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To improve coordination of Federal efforts to identify and mitigate health and national security risks through maintaining a list of essential medicines, conducting a risk assessment of essential medicine supply chains, and creating a monitoring system to map essential medicine supply chains using data analytics.

IN THE SENATE OF THE UNITED STATES

MAY 15, 2025

Mr. PETERS (for himself, Mr. LANKFORD, Ms. ERNST, Mr. COTTON, Mr. KAINE, Mr. KING, and Mr. SCOTT of Florida) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To improve coordination of Federal efforts to identify and mitigate health and national security risks through maintaining a list of essential medicines, conducting a risk assessment of essential medicine supply chains, and creating a monitoring system to map essential medicine supply chains using data analytics.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Mapping America’s
5 Pharmaceutical Supply Act” or the “MAPS Act”.

1 **SEC. 2. ESSENTIAL MEDICINES LIST.**

2 (a) IN GENERAL.—The Secretary, in coordination
3 with the heads of other relevant Federal departments and
4 agencies and in consultation with, as appropriate, stake-
5 holders who have relevant expertise, shall update and
6 maintain a list of essential medicines (referred to in this
7 Act as the “Essential Medicines List”), initially developed
8 in response to Executive Order 13944 (85 Fed. Reg.
9 49929), to include active pharmaceutical ingredients and
10 drugs—

11 (1) that are directly related to responding to
12 chemical, biological, radiological, or nuclear threats
13 and incidents covered by the National Response
14 Framework;

15 (2) of greatest priority for providing health care
16 and identified as being at high risk of shortage;

17 (3) the shortage of which would have an ad-
18 verse health outcome on patients with chronic condi-
19 tions; or

20 (4) that the Secretary of Defense determines to
21 be critical for military preparedness.

22 (b) UPDATES TO LIST.—The Secretary shall update
23 the Essential Medicines List regularly, on a timeframe
24 that the Secretary determines necessary and appropriate,
25 and not less frequently than every 2 years.

1 (c) COMPILATION OF INITIAL LIST.—The Secretary
 2 shall complete the first updates to the Essential Medicines
 3 List required pursuant to subsection (a) not later than
 4 180 days after the date of enactment of this Act.

5 (d) PUBLICATION OF LIST.—The Secretary shall
 6 publish the Essential Medicines List promptly after each
 7 update pursuant to subsection (b) or (c).

8 **SEC. 3. ESSENTIAL MEDICINES RISK ASSESSMENT.**

9 (a) IN GENERAL.—The Secretary, in coordination
 10 with the Secretary of Defense and in consultation with the
 11 heads of other relevant departments and agencies, shall
 12 conduct a comprehensive risk assessment of the supply
 13 chains for active pharmaceutical ingredients and drugs in-
 14 cluded on the Essential Medicines List described in section
 15 2.

16 (b) CONTENTS OF ESSENTIAL MEDICINES RISK AS-
 17 SESSMENT.—At a minimum, the risk assessment under
 18 subsection (a) shall identify, to the extent available—

19 (1) key starting materials and excipients used
 20 in manufacturing the active pharmaceutical ingredi-
 21 ents and drugs on the Essential Medicines List;

22 (2) the active pharmaceutical ingredients and
 23 drugs on the Essential Medicines List that rely on
 24 a high-risk foreign supplier or foreign entity of con-
 25 cern (as defined in section 9901(8) of the William

1 M. (Mac) Thornberry National Authorization Act for
2 Fiscal Year 2021 (15 U.S.C. 4651(8))) for more
3 than 50 percent of production;

4 (3) the active pharmaceutical ingredients and
5 drugs on the Essential Medicines List that are
6 sourced exclusively or primarily from foreign estab-
7 lishments, including drugs manufactured domesti-
8 cally from active pharmaceutical ingredients sourced
9 exclusively or primarily from foreign establishments;

10 (4) current domestic manufacturing capabilities
11 for active pharmaceutical ingredients and drugs on
12 the Essential Medicines List, including the key
13 starting materials and excipients of such ingredients
14 and drugs, and any cost-effective manufacturing
15 technologies, including advanced manufacturing;

