

119TH CONGRESS
1ST SESSION

H. R. 4191

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 HOUSE OF REPRESENTATIVES

JUNE 26, 2025

Ms. MATSUI (for herself and Mr. CRENSHAW) introduced the following bill;
which was referred to the Committee on Energy and Commerce

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; or

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

20 (b) UPDATES TO LIST.—The Secretary shall review
21 the Essential Medicines List regularly, on a timeframe
22 that the Secretary determines necessary and appropriate,
23 and not less frequently than every 2 years; and shall up-
24 date the Essential Medicines List as necessary based on
25 the findings of such review.

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 consultation
10 with the heads of other relevant departments and agen-
11 cies, shall conduct a comprehensive risk assessment of the
12 supply chains for active pharmaceutical ingredients and
13 drugs included on the Essential Medicines List described
14 in section 2.

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

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

21 (2) the active pharmaceutical ingredients and
22 drugs on the Essential Medicines List that rely on
23 a foreign supplier for more than 50 percent of pro-
24 duction;

1 (3) the active pharmaceutical ingredients and
2 drugs on the Essential Medicines List that are
3 sourced exclusively or primarily from a single sup-
4 plier, including drugs manufactured domestically
5 from active pharmaceutical ingredients sourced ex-
6 clusively or primarily from a single supplier;

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

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

18 (6) any deficiencies, lack of authorities, or limi-
19 tations in policy or process that reduce the ability of
20 the Federal Government to address any identified
21 public health or national security risks related to
22 supply chains for active pharmaceutical ingredients
23 and drugs included on the Essential Medicines List;
24 and

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

5 (c) REPORT ON ASSESSMENT.—

6 (1) SUBMISSION OF REPORT.—Not later than
7 180 days after the date of enactment of this Act,
8 and annually thereafter, the Secretary, in consulta-
9 tion with the heads of relevant Federal departments
10 and agencies consulted under subsection (a), shall
11 submit a report with the findings under subsection
12 (b) to the relevant Committees of Congress.

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

14 (a) PHARMACEUTICAL SUPPLY CHAIN MAPPING.—
15 The Secretary of Health and Human Services (referred
16 to in this section as the “Secretary”), in coordination with
17 the heads of other relevant Federal departments and agen-
18 cies, shall ensure coordination of efforts of the Depart-
19 ment of Health and Human Services, including through
20 public-private partnerships, to—

21 (1) map, or otherwise visualize, the supply
22 chains, from manufacturing of key starting mate-
23 rials through manufacturing of finished dosage
24 forms and distribution, of drugs (as defined in sec-
25 tion 201 of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 321)) included on the Essential
2 Medicines List under section 2; and

3 (2) use data analytics to identify supply chain
4 vulnerabilities that pose a threat to public health or
5 national security, as determined by the Secretary or
6 the heads of other relevant Federal departments and
7 agencies.

8 (b) REQUIREMENTS.—In carrying out subsection (a),
9 the Secretary shall—

10 (1) describe the roles and responsibilities of
11 agencies and offices within the Department of
12 Health and Human Services related to monitoring
13 such supply chains and assessing any related
14 vulnerabilities; and

15 (2) facilitate the exchange of information be-
16 tween Federal departments, agencies, and offices, as
17 appropriate and necessary to enable such agencies
18 and offices to carry out roles and responsibilities de-
19 scribed in paragraph (1) related to drugs described
20 in subsection (a)(1). Such information should in-
21 clude, at a minimum—

22 (A) the location of establishments reg-
23 istered under subsection (b), (c), or (i) of sec-
24 tion 510 of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 360) involved in the pro-

1 duction of active pharmaceutical ingredients
2 and finished dosage forms of drugs described in
3 subsection (a)(1), and the amount of such in-
4 gredients and finished dosage forms produced
5 at each such establishment;

6 (B) to the extent available and as appro-
7 priate, the location of establishments so reg-
8 istered involved in the production of the key
9 starting materials and excipients needed to
10 produce the active pharmaceutical ingredients
11 and finished dosage forms, and the amount of
12 such materials and excipients produced at each
13 such establishment; and

14 (C) any regulatory actions with respect to
15 such drugs or the establishments manufac-
16 turing such drugs, including with respect to in-
17 spections and related regulatory activities con-
18 ducted under section 704 of such Act (21
19 U.S.C. 374), the seizure of such a drug pursu-
20 ant to section 304 of such Act (21 U.S.C. 334),
21 any recalls of such a drug; inclusion of such a
22 drug on the drug shortage list under section
23 506E of such Act (21 U.S.C. 356e), or prior re-
24 ports of a discontinuance or interruption in the

1 production of such a drug under section 506C
2 of such Act (21 U.S.C. 356c).

3 (c) REPORT.—Not later than 18 months after the
4 date of enactment of this Act, and annually thereafter,
5 the Secretary, in consultation with the heads of agencies
6 with which the Secretary coordinates under subsection (a),
7 shall submit a report to the relevant committees of Con-
8 gress on—

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

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

16 (3) the roles and responsibilities described in
17 subsection (b)(1), including the identification of any
18 gaps, data limitations, or areas of unnecessary dupli-
19 cation between such roles and responsibilities;

20 (4) the extent to which Federal agencies use
21 data analytics to conduct predictive modeling of an-
22 ticipated drug shortages or risks associated with
23 supply chain vulnerabilities that pose a threat to na-
24 tional security; and

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

3 **SEC. 5. DEFINITIONS.**

4 In this Act:

5 (1) **ADVANCED MANUFACTURING.**—The term
6 “advanced manufacturing” has the meaning given
7 the term “advanced and continuous pharmaceutical
8 manufacturing” in section 3016(h) of the 21st Cen-
9 tury Cures Act (21 U.S.C. 399h(h)).

10 (2) **CYBERSECURITY THREAT.**—The term “cy-
11 bersecurity threat” has the meaning given such term
12 in section 2200 of the Homeland Security Act of
13 2002 (6 U.S.C. 650).

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

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

20 **SEC. 6. ADDITIONAL PROVISIONS.**

21 (a) **CLARIFICATION.**—The participation of the Sec-
22 retary in developing and updating the list of essential
23 medicines under section 2 shall be deemed to be full satis-
24 faction of the requirements applicable to such Secretary

1 under section 3 of Executive Order 13944 (85 Fed. Reg.
2 49929).

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

14 (c) CYBERSECURITY MEASURES.—The Secretary
15 shall ensure that robust cybersecurity measures are in
16 place to prevent inappropriate access to, or unauthorized
17 disclosure of, the information identified, exchanged, or dis-
18 closed under sections 3 and 4.

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