118TH CONGRESS
1ST SESSION

S. 3385

To prohibit contracting with certain biotechnology providers.

IN THE SENATE OF THE UNITED STATES

DECEMBER 4, 2023

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.

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

SECTION 1. PROHIBITION ON CONTRACTING WITH CERTAIN BIOTECHNOLOGY PROVIDERS.

(a) IN GENERAL.—The head of an Executive agency may not—

(1) procure or obtain or extend or renew a contract to procure or obtain any covered biotechnology equipment or service; or

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

(A) uses covered biotechnology equipment or services acquired after the date of the enactment of this Act; or

(B) that enters into any contract the performance of which such entity knows or has reason to believe will require the direct use of covered biotechnology equipment or services.

(b) PROHIBITION ON LOAN AND GRANT FUNDS.—The head of an Executive agency may not obligate or expend loan or grant funds to—

(1) procure or obtain or extend or renew a contract to procure or obtain any covered biotechnology equipment or service; or

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

(c) EFFECTIVE DATE.—The prohibitions under subsections (a) and (b) shall take effect 180 days after the date of the enactment of this Act.

(d) WAIVER AUTHORITIES.—

(1) SPECIFIC BIOTECHNOLOGY EXCEPTION.—

(A) WAIVER.—The head of an Executive agency may waive the prohibitions under subsection (a) and (b) on a case-by-case basis—

(i) with the approval of the Director of the Office of Management and Budget, in consultation with the Federal Acquisition Security Council and the Secretary of Defense; and

(ii) if such head submits a notification and justification to the appropriate congressional committees not later than 30 days after granting such waiver.

(B) DURATION.—

(i) IN GENERAL.—Except as provided in clause (ii), a waiver granted under subparagraph (A) shall last for a period of not more than 180 days.

(ii) EXTENSION.—The Director of the Office of Management and Budget, in consultation with the Federal Acquisition Security Council and the Secretary of Defense, may extend a waiver granted under subparagraph (A) one time, for a period up to 180 days after the date on which the waiver would otherwise expire, if such an extension is in the national security interests of the United States and the Director

submits to the appropriate congressional committees a notification of such waiver.

(2) OVERSEAS HEALTH CARE SERVICES.—The head of an Executive agency may waive the prohibitions under subsections (a) and (b) with respect to a contract, subcontract, or transaction for the acquisition or provision of health care services overseas on a case-by-case basis—

(A) if the head of such Executive agency determines that the waiver is—

(i) necessary to support the mission or activities of the employees of such Executive agency described in subsection (e)(2)(A); and

(ii) in the interest of the United States;

(B) with the approval of the Director of the Office of Management and Budget, in consultation with the Federal Security Acquisition Council and the Secretary of Defense; and

(C) if such head submits a notification and justification to the appropriate congressional committees not later than 30 days after granting such waiver.

(e) EXCEPTIONS.—The prohibitions under subsections (a) and (b) shall not apply to—

(1) any activity subject to the reporting requirements under title V of the National Security Act of 1947 (50 U.S.C. 3091 et seq.) or any authorized intelligence activities of the United States;

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

(A) employees of the United States, including members of the uniformed services (as defined in section 101(a) of title 10, United States Code), whose official duty stations are located overseas; or

(B) employees of contractors or subcontractors of the United States—

(i) who are performing under a contract that directly supports the missions or activities of individuals described in subparagraph (A); and

(ii) whose primary duty stations are located overseas; or

(3) the acquisition, use, or distribution of genetic sequencing data, however complied, that is commercially available.

(f) EVALUATION OF CERTAIN BIOTECHNOLOGY ENTITIES.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Defense shall determine whether Wuxi AppTec, AxBio, and any subsidiary, affiliate, or successor of such entities, or any other entity headquartered in or organized under the laws of the People's Republic of China is a biotechnology company of concern.

(g) REGULATIONS.—

(1) GUIDANCE.—Not later than 180 days after the date of the enactment of this Act, the Director of the Office of Management and Budget, in coordination with the Federal Acquisition Security Council, the Federal Acquisition Regulatory Council, the Secretary of Defense, and other heads of Executive agencies as determined appropriate by the Director of the Office of Management and Budget, shall establish guidance, as necessary, to implement the requirements of this section.

(2) FEDERAL ACQUISITION REGULATION.—Not later than 270 days after the date of the enactment of this Act, the Federal Acquisition Regulatory Council shall revise the Federal Acquisition Regulation as necessary to implement the requirements of this section.

(h) DEFINITIONS.—In this section:

(1) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term ''appropriate congressional committees'' means—

(A) the Committee on Armed Services and the Committee on Homeland Security and Governmental Affairs of the Senate; and

(B) the Committee on Armed Services, the Committee on Foreign Affairs, the Committee on Oversight and Accountability, the Committee on Energy and Commerce, and the Select Committee on Strategic Competition between the United States and the Chinese Communist Party of the House of Representatives.

(2) BIOTECHNOLOGY COMPANY OF CONCERN.—The term ''biotechnology company of concern'' means—

(A) the BGI Group, MGI Group, or Complete Genomics, or any subsidiary, parent, affiliate, or successor of such entities; and

(B) any entity that—

(i) is subject to the jurisdiction, direction, or control of a foreign adversary;

(ii) operates primarily in the biotechnology industry; and

(iii) the Secretary of Defense deems to pose a risk to the national security of the United States.

(3) BIOTECHNOLOGY EQUIPMENT OR SERVICE.—The term ''biotechnology equipment or service'' means—

(A) any instrument, apparatus, machine, or device, including components and accessories thereof, that is designed for use in the research, development, production, or analysis of biological materials as well as any software, firmware, or other digital components that are specifically designed for use in, and necessary for the operation of, such an instrument, apparatus, machine, or device;

(B) any service for the research, development, production, analysis, detection, or provision of information related to biological materials, including—

(i) advising, consulting, or support services provided by a biotechnology company of concern with respect to the use or implementation of a instrument, apparatus, machine, or device described in subparagraph (A); and

(ii) disease detection, genealogical information, and related services; and

(C) any other service, instrument, apparatus, machine, component, accessory, device, software, or firmware that the Federal Acquisition Security Council, in coordination with the Secretary of Defense and such other heads of Executive agencies (as determined by the Federal Acquisition Security Council), determines appropriate.

(4) CONTROL.—The term ''control'' has the meaning given to that term in section 800.208 of title 31, Code of Federal Regulations, or any successor regulations.

(5) COVERED BIOTECHNOLOGY EQUIPMENT OR SERVICE.—The term ''covered biotechnology equipment or service'' means a biotechnology equipment or service produced or provided by a biotechnology company of concern.

(6) EXECUTIVE AGENCY.—The term ''Executive agency'' has the meaning given such term in section 105 of title 5, United States Code.

(7) FOREIGN ADVERSARY.—The term ''foreign adversary'' has the meaning given the term ''covered

nation'' in section 4872(d) of title 10, United States Code.

(8) OVERSEAS.—The term ''overseas'' means any area outside of the United States, the Commonwealth of Puerto Rico, or a territory or possession of the United States.

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