

116TH CONGRESS
2D SESSION

S. 3538

To require the Secretary of Defense to submit to Congress a report on the reliance by the Department of Defense on imports of certain pharmaceutical products made in part or in whole in certain countries, to establish postmarket reporting requirements for pharmaceuticals, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 19, 2020

Mr. RUBIO (for himself, Ms. WARREN, Mr. CRAMER, Mr. MURPHY, and Mr. KAINE) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To require the Secretary of Defense to submit to Congress a report on the reliance by the Department of Defense on imports of certain pharmaceutical products made in part or in whole in certain countries, to establish postmarket reporting requirements for pharmaceuticals, 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 “Strengthening Amer-
5 ica’s Supply Chain and National Security Act”.

1 **SEC. 2. REPORT ON RELIANCE BY DEPARTMENT OF DE-**
2 **FENSE ON PHARMACEUTICAL PRODUCTS**
3 **FROM CERTAIN COUNTRIES.**

4 (a) IN GENERAL.—Not later than one year after the
5 date of the enactment of this Act, the Secretary of De-
6 fense, in coordination with the Secretary of Health and
7 Human Services, shall submit to the appropriate congres-
8 sional committees a classified report on the reliance by the
9 Department of Defense on imports of certain pharma-
10 ceutical products made in part or in whole in a covered
11 country.

12 (b) ELEMENTS.—The report required by subsection
13 (a) shall—

14 (1) analyze the percent of pharmaceutical prod-
15 ucts used by the Department of Defense that are
16 made in part or in whole in a covered country, in-
17 cluding—

18 (A) drugs;

19 (B) active ingredients;

20 (C) raw pharmaceutical components;

21 (D) nonprescription drugs intended for
22 human use; and

23 (E) any other pharmaceutical product, or
24 its components, as the Secretary considers ap-
25 propriate;

1 (2) assess the products identified under para-
2 graph (1) to determine—

3 (A) whether the Department of Defense
4 can procure the product from other sources;

5 (B) whether reliance by the Department of
6 Defense on the product is likely, or has signifi-
7 cant potential, to be used for a military, geo-
8 political, or economic advantage against the
9 United States;

10 (C) whether reliance on the product cre-
11 ates a risk for the United States; and

12 (D) what impact there would be if access
13 to the product was terminated;

14 (3) set forth recommendations to ensure that by
15 2025 no pharmaceutical products purchased for
16 beneficiaries of health care from the Department of
17 Defense or any associated program are made in part
18 or in whole in a covered country;

19 (4) assess the resilience and capacity of the cur-
20 rent supply chain and industrial base to support na-
21 tional defense if no pharmaceutical products pur-
22 chased for beneficiaries of health care from the De-
23 partment of Defense or any associated program are
24 made in part or in whole in a covered country, in-
25 cluding with respect to—

1 (A) the manufacturing capacity of the
2 United States;

3 (B) gaps in domestic manufacturing capa-
4 bilities, including non-existent, extinct, threat-
5 ened, and single-point-of-failure capabilities;
6 and

7 (C) supply chains with single points of fail-
8 ure and limited resiliency;

9 (5) set forth recommendations—

10 (A) to diversify supply of pharmaceutical
11 products away from complete dependency on
12 sources of supply in countries that are competi-
13 tors of the United States or politically unstable
14 that may cut off supply in the United States;

15 (B) to address critical bottlenecks in the
16 supply of pharmaceutical products in the
17 United States; and

18 (C) to mitigate single points of failure and
19 limited resilience of supply chains for pharma-
20 ceutical products in the United States; and

21 (6) set forth recommendations for legislative
22 and administrative action necessary to avoid, or pre-
23 pare for, contingencies identified in the report.

24 (c) PUBLICATION OF UNCLASSIFIED SUMMARY.—

25 Concurrent with the submittal of the report required by

1 subsection (a), the Secretary of Defense shall publish on
2 a publicly available internet website of the Department of
3 Defense an unclassified summary of the report.

