[DISCUSSION DRAFT]

119TH CONGRESS
2D SESSION

H. R. _____

To direct the Secretary of Commerce to promote competitiveness in biomanufacturing in the United States, identify supply-chain and commercialization vulnerabilities relating to critical biomanufacturing inputs and domestic production capacity, improve transparency regarding Federal processes applicable to biomanufactured products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To direct the Secretary of Commerce to promote competitiveness in biomanufacturing in the United States, identify supply-chain and commercialization vulnerabilities relating to critical biomanufacturing inputs and domestic production capacity, improve transparency regarding Federal processes applicable to biomanufactured products, 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 ''Biomanufacturing Excellence, Domestic Resilience, Output, and Competitive Know-how Act'' or the ''BEDROCK Act''.

SEC. 2. ACTIVITIES RELATED TO PROMOTING COMPETITIVENESS IN BIOMANUFACTURING IN THE UNITED STATES.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall begin carrying out the activities described in subsection (b) to promote commercial competitiveness with respect to biomanufacturing and biomanufactured products in the United States.

(b) ACTIVITIES DESCRIBED.—The activities described in this subsection are the following:

(1) Identify the following:

(A) Any Federal process, resource, or publicly available information that promotes commercial competitiveness with respect to biomanufacturing and biomanufactured products in domestic and foreign commerce.

(B) Any barrier to private sector investment in biomanufacturing, market adoption of biomanufactured products, or domestic production of such products, including barriers arising from unclear, duplicative, or unpredictable Fed-

eral processes applicable to the commercialization of such products.

(C) Any vulnerability, chokepoint, supplier concentration, single point of failure, market barrier, or other constraint affecting a supply-chain for a critical biomanufacturing input, including any such vulnerability, chokepoint, or other constraint related to a foreign adversary or an entity incorporated in a foreign adversary.

(D) Any opportunity for a private sector entity or policymaker to strengthen domestic production, supplier diversification, commercialization, and supply-chain resilience related to biomanufacturing or biomanufactured products.

(E) The availability of domestic production capacity and other resources relevant to the commercial manufacturing of biomanufactured products in the United States, including amino acids, industrial enzymes, microbial strains, cell lines, cell banks, bioreactors, and single-use bioprocessing components.

(2) Facilitate voluntary consultations with non-Federal entities to promote commercial competitive-

ness with respect to biomanufacturing and biomanufactured products, including consultations related to the practices described in subsection (d).

(3) Consult with relevant Federal agencies, including the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, and the Administrator of the Environmental Protection Agency, as the Secretary determines appropriate, with respect to matters affecting competitiveness with respect to biomanufacturing, supply-chain resilience related to biomanufacturing, and commercial manufacturing of biomanufactured products.

(4) Maintain a publicly available web resource that, to the extent practicable, consolidates or links to existing publicly available Federal resources relevant to the commercialization of biomanufactured products, including the pathway map required under subsection (e), agency points of contact, practices identified and made publicly available under subsection (d), and other publicly available information identified by the Secretary.

(5) Serve as a point of coordination for non-Federal entities seeking publicly available information regarding Federal processes relevant to the

commercialization of biomanufactured products, including by referring such entities to the appropriate Federal agencies.

(c) ASSESSMENT.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, and every 2 years thereafter until the date described in subsection (h), the Secretary shall conduct an assessment with respect to the following:

(A) The current and, to the extent practicable, reasonably foreseeable future availability of critical biomanufacturing inputs and domestic production capacity relevant to biomanufacturing in the United States.

(B) The extent to which private sector entities in the United States rely on foreign adversaries or entities incorporated in foreign adversaries for critical biomanufacturing inputs or domestic production capacity relevant to biomanufacturing.

(C) Any vulnerability, chokepoint, single point of failure, supplier concentration, market barrier, or other constraint impacting the access by private sector entities to critical bio-

manufacturing inputs or domestic capacity relevant to biomanufacturing.

(D) The availability of substitutes for critical biomanufacturing inputs in the United States and in non-foreign adversaries.

(E) Any estimate for lead times and economic or operational barriers related to reducing reliance by private sector entities on foreign adversaries or entities incorporated in foreign adversaries with respect to critical biomanufacturing inputs or domestic production capacity relevant to biomanufacturing.

(F) Any barrier affecting private sector entities seeking to transition biomanufacturing processes or biomanufactured products to commercial production, including barriers to commercial manufacturing or market adoption arising from unclear, duplicative, or unpredictable Federal processes applicable to commercialization, processes for which commercialization review is divided among multiple Federal agencies, and barriers arising from limited access to shared pilot-scale and demonstration-scale manufacturing capacity.

(G) Any opportunity for domestic producers and suppliers to expand the capacity of, improve the reliability of, and diversify supply chains for critical biomanufacturing inputs.

(H) Any impact to commerce and biomanufacturing in the United States if a vulnerability, chokepoint, single point of failure, supplier concentration, market barrier, or other constraint identified under subparagraph (C) is not addressed, including potential consequences for domestic supply-chain resilience and access to biomanufactured products.

