

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

4.1b 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.

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

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 challenge:** 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.

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 offices 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.

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
5: Build the Biotechnology Workforce of the Future	4.4a Congress must direct the Executive Branch to advance safe, secure, and responsible biotechnology research and innovation.	DOC	\$1.04 billion
	5.1a Congress must direct the Office of Personnel Management to provide workforce training in biotechnology across the interagency.	Office of Personnel Management (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