



(Original Signature of Member)

116TH CONGRESS
2D SESSION

H. R.

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

Mr. FLORES introduced the following bill; which was referred to the Committee on _____

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Safe and Secure Medi-
3 cine Supply for Hardworking Americans Act of 2020”.

4 **SEC. 2. TABLE OF CONTENTS.**

5 The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Safe drug and device importation.

Sec. 4. Imposition of additional duties on drugs from China, India, and other
countries.

Sec. 5. Secure Medicines Supply Fund.

Sec. 6. Registry of drugs manufactured outside the United States.

Sec. 7. Country-of-origin labeling.

6 **SEC. 3. SAFE DRUG AND DEVICE IMPORTATION.**

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

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

13 (b) ISSUANCE OF ORDER.—The Federal Food, Drug,
14 and Cosmetic Act is amended by inserting after section
15 809 of such Act (21 U.S.C. 384e) the following new sec-
16 tion:

17 **“SEC. 810. BANNED FOREIGN FACILITIES.**

18 “(a) DETERMINATION.—The Secretary shall issue an
19 order determining a facility to be a banned foreign facility
20 if—

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

4 “(2) a Class I or Class II recall is issued by the
5 Food and Drug Administration for any drug or de-
6 vice that is manufactured or processed at such facil-
7 ity.

8 “(b) DURATION.—

9 “(1) BANNED FACILITIES WITH CLASS I RE-
10 CALL.—For a banned facility for which a Class I re-
11 call is issued as described in subsection (a)(2):

12 “(A) The designation of the banned facility
13 pursuant to an order under subsection (a),
14 based on an initial Class I recall of a drug or
15 device manufactured or processed at the facil-
16 ity, shall be in effect for the 10-year period be-
17 ginning on the date that is one year after the
18 issuance of the order.

19 “(B) The designation of the banned facility
20 pursuant to an order under subsection (a),
21 based on a subsequent Class I recall of a drug
22 or device manufactured or processed at the fa-
23 cility, shall be in effect permanently beginning
24 on the date that is one year after the issuance
25 of such order.

1 “(2) BANNED FACILITIES WITH CLASS II RE-
2 CALL.—For a banned facility for which a class II re-
3 call is issued as described in subsection (a)(2):

4 “(A) The designation of the banned facility
5 pursuant to an order under subsection (a),
6 based on an initial Class II recall of a drug or
7 device manufactured or processed at the facil-
8 ity, shall be in effect for the 5-year period be-
9 ginning on the date that is one year after the
10 issuance of the order.

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

17 “(i) if the initial 5-year period under
18 subparagraph (A) has concluded, one year
19 from the date of the first subsequent re-
20 call; or

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

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

1 based on a second subsequent Class II recall of
2 a drug or device manufactured or processed at
3 the facility, shall be in effect permanently be-
4 ginning—

5 “(i) if the first subsequent 5-year pe-
6 riod under subparagraph (B) has con-
7 cluded, one year after the issuance of the
8 order; or

9 “(ii) if the first subsequent 5-year pe-
10 riod under subparagraph (B) has not con-
11 cluded, immediately.

12 “(c) DEFINITION.—In this section:

13 “(1) The term ‘banned facility’ means a banned
14 foreign facility for which an order is in effect under
15 subsection (a).

16 “(2) The terms ‘Class I’ and ‘Class II’, in con-
17 nection with a recall, mean classified as Class I or
18 Class II, respectively, by the Food and Drug Admin-
19 istration pursuant to section 7.41 of title 21, Code
20 of Federal Regulations (or any successor regula-
21 tions).”.

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

1 (d) CIVIL MONETARY PENALTIES.—Subsection (f) of
2 section 303 of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 333) is amended by adding at the end the fol-
4 lowing new paragraph:

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

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

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

11 “(ii) \$100,000,000 if the violation is a sub-
12 sequent violation of section 301(fff) by such
13 person; and

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

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

18 “(ii) \$50,000,000 if the violation is a sub-
19 sequent violation of section 301(fff) by such
20 person.”.

21 **SEC. 4. IMPOSITION OF ADDITIONAL DUTIES ON DRUGS**

22 **FROM CHINA, INDIA, AND OTHER COUNTRIES.**

23 (a) DRUGS FROM CHINA.—

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

1 being imported or offered for import into the United
2 States (within the meaning of section 801 of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 381(a))) from the People's Republic of China.

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

7 (b) DRUGS FROM INDIA.—

8 (1) IN GENERAL.—In addition to any other
9 duty, there is imposed a duty on drugs which are
10 being imported or offered for import into the United
11 States (within the meaning of section 801 of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 381(a))) from the Republic of India.

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

16 (c) DRUGS FROM OTHER COUNTRIES.—

17 (1) IN GENERAL.—In addition to any other
18 duty, there is imposed a duty on drugs which are
19 being imported or offered for import into the United
20 States (within the meaning of section 801 of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 381(a))) from any foreign country other than the
23 People's Republic of China or the Republic of India.

