

119TH CONGRESS
1ST SESSION

S. 3469

To prohibit contracting with certain biotechnology providers.

IN THE SENATE OF THE UNITED STATES

DECEMBER 11, 2025

Mr. PETERS (for himself and Mr. HAGERTY) introduced the following bill;
which was read twice and referred to the Committee on Homeland Security and Governmental Affairs

A BILL

To prohibit contracting with certain biotechnology providers.

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 “BIOSECURE Act of
5 2025”.

6 **SEC. 2. PROHIBITION ON CONTRACTING WITH CERTAIN**
7 **BIOTECHNOLOGY PROVIDERS.**

8 (a) IN GENERAL.—The head of an executive agency
9 may not—

1 (1) procure or obtain any biotechnology equip-
2 ment or service produced or provided by a bio-
3 technology company of concern; or

4 (2) enter into a contract, or extend or renew a
5 contract, with any entity that—

6 (A) uses biotechnology equipment or serv-
7 ices produced or provided by a biotechnology
8 company of concern and acquired after the ap-
9 plicable effective date in subsection (c) in per-
10 formance of the contract with the executive
11 agency; or

12 (B) enters into any contract the perform-
13 ance of which such entity knows will require, in
14 performance of the contract with the executive
15 agency, the use of biotechnology equipment or
16 services produced or provided by a bio-
17 technology company of concern and acquired
18 after the applicable effective date in subsection
19 (c).

20 (b) PROHIBITION ON LOAN AND GRANT FUNDS.—

21 The head of an executive agency may not obligate or ex-
22 pend loan or grant funds to, and a loan or grant recipient
23 may not use loan or grant funds to—

1 (1) procure, obtain, or use any biotechnology
2 equipment or services produced or provided by a bio-
3 technology company of concern; or

4 (2) enter into a contract, or extend or renew a
5 contract, with an entity described in subsection
6 (a)(2).

7 (c) EFFECTIVE DATES.—

8 (1) CERTAIN ENTITIES.—With respect to the
9 biotechnology companies of concern covered by sub-
10 section (f)(2)(A), the prohibitions under subsections
11 (a) and (b) shall take effect 60 days after the Fed-
12 eral Acquisition Regulation is revised pursuant to
13 subsection (h).

14 (2) OTHER ENTITIES.—With respect to the bio-
15 technology companies of concern covered by sub-
16 paragraphs (B) or (C) of subsection (f)(2), the pro-
17 hibitions under subsections (a) and (b) shall take ef-
18 fect 90 days after the Federal Acquisition Regula-
19 tion is revised pursuant to subsection (h).

20 (3) RULES OF CONSTRUCTION.—

21 (A) EXCLUSIONS.—Prior to the date that
22 is five years after a revision to the Federal Ac-
23 quisition Regulation pursuant to subsection (h)
24 that identifies a biotechnology company of con-
25 cern covered by subsection (f)(2), subsections

1 (a)(2) and (b)(2) shall not apply to bio-
2 technology equipment or services produced or
3 provided under a contract or agreement, includ-
4 ing previously negotiated contract options, en-
5 tered into before the applicable effective date
6 under paragraphs (1) and (2).

7 (B) SAFE HARBOR.—The term “bio-
8 technology equipment or services produced or
9 provided by a biotechnology company of con-
10 cern” shall not be construed to refer to any bio-
11 technology equipment or services that were for-
12 merly, but are no longer, produced or provided
13 by biotechnology companies of concern.

14 (d) WAIVER AUTHORITIES.—

15 (1) SPECIFIC BIOTECHNOLOGY EXCEPTION.—

16 (A) WAIVER.—The head of the applicable
17 executive agency may waive the prohibition
18 under subsections (a) and (b) on a case-by-case
19 basis—

20 (i) with the approval of the Director
21 of the Office of Management and Budget;
22 and

23 (ii) if such head submits a notification
24 and justification to the appropriate con-

1 gressional committees not later than 30
2 days after granting such waiver.

3 (B) DURATION.—

4 (i) IN GENERAL.—Except as provided
5 in clause (ii), a waiver granted under sub-
6 paragraph (A) shall last for a period of not
7 more than 365 days.

