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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To require the Secretary of Health and Human Services to establish a
list of essential medicines, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. MATSUI introduced the following bill; which was referred to the
Committee on _____

A BILL

To require the Secretary of Health and Human Services
to establish a list of essential medicines, 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,*

3 **SECTION 1. SHORT TITLE.**

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

6 **SEC. 2. ESSENTIAL MEDICINES LIST UPDATE.**

7 (a) IN GENERAL.—The Secretary of Health and
8 Human Services (in this section referred to as the “Sec-

1 retary”) shall establish and maintain a list of essential
2 medicines.

3 (b) CRITERIA.— The list under subsection (a) shall
4 consist of drugs and active pharmaceutical ingredients
5 that—

6 (1) are reasonably likely to be required to re-
7 spond to a public health emergency or to a chemical,
8 biological, radiological, or nuclear threat; or

9 (2) the shortage of which would pose a signifi-
10 cant threat to the United States health care system
11 or at-risk populations.

12 (c) SELECTION.—The Secretary shall select drugs
13 and active pharmaceutical ingredients for inclusion on the
14 list under subsection (a)—

15 (1) based on the criteria specified in subsection
16 (b); and

17 (2) from the list of essential medicines, medical
18 countermeasures, and critical inputs developed by
19 the Food and Drug Administration in response to
20 Executive Order 13944 (85 Fed. Reg. 49929) and
21 other relevant assessments or lists.

22 (d) PROCESS.—

23 (1) IN GENERAL.—Before finalizing the list
24 under subsection (a) or any update to such list, the
25 Secretary shall—

1 (A) publish a proposed list or update, as
2 applicable; and

3 (B) provide an opportunity for public com-
4 ment on the proposed list or update.

5 (2) INITIAL LIST.—The Secretary shall—

6 (A) publish the proposed initial list under
7 subsection (a) not later than 6 months after the
8 date of enactment of this Act; and

9 (B) publish the final initial list under sub-
10 section (a) not later than 1 year after such date
11 of enactment.

12 (3) REGULAR REVIEW.—The Secretary shall
13 regularly review the list under subsection (a) to de-
14 termine whether any updates should be made pursu-
15 ant to paragraph (1).

16 (e) RELATION TO EXECUTIVE ORDER.—The partici-
17 pation of the Secretary in establishing, maintaining, and
18 updating the list under subsection (a) shall be deemed to
19 be full satisfaction of the requirements applicable to the
20 Secretary under section 3 of Executive Order 13944 (85
21 Fed. Reg. 49929).

22 **SEC. 3. FEDERAL UNITED STATES PHARMACEUTICAL SUP-**
23 **PLY CHAIN MAPPING.**

24 (a) IN GENERAL.—The Secretary of Health and
25 Human Services, in coordination with the heads of other

1 relevant agencies, shall support efforts, including through
2 public-private partnerships, to map the entire United
3 States pharmaceutical supply chain, from inception to dis-
4 tribution, and use data analytics to identify supply chain
5 vulnerabilities and other national security threats. Such
6 activities shall include, at a minimum—

7 (1) defining agency roles in monitoring the
8 pharmaceutical supply chain and communicating
9 supply chain vulnerabilities; and

10 (2) with respect to drugs and active pharma-
11 ceutical ingredients on the list of essential medicines
12 under section 2(a), establishing a database that shall
13 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—

19 (i) the finished dosage forms of the
20 drugs on such list;

21 (ii) the active pharmaceutical ingredi-
22 ents of such drugs; or

23 (iii) active pharmaceutical ingredients
24 on such list;

1 (B) the amount of such finished dosage
2 forms and active pharmaceutical ingredients
3 produced at each such establishment;

4 (C) to the extent available—

5 (i) the location of establishments in-
6 volved in the production of the key starting
7 materials and excipients used to produce
8 the finished dosage forms and active phar-
9 maceutical ingredients referred to in sub-
10 paragraph (A); and

11 (ii) the amount of such materials and
12 excipients produced at each such establish-
13 ment; and

14 (D) any regulatory actions with respect to
15 the establishments referred to in subparagraph
16 (A) or (C), including with respect to—

17 (i) labeling requirements;

18 (ii) registration and listing informa-
19 tion required to be submitted under section
20 510 of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 360);

22 (iii) inspections and related regulatory
23 activities conducted under section 704 of
24 such Act (21 U.S.C. 374);

1 (iv) the seizure of such a drug or ac-
2 tive pharmaceutical ingredient pursuant to
3 section 304 of such Act (21 U.S.C. 334);

4 (v) any recalls of a drug or active
5 pharmaceutical ingredient on the list of es-
6 sential medicines under section 2(a), or a
7 drug containing an active pharmaceutical
8 ingredient on such list;

9 (vi) inclusion of such a drug or active
10 pharmaceutical ingredient on the drug
11 shortage list under section 506E of such
12 Act (21 U.S.C. 356e); or

13 (vii) prior reports of a discontinuance
14 or interruption in the production of such a
15 drug or active pharmaceutical ingredient
16 under 506C of such Act (21 U.S.C. 356c).

17 (b) REPORT.—Not later than 18 months after the
18 date of enactment of this Act, and annually thereafter,
19 the Secretary of Health and Human Services, in consulta-
20 tion with the heads of agencies with which such Secretary
21 coordinates under subsection (a), shall submit a report to
22 Congress on—

23 (1) progress on implementing subsection (a), in-
24 cluding any timelines for full implementation;

1 (2) gaps in data needed for full implementation
2 of such subsection;

3 (3) how the database established pursuant to
4 subsection (a) increases Federal visibility into the
5 pharmaceutical supply chain;

6 (4) how Federal agencies are able to use data
7 analytics to conduct predictive modeling of antici-
8 pated drug shortages or national security threats;
9 and

10 (5) the extent to which industry has cooperated
11 in mapping the pharmaceutical supply chain.

12 (c) CONFIDENTIAL COMMERCIAL INFORMATION.—
13 The exchange of information among the Secretary of
14 Health and Human Services and the heads of other rel-
15 evant agencies for purposes of carrying out this section
16 shall not be a violation of section 1905 of title 18, United
17 States Code.

18 (d) CLARIFICATION.—The information in the data-
19 base established pursuant to subsection (a) shall not be
20 publicly disclosed. Nothing in this subsection shall be con-
21 strued to relieve the Secretary of Health and Human Serv-
22 ices from the Secretary's obligation to provide information
23 to Congress.