I

116TH CONGRESS
2D SESSION

H. R. 6393

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 HOUSE OF REPRESENTATIVES

MARCH 25, 2020

Mr. WALTZ (for himself and Mr. MCGOVERN) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committees on Armed Services, Oversight and Reform, and Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Strengthening America's Supply Chain and National Security Act''.

SEC. 2. REPORT ON RELIANCE BY DEPARTMENT OF DEFENSE ON PHARMACEUTICAL PRODUCTS FROM CERTAIN COUNTRIES.

(a) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Defense, in coordination with the Secretary of Health and Human Services, shall submit to the appropriate congressional committees a classified report on the reliance by the Department of Defense on imports of certain pharmaceutical products made in part or in whole in a covered country.

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

(1) analyze the percent of pharmaceutical products used by the Department of Defense that are made in part or in whole in a covered country, including—

(A) drugs;

(B) active ingredients;

(C) raw pharmaceutical components;

(D) nonprescription drugs intended for human use; and

(E) any other pharmaceutical product, or its components, as the Secretary considers appropriate;

(2) assess the products identified under paragraph (1) to determine—

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

(B) whether reliance by the Department of Defense on the product is likely, or has significant potential, to be used for a military, geopolitical, or economic advantage against the United States;

(C) whether reliance on the product creates a risk for the United States; and

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

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

(4) assess the resilience and capacity of the current supply chain and industrial base to support national defense if no pharmaceutical products purchased for beneficiaries of health care from the De-

partment of Defense or any associated program are made in part or in whole in a covered country, including with respect to—

(A) the manufacturing capacity of the United States;

(B) gaps in domestic manufacturing capabilities, including non-existent, extinct, threatened, and single-point-of-failure capabilities; and

(C) supply chains with single points of failure and limited resiliency;

(5) set forth recommendations—

(A) to diversify supply of pharmaceutical products away from complete dependency on sources of supply in countries that are competitors of the United States or politically unstable that may cut off supply in the United States;

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

(C) to mitigate single points of failure and limited resilience of supply chains for pharmaceutical products in the United States; and

(6) set forth recommendations for legislative and administrative action necessary to avoid, or prepare for, contingencies identified in the report.

(c) PUBLICATION OF UNCLASSIFIED SUMMARY.—Concurrent with the submittal of the report required by subsection (a), the Secretary of Defense shall publish on a publicly available internet website of the Department of Defense an unclassified summary of the report.

(d) DEFINITIONS.—In this section:

(1) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term ''appropriate congressional committees'' means—

(A) the Committee on Armed Services, the Select Committee on Intelligence, the Committee on Finance, the Committee on Banking, Housing, and Urban Affairs, and the Committee on Health, Education, Labor, and Pensions of the Senate; and

(B) the Committee on Armed Services, the Permanent Select Committee on Intelligence, the Committee on Ways and Means, the Committee on Financial Services, and the Committee on Energy and Commerce of the House of Representatives.

(2) COVERED COUNTRY.—The term ''covered country'' means—

(A) China; and

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

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

(4) NONPRESCRIPTION DRUG.—The term ''nonprescription drug'' has the meaning given that term in section 760(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379aa(a)(2)).

SEC. 3. MODIFICATION OF RULES OF ORIGIN FOR PHARMACEUTICAL PRODUCTS.

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

(1) in clause (i), by striking ''instrumentality, or'' and inserting ''instrumentality,'';

(2) in clause (ii)—

(A) by inserting ‘‘, other than an active pharmaceutical ingredient,’’ after ‘‘part of materials’’; and

(B) by striking the period at the end and inserting ‘‘, or’’; and

(3) by inserting before the period at the end the following: ‘‘(iii) in the case of an article which consists of an active pharmaceutical ingredient, the pharmaceutical ingredient is wholly the growth, product, or manufacture of that country or instrumentality’’.

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

SEC. 4. POSTMARKET REPORTING REQUIREMENTS FOR PHARMACEUTICALS.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall ensure that each holder of an ap-

proved application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or under section 351 of the Public Health Service Act (42 U.S.C. 262) annually submit, as part of the postmarket annual report required by the Secretary under section 314.81(b)(2) of title 21, Code of Federal Regulations (or any successor regulation), the following information:

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

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

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

(1) annually provide the information reported in paragraphs (1) and (2) of subsection (a) to the Secretary of Defense for purposes of understanding the dependency on foreign manufacturers of drugs used by members of the Armed Forces; and

(2) publish the information reported under such paragraphs on a publicly available internet website

of the Federal Government in a single, aggregate form, without disclosing proprietary information.

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