16 (5) public health and national security risks, in-
17 cluding cybersecurity threats and critical infrastruc-
18 ture designations specific to the supply chains of ac-
19 tive pharmaceutical ingredients and drugs included
20 on the Essential Medicines List;

21 (6) any deficiencies, lack of authorities, or limi-
22 tations in policy or process that reduce the ability of
23 the Federal Government to address any identified
24 public health or national security risks related to
25 supply chains for active pharmaceutical ingredients

1 and drugs included on the Essential Medicines List;
2 and

3 (7) how the Federal Government will mitigate
4 such national security risks, including through the
5 use of authorities under the Defense Production Act
6 of 1950 (50 U.S.C. 4501 et seq.).

7 (c) REPORT ON ASSESSMENT.—

8 (1) SUBMISSION OF REPORT.—Not later than
9 180 days after the date of enactment of this Act,
10 and annually thereafter, the Secretary, in consulta-
11 tion with the heads of relevant Federal departments
12 and agencies consulted under subsection (a), shall
13 submit a report with the findings under subsection
14 (b) to—

15 (A) the Committee on Armed Services, the
16 Committee on Health, Education, Labor, and
17 Pensions, and the Committee on Homeland Se-
18 curity and Governmental Affairs of the Senate;

19 (B) the Committee on Armed Services, the
20 Committee on Energy and Commerce, and the
21 Committee on Homeland Security of the House
22 of Representatives; and

23 (C) the Office of the Director of National
24 Intelligence.

1 (2) PUBLICATION OF REPORT.—Not later than
2 1 year after the date of enactment of this Act, the
3 Secretary, in consultation with the heads of relevant
4 Federal departments and agencies consulted under
5 subsection (a), shall release a public version of the
6 report submitted under paragraph (1).

7 **SEC. 4. U.S. PHARMACEUTICAL SUPPLY CHAINS MAPPING.**

8 (a) PHARMACEUTICAL SUPPLY CHAIN MAPPING.—
9 The Secretary of Health and Human Services (referred
10 to in this section as the “Secretary”), in coordination with
11 the heads of other relevant Federal departments and agen-
12 cies, shall ensure coordination of efforts of the Depart-
13 ment of Health and Human Services, including through
14 public-private partnerships, to—

15 (1) map, or otherwise visualize, the supply
16 chains, from manufacturing of key starting mate-
17 rials through manufacturing of finished dosage
18 forms and distribution, of drugs (as defined in sec-
19 tion 201 of the Federal Food, Drug, and Cosmetic
20 Act (21 U.S.C. 321)) included on the Essential
21 Medicines List under section 2; and

22 (2) use data analytics to identify supply chain
23 vulnerabilities that pose a threat to national secu-
24 rity, as determined by the Secretary or the heads of
25 other relevant Federal departments and agencies.

1 (b) REQUIREMENTS.—In carrying out subsection (a),
2 the Secretary shall—

3 (1) describe the roles and responsibilities of
4 agencies and offices within the Department of
5 Health and Human Services related to monitoring
6 such supply chains and assessing any related
7 vulnerabilities; and

8 (2) facilitate the exchange of information be-
9 tween Federal departments, agencies, and offices, as
10 appropriate and necessary to enable such agencies
11 and offices to carry out roles and responsibilities de-
12 scribed in paragraph (1) related to drugs described
13 in subsection (a)(1), which may include—

14 (A) the location of establishments reg-
15 istered under subsection (b), (c), or (i) of sec-
16 tion 510 of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 360) involved in the pro-
18 duction of active pharmaceutical ingredients
19 and finished dosage forms of drugs described in
20 subsection (a)(1), and the amount of such in-
21 gredients and finished dosage forms produced
22 at each such establishment;

23 (B) to the extent available and as appro-
24 priate, the location of establishments so reg-
25 istered involved in the production of the key

1 starting materials and excipients needed to
2 produce the active pharmaceutical ingredients
3 and finished dosage forms, and the amount of
4 such materials and excipients produced at each
5 such establishment; and

6 (C) any regulatory actions with respect to
7 such drugs or the establishments manufac-
8 turing such drugs, including with respect to in-
9 spections and related regulatory activities con-
10 ducted under section 704 of such Act (21
11 U.S.C. 374), the seizure of such a drug pursu-
12 ant to section 304 of such Act (21 U.S.C. 334),
13 any recalls of such a drug; inclusion of such a
14 drug on the drug shortage list under section
15 506E of such Act (21 U.S.C. 356e), or prior
16 drug shortages reports of a discontinuance or
17 interruption in the production of such a drug
18 under 506C of such Act (21 U.S.C. 355d).

