.....

(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To improve the security of nucleic acid synthesis in interstate and foreign commerce, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. PFLUGER introduced the following bill; which was referred to the Committee on _____

A BILL

To improve the security of nucleic acid synthesis in interstate and foreign commerce, 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 ''Biosecurity Modernization and Innovation Act''.

SEC. 2. REQUIREMENTS FOR COVERED ENTITIES WITH RESPECT TO HIGH-RISK SEQUENCES.

(a) IN GENERAL.—A covered entity shall establish a program of reasonable administrative and technical proto-

cols to carry out, with respect to any nucleic acid sequence made available in interstate or foreign commerce by such covered entity, the following requirements:

(1) Verify the identity of any buyer or prospective buyer of such a nucleic acid sequence, including with respect to any such nucleic acid sequence generated by a benchtop nucleic acid synthesizer.

(2) Establish the purpose for which any such buyer or prospective buyer seeks to obtain any such nucleic acid sequence.

(3) Identify whether such a nucleic acid sequence, including any such nucleic acid sequence generated by a benchtop nucleic acid synthesizer, is a covered sequence as determined by the Secretary under paragraph (1)(A) of subsection (e), and on the list established and made available under paragraph (1)(C) of such subsection.

(4) Establish risk-based criteria for refusing the sale of a covered sequence to a buyer, prospective buyer, or any combination thereof, and document each instance of refusal by the covered entity in accordance with such criteria.

(5) Provide timely notification to the Secretary if the covered entity has a reasonable belief that such a buyer or prospective buyer is likely to use a

covered sequence in a manner that poses a high risk to the national security of the United States or to the security and safety of persons in the United States.

(6) Ensure regular independent assessment of compliance by the covered entity with paragraphs (1) through (5) and paragraph (7), including through adversarial testing, third-party certifications, independent internal or external audits, direct examination by the Secretary, or any combination thereof.

(7) Maintain records sufficient to demonstrate to the Secretary compliance with the requirements described in paragraphs (1) through (6) for a period of not less than 5 years, as practicable.

(b) GUIDANCE.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary, in consultation with relevant heads of other Federal departments, agencies, or offices, as appropriate, shall issue guidance that identifies the following:

(A) Approaches, best practices, frameworks, and methods that may be implemented,

alone or in combination, by a covered entity to satisfy the requirements under subsection (a).

(B) How a covered entity may ensure regular independent assessment of compliance as described in paragraph (6) of such subsection.

(C) What constitutes a timely notification under paragraph (5) of such subsection, including by when and in what manner a covered entity is required to provide such a notification to the Secretary.

(2) ENFORCEMENT PLAN.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall issue guidance relating to the priorities of the Secretary for enforcing the requirements under subsection (a).

(3) PROCESS.—Any guidance issued by the Secretary under paragraphs (1) and (2) shall be developed through a covered process.

(4) NO CONFERRING OF RIGHTS OR BINDING EFFECT.—Any guidance issued by the Secretary under paragraphs (1) and (2) may not confer any rights on any person, State, or locality or bind the Secretary or any person recommended in such guidance.

(c) NOTIFICATION, COORDINATION, AND DIRECT EXAMINATION.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall establish a means, using a covered process, for the Secretary to carry out the following:

(1) Accept a notification provided by a covered entity under paragraph (5) of subsection (a).

(2) Facilitate coordination with covered entities and stakeholders to identify a buyer, prospective buyer, or any combination thereof, that has split orders across two or more covered entities with the purpose of obtaining or synthesizing a covered sequence.

(3) At the request of a covered entity, provide direct examination to carry out the requirement under paragraph (6) of such subsection.

(d) IDENTIFICATION OF APPROACHES, BEST PRACTICES, FRAMEWORKS, AND METHODS.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall, in consultation with the relevant heads of other Federal departments, agencies, or offices, as appropriate, regularly consult with stakeholders, including persons from academia and the private sector, to identify the approaches, best practices, frame-

works, and methods under subsection (b)(1)(A), including related to the following:

(A) Improving the accuracy, efficiency, and reliability of any administrative and technical protocols required under subsection (a), including with respect to the independent assessment requirement under paragraph (6) of such subsection.

(B) How a covered entity may offer an expedited review process to a previous buyer of such covered entity with respect to which the covered entity has carried out the requirements under paragraphs (1) and (2) of subsection (a).

(C) How the Secretary and any covered entity may identify nucleic acid sequences with a low potential for misuse.

(D) How the Secretary and any covered entity may identify nucleic acid sequences, including novel nucleic acid sequences, that may be used in a manner that would pose a high risk to the national security of the United States or to the security and safety of persons in the United States.

(E) Mitigate any risk related to misuse of benchtop nucleic acid synthesizers.

(2) REPORT.—Not later than 2 years after the date of the enactment of this Act, and annually thereafter for 6 years, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate a report—

(A) developed through a covered process; and

(B) that includes information related to any approaches, best practices, frameworks, or methods identified under paragraph (1).