8 (ii) EXTENSION.—The head of the ap-
9 plicable executive agency, with the ap-
10 proval of the Director of the Office of
11 Management and Budget, and in coordina-
12 tion with the Secretary of Defense, may
13 extend a waiver granted under subpara-
14 graph (A) one time, for a period up to 180
15 days after the date on which the waiver
16 would otherwise expire, if such an exten-
17 sion is in the national security interests of
18 the United States and if such head sub-
19 mits a notification and justification to the
20 appropriate congressional committees not
21 later than 10 days after granting such
22 waiver extension.

23 (2) OVERSEAS HEALTH CARE SERVICES.—The
24 head of an executive agency may waive the prohibi-
25 tions under subsections (a) and (b) with respect to

1 a contract, subcontract, or transaction for the acqui-
2 sition or provision of health care services overseas on
3 a case-by-case basis—

4 (A) if the head of such executive agency
5 determines that the waiver is—

6 (i) necessary to support the mission or
7 activities of the employees of such execu-
8 tive agency described in subsection
9 (e)(2)(A); and

10 (ii) in the interest of the United
11 States;

12 (B) with the approval of the Director of
13 the Office of Management and Budget, in con-
14 sultation with the Secretary of Defense; and

15 (C) if such head submits a notification and
16 justification to the appropriate congressional
17 committees not later than 30 days after grant-
18 ing such waiver.

19 (e) EXCEPTIONS.—The prohibitions under sub-
20 sections (a) and (b) shall not apply to—

21 (1) any activity subject to the reporting require-
22 ments under title V of the National Security Act of
23 1947 (50 U.S.C. 3091 et seq.) or any authorized in-
24 telligence activities of the United States;

1 (2) the acquisition or provision of health care
2 services overseas for—

3 (A)(i) employees of the United States, in-
4 cluding members of the uniformed services (as
5 defined in section 101(a) of title 10, United
6 States Code), and dependents of such employ-
7 ees;

8 (ii) covered beneficiaries (as defined in sec-
9 tion 1072 of title 10, United States Code) not
10 otherwise described in clause (i); or

11 (iii) any other beneficiary if such acquisi-
12 tion or provision is carried out or administered
13 by the head of a department or agency of the
14 Federal Government; or

15 (B) employees of contractors or sub-
16 contractors of the United States—

17 (i) who are performing under a con-
18 tract that directly supports the missions or
19 activities of individuals described in sub-
20 paragraph (A)(i); and

21 (ii) whose primary duty stations are
22 located overseas or are on permissive tem-
23 porary duty travel overseas;

1 (3) the acquisition, use, or distribution of
2 human multiomic data, lawfully compiled, that is
3 commercially or publicly available; or

4 (4) the procurement of medical counter-
5 measures, medical products, and related supplies, in-
6 cluding ancillary medical supplies, in direct response
7 to a public health emergency declared pursuant to
8 section 319 of the Public Health Service Act (42
9 U.S.C. 247d).

10 (f) EVALUATION OF CERTAIN BIOTECHNOLOGY EN-
11 TITIES.—

12 (1) ENTITY CONSIDERATION.—Not later than
13 one year after the date of the enactment of this Act,
14 the Director of the Office of Management and Budg-
15 et shall publish a list of the entities that constitute
16 biotechnology companies of concern based on a list
17 of suggested entities that shall be provided by the
18 Secretary of Defense in coordination with the Attor-
19 ney General, the Secretary of Health and Human
20 Services, the Secretary of Commerce, the Director of
21 National Intelligence, the Secretary of Homeland Se-
22 curity, the Secretary of State, and the National
23 Cyber Director.

