118TH CONGRESS
2D SESSION

H. R. ____

To prohibit contracting with certain biotechnology providers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. GALLAGHER introduced the following bill; which was referred to the Committee on ____________________

A BILL

To prohibit contracting with certain biotechnology providers, 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 “BIOSECURE Act”.

SEC. 2. FINDINGS; SENSE OF CONGRESS.

(a) FINDINGS.—Congress finds the following:

(1) The Government of the People’s Republic of China (PRC) seeks to dominate biotechnology as an industry of the future.
In recent years, the PRC has pursued a strategy known as “military-civil fusion” that merges public and private industries to enable the military modernization of the People’s Liberation Army (PLA).

In the PRC’s 14th Five-Year Plan, the PRC emphasized the use of artificial intelligence for biological discovery and called to accelerate the development of biotechnology.

PRC biotechnology companies have repeatedly collaborated with PLA entities, including Third Military Medical University and the PLA’s Key Laboratory of High-Altitude Medicine.

PRC law requires companies that are controlled by a PRC entity, like BGI, to comply with PRC national security laws, which provide the Chinese Communist Party (CCP) with the power to compel Chinese companies to turn over their data.

Pursuant to the PRC’s laws, the PRC can require a company headquartered in the PRC to surrender all its data to the Government of the PRC, making it an espionage tool of the CCP.

The National Intelligence Law, passed in China in 2017, states that “any organization” must assist or cooperate with CCP intelligence work.
(8) China’s 2014 counter-espionage law also states that “relevant organizations . . . may not refuse” to collect evidence for an investigation.

(9) The PRC’s Data Security Law of 2021 states that the Government has the power to access and control private data.

(10) The PRC’s counter-espionage law grants PRC state security agencies nearly unfettered discretion, if acting under an effectively limitless capacious understanding of national security, to access data from companies.

(11) The executive branch has determined that BGI, formerly known as Beijing Genomics Institute, is a national security threat.

(12) In October 2022, the Department of Defense added BGI Genomics Co., LTD (BGI) to the Department of Defense’s list of PRC Military Companies.

(13) In March 2023, the Department of Commerce added BGI Tech Solutions (Hong Kong) a subsidiary of BGI, to the Entity List for concerns the unit poses a significant risk to contributing to PRC Government surveillance.

(14) In February 2021, the National Counter-intelligence and Security Center published a public
advisory that the Government of the PRC seeks to leverage access to genetic data to conduct repression and surveillance with mention of BGI’s role in this campaign.

(15) BGI is engaged in global campaign to collect foreign person’s genetic data.

(16) As of October 2023, United States press reports BGI operates genetic collection sites or “Fire-Eye” laboratories, in over 30 countries.

(17) According to a July 2021 United States press report, BGI collected genetic data from millions of pregnant women through prenatal tests. BGI reportedly has worked with the PLA to improve “population quality” in the PRC.

(18) BGI operates the China National GeneBank, the world’s largest repository of genetic data.

(19) MGI and Complete Genomics are subsidiaries and direct affiliates of BGI that have access to the United States market and population.

(20) In 2013, BGI purchased United States genomic sequencing firm Complete Genomics.

(21) According to MGI’s previous Securities and Exchange Commission disclosures, MGI is “part of the BGI” group and BGI “established” MGI.
(22) According to an April 2023 United States press report, BGI founder, Wang Jian, holds 47 percent of MGI shares.

(23) According to corporate disclosures, Complete Genomics is owned by MGI and is therefore owned by BGI.

(24) WuXi AppTec presents a national security threat to the United States.

(25) According to PRC press, WuXi AppTec has sponsored Military-Civil Fusion events in the PRC.

(26) WuXi AppTec has received investments from a “Military-Civil Integration Selected Hybrid Securities Investment Fund”.

(27) According to PRC press, WuXi AppTec has granted awards to PLA researchers and invited PLA institutes to participate in the selection process of company awards.

(28) Chris Chen, CEO of WuXi Biologies, was previously an adjunct professor at the PLA’s Academy of Military Medical Sciences.

(b) SENSE OF CONGRESS.—It is the sense of Congress that the time has come to—

(1) stop United States taxpayer dollars from flowing to foreign adversary biotech companies like BGI that have ties to the PLA; and
(2) prevent United States taxpayers from buying biotech equipment from foreign adversaries that facilitate the transfer of United States persons genetic data to a foreign adversary.

SEC. 3. PROHIBITION ON CONTRACTING WITH CERTAIN BIOTECHNOLOGY PROVIDERS.