4 (d) DEFINITIONS.—In this section:

5 (1) APPROPRIATE CONGRESSIONAL COMMIT-
6 TEES.—The term “appropriate congressional com-
7 mittees” means—

8 (A) the Committee on Armed Services, the
9 Select Committee on Intelligence, the Com-
10 mittee on Finance, the Committee on Banking,
11 Housing, and Urban Affairs, and the Com-
12 mittee on Health, Education, Labor, and Pen-
13 sions of the Senate; and

14 (B) the Committee on Armed Services, the
15 Permanent Select Committee on Intelligence,
16 the Committee on Ways and Means, the Com-
17 mittee on Financial Services, and the Com-
18 mittee on Energy and Commerce of the House
19 of Representatives.

20 (2) COVERED COUNTRY.—The term “covered
21 country” means—

22 (A) China; and

23 (B) any other country as determined by
24 the Secretary of Defense for national security
25 purposes.

1 (3) DRUG.—The term “drug” means a product
 2 subject to regulation under section 505 or section
 3 802 of the Federal Food, Drug, and Cosmetic Act
 4 (21 U.S.C. 355 or 382) or under section 351 of the
 5 Public Health Service Act (42 U.S.C. 262).

6 (4) NONPRESCRIPTION DRUG.—The term “non-
 7 prescription drug” has the meaning given that term
 8 in section 760(a)(2) of the Federal Food, Drug, and
 9 Cosmetic Act (21 U.S.C. 379aa(a)(2)).

10 **SEC. 3. MODIFICATION OF RULES OF ORIGIN FOR PHARMA-**
 11 **CEUTICAL PRODUCTS.**

12 (a) TRADE AGREEMENTS.—Section 308(4)(B) of the
 13 Trade Agreements Act of 1979 (19 U.S.C. 2518(4)(B))
 14 is amended—

15 (1) in clause (i), by striking “instrumentality,
 16 or” and inserting “instrumentality,”;

17 (2) in clause (ii)—

18 (A) by inserting “, other than an active
 19 pharmaceutical ingredient,” after “part of ma-
 20 terials”; and

21 (B) by striking the period at the end and
 22 inserting “, or”; and

23 (3) by inserting before the period at the end the
 24 following: “(iii) in the case of an article which con-
 25 sists of an active pharmaceutical ingredient, the

1 pharmaceutical ingredient is wholly the growth,
2 product, or manufacture of that country or instru-
3 mentality”.

4 (b) FEDERAL ACQUISITION REGULATION.—Not later
5 than 180 days after the date of the enactment of this Act,
6 the President shall prescribe regulations to update sec-
7 tions 52.225–5 and 25.003 of title 48, Code of Federal
8 Regulations (or successor regulations) to be consistent
9 with rules of origin determinations for active pharma-
10 ceutical ingredients made under section 308(4)(B) of the
11 Trade Agreements Act of 1979 (19 U.S.C. 2518(4)(B)),
12 as amended by subsection (a).

13 **SEC. 4. POSTMARKET REPORTING REQUIREMENTS FOR**
14 **PHARMACEUTICALS.**

15 (a) IN GENERAL.—The Secretary of Health and
16 Human Services, acting through the Commissioner of
17 Food and Drugs, shall ensure that each holder of an ap-
18 proved application under section 505 of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 355) or under section
20 351 of the Public Health Service Act (42 U.S.C. 262) an-
21 nually submit, as part of the postmarket annual report
22 required by the Secretary under section 314.81(b)(2) of
23 title 21, Code of Federal Regulations (or any successor
24 regulation), the following information:

1 (1) The names and addresses of the sources of
2 active and inactive ingredients of the drug.

3 (2) For each active and inactive ingredient of
4 the drug, the percentage of the aggregate amount of
5 such ingredient used in the manufacture of the drug
6 during the reporting period that is from each of the
7 sources identified under paragraph (1).

8 (b) DISCLOSURE OF INFORMATION.—The Secretary
9 of Health and Human Services shall—

10 (1) annually provide the information reported in
11 paragraphs (1) and (2) of subsection (a) to the Sec-
12 retary of Defense for purposes of understanding the
13 dependency on foreign manufacturers of drugs used
14 by members of the Armed Forces; and

15 (2) publish the information reported under such
16 paragraphs on a publicly available internet website
17 of the Federal Government in a single, aggregate
18 form, without disclosing proprietary information.

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