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(Original Signature of Member)

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Biomanufacturing Ex-
3 cellence, Domestic Resilience, Output, and Competitive
4 Know-how Act” or the “BEDROCK Act”.

5 **SEC. 2. ACTIVITIES RELATED TO PROMOTING COMPETI-**
6 **TIVENESS IN BIOMANUFACTURING IN THE**
7 **UNITED STATES.**

8 (a) IN GENERAL.—Not later than 1 year after the
9 date of the enactment of this Act, the Secretary shall des-
10 ignate a senior official to—

11 (1) lead the activities of the Department of
12 Commerce relating to biomanufacturing and bio-
13 manufactured products in the United States;

14 (2) carry out the activities described in sub-
15 section (b); and

16 (3) promote commercial competitiveness with
17 respect to such biomanufacturing and biomanufac-
18 tured products.

19 (b) ACTIVITIES DESCRIBED.—The activities de-
20 scribed in this subsection are the following:

21 (1) Identify the following:

22 (A) Any Federal process, resource, or pub-
23 licly available information relevant to promoting
24 commercial competitiveness with respect to bio-
25 manufacturing and biomanufactured products
26 in domestic and foreign commerce.

1 (B) Any barrier to private sector invest-
2 ment in biomanufacturing, market adoption of
3 biomanufactured products, or domestic produc-
4 tion of such products, including barriers arising
5 from unclear, duplicative, or unpredictable Fed-
6 eral processes related to the commercialization
7 of such products.

8 (C) Any vulnerability, chokepoint, supplier
9 concentration, single point of failure, market
10 barrier, or other constraint affecting a supply
11 chain related to a critical biomanufacturing
12 input, including any such vulnerability,
13 chokepoint, supplier concentration, single point
14 of failure, market barrier, or other constraint
15 related to a foreign adversary or a foreign ad-
16 versary entity.

17 (D) Any opportunity for a private sector
18 entity or policymaker to strengthen domestic
19 production, supplier diversification, commer-
20 cialization, and supply chain resilience related
21 to biomanufacturing or biomanufactured prod-
22 ucts.

23 (E) The availability of domestic production
24 capacity, inputs, equipment, and other re-
25 sources related to the commercial manufac-

1 turing of biomanufactured products in the
2 United States, including with respect to the fol-
3 lowing:

- 4 (i) Amino acids.
- 5 (ii) Industrial enzymes.
- 6 (iii) Microbial strains.
- 7 (iv) Cell lines.
- 8 (v) Cell banks.
- 9 (vi) Bioreactors.
- 10 (vii) Single-use bioprocessing compo-
11 nents.

12 (2) Facilitate consultations, on a voluntary
13 basis, for participating non-Federal entities to pro-
14 mote commercial competitiveness with respect to bio-
15 manufacturing and biomanufactured products, in-
16 cluding consultations required pursuant to sub-
17 section (d)(3).

18 (3) Consult with the heads of relevant Federal
19 agencies, and any relevant agency point of contact,
20 including the Secretary of Health and Human Serv-
21 ices, acting through the Commissioner of Food and
22 Drugs, and the Administrator of the Environmental
23 Protection Agency, as the Secretary determines ap-
24 propriate, with respect to matters affecting the com-
25 petitiveness of biomanufacturing, supply-chain resil-

1 ience, and the commercial manufacturing of bio-
2 manufactured products.

3 (4) Maintain a publicly available web resource
4 that consolidates or provides links to publicly avail-
5 able Federal resources relevant to the commer-
6 cialization of biomanufactured products, as deter-
7 mined appropriate by the Secretary, including the
8 following information and resources:

9 (A) Any practice identified and made pub-
10 licly available under subsection (d).

11 (B) The report required under subsection
12 (e)(1).

13 (C) Any point of contact designated under
14 subsection (e)(3) or otherwise made publicly
15 available by a relevant Federal agency.

16 (5) Serve as a point of coordination for non-
17 Federal entities seeking publicly available informa-
18 tion related to a Federal process identified under
19 paragraph (1)(A), including by referring such enti-
20 ties to the appropriate Federal agency or point of
21 contact.