24 (2) RATE OF DUTY.—

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

4 (B) EXCEPTION.—In the case of a drug
5 that includes one or more active pharmaceutical
6 ingredients originating from the People’s Re-
7 public of China or the Republic of India, the
8 rate of duty imposed by paragraph (1) shall
9 be—

10 (i) 25 percent ad valorem for those
11 containing an active pharmaceutical ingre-
12 dient from China; and

13 (ii) 20 percent ad valorem for those
14 containing an active pharmaceutical ingre-
15 dient from India.

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

21 **SEC. 5. SECURE MEDICINES SUPPLY FUND.**

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

1 be deposited to the Fund pursuant to subsection (b) to
2 be used, in accordance with subsection (c), for the purpose
3 of supporting and incentivizing pharmaceutical or device
4 companies to invest in new pharmaceutical or device man-
5 ufacturing capacity in the 50 States, the District of Co-
6 lumbia, Puerto Rico, the Virgin Islands, Guam, American
7 Samoa, and the Commonwealth of the Northern Mariana
8 Islands.

9 (b) REQUIREMENTS.— To be eligible for investment
10 under subsection (a), new pharmaceutical or device manu-
11 facturing capacity shall meet each of the following:

12 (1) The products supported by the new pharma-
13 ceutical or device manufacturing capacity do not use
14 active pharmaceutical ingredients or parts manufac-
15 tured in China or India.

16 (2) At least 50 percent of the active pharma-
17 ceutical ingredients or parts for the total product
18 line of the respective company is manufactured in
19 any of the 50 States, the District of Columbia,
20 Puerto Rico, the Virgin Islands, Guam, American
21 Samoa, or the Commonwealth of the Northern Mar-
22 iana Islands.

23 (c) FUNDING.—

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

4 (2) FINES.—Amounts collected from civil mone-
5 tary penalties imposed pursuant to paragraph (10)
6 of section 303(f) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 333(f)), as added by sec-
8 tion 3(d), shall be deposited in the Fund, to remain
9 available until expended.

10 (d) DISTRIBUTION OF FUNDS.—

11 (1) GRANTS.—The Secretary of Health and
12 Human Services shall establish a grant program to
13 support and incentivize pharmaceutical or device
14 companies to manufacture prescription drugs, active
15 pharmaceutical ingredients, or devices in any of the
16 50 States, the District of Columbia, Puerto Rico, the
17 Virgin Islands, Guam, American Samoa, and the
18 Commonwealth of the Northern Mariana Islands.

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

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

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

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

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

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

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

15 (2) The distribution of such amounts pursuant
16 to grants under this section during the last three fis-
17 cal years, including the allocation of such amounts
18 for—

19 (A) new or expanded manufacturing capac-
20 ity;

21 (B) training workers; and

22 (C) developing new prescription drugs, new
23 active pharmaceutical ingredients, or new anti-
24 biotics.

1 (f) DEVICE.—In this section, the term “device” has
2 the meaning given to such term in section 201 of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C. 321).

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

7 (h) UNUSED FUNDS RETURNED TO THE GENERAL
8 FUND OF THE TREASURY.—If any amounts remain in the
9 Fund after the date described in subsection (f), the Sec-
10 retary of the Treasury shall transfer such amounts to the
11 general fund of the Treasury.

12 **SEC. 6. REGISTRY OF DRUGS MANUFACTURED OUTSIDE**
13 **THE UNITED STATES.**

14 The Federal Food, Drug, and Cosmetic Act is amend-
15 ed by inserting after section 524A of such Act (21 U.S.C.
16 360n–1) the following new section:

17 **“SEC. 524B. REGISTRY OF DRUGS MANUFACTURED OUT-**
18 **SIDE THE UNITED STATES.**

19 “(a) IN GENERAL.—The Secretary shall compile and
20 maintain a registry of all drugs approved under subsection
21 (c) or (j) of section 505 of this Act or licensed under sub-
22 section (a) or (k) of section 351 of the Public Health Serv-
23 ice Act, and any active pharmaceutical ingredients in such
24 drugs, that are manufactured outside of the United

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

3 “(b) ADDITIONAL LIST.—

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

11 “(2) CONTENTS.—The list of drugs under para-
12 graph (1) shall—

13 “(A) identify both the drugs and the asso-
14 ciated sole-source country;

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

16 “(C) be publicly available.

17 “(c) REQUIREMENT.—The registry under subsection
18 (a) shall, with respect to each drug included on the reg-
19 istry, provide information about the drug’s supply chain,
20 including each step in the supply chain that occurs prior
21 to the drug’s importation into the United States.”.

22 **SEC. 7. COUNTRY-OF-ORIGIN LABELING.**

23 Section 502 of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 352) is amended by adding at the end the
25 following:

- 1 “(ee) If it is a drug and its labeling does not specify
- 2 the country of origin of each active pharmaceutical ingre-
- 3 dient contained in the drug.”.