

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—
- "(1) are manufactured outside of the United
- 13 States; and
- "(2) are determined by the Secretary to be crit-
- 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),
2	(2) the applicable percentage otherwise deter

- (2) the applicable percentage otherwise determined under section 168(k)(6) of such Code with respect to such property shall be 100 percent, and
- 6 (3) paragraph (8) of such section shall not 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)).

4

5

- 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.
- 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.