22 (c) ASSESSMENT.—

23 (1) IN GENERAL.—Not later than 1 year after
24 the date of the enactment of this Act, and every 2
25 years thereafter, the Secretary, acting through the

1 senior official designated pursuant to subsection (a),
2 shall conduct an assessment with respect to the fol-
3 lowing:

4 (A) The current and, to the extent prac-
5 ticable, reasonably foreseeable future avail-
6 ability of critical biomanufacturing inputs and
7 domestic production capacity related to bio-
8 manufacturing in the United States.

9 (B) The extent to which private sector en-
10 tities in the United States rely on foreign ad-
11 versaries or foreign adversary entities for crit-
12 ical biomanufacturing inputs or production ca-
13 pacity related to biomanufacturing.

14 (C) Any vulnerability, chokepoint, single
15 point of failure, supplier concentration, market
16 barrier, or other constraint impacting the ac-
17 cess of a private sector entity to critical bio-
18 manufacturing inputs or domestic production
19 capacity related to biomanufacturing.

20 (D) The availability of substitutes for crit-
21 ical biomanufacturing inputs in the United
22 States, including from other sources that are
23 not foreign adversaries or foreign adversary en-
24 tities.

1 (E) Estimated lead times and economic or
2 operational barriers to reducing reliance by pri-
3 vate sector entities on a foreign adversary or a
4 foreign adversary entity for critical biomanufac-
5 turing inputs or production capacity related to
6 biomanufacturing.

7 (F) Any barrier identified under subsection
8 (b)(1)(B), including the following:

9 (i) Any Federal process for which a
10 review related to commercialization is di-
11 vided among multiple Federal agencies.

12 (ii) Any barrier arising from limited
13 access to shared pilot-scale and demonstra-
14 tion-scale manufacturing capacity.

15 (G) Any opportunity for domestic pro-
16 ducers and suppliers to expand the capacity of,
17 improve the reliability of, and diversify supply
18 chains for critical biomanufacturing inputs.

19 (H) Any impact on commerce and bio-
20 manufacturing in the United States if a vulner-
21 ability, chokepoint, single point of failure, sup-
22 plier concentration, market barrier, or other
23 constraint identified under subparagraph (C) is
24 not addressed, including any impact on relevant

1 domestic supply-chain resilience and access to
2 biomanufactured products.

3 (I) Biomanufacturing capacity located out-
4 side of the United States, including capacity at
5 contract manufacturing facilities and company-
6 owned facilities, and capacity owned or con-
7 trolled by foreign adversaries or foreign adver-
8 sary entities, to—

9 (i) compare such biomanufacturing
10 capacity with the biomanufacturing capac-
11 ity of the United States; and

12 (ii) assess the impact of such capacity
13 on domestic industry.

14 (2) PRIORITIZATION.—In conducting the as-
15 sessment under paragraph (1), the Secretary, acting
16 through the senior official designated pursuant to
17 subsection (a), shall prioritize the matters described
18 in such paragraph based on the following:

19 (A) The commercial significance of the rel-
20 evant affected critical biomanufacturing input
21 or production capacity.

22 (B) Potential consequences for commerce
23 in the United States.

24 (C) The extent of reliance on foreign ad-
25 versaries or foreign adversary entities.

1 (D) Estimated lead times and barriers to
2 reducing such reliance.

3 (E) The availability of substitute sources.

4 (3) PRIORITIZED ACTION PLAN.—Based on
5 each assessment under paragraph (1), the Secretary
6 shall prepare and include in any report submitted
7 and made publicly available under subsection (g) a
8 prioritized action plan that—

9 (A) ranks each supply-chain risk and com-
10 mercialization barrier identified in the assess-
11 ment by commercial significance and potential
12 consequence for commerce in the United States;

13 (B) identifies actions the Secretary may
14 take to improve supply-chain visibility, stake-
15 holder coordination, and access to information
16 related to the commercialization of biomanufac-
17 tured products;

18 (C) identifies existing Federal financial as-
19 sistance programs and other Federal resources
20 that may address any such supply-chain risk or
21 commercialization barrier;

22 (D) identifies any program or resource de-
23 scribed in subparagraph (C) that should be
24 added to the web resource maintained under
25 subsection (b)(4); and

1 (E) identifies opportunities for the Sec-
2 retary to coordinate with relevant Federal agen-
3 cies and non-Federal entities to reduce such
4 risks and barriers.

