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# Congress of the United States

## House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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December 15, 2025

**MEMORANDUM**

TO: Members of the Subcommittee on Oversight and Investigations
FROM: Committee Majority Staff
RE: Subcommittee on Oversight and Investigations Hearing on December 17, 2025

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## I. INTRODUCTION

The Subcommittee on Oversight and Investigations will hold a hearing on Wednesday, December 17, 2025, at 10:15 a.m. (ET), in 2123 Rayburn House Office Building. The hearing is entitled, "Examining Biosecurity at the Intersection of AI and Biology."

## II. WITNESSES

- **Matthew F. McKnight, MPP, MBA,** General Manager, Biosecurity, Ginkgo Bioworks;
- **James Diggans, PhD,** Vice President, Policy and Biosecurity, Twist Bioscience Corporation;
- **Jassi Pannu, MD**, Assistant Professor, Department of Environmental Health and Engineering, Johns Hopkins Bloomberg School of Public Health and Senior Scholar, Johns Hopkins Center for Health Security; and
- **Fiona Havers, MD, MHS, FIDSA**, Former Lead of the Centers for Disease Control and Prevention Respiratory Virus Hospitalization Surveillance Network Team.

## III. BACKGROUND

Rapid advances in synthetic biology, gene-editing technologies, and artificial intelligence (AI) in the last decade have opened the door to important scientific advancement. At the same time, these advancements have the potential to be misused and lower some of the barriers that prevent the manipulation and production of dangerous biological agents. Moreover, tools that were once limited to high-end research laboratories are now accessible globally, including to state and non-state actors with malicious intent. These developments present both unprecedented

opportunities for biomedical innovation and profound new risks to national and global security.[1] This hearing will examine the emerging threat landscape arising from the convergence of AI and biotechnology, assess the adequacy of the current U.S. oversight system, and explore ways to mitigate risks while supporting the U.S.'s technical leadership and enabling scientific progress.

The combination of AI and synthetic biology represents a watershed moment in the research and development of the life sciences. As AI systems become capable of designing organisms with traits beyond natural developmental limits, the U.S. must examine whether existing biosafety, biosecurity, and AI governance structures remain adequate. Prominent technology leaders have warned that adversarial nations such as North Korea, Iran, and Russia could rapidly leverage AI-enabled biological design capabilities in the absence of strong U.S. and allied safeguards.[2]

Synthetic biology encompasses the tools and techniques used to modify or create biological organisms.[3] Although genetic manipulation dates back to selective breeding and early deoxyribonucleic acid (DNA) research in the mid-20th century, recent breakthroughs have revolutionized biotechnological capabilities.[4] Beginning in the 1970s, scientists successfully altered the genomes of viruses, bacteria, and eventually mammals and plants.[5] The emergence of the gene-editing tool CRISPR-Cas9 (Clustered Regularly Interspaced Short Palindromic Repeats and CRISPR-associated protein 9) in the past decade revolutionized biotechnology.[6] This tool acts like molecular scissors to cut and modify DNA by making precise genetic manipulation

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[1] Ashish Jha et al., *The U.S. could soon face a threat 'more powerful' than nuclear weapons*, THE WASHINGTON POST (Nov. 11, 2024), https://www.washingtonpost.com/opinions/2024/11/11/biological-fwarfare-prevention/; *see also* NATIONAL SECURITY COMMISSION ON EMERGING BIOTECHNOLOGY (NSCEB), *Charting the Future of Biotechnology* 116 (Apr. 2025), https://www.biotech.senate.gov/wp-content/uploads/2025/10/NSCEB-%E2%80%93-Full-Report-%E2%80%93-Sep-30-.25.pdf.

[2] Fiona Jackson, *OpenAI Warns Its Next AI Models May Help Bad Actors Create Bioweapons,* EWEEK (June 20, 2025), https://www.eweek.com/news/openai-ai-models-bioweapons/.

[3] Nicholas Cropper, *CRISPR is Making Bioweapons More Accessible,* AMERICAN SECURITY PROJECT (Apr. 29, 2020), https://www.americansecurityproject.org/crispr-is-making-bioweapons-more-accessible/.

