AMENDMENT TO
RULES COMMITTEE PRINT 119–8
OFFERED BY MR. MOOLENAAR OF MICHIGAN

At the end of subtitle A of title XVII, add the following:

SEC. 17___. 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 any biotechnology equipment or service produced or provided by a biotechnology company of concern and acquired after the applicable effective date described in subsection (c) in performance of the contract with such executive agency; or

(B) enters into any contract the performance of which such entity knows or has reason to believe will require, in performance of the

contract with such executive agency, the use of any biotechnology equipment or service produced or provided by a biotechnology company of concern and acquired after the applicable effective date described 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, and a loan or grant recipient may not use loan or grant funds to—

(1) procure, obtain, or use 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 an entity described in subsection (a)(2).

(c) EFFECTIVE DATES.—

(1) CERTAIN ENTITIES.—With respect to a biotechnology company of concern described in subsection (k)(2)(A), the prohibitions described in subsections (a) and (b) shall take effect 60 days after the date on which the Federal Acquisition Regulation is revised pursuant to subsection (h).

(2) OTHER ENTITIES.—With respect to a biotechnology company of concern described in subsection (k)(2)(B) or (k)(2)(C), the prohibitions de-

scribed in subsections (a) and (b) shall take effect 90 days after the date on which the Federal Acquisition Regulation is revised pursuant to subsection (h).

(3) RULES OF CONSTRUCTION.—

(A) EXCLUSIONS.—Prior to the date that is 5 years after a revision to the Federal Acquisition Regulation pursuant to subsection (h) that pertains to a biotechnology company of concern described in subsections (k)(2)(A) and (k)(2)(B), subsections (a)(2) and (b)(2) do not apply to any biotechnology equipment or service produced or provided pursuant to a contract or agreement, including any previously negotiated contract option, entered into before the effective date described in paragraph (2).

(B) SAFE HARBOR.—The term ''biotechnology equipment or service produced or provided by a biotechnology company of concern'' may not be construed to refer to any biotechnology equipment or service that formerly, but no longer, was produced or provided by a biotechnology company of concern.

(d) WAIVER AUTHORITIES.—

(1) CASE-BY-CASE WAIVER.—The head of the applicable executive agency may waive the prohibitions described in subsections (a) and (b) on a case-by-case basis—

(A) with the approval of the Director of the Office of Management and Budget, in consultation with the Secretary of Defense;

(B) if such head submits a notification and justification to the appropriate congressional committees not later than 30 days after the date on which such head grants such waiver; and

(C) if such waiver is limited to a period of not more than 365 days.

(2) PUBLIC HEALTH EMERGENCY WAIVER.—The head of the applicable executive agency may waive the prohibitions described in subsections (a) and (b) on a case-by-case basis for the procurement of specific medical countermeasures, medical products, and related supplies (including ancillary medical supplies that are not available in sufficient quantity from a source that is not a biotechnology company of concern and that are necessary for the direct response to a public health emergency de-

clared pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d))—

(A) with the approval of the Director of the Office of Management and Budget, in consultation with the Secretary of Defense;

(B) if such head submits a notification and justification to the appropriate congressional committees not later than 30 days after the date on which such head grants such waiver; and

(C) if such waiver is limited to the duration of such public health emergency or a period of not more than 180 days (whichever is shorter).

(3) EXTENSION.—The head of the applicable executive agency, with the approval of the Director of the Office of Management and Budget and in consultation with the Secretary of Defense, may extend a waiver granted under paragraph (1) or (2) 1 time, for a period of not more than 180 days after the date on which such waiver would otherwise expire, if—

(A) such an extension is in the national security interests of the United States; and

(B) such head submits a notification and justification to the appropriate congressional committees not later than 10 days after the date on which such head grants such extension.

(4) OVERSEAS HEALTH CARE SERVICES.—The head of an executive agency may waive the prohibitions described in 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 such head determines that such 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 and in consultation with 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 the date on which such head grants such waiver.

(e) EXCEPTIONS.—The prohibitions described in subsections (a) and (b) do not apply to—

(1) any activity subject to the reporting requirements described in 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), with official duty stations located overseas or who are on permissive temporary duty travel overseas; or

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

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

(ii) with primary duty stations located overseas or who are on permissive temporary duty travel overseas; or

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

(f) EVALUATION OF CERTAIN BIOTECHNOLOGY ENTITIES.—

(1) ENTITY DETERMINATION.—Not later than 365 days after the date of the enactment of this section, the Director of the Office of Management and Budget shall publish a list of entities that are a biotechnology company of concern.

(2) GUIDANCE.—Not later than 180 days after the publication of the list pursuant to paragraph (1) and any update to such list pursuant to paragraph (3), 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, the Secretary of State, and the National Cyber Director, shall establish guidance as necessary to implement the requirements of this section.

(3) UPDATES.—The Director of the Office of Management and Budget, in coordination with or based on a recommendation provided by the Sec-

retary 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, the Secretary of State, and the National Cyber Director, shall periodically (and not later than annually) review and, as appropriate, remove entities from or add entities to the list published pursuant to paragraph (1) and notify the appropriate congressional committees of any such removals or additions.

