chapter 5

Build the Biotechnology Workforce of the Future

America's greatest strength has always been its people. Bold, creative, and driven individuals have propelled the United States' unyielding pursuit of progress. That same spirit of progress must be harnessed to build a workforce that can lead the world in biotechnology innovation.

To fully realize biotechnology's potential to defend, build, nourish, and heal, the United States must strengthen and sustain a talent pipeline.

The need for talented biotechnology workers has never been more urgent. Tomorrow's biotechnology workforce will be comprised of people of all backgrounds, experiences, and skillsets. The United States will still need scientists, researchers, and will also need technicians, educators, policymakers, business leaders, and innovators at every level.[270] It is these problem-solvers and creative thinkers who will lead the charge into a healthier, more secure, and more prosperous future.

To build this workforce, the U.S. government, academic community, and private sector must work together to advance bioliteracy. Bioliteracy is the ability to understand and engage with biology and biotechnology.[271] Ideally, Americans will soon understand biology and biotechnology in the same way that they understand how computers and information technology interact with their daily lives. Widespread bioliteracy will mean a more informed, empowered, and resilient society capable of leveraging science and technology to solve a wide range of global challenges.

There are three critical workforce gaps that this chapter addresses: the U.S. federal workforce, the country's domestic workforce, and foreign talent.

Congressional offices and federal agencies consistently highlight the growing demand for skilled biotechnology professionals. There are very few biotechnology experts in the federal government, and many of those existing workers are busy running current biotechnology programs. There are very few senior officials at the Assistant Secretary level or higher that are trained in biotechnology or life sciences. A small fraction of Members of Congress are trained scientists. Across the rest of the federal government, many workers have not had biology training since high school. Government officials cannot design or execute policies and programs affecting biotechnology without a general understanding of the underlying concepts.

The United States is also not prepared to meet the broader domestic workforce needs of the country's growing and evolving biotechnology industry. There has been a major, sustained demand for workers familiar with new vaccine platforms, advanced computational and AI-driven biotechnology, cell and gene therapies, and precision medicine since 2017. But the United States' supply of workers is failing to meet this demand.

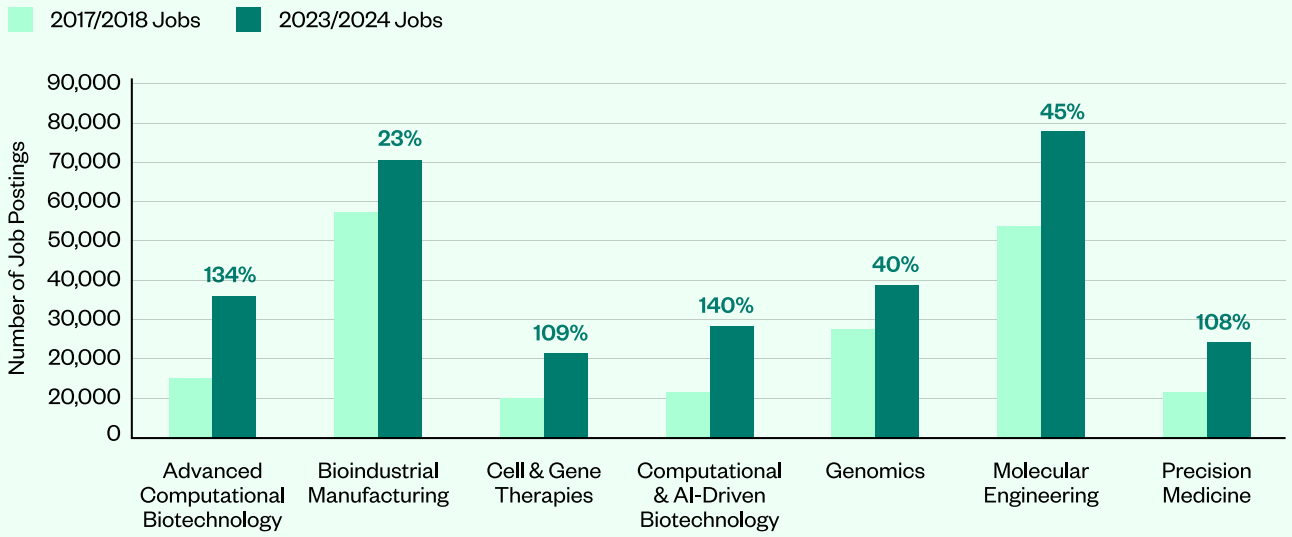
"In order to support the biotechnology industry of the coming decades, we need to invest in our workforce. We are fortunate to live in a time where biotechnology will have such an enormous impact on our everyday lives. I have had the privilege of working with, encouraging, and mentoring the next generation of STEM innovators, from kindergartners through postdoctoral fellows, in my 30 years as a STEM educator. In those years, I have worked with eager learners who are immensely curious and have a drive for innovation to solve the most challenging problems facing our nation and our planet. To prepare a biotech workforce of the future, we need to invest in our domestic talent pipelines. And as we continue to build and support our homegrown talent, it is important that we create a welcoming and supportive ecosystem where the best global talent will seek to come and contribute to our innovation ecosystem.

To prepare and enable the future workforce to lead us, we now have the opportunity as well as the urgency to build policies that support the development of a workforce capable and confident in developing and implanting the next innovations to heal, nourish, feed, and protect the nation. These policies supporting talent development will expose people at all stages of learning, from our youngest learners to our countries leaders, to cutting edge STEM technologies and their potentials. They will also provide access to new educational pathways to future biotech careers, especially in translating and scaling technologies, which will require a basic STEM understanding and an interdisciplinary skill set. And they will provide opportunities for the American people to feel comfortable with the complex concepts of biotechnology, as it relates to their health, their food, and their environment."

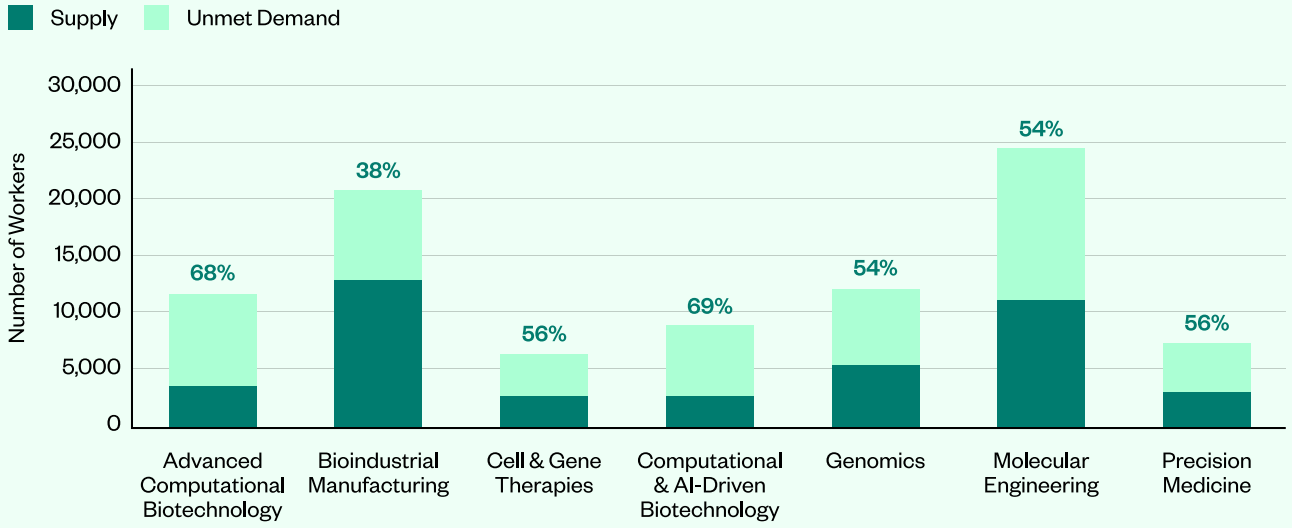
- Commissioner Angela Belcher

In this global race for biotechnology talent, the United States is losing ground to China.[272] The sheer size of China's population gives the country a natural advantage over the United States in human capital. China produces far more STEM PhDs and master's degree holders than the United States does, and it and other countries are quickly becoming compelling alternative destinations for the world's best biotechnology minds.[273] Top U.S. scientists have been offered custom buildings, facilities, and entire departments at institutions in China. Even early-stage researchers have been targeted, with post-docs receiving extremely competitive offers to start labs in China.

Demand for emerging biotechnology workers has grown over the last five years



There is unmet demand for talent in almost every emerging biotechnology role

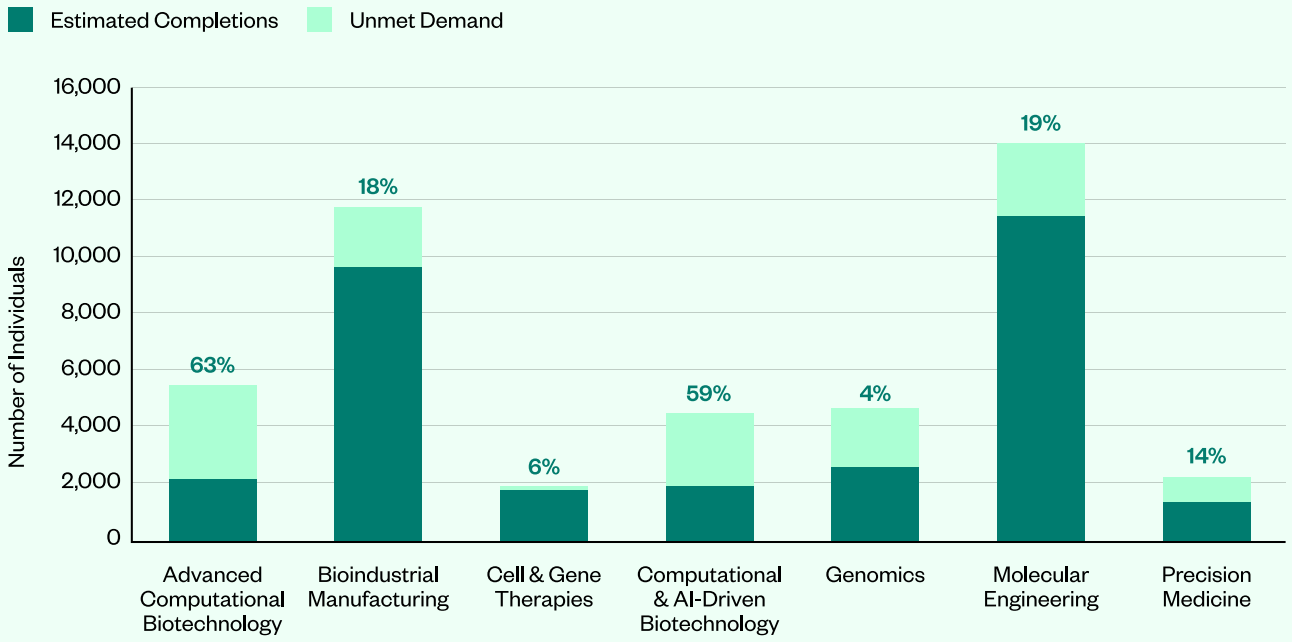


If the United States is to stay globally competitive, it must remain the top destination for the best and brightest in biotechnology. Maintaining that position will require new mechanisms to attract and retain trusted, highly skilled talent from around the world, as well as improved vetting and screening mechanisms to protect against foreign espionage and forced technology transfer. The government must also ensure that those vetting and screening mechanisms do not discourage international students and innovators from bringing their talents and innovations to the United States.

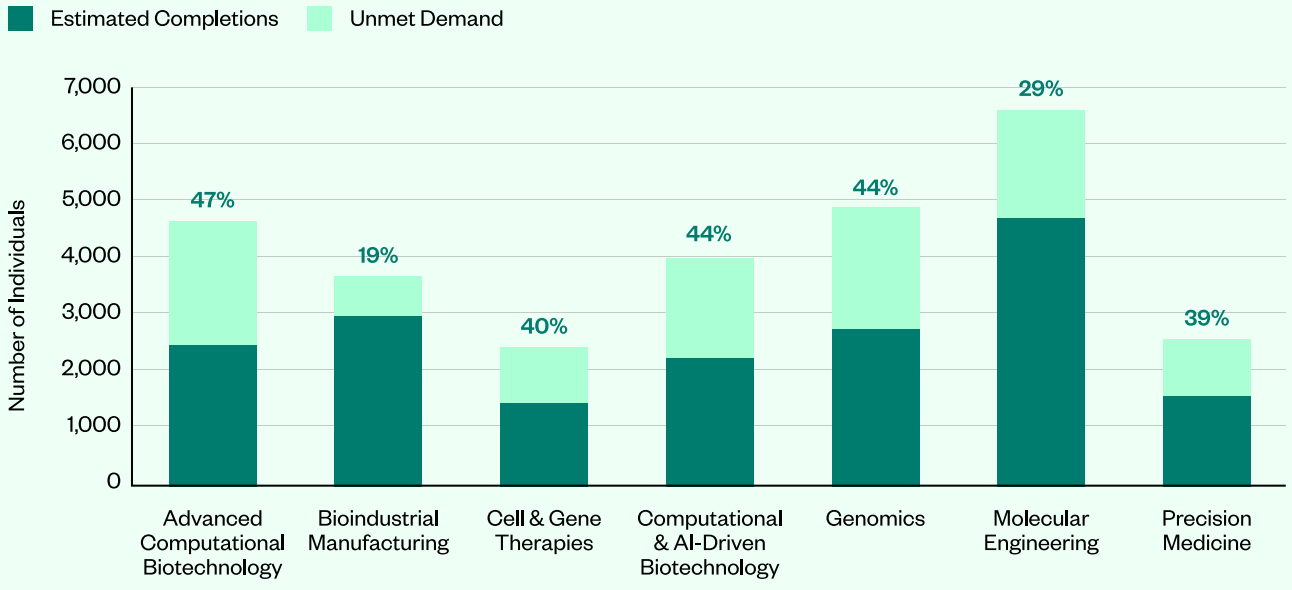
The federal government has a clear and distinct role in addressing workforce development in the federal government, in the country at large, and internationally. The U.S. government is in charge of its own federal workforce; Congress has the power to set policies for recruiting, retaining, and screening foreign talent; and there is precedent for the federal government to prioritize national-level education initiatives of strategic national security importance.[274]

Most domestic workforce and education initiatives, however, are handled at the state and local levels. While the Commission is focused on actions that the federal government is uniquely positioned to take, state and local policies can bolster its efforts with the support of the private sector. Industry can also support community bioliteracy alongside workforce development.

