

116TH CONGRESS
2D SESSION

H. R. 8987

To amend the Public Health Service Act to incentivize the manufacture of certain medicines in the United States and to enhance the security of the United States pharmaceutical supply chain, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 16, 2020

Mr. JOYCE of Pennsylvania 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

A BILL

To amend the Public Health Service Act to incentivize the manufacture of certain medicines in the United States and to enhance the security of the United States pharmaceutical supply chain, 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 “Enhancing the Secu-
5 rity of the U.S. Pharmaceutical Supply Chain Act of
6 2020”.

1 **SEC. 2. TABLE OF CONTENTS.**

2 The table of contents for this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Identification, development, and procurement of priority medicines.

Sec. 4. Priority medicine production credit.

Sec. 5. Improving regulatory efficiencies for transfer of drugs.

3 **SEC. 3. IDENTIFICATION, DEVELOPMENT, AND PROCURE-**
 4 **MENT OF PRIORITY MEDICINES.**

5 (a) PRIORITY MEDICINES.—Title XXVIII of the Pub-
 6 lic Health Service Act (42 U.S.C. 300hh et seq.) is amend-
 7 ed by adding at the end the following:

8 **“SEC. 2804. IDENTIFICATION OF PRIORITY MEDICINES.**

9 “(a) PRIORITY MEDICINES.—The Secretary shall
 10 designate as a priority medicine each covered product
 11 that—

12 “(1)(A) is necessary for use in a public health
 13 emergency declared under section 319; or

14 “(B) is at high risk of becoming in short sup-
 15 ply; and

16 “(2) has a vulnerable global supply chain.

17 “(b) GLOBAL SUPPLY CHAIN VULNERABILITY.—In
 18 determining whether a covered product has a vulnerable
 19 global supply chain under subsection (a)(2), the Secretary
 20 shall consider—

21 “(1) the findings of the National Academies of
 22 Sciences, Engineering, and Medicine in the report

1 published pursuant to section 4111 of the CARES
2 Act (Public Law 116–136);

3 “(2) the number of manufacturers of each cov-
4 ered product;

5 “(3) the manufacturing locations, and amount
6 produced, of each covered product;

7 “(4) the history of the importation of each pri-
8 ority medicine; and

9 “(5) the probability of the imposition of duties
10 on the importation of each covered product.

11 “(c) CONSULTATION.—In carrying out subsection
12 (a), the Secretary shall consult with the Public Health
13 Emergency Medical Countermeasures Enterprise estab-
14 lished under section 2811–1.

15 “(d) PUBLICATION OF LIST.—The Secretary shall—

16 “(1) not later than 180 days after the date of
17 enactment of this section, publish a preliminary list
18 of priority medicines;

19 “(2) provide an opportunity for public comment
20 on such preliminary list;

21 “(3) not later than 1 year after such date of en-
22 actment, publish a final list of priority medicines;
23 and

24 “(4) on an annual basis, review and, as appro-
25 priate, update such list.

1 “(e) DEFINITIONS.—In this section:

2 “(1) ACTIVE PHARMACEUTICAL INGREDIENT.—

3 The term ‘active pharmaceutical ingredient’—

4 “(A) means any component that is in-
5 tended to furnish pharmacological activity or
6 other direct effect in the diagnosis, cure, miti-
7 gation, treatment, or prevention of a disease, or
8 to affect the structure or any function of the
9 body of a human or animal; and

10 “(B) does not include—

11 “(i) intermediates used in the syn-
12 thesis of a drug product; or

13 “(ii) components that may undergo
14 chemical change in the manufacture of a
15 drug product and be present in a drug
16 product in a modified form that is in-
17 tended to furnish such activity or effect.

18 “(2) COVERED PRODUCT.—The term ‘covered
19 product’ means a drug (including a biological prod-
20 uct) or an active pharmaceutical ingredient.

21 “(3) PRIORITY MEDICINE.—The term ‘priority
22 medicine’ means a priority medicine for which a des-
23 ignation is in effect under subsection (a).”.

24 (b) NATIONAL STRATEGIC HEALTH STRATEGY.—

25 Section 2802(b) of the Public Health Service Act (42

1 U.S.C. 300hh–1(b)) is amended by adding at the end the
2 following:

3 “(11) PRIORITY MEDICINES.—Supporting the
4 identification, production, and procurement of pri-
5 ority medicines designated under section 2804.”.

