116TH CONGRESS
2D SESSION

S. 3635

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, or reimbursement for, drugs manufactured in China, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 6, 2020

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

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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, or reimbursement for, drugs manufactured in China, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Protecting Our Pharmaceutical Supply Chain from China Act of 2020''.

SEC. 2. COUNTRY OF ORIGIN OF DRUGS.

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

"SEC. 524B. REGISTRY OF DRUGS PRODUCED OUTSIDE THE UNITED STATES.

''(a) IN GENERAL.—The Secretary shall compile and maintain a list of all drugs approved under subsection (c) or (j) of section 505 of this Act or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act, and any active ingredients in such drugs, that—

''(1) are manufactured outside of the United States; and

''(2) are determined by the Secretary to be critical to the health and safety of consumers in the United States.

''(b) ADDITIONAL LIST.—In conjunction with the list described in subsection (a), the Secretary shall compile and maintain a list of drugs included on such list that are exclusively produced in, or use active or inactive ingredients produced in, the People's Republic of China.

''(c) REQUIREMENT.—The list described in subsection (a) shall, with respect to each drug included on the list, provide information about the drug's supply chain, including each step in the supply chain that occurs prior to the drug's importation into the United States.''.

(b) FEDERAL HEALTH PROGRAM PURCHASE OF, OR REIMBURSEMENT FOR, DRUGS.—

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

(A) By 2022, a purchaser of, or reimbursor for, drugs described in this subsection shall purchase drugs or reimburse for drugs only if such drugs contain 60 percent or more of their active pharmaceutical ingredients manufactured in countries—

(i) other than the People's Republic of China; and

(ii) that meet the Food and Drug Administration's health and safety standards.

(B) By 2023, a purchaser of, or reimbursor for, drugs described in this subsection shall purchase drugs or reimburse for drugs only if such drugs contain 100 percent of

their active pharmaceutical ingredients manufactured in countries—

(i) other than the People's Republic of China; and

(ii) that meet the Food and Drug Administration's health and safety standards.

(2) WAIVERS.—The Secretary of Health and Human Services may issue waivers of the requirements under paragraph (1) for any agency or program that is unable to meet such requirements and demonstrates a need for the waiver. No waiver may be issued under this paragraph for drugs that are purchased on or after January 1, 2025.

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

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

SEC. 3. TEMPORARY 100 PERCENT EXPENSING FOR PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURING PROPERTY.

(a) IN GENERAL.—For purposes of section 168(k) of the Internal Revenue Code of 1986, in the case of any qualified pharmaceutical and medical device manufac-

turing property which is placed in service after December 31, 2019, and before January 1, 2026—

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

(2) the applicable percentage otherwise determined under section 168(k)(6) of such Code with respect to such property shall be 100 percent, and

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

(b) QUALIFIED PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURING PROPERTY.—For purposes of this section, the term ''qualified pharmaceutical and medical device manufacturing property'' means any tangible property placed in service in the United States as part of the construction or expansion of property for the manufacture of drugs (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))) or medical devices (as defined in section 201(h) of such Act (21 U.S.C. 321(h))).

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

SEC. 4. RULE OF CONSTRUCTION.

Nothing in this Act shall be construed to divert the resources of the Food and Drug Administration from responding to the COVID–19 public health emergency.

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