(e) REPORT AND RECOMMENDATIONS.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, and every 2 years thereafter for 6 years, the Secretary shall publish on a publicly available website a report that includes the following:

(A) An assessment on the following:

(i) The economic competitiveness of the United States with respect to biotechnology, including the manufacturing of nucleic acids.

(ii) The ability of the Secretary, covered entities, and any other relevant entity

to mitigate any national security risk related to covered sequences manufactured and sold in interstate or foreign commerce.

(B) Any legislative recommendation related to the following:

(i) Advancing such competitiveness.

(ii) Mitigating any such national security risk.

(2) PUBLIC CONSULTATION.—In carrying out paragraph (1), the Secretary shall use a covered process.

(3) CONGRESSIONAL NOTIFICATION.—Prior to publishing a report under paragraph (1), the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate such report.

(f) COVERED SEQUENCE LIST.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, and regularly thereafter, the Secretary, in consultation with the relevant heads of other Federal departments, agencies, or offices, as appropriate, shall carry out the following:

(A) A determination of whether a nucleic acid sequence is a covered sequence.

(B) If the Secretary makes a determination that a nucleic acid sequence is a covered sequence, make available to covered entities a statement that explains the basis for such determination, including any basis specified in paragraph (2), as applicable.

(C) Establish and make available to covered entities a list that includes any such covered sequence.

(D) Establish a procedure to make any such statement and such list available to stakeholders in a manner that does not pose an unacceptable risk to the national security of the United States or the security and safety of United States persons.

(2) BASIS.—A determination under paragraph (1)(A) shall be based on one or more of the following:

(A) An assessment by the head of any other Federal agency, including a relevant national security agency or public health agency.

(B) A submission by a member of the public or a covered entity under paragraph (3)(A).

(C) A determination by the Secretary that a nucleic acid sequence poses an imminent or high likelihood of use in such a manner that it poses an unacceptable risk to the national security of the United States or the security and safety of United States persons.

(3) UPDATES.—

(A) IN GENERAL.—The Secretary shall update, as the Secretary determines appropriate, any list established and made available to covered entities under subparagraph (C) of paragraph (1), and any statement or list made available to stakeholders pursuant to the procedure established under subparagraph (D) of such paragraph, including in response to a novel nucleic acid sequence.

(B) SUBMISSION PROCESS.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall, through a covered process, establish a process for the following:

(i) A member of the public to submit to the Secretary a recommendation related to adding a nucleic acid sequence to, removing a covered sequence from, or other-

wise modifying any list established and made available to covered entities under subparagraph (C) of paragraph (1), and any statement or list made available to stakeholders pursuant to the procedure established under subparagraph (D) of such paragraph.

(ii) A covered entity to carry out the following:

(I) Submit to the Secretary a request for the Secretary to review the inclusion of a covered sequence in any list established and made available to covered entities under subparagraph (C) of paragraph (1), and any statement or list made available to stakeholders pursuant to the procedure established under subparagraph (D) of such paragraph, to remove the covered sequence from, or otherwise modify, such list or statement.

(II) Submit evidence to the Secretary related to such request.

(C) CONFIDENTIALITY.—Any information related to a recommendation, request, or evi-

dence submitted pursuant to the process established under subparagraph (B) shall be treated as a trade secret and commercial or financial information, and shall be exempt from disclosure, under section 552(b)(4) of title 5, United States Code.

(D) OPTION TO REQUEST NONDISCLOSURE.—In carrying out subparagraph (B), the Secretary shall offer any member of the public or covered entity that utilizes the process established under such subparagraph the ability to request that any information related to a recommendation, request, or evidence submitted pursuant to such process is not published or disclosed in any identifiable form, including any publication or disclosure of any such information that would allow the identity of the member of the public or covered entity to be reasonably inferred.

(4) CONGRESSIONAL NOTIFICATION.—With respect to any list established and made available to covered entities under subparagraph (C) of paragraph (1), and any statement or list made available to stakeholders pursuant to the procedure estab-

lished under subparagraph (D) of such paragraph, the Secretary shall—

(A) at least 5 days before establishing and making available such a list under such paragraph, or adding a nucleic acid sequence to, removing a covered sequence from, or otherwise modifying such list, submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate such list; and

(B) provide to such committees a briefing related to such list, upon request by such committees.

(g) ENFORCEMENT.—

(1) AUTHORITY.—The Secretary shall have the authority to carry out any of the following to enforce subsection (a):

(A) Require, inspect, and compel the provision of any physical and electronic records and any other information from such covered entity.

(B) Administer oaths or affirmations and require any person to appear and testify or to appear and produce any such record or other information by subpoena.

(C) Conduct investigations within the United States and outside the United States.

(2) CIVIL ACTIONS.—

(A) IN GENERAL.—The Secretary may commence a civil action against a covered entity for a violation of subsection (a) in any district court of the United States for appropriate relief, including—

(i) the penalty described under subparagraph (B); or

(ii) an injunction.

