

118TH CONGRESS
2D SESSION

S. 5419

To require the Secretary of Health and Human Services to maintain a list of the country of origin of certain critical drugs marketed in the United States, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 4, 2024

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

A BILL

To require the Secretary of Health and Human Services to maintain a list of the country of origin of certain critical drugs marketed in the United States, 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 “Protecting Our Essen-
5 tial Medicines Act”.

1 **SEC. 2. LIST OF CRITICAL DRUGS PRODUCED OUTSIDE THE**
 2 **UNITED STATES.**

3 Subchapter A of chapter V of the Federal Food,
 4 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
 5 ed by adding at the end the following:

6 **“SEC. 524C. LIST OF CRITICAL DRUGS PRODUCED OUTSIDE**
 7 **THE UNITED STATES.**

8 “(a) LIST OF CRITICAL DRUGS.—

9 “(1) IN GENERAL.—For purposes of strength-
 10 ening the public health supply chain and industrial
 11 base, and increasing the manufacture of essential
 12 drugs, including biological products, and critical in-
 13 puts of such drugs in the United States, the Sec-
 14 retary shall compile and maintain a list of each drug
 15 that is—

16 “(A) approved under subsection (c) or (j)
 17 of section 505 of this Act or licensed under sub-
 18 section (a) or (k) of section 351 of the Public
 19 Health Service Act;

20 “(B) imported into the United States; and

21 “(C)(i) determined by the interagency task
 22 force established under subsection (e) to be crit-
 23 ical to the health and safety of consumers in
 24 the United States;

25 “(ii) determined by such task force to be
 26 a drug the shortage of which would have an ad-

verse health outcome on patients with chronic conditions; or

“(iii) a qualified countermeasure, as defined in section 319F–1(a)(2) of the Public Health Service Act, a qualified pandemic or epidemic product, as defined in section 319F–3(i) of such Act, or a security countermeasure, as defined in section 319F–2(c) of such Act.

“(2) SUPPLY CHAIN INFORMATION.—The list required by paragraph (1) shall, with respect to each drug included on the list, provide information about each facility registered under section 510 that is involved in the manufacture, preparation, propagation, compounding, or processing of the drug or an ingredient of the drug.

“(3) NO PUBLIC DISCLOSURE.—The list required by paragraph (1), and any portion thereof, shall not be publicly disclosed, and nothing in paragraph (1) or (2) shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

“(4) PERMISSIBLE DISCLOSURE TO NATIONAL SECURITY AGENCIES OF THE FEDERAL GOVERN-

1 MENT.—The list required by paragraph (1) (and any
2 portion thereof) may be disclosed by the Secretary
3 only—

4 “(A) within the Department of Health and
5 Human Services and pursuant to reporting
6 under subsection (e); and

7 “(B) for purposes of evaluating supply
8 chain vulnerabilities and other national security
9 issues, with national security agencies of the
10 Federal Government, including all elements of
11 the Department of Defense and national intel-
12 ligence agencies.

13 “(5) DEFINITION.—In this subsection, the term
14 ‘critical inputs’ means active pharmaceutical ingredi-
15 ents, starting material for active pharmaceutical in-
16 gredients, and other ingredients of drugs that the
17 Commissioner of Food and Drugs determines to be
18 critical in assessing the safety and effectiveness of
19 drugs described in paragraph (1).

20 “(b) ADDITIONAL LISTS.—

21 “(1) IN GENERAL.—In conjunction with the list
22 under subsection (a), the Secretary shall, in con-
23 sultation with the interagency task force established
24 under subsection (e), compile and maintain—

“(A) a list of drugs included on the list under subsection (a) that are exclusively produced in, or use active pharmaceutical ingredients produced in, a foreign entity of concern (as defined in section 9901(8) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021); and

“(B) a list identifying the top 3 countries from which the United States imports drugs described in subsection (a)(1).

“(2) DISCLOSURE.—

“(A) LIST OF DRUGS.—

“(i) NO PUBLIC DISCLOSURE.—The list required by paragraph (1)(A) (and any portion thereof) shall not be publicly disclosed.