5 (d) VOLUNTARY PRACTICES.—

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

12 (A) The commercialization of biomanufac-
13 turing processes and biomanufactured products.

14 (B) The readiness of biomanufacturing
15 processes or biomanufactured products for com-
16 mercial production.

17 (C) The reliability and operational consist-
18 ency of biomanufacturing processes and the
19 quality of biomanufactured products.

20 (D) Supplier qualification, supplier diver-
21 sification, and commercial supply chain risk
22 management for critical biomanufacturing in-
23 puts.

24 (E) The voluntary sharing of nonpropri-
25 etary information related to biomanufacturing

1 process and the supply chains for biomanufac-
2 turing processes or biomanufactured products
3 that is necessary to support commercialization
4 and commercial manufacturing, including the
5 secure and portable transfer of information that
6 a process originator elects to share with a man-
7 ufacturing partner, as appropriate.

8 (F) The protection of trade secrets, con-
9 fidential business information, and intellectual
10 property relating to biomanufacturing.

11 (G) The participation of small and me-
12 dium-sized businesses and manufacturers in
13 biomanufacturing.

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

16 (I) The use of digital, computational, auto-
17 mated, or artificial intelligence tools in commer-
18 cial biomanufacturing to improve reliability, ef-
19 ficiency, product quality, and consistency.

20 (2) EXISTING PRACTICES.—In carrying out
21 paragraph (1), the Secretary shall—

22 (A) prioritize identifying existing practices,
23 including practices issued or maintained by in-
24 dustry-led organizations, and making such prac-
25 tices publicly available; and

1 (B) avoid unnecessary duplication of such
2 practices.

3 (3) CONSULTATION.—In carrying out para-
4 graph (1), the Secretary shall consult with non-Fed-
5 eral entities, including the following:

6 (A) The following private sector entities:

7 (i) Manufacturers and suppliers of
8 critical biomanufacturing inputs.

9 (ii) Small and medium-sized busi-
10 nesses and manufacturers of biomanufac-
11 tured products.

12 (iii) Companies seeking to commer-
13 cialize, produce, or use biomanufactured
14 products.

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

17 (B) State, local, Tribal, territorial, and re-
18 gional commerce or manufacturing organiza-
19 tions.

20 (C) Experts in commercial supply-chain re-
21 silience, manufacturing, and competitiveness.

22 (4) PRIORITIZATION OF UNITED STATES AND
23 TRUSTED STAKEHOLDERS.—In carrying out para-
24 graph (3), the Secretary shall prioritize, to the ex-
25 tent practicable, input from non-Federal entities in

1 the United States and other stakeholders that are
2 neither foreign adversaries nor foreign adversary en-
3 tities.

4 (5) PUBLIC INPUT.—

5 (A) IN GENERAL.—The Secretary shall
6 provide at least 1 opportunity for the public to
7 submit input under this subsection.

8 (B) METHODS.—The Secretary may solicit
9 public input under this subsection through
10 making requests for information, workshops,
11 roundtables, meetings with non-Federal entities,
12 or any other means the Secretary determines
13 appropriate.

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

16 (1) REPORT.—Not later than 1 year after the
17 date of the enactment of this Act, the Secretary, in
18 consultation with the heads of relevant Federal
19 agencies, shall submit to the appropriate congres-
20 sional committees and make publicly available a re-
21 port that identifies and maps any Federal process
22 that may apply to the commercialization of biomanu-
23 factured products and critical biomanufacturing in-
24 puts, as the Secretary determines appropriate.

