

116TH CONGRESS
2D SESSION

S. 3537

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 China, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 19, 2020

Mr. COTTON (for himself, Mrs. BLACKBURN, and Mr. CRUZ) introduced the following bill; which was read twice and referred to the Committee on Finance

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 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 “Protecting Our Phar-
5 maceutical Supply Chain from China Act of 2020”.

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 **UNITED STATES.**

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 drug’s supply chain,
25 including each step in the supply chain that occurs prior
26 to the drug’s importation into the United States.”.

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

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

12 (A) By 2022, a purchaser of drugs de-
13 scribed in this subsection shall only purchase
14 drugs that contain 60 percent or more of their
15 active pharmaceutical ingredients manufactured
16 in countries—

17 (i) other than the People’s Republic of
18 China; and

19 (ii) that meet the Food and Drug Ad-
20 ministration’s health and safety standards.

21 (B) By 2023, a purchaser of drugs de-
22 scribed in this subsection shall only purchase
23 drugs that contain 100 percent of their active
24 pharmaceutical ingredients manufactured in
25 countries—

1 (i) other than the People’s Republic of
2 China; and

3 (ii) that meet the Food and Drug Ad-
4 ministration’s health and safety standards.

5 (2) WAIVERS.—The Secretary of Health and
6 Human Services may issue waivers of the require-
7 ments under paragraph (1) for any agency or pro-
8 gram that is unable to meet such requirements and
9 demonstrates a need for the waiver. No waiver may
10 be issued under this paragraph for drugs that are
11 purchased on or after January 1, 2025.

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

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

18 **SEC. 3. TEMPORARY 100 PERCENT EXPENSING FOR PHAR-**
19 **MACEUTICAL AND MEDICAL DEVICE MANU-**
20 **FACTURING PROPERTY.**

21 (a) IN GENERAL.—For purposes of section 168(k) of
22 the Internal Revenue Code of 1986, in the case of any
23 qualified pharmaceutical and medical device manufac-
24 turing property which is placed in service after December
25 31, 2019, and before January 1, 2026—

1 (1) such property shall be treated as qualified
2 property (within the meaning of such section),

3 (2) the applicable percentage otherwise deter-
4 mined under section 168(k)(6) of such Code with re-
5 spect to such property shall be 100 percent, and

6 (3) paragraph (8) of such section shall not
7 apply.

8 (b) **QUALIFIED PHARMACEUTICAL AND MEDICAL**
9 **DEVICE MANUFACTURING PROPERTY.**—For purposes of
10 this section, the term “qualified pharmaceutical and med-
11 ical device manufacturing property” means any tangible
12 property placed in service in the United States as part
13 of the construction or expansion of property for the manu-
14 facture of drugs (as defined in section 201(g) of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))
16 or medical devices (as defined in section 201(h) of such
17 Act (21 U.S.C. 321(h)).

18 (c) **TERMINATION.**—This section shall not apply to
19 any property placed in service after December 31, 2025.

20 **SEC. 4. RULE OF CONSTRUCTION.**

21 Nothing in this Act shall be construed to divert the
22 resources of the Food and Drug Administration from re-
23 sponding to the COVID-19 public health emergency.

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