The current rate of bachelor's completions is insufficient to meet current demand for emerging biotechnology talent



The current rate of master's and PhD completions is insufficient to meet current demand for emerging biotechnology talent



Section 5.1

Equip the U.S. Government with Necessary Biotechnology Resources and Expertise

New technologies and concepts emerge in biotechnology all the time, and biotechnology is increasingly converging with other emerging technologies, including AI and quantum. The U.S. government workforce must maintain sufficient, up-to-date understanding of biotechnology in order to effectively legislate, implement, and assess biotechnology policy.[275] Properly trained and equipped federal departments and agencies, along with Congressional offices, can readily act on U.S. national priorities for biotechnology.

5.1a Recommendation

Congress must direct the Office of Personnel Management (OPM) to provide workforce training in biotechnology across the interagency.

The OPM plays a key role in federal workforce training, including overseeing training programs across agencies. As the federal government increasingly stands up new programming and initiatives for biotechnology, it is only becoming more important that federal employees and contractors have the right knowledge and proficiency to carry out operations.

Congress must direct the OPM and relevant executive agencies to develop cross-disciplinary training programs for federal employees that are focused on biotechnology, AI, and other critical and emerging technologies.

The OPM should consult with leadership and workforce training managers at relevant executive agencies to develop the training and determine which federal employees and contractors must take and implement it. The OPM should create different training tracks to meet a wide range of needs across the federal workforce. Curricula can be tailored for employees in different roles, whether in leadership and policy positions or technical and acquisitions ones.

At a minimum, training programs should cover:

- the science underlying biotechnology;
- technological features of biotechnology;
- ways in which AI can be leveraged to advance discoveries in biotechnology;
- ways in which the federal government can benefit from biotechnology;
- the risks posed by biotechnology and ways to mitigate them; and
- future trends in biotechnology such as intersections with quantum computing, autonomous systems, advanced manufacturing, and other technologies.

Training programs should be updated each year to cover advances in biotechnology and its convergence with other critical and emerging technologies.

To complement this training, the federal government should develop a national biotechnology workforce framework, conduct an interagency assessment of workforce needs, and offer guidance on federal agencies' authorities for biotechnology-related hiring. (For more details on a national biotechnology workforce framework, see Appendix E.)

Develop a National Biotechnology Workforce Framework

Successful biotechnology training, including within the federal government, requires accurate data on the biotechnology workforce. But unlike with more established industries, the United States needs a common language to define and categorize biotechnology jobs and skills across the public and private sectors.[276] As a result, government, industry, and academia have a limited understandings of their biotechnology workforce needs and of subsequent best practices for driving that workforce development.

To train federal employees in biotechnology, the OPM needs a baseline framework that defines biotechnology jobs and the knowledge and skills needed to perform them. The National Institute of Standards and Technology (NIST) should develop this framework in partnership with academia, industry, nonprofits, and relevant federal agencies. For the framework to be an enduring and useful resource, it should be regularly updated at least once every three years to keep pace with changes in occupations as biotechnology evolves.

Conduct an Interagency Assessment of Biotechnology Workforce Needs

The OPM should assess the interagency workforce to identify training gaps and create effective workforce development programs for federal government personnel and contractors. The OPM should consult with the leadership of relevant federal departments and agencies to quantify and characterize current U.S. government positions contributing to biotechnology, as well as positions that will be needed in the next five

Conduct an Interagency Assessment

Congressional Staffer
Advises members of Congress on science and technology-related legislation, including biotechnology, and the potential impacts on their constituents.

Department of State Regional Technology Officer
Liaises between the United States and other countries on technology issues, including biotechnology, to promote collaboration and ensure that U.S. interests and priorities are protected.

Department of Defense Acquisition Officer
Identifies, advances, and procures critical biotechnology solutions to meet military needs by contracting with biotechnology companies, research institutions, and others.

Department of Homeland Security Intelligence Analyst
Conducts intelligence assessments of risks and threats related to biotechnology to inform policymakers charged with ensuring public safety and protecting U.S. national security interests.

National Science Foundation Program Director
Manages U.S. government funding for research and education programs and initiatives across different fields of science and engineering, including biotechnology.

Department of Energy National Labs Scientist
Engages in groundbreaking research to advance national priorities, such as developing scalable biotechnology innovations to address U.S. energy, health, and national security needs.

Department of Agriculture Biotechnologist
Regulates the testing and movement of organisms produced with biotechnology to protect U.S. agriculture and the environment while promoting innovation.

Department of Commerce Advisor
Analyzes imports, exports, and investments related to critical technologies, including biotechnology, to promote U.S. supply chain resilience and economic competitiveness.

and ten years to advance federal biotechnology efforts. Descriptions of positions should include details on required competencies and qualifications, including security clearances. Federal agencies should also assess additional education needs and challenges to developing the biotechnology workforce. Overseeing biotechnology workforce development could also be one of the functions of the National Biotechnology Coordination Office (NBCO) (see recommendation 1.1a).

Establish Guidance for Biotechnology Hiring Authorities by Federal Agencies

The OPM should provide guidance to federal agencies on existing hiring authorities to recruit biotechnology talent, as well as pilot mechanisms to improve hiring processes.

An example of one such pilot mechanism is Subject Matter Expert Qualification Assessments (SME-QA), a process whereby experts partner with federal human resource specialists to expedite the hiring of qualified technical talent.[277]

Additional examples of hiring authorities include direct hiring authorities, such as the government-wide STEM direct hiring authority, which expedites hiring of STEM personnel; excepted service authorities, such as the Department of Energy's (DOE)'s EJ Pay Plan, which allows for the recruitment and compensation of highly qualified scientific personnel; and fellowships, such as the American Association for the Advancement of Science (AAAS) Science & Technology Policy Fellowship, which provides scientists and engineers opportunities to serve across all branches of the federal government.

By increasing awareness and providing clear guidance on the use of existing authorities to recruit biotechnology professionals, the federal government would be better positioned to build a qualified pool of talent and expertise.

Expand the Use of Existing Public-Private Talent Exchange Authorities

Federal agencies should expand their use of existing public-private talent exchange authorities, such as those established by the Government Employees Training Act, to bolster the biotechnology workforce.

The government needs to stimulate information exchange with academia and industry to keep government workers' knowledge current. Public-private talent exchanges help upskill federal biotechnology personnel, particularly those responsible for purchasing, investing in, or regulating biotechnology products. These exchanges also help government employees better understand commercial perspectives, work more effectively with industry partners, and respond to cutting-edge industry trends.[278]

5.1b Recommendation

Congress must ensure that federal agencies have the necessary expertise across national security and emerging biotechnology issues.

The U.S. federal government must increase its understanding of biotechnology, particularly among diplomatic and national security personnel. The following actions would ensure a bioliterate national security federal workforce.

Require Mandatory Biotechnology and Biosecurity Training for Relevant Federal Agencies and Personnel

Congress should require that relevant federal agencies define core competencies for biotechnology and biosecurity, including outlining requirements for refresher training on the latest advances in biotechnology science, laboratory work, equipment, and software. Departments including the Department of Agriculture (USDA), the Department of Health and Human Services (HHS), and the Department of Energy (DOE) should develop and update core competencies, or required skills, for biotechnology and biosecurity, with relevant staff receiving that training every two to three years. Agencies should disseminate these core competencies to the Department of Defense (DOD) and intelligence community (IC) (see recommendation 3.2e).

Initiate Security Clearances for Additional Personnel Working on Biotechnology Across the U.S. Government

Across the U.S. government, there are too few personnel who work on biotechnology-related issues that have security clearances. Some biotechnology experts at agencies such as the USDA or the HHS are not appropriately cleared to receive information that would be highly relevant to their jobs. Those agencies also lack the administrative and operational infrastructure to ensure that their cleared personnel can access relevant classified information in a timely manner.

Congress should direct relevant federal agencies, including the USDA and the HHS, to ensure that the right people are working on biotechnology and that they have the security clearances they need to effectively make policy decisions on behalf of the American people.

Maintain a Bench of Cleared Biotechnology Experts to Advise on National Security Issues

The U.S. government needs access to biotechnology experts outside of government, as well as the ability to share classified information with them as necessary, so that those experts can provide targeted technical expertise that informs policy decisions.

Additionally, the U.S. government already spends time and money investigating and granting clearances to in-house biotechnology experts who may leave the government and lose their clearances. This is an inefficient use of government resources and institutional knowledge. It would be in the government's best interest to maintain relationships with these cleared experts even after they leave government.

Congress should direct relevant federal agencies to maintain a bench of cleared biotechnology experts, which should include former federal employees when possible, who can advise on national security issues.

Expand the Number of Biotechnology Professionals in the Department of State

The Department of State (DOS) should use existing hiring authorities to expand the representation of biotechnology experts in its regional and functional bureaus and in its Office of the Special Envoy for Critical and Emerging Technology (S/TECH). To engage in biotechnology diplomacy, the DOS must understand both biotechnology itself and the geopolitical implications of this sector. DOS should be well resourced and staffed with diplomats with expertise in emerging biotechnology. One example of an existing DOS program that the United States should leverage and expand is the Regional Technology Officer (RTO) program. RTOs dedicated to biotechnology across regional bureaus would improve U.S. biotechnology diplomacy, allow for more knowledgeable information gathering, and put the United States in a better position to negotiate and leverage international technology agreements.

The DOS should expand the number of biotechnology experts in its regional and functional bureaus, as well as within the S/TECH. Appointing a senior official with biotechnology experience under the S/TECH and designating new RTOs would elevate the importance of biotechnology and signal to the rest of the world that America is ready to lead.

Train U.S. Diplomats on Biotechnology

The DOS incentivizes Foreign Service Officers (FSOs) and other civil servants to pursue training opportunities related to emerging technologies. As America's envoys abroad, FSOs need to be well-versed in emerging technology, including biotechnology, to effectively assess opportunities and risks and advance U.S. interests. The DOS should establish a strong emerging technology training program to help American diplomats develop bioliteracy. It should also create a biotechnology "deep dive" course aimed at educating staff whose work is more closely tied to biotechnology.

5.1c Recommendation

Congress should receive accurate, timely, and nonpartisan scientific and technical counsel.

Congress needs lasting educational architecture that combines easy access to external biotechnology experts with up-to-date internal resources.[279] Over the past three decades, resources dedicated to in-house Congressional science and technology assessment have fallen.[280] Most notably, the Office of Technology Assessment (OTA), a legislative branch agency established to investigate, assess, and analyze emerging technologies for Congress, was defunded in 1995 as part of a broader effort to reduce the size of the federal government.[281] Currently, both the Science, Technology Assessment, and Analytics (STAA) office, which is part of the Government Accountability Office (GAO), and the Congressional Research Service (CRS) provide Congress with issue-specific technical expertise.[282] But as lawmakers increasingly vote on legislation related to biotechnology, they will need more consistent access to biotechnology expertise to legislate effectively.

Congress should establish enduring in-house expertise to advise lawmakers on issues of biotechnology and national security policy. Specifically, Congress should:

- **Strengthen hiring and pay authorities for CRS so that it can better secure the requisite technical expertise to advise Congress at the intersection of technology and national security;**
- **Codify the GAO's STAA office and appropriate additional funds so that it can hire more scientists and engineers.** Congress should adopt recommendation No. 141 of the Select Committee on the Modernization of Congress's Final Report, which would authorize STAA and make it a permanent part of the GAO.[283] The GAO also needs at least 50 more scientists and engineers to support additional technology assessments and bolster its technology forecasting capacity.
- **Establish an Office of the Congressional Science and Technology Advisor (OCSTA).** OCSTA would help to coordinate the successful work already being done by CRS and STAA and ensure that Congressional offices are kept regularly apprised of the resources available to them.
- **Establish a fellowship pipeline that provides opportunities for executive branch employees with biotechnology expertise to complete rotations in Congressional offices.**
- **Host a biannual science and technology fellowship fair.** This exhibition would be a recurring opportunity to match available science and technology fellows from existing programs with Congressional offices in need.
- **Establish a standing Congressional Commission on Responsibility and Ethics in Innovation (CREI).** This independent standing body would provide nonpartisan guidance and policy options on the ethical aspects of future legislative pathways regarding emerging technology.

(For specific implementation details on these recommendations to better resource Congress for technology competition, see Appendix E.)

In addition to these recommendations, Congress should receive regular briefings from the relevant federal agencies related to biotechnology policy, including opportunities, threats, and critical technology developments. Many recommendations within this report would require Congressional oversight, and Congress should be appropriately conversant in the underlying technology.

Section 5.2

Support Job Creation Across the United States for Americans at All Skill Levels

In the United States, education and training programs are not aligned with the skills that the biotechnology industry demands. As a result, American workers are not being adequately prepared for biotechnology careers.

To increase bioliteracy across the country, Americans of all ages will need to be excited about biology. The Commission learned about good ways to foster such enthusiasm, from community "LABraries" to curricula developers like BioBuilder to high schoolers' participation in international competitions like International Genetically Engineered Machine (iGEM).[284] There are more biotechnology education efforts that are not within the federal government's purview but are valuable components of broader bioliteracy. State and local governments have additional authorities to strengthen biotechnology education from kindergarten through post-secondary programs. Private companies, non-profits, and community leaders should also play an active role in contributing to local biotechnology. In the coming months, the Commission will seek more opportunities to raise awareness of positive examples of bioliteracy in action to inspire local communities to pursue similar objectives.

At the same time, the Commission recognizes that the federal government has a specific role to play in supporting job creation—namely, standardizing credentials, aggregating national data, and driving future-focused education and training programs.

5.2a Recommendation

Congress must maximize the impact of biomanufacturing workforce training programs.

