

Congress of the United States

Washington, D.C. 20515

April 1, 2024

The Honorable Arati Prabhakar
Director, Office of Science and Technology Policy
Executive Office of the President
1650 Pennsylvania Avenue
Washington, DC 20504

Dear Director Prabhakar,

We write regarding the Biden Administration's *Executive Order (EO) 14110 on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence*. In particular, we support the EO's directives to departments and agencies to mitigate risk and reduce misuse of synthetic nucleic acids, including by the development of a screening framework and federal purchasing restrictions (4.4. Reducing Risks at the Intersection of AI and CBRN Threats). Given advances in biotechnology and the proliferation of high containment labs, common-sense oversight of synthetic nucleic acids has never been more necessary.

We encourage the Office of Science and Technology Policy to develop the framework required by the EO effectively and without delay. In our view, effective implementation would include investments in the resources necessary to support gene synthesis screening, biannual reporting from confidential stress-testing, and international harmonization of screening efforts.

Recent statements by the Administration articulate the view that the United States must "seize the tremendous promise and manage the risks posed by Artificial Intelligence (AI) and protect Americans' rights and safety."¹ The recent EO highlights key elements that are essential for studying and understanding the risks that AI poses in the context of Chemical, Biological, Radiological, and Nuclear (CBRN) defense.

Advances in our ability to synthesize DNA have been critical for scientific progress. DNA synthesis facilitates fundamental biology research and lifesaving drug development. However, recent advances in biotechnology and artificial intelligence tools have raised concerns about the reduced barriers to the *de novo* creation of viable pathogens starting with little more than digital information and an order of synthetic nucleic acids.^{2,3,4,5} While *de novo* synthesis is still not straightforward in practice, the screening of synthetic nucleic acids and the customers ordering

¹ "Biden-Harris Administration Secures Voluntary Commitments from Leading Artificial Intelligence Companies to Manage the Risks Posed by AI," White House, July 2023, <https://www.whitehouse.gov/briefing-room/statements-releases/2023/07/21/fact-sheet-biden-harris-administration-secures-voluntary-commitments-from-leading-artificial-intelligence-companies-to-manage-the-risks-posed-by-ai/>

² Christopher Mouton et al., *The Operational Risks of AI in Large-Scale Biological Attacks*, Rand: Global and Emerging Risks, January 25, 2024, https://www.rand.org/pubs/research_reports/RRA2977-2.html

³ Emily Soice et al., *Can large language models democratize access to dual-use biotechnology?*, Cornell University, June 6, 2023, <https://arxiv.org/abs/2306.03809>

them is a critical checkpoint, as it lies at the interface between a digital model providing sensitive pathogen information and a bad actor turning that information into a biological hazard. Despite the importance of screening synthetic nucleic acids, it is still not a universal practice, or well harmonized between different practitioners.⁶

We applaud the ongoing efforts to reduce this risk, including the issuance of the updated Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids by the Department of Health and Human Services and the voluntary, proactive steps that gene synthesis companies have already taken, for example through international collaboration to apply a common protocol to screen customers.^{7,8,9,10} These efforts illustrate how DNA synthesis can be secured from misuse without impeding legitimate scientific or commercial research.

As a DNA synthesis screening framework is established, we are mindful of the importance of effective implementation, which should include:

- Investments in the infrastructure and resources necessary to support screening. There is a significant need for a confidential and secure federal sequence of concern (SOC) database to facilitate screening. Authority regarding the management and oversight of such a database should be clearly assigned, with relevant agency coordination. In addition, to prevent malicious circumvention, a secure industry database is needed that allows companies to share information about orders that raise alarms. Current efforts have had limited impact because they rely on bespoke private databases or ask companies to share too much proprietary information. Additional investment in customer screening and verification especially for international orders is needed, and could draw on the experience of banks in implementing the ‘Know Your Customer’ regime.
- Biannual confidential reporting from confidential stress-testing. Regular stress-testing exercises, including red-teaming (e.g. by having third parties attempt to order sequences of concern from nucleic acid synthesis companies), are critical to uncover vulnerabilities, reveal risks and improve the effectiveness of gene synthesis screening processes. The EO recognizes this and directs the Department of Homeland Security to lead such efforts. Stress-testing should also encompass rigorous evaluation of gene synthesis equipment,

⁴ Sophie Rose and Cassidy Nelson, *Understanding AI-Facilitated Biological Weapon Development*, The Center for Long Term Resilience, October 18, 2023, <https://www.longtermresilience.org/post/report-launch-examining-risks-at-the-intersection-of-ai-and-bio>

⁵ Sarah Carter et al., *The Convergence of Artificial Intelligence and the Life Sciences: Safeguarding Technology, Rethinking Governance, and Preventing Catastrophe*, NTI:bio, October 30, 2023, <https://www.nti.org/analysis/articles/the-convergence-of-artificial-intelligence-and-the-life-sciences/>

⁶ Arianne Kane and Michael T. Parker, *Screening State of Play: The Biosecurity Practices of Synthetic DNA Providers*, Applied Biosafety, February 13, 2024, <https://www.liebertpub.com/doi/10.1089/apb.2023.0027>

⁷ *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*, Department of Health and Human Services, 2023, <https://www.phe.gov/preparedness/legal/guidance/syndna/documents/syndna-guidance.pdf>

