

117TH CONGRESS
1ST SESSION

S. 3401

To require the Secretary of Health and Human Services to maintain a list of the country of origin of all drugs marketed in the United States, to ban the use of Federal funds for the purchase of drugs manufactured in the People’s Republic of China, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 15, 2021

Mr. COTTON (for himself and Mr. BRAUN) 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 all drugs marketed in the United States, to ban the use of Federal funds for the purchase of drugs manufactured in the People’s Republic of China, 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 “Anyone But China
5 Safe Drug Act” or the “ABC Safe Drug Act”.

1 **SEC. 2. COUNTRY OF ORIGIN OF DRUGS.**

2 (a) IN GENERAL.—Subchapter A of chapter V of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
4 et seq.) is amended by adding at the end the following:

5 **“SEC. 524B. REGISTRY OF DRUGS PRODUCED OUTSIDE THE**
6 **US.**

7 “(a) IN GENERAL.—The Secretary shall compile and
8 maintain a list of all drugs approved under subsection (c)
9 or (j) of section 505 of this Act or licensed under sub-
10 section (a) or (k) of section 351 of the Public Health Serv-
11 ice Act, and any active ingredients in such drugs, that—

12 “(1) are manufactured outside of the United
13 States; and

14 “(2) are determined by the Secretary to be crit-
15 ical to the health and safety of consumers in the
16 United States.

17 “(b) ADDITIONAL LIST.—In conjunction with the list
18 described in subsection (a), the Secretary shall compile
19 and maintain a list of drugs included on such list that
20 are exclusively produced in, or use active or inactive ingre-
21 dients produced in, the People’s Republic of China.

22 “(c) REQUIREMENT.—The list described in sub-
23 section (a) shall, with respect to each drug included on
24 the list, provide information about the supply chain of the
25 drug, including each step in the supply chain that occurs
26 prior to importation of the drug into the United States.”.

1 (b) FEDERAL HEALTH PROGRAM PURCHASE OF
2 DRUGS.—

3 (1) IN GENERAL.—Notwithstanding any other
4 provision of law, with respect to the purchase of a
5 drug by the Department of Health and Human
6 Services, the Department of Veterans Affairs, the
7 Department of Defense, or any other Federal health
8 care program (as defined in section 1128B(f) of the
9 Social Security Act (42 U.S.C. 1320a–7b(b))), the
10 following shall apply:

11 (A) Beginning on January 1, 2024, such
12 agency or program may purchase only drugs for
13 which 60 percent or more of the active pharma-
14 ceutical ingredients are manufactured in coun-
15 tries described in paragraph (2).

16 (B) Beginning on January 1, 2026, such
17 agency or program may purchase only drugs for
18 which 100 percent of the active pharmaceutical
19 ingredients are manufactured in countries de-
20 scribed in paragraph (2).

21 (2) COUNTRIES DESCRIBED.—The countries de-
22 scribed in this paragraph are countries—

23 (A) other than People’s Republic of China;
24 and

1 (B) that meet the health and safety stand-
2 ards of the Food and Drug Administration.

3 (3) WAIVERS.—The Secretary of Health and
4 Human Services may issue waivers of the require-
5 ments under paragraph (1) for any agency or pro-
6 gram that is unable to meet such requirements and
7 demonstrates a need for the waiver. No waiver may
8 be issued under this paragraph for drugs that are
9 purchased on or after January 1, 2027.

10 (c) LABELING REQUIREMENT.—Section 502 of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352)
12 is amended by adding at the end the following:

13 “(gg) If it is a drug and its labeling does not specify
14 the country of origin of each active ingredient contained
15 in the drug.”.

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