[4] Daniel L. Hartl & Vitezslav Orel, *What did Gregor Mendel think he discovered?,* 131 GENETICS 245 (June 01, 1992), https://academic.oup.com/genetics/article-abstract/131/2/245/6007316?redirectedFrom=fulltext.

[5] David A. Jackson et. al., *Biochemical method for inserting new genetic information into DNA of simian virus 40: Circular SV40 DNA molecules containing lambda phage genes and the galactose operon of escherichia coli,* 69 Proceedings of the National Academy of Sciences 2904-2909 (Oct. 15, 1972), https://www.pnas.org/doi/10.1073/pnas.69.10.2904?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub++0pubmed; *see also* Stanley N. Cohen & Annie C. Chang, *Recircularization and autonomous replication of a sheared R-factor DNA segment in escherichia coli transformants,* 70 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES 1293-1297 (May 15, 1973), https://www.pnas.org/doi/10.1073/pnas.70.5.1293?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed; *see also* Rudolf Jaenisch & Beatrice Mintz*, Simian virus 40 DNA sequences in DNA of healthy adult mice derived from preimplantation blastocysts injected with viral DNA,* 71 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES 1250-1254 (Apr. 15, 1974); *see also* Peggy G. Lemaux*, Genetically engineered plants and foods: A scientist's analysis of the issues (part I),* 59 ANNUAL REVIEW OF PLANT BIOLOGY 771-812 (June 2008), https://www.annualreviews.org/content/journals/10.1146/annurev.arplant.58.032806.103840.

[6] Yuanyuan Xu & Zhanjun Li, *CRISPR-Cas Systems: Overview, innovations and applications in human disease research and Gene Therapy*, 18 COMPUTATIONAL AND STRUCTURAL BIOTECHNOLOGY JOURNAL 2401-2415 (Sept. 8, 2020), https://www.csbj.org/article/S2001-0370(20)30384-6/fulltext.

faster, simpler, and far less expensive.[7] CRISPR-Cas9 adapts a naturally occurring bacterial immune defense system to edit DNA, allowing researchers to use a cell's own DNA to add or delete pieces of genetic material, or even replace entire segments of DNA sequences.[8] Today, a basic CRISPR-Cas9 editing kit can be purchased online for under $300, making gene editing tools more accessible.[9]

While biological manipulation dates back hundreds of years, more recent advances in AI have had profound effects on the biological sciences. There are two major advancements in AI of particular concern. First, large language models (LLMs) are lowering informational barriers for perpetrating biological attacks.[10] Moreover, AI-enabled biotechnology has eroded traditional "passive" biodefense barriers—such as cost, expertise, and supply-chain constraints—that previously limited the feasibility of biological weapons development.[11]

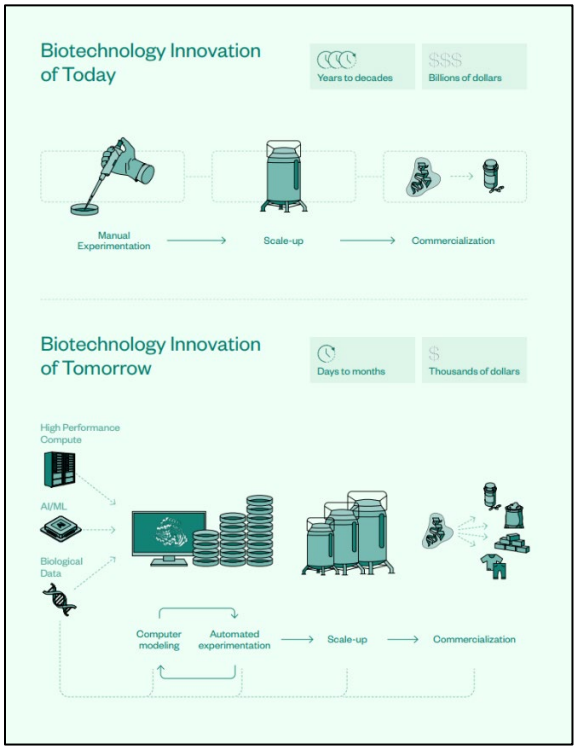


Figure 1: The Future of Biotechnology Innovation[12]

