

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.

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## 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.

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, OR  
2 REIMBURSEMENT FOR, 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, or re-  
10 imbursement for, a drug by such agency or program,  
11 the following shall apply:

12 (A) By 2022, a purchaser of, or  
13 reimbursor for, drugs described in this sub-  
14 section shall purchase drugs or reimburse for  
15 drugs only if such drugs contain 60 percent or  
16 more of their active pharmaceutical ingredients  
17 manufactured in countries—

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

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

22 (B) By 2023, a purchaser of, or  
23 reimbursor for, drugs described in this sub-  
24 section shall purchase drugs or reimburse for  
25 drugs only if such drugs contain 100 percent of

1           their active pharmaceutical ingredients manu-  
2           factured in countries—

3                   (i) other than the People’s Republic of  
4                   China; and

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

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

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

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

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

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

1 turing property which is placed in service after December  
2 31, 2019, and before January 1, 2026—

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

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

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

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

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

1 **SEC. 4. RULE OF CONSTRUCTION.**

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

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