6 (c) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
7 TERMEASURES ENTERPRISE RECOMMENDATIONS.—Sec-
8 tion 2811–1(c)(1) of the Public Health Service Act (42
9 U.S.C. 300hh–10a(c)) is amended by adding at the end
10 the following:

11 “(E) Provide recommendations to the Sec-
12 retary with respect to the priority medicines
13 designated under section 2804.”.

14 (d) STRATEGIC PLAN FOR COUNTERMEASURE RE-
15 SEARCH, DEVELOPMENT, AND PROCUREMENT.—Section
16 319L(b) of the Public Health Service Act (42 U.S.C.
17 247d–7e(b)) is amended—

18 (1) in paragraph (2)—

19 (A) in subparagraph (B), by striking
20 “and” at the end;

21 (B) in subparagraph (C), by striking the
22 period at the end and inserting “; and”; and

23 (C) by adding at the end the following:

1 “(D) the development and procurement of
2 priority medicines designated under section
3 2804.”; and

4 (2) by adding at the end the following:

5 “(3) PRIORITY MEDICINES.—With respect to
6 the development and procurement of priority medi-
7 cines, the Secretary shall promote a diverse and sus-
8 tainable supply chain, including through grants and
9 purchases.”.

10 (e) CRITICAL DRUG CONSIDERATION.—Section 3101
11 of the CARES Act (Public Law 116–136) is amended—

12 (1) by redesignating subsection (d) as sub-
13 section (e); and

14 (2) after executing the redesignation in para-
15 graph (1), by inserting after subsection (c) the fol-
16 lowing:

17 “(d) CONSIDERATION.—With respect to any analysis
18 of a critical drug under subsection (b)(1), the Secretary
19 shall consider the vulnerability of such drug with respect
20 to the global supply chain, including an analysis of—

21 “(1) the number of manufacturers of such
22 drug;

23 “(2) the manufacturing locations, and amounts
24 produced, of such drug;

1 “(3) the history of the importation of such
2 drug; and

3 “(4) the probability of the imposition of duties
4 on the importation of such drug.”.

5 **SEC. 4. PRIORITY MEDICINE PRODUCTION CREDIT.**

6 (a) IN GENERAL.—Subpart D of part IV of sub-
7 chapter A of chapter 1 of the Internal Revenue Code of
8 1986 is amended by adding at the end the following new
9 section:

10 **“SEC. 45U. PRIORITY MEDICINE PRODUCTION CREDIT.**

11 “(a) GENERAL RULE.—For purposes of section 38,
12 the priority medicine production credit determined under
13 this section for the taxable year is an amount equal to
14 50 percent of the qualified priority medicine expenses for
15 the taxable year.

16 “(b) QUALIFIED PRIORITY MEDICINE EXPENSES.—

17 “(1) QUALIFIED PRIORITY MEDICINE EX-
18 PENSES.—The term ‘qualified priority medicine ex-
19 penses’ means direct and indirect costs paid or in-
20 curred by the taxpayer during the taxable year for
21 the production of priority medicines.

22 “(2) PRIORITY MEDICINES.—For purposes of
23 this section, a ‘priority medicine’ is a medicine that
24 was included, within the 5 calendar years imme-
25 diately preceding the taxable year, on the list devel-

oped and published by the Secretary of Health and Human Services pursuant to section 2804(d) of the Public Health Service Act.

“(3) COORDINATION WITH SECTION 263A.—

“(A) COORDINATION WITH SECTION 263A.—In applying section 263A, indirect costs shall be allocated between the production of priority medicines and the production of other medicines based on the ratio in which the number of doses of the priority medicines produced in the taxable year bears to the total number of doses of all medicines produced by the taxpayer in that taxable year to which the expense is attributable.

“(B) REGULATIONS AND GUIDANCE.—The Secretary shall by regulation or other guidance prescribe rules for the proper allocation of indirect costs described in subparagraph (A).”.

(b) CREDIT ALLOWED AS BUSINESS CREDIT.—Section 38(b) of the Internal Revenue Code of 1986 (relating to current year business credit) is amended by striking “plus” at the end of paragraph (32), by striking the period at the end of paragraph (33) and inserting “, plus”, and adding at the end the following new paragraph:

1 “(34) the priority medicine production credit
2 determined under section 45U.”.