[7] *What is CRISPR-Cas9?* YOUR GENOME (last accessed Dec. 9, 2025), https://www.yourgenome.org/theme/what-is-crispr-cas9/.
[8] *What are genome editing and CRISPR-Cas9?* MedlinePlus (last visited Dec. 1, 2025), https://medlineplus.gov/genetics/understanding/genomicresearch/genomeediting/.
[9] Nicholas Cropper, *CRISPR is Making Bioweapons More Accessible*, AMERICAN SECURITY PROJECT (Apr. 29, 2020), https://www.americansecurityproject.org/crispr-is-making-bioweapons-more-accessible/.
[10] Georgia Adamson & Gregory C. Allen, *Opportunities to Strengthen U.S. Biosecurity from AI-Enabled Bioterrorism: What Policymakers Should Know*, CENTER FOR STRATEGIC AND INTERNATIONAL STUDIES (Aug. 6, 2025), https://www.csis.org/analysis/opportunities-strengthen-us-biosecurity-ai-enabled-bioterrorism-what-policymakers-should.
[11] Anthropic, *Why do we take LLMs seriously as a potential source of biorisk?* (Sept. 5, 2025), https://red.anthropic.com/2025/biorisk/.
[12] NSCEB, *Charting the Future of Biotechnology* 116 (Apr. 2025), https://www.biotech.senate.gov/wp-content/uploads/2025/10/NSCEB-%E2%80%93-Full-Report-%E2%80%93-Sep-30-.25.pdf.

According to a study by Gryphon Scientific, advanced LLMs such as Anthropic's Claude and OpenAI's ChatGPT can provide users detailed, technically accurate guidance across the entire spectrum of biological weapon development.[13] For example, LLMs have been shown to:

- Assist trained scientists by advising on agent formulation, environmental release parameters, or optimal targeting strategies—topics traditionally outside formal scientific training.[14]

- Support inexperienced individuals by identifying exploitable pathogen strains, describing acquisition pathways, or troubleshooting complex laboratory protocols.[15]

- Help bypass biosecurity safeguards designed to prevent unauthorized access to regulated pathogens.[16]

Second, AI biological design tools (BDT) may assist malign actors in developing novel pathogens that could pose a threat.[17] A recent paper by the Nuclear Threat Initiative defined BDTs as "technologies that enable the engineering of biological systems. These tools are trained on biological data and are developed to provide insights, predictions, and designs related to biological systems."[18] While BDTs have the potential to accelerate progress, "there are risks BDTs could be misused to design dangerous pathogens, and few safeguards exist to ensure that the benefits of these technologies can be realized safely and securely."[19] For example, on February 19, 2025, researchers announced the release of Evo 2, the largest open-source AI model for biology.[20] The model is trained on 9.3 trillion nucleotides from over 100,000 species.[21] In addition, the 2024 Nobel Prize in Chemistry went to developers of Google DeepMind's AlphaFold "for accurately predicting the three-dimensional structure of proteins from their amino acid sequences."[22] Although BDTs make valuable scientific advances, they can generate "presumably more capable future tools," including harmful ones.[23]

## A. Risks of AI-Enabled Biotechnology

Advanced AI-enabled biotechnology presents novel risks to biosecurity. In 2023, biosecurity experts warned senior U.S. officials that AI-enabled biotechnology systems may soon