1 (2) CONTENTS.—The report required under
2 paragraph (1) shall do the following:

3 (A) Organize any Federal process identi-
4 fied and mapped under such paragraph by cat-
5 egory of biomanufactured product or critical
6 biomanufacturing input, as the Secretary deter-
7 mines appropriate.

8 (B) Identify the following:

9 (i) Any publicly available point of con-
10 tact for a Federal agency and any existing
11 public guidance related to any such Fed-
12 eral process.

13 (ii) Overlaps, gaps, ambiguities, and
14 timing or predictability concerns related to
15 any such Federal process.

16 (iii) Opportunities to improve the clar-
17 ity and predictability of, and reduce dupli-
18 cation among, any such Federal process.

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

22 (A) the Secretary of Health and Human
23 Services, acting through the Commissioner of
24 Food and Drugs, shall—

1 (i) designate a point of contact to as-
2 sist non-Federal entities in identifying pub-
3 licly available information related to any
4 process of the Food and Drug Administra-
5 tion that may apply to biomanufactured
6 products or critical biomanufacturing in-
7 puts; and

8 (ii) ensure such point of contact co-
9 ordinates, as appropriate, with relevant
10 components of the Food and Drug Admin-
11 istration in carrying out clause (i); and

12 (B) the Administrator of the Environ-
13 mental Protection Agency shall designate a
14 point of contact to assist non-Federal entities in
15 identifying publicly available information re-
16 lated to laws administered by the Administrator
17 of the Environmental Protection Agency that
18 may apply to biomanufactured products or crit-
19 ical biomanufacturing inputs.

20 (4) INTEGRATION WITH EXISTING RE-
21 SOURCES.—

22 (A) IN GENERAL.—In carrying out para-
23 graphs (1) and (2), the Secretary may incor-
24 porate or rely on a substantially similar existing
25 Federal resource, report, assessment, map, or

1 other activity if the Secretary determines that it
2 substantially addresses the applicable require-
3 ment.

4 (B) INCLUSION IN REPORT.—If the Sec-
5 retary incorporates or relies on a substantially
6 similar existing Federal resource, report, as-
7 sessment, map, or other activity under subpara-
8 graph (A), the Secretary shall include in the re-
9 port required under paragraph (1) the fol-
10 lowing:

11 (i) An identification of the resource,
12 report, assessment, map, or other activity.

13 (ii) An explanation of how the re-
14 source, report, assessment, map, or other
15 activity addresses the applicable require-
16 ment.

17 (5) UPDATES.—The Secretary shall update the
18 report required under paragraph (1) to reflect any
19 material change to any Federal process described in
20 such paragraph, as the Secretary determines appro-
21 priate.

22 (f) PROTECTION OF INFORMATION.—

23 (1) IN GENERAL.—The Secretary may not pub-
24 licly disclose any nonpublic information voluntarily

1 submitted by a non-Federal entity under this section
2 that—

3 (A) constitutes a trade secret or confiden-
4 tial business information; or

5 (B) is sensitive supply-chain vulnerability
6 information.

7 (2) EXEMPTION FROM DISCLOSURE.—Informa-
8 tion described in paragraph (1) shall be exempt from
9 disclosure under section 552(b)(3) of title 5, United
10 States Code.

11 (3) IDENTIFICATION AND DETERMINATION.—

12 (A) IN GENERAL.—The Secretary shall es-
13 tablish a process for a non-Federal entity that
14 voluntarily submits information under this sec-
15 tion to identify whether the entity considers
16 such information to be nonpublic information
17 described in paragraph (1).

18 (B) DETERMINATION.—If a non-Federal
19 entity makes an identification under the process
20 required by subparagraph (A), with respect to
21 information voluntarily submitted under this
22 section by such entity, the Secretary shall de-
23 termine whether such information is nonpublic
24 information described in paragraph (1).

1 (C) TREATMENT PENDING DETERMINA-
2 TION.—The Secretary may not publicly disclose
3 any information with respect to which a non-
4 Federal entity makes an identification under
5 paragraph (3)(A) unless the Secretary has de-
6 termined such information is not nonpublic in-
7 formation described in paragraph (1).

