

118TH CONGRESS
1ST SESSION

S. 3143

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

IN THE SENATE OF THE UNITED STATES

OCTOBER 26, 2023

Mr. RUBIO (for himself, Mr. ROUNDS, and Mr. CRAMER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

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 “Further Strengthening
5 America’s Supply Chain and National Security Act”.

6 **SEC. 2. MODIFICATION OF RULES OF ORIGIN FOR PHARMA-**
7 **CEUTICAL PRODUCTS.**

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

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

3 (2) in clause (ii), by inserting “, other than an
4 active pharmaceutical ingredient,” after “part of
5 materials”; and

6 (3) by striking the period at the end and insert-
7 ing “, or (iii) in the case of an article which consists
8 of an active pharmaceutical ingredient, the pharma-
9 ceutical ingredient is wholly the growth, product, or
10 manufacture of that country or instrumentality.”.

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

20 **SEC. 3. POSTMARKET REPORTING REQUIREMENTS FOR**
21 **PHARMACEUTICALS.**

22 (a) IN GENERAL.—The Secretary of Health and
23 Human Services, acting through the Commissioner of
24 Food and Drugs, shall ensure that each holder of an ap-
25 proved application under section 505 of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355) or under section
2 351 of the Public Health Service Act (42 U.S.C. 262) an-
3 nually submit, as part of the postmarket annual report
4 required by the Secretary under section 314.81(b)(2) of
5 title 21, Code of Federal Regulations (or any successor
6 regulation), the following information:

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

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

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

16 (1) annually provide the information reported in
17 paragraphs (1) and (2) of subsection (a) to the Sec-
18 retary of Defense for purposes of understanding the
19 dependency on foreign manufacturers of drugs used
20 by members of the Armed Forces; and

21 (2) publish the information reported under such
22 paragraphs on a publicly available internet website
23 of the Federal Government in a single, aggregate
24 form, without disclosing proprietary information.

1 **SEC. 4. ADDITIONAL RISK FACTORS FOR CONSIDERATION**
2 **DURING INSPECTIONS OF DRUG AND DEVICE**
3 **ESTABLISHMENTS.**

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

6 (1) by redesignating subparagraph (G) as sub-
7 paragraph (J); and

8 (2) by inserting after subparagraph (F) the fol-
9 lowing:

10 “(G) Whether the establishment has been
11 inspected by an entity that carries out inspec-
12 tions on behalf of a foreign government deter-
13 mined to be a foreign adversary under section
14 7.4 of title 15, Code of Federal Regulations (or
15 successor regulations).

16 “(H) The particular drugs or devices (with
17 a focus on drugs and devices included on the
18 list of essential medicines pursuant to section
19 3(e) of Executive Order 13944 (85 Fed. Reg.
20 49929)) manufactured, prepared, propagated,
21 compounded, or processed in the establishment,
22 with particular attention to the number of other
23 establishments globally that also manufacture,
24 prepare, propagate, compound, or process the
25 same drug or device from which the United
26 States sources such drug or device.

1 “(I) Whether the establishment is located
2 in a country with a history or 1 or more pre-
3 vious instances of exporting illicit drugs or pre-
4 cursor chemicals to the United States, as deter-
5 mined by the Secretary by reference to the most
6 recent report submitted to Congress pursuant
7 to section 489 of the Foreign Assistance Act of
8 1961.”.

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