Exemplary federal workforce and training efforts include the InnovATEBIO National Biotechnology Education Center, the National Science Foundation's (NSF) Experiential Learning for Emerging and Novel Technologies (ExLENT) program, Bioindustrial Manufacturing and Design Ecosystem's (BioMADE) Scalable Comprehensive Workforce Readiness Initiatives, BioFabUSA's Biofabrication Technician Registered Apprenticeship Program, and the National Institute for Innovation in Manufacturing Biopharmaceuticals's (NIIMBL) eXperience program.[285] The Department of Defense SkillBridge Program and BioMADE's Warfighter-to-Scientist workshops train servicemembers for biotechnology careers.[286]

These federally funded programs and initiatives aim to reach high schools, vocational-technical schools, community colleges, four-year institutions, community workforce development centers, and even individual students. They prepare Americans for biotechnology and biomanufacturing careers, particularly entry-level technician positions. These programs expose students and workers to careers in biotechnology, provide training with industry-informed curricula, present hands-on learning opportunities, and offer credentials that validate skills to employers. They also engage veterans, who bring unique skills and experiences to the industry.[287] Currently, these programs have limited capacity, infrastructure, and reach. With the right resources, they could have an even broader nationwide impact.

Congress must expand these and other federal biomanufacturing workforce training programs and enable more participation from more regions and states. Congress must also require that programs coordinate trainings to maximize their impact, as well as require that programs assess their efficacy and accreditation.

Congress should stipulate that federal biotechnology and biomanufacturing workforce training programs not only bring more workers into the industry but also help workers upskill and stay current with the latest advances.

Standardizing Biomanufacturing Skills and Accreditation

A major impediment to the biomanufacturing workforce is the lack of standardization of skills-based training. Skills-based training programs range from courses taught at vocational-technical schools to apprenticeships. Without standardizing the training and accreditation of these programs, however, employers may not know what specific skills a job applicant has gained from them. At the same time, biomanufacturing workers might have to repeat trainings to satisfy job requirements, wasting money and time.

Accreditation provides a standardized way to validate a worker's knowledge, skills, and competencies, ensuring that they meet industry-recognized benchmarks. Although there are discrete skills assessment efforts in the biosciences industry, these mechanisms have not been widely adopted.[288] The federal government has the authority to develop and promulgate benchmarks for workforce standardization, but there is no current effort to do so for biomanufacturing.

Congress should require the Department of Commerce (DOC), the Department of Labor (DOL), and other relevant agencies to develop and promote nationally recognized competency models for biomanufacturing training and education.

Such accreditation programs should focus on a wide variety of biotechnology training, spanning pharmaceuticals, agriculture, and research labs. For example, microcredentials for specific manufacturing disciplines, for common biotechnology techniques like growing cells in a laboratory, and for laboratory safety would be broadly useful across the industry—and therefore valuable for workers and prospective employers.

"Biotechnology is rapidly transforming national security, yet Congress lacks the internal technical expertise to provide effective oversight. As Staff Director for the House Armed Services Committee, I saw firsthand how this emerging technology drives transformative innovations in material science, health, energy, and supply chains while its convergence with AI amplifies opportunities and risks. Despite these growing challenges, Congress relies heavily on external experts, leaving lawmakers without the in-house knowledge to critically evaluate input and align policies with national security priorities. To address this gap, Congress must invest in staff development, offer competitive salaries, and strengthen partnerships to ensure policymakers are equipped to safeguard America's security and global leadership in this rapidly evolving landscape."

• Commissioner Paul Arcangeli

5.2b Recommendation

Congress should expand educational efforts in biotechnology for American students.

Not all states make biology a high school graduation requirement. Less than 30 percent of public high school biology classes include molecular biology, a foundational precursor to biotechnology.[289] High school is often the final opportunity most Americans have to receive a STEM education, including the chance to take biology and biotechnology classes. Given how many Americans enter the workforce immediately after high school, this juncture is a critical moment to motivate interest in biotechnology careers and provide quality education to enable success in biotechnology jobs.

Previous federal efforts, such as the National Defense Education Act (NDEA) of 1958, helped lay the foundation for science education in the United States.[290] To meet the rising demand for skilled professionals, especially in critical and emerging technologies, leading experts have called for a NDEA 2.0 to invest in modernized STEM education.[291] For example, the Next Generation Science Standards (NGSS) is a state-level initiative developed with input from federal agencies that provides voluntary standards for states to improve STEM education. To date, however, only 20 states and the District of Columbia have adopted these benchmarks.[292] Limited resources—including to support teachers—and insufficient classroom time have slowed the uptake of these standards.[293]

While the federal government's role in directly affecting education policies and curricula is limited, there are specific federal authorities to support and encourage state-level education in biotechnology—including workforce training and technical education—by providing resources, funding, and guidance to help states strengthen their educational programs and align them with national priorities.

The federal government can help enable a comprehensive ecosystem to support student success from high school to career. Congress should expand biotechnology education through:

- a new National Science Foundation (NSF) grant program to support student-to-career pathways in biotechnology that ensure a seamless transfer of relevant credentials (such as certificates, degrees, and apprenticeships) among educational institutions for students to obtain all levels of biotechnology jobs;
- a Biotechnology Scholarship for Service program to incentivize undergraduate and graduate students to pursue biotechnology-related fields of study with conditional guarantee of government employment; and
- a Biotechnology for All High School Students initiative comprising a grant program and establishing a consortium to advance nationwide secondary education (grades 9-12) through the NSF and the Department of Education.

(For additional details on supporting student-to-career pathways, a Biotechnology Scholarship for Service program, and a Biotechnology for All High School Students initiative, see Appendix F.)

Less than 30 percent of public high school biology classes teach molecular biology, a foundational precursor to biotechnology.

Section 5.3

Attract and Retain Trusted Foreign Talent

The United States remains a top destination for the world's leading STEM researchers and promising young scientists, thanks to its research universities, open research environment, free exchange of ideas, and regional innovation clusters.[294; 295] The number of international students who come to the United States to pursue degrees in biological and biomedical sciences has grown steadily since 1999, reaching an all-time high of over 53,000 in 2024.[296] These students, along with budding biotechnology innovators from abroad, have been a boon to the United States.

But the United States struggles to retain much of this talent. Current policies make it difficult for foreign STEM students and professionals to stay permanently in America, start businesses, and contribute to the U.S. economy and innovation base, particularly in the defense sector.[297] The Commission heard from experts in industry and academia that China is actively recruiting graduates from American universities as part of a long-term effort to surpass the United States.

Today, the United States educates and trains foreign-born experts, but its competitors end up reaping the rewards of that investment. And those rewards are considerable: these highly educated and credentialed biotechnologists have access to American research and intellectual property, they often generate pathbreaking inventions, and they often go on to establish valuable startups. But many do so outside of the United States, largely because U.S. immigration policy forces them to leave. This failure puts the United States at a strategic disadvantage.

China's approach to recruiting and retaining foreign talent stands in stark contrast. The Chinese government invests vast sums of money to attract international students and workers, using state-of-the-art, multi-million-dollar research facilities and large cash incentives to lure them to China.

It is not just adversaries that are taking advantage of American weakness but allies, too. In 2023, Canada introduced a pilot program offering three-year work permits for workers who are in the United States on temporary H-1B specialty occupation visas, which can include advanced degree holders in biotechnology.[298] The program was so popular that it reached its 10,000 limit in a single day.[299] Competitive efforts of this kind will only become more ambitious and effective if the United States does not act to retain the best and brightest.

> "The status quo is changing. COVID-19 has shifted the dreams of many Chinese students. Maybe top students used to want to come to the United States for their PhD or postdoc, but I sense the proportion is now decreasing...Students in China don't think about America as some 'scientific Mecca' in the same way their advisors might have done. U.S. policymakers should take note and build better educational programs here."
>
> - Niko McCarty, Founding Editor of Asimov Press

5.3a Recommendation

Congress should authorize new green cards for biotechnology talent, especially from allied and partner countries.

These new green cards would help the United States retain more of the thousands of foreign students who graduate with relevant degrees or equivalent professional qualifications in biotechnology and other related fields.

Congress could authorize the Secretary of Homeland Security to determine the eligibility of foreign biotechnology experts based on factors including education, work history, special skills, and letters of endorsement from public and private entities.

In the 118th Congress, Senator Todd Young (R-IN) introduced S.5644, the Heartland Visa Act of 2024, which similarly focuses on increasing the number of high-skilled immigrants in the United States.[300] While this bill does not focus solely on biotechnology or critical and emerging technologies, it would provide a mechanism for a new visa category for high-skilled foreign talent to seek employment in economically disadvantaged U.S. counties where the population is declining. This legislation would complement the proposed biotechnology green cards, since the bill focuses on location while this proposal focuses on critical subject-matter expertise.

5.3b Recommendation

Congress should optimize the vetting process for foreign nationals to prevent illicit technology transfer.

The U.S. government should gather the information it needs to develop, update, and enforce its policies regarding visa screening, vetting, and restrictions to both protect and promote U.S. interests. A review of current federal visa control processes would improve the government's capabilities and decision-making to better protect against threats to sensitive technologies, while still enabling top foreign talent to contribute to the U.S. economy. Drawing on the findings of that review, policymakers could make informed decisions about the efficacy of current processes.

The GAO should audit the U.S. government's current visa restrictions, screening, and vetting and make recommendations to better protect against espionage and illicit transfer of critical and emerging technologies by countries of concern. Recent federal efforts in this area include the National Science Foundation's Safeguarding the Entire Community of the U.S. Research Ecosystem (SECURE) Center, which serves as an information clearinghouse for the research community to mitigate foreign risks to the U.S. research enterprise; Presidential Proclamation 10043, which prohibits Chinese students with People's Liberation Army (PLA) associations from obtaining student and exchange visitor visas; and the National Vetting Center, which coordinates interagency vetting efforts.[301]

In its audit, the GAO should review research security policies, procedures, and resources, including those regarding federal agencies, institutions of higher education, and technology companies (such as new federal agency guidelines and the SECURE Center). The GAO should also assess the effectiveness of those current policies and procedures.

Intermission

NSCEB on the Road

Over the last two years, the Commission traveled the world to gain a deeper understanding of the global biotechnology landscape. The Commission met with scientists, government ministers, biomanufacturing workers, ambassadors, industry leaders, and start-up founders, witnessing firsthand biotechnology innovations abroad. The Commission observed the unique strengths of our allies and partners, from state-of-the art scale-up infrastructure to robust training programs to regulatory environments that accelerate innovation.

As biotechnology continues to evolve and present new opportunities and risks, cross-border collaborations with allies and partners—spanning joint research efforts, trade agreements, and talent exchanges—will be key to fostering a brighter, more prosperous, and safer future.

Belgium

Belgium is a global leader in biomanufacturing, with state-of-the art scale-up facilities. Commissioners went on a hard-hat tour of Steelanol, a company that is harnessing microbes that can convert industrial gas emissions into ethanol, which is repurposed into consumer products like athletic gear. The Commission also visited the Bio Base Europe Pilot Plant (BBEPP), a pilot-scale facility that helps innovators scale up biotechnology-based products.

In a series of discussions with NATO's Deputy Secretary General and government leaders from the European Union, the Commission discussed the alignment of European and U.S. priorities on biotechnology and national security, as well as the importance of bioliteracy in government.

Denmark

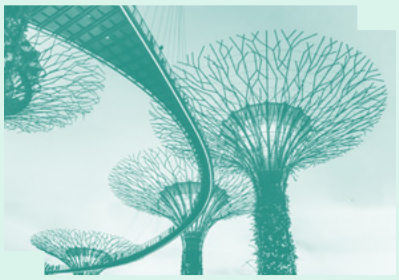
Denmark's highly integrated ecosystem accelerates biotechnology innovation by fostering collaboration between the public sector and private industry.

The Commission met with Novo Nordisk, the biopharmaceutical powerhouse behind the weight-loss drugs Ozempic and Wegovy, that has a market value greater than Denmark's GDP. The Commission learned how the Danish government's unique relationship with industry, including government incentives and support, positions Denmark as a global biotech hub. The Novo Nordisk Foundation further strengthens this ecosystem by supporting biotechnology entrepreneurs through initiatives such as the BioInnovation Institute, a life sciences incubator.

Germany

In Germany, the Commission got a firsthand look, and firsthand taste, of cutting-edge biotechnology research and development (R&D). Commissioners had the opportunity to meet with leaders of Formo and try their biomanufactured cheese. Commissioners also met with a company that is 3D printing human tissue with the hope of being able to make organs for use in transplants.

Singapore



Commissioners learned how Singapore's government is providing biotechnology companies with efficient, predictable, and flexible regulatory frameworks that enable rapid transition from research to commercialization. Commissioners met with Singapore's Deputy Prime Minister and the Ministers of Trade and Industry, Defence, and Foreign Affairs, as well as industry leaders, to discuss how biotechnology can strengthen the U.S.-Singapore relationship.

Japan

Japan is on the cutting edge of not only biotechnology R&D but also government policy. The country's forward-thinking approach was evident during a tour of Sanatech Seed's greenhouses, where Commissioners had the opportunity to taste GABA-enriched tomatoes, the first CRISPR-edited food to enter the international market. In meetings with Japan's Council for Science, Technology, and Innovation, the Commission learned how Japan is leveraging its legacy expertise in technology innovation and manufacturing, ranging from regional technology hubs to producing high-end research instrumentation, to guide the country's whole-of-government approach to advancing biotechnology.

Sweden

Sweden's recent accession to the North Atlantic Treaty Organiation (NATO) opened opportunities to discuss its whole-of-government approach to integrating national security and biotechnology innovation. Through a series of meetings with government officials, including the Minister of Foreign Affairs and members of the National Security Council, Commissioners discussed Sweden's recently adopted National Security Strategy. This strategy shared themes with the Commission's own work, touching on topics including technological adoption, China's growing military and technological ambitions, and the importance of working with like-minded countries.

United Kingdom

As one of the United States' closest allies, the United Kingdom offers numerous opportunities to leverage and strengthen the Special Relationship for biotechnology advancement. The Commission met with industry innovators, investors, and government leaders, including the Minister for Science and leaders of the UK Biobank. The Commission also explored potential joint efforts on biological data collection, financing technologies for national security, and fostering biotechnology innovation and commercialization.

