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116TH CONGRESS
2D SESSION

H. R. 6885

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the importation of a drug or device that was manufactured at a banned foreign facility, to create incentives for pharmaceutical or device companies to increase manufacturing capacity in the United States, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 15, 2020

Mr. FLORES introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the importation of a drug or device that was manufactured at a banned foreign facility, to create incentives for pharmaceutical or device companies to increase manufacturing capacity in the United States, 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 ''Safe and Secure Medicine Supply for Hardworking Americans Act of 2020''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

SEC. 3. SAFE DRUG AND DEVICE IMPORTATION.

(a) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(fff) The importation of a drug or device that was manufactured or processed at a banned foreign facility for which an order is in effect under section 810.''.

(b) ISSUANCE OF ORDER.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 809 of such Act (21 U.S.C. 384e) the following new section:

''SEC. 810. BANNED FOREIGN FACILITIES.

''(a) DETERMINATION.—The Secretary shall issue an order determining a facility to be a banned foreign facility if—

''(1) the facility manufactures or processes any drug or device that is imported into the United States; and

''(2) a Class I or Class II recall is issued by the Food and Drug Administration for any drug or device that is manufactured or processed at such facility.

''(b) DURATION.—

''(1) BANNED FACILITIES WITH CLASS I RECALL.—For a banned facility for which a Class I recall is issued as described in subsection (a)(2):

''(A) The designation of the banned facility pursuant to an order under subsection (a), based on an initial Class I recall of a drug or device manufactured or processed at the facility, shall be in effect for the 10-year period beginning on the date that is one year after the issuance of the order.

''(B) The designation of the banned facility pursuant to an order under subsection (a), based on a subsequent Class I recall of a drug or device manufactured or processed at the facility, shall be in effect permanently beginning on the date that is one year after the issuance of such order.

''(2) BANNED FACILITIES WITH CLASS II RECALL.—For a banned facility for which a class II recall is issued as described in subsection (a)(2):

''(A) The designation of the banned facility pursuant to an order under subsection (a), based on an initial Class II recall of a drug or device manufactured or processed at the facility, shall be in effect for the 5-year period beginning on the date that is one year after the issuance of the order.

''(B) The designation of the banned facility pursuant to an order under subsection (a), based on a first subsequent Class II recall of a drug or device manufactured or processed at the facility, may be renewed to be in effect for a period of 5 years beginning—

''(i) if the initial 5-year period under subparagraph (A) has concluded, one year from the date of the first subsequent recall; or

''(ii) if the initial 5-year period under subparagraph (A) has not concluded, at the conclusion of such initial 5-year period.

''(C) The designation of the banned facility pursuant to an order under subsection (a),

based on a second subsequent Class II recall of a drug or device manufactured or processed at the facility, shall be in effect permanently beginning—

''(i) if the first subsequent 5-year period under subparagraph (B) has concluded, one year after the issuance of the order; or

''(ii) if the first subsequent 5-year period under subparagraph (B) has not concluded, immediately.

''(c) DEFINITION.—In this section:

''(1) The term 'banned facility' means a banned foreign facility for which an order is in effect under subsection (a).

''(2) The terms 'Class I' and 'Class II', in connection with a recall, mean classified as Class I or Class II, respectively, by the Food and Drug Administration pursuant to section 7.41 of title 21, Code of Federal Regulations (or any successor regulations).''.

(c) APPLICABILITY.—Section 810 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), applies only with respect to recalls issued or reissued on or after the date of enactment of this Act.

(d) CIVIL MONETARY PENALTIES.—Subsection (f) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following new paragraph:

''(10) Any person who violates section 301(fff) shall be subject to a civil money penalty not to exceed—

''(A) if the violation involves a Class I recall, as described in section 810(a)(2)—

''(i) $25,000,000 if the violation is the first violation of section 301(fff) by such person; and

''(ii) $100,000,000 if the violation is a subsequent violation of section 301(fff) by such person; and

''(B) if the violation involves a Class II recall, as described in section 810(a)(2)—

''(i) $10,000,000 if the violation is the first violation of section 301(fff) by such person; and

''(ii) $50,000,000 if the violation is a subsequent violation of section 301(fff) by such person.''.

SEC. 4. IMPOSITION OF ADDITIONAL DUTIES ON DRUGS FROM CHINA, INDIA, AND OTHER COUNTRIES.

(a) DRUGS FROM CHINA.—

(1) IN GENERAL.—In addition to any other duty, there is imposed a duty on drugs which are

being imported or offered for import into the United States (within the meaning of section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a))) from the People's Republic of China.

(2) RATE OF DUTY.—The rate of duty imposed by paragraph (1) shall be 25 percent ad valorem.

(b) DRUGS FROM INDIA.—

(1) IN GENERAL.—In addition to any other duty, there is imposed a duty on drugs which are being imported or offered for import into the United States (within the meaning of section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a))) from the Republic of India.

(2) RATE OF DUTY.—The rate of duty imposed by paragraph (1) shall be 20 percent ad valorem.

