II

118TH CONGRESS
1ST SESSION

S. 2356

To require the Secretary of Health and Human Services to update guidance with respect to gene synthesis, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 18, 2023

Mr. HICKENLOOPER (for himself and Mr. BUDD) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To require the Secretary of Health and Human Services to update guidance with respect to gene synthesis, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Gene Synthesis Safety and Security Act''.

SEC. 2. GENE SYNTHESIS.

(a) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Sec-

retary'') shall update the Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA to account for scientific and technological advancements with respect to mitigating risk of unauthorized individuals or individuals with malicious intent from using nucleic acid synthesis technologies to obtain biological agents or toxins of concern. Such guidance shall include recommendations related to—

(1) screening for sequences that the Secretary determines may contribute to toxicity, pathogenicity, or virulence;

(2) screening and verification of the identity and legitimacy of customers;

(3) the identification, evaluation, and use of appropriate software or other tools to enable the screening described in paragraphs (1) and (2);

(4) ensuring nucleic acid synthesis activities are carried out in compliance with existing regulations under part 73 of chapter 42, part 331 of chapter 7, part 121 of chapter 9, and part 774 of chapter 15, Code of Federal Regulations (or successor regulations);

(5) implementing appropriate safeguards, which may include the use of such software or other tools,

in gene synthesis equipment to facilitate screening of nucleic acid sequences and, as applicable, customers;

(6) maintaining records of customer orders, metadata, and screening system or protocol performance in specified formats, which may include standardized machine-readable and interoperable data formats; and

(7) other recommendations as determined appropriate by the Secretary.

(b) SEQUENCES OF CONCERN.—The Secretary shall maintain a public docket to solicit recommendations on potential sequences of concern and, in consultation with other Federal departments and agencies and non-Federal experts, as appropriate, review and update, on a regular basis, a list of sequences of concern to facilitate screening under subsection (a)(1).

(c) LANDSCAPE REVIEW.—The Secretary, in coordination with other Federal departments and agencies, as appropriate, shall conduct a landscape review of providers and manufacturers of gene synthesis equipment, products, software, and other tools with the purpose of understanding the number, types, and capabilities of products and equipment that exist domestically and to inform the development of any updates to the guidance under subsection (a).

(d) TECHNICAL ASSISTANCE.—The Secretary, in consultation with other Federal departments and agencies, shall provide technical assistance upon request of a gene synthesis provider, manufacturer of gene synthesis equipment, or developer of software or other screening tools to support implementation of the recommendations included in the guidance under subsection (a).

(e) DEFINITIONS.—In this section:

(1) GENE SYNTHESIS EQUIPMENT.—The term ''gene synthesis equipment'' means equipment needed to produce gene synthesis products.

(2) GENE SYNTHESIS PRODUCT.—The term ''gene synthesis product''—

(A) means custom single-stranded or double-stranded DNA, or single-stranded or double-stranded RNA, which has been chemically or enzymatically synthesized or otherwise manufactured de novo and is of a length exceeding the screening threshold, as determined by the Secretary; and

(B) does not include—

(i) base chemical subunits, such as individual nucleotides or nucleosides, or oligonucleotides shorter than the screening threshold typically used as polymerase

chain reaction primers, as determined by the Secretary;

(ii) by-products generated during sequencing that are not useful for assembly or cloning, as determined by the Secretary; or

(iii) products generated from cloning or assembling of existing gene or gene fragment material, in circumstances in which the gene synthesis provider has no access or notice to the sequence design, as determined by the Secretary.

(3) GENE SYNTHESIS PROVIDER.—The term ''gene synthesis provider'' means an entity that synthesizes and distributes gene synthesis products, including bacteria, viruses, or fungi containing recombinant or synthetic nucleic acid molecules, for delivery to a customer.

(4) MANUFACTURER OF GENE SYNTHESIS EQUIPMENT.—The term ''manufacturer of gene synthesis equipment'' means an entity that produces and sells equipment for synthesizing gene synthesis products.

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