Chapter 6

Mobilize the Collective Strengths of Our Allies and Partners

Momentum for biotechnology is building around the world, and the United States must keep pace. To collectively maximize the benefits of biotechnology, it must work with allies and likeminded countries to pool expertise, talent, and capital, all in an effort to defend, build, heal, and nourish.

U.S. allies and partners are prioritizing biotechnology. The North Atlantic Treaty Organization (NATO), for example, released a strategy in 2024 to foster the responsible development and adoption of emerging biotechnologies.[302] The alliance is also investing in technologies with national security implications through its Defence Innovation Accelerator for the North Atlantic (DIANA) and its NATO Innovation Fund (NIF).[303] There are opportunities to leverage shared resources, whether they be joint capital, data, or research and development (R&D) capabilities, in support of biotechnology advancement.

The United States must renew its commitment to its closest allies and forge new partnerships with nations that have complementary goals, capabilities, and expertise. Nearly every country has something valuable to offer: some boast advanced biomanufacturing capabilities, others are at the leading edge of computational biology, and others still are pioneering bio-based chemicals and regenerative medicine.[304]

The U.S. government should expand biotechnology diplomacy, including commercial and regulatory diplomacy to expand market access and boost aggregate demand for biotechnology products. The United States must work with allies to ensure that biotechnologies are not misused and together set norms and standards based on shared values. The United States and its allies and partners must also work together to standardize approaches to biotechnology protection.

The following recommendations chart a course of action for the United States to promote and protect biotechnology alongside its allies and partners.

"We have seen our allies and partners make considerable strides in addressing all aspects of biotechnology, recognizing as they do that maintaining the Free World's lead in all fields is a national security imperative. Working together we will realize synergies that will ensure that lead for years to come."

- Commissioner Dov Zakheim

Section 6.1

Promote Biotechnology with U.S. Allies and Partners

Advancing biotechnology is an international endeavor; it requires the United States to identify complementary capabilities, expertise, and resources with allies and partners. The Commission's recommendations in this section support the federal departments and agencies that engage in biotechnology diplomacy. By pooling their capabilities, the United States and its allies and partners can develop shared solutions to universal challenges.

In recent years, the Department of State (DOS) has greatly expanded its capacity for technology diplomacy, particularly on cyber and digital issues, through the creation of new positions, trainings, and grants. But it and other federal agencies have neither the resources nor the staff needed to cover the breadth and depth of biotechnology diplomacy.

6.1a Recommendation

Congress must include biotechnology in the scope of the Department of State's (DOS) International Technology Security and Innovation (ITSI) Fund to appropriately fund international biotechnology policy, research and development (R&D), and secure supply chains.

Congress established the ITSI Fund in 2022 to strengthen telecommunications networks and semiconductor supply chain security, authorizing $500 million over five years.[305] This fund is designed to enable the DOS to nimbly deploy resources toward digital diplomacy and high-value cooperation opportunities in the semiconductor sector.

Congress must expand the scope of the ITSI Fund to encompass a wider range of technologies and set aside dedicated funds for biotechnology. The Secretary of State should coordinate with leadership across relevant U.S. departments and agencies to maximize the impact of international biotechnology diplomacy and complement other federal funding sources. The Secretary should also submit annual reports to Congress detailing the use of these funds, including programs, projects, and activities conducted with foreign partners. Suggested programs include coordinated R&D and strengthened global supply chains for biomanufacturing. The DOS should examine how to direct funds and resources to other federal agencies that work with foreign partners on biotechnology to advance shared goals.

Technology	Tech monopoly risk	Top 3 countries		
Synthetic biology	High	China 57.7%	U.S. 13.1%	India 2.7%
Biological manufacturing	Medium	China 28.5%	India 10.3%	U.S. 8.5%
Novel antibiotics and antivirals	Medium	China 29.7%	U.S. 11.6%	India 11.3%
Genetic engineering	Low	U.S. 37.0%	China 29.0%	Germany 4.7%
Genomic sequencing and analysis	Low	China 35.6%	U.S. 22.2%	U.K. 3.9%
Nuclear medicine and radiotherapy	Low	U.S. 27.1%	China 21.1%	Germany 6.3%
Vaccines and medical countermeasures	Low	U.S. 26.4%	China 14.0%	U.K. 6.0%

Snapshot of the top five countries ranked by their proportion of high-impact research outputs from 2019-2023 in biotechnology, gene technologies, and vaccines. "Technology monopoly risk" measures the risk of concentration of scientific and technological research expertise within a single country. A high technology monopoly risk (red) is a potential indicator for future breakthroughs in technology capability. This metric is a combination of two factors: (1) the lead country's share of the world's top 10 institutions, and (2) the lead country's lead over its closest competitor (ratio of top 10% publications). (Source: ASPI's Two-decade Critical Technology Tracker)[lvi]

Advancing biotechnology is an international endeavor; it requires the United States to identify complementary capabilities, expertise, and resources with allies and partners.

6.1b Recommendation

Congress should direct the Department of State (DOS) and other agencies to promote the U.S. biotechnology industry in foreign markets, including through commercial diplomacy.

Commercial diplomacy aims to create business opportunities between countries. It can include trade promotion, economic cooperation, and shared policy development. Multiple federal agencies engage in commercial diplomacy, including the DOS, the Department of Commerce (DOC), the Foreign Agricultural Service (FAS) within the U.S. Department of Agriculture (USDA), and the Office of the United States Trade Representative (USTR). These agencies negotiate bilateral and multilateral trade agreements, coordinate trade missions, and mitigate trade barriers. Expanding market access is particularly critical to ensuring that American biotechnology products sell well internationally. Currently, federal staffing and funding for these activities is insufficient and uncoordinated, particularly when it comes to biotechnology diplomacy.

Congress should ensure that commercial diplomacy efforts for biotechnology are appropriately funded and coordinated. In particular, Congress should direct the DOS, the DOC, the FAS, the USTR, and other relevant agencies to promote the U.S. biotechnology industry in foreign markets, including by offering biotechnology training for Foreign Service Officers (FSOs) (see recommendation 5.1b). The National Biotechnology Coordination Office (NBCO) (see recommendation 1.1a) would help coordinate U.S. government efforts within and across sectors. Congress should also ensure adequate funding for U.S. trade and diplomatic agencies, including the DOS, USTR, and the FAS, to support bioliteracy programs that clearly communicate the benefits and risks of biotechnology, thereby fostering public acceptance and expanding markets.

6.1c Recommendation

Congress should expand regulatory diplomacy for biotechnology.

Different countries regulate biotechnology products through different frameworks, resulting in divergent standards and data requirements. These differences can pose trade barriers and delay the commercialization of useful products. Through regulatory diplomacy, the United States works with other countries to resolve trade barriers that occur due to regulation. As with commercial diplomacy, multiple agencies are involved in regulatory diplomacy, including the DOS, the USTR, the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and multiple agencies within the USDA. To be effective, regulatory diplomacy needs to be well-funded, well-staffed, and coordinated across federal agencies.

Commercial diplomacy and regulatory diplomacy are closely linked. Without an efficient regulatory system, there cannot be a thriving global market, and without market demand, governments generally do not prioritize establishing or reforming regulatory frameworks. The Commission recommends that commercial and regulatory diplomacy be coordinated across U.S. agencies and that similar personnel and approaches that are leveraged for commercial diplomacy be used for regulatory diplomacy.

Congress should direct and resource diplomatic, regulatory, and trade agencies to increase and coordinate their efforts on regulatory diplomacy in both bilateral and multilateral settings, including international standard-setting bodies. All these efforts should work toward global regulatory convergence for biotechnology products. Regulatory convergence could include synchronized approvals, shared or concurrent review, or alignment with international standards for risk assessment.

(For more details on expanding regulatory diplomacy for biotechnology, see Appendix G.)

6.1d Recommendation

Congress should require the Department of State (DOS) to form reciprocal biological data-sharing agreements with other countries.

On its own, the United States has a finite amount of high-quality biological data that is AI-ready, limiting the types of advancements it can make. These biological data include:

Types of biological samples that are particular to a country, such as genetic sequences from native plants, animals, fungi, and bacteria.

In Section 4.1 of this report, the Commission recommends a Sequencing Public Lands Initiative to collect new data to drive innovations. The United States could share this data with other countries that are willing to reciprocate. Many other countries, including close allies such as the United Kingdom, Australia, Japan, and South Korea, maintain their own sets of biological data, which include unique data assets (such as data about organisms that cannot be found elsewhere).

Specific measurement capabilities based on technological advancement.

The scientific areas that different countries focus on shape the types of data collection capabilities they have. For example, Australia's state and federal governments have invested heavily in the study of RNA, which could yield unparalleled capabilities to sequence and measure RNA.[306]

Despite this wealth of data among U.S. allies, the United States lacks adequate mechanisms to collaborate with these countries to collectively advance biotechnology and other data-driven technologies.

Working with allies on biological data becomes increasingly important when adversaries are building their own large biological data repositories, including through unethical or coercive practices.

To encourage secure and effective collaborations, the DOS, in consultation with the National Institute of Standards and Technology (NIST) and other relevant agencies, should form international agreements and standing bodies with U.S. allies and partners to:

- facilitate reciprocal pooling and sharing of biological data to advance collaborative research;
- implement and enforce data standards to ensure that shared data is AI-ready; and
- reach agreements on the fair collection, storage, and use of biological data that are in line with shared norms and values.

These standards would ensure that adequate informed consent is provided when collecting data and that there is reciprocity of biological data sharing between countries to prevent asymmetries. The agreements should also promote the use of public-private partnerships to bolster collaborative research involving the exchange of biological data, provided there are adequate protections and reciprocity.

These agreements could take the form of new bilateral or multilateral agreements with countries that have a proven track record of robust biodata collection efforts. Or they could leverage existing multilateral relationships such the AUKUS security partnership—especially within Pillar Two, which concerns the collaborative development of advanced technologies—or the Quad or G7.[307]

Because bilateral and multilateral agreements are established on a project-by-project basis by U.S. researchers and their collaborators, the Commission encourages the DOS to expand these agreements as needed and in a form that most benefits the biotechnology community.

6.1e Recommendation

Congress should direct the Department of State (DOS) and the Department of Defense (DOD) to encourage North Atlantic Treaty Organization (NATO) countries to aggregate demand and pool purchasing power for biotechnology products.

Without clear and consistent government signals for demand, biotechnologies with defense applications will fail to scale. Defense market commitments from the United States alone may not be enough to shift the global landscape for biotechnology, but U.S. allies are also looking to biotechnology to meet their national security needs.

In 2023, NATO members from Europe and Canada collectively spent an estimated $429.2 billion on defense, while the United States spent an additional $875.6 billion on defense.[308] The alliance's 32 member countries represent an untapped market force for biotechnology innovation, which opens up an opportunity for companies to address the combined defense needs of NATO allies.

Establishing joint advance market commitments and offtake agreements to aggregate demand would create stronger market incentives to scale products. Past examples of advance market commitments have been trialed successfully at the international level. For example, with the COVID-19 Vaccines Global Access (COVAX) initiative, the United States and other countries made joint market commitments to biopharmaceutical companies, an effort that proved critical to the successful commercialization of COVID-19 vaccines.[309]

The United States should encourage NATO countries to aggregate demand and pool their purchasing power for biotechnology products. Congress should direct the DOS, in consultation with the DOD, to develop a diplomatic strategy for establishing a forum within NATO for the purposes of pooling the purchasing power of NATO allies towards emerging biotechnologies. This strategy should:

- the determination of criteria for critical needs that could be fulfilled by biotechnology to further NATO's aims such as biobased energetics;
- the establishment of information-sharing and contracting mechanisms to carry out the advance market commitments and offtake agreements among NATO allies; and
- And initial determination of U.S. market supply and demand in the biotechnology industry that would meet the above outlined critical needs.

Upon completion of the strategy, the DOS should report the strategy to Congress, and the DOS and the DOD should carry it out.

Deepen Collaboration with Allies and Partners

Congress should establish a fellowship program for nationals of NATO member states to collaborate with U.S. federal researchers and policymakers on initiatives at the intersection of emerging biotechnology, international security, and defense.

Creating a NATO fellowship program with the express goal of fostering those ties in biotechnology would benefit the United States and its allies. Fellows would work at Congressional offices and federal agencies, providing scientific and technical expertise to advance policies and research.

Section 6.2

Protect Biotechnology with U.S. Allies and Partners

At the same time as it promotes biotechnologies with its allies and partners, the U.S. government must coordinate efforts with them to protect biotechnology from misuse by adversaries and prevent it from causing unanticipated harm. The U.S. government should work with allies and partners to standardize approaches toward adversarial capital (see Section 2.5), country-wide export controls (see Section 3.3), and data security (see Section 4.2) to ensure that U.S. and allied technologies are not misused by adversaries. These efforts should also include ensuring that international norms and standards are rooted in safety, security, and responsibility.

6.2a Recommendation

Congress should direct the Department of State (DOS), along with the National Institute of Standards and Technology (NIST), to support the development of international norms and standards, including defining shared values and interests in biotechnology.

U.S. participation in standards setting bodies, like the International Organization for Standardization (ISO), has remained flat over the past two decades. Meanwhile, China's participation in such bodies has ballooned. China participates in 200 more ISO technical committees that work to set international standards, compared to the United States.[310]

The international community is increasingly converging on a common set of biotechnology standards. Active and engaged U.S. leadership in these forums will be critical to ensuring that American interests are fully represented as global standards are set. Allowing China to dominate the conversation diminishes both the United States' biotechnology industry and its own national security. The ISO, for example, has already published a variety of biotechnology standards covering topics ranging from cleanrooms to biobanking to DNA sequencing.[311]

While the United States has a voice in these forums, the limited size of its delegations constrains its effectiveness. The DOS, along with the NIST and other agencies, should work with affected stakeholders in industry and academia to foster greater U.S. engagement and leadership in these forums. The DOS should further ensure that these activities are coordinated with interagency partners, including trade agencies and agencies with a role in biosafety and biosecurity (see Section 4.4a).

6.2b Recommendation

Congress should require the Department of State (DOS) to create a strategy for harmonizing multilateral export controls.