(B) PENALTY.—The penalty for a violation of subsection (a) may not exceed $750,000 per violation (as adjusted on January 1 each year by the percentage increase, if applicable, in the consumer price index for all urban consumers published by the Bureau of Labor Statistics with respect to the 12-month period preceding the date of such adjustment).

(C) RIGHT TO CURE.—

(i) IN GENERAL.—The Secretary may initiate a civil action under subparagraph (A) only if—

(I) the Secretary has provided to the relevant covered entity a written

notice that describes the alleged violation and identifies the provision under subsection (a) related to such alleged violation; and

(II) at least 30 days have passed since the date on which such written notice was so provided.

(ii) EFFECT OF CURE.—If a covered entity that receives a written notice under clause (i)(I) cures the alleged violation described in such notice not later than 30 days after the date on which such covered entity was provided such notice, the Secretary shall consider the requirements under subsection (a) as satisfied with respect to such covered entity.

(iii) FAILURE TO CURE.—After carrying out clause (i), the Secretary may initiate an action under subparagraph (A)—

(I) if the relevant covered entity fails to cure the alleged violation described in the written notice provided pursuant to clause (i)(I); or

(II) if, after the curing the alleged violation as specified in clause

(ii), the covered entity violates the relevant provision under subsection (a) again.

(3) RELATION TO GUIDANCE.—The Secretary may not commence a civil action under paragraph (2) solely on the basis that a covered entity has carried out the requirements under subsection (a) in a manner that is inconsistent with any guidance issued under subsection (b)(1).

(h) RELATIONSHIP WITH OTHER FEDERAL GUIDELINES AND RECOMMENDATIONS.—The requirements in subsection (a) shall supersede any Federal guideline or recommendation related to the screening of nucleic acid sequences made available in interstate or foreign commerce if such guideline or recommendation is voluntary and in effect before the date of the enactment of this Act.

(i) PREEMPTION.—

(1) IN GENERAL.—No State or political subdivision of a State may prescribe, maintain, or enforce any law, rule, regulation, requirement, standard, or other provision having the force and effect of law to the extent such law, rule, regulation, requirement, standard, or other provision is covered by a requirement under subsection (a).

(2) EXCEPTION.—Notwithstanding paragraph (1), nothing in this Act may be construed to preempt any law, rule, requirement, or regulation of a State, or political subdivision of a State, with respect to any of the following:

(A) Contract, tort, or product liability.

(B) Consumer protection, data privacy, or data security.

(C) Any such generally applicable law, rule, requirement, or regulation of a State, or a political subdivision of a State, as it relates to public health.

(D) The procurement or use of nucleic acids or nucleic acid sequences by a State or a political subdivision of a State.

(j) RULE OF CONSTRUCTION.—Nothing in this Act may be construed to prohibit a covered entity from synthesizing a nucleic acid sequence or prohibit a covered entity from producing equipment for synthesizing a nucleic acid, including a benchtop nucleic acid synthesizer.

(k) EFFECTIVE DATE.—The requirement under subsection (a) shall take effect on the date that is 1 year after the date of the enactment of this Act.

(l) DEFINITIONS.—In this section:

(1) BENCHTOP NUCLEIC ACID SYNTHESIZER.—The term ''benchtop nucleic acid synthesizer'' means a product, device, or integrated system in interstate or foreign commerce that is—

(A) capable of generating de novo a nucleic acid sequence—

(i) at the direction of an end user of such product, device, or system; or

(ii) without requiring an end user of such product, device, or system to submit to another covered entity an order to perform the generation of such nucleic acid sequence; and

(B) intended for distribution to, or use by, end users other than the developer of the product, device, or system, regardless of the physical dimensions of such product, device, or system.

(2) COVERED ENTITY.—

(A) IN GENERAL.—The term ''covered entity'' means a person operating in interstate or foreign commerce who—

(i) synthesizes and sells nucleic acids to a person in the United States or in a foreign country; or

(ii) produces, distributes, sells, or resells equipment for synthesizing nucleic acids, including a benchtop nucleic acid synthesizer, to persons in the United States or in a foreign country.

(B) EXCEPTION.—Subparagraph (A) does not apply to the extent a person produces, distributes, sells, or resells synthetic acids within a commercial entity solely for the internal use of such commercial entity.

(3) COVERED PROCESS.—The term ''covered process'' means, with respect to the implementation of a requirement under this section, a process by which the Secretary—

(A) publishes in the Federal Register a request for public feedback on the matters described in such provision;

(B) provides the public with an opportunity to comment on the matters described in subparagraph (A) for a period of not less than 60 days;

(C) ensures that public comments made under subparagraph (B) that are not marked confidential are available for public inspection; and

(D) demonstrates consideration of any such public comments with respect to such implementation.

(4) SECRETARY.—The term ''Secretary'' means the Secretary of Commerce, acting through the Office of the Secretary.