“(ii) PERMISSIBLE DISCLOSURE TO NATIONAL SECURITY AGENCIES OF THE FEDERAL GOVERNMENT.—The list required by paragraph (1)(A), and any portion thereof, may be disclosed by the Secretary only—

“(I) within the Department of Health and Human Services, and pur-

1 suant to reporting under subsection
2 (f); and

3 “(II) for purposes of evaluating
4 supply chain vulnerabilities and other
5 national security issues, with national
6 security agencies of the Federal Gov-
7 ernment.

8 “(B) LIST OF TOP 3 COUNTRIES.—The
9 Secretary shall publicly disclose the list required
10 by paragraph (1)(B), but may not include in
11 any such disclosure—

12 “(i) information about an identifiable
13 drug or active pharmaceutical ingredient;
14 or

15 “(ii) proprietary information regard-
16 ing a drug or active pharmaceutical ingre-
17 dient, including information that is a trade
18 secret or confidential information subject
19 to section 552(b)(4) of title 5, United
20 States Code, or section 1905 of title 18,
21 United States Code.

22 “(c) TIMELINES.—

23 “(1) INITIAL LIST.—The Secretary shall com-
24 pile the initial lists of drugs under subsections (a)
25 and (b) not later than 180 days after the date of en-

1 actment of the Protecting Our Essential Medicines
2 Act.

3 “(2) UPDATES.—The Secretary shall update
4 the lists of drugs under subsections (a) and (b), as
5 the Secretary determines necessary and appropriate,
6 and not less frequently than every 2 years.

7 “(d) CYBERSECURITY MEASURES.— Prior to sharing
8 of any lists required by subsection (a) or (b), within the
9 Department of Health and Human Services or to national
10 security agencies, the Secretary shall ensure that robust
11 cybersecurity measures are in place to prevent inappro-
12 priate access to, or unauthorized disclosure of, the list or
13 any information related to the list.

14 “(e) INTERAGENCY TASK FORCE.—

15 “(1) ESTABLISHMENT.—Not later than 30 days
16 after the date of enactment of the Protecting Our
17 Essential Medicines Act, the Secretary shall estab-
18 lish an interagency task force for purposes of identi-
19 fying drugs to include in the list of critical drugs, as
20 described in subsection (a)(1)(C) and consulting
21 with the Secretary with respect to compiling, main-
22 taining, and updating the list under subsection (b).
23 The task force shall be comprised of representatives
24 of the Federal Government as the Secretary, in con-
25 sultation with the Commissioner of Food and Drugs,

1 the Director of the Centers for Disease Control and
2 Prevention, the Secretary of Defense, the Assistant
3 Secretary for Preparedness and Response, the Sec-
4 retary of Homeland Security, the Commissioner of
5 U.S. Customs and Border Protection, and the Direc-
6 tor of National Intelligence, determines appropriate.

7 “(2) PROCEDURES.—Not later than 60 days
8 after the date of enactment of the Protecting Our
9 Essential Medicines Act, the task force established
10 under paragraph (1) shall submit a report on the
11 procedures such task force will follow in making de-
12 terminations with respect to drugs as described in
13 clauses (i) and (ii) of subsection (a)(1)(C) to—

14 “(A) the Committee on Health, Education,
15 Labor, and Pensions, the Committee on Fi-
16 nance, and the Committee on Armed Services of
17 the Senate; and

18 “(B) the Committee on Energy and Com-
19 merce, the Committee on Ways and Means, and
20 the Committee on Armed Services of the House
21 of Representatives.

22 “(f) REPORTING.—Upon compiling the initial list of
23 drugs as required under subsections (a) and (b), and upon
24 making each update to such lists as described in sub-

1 section (c)(2), the Secretary shall submit the list of drugs

2 to—

3 “(1) the Secretary of Defense;

4 “(2) the Attorney General; and

5 “(3) the Director of National Intelligence.”.

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