The United States should also work with its allies and partners to protect against biotechnology misuse by harmonizing multilateral export controls. Currently, however, emerging technologies evolve faster than countries can harmonize multilateral export controls, a process that can take years. This dynamic is compounded by other long-standing problems with existing multilateral export control regimes.

For example, the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Use Goods and Technologies includes Russia and operates by consensus and, as a result, has made only minor updates to its control lists in recent years.[312] Without harmonization, countries can differ on what biotechnology-related equipment they restrict. The lack of a unified monitoring system allows adversaries to shop around and buy technology from countries with more lax restrictions.

Export controls often lag behind both technological advances and geopolitical changes. Without a forcing mechanism to continuously update them, the United States and its allies will find that biotechnology-related equipment restrictions become less relevant and therefore less effective over time.

Within the next year, the DOS should develop a new strategy for harmonizing multilateral export controls on conventional arms and dual-use goods and technologies. This strategy should lay out how export controls can reflect contemporary geopolitical and technological dynamics, such as overcoming the limitations in the Wassenaar regime. Working with the National Security Council, relevant agencies, and key allies and partners, the DOS should report to Congress on the new strategy and a plan for implementing it.

Appendices

Appendix A

Technical Glossary

Advance market commitment
A buyer's agreement to purchase a product that does not yet exist, if a developer can make it at scale.

Autonomous laboratories
Fully automated and guided by artificial intelligence and machine learning software to plan, execute, learn, improve, and repeat experiments based on a desired outcome.

Biobased
A product or process that is composed of or derived from, in whole or in significant part, biological material.

Biodefense
Actions designed to counter biological threats, reduce risks, and prepare for, respond to, and recover from bioincidents, whether naturally occurring, accidental, or deliberate in origin and whether impacting human, animal, plant, or environmental health.

Bioliteracy
The concept of imbuing people, personnel, or teams with an understanding of and ability to engage with biology and biotechnology.

"Biological dominance" or *zhishengquan* (制生权)
The recognition by China's government and military of biology as a domain of warfare and its elevation in their strategic thinking.

Biological data
The information, including associated descriptors, derived from the structure, function, or process of biological systems that is either measured, collected, or aggregated for analysis.

Biomass
Any material of biological origin that is available on a renewable or recurring basis. Examples of biomass include plants, trees, algae, and waste material such as crop residue, wood waste, animal waste and byproducts, food waste, and yard waste.

Biomanufacturing
The use of biological systems to produce goods and services at commercial scale.

Biomining
To use microorganisms to extract metals of economic interest from rock ores or mine waste. Biomining techniques may also be used to clean up sites that have been polluted with metals.

Bioprocessing
The use of biological systems to process materials for biomanufacturing, including transformation of biomass before a reaction (upstream processing) or separation or purification of the resulting materials (downstream processing). Sometimes used synonymously with biomanufacturing.

Bioremediation
A process whereby organisms, cells, or cellular components are used for environmental decontamination.

Biosafety
Practices, controls, and containment infrastructure that reduce the risk of unintentional exposure to, contamination with, release of, or harm from pathogens, toxins, and biological materials.

Biosafety levels
Used to identify the protective measures needed in a laboratory setting to protect workers, the environment, and the public. At any given biosafety level, there are strict requirements for laboratory design, personal protective equipment, and biosafety equipment.

Biosecurity
Security measures designed to prevent the loss, theft, misuse, diversion, unauthorized possession or material introduction, or intentional release of pathogens, toxins, biological materials, and related information and/or technology.

Biosurveillance
A systematic process to survey the environment or location of interest for bacteria, fungi, viruses, or other biological entities that might cause disease in people, animals, or plants in support of detection and identification efforts and corresponding public health or safety.

Biotechnology
The application of science and engineering in the direct or indirect use of living organisms, or parts or products of living organisms, including modified forms.

Current Good Manufacturing Practice (CGMP)
Regulations enforced by the FDA that provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities.

Chassis
In the context of biomanufacturing, a biological frame or architecture, usually an organism, where components can be added, changed, or removed to create new

Clinical trials
Research studies designed to answer specific questions about the safety or effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments.

Cloud labs
Physical laboratories that are equipped with lab automation that can be programmed and controlled remotely by scientists to conduct biological experiments.

Commercial diplomacy
Diplomacy that aims to create business opportunities between countries. It can include trade promotion, economic cooperation, and shared policy development.

Countervailing duty
An additional tax or tariff placed on imported goods to offset certain kinds of subsidies provided by an exporting country.

Critical inputs
Raw materials or consumables whose shortages have the potential to cause a significant delay in biomanufacturing. These are often low-margin chemicals and biological materials, including amino acids, that are necessary to sustain scaled biomanufacturing.

Critical and emerging technologies (CETs)
A subset of advanced technologies that are potentially significant to U.S. national security.

CRISPR-Cas9
Short for "clustered regularly interspaced short palindromic repeats," CRISPR is a technology that scientists use to selectively modify the DNA of living organisms. CRISPR was adapted from naturally occurring systems found in bacteria.

Dual use research of concern
Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be misapplied to do harm with no, or only minor, modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

Export controls
Federal laws and regulations that limit the transfer of funds, goods, services, and technology to non-U.S. individuals and organizations to promote national security interests.

Federal Select Agent Program
A joint program between CDC and APHIS that oversees the possession, use, and transfer of select agents and toxins, which pose a threat to public, animal, or plant health.

Feedstock
Materials used directly in manufacturing processes and transformed into intermediate or finished products.

Forecasting
Statements or assertions about future events based on quantitative and qualitative analysis and modeling.

Foresight
Method for systematically considering a longer time horizon and broader scope of issues than other forms of planning.

Gene synthesis
Methods used in synthetic biology that enable the creation and modification of genetic sequences by assembling and constructing nucleic acids. Also known as DNA synthesis.

Gene synthesis screening
A process by which gene synthesis activities are screened for potential risk by understanding a) whether the combination of sequences or the customer ordering them is concerning, b) whether the sequences printed match what was ordered, and c) who is responsible for acting when concerns arise. Also known as nucleic acid synthesis screening.

Genomics
The study of all or a significant portion of genetic material and their function(s) in an organism.

Greenfield investments
A form of foreign direct investment (FDI) in which a company establishes a completely new business operation in a foreign country by constructing new physical facilities. This typically involves building new factories, offices, or distribution centers, rather than purchasing or merging with an existing enterprise in the host country.

Laboratory automation
Process that involves robotics, computers, liquid handling, and other advanced technologies to complete biological experimentation.

Microorganisms/microbes
Small living organisms such as bacteria, algae, and fungi. Although viruses are not considered living organisms, they are sometimes classified as microorganisms.

Military-Civil Fusion (MCF)
An aggressive, national strategy of the Chinese Communist Party (CCP) to enable the PRC to develop the most technologically advanced military in the world. A key part of MCF is the elimination of barriers between China's civilian research and commercial sectors, and its military and defense industrial sectors.

Offtake agreement
A buyer's agreement to purchase an existing product over multiple orders over a period of time.

Precision medicine
A form of medicine that uses information about a person's genes, proteins, environment, and lifestyle to prevent, diagnose, or treat disease.

Protein design
A technique by which scientists create proteins, sometimes with enhanced or novel functional properties. Also known as protein engineering.

Regulatory diplomacy
Diplomacy that aims to resolve trade barriers that occur due to regulation. It can include synchronized approvals, shared or concurrent review, or alignment with international standards for risk assessment.

Scale-up
The increase of manufacturing processes, including production levels and technologies, from a laboratory scale to a commercial scale that meets market demand.

Strategic investment
Investments made to achieve specific objectives beyond financial returns, such as national security goals or gaining access to new technologies. Strategic investments align with the investor's long-term goals, such as achieving competitive advantage or synergies.

Subject Matter Expert Qualification Assessments (SME-QA)
In 2019, the first Trump Administration piloted a federal hiring process whereby subject matter experts (SMEs) develop required qualifications with human resources specialists to help federal hiring managers receive higher quality candidate lists and hire qualified experts more quickly.

Synthetic biology
The design, construction, and/or assembly of the components of living systems (including genetic circuits, enzymes, metabolic pathways, etc.) to achieve an intended function or outcome.

Wargaming
The simulation of a military operation involving two or more opposing forces using rules, data, and procedures designed to depict an actual or assumed real life situation.

Wassenaar Arrangement
A multilateral export control regime comprising 42 Participating States that was established to contribute to regional and international security and stability by promoting transparency and greater responsibility in transfers of conventional arms and dual-use goods and technologies.

Appendix B

Acronyms Found in this Report

AAAS
American Association for the Advancement of Science

ABPDU
Advanced Biofuels and Bioproducts Process Development Unit

AI
artificial intelligence

AI/ML
artificial intelligence/machine learning

AMC
advance market commitment

APHIS
Animal and Plant Health Inspection Service

APIs
active pharmaceutical ingredients (Chapter 2)

API
application programming interface (Chapter 4)

ASPR
Administration for Strategic Preparedness and Response

B2B
business-to-business

BARDA
Biomedical Advanced Research Development Authority

BBEPP
Bio Based Europe Pilot Plant

BGI
previously Beijing Genomics Institute

BIO-ISAC
Bioeconomy Information Sharing and Analysis Center

BioMADE
Bioindustrial Manufacturing and Design Ecosystem

BRAG
Biotechnology Risk Assessment Research Grants

BSL-3/BSL-4
Biosafety level 3/4

BWC
UN Biological Weapons Convention

CASA-Bio
Catalyzing Across Sectors to Advance the Bioeconomy

CBP
Customs and Border Patrol

CCL
Commerce Control List

CCP
Chinese Communist Party

CFIUS
Committee on Foreign Investment in the United States

CGMP
Current Good Manufacturing Practice

CIA
Central Intelligence Agency

CISA
Cybersecurity and Infrastructure Security Agency

CMC
Chemistry, Manufacturing and Controls

COVAX
COVID-19 Vaccines Global Access

CREI
Congressional Commission on Responsibility and Ethics in Innovation

CRISPR/CRISPR-Cas
clustered regularly interspaced short palindromic repeats-Cas

CRS
Congressional Research Service

CTA
Critical Technology Areas

CVD
Countervailing Duties

DARPA
Defense Advanced Research Projects Agency

DBIMP
Distributed Bioindustrial Manufacturing Program

DHS
Department of Homeland Security

DIA
Defense Intelligence Agency

DIANA
Defense Innovation Accelerator for the North Atlantic

DIB
Defense Innovation Board

DNA
deoxyribonucleic acid

DOC
Department of Commerce

DOD
Department of Defense

DOE
Department of Energy

DOI
Department of the Interior

DOJ
Department of Justice

DOL
Department of Labor

DOS
Department of State

DPA
Defense Production Act

DURC
dual use research of concern

EO
Executive Order

EOP
Executive Office of the President

EPA
Environmental Protection Agency

ExLENT
Experiential Learning for Emerging and Novel Technology

FAR
Federal Acquisition Regulation

FAS
Foreign Agricultural Service (U.S. Department of Agriculture)

FBI
Federal Bureau of Investigation

FDA
Food and Drug Administration

FIRRMA
Foreign Investment Risk Review Modernization Act

FSAP
Federal Select Agent Program

FSO
Foreign Service Officer

FTC
Federal Trade Commission

FY
Fiscal Year

GAO
Government Accountability Office

GHIC
Global Health Investment Corporation

GSA
General Services Administration

GTLA
Global Technology Leadership Act

HHS
U.S. Department of Health and Human Services

HSI
Homeland Security Investigations

IBRF
Integrated Biorefinery Research Facility

IC
Intelligence Community

iGEM
International Genetically Engineered Machine

IQT
In-Q-Tel

ISO
International Organization for Standardization

ITA
International Trade Administration

ITSI
International Technology Security and Innovation

ITC
International Trade Commission

LLM
Large Language Model

MCF
Military-Civil Fusion

MIL-SPECs
military specifications

NASA
National Aeronautics and Space Administration

NASEM
National Academies of Sciences, Engineering, and Medicine

NATO
North Atlantic Treaty Organization

NBCO
National Biotechnology Coordination Office

NCBI
National Center for Biotechnology Information

NDAA
National Defense Authorization Act

NDEA
National Defense Education Act

NGSS
Next Generation Science Standards

NIF
NATO Innovation Fund

NIH
National Institutes of Health

NIIMBL
National Institute for Innovation in Manufacturing Biopharmaceuticals

NIPP
National Infrastructure Protection Plan

NIST
National Institute of Standards and Technology

NIU
National Intelligence University

NREL
National Renewable Energy Laboratory

NSA
National Security Agency

NSCEB
National Security Commission on Emerging Biotechnology

NSF
National Science Foundation

OCET
Office of Critical and Emerging Technology

OCSTA
Office of the Congressional Science and Technology (S&T) Advisor

ODNI
Office of the Director of National Intelligence

OGCA
Office of Global Competition Analysis

OIRA
Office of Information and Regulatory Affairs

OMB
Office of Management and Budget

OPM
Office of Personnel Management

OSTP
Office of Science and Technology Policy

OTA
Other Transaction Authority (Chapters 2 and 3)

OTA
Office of Technology Assessment (Chapter 5)

PADFA
Protecting Americans' Data from Foreign Adversaries Act

PEPP
Pathogens with Enhanced Pandemic Potential

PPD
Presidential Policy Directive 21

PFAS
Per- and polyfluoroalkyl substances

PLA
People's Liberation Army

PRC
People's Republic of China

PVP
Process Verified Program

QbD
Quality by Design

Quad
Quadrilateral Security Dialogue

R&D
research & development

RNA
Ribonucleic acid

RTO
Regional Technology Officer

SBICCT Initiative
Small Business Investment Company Critical Technology Initiative

SBA
Small Business Administration

SBIR
Small Business Innovation Research

SEC
U.S. Securities and Exchange Commission

SECURE
Safeguarding the Entire Community of the U.S. Research Ecosystem Center (NSF)

SME-QA
Subject Matter Expert Qualification Assessments

STAA
Science, Technology Assessment, and Analytics (GAO)

S/TECH
Office of the Special Envoy for Critical and Emerging Technology

STTR
Small Business Technology Transfer

S&T
Science and Technology

T-BRSC
Tri-Service Biotechnology for a Resilient Supply Chain program

TSA
Transportation Security Administration

USDA
U.S. Department of Agriculture

USGS
U.S. Geological Survey

USTR
United States Trade Representative

VIP
Veterinary Innovation Program

WHO
World Health Organization

WOBD
Web of Biological Data

Appendix C

More Details on Biological Data Standards (4.1)

4.1 Treat Biological Data as a Strategic Resource

4.3b Recommendation

Congress should authorize the National Institute of Standards and Technology (NIST) to create standards that researchers must meet to ensure that U.S. biological data is ready for use in AI models.

