COMMITTEE ON
SCIENCE, SPACE AND TECHNOLOGY
CHAIRMAN BRIAN BABIN

SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

AND SUBCOMMITTEE ON ENERGY

HEARING CHARTER

"*Pursuing the Golden Age of Innovation: Strategic Priorities in Biotechnology*"

June 5, 2025
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

Purpose

The purpose of the hearing is to examine the findings and recommendations of the National Security Commission on Emerging Biotechnology and assess the current U.S. biotechnology research and development (R&D) ecosystem. By engaging with witnesses from academia, industry, and the National Labs, the Committee will have the opportunity to discuss emerging biotechnology research, barriers to innovation, and whole-of-nation strategies for safeguarding America's leadership in this rapidly evolving field. This will also serve as a forum to discuss the role of the federal government in funding and derisking fundamental biotechnology R&D.

Witnesses

- **Dr. Drew Endy**, Hoover Institution Science and Senior Fellow, Martin Family Fellow in Undergraduate Education for Bioengineering, Stanford University
- **Ms. Deborah Gracio,** Associate Lab Director, National Security, Pacific Northwest National Laboratory
- **Dr. Stephen Techtmann,** Associate Professor of Biological Science, Michigan Technological University
- **Dr. Kelvin Lee**, Institute Director, National Institute for Innovation in Manufacturing Biopharmaceuticals

Key Questions

1. What is the federal government's role in supporting biotechnology research and development, and how do we ensure that such investments are not duplicative of private sector activities?
2. What are the barriers to innovation and how can Congress help to overcome them?
3. What specific policy recommendations from the National Security Commission on Emerging Biotechnology address the most pressing needs of biotechnology researchers, particularly those areas accelerated by advances in AI and synthetic biology?
4. How should the federal government restructure its approach to biotechnology to effectively respond to rapidly evolving threats while supporting American leadership in biotech innovation?
5. How can the United States best balance national security concerns with the need to maintain an open research environment that fosters innovation in biotechnology?
6. Given the constrained fiscal environment, should Congress prioritize federal investments in biotechnology over other scientific fields and what opportunities exist for leveraging increasing private R&D investments?

Background

Biotechnology is the use of biological systems for technological or industrial purposes. Synthetic or engineering biology is the application of engineering principles and the use of systematic design tools to manipulate cellular systems at the genetic level to construct novel materials, produce energy, provide food, and maintain or enhance human health and the environment.[1]

Humans have used biotechnology or bioengineered products for millennia through the selective breeding of plants and animals to produce desirable traits in offspring. In the mid-1800s, scientists discovered the underpinnings of genes, the internal units of information that account for observable traits, which are passed from one generation to the next.[2] This discovery led to a new wave of biotechnology focused on plants and organisms.

In 1973, the modern age of biotechnology began when American scientists Dr. Stanley Cohen and Dr. Herbert Boyer devised recombinant DNA technology, the deliberate introduction of deoxyribonucleic acid (DNA) from one organism into another. Their work enabled the production of genetically engineered human insulin in 1982, the first such product approved for sale in the United States.[3]

Funded by the Department of Energy and the National Institutes of Health, the Human Genome Project was launched in 1990. This international collaboration generated the first complete set of DNA instructions found in a human cell, thereby accelerating the study of human biology and leading to many scientific breakthroughs in biotechnology.[4]

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[1] Tuiken, T., "Synthetic/Engineering Biology: Issues for Congress", CRS Report R47265, September 30, 2022.
[2] Caplan, S., "The Birth of Genetics: An excerpt from *Today's Curiosity is Tomorrow's Cure*", American Society for Biochemistry and Molecular Biology, February 24, 2022, https://www.asbmb.org/asbmb-today/science/022422/the-birth-of-genetics.
[3] Science History Institute Museum and Library, "Herbert W. Boyer and Stanley N. Cohen", accessed May 29, 2025, https://www.sciencehistory.org/education/scientific-biographies/herbert-w-boyer-and-stanley-n-cohen/.
[4] National Human Genome Research Institute, NIH, "Fact Sheet: The Human Genome Project" accessed May 27,

Around the turn of the century, the field of synthetic biology was founded based on the transformational assertion that engineering techniques could be harnessed to manipulate cellular systems for novel purposes. By the mid-2000s, the field had grown dramatically and researchers from biology, chemistry, physics, engineering, and computer science were collaborating to design, construct, and characterize biological systems.[5]