1 (2) BIOTECHNOLOGY COMPANIES OF CONCERN
2 DEFINED.—In this section, the term “biotechnology
3 company of concern” means any of the following:

4 (A) An entity that—

5 (i) is to any extent involved in the
6 manufacturing, distribution, provision, or
7 procurement of any biotechnology equip-
8 ment or service, as determined by the proc-
9 ess established in paragraph (1); and

10 (ii) is identified in the annual list pub-
11 lished in the Federal Register by the De-
12 partment of Defense of Chinese military
13 companies operating in the United States
14 pursuant to section 1260H of the William
15 M. (Mac) Thornberry National Defense
16 Authorization Act for Fiscal Year 2021
17 (Public Law 116–283; 134 Stat. 3965; 10
18 U.S.C. 113 note).

19 (B) Any entity that is determined by the
20 process established in paragraph (1) to meet
21 each of the following criteria:

22 (i) Is subject to the administrative
23 governance structure, direction, control, or
24 operates on behalf of the government of a
25 foreign adversary.

1 (ii) Is to any extent involved in the
2 manufacturing, distribution, provision, or
3 procurement of a biotechnology equipment
4 or service.

5 (iii) Poses a risk to the national secu-
6 rity of the United States based on—

7 (I) engaging in joint research
8 with, being supported by, or being af-
9 filiated with a foreign adversary's
10 military, internal security forces, or
11 intelligence agencies;

12 (II) providing multiomic data ob-
13 tained via biotechnology equipment or
14 services to the government of a for-
15 eign adversary; or

16 (III) obtaining human multiomic
17 data via the biotechnology equipment
18 or services without express and in-
19 formed consent.

20 (C) Any subsidiary, parent, or successor of
21 an entity described in subparagraphs (A) or
22 (B), provided it meets the criteria set forth in
23 clauses (i) through (iii) of subparagraph (B), as
24 determined by the process established in para-
25 graph (1).

1 (3) GUIDANCE.—Not later than 180 days after
2 publication of the list pursuant to paragraph (1),
3 and any update to the list pursuant to paragraph
4 (4), the Director of the Office of Management and
5 Budget, in coordination with the Secretary of De-
6 fense, the Attorney General, the Secretary of Health
7 and Human Services, the Secretary of Commerce,
8 the Director of National Intelligence, the Secretary
9 of Homeland Security, the Secretary of State, and
10 the National Cyber Director, shall establish guidance
11 as necessary to implement the requirements of this
12 section.

13 (4) UPDATES.—The Director of the Office of
14 Management and Budget, in coordination with or
15 based on a recommendation provided by the Sec-
16 retary of Defense, the Attorney General, the Sec-
17 retary of Health and Human Services, the Secretary
18 of Commerce, the Director of National Intelligence,
19 the Secretary of Homeland Security, the Secretary
20 of State, and the National Cyber Director, or upon
21 receipt of a request pursuant to paragraph (7), shall
22 periodically, though not less than annually, review
23 and, as appropriate, add entities to or remove enti-
24 ties from the list of biotechnology companies of con-

1 cern, and notify the appropriate congressional com-
2 mittees of any such modifications.

3 (5) NOTICE OF A DESIGNATION AND REVIEW.—

4 (A) IN GENERAL.—A notice of a designa-
5 tion as a biotechnology company of concern
6 under paragraph (2)(B) shall be issued to any
7 biotechnology company of concern named in the
8 designation—

9 (i) advising that a designation has
10 been made;

11 (ii) identifying the criteria relied upon
12 under such subparagraph and, to the ex-
13 tent consistent with national security and
14 law enforcement interests, the information
15 that formed the basis for the designation;

16 (iii) advising that, within 90 days
17 after receipt of notice, the biotechnology
18 company of concern may submit informa-
19 tion and arguments in opposition to the
20 designation;

21 (iv) describing the procedures gov-
22 erning the review and possible issuance of
23 a designation pursuant to paragraph (1);
24 and

1 (v) where practicable, identifying miti-
2 gation steps that could be taken by the
3 biotechnology company of concern that
4 may result in the rescission of the designa-
5 tion.

6 (B) CONGRESSIONAL NOTIFICATION RE-
7 QUIREMENTS.—

8 (i) NOTICE OF DESIGNATION.—The
9 Director of the Office of Management and
10 Budget shall submit the notice required
11 under subparagraph (A) to the Committee
12 on Homeland Security and Governmental
13 Affairs of the Senate and the Committee
14 on Oversight and Government Reform of
15 the House of Representatives.