Authorize a Hub for Biotechnology, Biometrology, and Biological Data Standards

Congress should authorize the National Institute of Standards and Technology (NIST) as a hub for biotechnology, biometrology, and biological data standards.

Every aspect of biotechnology, from data to biomanufacturing processes to safety and security, needs standards that are agreed upon by stakeholders from the private sector and academia. Establishing a suite of standards and frameworks for biotechnology development will establish one common 'language' for the biotechnology industry. Standards would improve research, manufacturing, product adoption, and collaboration along the product development pipeline. The development of such standards will give industry the opportunity to work closely with government to ensure the needs of different companies are heard and incorporated in the development of standards.

To accomplish this, and ensure a stable path forward for biotechnology, Congress should authorize the NIST to serve as a hub for biotechnology and biological data standards.

The scope of responsibilities for a newly emboldened biotechnology arm at NIST should include developing:

- definitions and frameworks for AI-ready biological data;
- instrumentation and practices for biometrology;
- standards for industrial biomanufacturing;
- necessary standards necessary for biomanufacturing processes;
- standards for physical biomanufacturing infrastructure;
- standards for biosafety, biosecurity, and responsible innovation; and
- a continually updated lexicon related to biotechnology and biomanufacturing.

Congress should appropriate $640 million to the NIST over five years for this work, with $20 million per year for years one and two and $200 million a year beyond that. During the first two years, the NIST would inventory existing biological data and biotechnology standards and work with partners and stakeholders to set up the program. In year three and beyond, the NIST would expand the program to provide data management resources for biological data, provide complete cybersecurity frameworks, hire necessary staff, work with the biotechnology industry, and coordinate with federal funding agencies related to all aspects of biotechnology standards.

Appendix D

More Details on Grand Challenges for Biotechnology (4.3)

4.3 Launch Research Grand Challenges to Unlock Leap-Ahead Capabilities

4.3b Recommendation

Congress should initiate a grand research challenge focused on making biotechnology predictably engineerable.

The engineering paradigm of model, make, and measure, explains an iterative cycle of designing a product or process ("model"), creating something based on that model ("make"), collecting data on how well the product or process works ("measure"), and then starting the whole process over again based on the information obtained from previous cycles. To accomplish this engineering paradigm for biological systems, the Commission proposes component challenges that would break down predictable engineering into individual tasks.

1. **Solve the Genotype-To-Phenotype Relationship:** Engineering biology in a safe and predictable way requires researchers to understand the relationship between genetic make-up (genotype), and how this orchestrates the physical characteristics of living things (phenotype).
2. **Develop More Precise Engineering Tools:** In select contexts, researchers have developed impressive abilities to engineer the biology of animals, plants, and microorganisms. More precise biological tools are needed to make predictable and reliable edits in organisms that avoid unintended effects.
3. **Create a Digital Twin of the Cell:** Much like how meteorologists can observe and model weather conditions anywhere in the world from their own computer, a digital twin could allow researchers to digitally monitor and predict the activity of its physical counterpart.
4. **Identify Indicators of Successful Bioengineering Scale-up:** Researchers should establish measurements and tests to determine the potential scalability of biological processes and incorporate those considerations into early-stage research and development (R&D).

Solving these component problems would bring the United States closer to programming biology in ways that would revitalize the U.S. manufacturing base and help Americans live longer and healthier lives. In addition, these challenges would spur countless other research efforts to solve the additional, smaller challenges wrapped up in each question.

The Commission categorizes these smaller challenges, or keystone challenges, into four areas: foundational research, advanced measurement techniques, experimental tools, and computational models. Through extensive

research, stakeholder interviews, and surveys, the Commission developed a list of keystone challenges that are critical to solving larger problems and realizing major advances for humankind. This list is not comprehensive, but these research areas are a good starting point for the United States' broader grand challenge of engineering biology. Additionally, while many of these are longstanding areas of research, they are topics where key knowledge gaps impede biotechnology advances.

Area 1 – Foundational Research

Advance Understanding of How Proteins Function: Even though proteins are extraordinarily well-studied, there is still a critical gap in predicting and understanding what functions a particular protein will have. Building on recent leaps in predicting protein structure, there is a need for a better understanding of how sequence and chemical changes affect protein function. This would complement the existing field of DNA research and strengthen scientists' understanding of how cells behave.

Deepen Knowledge of RNA Biology: Much is still unknown about RNA's chemistry, structure, and function. Better understanding RNA's various forms and functions could unlock even greater therapeutic and biological engineering potential.

Characterize All Metabolites: The current state of measurement and analytical techniques make it prohibitively difficult to get a complete snapshot of all the small chemical components in living cells. Studying and identifying these small molecules would unlock advances in biomanufacturing by revealing which chemicals and materials can be produced by different organisms.

Enhance Understanding of Microbiomes: While many have heard of the well-studied gut microbiome, communities of microorganisms exist everywhere in the world. Exploring the constitution and interactions of microbial communities would open new possibilities for health, environmental remediation, and agriculture. For example, understanding and optimizing the ecosystem of microbes in the soils could promote crop growth and help prevent plant-related disease.

Understand Quantum Effects in Biological Systems: Studying quantum effects in biological systems, such as electron transfer in photosynthesis, could provide vital insights into biological processes. These insights could inform the development of novel ways to treat disease, produce energy, and navigate the planet.

Build Minimally Synthetic Cells: Creating synthetic cells across life domains (such as microbes, plants, and animals) would accelerate researchers' understanding of biology's basic building blocks, opening the door to advances in engineering biological systems.

Increase Understanding of a Wider Array of Plant Species: To date, most plant research has focused on a very small number of species. Deepening researchers' understanding of the molecular make-up and physiological characteristics of different plant species would lead to higher crop yields and critical advances in developing food.

Area 2 – Advanced Measurement Techniques

Develop Non-Destructive Measurement Technologies: Emerging measurement innovations such as quantum sensing and Raman spectroscopy allow researchers to test biological samples without destroying them, preserving valuable specimens for further analysis.

Create a Rapid, High-Quality Data Collection Capacity: The development of automated instrumentation for data collection ensures faster, standardized data gathering, which is critical for advancing computational modeling and analysis.

Develop Instrumentation that Includes Spatial and Time-Point Information: Moving beyond 2D measurements would generate data that include an understanding of where and when the data collection happened. This would enable a more accurate understanding of dynamic biological systems.

Improve Mapping and Measuring of Molecular Interactions: Improvements in tracking how biomolecules bind and interact with one another would make it easier to develop pharmaceuticals that bind to a particular target and support the development of more precise tools for engineering biology.

Area 3 – Experimental Tools

Develop Unique Capabilities for DNA/RNA Synthesis: While the affordability and scalability of DNA and RNA synthesis is critical, new techniques are needed to synthesize longer segments of DNA or RNA, incorporate new nucleic acid structures, and accomplish both tasks faster. These techniques would be critical for all aspects of biotechnology and have far-reaching national security applications.

Characterize New Organisms: Current research focuses on a small number of well-researched and well-characterized organisms. Discovering, characterizing, and optimizing new and emerging organisms would further basic biological research and provide more options for biomanufacturing.

Harness Miniaturization, Nanofabrication, and Microfluidics: While there is a large body of research on miniaturization for biotechnology, the movement from small-scale demonstration to implementation is usually fraught with challenges. Additional research is needed to achieve precise control over micro- and nano-scale processes, control that would enhance data collection and improve .

Advance Organoids and Organs-on-a-chip Models to Unlock Unique Experimental Capabilities: These 3D cell culture techniques such as organoids and organs-on-a-chip enhance scientists' understanding of complex biological processes, while bridging the gap between animal models, human clinical trials, and in vitro testing. Improving scalability and reliability of organoids and organs-on-a-chip models could improve drug discovery and reduce reliance on animal models for drug testing.

Establish and Characterize Standards for Key Biological Inputs: Currently, there are very few internationally recognized standards related to biotechnology, a dearth that leads to inconsistencies in R&D methodologies and problems with reproducibility. Similar to how every electric circuit, no matter where it is produced across the country, has the same component parts that are described and named in line with national standards, the United States needs standard inputs to support biotechnology research, experimentation, and scale-up.

Area 4 – Computational Models

Improve Bio-AI Tools and Encourage Safe Integration into Research: Bio-AI tools can assist in designing proteins, viral vectors, and other biological agents. As these tools continue to evolve and provide known and updated biological information, they will speed up research and reduce experimentation time.

Train Scientific Large Language Models (LLMs) with Biological Data: LLMs trained on biological data, such as DNA or protein sequences, will improve exponentially over time and drive novel molecular insights.

Breakthroughs on any of these keystone challenges would have a catalyzing effect on other biotechnology research. But the greatest promise lies in their convergence, especially when interdisciplinary areas such as computational modeling merge with physical biotechnology R&D. This list does not aim to exclude such convergences but rather encourage them through the identification of overarching topics.

4.3c Recommendation

Congress should initiate a grand research challenge focused on making biomanufacturing scale-up predictable, rapid, and cost-competitive.

The second grand challenge recommendation is related to the science of scale-up. Below the Commission outlines specific areas of scale-up research and cost distribution.

Area 1 – Chassis

Develop Emerging Chassis and Cell-Free Systems: Research and characterization into biological systems and components at different scales would enable new engineering tools and improve the performance of platforms, called "chassis," that are customized to produce bioproducts. This research would accelerate the use of emerging chassis, such as multicellular, multi-species, and cell-free systems, expanding what can be made with biology.

Area 2 – Biomass and Feedstocks

Optimize Biomass Conversion and Develop Alternatives: Developing new or improved conversion technologies would maximize the usability and yield from both traditional sources of agricultural-derived biomass and next-generation feedstocks, such as municipal and manufacturing waste. In addition to breaking down biomass into sugar, efficient conversions should expand to yield other feedstock types and usable bioproducts, helping the United States use what it has to make what it needs.

Area 3 – Process Technology and Equipment

Create Hardware, Software, and Digital Signal Processing Tools: Process intensification through the development of biomanufacturing-specific hardware, software, and digital signal processing tools would enable the adoption and vertical integration of bioproduction at every scale. Prioritizing holistic, as opposed to standalone, R&D in these areas would enhance access and efficiency across all bioprocessing operations, including modular equipment.

Area 4 – Critical Inputs

Reimagine Biomanufacturing Basic Biological Components and Chemicals: Leveraging breakthroughs across the other three areas of this challenge to specifically reimagine cost-competitive biomanufacturing processes would produce vital production inputs for which the United States relies on foreign suppliers, including adversaries who could weaponize this reliance by cutting off U.S. access. Key examples of such inputs include amino acids, many of which either rely on or struggle to compete at cost with offshore production.

[i] Allison Berke, "Accelerating Biomanufacturing and Producing Cost-Effective Amino Acids Through a Grand Challenge," Federation of American Scientists, May 15, 2023, https://fas.org/publication/accelerating-biomanufacturing-and-producing-cost-effective-amino-acids-through-a-grand-challenge/.; Natalie Damaso et al., Project 4133 Assessing Emerging Biotech: Biomanufacturing (MIT Lincoln Laboratory, 2024).

Grand Three-Year Biomanufacturing Scale-Up Challenge: Example Lead Agency and Funding Details

Scale-up Focused Research Challenge: Topic Areas	Agency Lead	Funding Amounts (in millions)*			
		Year 1	Year 2	Year 3	Total
Chassis (Emerging Chassis and Cell-Free Systems)	National Science Foundation (NSF)	$25	$35	$40	$100
Feedstocks (Biomass Conversion and Alternatives)	Department of Agriculture (USDA)	$30	$45	$50	$125
Process Technology and Equipment (Hardware, Software, and Digital Signal Processing Tools)	Department of Energy (DOE)	$50	$60	$65	$175
Critical Inputs (Basic Biological Components and Chemicals)	Advanced Research Projects Agency for Health (ARPA-H)	$25	$30	$35	$90

*Congress could authorize incrementally larger funding amounts each additional year to ensure that funding is appropriated in proportion to demonstrated progress. An interagency coordinating body would conduct oversight and assess progress.

Inspiring Innovation Through Outcomes-Driven Funding

Related to the above enabling recommendations on grand challenges, the Commission proposes a specific implementation model that would focus on outcomes-driven funding.

With the immense landscape of biotechnology research funding that currently exists within the U.S. government, the Commission deliberately chose to not make specific recommendations on which departments or agencies should fund which grand challenge components. Many of these agencies will have equities and interests in the research areas noted above. It is important to allow experts to make decisions about projects that fit in their portfolio and to develop ways to coordinate with other departments or agencies toward specific goals.

One way to encourage the kind of research that advances a biotechnology grand challenge is to use an outcomes-driven model that implements a mechanism to "pay for success." Most early-stage research funding in the United States is distributed based on hypothesis-driven or exploratory scientific questions (for instance, "we believe a cell works in this way," or "we want to better understand how this part of a cell operates"). While this style of scientific exploration is a critical part of the U.S. research enterprise, American innovators need funding that drives toward specific outcomes (such as, "create a computational representation of the entire cell").

Such funding models tend to produce usable results more quickly because of their incentive structure. Versions of outcomes-driven research funding are used by the Defense Advanced Research Projects Agency (DARPA) and other agencies that use the DARPA model, and there are myriad research challenges where departments or agencies ask researchers and developers to accomplish an end goal with plans to reward success.

These funding models provide opportunities for teams to compete in pursuit of a common goal and for successful teams to receive further funding. Such a model should include the following parameters:

- **A base level of funding for all participating teams:** All selected research teams receive a base level of funding to tackle the challenge.
- **Tiered outcomes and awards:** The selected teams would have different opportunities throughout the research process to reach milestones and receive funding to continue their research.
- **Defined outcomes and milestones:** Require program managers to develop and make available the parameters they will use to assess projects.