Today, the biotechnology industry is a large and growing sector of the U.S. economy, employing over 2.29 million Americans across more than 150,000 companies in every state.[6] The bioscience industry's total economic impact on the U.S. economy, as measured by overall output, totaled more than $3.2 trillion in 2023.[7]

Biotechnology Innovations

Biotechnology is continuously evolving with new areas of innovation emerging regularly, especially at the intersection with other cutting-edge fields such as artificial intelligence and quantum information science. As a potential general-purpose technology, biotechnology applications are far-reaching and could help lay the foundation for a stronger, more resilient manufacturing base.[8]

DNA Sequencing

DNA sequencing is a process used to determine the sequence of individual genes, larger genetic regions, or an entire genome. Improved technology and automation have increased speed and lower costs to the point where individual genes can be sequenced routinely, and an entire human genome can be sequenced for about one thousand dollars.[9]

Beyond human applications, DNA sequencing has become a valuable tool across many fields, including agricultural biology. The ability to reveal genomic variation in crops and livestock is critical for predicting traits in progeny, screening for diseases, and testing crop quality and purity.

2025, available at https://www.genome.gov/about-genomics/educational-resources/fact-sheets/human-genome-project.

[5] Cameron, D., Bashor, C. & Collins, J. A brief history of synthetic biology. *Nat Rev Microbiol* **12**, 381–390 (2014). https://doi.org/10.1038/nrmicro3239.

[6] TEConomy/BIO 2024 U.S. Bioscience Economy Report. Available at: https://bio.widen.net/s/hflmb92hwx/the-us-bioscience-economy-driving-economic-growth-and-opportunities-in-states-and-regions.

[7] *Id.*

[8] *Biotechnology and Synthetic* Biology, in THE STANFORD EMERGING TECHNOLOGY REVIEW 2025, pg. 39-51, (Stanford University and Hoover Institution, 2025), https://setr.stanford.edu/sites/default/files/2025-01/SETR2025_web-240128.pdf.

[9] National Institutes of Health, DNA Sequencing Fact Sheet, Available at: https://www.genome.gov/10001177

Gene Editing

Gene or genome editing is a type of genetic engineering in which DNA is inserted, replaced, or removed from a genome using molecular "scissors."[10] The CRISPR-Cas9 gene editing technique, named "Breakthrough of the Year" in 2015,[11] quickly became one of the most popular ways to perform genome engineering.

Utilizing a modified bacterial protein and a ribonucleic acid (RNA) that guides it to a specific DNA sequence, the CRISPR system provides a simple and fast way to control genes in many species. While gene editing traditionally involved the insertion, removal, or modification of a single gene, CRISPR-Cas9 technology allows multiple genes to be edited simultaneously, potentially offering lower costs for research and manufacturing.[12]

Synthetic Biology

An important modern approach to biotechnology, synthetic biology is an emerging interdisciplinary field that uses advances in biology, engineering, and computer science to modify living systems or build novel systems.[13] This includes creating new genetic code, or DNA, which does not currently exist in nature. Already, food production, material sourcing, and personalization of medicine has been changed by synthetic biology.[14]

Artificial Intelligence

Artificial intelligence is transforming biotechnology research by dramatically accelerating the discovery of new drugs and biological systems. AI-driven drug discovery research has increased significantly, with a 421 percent growth in publications since 2019, reflecting the field's rapid adoption of AI and related technologies.[15] An example is Google DeepMind's AlphaFold, which can predict the three-dimensional structure of proteins (which perform most functions in living cells) in just minutes rather than the years it once took scientists.[16] This Nobel Prize-winning breakthrough is crucial because understanding protein shapes is essential for designing drugs that precisely target specific diseases.[17]

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[10] National Geographic Society, "Molecular Scissors", October 2024, Available at: https://education.nationalgeographic.org/resource/molecular-scissors/.

[11] John Travis, "Making the Cut: CRISPR Genome-Editing Technology Shows Its Power," *Science*, vol. 350, no. 6267 (December 2015), p. 1456.

[12] Gallo, M. and Sarata, K., "Advanced Gene Editing: CRISPR-Cas9", CRS Report R44824, December 7, 2018.

[13] *Supra* note 7.

[14] Voigt, C., *Synthetic biology 2020-2030: six commercially available products that are changing our world,* Nature Communications, 2020, 11:6379, available at https://doi.org/10.1038/s41467-020-20122-2.