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[13] *Written Statement by Rocco Casagrande, PhD., Executive Chair, Gryphon Scientific, before U.S. Senate AI Forum: Risk, Alignment and Guarding Against Doomsday Scenarios* (Dec. 6, 2023), https://www.schumer.senate.gov/imo/media/doc/Rocco%20Casagrande%20-%20Statement.pdf.
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] G. Adamson & G. Allen, *supra* note 10.
[18] Sarah R. Carter et al., *Developing Guardrails for Biodesign Tools*, Nuclear Threat Initiative Report (Nov. 14, 2024), https://www.nti.org/analysis/articles/developing-guardrails-for-ai-biodesign-tools/.
[19] *Id.*
[20] Arc Institute, *AI can now model and design the genetic code for all domains of life with Evo 2* (Feb. 19, 2025), https://arcinstitute.org/news/evo2.
[21] *Id.*
[22] G. Adamson and G. Allen, *supra* note 10.
[23] *Id.*

allow not only the recreation of known pathogens, but the design of entirely novel agents with enhanced lethality or transmissibility.[24] Some analysts have warned that AI-enabled synthetic pathogens could surpass the global impact of COVID-19, with one industry leader estimating the plausible creation of a pathogen combining Ebola-level fatality with influenza-like transmissibility—potentially causing "more than a billion deaths in a matter of months."[25]

A 2025 forecasting study reported that rapid progress in AI systems may have increased human-caused pandemic risk fivefold in a single year.[26] Another 2025 study showed that frontier AI models (the most advanced forms of AI) now outperform PhD-level virologists on complex laboratory troubleshooting tasks—improving legitimate research but also lowering the threshold for misuse by non-experts.[27]

As with other biotechnology, AI-enabled biotechnology would likely have a dual-use function.[28] While AI offers incredible potential, such as accelerated drug discovery, there are also great risks, some of which we may not yet fully understand.[29] For example, AI-enabled biotechnology could be misused to create new bioweapons.[30] A 2022 study demonstrated that AI drug discovery programs can be used to create more than 40,000 toxic molecules, including some agents that were known chemical warfare molecules.[31]

Adversarial exploitation of frontier models, like Anthropic's Claude, is possible. In 2023, Anthropic voluntarily pledged not to release earlier versions of Claude it feared were capable of assisting malign actors to develop bioweapons or engineer a novel pandemic pathogen until appropriate safety systems were developed.[32] The latest version of Claude, Opus 4, was launched in May 2025, and incorporates the strictest safety measures designed to prevent scientific misuse of any Anthropic model to date.[33] For example, Opus 4 has internal constraints that prevent the model from assisting with certain tasks related to chemical, biological, radiological, or nuclear weapons development.[34] According to a statement from Anthropic, "improving model

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[24] Riley Griffin, *AI-Made Bioweapons Are Washington's Latest Security Obsession,* BLOOMBERG LAW NEWS (Aug. 2, 2024), https://www.bloomberg.com/news/features/2024-08-02/national-security-threat-from-ai-made-bioweapons-grips-us-government.
[25] Roger Brent et al., *The New Bioweapons: How Synthetic Biology Could Destabilize the World,* FOREIGN AFFAIRS (Aug. 20, 2024), https://www foreignaffairs.com/world/new-bioweapons-covid-biology; *see also* Joshua Keating, *Will we know if the next plague is human-made?* VOX, (July 8, 2025) (quote from Mustafa Suleyman, CEO, Microsoft AI) https://www.vox.com/future-perfect/417791/ai-bioweapons-detection-pandemics-ginkgo-endar-bioradar.
[26] Billy Perrigo, *In the Loop: Is AI Making the Next Pandemic More Likely?,* TIME (July 1, 2025), https://time.com/7298731/in-the-loop-pandemic-ai-study/.
[27] *Id.*
[28] Scott Hadly, *Managing risks in AI-powered biomedical research*, Stanford Human Centered Artificial Intelligence, https://hai.stanford.edu/news/managing-risks-ai-powered-biomedical-research (last visited Dec. 8, 2025).
[29] *Id*.
[30] *Id.*
[31] Fabio Urbina et al., *Dual use of artificial-intelligence-powered drug discovery*, 4 Nature Machine Intelligence 189-191 (Mar. 07, 2022), https://www.nature.com/articles/s42256-022-00465-9.
[32] Billy Perrigo, *Exclusive: New Claude Model Triggers Stricter Safeguards at Anthropic,* TIME (May 22, 2025), https://time.com/7287806/anthropic-claude-4-opus-safety-bio-risk/.
[33] *Id.*
[34] Anthropic, *Why do we take LLMs seriously as a potential source of biorisk?* (Sept. 5, 2025), https://red.anthropic.com/2025/biorisk.

