

118TH CONGRESS
1ST SESSION

H. R. 4702

To require the Secretary of Health and Human Services to prescribe a regulation reducing the risks in gene synthesis products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 18, 2023

Ms. ESHOO introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To require the Secretary of Health and Human Services to prescribe a regulation reducing the risks in gene synthesis products, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Securing Gene Syn-
5 thesis Act”.

6 **SEC. 2. REQUIREMENTS FOR THE DISSEMINATION OF SYN-**
7 **THETIC GENETIC MATERIAL.**

8 Section 351A of the Public Health Service Act (42
9 U.S.C. 262a) is amended—

1 (1) in subsection (b)(2), by striking the semi-
2 colon at the end and inserting the following: “, in-
3 cluding by—

4 “(A) assessing uncertainties, risks, costs,
5 and benefits associated with the implementation
6 of different types of protocols or other regula-
7 tions to reduce the risk of potential misuse of
8 de novo gene synthesis products;

9 “(B) determining the types of protocols or
10 other regulations that could detect the potential
11 misuse of de novo gene synthesis products while
12 generating benefits that are larger than their
13 costs;

14 “(C) requiring gene synthesis providers or
15 manufacturers of gene synthesis equipment to
16 implement screening protocols to detect misuse
17 of de novo gene synthesis products;

18 “(D) verifying or provisionally verifying
19 that gene synthesis providers and manufactur-
20 ers of gene synthesis equipment adhere to the
21 regulation prescribed pursuant to subparagraph
22 (C); and

23 “(E) assessing, collecting, and waiving fees
24 for enforcing the regulation prescribed pursuant
25 to subparagraph (C); and

1 “(F) requiring any entity receiving Federal
2 funds, or any Federal agency, which purchases
3 de novo gene synthesis products from a gene
4 synthesis provider or gene synthesis equipment
5 from a manufacturer of gene synthesis equip-
6 ment to purchase such products and equipment
7 only if such providers or manufacturers are
8 verified or provisionally verified pursuant to
9 subparagraph (D);”;

10 (2) in subsection (e)(1), by striking the period
11 at the end and inserting “, including through the
12 revocation of Federal research funding for any entity
13 found to be in violation of subsection (b)(2)(E), or
14 through the withholding of such funding for such an
15 entity until the entity demonstrates compliance with
16 such subsection.”;

17 (3) in subsection (k), by adding at the end the
18 following:

19 “(4) USE OF GENE SYNTHESIS PRODUCTS AND
20 GENE SYNTHESIS EQUIPMENT BY FEDERAL AGEN-
21 CIES.—Not later than January 1, 2026, the Sec-
22 retary shall report to the appropriate committees of
23 Congress a description of the policies and procedures
24 adopted by all agencies that fund or conduct life
25 sciences research involving gene synthesis products

1 or gene synthesis equipment to comply with this sec-
2 tion.”;

3 (4) in subsection (l)—

4 (A) by redesignating paragraphs (2), (3),
5 (4), (5), (6), (7), and (8) as paragraphs (5),
6 (6), (8), (9), (10), (11), and (12), respectively;

7 (B) by inserting after paragraph (1) the
8 following:

9 “(2) The term ‘gene synthesis equipment’
10 means equipment that can produce gene synthesis
11 product, regardless of the technical mechanism by
12 which such equipment works.

13 “(3) The term ‘gene synthesis product’—

14 “(A) means custom single-stranded or dou-
15 ble-stranded DNA, or single-stranded or double-
16 stranded RNA, which has been chemically or
17 enzymatically synthesized or otherwise manu-
18 factured de novo and is of a length exceeding
19 the screening threshold; and

20 “(B) does not include—

21 “(i) base chemical subunits, such as
22 individual nucleotides or nucleosides, or
23 oligonucleotides shorter than the screening
24 threshold typically used as polymerase
25 chain reaction primers;

1 “(ii) byproducts generated during se-
2 quencing that are not useful for assembly
3 or cloning, as determined by the Secretary;
4 or

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

11 “(4) The term ‘gene synthesis provider’—

12 “(A) means—

13 “(i) an entity that creates gene syn-
14 thesis product for delivery to a customer in
15 the United States; or

16 “(ii) a distributor of gene synthesis
17 product in the United States, including an
18 entity that manufactures gene synthesis
19 product for use by another party, whether
20 such other party is inside and outside of
21 the entity; and

22 “(B) does not include—

23 “(i) an entity making gene synthesis
24 products for the entity’s own use, in cir-
25 cumstances in which the sequence has been

1 previously screened in compliance with this
2 section;

3 “(ii) an entity that manufactures gene
4 synthesis products in the process of devel-
5 oping or manufacturing another product
6 for a customer, unless the gene synthesis
7 product is provided to the end user thereof;
8 or

9 “(iii) any class of entity that the Sec-
10 retary chooses to exempt, after consider-
11 ation of the costs and benefits of exempt-
12 ing that class of entity from regulation
13 under this section as a gene synthesis pro-
14 vider.”;

15 (C) by inserting after paragraph (6), as so
16 redesignated, the following:

17 “(7) The term ‘manufacturer of gene synthesis
18 equipment’ means an entity that produces for sale
19 gene synthesis equipment.”; and

20 (D) by adding at the end the following:

21 “(13) The term ‘screening threshold’ means the
22 minimal length of de novo gene synthesis product
23 which ensures that the results of such screening con-
24 tain enough information to allow an unambiguous
25 analysis of such product’s potential misuse.”; and

1 (5) in subsection (m), by striking “for each of
2 the fiscal years 2023 through 2027” and inserting
3 “for fiscal year 2023 and each subsequent fiscal
4 year”.

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