19 (c) REPORT.—Not later than 18 months after the
20 date of enactment of this Act, and annually thereafter,
21 the Secretary, in consultation with the heads of agencies
22 with which the Secretary coordinates under subsection (a),
23 shall submit a report to the relevant committees of Con-
24 gress on—

1 (1) the current status of efforts to map and
2 analyze pharmaceutical supply chains, as described
3 in subsection (a);

4 (2) activities of the Secretary carried out under
5 this section to coordinate efforts as described in sub-
6 section (a), including information sharing between
7 relevant Federal departments, agencies, and offices;

8 (3) the roles and responsibilities described in
9 subsection (b)(1), including the identification of any
10 gaps, data limitations, or areas of unnecessary dupli-
11 cation between such roles and responsibilities;

12 (4) the extent to which Federal agencies use
13 data analytics to conduct predictive modeling of an-
14 ticipated drug shortages or risks associated with
15 supply chain vulnerabilities that pose a threat to na-
16 tional security; and

17 (5) the extent to which the Secretary has en-
18 gaged relevant industry in such mapping.

19 **SEC. 5. DEPARTMENT OF DEFENSE BIENNIAL REPORTS.**

20 Not later than 180 days after the date of enactment
21 of this Act, and every 180 days thereafter, the Secretary
22 of Defense shall submit to the congressional committees
23 described in subparagraphs (A) and (B) of section 3(c)(1)
24 a report that lists all drugs purchased by the Department

1 of Defense during the 180-day period preceding the date
2 of the report—

3 (1) that contain key starting materials,
4 excipients, or active pharmaceutical ingredients
5 sourced from the People’s Republic of China; or

6 (2) for which the finished drug product was
7 manufactured in the People’s Republic of China.

8 **SEC. 6. DEFINITIONS.**

9 In this Act:

10 (1) **ADVANCED MANUFACTURING.**—The term
11 “advanced manufacturing” has the meaning given
12 the term “advanced and continuous pharmaceutical
13 manufacturing” in section 3016(h) of the 21st Cen-
14 tury Cures Act (21 U.S.C. 399h(h)).

15 (2) **CYBERSECURITY THREAT.**—The term “cy-
16 bersecurity threat” has the meaning given such term
17 in section 2200 of the Homeland Security Act of
18 2002 (6 U.S.C. 650).

19 (3) **DRUG.**—The term “drug” has the meaning
20 given such term in section 201(g) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)).

22 (4) **SECRETARY.**—The term “Secretary”, except
23 as otherwise specified, means the Secretary of
24 Health and Human Services.

1 **SEC. 7. ADDITIONAL PROVISIONS.**

2 (a) CLARIFICATION.—The participation of the Sec-
3 retary in developing and updating the list of essential
4 medicines under section 2 shall be deemed to be full satis-
5 faction of the requirements applicable to such secretary
6 under section 3 of Executive Order 13944 (85 Fed. Reg.
7 49929).

8 (b) CONFIDENTIAL COMMERCIAL INFORMATION.—
9 The exchange of information among the Secretary and the
10 heads of other relevant Federal departments and agencies
11 for purposes of carrying out sections 3 and 4 shall not
12 be a violation of section 1905 of title 18, United States
13 Code. This section shall not be construed to affect the sta-
14 tus, if any, of such information as trade secret or confiden-
15 tial commercial information for purposes of section 301(j)
16 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 331(j)), section 552 of title 5, United States Code, or sec-
18 tion 1905 of title 18, United States Code.

19 (c) CYBERSECURITY MEASURES.—The Secretary
20 shall ensure that robust cybersecurity measures are in
21 place to prevent inappropriate access to, or unauthorized
22 disclosure of, the information identified, exchanged, or dis-
23 closed under sections 3 and 4.

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