(I) Global biomanufacturing production capacity, including contract and company-owned facilities, to compare biomanufacturing capacity in the United States with biomanufacturing capacity in other countries, including capacity associated with entities incorporated in foreign adversaries, and to assess the impact of such capacity on domestic industry.

(2) PRIORITIZATION.—In conducting the assessment under paragraph (1), the Secretary shall prioritize matters based on the commercial significance of the affected critical biomanufacturing input, the potential consequences for commerce in

the United States, the extent of involvement by foreign adversaries or entities incorporated in foreign adversaries, the availability of substitutes, and the estimated lead times and barriers for reducing reliance on foreign adversaries and foreign adversary entities.

(3) PRIORITIZED ACTION PLAN.—Based on each assessment under paragraph (1), the Secretary shall prepare a prioritized action plan that—

(A) ranks, by commercial significance and potential consequences for commerce in the United States, the supply-chain risks and commercialization barriers identified in the assessment;

(B) identifies actions the Department of Commerce may take under existing authorities to improve supply-chain visibility, stakeholder coordination, and access to information regarding the commercialization of biomanufactured products;

(C) identifies existing Federal financial assistance programs and other existing Federal resources that may be available to address the supply-chain risks and commercialization barriers identified in the assessment, and consoli-

dates publicly available information regarding such programs and resources for reference by non-Federal entities; and

(D) identifies opportunities for the Department of Commerce to coordinate with relevant Federal agencies, private sector entities, and non-Federal entities to reduce such risks and barriers.

(d) VOLUNTARY PRACTICES.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, and as the Secretary determines appropriate thereafter, the Secretary shall identify and make publicly available industry-led, evidence-based, or widely accepted practices related to the following:

(A) The commercialization of biomanufacturing.

(B) The readiness of biomanufacturing processes or biomanufactured products for commercial production.

(C) The process reliability, operational consistency, and supply assurance of biomanufacturing processes and biomanufactured products.

(D) Supplier qualification, supplier diversification, and commercial supply chain risk

management for critical biomanufacturing inputs.

(E) The voluntary sharing of nonproprietary information relating to the process, performance, and supply-chain of biomanufacturing processes or biomanufactured products necessary to support commercialization and commercial manufacturing, including the secure and portable transfer of information that a process originator elects to share with a manufacturing partner, as appropriate.

(F) The protection of trade secrets, confidential business information, and intellectual property relating to biomanufacturing.

(G) The participation of small and medium-sized businesses and manufacturers in biomanufacturing.

(H) The use of biomanufactured products in domestic and foreign commerce.

(I) The use of digital, computational, automated, or artificial intelligence tools in commercial biomanufacturing to improve reliability, efficiency, and quality consistency.

(2) EXISTING PRACTICES.—In carrying out paragraph (1), the Secretary shall prioritize identi-

fying and making accessible existing practices, including practices issued or maintained by industry-led organizations, and shall avoid unnecessary duplication of such practices.

(3) CONSULTATION.—In carrying out paragraph (1), the Secretary shall consult with non-Federal entities, including the following:

(A) The following private sector entities:

(i) Manufacturers and suppliers of critical biomanufacturing inputs.

(ii) Small and medium-sized businesses and manufacturers of biomanufactured products.

(iii) Companies seeking to commercialize, produce, or use biomanufactured products.

(iv) Investors, accelerators, and other entities involved in commercialization.

(B) State, local, Tribal, territorial, and regional commerce or manufacturing organizations.

(C) Nonprofit organizations, industry associations, technical organizations, and experts in commercial supply-chain resilience, manufacturing, and competitiveness.

(4) METHODS.—The Secretary may solicit public input under this subsection through requesting information, workshops, roundtables, or meetings with non-Federal entities, or any other means the Secretary determines appropriate.

(5) PRIORITIZATION OF UNITED STATES AND TRUSTED STAKEHOLDERS.—If the Secretary carries out paragraph (3), the Secretary shall prioritize, to the extent practicable, input from non-Federal entities in the United States and other stakeholders that are not a foreign adversary or an entity incorporated in a foreign adversary.

(6) PUBLIC INPUT.—The Secretary shall provide not less than 1 opportunity for the public to submit input under this subsection.

(e) FEDERAL COMMERCIALIZATION PATHWAY MAP; AGENCY POINTS OF CONTACT.—

(1) PATHWAY MAP.—Not later than 1 year after the date of the enactment of this Act, the Secretary, in consultation with the heads of relevant Federal agencies, shall submit to the appropriate congressional committees and make publicly available a report that maps Federal processes that may apply to the commercialization of biomanufactured

products and, as appropriate, critical biomanufacturing inputs.

(2) CONTENTS.—The report required under paragraph (1) shall—

(A) organize such processes by category of biomanufactured product or, as appropriate, critical biomanufacturing input;

(B) identify publicly available agency points of contact and existing public guidance relevant to such processes;

(C) identify overlaps, gaps, ambiguities, and timing or predictability concerns among such processes; and

(D) identify opportunities, consistent with existing law, to improve the clarity and predictability of, and reduce duplication among, such processes.