- **Incentivize interdisciplinary collaboration:** As a part of the selection or outcome criteria, interdisciplinary teams working collaboratively with other institutions or groups should be favored.
- **Significant awards for solving a grand challeng:** For a team (or teams) that are successful, there should be significant awards in the form of funding, access to scale-up infrastructure, or opportunities to connect directly with venture capital.

The grand challenges research funding described above is a slight variation on existing models, with the intent of bringing together interdisciplinary teams and creating an environment that fosters faster innovation and moves all of biotechnology forward.

A portion of new funding meant to address an overarching grand challenge for biotechnology research should be built to reward success in solving hard, ambitious scientific challenges that unlock important leap-ahead capabilities.

A central department or agency, in collaboration with other research funding agencies, could build and coordinate a program to accomplish this recommendation. The DARPA, for example, has long worked with other agencies on rewarding success for ambitious challenges. Another example of a collaborative research funding model is Catalyzing Across Sectors to Advance the Bioeconomy (CASA-Bio,) which is an effort led by the National Science Foundation (NSF) with input from multiple other departments and agencies. The NSF created Bioeconomy Initiatives, which focus on different biotechnology research goals such as "accelerated breeding for a resilient bioeconomy."

An additional component to consider related to this recommendation is creating ways to get buy-in from private funders. Any department or agency could work with private funders to collaborate on specific grand challenges. The United States could leverage private foundation funding in basic research to increase the pool of available funding to reach these ambitious goals.

Such funding structures would imbue research challenges with a spirit of constructive competition, while only deploying taxpayer dollars when ambitious goals are met. The fruits of this funding could enable new capabilities that would make biotechnology more affordable and effective for Americans.

Appendix E

More Details on Equipping the U.S. Government Workforce (5.1)

5.1 Equip the U.S. Government Workforce with Necessary Biotechnology Resources and Expertise

5.1a Recommendation

Congress must direct the Office of Personnel Management (OPM) to provide workforce training in biotechnology across the interagency.

Develop a National Biotechnology Workforce Framework

Congress should direct the National Institute of Standards and Technology (NIST) to develop a workforce framework that defines biotechnology jobs, along with the knowledge and skills necessary to perform them.

A national workforce framework for biotechnology would model off the successful National Initiative for Cybersecurity Education (NICE) framework developed by the NIST. Employers within and outside of government, could use this framework to conduct workforce assessments and identify skill and knowledge gaps, improve hiring and retention, and establish strategic workforce development initiatives. Educators could use it to develop curricula and skills assessments that reflect employers' needs. Meanwhile, prospective talent, including students, job seekers, and current employees could use the framework to learn about position requirements, identify gaps in their own skills, and better prepare to demonstrate their capabilities.

The NIST should develop the framework in partnership with academia, industry, nonprofits, and federal agencies and include information for how individuals with nontechnical or other nontraditional backgrounds and education may use their skills. The framework should be reviewed and updated at least once every three years. To encourage adoption and success, the NIST should focus on communicating the value of the framework and developing a framework performance assessment.

5.1c Recommendation

Congress should receive accurate, timely, and nonpartisan scientific and technical counsel.

The U.S. government lacks sufficient understanding and capacity to engage with biology and biotechnology. As lawmakers increasingly vote on legislation related to biotechnology, they would need more consistent access to biotechnology expertise to legislate effectively.

In light of recent Supreme Court rulings related to administrative law, Congress must now draft legislation with greater technical precision to ensure specific outcomes, as the federal agencies they oversee may have less authority to interpret broader policies.

At present, Congressional offices have limited access to biotechnology expertise:

- Individual Congressional offices can directly hire subject matter experts if they choose to do so. However, resourcing for member and committee offices varies, and members must weigh hiring specific technical experts against policy professionals who cover broader issue sets.
- Congressional offices can request technical information in the form of primers or briefings from the Congressional Research Service (CRS). The CRS releases approximately 700 reports per year, the majority of which summarize policy issues and do not include technical assessments. The CRS also has limited staff to address the many requests from offices. Staffing at the CRS decreased by 29 percent between 1985 and 2017. Additionally, the CRS is a point-in-time resource and relies heavily on offices knowing the right questions to ask. The CRS's mandate does not require continually engaging with agencies to identify and monitor biotechnology-specific advancements, offering its employees continuing education opportunities to keep them up to date on recent breakthroughs, or regularly reporting findings back to Congressional offices.
- The Government Accountability Office (GAO) established the Science, Technology Assessment, and Analytics (STAA) office in 2019 to bolster its capacity for technical reports. The STAA office releases regular assessments on discrete issues, typically in response to a Congressional request or mandate. This work also includes shorter spotlights and trends papers covering topics such as generative AI in healthcare, gene editing, and plastics biorecycling.
- Congressional offices can also hire fellows from a range of programs (such as the American Association for the Advancement of Science (AAAS), Brookings, Horizon, and TechCongress) to augment full-time staff. At present, however, Congressional offices bear the burden of finding fellows from organizations, applying for the fellows to join their offices, and training them for a short-term rotation. When fellowships end, expertise leaves with them. The existing process can be especially difficult for new Congressional offices or offices without an established internal process for fellowships.

Some resources, such as assessments from the GAO or detailees from legislative and executive agencies, primarily support Congressional committee chairs and ranking members. Committees have taken advantage of the opportunity to detail employees from external agencies, as detailees have increased by 300 percent in the past 30 years, but these resources more regularly benefit committees and returning member offices.

The following details for recommendation 5.1c envision a legislative branch that is equipped and empowered to maximize the effect of legislation to promote and protect U.S. leadership at the nexus of emerging biotechnology and national security. Congressional staffers should have the confidence to engage with, write, and champion meaningful legislation on these issues. The more bioliterate policymakers are, the better they can support and govern U.S. biotechnologies.

Support the Congressional Research Service (CRS) to Better Advise Congressional Offices on Biotechnology and National Security

Congress should strengthen hiring and pay authorities for the Congressional Research Service (CRS) to better secure the requisite technical expertise to advise Congress at the intersection of technology and national security.

The CRS maintains a robust internal system to receive and task biotechnology-specific requests from staffers and members of Congress, including cross-disciplinary review of questions and proposed responses. As biotechnology becomes increasingly integrated across all sectors of the economy, Congress should require a biannual report from the CRS about its personnel needs, so that the office always has expertise that matches Congress's real-time needs. Ultimately, the CRS should maintain a cadre of

biotechnology experts and interdisciplinary technology experts to provide support to Congressional offices in need.

Codify the GAO's Science, Technology Assessment, and Analytics office to Support Additional Technology Assessments and Bolster its Technology Forecasting Capacity

Congress should codify the Government Accountability Office's (GAO) Science, Technology Assessment, and Analytics (STAA) office and appropriate additional funds so that it can hire more scientists and engineers.

Congress should adopt Recommendation No. 141 of the Select Committee on the Modernization of Congress's Final Report, which would authorize the STAA office and make it a permanent part of the GAO. Congress should also appropriate funds to hire 50 more scientists and engineers to support additional STAA technology assessments and bolster their technology forecasting capacity. This expansion would roughly double the STAA office's science and engineering staff, providing Congress additional technical expertise through a range of work products.

This permanence, along with an expansion of technology assessment staff, would allow the STAA office to dramatically expand its bandwidth for current projects and increase its technology forecasting capacity.

Establish an Office of the Congressional Science and Technology Advisor

Congress should establish an Office of the Congressional Science and Technology Advisor (OCSTA).

Congressional offices are often short on time and cover a wide range of topics. While these office benefit from successful science and technology (S&T) work being done by the CRS and STAA office, they do not have a central point of contact for nonpartisan technical advice. It is important that Congressional offices are aware of the resources available to them and have an efficient way to request information and resources. This proposal seeks to ensure that Congressional offices and committees easily find rigorous, relevant, and up-to-date scientific advice.

Based on the National Academy of Public Administration (NAPA)'s recommendation, Congress should establish an Office of the Congressional Science and Technology Advisor (OCSTA) to coordinate with the CRS and the STAA office. The OCSTA's mandate would be to receive and action requests for technology education and longer-term technology assessments from any member of Congress.

This mandate would include convening monthly bipartisan and bicameral briefings with industry leaders. These sessions would serve as off-the-record time for staffers to hear from experts on the latest innovations and opportunities across disciplines. It would also include supporting the recruitment and hiring of emerging technology advisors for major committees, maintaining a database of open science and technology fellowship opportunities within offices and available fellows for placement for both the House and Senate, and evaluating possible conflicts of interest for fellowships from external organizations.

Expand Integration of Science and Technology Experts into Congressional Offices

Congress should establish a fellowship pipeline that provides opportunities for executive branch employees with biotechnology expertise to complete rotations in congressional offices.

Congress should require that the OCSTA maintain a database of open science and technology fellowship opportunities within offices and available fellows for placement for both the House of Representatives and Senate. This should include profile matching between Congressional offices seeking fellows, agency fellowships and detailee opportunities, and vetted external organizations seeking to place fellows. The OCSTA should also hold a biannual briefing for Congressional offices on how to integrate fellows from existing programs and how to design internal programs for fellows to contribute to policy work. The House should consider adopting the recommendation from the Select Committee on the Modernization of Congress' Final Report to clarify rules to allow fellows and detailees to receive the same resources as professional staff.

Part of the OCSTA's purview should be to evaluate the perception and possible presence of conflicts of interest for fellowships from external organizations. This vetting would be essential for member offices.

Host a Biannual Job Fair to Match Available Fellows with Congressional Offices

The Chief Administrative Officer and the Senate Employment Office should co-host a biannual science and technology fellowship fair, bringing together congressional offices that are looking for subject matter expertise with technology fellowship programs that have available personnel.

Regular opportunities for Congressional staff to learn firsthand about technology fellowship programs would ensure that member and committee offices know about the resources available to them and can access these esteemed networks.

Just as Congress has taken a greater interest in AI,

lawmakers and Congressional staff should engage permanently and seriously with biotechnology. Congressional offices are on the front lines of U.S. technology policy development, leading the United States' agenda to promote and protect critical and emerging technologies. Taken together, the above recommendations would ensure holistic and consistent access to biotechnology expertise across the legislative branch, empowering U.S. policymakers with the tools they need to unleash American potential and drive the bioindustrial revolution forward.

The Commission strongly supports efforts to increase bioliteracy for every American, including those serving in Congress and the federal government, to best capture the benefits of the bioindustrial revolution and support the premier biotechnology workforce of the future.

Launch a Congressional Commission on Responsibility and Ethics in Innovation

Congress should establish a standing Congressional Commission on Responsibility and Ethics in Innovation to provide guidance on the responsible and ethical aspects of future legislative pathways regarding emerging technology.

In addition to gaps in its technical knowledge, Congress is also grappling with a range of ethical and responsible innovation issues related to biotechnology. Congress's ability to deliberate over ethically charged issues around research and innovation is key to its effectiveness as a legislature, but there is currently no standing body to deliberate on these issues. While past determined by the courts or by presidential commissions, Congress would benefit from an independent, bipartisan, consultative body of experts.

Establishing such a body would both provide a dedicated space for addressing contentious issues and enable Congress to craft legislation that aligns the normative goals of the law with the technical likelihood of them being achieved.

Appendix F

More Details on Supporting American Job Creation (5.2)

5.2 Support Job Creation Across the United States for Americans at All Skill Levels

5.ba Recommendation

Congress should expand educational efforts in biotechnology for American students.

Support Student-to-Career Pathways

Congress should direct the National Science Foundation (NSF) to establish a new grant program to support student-to-career pathways that ensure seamless transfer of credentials.

Funding at both the federal and state level does not encourage partnerships and collaboration among high schools and, two-year and four-year institutions of higher education (IHEs). Educational institutions often operate in silos and do not coordinate their curricula, making it hard for students to explain credentials from one institution to another. The demand for highly skilled technical workers in an evolving biotechnology sector often requires individuals to "stack" credentials, moving sequentially along a training pathway to increasingly advanced and higher paying jobs. Without ways of accumulating credentials, students must often repeat coursework, which requires additional resources and time before they can enter the workforce. Lacking seamless education pathways with off-ramps to well-paying jobs, students encounter dead-ends and mismatches between their credentials and the industry's needs.

The federal government should encourage coordination of workforce training by offering funding to high schools, community colleges, vocational-technical schools, colleges and universities to partner with one another and with industry stakeholders to develop curricula and training programs that would better serve the needs of the local and regional biotechnology workforce. Coordinating workforce training across educational institutions and enabling students to accumulate credentials to advance to different and higher paying jobs would build stronger local and

regional talent pipelines of skilled workers for biotechnology jobs at every level.

A grant program established within the NSF would support student-to-career pathways from high school to two-year IHEs and from two-year to four-year IHEs. The grant program should operate in three phases:

Phase I – Partnership and Development: In this phase, the NSF would issue grants to education teams (comprised of faculty, deans, and program directors from high schools and two- and four-year IHEs) to develop articulated career pathways with stackable credentials (such as diplomas, certificates, apprenticeships, and degrees) and exit points leading to all levels of biotechnology jobs. Teams should consult with local and regional industry stakeholders to determine the needed skills, competencies, and positions. The NSF should prioritize funding for rural and under-resourced areas that might not otherwise be able to stand up such programs on their own. The NSF would issue 30 annual grants of $300,000 apiece.

Phase II – Implementation: The NSF would then select education teams that have successfully completed Phase I to receive larger grants to implement articulation plans, codevelop curricula, and collect data on student outcomes. Teams would have to appoint and regularly consult with an industry advisory board to ensure that curricula align with industry needs. These curricula should be cross-disciplinary and cover supply chain issues, AI, advanced manufacturing, and other relevant fields. The NSF would issue 15 additional grants of $2 million apiece.

Experiential, hands-on learning is critical at every level of education to ensure that training simulates industry work environments. Teams could request $50,000 to $350,000 in supplemental funding to purchase training equipment and instrumentation similar to what is used in industry. Teams would also be encouraged to partner with local or regional national labs, municipal labs, and companies to obtain access to facilities and instrumentation.