(c) DRUGS FROM OTHER COUNTRIES.—

(1) IN GENERAL.—In addition to any other duty, there is imposed a duty on drugs which are being imported or offered for import into the United States (within the meaning of section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a))) from any foreign country other than the People's Republic of China or the Republic of India.

(2) RATE OF DUTY.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the rate of duty imposed by paragraph (1) shall be 10 percent ad valorem.

(B) EXCEPTION.—In the case of a drug that includes one or more active pharmaceutical ingredients originating from the People's Republic of China or the Republic of India, the rate of duty imposed by paragraph (1) shall be—

(i) 25 percent ad valorem for those containing an active pharmaceutical ingredient from China; and

(ii) 20 percent ad valorem for those containing an active pharmaceutical ingredient from India.

(d) EFFECTIVE DATE.—The provisions of this section shall apply to articles described in subsections (a), (b), and (c) entered, or withdrawn from warehouse for consumption, on or after the date that is 15 days after the date of the enactment of this Act.

SEC. 5. SECURE MEDICINES SUPPLY FUND.

(a) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the Secure Medicines Supply Fund (in this section referred to as the ''Fund''), consisting of such amounts as may

be deposited to the Fund pursuant to subsection (b) to be used, in accordance with subsection (c), for the purpose of supporting and incentivizing pharmaceutical or device companies to invest in new pharmaceutical or device manufacturing capacity in the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(b) REQUIREMENTS.—To be eligible for investment under subsection (a), new pharmaceutical or device manufacturing capacity shall meet each of the following:

(1) The products supported by the new pharmaceutical or device manufacturing capacity do not use active pharmaceutical ingredients or parts manufactured in China or India.

(2) At least 50 percent of the active pharmaceutical ingredients or parts for the total product line of the respective company is manufactured in any of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands.

(c) FUNDING.—

(1) DUTIES.—Amounts collected from duties imposed pursuant to section 4 shall be deposited in the Fund, to remain available until expended.

(2) FINES.—Amounts collected from civil monetary penalties imposed pursuant to paragraph (10) of section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)), as added by section 3(d), shall be deposited in the Fund, to remain available until expended.

(d) DISTRIBUTION OF FUNDS.—

(1) GRANTS.—The Secretary of Health and Human Services shall establish a grant program to support and incentivize pharmaceutical or device companies to manufacture prescription drugs, active pharmaceutical ingredients, or devices in any of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(2) LIMITATIONS ON USE OF FUNDS.—As a condition on receipt of a grant under this section, the recipient of the grant shall agree to use—

(A) not more than 10 percent of the grant for new or expanded manufacturing capacity;

(B) not more than 50 percent of the grant for training manufacturing workers; and

(C) not more than 25 percent of the grant for developing one or more new prescription drugs, new active pharmaceutical ingredients, or new antibiotics.

(3) SOURCE OF FUNDING.—All amounts used to carry out this section shall be derived from the Fund.

(e) REPORT.—Not later than one year after the date of enactment of this Act, and annually thereafter, the Secretary of Health and Human Services shall submit to the Congress a report on the Fund. Each such report shall address the following:

(1) The amounts deposited into the Fund in the most recent three fiscal years.

(2) The distribution of such amounts pursuant to grants under this section during the last three fiscal years, including the allocation of such amounts for—

(A) new or expanded manufacturing capacity;

(B) training workers; and

(C) developing new prescription drugs, new active pharmaceutical ingredients, or new antibiotics.

(f) DEVICE.—In this section, the term ''device'' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(g) SUNSET.—This section (other than subsection (e)) shall cease to have effect beginning on the date that is 10 years after the date of the enactment of this Act.

(h) UNUSED FUNDS RETURNED TO THE GENERAL FUND OF THE TREASURY.—If any amounts remain in the Fund after the date described in subsection (f), the Secretary of the Treasury shall transfer such amounts to the general fund of the Treasury.

SEC. 6. REGISTRY OF DRUGS MANUFACTURED OUTSIDE THE UNITED STATES.

The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 524A of such Act (21 U.S.C. 360n–1) the following new section:

''SEC. 524B. REGISTRY OF DRUGS MANUFACTURED OUTSIDE THE UNITED STATES.

''(a) IN GENERAL.—The Secretary shall compile and maintain a registry 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 pharmaceutical ingredients in such drugs, that are manufactured outside of the United

States. The Secretary shall update such registry at least biannually.

''(b) ADDITIONAL LIST.—

''(1) IN GENERAL.—In conjunction with the registry under subsection (a), the Secretary shall compile and maintain a list of those drugs included in the registry for which 50 percent or more of their active pharmaceutical ingredients are manufactured in locations within a single country outside the United States.

''(2) CONTENTS.—The list of drugs under paragraph (1) shall—

''(A) identify both the drugs and the associated sole-source country;

''(B) be updated at least bi-annually; and

''(C) be publicly available.

''(c) REQUIREMENT.—The registry under subsection (a) shall, with respect to each drug included on the registry, 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.''.

SEC. 7. COUNTRY-OF-ORIGIN LABELING.

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 pharmaceutical ingredient contained in the drug.''.

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