performance on our evaluations meant we could no longer confidently rule out the ability of our most advanced model to uplift people with basic STEM [science, technology, engineering, and mathematics] backgrounds if they were to try to develop such weapons" without an enhanced safety framework.[35]

Additionally, in July 2025, OpenAI upgraded the potential biological risk level for its latest ChatGPT-5 model due to its "capabilities that create new risks of severe harm."[36] To mitigate this risk, OpenAI implemented additional safeguards within the model, including comprehensive threat modeling, dual-use refusal training, classifiers and reasoning monitors, adversarial red-teaming, and enforcement pipelines with external experts and government entities.[37]

## B. Beneficial Applications of AI in Biotechnology

Despite the risks, the integration of AI and biotechnology has the potential to drive extraordinary scientific progress. The 2024 Nobel Prize in Chemistry was awarded for AI tools capable of predicting protein structures—solving a major challenge that has hindered drug development for decades.[38] Other advances demonstrated the ability to design entirely new proteins, enabling applications in medicine, vaccines, nanotechnology, diagnostics, and environmental remediation.[39]

AI-enabled biotechnology is already showing benefits today as can be seen in some late phase clinical trials. For example, one therapeutics company has used AI to develop two therapies engineered for treating asthma in patients with a severe form of the disease and other severe respiratory diseases.[40] Using AI, researchers were able to develop new therapies that had a better ability to bind to their target than previous treatments by up to 20 times.[41] This increased ability increases its efficacy over the standard treatment.[42] This therapy has just entered Phase 3 clinical trials for asthma and Phase 1 clinical trials for chronic obstructive pulmonary disease (COPD). [43] If successful, and with Food and Drug Administration (FDA) approval, this would be among the first AI-enabled drugs to come to the U.S. market.[44]

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[35] *Id.*
[36] OpenAI, *Preparing for future AI capabilities in biology* (Jun. 18, 2025), https://openai.com/index/preparing-for-future-ai-capabilities-in-biology/.
[37] *Id.*
[38] Press Release, THE ROYAL SWEDISH ACADEMY OF SCIENCES, Nobel Prize in Chemistry 2024 (Oct. 9, 2024), https://www nobelprize.org/uploads/2024/10/press-chemistryprize2024-3.pdf.
[39] *Id.*
[40] Generate: Biomedicines, *Generate:Biomedicines to Initiate Global Phase 3 Studies of GB-0895, a Long-Acting Anti-TSLP Antibody for Severe Asthma Engineered with AI*, https://generatebiomedicines.com/media-center/generatebiomedicines-to-initiate-global-phase-3-studies-of-gb-0895-a-long-acting-anti-tslp-antibody-for-severe-asthma-engineered-with-ai (last visited Dec 8, 2025).
[41] Tanvi Gawde et al., *A long-acting high affinity anti-TSLP antibody (GB-0895) for severe asthma identified leveraging a proprietary machine learning platform*, EUROPEAN RESPIRATORY SOCIETY (2024), https://publications.ersnet.org/content/erj/64/suppl68/pa2983.
[42] *Id.*
[43] *Id.*
[44] *Id.*

### C. Case Study: AI-Designed Viruses at Stanford University

In December 2024, scientists from Stanford, Princeton, the Massachusetts Institute of Technology, the University of Cambridge, and other institutes assessed "that existing studies around AI-related biorisk are nascent, often speculative in nature, or limited in terms of their methodological maturity and transparency."[45] That assessment has been superseded by recent events, which illustrates the fast-changing nature of AI development and the threat landscape.[46] Specifically, in September 2025, Stanford researchers demonstrated the first complete viral genome designed using AI.[47] Taking a known virus that infects bacteria as a template, the researchers used an AI program that creates genetic sequences to generate approximately 300 candidate viral genomes.[48] This AI program was based on training from over 2 million viral sequences; produced functional synthetic viruses that infect bacteria; and created viruses with mutations not found in nature, some predicted by experts to be non-viable.[49] Notably, the AI program generated viruses that outperformed natural strains in infecting and killing *E. coli* bacteria.[50]

This study demonstrates that AI can generate entirely new, functional biological entities with enhanced capabilities—holding promise for fighting antibiotic-resistant infections while also raising profound biosecurity concerns.[51] For instance, the same method could be used for nefarious purposes in which a state or non-state actor chooses to develop a pathogen with increased lethality or pathogenicity against humans, livestock, or agriculture.