Phase III – Sustainment: After the implementation phase, teams would focus on sustaining articulated pathways and working with state and local partners to promote the adoption of those pathways. Updates to curricula, skill standards, and training equipment would be made to ensure that the industry's workforce needs continue to be met.

Create a Biotechnology Scholarship for Service Program

Congress should establish a Biotechnology Scholarship for Service program to incentivize undergraduate and graduate students in biotechnology programs.

To encourage more technically trained students and professionals to pursue careers in public service, the government needs to create more direct career pathways into the public sector. As the biotechnology sector continues to expand, the demand for technical talent will only grow. Providing young biotechnology talent from colleges and universities with clear pathways into and conditional guarantees of government employment would entice students from a wider range of backgrounds to pursue a government career they might not have otherwise considered.

Congress should create a Biotechnology Scholarship for Service program to support undergraduate and graduate (Master's and PhD) students in biotechnology and related programs, with a public service obligation immediately following graduation that is equivalent in length to that of their scholarship.

The NSF should establish a biotechnology scholarship for service program. Recipients would have to agree to a public service obligation at a federal agency (or an approved state, local, or tribal government agency) following graduation that is equivalent in length to that of the scholarship. The Office of Personnel Management (OPM) and the NSF should create memorandums of understanding (MOUs) with federal agencies to ensure conditional offers of employment for students who complete the degree program.

Successful scholars could contribute to the U.S. government's expertise through biotechnology research and development (R&D) activities at federal agencies including the National Institutes of Health (NIH), the Department of Defense (DOD), and the Department of Energy (DOE). They could also do so by providing technical expertise across different funding agencies' program offices, policy offices, regulatory agencies such as at the Department of Agriculture (USDA), the Environmental Protection Agency (EPA), the Office of Science and Technology Policy (OSTP), and the NSF. Scholars could also complete their public service at the local level through state or municipal policy offices and labs.

Strengthen High School Biotechnology Education

Congress should establish a Biotechnology for All High School Students initiative that would comprise a grant program and would establish a consortium to advance biotechnology education at the secondary level (grades 9-12) nationwide.

Education is a strategic long-term investment, and the United States does not have time to waste. Investments today in high-quality biotechnology education for high school students would yield a pipeline of homegrown talent in the coming decades that would drive U.S. innovation, competitiveness, and economic security. Introducing students to biotechnology early in their education exposes them to scientific concepts and develops their confidence in science, technology, engineering, and mathematics (STEM) and critical thinking.

Congress should establish a Biotechnology for All High School Students initiative that would comprise a grant

program and would establish a consortium to advance biotechnology education at the secondary (grades 9-12) level nationwide. The NSF and the Department of Education would administer the grant program, offering high school teachers professional development opportunities to teach biotechnology courses. The program would also provide state and local school districts with resources and tools to define and evaluate biotechnology education pathways at the high school level.

The consortium, comprised of federal, state, and local leaders, would advise and assist on matters relating to high school biotechnology education. It would coordinate public-private partnerships across federal, state and local stakeholders; support educator training and professional development; and enable access to instructional material and resources for curriculum development.

Appendix G

More Details for Promoting Biotechnology with U.S. Allies and Partners (6.1)

6.1 Promote Biotechnology with U.S. Allies and Partners

6.1c Recommendation

Congress should expand regulatory diplomacy for biotechnology.

As described in Section 6.1 of this report, differences in the ways that countries regulate biotechnology products can create trade barriers. Delays in approval for biotechnology products by trading partners can delay or prevent commercialization of those products in the United States. Diplomatic, regulatory, and trade agencies can work towards global regulatory convergences in multiple venues, including multilateral organizations, bilateral engagements, and technical working groups.

There are many multilateral organizations where the United States should continue to engage and, where possible, strengthen its participation. For example, the Organization for Economic Cooperation and Development (OECD) has long worked to advance shared approaches for biotechnology risk assessment. Partnerships such as Asia-Pacific Economic Cooperation (APEC) and the Inter-American Institute for Cooperation on Agriculture (IICA) have resulted in slow but steady movement towards science-based, risk-proportionate regulation. In recent years, multiple African countries have moved to establish regulatory frameworks and approve the cultivation of biotechnology crops, including South Africa, Kenya, Nigeria, and Malawi.

By expanding its engagement with and investment in international organizations and individual countries, the United States could better support science-based biotechnology regulation and build stronger partnerships in every region of the world. Currently, the Department of State (DOS) provides some biotechnology-related project funding to posts overseas to support activities, such as workshops for scientists, regulators, and policymakers. These activities can help advance science-based regulation and promote the acceptance of biotechnology products, leading to increased market access for American biotechnology products.

To strengthen diplomatic efforts, the U.S. government should consider establishing additional technical working groups with other countries. These would focus on exchanging technical information between regulators to inform policy and explore agreements for data sharing. As global investment in this sector increases, other nations, both inside and outside of the North Atlantic Treaty Organization (NATO), will look to create these kinds of agreements and align regulations.

In addition, to address trade with countries that delay or deny regulatory approvals for U.S. biotechnology products, the U.S. government could encourage mechanisms that enable "identity preservation" during production and handling. This would allow biotechnology products that are approved in the United States to be produced and sold domestically, while ensuring that products are not exported to countries that have not yet provided regulatory approval. Identity preservation is already used voluntarily in agricultural trade, such as to separate soybeans with heart-healthy oils from conventional soybeans. One way to verify identity-preserved systems is with third-party audits (see recommendation 2.1a). An identity-preserved system for some biotechnology products could foster confidence among trading partners and would facilitate trade overall.

Appendix H

Five-Year Recommendation Funding Table

Chapter/Pillar	Recommendation	Agency	Funding over 5 years
1: Prioritize Biotechnology at the National Level	1.1a Congress must establish a National Biotechnology Coordination Office (NBCO) in the Executive Office of the President with a director, appointed by the President, who would coordinate interagency actions on biotechnology competition and regulation.	Executive Office of the President (EOP), National Science Foundation (NSF)	$32 million
	1.2a Congress should direct each relevant agency to designate a senior official to lead biotechnology policy.	EOP, Department of Agriculture (USDA), Department Commerce (DOC), Department of Defense (DOD), Department of Energy (DOE), Department of Health and Human Services (HHS), Department of Homeland Security (DHS), Department of the Interior (DOI), Department of State (DOS), Environmental Protection Agency (EPA), National Aeronautics and Space Administration (NASA), NSF, Office of the Director of National Intelligence (ODNI)	$0
	1.3a Congress should establish the Office of Global Competition Analysis to develop timely data and technology forecasting to inform policymakers' decisions.	EOP	$150 million
2: Mobilize the Private Sector to Get U.S. Products to Scale	2.1a Congress must direct federal regulatory agencies to create simple pathways to market and exempt familiar products from unnecessary regulation.	EOP, USDA, HHS, EPA	$100 million
	2.1b Congress should direct federal regulatory agencies to prepare for novel products to come to market.	HHS, EPA, NSF	$270 million
	2.2a Congress must establish and fund an Independence Investment Fund, led by a non-governmental manager, that would invest in technology startups that strengthen U.S. national and economic security.	DOC	$1.065 billion

2.2b Congress should direct the Department of Energy and the Department of Health and Human Services to use existing authorities to smooth out unpredictable and inconsistent demand for biotechnology products through advance market commitments (AMCs) and offtake agreements and provide new authorities where necessary.	DOE, HHS	$200 million
2.2c Congress should restore full and immediate expensing of research and development (R&D) expenditures.	Department of Treasury (Treasury)	$0
2.2d Congress should improve the effectiveness and reach of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs to support early-stage innovation.	Small Business Administration (SBA)	$0
2.3a Congress must authorize and fund the Department of Energy and the Department of Commerce to develop a network of manufacturing facilities across the country for precommercial bioindustrial product scale-up.	DOE, DOC	$800 million
2.3b Congress should direct the Department of Commerce to create a public-private biopharmaceutical manufacturing center of excellence focused on developing and scaling new ways to make medicines.	DOC	$120 million
2.4a Congress must direct the Department of Homeland Security to ensure that biotechnology infrastructure and data are covered under "critical infrastructure."	DHS	$0
2.5a Congress must require public companies to disclose single points of supply chain vulnerability located in foreign countries of concern.	U.S. Securities and Exchange Commission (SEC)	$0
2.5b Congress must prohibit companies that work with U.S. national security agencies and the Department of Health and Human Services from using certain Chinese biotechnology suppliers deemed to pose a national security threat.	DOD, HHS, ODNI	$0
2.5c Congress should reform the Committee on Foreign Investment in the United States (CFIUS) to better and more nimbly screen the highest-impact, highest-risk types of investment in critical technology sectors in the United States.	Treasury	$75 million
2.5d Congress should direct the International Trade Commission to investigate Chinese dumping or oversupply of biotechnology products and services.	International Trade Commission (ITC)	$10 million

3: Maximize the Benefits of Biotechnology for Defense	3.1a Congress must direct the Department of Defense to consult with stakeholders to define principles for ethical use of biotechnology for the U.S. military.	DOD	$0
	3.2a Congress must direct the Department of Defense to work with private companies to build commercial facilities across the country to biomanufacture products that are critical for Department of Defense needs.	DOD	$762 million
	3.2b Congress should continue oversight of and support for BioMADE's efforts to create a network of facilities that precommercial bioindustrial companies across the country can use to meet Department of Defense needs.	DOD	$0
	3.2c Congress should require changes to military specifications (MIL-SPECs) to enable biotechnology companies to more easily sell their products to the Department of Defense.	DOD	$0
	3.2d Congress should require the Department of Defense to enter into advance market commitments (AMCs) and offtake agreements for biotechnology products that are needed for defense.	DOD	$200 million
	3.2e Congress should require the Department of Defense and other agencies involved in national security to train their workforces to be ready for biotechnology.	DOD, DHS, ODNI	$50 million
	3.3a Congress must require outbound investment rules that ensure U.S. capital does not support Chinese development of certain biotechnologies that could pose a national security risk.	Treasury	$0
	3.3b Congress should direct the Department of Commerce to consider country-wide export controls blocking the sale of specific, highly sophisticated U.S. biotechnology items to China that would pose a substantial risk to national security if used for military end-uses.	DOD	$0
	3.3c Congress should require the Department of Defense to incorporate military-relevant applications of emerging biotechnology into wargaming exercises.	DOD	$200 million
	3.3d Congress should resource the intelligence community to prioritize understanding adversaries' development of biotechnology and its diverse applications.	ODNI	$200 million

4: Out-Innovate Our Strategic Competitors	4.1a Congress must authorize the Department of Energy to create a Web of Biological Data (WOBD), a single point of entry for researchers to access high-quality data.	DOE	$700 million
	4.1b Congress should authorize the National Institute of Standards and Technology to create standards that researchers must meet to ensure that U.S. biological data is ready for use in AI models.	DOC	$890 million
	4.1c Congress should authorize and fund the Department of Interior to create a Sequencing Public Lands Initiative to collect new data from U.S. public lands that researchers can use to drive innovation.	DOI	$355 million
	4.1d Congress should authorize the National Science Foundation to establish a network of "cloud labs," giving researchers state-of-the-art tools to make data generation easier.	NSF	$80 million
	4.2a Congress must conduct oversight of existing policies, and add new authorities as warranted, to ensure that China cannot obtain bulk and sensitive biological data from the United States.	DOJ, Federal Trade Commission (FTC)	$0
	4.3a Congress must establish Centers for Biotechnology within the existing National Laboratory network to support grand research challenges.	DOE	$1.2 billion
	4.3b Congress should initiate a grand research challenge focused on making biotechnology predictably engineerable.	EOP	$5 billion
	4.3c Congress should initiate a grand research challenge focused on making biomanufacturing scale-up predictable, rapid, and cost-competitive.	EOP	$490 million
	4.4a Congress must direct the Executive Branch to advance safe, secure, and responsible biotechnology research and innovation.	DOC	$1.04 billion
5: Build the Biotechnology Workforce of the Future	5.1a Congress must direct the Office of Personnel Management to provide workforce training in biotechnology across the interagency.	Office of Personnel Managment (OPM)	$50 million
	5.1b Congress must ensure that federal agencies have the necessary expertise across national security and emerging biotechnology issues.	USDA, HHS, DOE, DOD, ODNI, DOS	$100 million
	5.1c Congress should receive accurate, timely, and nonpartisan scientific and technical counsel.	Government Accountability Office (GAO), Congress	$73 million
	5.2a Congress must maximize the impact of biomanufacturing workforce training programs.	EOP, DOC, DOL	$175 million

	5.2b Congress should expand educational efforts in biotechnology for American students.	Department of Education (DOEd), NSF	$235 million
	5.3a Congress should authorize new green cards for biotechnology talent, especially from allied and partner countries.	DHS	$0
	5.3b Congress should optimize the vetting process for foreign nationals to prevent illicit technology transfer.	DHS	$0
6: Mobilize the Collective Strengths of Our Allies and Partners	6.1a Congress must include biotechnology in the scope of the Department of State's International Technology Security and Innovation Fund to appropriately fund international biotechnology policy, research and development (R&D), and secure supply chains.	DOS	$300 million
	6.1b Congress should direct the Department of State and other agencies to promote the U.S. biotechnology industry in foreign markets, including through commercial diplomacy.	DOS	$20 million
	6.1c Congress should expand regulatory diplomacy for biotechnology.	DOS	$0
	6.1d Congress should require the Department of State to form reciprocal biological data-sharing agreements with other countries.	DOS	$50 million
	6.1e Congress should direct the Department of State and the Department of Defense to encourage North Atlantic Treaty Organization (NATO) countries to aggregate demand and pool purchasing power for biotechnology products.	DOD, DOS	$100 million
	6.2a Congress should direct the Department of State, along with the National Institute of Standards and Technology, to support the development of international norms and standards, including defining shared values and interests in biotechnology.	DOS, DOC	$50 million
	6.2b Congress should require the Department of State to create a strategy for harmonizing multilateral export controls.	DOS, DOC	$0
Total			**$15.142 billion**

Appendix I

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*This list includes Commission staff, fellows, detailees, and interns from March 2023 through April 2025.

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