GENE SYNTHESIS SCREENING

Nucleic acids (eg, RNA and DNA) are large biomolecules essential for all living organisms and viruses

Sequences of nucleic acids, the "building blocks of life," carry genetic information and are responsible for encoding that information into cells. It is now possible to artificially engineer these sequences — known as synthetic gene sequences. Providers in the US and around the world routinely synthesize these materials for use by life sciences labs and researchers.

Screening of gene synthesis orders and the customers who buy these materials can prevent their malicious misuse

All providers of synthetic nucleic acids should screen their customers and their purchase orders to prevent entities with bad intent from acquiring harmful sequences of nucleic acids. Such harmful sequences could be used to synthetically make dangerous pathogens or toxins. Gene synthesis screening allows providers to block the sale of specific nucleic acid sequences to those who have no beneficial or legitimate scientific purpose for acquiring them.

Gene synthesis screening is currently voluntary, providing paths for malicious actors to acquire dangerous materials

Many US-based providers voluntarily screen customer orders. However, to reduce costs, some companies, including some in the US and many outside the US, do not. This creates market conditions that favor companies that do not have to carry the modest cost of screening. As artificial intelligence makes it easier for more people to design increasingly dangerous viruses, this threat will continue to rise.

Recent executive action provides an opportunity to begin shutting down these pathways

The Office for Science and Technology Policy (OSTP) designed the US Framework for Nucleic Acid Synthesis Screening to encourage providers to implement comprehensive screening measures. All customers that receive federal funding will be required to implement this framework by April 2025. An estimated 75% of life sciences research is federally funded (as of late 2024), so this framework represents a significant step forward.

Congress could act to require all providers to adhere to the framework, and by providing funding for the development of a screening standard

Codifying the screening framework and extending it to all entities that purchase synthetic nucleic acids, not just federally funded researchers, would close that remaining 25% risk gap and reduce pathways for malicious actors to acquire dangerous nucleic acid sequences in the US. This approach could provide Congress with more oversight of the screening process and potential incidents that arise.

Congress could also provide the National Institute of Standards & Technology (NIST) with funding for the development of a screening standard, which would further help to develop the US screening market and promote beneficial competition amongst providers.

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