(a) In General.—The head of an executive agency may not—

(1) procure or obtain any biotechnology equipment or service produced or provided by a biotechnology company of concern; or

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

(A) uses biotechnology equipment or services produced or provided by a biotechnology company of concern and acquired after the applicable effective date in subsection (c) in performance of the contract; or

(B) enters into any contract the performance of which will require the direct use of biotechnology equipment or services produced or provided by a biotechnology company of concern and acquired after the applicable effective date in subsection (c).
(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 any biotechnology equipment or services produced or provided by a biotechnology company of concern; or

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

(c) **Effective Dates.**—

(1) **Certain Entities.**—With respect to the biotechnology companies of concern covered by subsection (f)(2)(A), the prohibitions under subsections (a) and (b) shall take effect 60 days after the issuance of the implementing guidance in subsection (f)(3) or the expiration of the deadline set forth in subsection (f)(3), whichever occurs first.

(2) **Other Entities.**—With respect to the biotechnology companies of concern covered by subsection (f)(2)(B), the prohibitions under subsections (a) and (b) shall take effect 180 days after the issuance of the implementing guidance in subsection (f)(3).

(d) **Waiver Authorities.**—

(1) **Specific Biotechnology Exception.**—
(A) WAIVER.—The head of an executive agency may waive the prohibition 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 365 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 Acquisition Security 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.

(c) 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 are on permissive temporary duty travel 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 are on permissive temporary duty travel overseas; or
(3) the acquisition, use, or distribution of human multiomic data, however compiled, that is commercially or publicly available.

(f) EVALUATION OF CERTAIN BIOTECHNOLOGY ENTITIES.—

(1) ENTITY CONSIDERATION.—Not later than 120 days after the date of the enactment of this Act, the Director of the Office of Management and Budget, in consultation with the Secretary of Defense, the Attorney General, the Secretary of Health and Human Services, the Secretary of Commerce, the Director of National Intelligence, the Secretary of Homeland Security, and the Secretary of State, shall develop a list of the entities that constitute biotechnology companies of concern.

(2) BIOTECHNOLOGY COMPANIES OF CONCERN DEFINED.—The term “biotechnology company of concern” means—

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

(B) any entity that—

(i) is subject to the jurisdiction, direction, control, or operates on behalf of the government of a foreign adversary;
(ii) is to any extent involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service; and

(iii) poses a risk to the national security of the United States based on—

(I) engaging in joint research with, being supported by, or being affiliated with a foreign adversary’s military, internal security forces, or intelligence agencies;

(II) providing multiomic data obtained via biotechnology equipment or services to the government of a foreign adversary; or

(III) obtaining human multiomic data via the biotechnology equipment or services without express and informed consent.

(3) GUIDANCE.—Not later than 120 days after the date of the enactment of this Act, the Director of the Office of Management and Budget, in consultation with the Secretary of Defense, the Attorney General, the Secretary of Health and Human Services, the Secretary of Commerce, the Director of
National Intelligence, the Secretary of Homeland Security, and the Secretary of State, shall establish guidance necessary to implement the requirements of this section.

(4) UPDATES.—The Director of the Office of Management and Budget, in consultation with the Secretary of Defense, the Attorney General, the Secretary of Health and Human Services, the Secretary of Commerce, the Director of National Intelligence, the Secretary of Homeland Security, and the Secretary of State, shall periodically, though not less than annually, review and, as appropriate, make a determination to modify the list of biotechnology companies of concern.

(g) REGULATIONS.—Not later than one year after the date of establishment of guidance required under subsection (f)(3), the Federal Acquisition Regulatory Council shall revise the Federal Acquisition Regulation as necessary to implement the requirements of this section.

(h) NO ADDITIONAL FUNDS.—No additional funds are authorized to be appropriated for the purpose of carrying out this section.

(i) 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 Com-
   mittee on Strategic Competition between the
   United States and the Chinese Communist
   Party of the House of Representatives.

(2) Biotechnology Equipment or Service.—The term “biotechnology equipment or service” means—

   (A) equipment, including genetic sequencers, mass spectrometers, polymerase chain reac-
   tion machines, or any other 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 equipment;

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

(i) advising, consulting, or support services 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 Director of the Office of Management and Budget, in consultation with the heads of Executive agencies, as determined appropriate by the Director of the Office of Management and Budget, determines appropriate.

(3) 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.

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

(5) **FOREIGN ADVERSARY.**—The term “foreign adversary” has the meaning given the term “covered nation” in section 4872(d) of title 10, United States Code.

(6) **MULTIOMIC.**—The term “multiomic” means data types that include genomics, epigenomics, transcriptomics, proteomics, and metabolomics.

(7) **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.