16 (ii) INFORMATION AND ARGUMENT IN
17 OPPOSITION TO DESIGNATIONS.—Not later
18 than 7 days after receiving any informa-
19 tion and arguments in opposition to a des-
20 ignation pursuant to subparagraph (A)(iii),
21 the Director of the Office of Management
22 and Budget shall submit such information
23 to the Committee on Homeland Security
24 and Governmental Affairs of the Senate
25 and the Committee on Oversight and Gov-

1 ernment Reform of the House of Rep-
2 resentatives.

3 (6) NO IMMEDIATE PUBLIC RELEASE.—Any
4 designation made under paragraph (1) or paragraph
5 (4) shall not be made publicly available until the Di-
6 rector of the Office of Management and Budget, in
7 coordination with appropriate agencies, reviews all
8 information submitted under paragraph (5)(A)(iii)
9 and issues a final determination that a company
10 shall remain listed as a biotechnology company of
11 concern.

12 (7) REMOVAL REQUESTS.—If an entity on the
13 list of biotechnology companies of concern believes it
14 no longer meets the definition of a biotechnology
15 company of concern as described in paragraph (2),
16 then it may provide information and arguments to
17 request removal from the list of biotechnology com-
18 panies of concern to the Director of the Office of
19 Management and Budget. The Director shall review
20 such information and reply to the entity within 90
21 days.

22 (g) EVALUATION OF NATIONAL SECURITY RISKS
23 POSED BY FOREIGN ADVERSARY ACQUISITION OF AMER-
24 ICAN MULTIOMIC DATA.—

1 (1) ASSESSMENT.—Not later than 270 days
2 after the enactment of this Act, the Director of Na-
3 tional Intelligence, in consultation with the Secretary
4 of Defense, the Attorney General of the United
5 States, the Secretary of Health and Human Serv-
6 ices, the Secretary of Commerce, the Secretary of
7 Homeland Security, the Secretary of State, and the
8 National Cyber Director, shall complete an assess-
9 ment of risks to national security posed by human
10 multiomic data from United States citizens that is
11 collected or stored by a foreign adversary from the
12 provision of biotechnology equipment or services.

13 (2) REPORT REQUIREMENT.—Not later than 30
14 days after the completion of the assessment devel-
15 oped under paragraph (1), the Director of National
16 Intelligence shall submit a report with such assess-
17 ment to the appropriate congressional committees.

18 (3) FORM.—The report required under para-
19 graph (2) shall be in unclassified form, but may in-
20 clude a classified annex.

21 (h) REGULATIONS.—Not later than one year after
22 the date of establishment of guidance required under sub-
23 section (f)(3), and as necessary for subsequent updates,
24 the Federal Acquisition Regulatory Council shall revise

1 the Federal Acquisition Regulation as necessary to imple-
2 ment the requirements of this section.

3 (i) REPORTING ON INTELLIGENCE ON NEFARIOUS
4 ACTIVITIES OF BIOTECHNOLOGY COMPANIES WITH
5 HUMAN MULTIOMIC DATA.—Not later than 180 days
6 after the date of the enactment of this Act, and annually
7 thereafter, the Director of National Intelligence, in con-
8 sultation with the heads of executive agencies, shall submit
9 to the appropriate congressional committees a report on
10 any intelligence in possession of such agencies related to
11 nefarious activities conducted by biotechnology companies
12 with human multiomic data. The report shall include in-
13 formation pertaining to potential threats to national secu-
14 rity or public safety from the selling, reselling, licensing,
15 trading, transferring, sharing, or otherwise providing or
16 making available to any foreign country of any forms of
17 multiomic data of a United States citizen.

18 (j) NO ADDITIONAL FUNDS.—No additional funds
19 are authorized to be appropriated for the purpose of car-
20 rying out this section.