⁸ Kelsey Piper, “It’s time to close the gene synthesis loophole that could lead to a human-made pandemic”, Vox, July 27, 2023, <https://www.vox.com/future-perfect/2023/7/27/23808920/gene-dna-synthesis-biotechnology-pandemic-viruses-twist-bioscience-pathogens-ginkgo-bioworks>

⁹ “Where Gene Synthesis and Biosecurity Align”, International Gene Synthesis Consortium, <https://genesynthesisconsortium.org/>

¹⁰ The International Biosecurity and Biosafety Initiative for Science, *The Common Mechanism: An Open-Source, Globally Available Tool for DNA Synthesis Screening*, <https://ibbis.bio/our-work/the-common-mechanism/>

including benchtop synthesizers, alongside a comprehensive assessment of the cybersecurity measures and practices of organizations involved in synthesis. Stress-testing in consultation with members of the intelligence community would ensure that such testing was informed by the best assessment of the threat landscape.

- International harmonization of gene synthesis screening via dialogue including with our strategic allies and relevant non-government organizations. Although many gene synthesis companies have voluntarily adopted screening practices, a lack of international harmonization is by far the most common concern that companies have highlighted. United States leadership in the development and harmonization of standards across borders is in our national interest. Screening domestic and international orders is important for national security and no United States company should be competitively disadvantaged by participating in screening. Ensuring that standards are harmonized across borders makes it easier for companies to comply and is crucial to prevent incidences of misuse and protect our nation's bioeconomy. Over the long term, a broader international approach to DNA synthesis screening is likely to be most effective.

As the agencies consider these recommendations, we urge them to consult with external technical experts, industry leaders, and other stakeholders who have produced thoughtful guidance on this topic^{11,12,13,14,15, 16,17,18}

We thank you for your service in promoting our nation's health security and request a briefing at your earliest convenience on OSTP's planned actions in support of the Executive Order related to gene synthesis screening. We look forward to your timely response.

Sincerely,

¹¹ Bridget Williams and Rowan Kane, *Preventing the Misuse of DNA Synthesis*, Institute for Progress, February 14, 2023, <https://ifp.org/preventing-the-misuse-of-dna-synthesis/>

¹² *National Biodefense Strategy and Implementation Plan*, October 2022, <https://www.whitehouse.gov/wp-content/uploads/2022/10/National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf>

¹³ *Comment on the Revised Screening Framework Guidance from the Technical Consortium for DNA Synthesis Screening*, NTI:bio, June 28, 2022, <https://www.nti.org/wp-content/uploads/2022/06/TC-Final-Comment-on-Revised-Guidance.pdf>

¹⁴ *National Security Commission on Emerging Biotechnology Interim Report*, December 2023, <https://www.biotech.senate.gov/wp-content/uploads/2024/01/Biotech-Commission-Dec2023-Report.pdf>

¹⁵ Sophie Rose and Cassidy Nelson, *Synthetic Nucleic Acid Screening- Overcoming challenges with implementation*, The Center for Long Term Resilience, November 2023, <https://www.longtermresilience.org/post/report-launch-overcoming-challenges-with-synthetic-nucleic-acid-screening-implementation>

¹⁶ Batalis et al., *Safeguarding Mail-Order DNA Synthesis in the Age of Artificial Intelligence*, Applied Biosafety, December 27, 2023, <https://www.liebertpub.com/doi/10.1089/apb.2023.0020>.

¹⁷ *Biosecurity Innovation and Risk Reduction: A Global Framework for Accessible, Safe, and Secure DNA Synthesis*, January 2020. https://www3.weforum.org/docs/WEF_Biosecurity_Innovation_Risk_Reduction.pdf

¹⁸ The International Biosecurity and Biosafety Initiative for Science, *The Common Mechanism: An Open-Source, Globally Available Tool for DNA Synthesis Screening*, <https://ibbis.bio/our-work/the-common-mechanism/>



Julia Brownley
Member of Congress



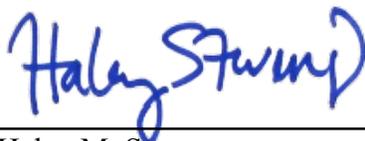
Andy Harris, M.D.
Member of Congress



Bill Foster
Member of Congress



Neal P. Dunn, M.D.
Member of Congress



Haley M. Stevens
Member of Congress



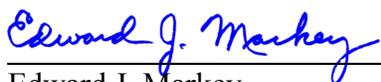
August Pfluger
Member of Congress



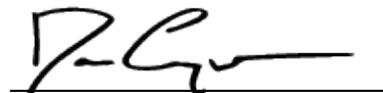
Sara Jacobs
Member of Congress



Rich McCormick, MD, MBA
Member of Congress



Edward J. Markey
United States Senator



Dan Crenshaw
Member of Congress

Cc:

The Honorable Antony Blinken, Department of State, Secretary
The Honorable Lloyd Austin, Department of Defense, Secretary

The Honorable Merrick Garland, Department of Justice, Attorney General
The Honorable Gina Raimondo, Department of Commerce, Secretary
The Honorable Xavier Becerra, Department of Health and Human Services, Secretary
The Honorable Jennifer Granholm, Department of Energy, Secretary
The Honorable Alejandro Mayorkas, Department of Homeland Security, Secretary
The Honorable Avril Haines, Office of the Director of National Intelligence, Director