(4) NOTICE OF POTENTIAL DESIGNATION AND REVIEW.—

(A) IN GENERAL.—The Director of the Office of Management and Budget shall issue to any entity under final consideration for determination as a biotechnology company of concern described in subsection (k)(2)(B) or (k)(2)(C) a notice—

(i) advising that such entity is under consideration;

(ii) identifying the criteria relied upon under subsection (k)(2)(B) or (k)(2)(C) and, to the extent consistent with national security and law enforcement interests, the

information that formed the basis for such consideration;

(iii) advising that, not later than 90 days after the date on which such entity receives such notice, such entity may submit to the Director of the Office of Management and Budget information and argument in opposition to being determined to be a biotechnology company of concern;

(iv) describing the procedures governing the review and possible issuance of a determination pursuant to paragraph (1); and

(v) where practicable, identifying mitigation steps such entity may take that may prevent such determination.

(B) CONGRESSIONAL NOTIFICATION REQUIREMENTS.—

(i) NOTICE OF POTENTIAL DETERMINATION.—The Director of the Office of Management and Budget shall submit the notice required by subparagraph (A) to the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Oversight and Govern-

ment Reform of the House of Representatives.

(ii) INFORMATION AND ARGUMENT IN OPPOSITION TO DETERMINATIONS.—Not later than 7 days after the date on which the Director of the Office of Management and Budget receives any information and argument pursuant to subparagraph (A)(iii), the Director of the Office of Management and Budget shall submit such information and argument to the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Oversight and Government Reform of the House of Representatives.

(5) NO IMMEDIATE PUBLIC RELEASE.—Any identifying information about any entity being considered for determination as a biotechnology company of concern pursuant to paragraph (1) or paragraph (3) may not be made publicly available until the Director of the Office of Management and Budget includes such entity on the list published pursuant to paragraph (1).

(g) EVALUATION OF NATIONAL SECURITY RISKS POSED BY FOREIGN ADVERSARY ACQUISITION OF AMERICAN MULTIOMIC DATA.—

(1) ASSESSMENT.—Not later than 270 days after the date of the enactment of this section, the Director of National Intelligence, in consultation with the Secretary of Defense, the Attorney General of the United States, the Secretary of Health and Human Services, the Secretary of Commerce, the Secretary of Homeland Security, the Secretary of State, and the National Cyber Director, shall complete an assessment of risks to national security posed by human multiomic data from United States citizens that is collected or stored by a foreign adversary from the provision of any biotechnology equipment or service.

(2) REPORT REQUIREMENT.—Not later than 30 days after the date on which the assessment is completed pursuant to paragraph (1), the Director of National Intelligence shall submit to the appropriate congressional committees a report that details the results of such assessment.

(3) FORM.—The report required by paragraph (2) shall be in unclassified form, but may include a classified annex.

(h) REGULATIONS.—Not later than 1 year after the date on which the guidance is established pursuant to subsection (f)(2), and as necessary for subsequent updates, the Federal Acquisition Regulatory Council shall revise the Federal Acquisition Regulation as necessary to implement the requirements of this section.

(i) REPORTING ON INTELLIGENCE ON NEFARIOUS ACTIVITIES OF BIOTECHNOLOGY COMPANIES WITH HUMAN MULTIOMIC DATA.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this section, and annually thereafter, the Director of National Intelligence, in consultation with the heads of executive agencies, shall submit to the appropriate congressional committees a report that details any intelligence in possession of such executive agencies that relates to nefarious activities conducted by biotechnology companies with human multiomic data.

(2) CONTENTS.—The report required by paragraph (1) shall include information relating to potential threats to national security or public safety from the selling, reselling, licensing, trading, transferring, sharing, or otherwise providing or making available to any foreign country of any forms of multiomic data of a United States citizen.

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

(k) DEFINITIONS.—In this section:

(1) The term ''appropriate congressional committees'' means—

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

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

(2) The term ''biotechnology company of concern'' means any of the following:

(A) An entity that is to any extent involved in the manufacturing, distribution, provision, or procurement of any biotechnology equipment or service and is identified in the annual list pub-

lished in the Federal Register by the Department of Defense of Chinese military companies operating in the United States pursuant to section 1260H(b)(2) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116–283; 10 U.S.C. 113 note).

(B) Any entity that is determined by the Director of the Office of Management and Budget, based on recommendations provided by the Secretary of Defense in coordination with the Attorney General, the Secretary of Health and Human Services, the Secretary of Commerce, the Director of National Intelligence, the Secretary of Homeland Security, the Secretary of State, and the National Cyber Director, to meet the following criteria:

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

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

(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 the military, internal security forces, or intelligence agencies of a foreign adversary;

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

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

(C) An entity determined by the Director of the Office of Management, in consultation with the Secretary of Commerce, Secretary of Defense, and Director of National Intelligence, to be a subsidiary, parent, affiliate, or successor of a listed biotechnology company of concern (if the entity meets the criteria described in clauses (i) through (iii) of subparagraph (B)).

(3) The term ''biotechnology equipment or service'' means—

(A) equipment, including genetic sequencers 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 an 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 is designed for use in the research, development, production, or

analysis of biological materials 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 in the interest of national security.

(4) The term ''contract'' (except as that term is used in subsection (b)(2) and subsection (c)(3)) means any contract subject to the Federal Acquisition Regulation issued under section 1303(a)(1) of title 41, United States Code, any transaction (other than a contract, a grant, or a cooperative agreement) entered into under section 4021 of title 10, United States Code, or any similar authority.

(5) The term ''control'' has the meaning given that term in section 800.208 of title 31, Code of Federal Regulations (or any successor regulation).

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

(7) The term ''foreign adversary'' has the meaning given the term ''covered nation'' in section 4872(f) of title 10, United States Code.

(8) The term ''multiomic'' means data types that include genomics, epigenomics, transcriptomics, proteomics, and metabolomics.

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

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