(3) AGENCY POINTS OF CONTACT.—Not later than 180 days after the date of the enactment of this Act—

(A) the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall designate a point of contact to assist non-Federal entities in identifying publicly available information regarding Food

and Drug Administration processes that may apply to biomanufactured products or critical biomanufacturing inputs and, as appropriate, to coordinate across relevant components of the Food and Drug Administration; and

(B) the Administrator of the Environmental Protection Agency shall designate a point of contact to assist non-Federal entities in identifying publicly available information regarding laws administered by the Environmental Protection Agency that may apply to biomanufactured products or critical biomanufacturing inputs.

(4) INTEGRATION WITH EXISTING RESOURCES.—In carrying out this section, the Secretary may satisfy a requirement to create, maintain, submit, or make publicly available a Federal resource, report, assessment, map, strategy, or activity by consolidating, linking to, or relying on a substantially similar Federal resource, report, assessment, map, strategy, or activity, including a resource, report, assessment, map, strategy, or activity carried out under another provision of law, if the Secretary determines that such resource, report, as-

sessment, map, strategy, or activity substantially addresses the applicable requirement.

(f) PROTECTION OF INFORMATION.—

(1) IN GENERAL.—The Secretary may not publicly disclose any nonpublic information obtained voluntarily from a non-Federal entity under this section that is a trade secret, confidential business information, or sensitive supply-chain vulnerability information.

(2) EXEMPTION FROM DISCLOSURE.—Information described in paragraph (1) shall be exempt from public disclosure under section 552 of title 5, United States Code, and section 552(b)(3) of such title shall apply to such information.

(3) DESIGNATION.—The Secretary may establish a process for a non-Federal entity voluntarily submitting information under this section to identify information the entity considers to be a trade secret, confidential business information, or sensitive supply-chain vulnerability information.

(4) AGGREGATE ANONYMIZED INFORMATION.—Nothing in this subsection shall be construed to prohibit the Secretary from disclosing aggregate or anonymized information that does not identify a spe-

cific non-Federal entity or disclose information described in paragraph (1).

(g) REPORTS.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, and every 2 years thereafter until the date described in subsection (h), the Secretary shall submit to the appropriate congressional committees, and make publicly available on a website of the Department of Commerce, a report that includes the following:

(A) A summary of any actions carried out by the Secretary under this section.

(B) The assessment under subsection (c), including any prioritized action plan prepared under subsection (c)(3).

(C) A summary of any practices identified and made publicly available under subsection (d).

(D) Any updates to the report required under subsection (e)(1).

(2) NONPUBLIC ANNEX.—The Secretary may submit to the appropriate congressional committees a nonpublic annex to a report required under paragraph (1) that includes any information described in paragraph (1) of subsection (f).

(h) TERMINATION.—

(1) IN GENERAL.—The requirements under subsections (a) through (e) and subsection (g) shall terminate on the date that is 5 years after the date of the enactment of this Act.

(2) EXCEPTION.—Paragraph (1) does not apply with respect to subsection (f), and the Secretary may continue to maintain any public resource created under this section before the date described in paragraph (1).

(i) DEFINITIONS.—In this section:

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

(A) the Committee on Energy and Commerce of the House of Representatives; and

(B) the Committee on Commerce, Science, and Transportation of the Senate.

(2) BIOMANUFACTURED PRODUCT.—The term ''biomanufactured product'' means a commercial good, material, chemical, protein, component, industrial input, or other product or substance in commerce that is produced, processed, or transformed through biomanufacturing.

(3) BIOMANUFACTURING.—The term ''biomanufacturing'' means the use of biological systems, including cells, cell-free systems, enzymes, or biomolecules, in manufacturing processes to produce, process, or transform commercial goods, materials, chemicals, proteins, components, industrial inputs, or other products or substances in commerce.

(4) CRITICAL BIOMANUFACTURING INPUT.—The term ''critical biomanufacturing input'' means an input, material, reagent, item of equipment, or software used in biomanufacturing that is commercially significant to biomanufacturing in the United States and subject to supply-chain risk, such as supplier concentration, reliance on a foreign adversary or entity that is incorporated in a foreign adversary, limited substitutes, or long lead times.

(5) FOREIGN ADVERSARY.—The term ''foreign adversary'' means a foreign government or foreign non-government person determined by the Secretary to be a foreign adversary under section 791.4 of title 15, Code of Federal Regulations, or any successor regulation.

(6) NON-FEDERAL ENTITY.—The term ''non-Federal entity'' means a State, local, Tribal, or territorial government, nonprofit organization, technical

organization, industry association, commerce or manufacturing organization, private sector entity, or other stakeholder.

(7) SECRETARY.—The term ''Secretary'' means the Secretary of Commerce.

(8) SENSITIVE SUPPLY-CHAIN VULNERABILITY INFORMATION.—The term ''sensitive supply-chain vulnerability information'' means nonpublic information obtained under this section, the disclosure of which the Secretary determines could reasonably be expected to reveal a vulnerability, dependency, chokepoint, or other weakness in a supply chain relevant to biomanufacturing in the United States.