### D. Regulatory Landscape

A pertinent national security regulatory infrastructure exists to help with securing dangerous pathogens. Specifically, in the aftermath of a bioterrorism attack in the 1990s and the anthrax mailings in 2001, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 required the U.S. Department of Health and Human Services (HHS) to establish and regulate a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety.[52] This list, known as the Federal Select Agent Program (FSAP), "is jointly [managed] by the Division of Select Agents and Toxins within the Centers for Disease Control and Prevention (CDC) and the Agriculture Select Agent Services within the U.S.

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[45] Aidan Peppin et al., *The reality of AI and Biorisk*, PROCEEDINGS OF THE 2025 ACM CONFERENCE ON FAIRNESS, ACCOUNTABILITY, AND TRANSPARENCY (June 23, 2025), https://dl.acm.org/doi/10.1145/3715275.3732048.
[46] *Id.*
[47] Samuel H. King et al., *Generative design of novel bacteriophages with genome language models,* bioRxiv preprint (2025), https://www.biorxiv.org/content/10.1101/2025.09.12.675911v1 full.pdf.
[48] *Id.*
[49] Elizabeth T. Ogunbunmi et al., *The effects of packaged, but misguided, single-stranded DNA genomes are transmitted to the outer surface of the ΦX174 capsid*, 95 JOURNAL OF VIROLOGY 10–1128 (Aug. 25, 2021), https://journals.asm.org/doi/10.1128/jvi.00883-21?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub++0pubmed.
[50] Samuel H. King et al., *Generative design of novel bacteriophages with genome language models,* bioRxiv preprint (2025), https://www.biorxiv.org/content/10.1101/2025.09.12.675911v1 full.pdf.
[51] *Id.*
[52] Pub. L. No. 107-188, as amended; 42 U.S.C. § 262a.

Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)."[53] Together, these components within CDC and APHIS regulate and oversee all high-containment laboratories in the U.S. that register to work with select agents."[54]

While the FSAP has been helpful in regulating existing biological agents and toxins, experts have noted that FSAP is inadequate to detect AI-generated novel sequences that do not match the 63 regulated toxins, pathogens, and bacteria on the Select Agents and Toxins List.[55] One expert noted that "just one sufficiently different genomic sequence could be enough to unleash a highly contagious virus or even start the next global pandemic."[56] In an April 2025 report, the National Security Commission on Emerging Biotechnology called measures like the FSAP "blunt and reactive" for "poorly understood" and "emerging" risks.[57]

Moreover, current U.S. frameworks—including the U.S. Government Policy for Oversight of Dual Use Research of Concern[58] and the HHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (P3CO framework)[59]—may not apply to AI-enabled biotechnological research because the organisms involved may not be on the Select Agents and Toxins List; the altered pathogen might not be known to infect humans; and much cutting-edge AI-assisted biological design occurs outside of federally funded research environments.

Since 2010, HHS and Office of Science and Technology Policy (OSTP) have published three major frameworks "to encourage companies to screen synthesis orders for harmful genetic content" and "to mitigate biosecurity risks."[60] In 2010, HHS released the "Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA."[61] This established the first set of baseline safety and security standards for the gene and genome synthesis industry, as well as for other providers of synthetic double-stranded DNA products.[62] The 2023 "HHS Screening Framework Guidance for Providers and Uses of Synthetic Nucleic Acids" updated the 2010 guidance and outlined the following actions: "providers should screen all nucleic acid sequences for 'best matches' to" federal select agents; "providers and customers should verify, track, and record any transfer of sequences of concern (SOC)"; "providers and equipment manufacturers