[15] Buntz, B., "2024: The year AI drug discovery and protein structure prediction took center stage – 2025 set to amplify growth," Drug Discovery and Development, November 25, 2024, available at https://www.drugdiscoverytrends.com/2024-the-year-ai-drug-discovery-and-protein-structure-prediction-took-center-stage-2025-set-to-amplify-growth/.

[16] Qiu, X., Li, H., Ver Steeg, G., & Godzik, A. (2024). Advances in AI for Protein Structure Prediction: Implications for Cancer Drug Discovery and Development. *Biomolecules*, 14(3), 339. https://doi.org/10.3390/biom14030339.

[17] The Nobel Prize in Chemistry 2024, "Summary," The Nobel Prize, October 12, 2024, https://www.nobelprize.org/prizes/chemistry/2024/summary/.

AI is also advancing other areas of biotechnology, such as clinical trial optimization, where machine learning algorithms can improve patient recruitment and predict trial outcomes, potentially reducing the high costs and failure rates that plague drug development.[18] Additionally, AI-powered tools are enabling researchers to design entirely new biological systems, from engineering microbes that can produce new fuels to creating novel enzymes (biological catalysts that speed reactions) for industrial manufacturing, opening possibilities that were previously beyond human capability.[19]

Biotechnology Applications

Emerging biotechnology has many applications outside of human health and is poised to play a critical role in other industries such as energy, agriculture, and industrial manufacturing.

Energy

The Department of Energy (DOE) has a wide array of biotechnology R&D programs that push the frontiers of science, national security, and applied energy. The Bioenergy Technologies Office (BETO) within the Office of Energy Efficiency and Renewable Energy (EERE) supports applied research in using biomass and waste resources to produce biofuels and bioproducts.[20] The Biological and Environmental Research (BER) program within the Office of Science works to provide an increased understanding of microbe and plant biology to develop advanced biofuels and bioproducts.[21] Through the Joint Genome Institute (JGI), DOE works to provide genome sequencing, analysis, and data acquisition to support mission needs in bioenergy, environmental remediation, and biogeochemical processing.[22]

DOE also has four Bioenergy Research Centers each taking distinct approaches toward accelerating the pathway to not only improving but scaling up bioproduct production processes and advanced biofuels. The Center for Advanced Bioenergy and Bioproducts Innovation (CABBI) is working with energy crops to economically convert biomass into valuable chemicals that can then be used as fuels or for other purposes.[23] The Center for Bioenergy Innovation (CBI) is working to strengthen the bioenergy supply chain by accelerating the domestication of high-density bioenergy plants and microbes. The Great Lakes Bioenergy Center (GLBRC) is developing technologies that increase the efficiency of processing biomass into advanced biofuels and bioproducts. Lastly, the Joint BioEnergy Institute (JBEI) uses advanced robotics, chemical engineering, molecular biology, and supercomputing capabilities to develop biofuels and bioproducts from biomass.

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[18] Fletcher, L. "AI in Drug Discovery 2024: Where are we now?", Front Line Genomics, April 3, 2024, available at https://frontlinegenomics.com/ai-in-drug-discovery-2024-where-are-we-now/.
[19] Wheeler, N.E. (2025). Responsible AI in biotechnology: balancing discovery, innovation and biosecurity risks. *Front. Bioeng. Biotechnol.* 13:1537471. doi: 10.3389/fbioe.2025.1537471
[20] About the Bioenergy Technologies Office | Department of Energy
[21] BER Biological Systems Science D... | U.S. DOE Office of Science (SC)
[22] BER DOE Joint Genome Institute | U.S. DOE Office of Science (SC)
[23] Bioenergy Research Centers | Genomic Science Program

Agriculture

The application of modern biotechnology to agriculture in the United States was established in the 1990s with the first successful commercialization of a biotechnology-derived crop. Many new crop varieties have since been developed and made available to farmers. In 2012, 88 percent of the corn, 94 percent of the cotton, and 93 percent of the soybeans planted in the U.S. were varieties produced through genetic engineering.[24] Biotechnology methods are being used to protect crops from environmental threats such as pests and drought, to reduce inputs, to improve the nutritional value of crops, and to increase harvest yields.