8 (g) REPORTS.—

9 (1) IN GENERAL.—Not later than 1 year after
10 the date of the enactment of this Act, and every 2
11 years thereafter, the Secretary, acting through the
12 senior official designated pursuant to subsection (a),
13 shall submit to the appropriate congressional com-
14 mittees, and make publicly available on a website of
15 the Department of Commerce, a report that includes
16 the following:

17 (A) A summary of any action carried out
18 by the Secretary under this section.

19 (B) Any assessment conducted under sub-
20 section (c).

21 (C) Any prioritized action plan prepared
22 under paragraph (3) of such subsection.

23 (D) A summary of any practices identified
24 and made publicly available under subsection
25 (d).

1 (E) Any updates related to the report re-
2 quired under subsection (e)(1).

3 (2) NONPUBLIC ANNEX.—The Secretary, acting
4 through the senior official designated pursuant to
5 subsection (a), may submit to the appropriate con-
6 gressional committees a nonpublic annex to a report
7 required under paragraph (1) that includes non-
8 public information described in subsection (f)(1).

9 (h) TERMINATION.—The requirements under sub-
10 sections (a) through (e) and subsection (g) shall terminate
11 on the date that is 5 years after the date of the enactment
12 of this Act.

13 (i) DEFINITIONS.—In this section:

14 (1) APPROPRIATE CONGRESSIONAL COMMIT-
15 TEES.—The term “appropriate congressional com-
16 mittees” means—

17 (A) the Committee on Energy and Com-
18 merce of the House of Representatives; and

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

21 (2) BIOMANUFACTURED PRODUCT.—The term
22 “biomanufactured product” means a commercial
23 good, material, chemical, protein, component, indus-
24 trial input, or other product or substance in com-

1 merce that is produced, processed, purified, or trans-
2 formed through biomanufacturing.

3 (3) BIOMANUFACTURING.—The term “bio-
4 manufacturing” means the use of biological systems,
5 including cells, cell-free systems, enzymes, or biomol-
6 ecules, in manufacturing processes to produce, proc-
7 ess, or transform commercial goods, materials,
8 chemicals, proteins, components, industrial inputs,
9 or other products or substances in commerce.

10 (4) CRITICAL BIOMANUFACTURING INPUT.—
11 The term “critical biomanufacturing input” means
12 an input, material, reagent, item of equipment, or
13 software used in biomanufacturing that is commer-
14 cially significant to biomanufacturing in the United
15 States and subject to supply-chain risk, such as sup-
16 plier concentration, reliance on a foreign adversary
17 or foreign adversary entity, limited substitutes, or
18 long lead times.

19 (5) FOREIGN ADVERSARY.—The term “foreign
20 adversary” means a foreign government or foreign
21 non-government person identified as a foreign adver-
22 sary under section 791.4 of title 15, Code of Federal
23 Regulations, or any successor regulation.

24 (6) FOREIGN ADVERSARY ENTITY.—The term
25 “foreign adversary entity” has the meaning given

1 the term “person owned by, controlled by, or subject
2 to the jurisdiction or direction of a foreign adver-
3 sary” in section 791.2 of title 15, Code of Federal
4 Regulations, or any successor regulation.

5 (7) NON-FEDERAL ENTITY.—The term “non-
6 Federal entity” means a State, local, Tribal, or ter-
7 ritorial government, nonprofit organization, technical
8 organization, industry association, commerce or
9 manufacturing organization, private sector entity, or
10 other stakeholder.

11 (8) SECRETARY.—The term “Secretary” means
12 the Secretary of Commerce.

13 (9) SENSITIVE SUPPLY-CHAIN VULNERABILITY
14 INFORMATION.—The term “sensitive supply-chain
15 vulnerability information” means nonpublic informa-
16 tion with respect to which the public disclosure of
17 such nonpublic information could be reasonably ex-
18 pected to reveal a vulnerability, dependency,
19 chokepoint, single point of failure, supplier con-
20 centration, or other weakness in a supply chain rel-
21 evant to biomanufacturing in the United States.