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[53] CENTERS FOR DISEASE CONTROL AND PREVENTION AND U.S. DEPARTMENT OF AGRICULTURE, Federal Select Agent Program, *2024 Annual Report of the Federal Select Agent Program* (last reviewed Sept. 3, 2025), https://www.selectagents.gov/index.htm.
[54] GOVERNMENT ACCOUNTABILITY OFFICE, GAO-18-145, *High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens* (Oct. 31, 2017), https://www.gao.gov/products/gao-18-145.
[55] G. Adamson and G. Allen, *supra* note 10.
[56] *Id.*
[57] NSCEB, *supra* note 12.
[58] EXECUTIVE OFFICE OF THE PRESIDENT, IMPLEMENTATION GUIDANCE FOR THE UNITED STATES GOVERNMENT POLICY FOR OVERSIGHT OF DUAL USE RESEARCH OF CONCERN AND PATHOGENS WITH ENHANCED PANDEMIC POTENTIAL (May 6, 2024), https://bidenwhitehouse.archives.gov/wp-content/uploads/2024/05/USG-DURC-PEPP-Implementation-Guidance.pdf.
[59] Todd Kuiken, CONG. RESEARCH SERV., IN12109, Improved Oversight of Pathogen Research: Recent Recommendations (Feb. 15, 2023), https://www.congress.gov/crs_external_products/IN/PDF/IN12109/IN12109.1.pdf.
[60] G. Adamson and G. Allen, *supra* note 10.
[61] *Id.*
[62] *Id.*

should strengthen cyber and informational security measures"; and "equipment manufacturers should perform customer-screening processes, integrate SOC screening capabilities into equipment, and take security measures to ensure equipment cannot be overridden by unauthorized actors."[63] The 2024 OSTP "Framework for Nucleic Acid Synthesis Screening" builds upon previous iterations, while incorporating updates on reporting processes, as well as cybersecurity and supply chain security practices.[64]

### E. Recent Executive Actions

The Trump Administration has taken steps to address biosecurity risks resulting from enhanced capabilities and access to novel technologies. Executive Order 14292, titled "Improving the Safety and Security of Biological Research," in part directs the OSTP Director, in coordination with the National Security Advisor and heads of relevant agencies, to revise or replace the 2024 "United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential."[65] This order is intended to strengthen top-down independent oversight and accountability of life sciences research while ensuring the U.S. remains a global leader in biotechnology.[66] The Executive Order also directs the OSTP Director, in coordination with the National Security Advisor, to revise or replace the 2024 Framework for Nucleic Acid Synthesis Screening to "ensure it takes a commonsense approach and effectively encourages providers of synthetic nucleic acid sequences to implement comprehensive, scalable, and verifiable synthetic nucleic acid procurement screening mechanisms to minimize the risk of misuse."[67]

In July 2025, the Trump Administration also released "Winning the Race: America's AI Action Plan," which highlights the need for the U.S. government's investment in biosecurity as a component of AI innovation.[68] The AI Action Plan requires all institutions receiving federal funding for scientific research to use nucleic acid synthesis tools and synthesis providers that have customer vetting and screening procedures, rather than relying on voluntary attestation.[69] Additionally, OSTP should "convene government and industry actors to develop a mechanism to facilitate data sharing between nucleic acid synthesis providers to screen for potentially fraudulent or malicious customers."[70] The AI Action Plan also includes evaluation of novel national security risks of frontier AI models.[71]

In a September 23, 2025, memo from the Office of Management and Budget Director, Russell Vought, and OSTP Director, Michael Kratsios, federal agencies were directed to

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[63] *Id.*
[64] *Id.*
[65] Exec. Order No. 14292, 90 Fed. Reg. 19611 (May 5, 2025), https://www federalregister.gov/documents/2025/05/08/2025-08266/improving-the-safety-and-security-of-biological-research.
[66] *Id.*
[67] *Id.*
[68] EXECUTIVE OFFICE OF THE PRESIDENT, WINNING THE RACE: AMERICA'S AI ACTION PLAN, 23 (July 2025), https://www.whitehouse.gov/wp-content/uploads/2025/07/Americas-AI-Action-Plan.pdf.
[69] *Id*.
[70] *Id.*
[71] *Id.* at 22.