Aside from biotechnology improving agricultural production, agricultural waste has the potential to serve as bio-feedstocks to support multiple industries, including the manufacturing of bio-based polymers, chemicals, sustainable materials, and aviation fuel. Recent investments in fundamental research to explore biorefining and biomanufacturing are contributing to the creation of a sustainable bioeconomy.[25]

Biomanufacturing

Biomanufacturing is the use of biological systems to create clinical and commercial products through processes such as fermentation.[26] Similar to the production of beer, biomanufacturers can use fermentation to make a variety of products, including pharmaceuticals,[27] baby formula,[28] textiles,[29] and bulletproof vests.[30] By using readily available materials like corn as feedstocks, biomanufacturing facilities can be established anywhere in the country, shortening supply chains and reducing vulnerabilities.[31]

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[24] USDA, "Biotechnology," Available at: https://www.usda.gov/farming-and-ranching/plants-and-crops/biotechnology.

[25] National Institute of Food and Agriculture, USDA, "NIFA Invests $8M in Biorefining and Biomanufacturing", https://www.nifa.usda.gov/about-nifa/announcements/nifa-invests-8m-biorefining-biomanufacturing-a1531#:~:text=Biorefining%20is%20the%20process%20of,into%20usable%20chemicals%20and%20bioproducts.

[26] National Security Commission on Emerging Biotechnology, "Biomanufacturing 101", April 2024, https://www.biotech.senate.gov/wp-content/uploads/2024/04/NSCEB_WP_Biomanufacturing.pdf.

[27] Carsanba, E., Pintado, M., & Oliveira, C. (2021). Fermentation Strategies for Production of Pharmaceutical Terpenoids in Engineered Yeast. *Pharmaceuticals (Basel, Switzerland), 14*(4), 295. https://doi.org/10.3390/ph14040295.

[28] Piephoff, Sarah. "Biomanufacturing human milk components to improve early-life nutrition." https://www.nature.com/articles/d43747-024-00023-9.

[29] Ramsey, A., "Fermented Fashion", Biotech Connection, November 24, 2020, https://biotechconnectionbay.org/viewpoint/fermented-fashion/.

[30] Rose, P., "Spider research: From bone regeneration to bulletproof vests", Military Times, February 23, 2021, https://www.militarytimes.com/opinion/commentary/2021/02/23/spider-silk-research-from-bone-regeneration-to-bulletproof-vests/.

[31] *Supra* note 25.

Research Security

As biotechnology advances, materials and equipment will become more accessible to the general public. However, the availability of benchtop DNA synthesizers coupled with hardware automation may pose a threat to society that should be thoughtfully considered.[32] The potential for bioengineered organisms to escape laboratories, whether through benign activities or the purposeful actions of malicious entities, poses a significant risk.[33] These risks are further amplified by the integration of AI in synthetic biology.

Any actions to mitigate such threats should aim to educate individuals about the risks associated with synthetic biology methods, while also protecting the ability of researchers to advance our knowledge for societal benefit and national defense. Synthetic biology itself could be a solution to some of our greatest security concerns. To maintain leadership in biotechnology, the United States should consider options that promote a research and innovation system that incorporates biosafety and biosecurity, while minimizing the risks associated with the misuse of technological advancements.[34]

Although many Americans interact with and consume biotechnology products daily, unlocking the full potential of this field will require a bioliterate society. The National Security Commission on Emerging Biotechnology defines "biolitteracy" as "the concept of imbuing people, personnel, or teams with an understanding of – and ability to engage with – biology and biotechnology." Ensuring broad access to foundational knowledge, including core competencies in biosecurity and biosafety, will foster a responsible and informed citizenry capable of realizing the promises of biotechnology for economic and societal benefit.[35]

Further Reading

Charting the Future of Biotechnology: An action plan for American security and prosperity (NSCEB report, congressionally directed in the FY2022 NDAA)
Synthetic/Engineering Biology: Issues for Congress (CRS)
Science & Tech Spotlight: Synthetic Biology (GAO)
Stanford Emerging Technology Review: Reporting on Key Technology Areas and their Policy Implications
Biomanufacturing 101
Bioliteracy for the Age of Biology
Summary of the 2019 White House Summit on America's Bioeconomy

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[32] Langenkamp, M., "Securing Benchtop DNA Synthesizers", Institute for Progress, December 10, 2024, https://ifp.org/securing-benchtop-dna-synthesizers/.
[33] *Supra* note 7.
[34] *Supra* note 7.
[35] NSCEB, "Fact Sheet: Bioliteracy for the Age of Biology". February 2024.