3 (c) CONFORMING AMENDMENTS.—

4 (1) COORDINATION WITH SECTION 59.—

5 (A) Section 59A(b)(1)(B)(ii) is amended—

6 (i) in subclause (I), by striking
7 “plus,” at the end;

8 (ii) in subclause (II), by striking the
9 period at the end, and inserting “, plus”;
10 and

11 (iii) by adding at the end the fol-
12 lowing:

13 “(III) the credit allowed under
14 section 38 for the taxable year which
15 is properly allocable to the priority
16 medicine production credit determined
17 under section 45U.”.

18 (B) Section 59A(b)(2)(B) is amended to
19 read as follows:

20 “(B) by reducing (but not below zero) the
21 regular tax liability (as defined in section
22 26(b)) for purposes of subparagraph (B) there-
23 of by the excess (if any) of the aggregate
24 amount of the credits allowed under this chap-
25 ter against such regular tax liability over the

1 credit allowed under section 38 for the taxable
 2 year which is properly allocable to the priority
 3 medicine production credit determined under
 4 section 45U, rather than the excess described in
 5 such paragraph.”.

6 (2) COORDINATION WITH RESEARCH CREDIT.—
 7 Section 41(c)(4)(A) is amended by striking “14”
 8 and inserting “20”.

9 (d) CLERICAL AMENDMENT.—The table of sections
 10 for subpart D of part IV of subchapter A of part IV of
 11 subchapter A of chapter 1 of the Internal Revenue Code
 12 of 1986 is amended by inserting after the item relating
 13 to section 45T the following new item:

“Sec. 45U. Priority medicine production credit.”

14 (e) EFFECTIVE DATE.—The amendments made by
 15 this section shall apply to qualified priority medicine ex-
 16 penses paid or incurred after December 31, 2020.

17 **SEC. 5. IMPROVING REGULATORY EFFICIENCIES FOR**
 18 **TRANSFER OF DRUGS.**

19 The Federal Food, Drug, and Cosmetic Act (21
 20 U.S.C. 301 et seq.) is amended by inserting after section
 21 505–1 of such Act (21 U.S.C. 355–1) the following:

22 **“SEC. 505–2. TRANSFER OF DRUGS TO DOMESTIC ESTAB-**
 23 **LISHMENTS.**

24 “(a) IN GENERAL.—Beginning not later than 90
 25 days after the date of the enactment of this section, the

1 Secretary shall expedite the review and approval of a sup-
2 plemental application to an abbreviated new drug applica-
3 tion approved under section 505(j) or a new drug applica-
4 tion approved under section 505(c) that seeks to transfer
5 manufacturing of one or more finished dosage forms of
6 a drug or one or more active pharmaceutical ingredients
7 therein from one or more foreign establishments to one
8 or more new or existing domestic establishments.

9 “(b) BEFORE SUPPLEMENTAL APPLICATION SUB-
10 MISSION.—

11 “(1) DEVELOPMENT AND PRE-SUBMISSION.—

12 After an applicant submits a meeting request with
13 respect to expedited review and approval of a supple-
14 mental application pursuant to subsection (a), the
15 Secretary shall—

16 “(A) not later than 30 days after receiving
17 such request, conduct a meeting with the appli-
18 cant to—

19 “(i) discuss the information necessary
20 to approve the supplemental application;
21 and

22 “(ii) if applicable, schedule a pre-ap-
23 proval inspection; and

1 “(B) not later than 60 days after receiving
2 such request, conduct a meeting with the appli-
3 cant to—

4 “(i) provide advice to the applicant
5 with respect to the supplemental applica-
6 tion; and

7 “(ii) if applicable, select a first drug
8 to be identified in accordance with sub-
9 section (c).

10 “(2) REVIEW AND APPROVAL.—In carrying out
11 subsection (a), the Secretary shall—

12 “(A) review and take action with respect to
13 a supplemental application not later than 6
14 months after the date of submission or resub-
15 mission of such application; and

16 “(B) where the Secretary recommends a
17 change to a domestic establishment following an
18 inspection of such establishment, reinspect the
19 establishment not later than 90 days after re-
20 ceiving a request from the applicant for rein-
21 spection.

22 “(3) RELATION TO FEE PERFORMANCE
23 GOALS.—The deadlines specified in paragraph (1)
24 supersede any conflicting performance goals identi-
25 fied in any statute reauthorizing the fee programs in

1 parts 2 and 7 of subchapter C of title VII of the
2 Federal Food, Drug, and Cosmetic Act.

