I

118TH CONGRESS
1ST SESSION

H. R. 6112

To establish postmarket reporting requirements for pharmaceuticals, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 26, 2023

Mr. WALTZ introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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

---

A BILL

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 ''Further Strengthening America's Supply Chain and National Security Act''.

SEC. 2. 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), by inserting '', other than an active pharmaceutical ingredient,'' after ''part of materials''; and

(3) by striking the period at the end and inserting '', or (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. 3. 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 approved 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.

SEC. 4. ADDITIONAL RISK FACTORS FOR CONSIDERATION DURING INSPECTIONS OF DRUG AND DEVICE ESTABLISHMENTS.

Section 510(h)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)(4)) is amended—

(1) by redesignating subparagraph (G) as subparagraph (J); and

(2) by inserting after subparagraph (F) the following:

"(G) Whether the establishment has been inspected by an entity that carries out inspections on behalf of a foreign government determined to be a foreign adversary under section 7.4 of title 15, Code of Federal Regulations (or successor regulations).

"(H) The particular drugs or devices (with a focus on drugs and devices included on the list of essential medicines pursuant to section 3(c) of Executive Order 13944 (85 Fed. Reg. 49929)) manufactured, prepared, propagated, compounded, or processed in the establishment,

with particular attention to the number of other establishments globally that also manufacture, prepare, propagate, compound, or process the same drug or device from which the United States sources such drug or device.

''(I) Whether the establishment is located in a country with a history or 1 or more previous instances of exporting illicit drugs or precursor chemicals to the United States, as determined by the Secretary by reference to the most recent report submitted to Congress pursuant to section 489 of the Foreign Assistance Act of 1961.''.

○