prioritize research and development funding to prepare for and respond to biological threats, including advancing biosecurity and nucleic acid screening methods.[72]

Lastly, the Trump Administration recently announced the Genesis Mission which aims to develop a coordinated national effort to unleash AI-accelerated innovation and discovery that can solve the most challenging problems of this century.[73] The Genesis Mission proposes to build an integrated AI platform to harness federal scientific datasets to train foundation models and create AI agents to accelerate scientific breakthroughs in many categories, including detecting and countering biological threats.[74]

## F. Prior Committee Activity

The Committee has a long-standing record of biosecurity oversight. Below are some of the Committee's more recent hearings related to biosecurity.

On February 1, 2023, the Subcommittee on Oversight and Investigations held a hearing entitled "Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events."[75] The hearing focused on a technical assessment released by the U.S. Government Accountability Office.[76]

On April 27, 2023, the Subcommittee on Oversight and Investigations held a hearing entitled "Biosafety and Risky Research: Examining if Science is Outpacing Policy and Safety."[77] The hearing highlighted the need for more monitoring of riskier high-containment laboratories conducting virus research.[78]

On May 11, 2023, the Subcommittee on Health held a hearing entitled "Preparing for and Responding to Future Public Health Security Threats."[79] The hearing featured two panels

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[72] EXECUTIVE OFFICE OF THE PRESIDENT, M-25-34/NSTM-2, MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES, 5 (Sept. 23, 2025), https://www.whitehouse.gov/wp-content/uploads/2025/09/M-25-34-NSTM-2-Fiscal-Year-FY-2027-Administration-Research-and-Development-Budget-Priorities-and-Cross-Cutting-Actions.pdf.
[73] Exec. Order No. 14363, 90 Fed. Reg. 55035 (Nov. 24, 2025), https://www federalregister.gov/documents/2025/11/28/2025-21665/launching-the-genesis-mission.
[74] *Id.*
[75] *Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce,* 118th Cong. (Feb.1, 2023), https://energycommerce house.gov/events/oversight-and-investigations-subcommittee-hearing-challenges-and-opportunities-to-investigating-the-origins-of-pandemics-and-other-biological-events.
[76] GOVERNMENT ACCOUNTABILITY OFFICE, *Pandemic Origins: Technologies and Challenges for Biological Investigations*, GAO-23-105406 (Jan. 2023), https://www.gao.gov/assets/gao-23-105406.pdf.
[77] *Biosafety and Risky Research: Examining if Science is Outpacing Policy and Safety: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce,* 118th Cong. (Apr. 27, 2023), https://energycommerce house.gov/events/oversight-and-investigations-subcommittee-hearing-the-biosafety-of-risky-research-examining-if-science-is-outpacing-policy-and-safety.
[78] *Id.*
[79] *Preparing for and Responding to Future Public Health Security Threats: Hearing before the Subcomm. on Health of the H. Comm. on Energy and Commerce,* 118th Cong. (May. 11, 2023), https://energycommerce.house.gov/events/health-subcommittee-hearing-preparing-for-and-responding-to-future-public-health-security-threats.

comprised of administration officials, advocates, stakeholders, and subject matter experts.[80] This hearing examined the background, history, and current state of our nation's preparedness and response infrastructure, lessons learned based on prior public health emergencies, and recommendations for how to improve our preparedness and immediate response capabilities against all possible threats.[81]

## IV. KEY QUESTIONS

The hearing may include discussion around the following key questions:

- What are the potential benefits of AI-enabled biotechnology?
- How can safe use of AI-enabled biotechnology improve the U.S.'s biosecurity posture?
- What are the actual and potential risks of AI-enabled biotechnology, including those related to biosecurity and biothreats?
- What steps are being taken to protect Americans from the risks of misuse of AI-enabled biotechnology?
- Is additional action necessary to protect Americans from misuse of AI-enabled biotechnology?

## V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Majority Committee staff at (202) 225-3641.

[80] *Id.*
[81] *Id.*