3 “(c) CONTENTS.—With respect to a supplemental ap-
4 plication under subsection (a) for a transfer of the site
5 of manufacture of multiple drugs that share a similar
6 manufacturing process, the Secretary shall—

7 “(1) request a list of the drugs;

8 “(2) from the list under paragraph (1), identify
9 a first drug to be transferred;

10 “(3) determine the criteria necessary to receive
11 approval of the supplemental application; and

12 “(4) require the applicant to demonstrate, as
13 part of such criteria, that each foreign establishment
14 from which the drugs are to be transferred has a
15 satisfactory inspection history with respect to the
16 drugs.

17 “(d) SUBSEQUENT TRANSFER OF DRUGS THAT
18 SHARE A SIMILAR MANUFACTURING PROCESS.—After the
19 approval of a supplemental application under subsection
20 (a) for the transfer of the manufacturing of a first drug
21 identified by the Secretary pursuant to subsection (c)(2)
22 from one or more foreign establishments to one or more
23 new or existing domestic establishments, the Secretary
24 may allow the applicant to so transfer drugs that share
25 a similar manufacturing process with such first drug pur-

1 suant to submission of a report under section 506A(d)(2)
2 rather than by requiring submission of a supplemental ap-
3 plication.

4 “(e) WORKING GROUP.—

5 “(1) ESTABLISHMENT.—Not later than 90 days
6 after the date of enactment of this section, the Sec-
7 retary shall establish an intra-agency working group
8 to be known as the Facility Transfer Working
9 Group.

10 “(2) MEMBERSHIP.—The Secretary shall ap-
11 point members of the Facility Transfer Working
12 Group from among officials and employees of the
13 Department of Health and Human Services who—

14 “(A) represent a cross-section of the De-
15 partment of Health and Human Services; and

16 “(B) have expertise on establishments used
17 to manufacture drugs.

18 “(3) DUTIES.—The Facility Transfer Working
19 Group shall—

20 “(A) assist the Secretary in carrying out
21 this section;

22 “(B) upon request by an applicant, con-
23 duct an informational site visit during the de-
24 velopmental phase to discuss requirements with

1 the applicant with respect to facility design, site
2 status, and validation;

3 “(C) not later than 30 days after con-
4 ducting an informational site visit under sub-
5 paragraph (B), provide advice and feedback to
6 the applicant with respect to facility issues that
7 may prevent approval of the supplemental ap-
8 plication under subsection (a), including any
9 issues with the facility transfer plans; and

10 “(D) participate in any pre-approval in-
11 spection required by the Secretary for an estab-
12 lishment or provide feedback to the Secretary
13 with respect to a supplemental application de-
14 scribed in subsection (a).

15 “(f) ADDITIONAL INFORMATIONAL VISITS.—Upon
16 request by the applicant, the Secretary may conduct infor-
17 mational site visits in addition to an informational site
18 visit conducted by the Facility Transfer Working Group
19 under subsection (e).

20 “(g) GUIDANCE.—

21 “(1) ISSUANCE.—Not later than 1 year after
22 the date of enactment of this section, the Secretary
23 shall issue guidance with respect to this section.

24 “(2) CONTENT.—The guidance issued under
25 this paragraph shall include—

1 “(A) the process by which an applicant
2 may seek expedited review and approval of a
3 supplemental application under subsection (a);
4 and

5 “(B) a description of the actions the Sec-
6 retary may take to expedite the submission and
7 review of such supplemental application.

8 “(h) DEFINITIONS.—In this section:

9 “(1) SATISFACTORY INSPECTION HISTORY.—
10 The term ‘satisfactory inspection history’ means,
11 with respect to a drug, a history consisting of one
12 or more inspections in which the most recent manu-
13 facturing inspection was a satisfactory manufac-
14 turing inspection during which—

15 “(A) no objectionable conditions or prac-
16 tices were found; or

17 “(B) objectionable conditions were found
18 and voluntary corrective action was left to the
19 manufacturer.

20 “(2) SIMILAR MANUFACTURING PROCESS.—The
21 term ‘similar manufacturing process’ means proc-
22 esses used to manufacture drugs that share at least
23 one unit operation having the same design prin-
24 ciple.”.

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