21 (k) DEFINITIONS.—In this section:

22 (1) APPROPRIATE CONGRESSIONAL COMMIT-
23 TEES.—The term “appropriate congressional com-
24 mittees” means—

1 (A) the Committee on Armed Services, the
2 Select Committee on Intelligence, the Com-
3 mittee on Homeland Security and Govern-
4 mental Affairs, the Committee on Health, Edu-
5 cation, Labor, and Pensions, the Committee on
6 Commerce, Science, and Transportation, and
7 the Committee on Foreign Relations of the Sen-
8 ate; and

9 (B) the Committee on Armed Services, the
10 Permanent Select Committee on Intelligence,
11 the Committee on Foreign Affairs, the Com-
12 mittee on Oversight and Government Reform,
13 the Committee on Energy and Commerce, and
14 the Select Committee on Strategic Competition
15 between the United States and the Chinese
16 Communist Party of the House of Representa-
17 tives.

18 (2) BIOTECHNOLOGY EQUIPMENT OR SERV-
19 ICE.—The term “biotechnology equipment or serv-
20 ice” means—

21 (A) equipment, including genetic sequenc-
22 ers, or any other instrument, apparatus, ma-
23 chine, or device, including components and ac-
24 cessories thereof, that is designed for use in the
25 research, development, production, or analysis

1 of biological materials as well as any software,
2 firmware, or other digital components that are
3 specifically designed for use in, and necessary
4 for the operation of, such equipment;

5 (B) any service for the research, develop-
6 ment, production, analysis, detection, or provi-
7 sion of information, including data storage and
8 transmission related to biological materials, in-
9 cluding—

10 (i) advising, consulting, or support
11 services with respect to the use or imple-
12 mentation of an instrument, apparatus,
13 machine, or device described in subpara-
14 graph (A); and

15 (ii) disease detection, genealogical in-
16 formation, and related services; and

17 (C) any other service, instrument, appa-
18 ratus, machine, component, accessory, device,
19 software, or firmware that is designed for use
20 in the research, development, production, or
21 analysis of biological materials that the Direc-
22 tor of the Office of Management and Budget, in
23 consultation with the heads of executive agen-
24 cies, as determined appropriate by the Director
25 of the Office of Management and Budget, de-

1 termines appropriate in the interest of national
2 security.

3 (3) CONTRACT.—Except as the term is used
4 under subsection (b)(2) and subsection (c)(3), the
5 term “contract” means—

6 (A) any contract subject to the Federal Ac-
7 quisition Regulation issued under section
8 1303(a)(1) of title 41, United States Code; or

9 (B) any transaction (other than a contract,
10 a grant, or a cooperative agreement) entered
11 into under section 4021 of title 10, United
12 States Code.

13 (4) CONTROL.—The term “control” has the
14 meaning given to that term in section 800.208 of
15 title 31, Code of Federal Regulations, or any suc-
16 cessor regulations.

17 (5) EXECUTIVE AGENCY.—The term “executive
18 agency” has the meaning given the term “Executive
19 agency” in section 105 of title 5, United States
20 Code.

21 (6) FOREIGN ADVERSARY.—The term “foreign
22 adversary” has the meaning given the term “covered
23 nation” in section 4872(f) of title 10, United States
24 Code.

1 (7) MULTIOMIC.—The term “multiomic” means
2 data types that include genomics, epigenomics,
3 transcriptomics, proteomics, and metabolomics.

4 (8) OVERSEAS.—The term “overseas” means
5 any area outside of the United States, the Common-
6 wealth of Puerto Rico, or a territory or possession
7 of the United States.

8 (1) COMPLIANCE WITH LIMITATION ON DRUG
9 PRICES.—For the purposes of section 1927(a)(1) of the
10 Social Security Act (42 U.S.C. 1396r–8(a)(1)), a manu-
11 facturer is deemed to meet the requirements of section
12 8126 of title 38, United States Code, including the re-
13 quirement of entering into a master agreement with the
14 Secretary of Veterans Affairs under such section, if the
15 Secretary of Veterans Affairs determines that the manu-
16 facturer would comply (and has offered to comply) with
17 the provisions of section 8126 of title 38, United States
18 Code, and would have entered into a master agreement
19 under such section, but for the prohibitions under sub-
20 sections (a) and (b) of this section.

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