

118TH CONGRESS
1ST SESSION

H. R. 2707

To mitigate drug shortages and provide incentives for maintaining, expanding, and relocating the manufacturing of active pharmaceutical ingredients, excipients, medical diagnostic devices, pharmaceuticals, and personal protective equipment in the United States, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 19, 2023

Mr. CARTER of Georgia (for himself, Mr. SOTO, Mrs. MILLER of West Virginia, Mr. CARTWRIGHT, Mr. HUDSON, Mr. BILIRAKIS, Mr. GRIFFITH, Mr. BALDERSON, Mr. VAN DREW, Mr. CRAWFORD, Mrs. HARSHBARGER, and Mr. LANGWORTHY) introduced the following bill; which was referred to the Committee on Ways and Means

A BILL

To mitigate drug shortages and provide incentives for maintaining, expanding, and relocating the manufacturing of active pharmaceutical ingredients, excipients, medical diagnostic devices, pharmaceuticals, and personal protective equipment 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 “Manufacturing API,
3 Drugs, and Excipients in America Act” or the “MADE
4 in America Act”.

5 **SEC. 2. CREDIT FOR PHARMACEUTICAL AND MEDICAL DE-**
6 **VICE PRODUCTION ACTIVITIES IN DIS-**
7 **TRESSED ZONES.**

8 (a) IN GENERAL.—Subpart D of part IV of sub-
9 chapter A of chapter 1 of the Internal Revenue Code of
10 1986 is amended by adding at the end the following new
11 section:

12 **“SEC. 45BB. DISTRESSED ZONE PHARMACEUTICAL AND**
13 **MEDICAL DEVICE PRODUCTION CREDIT.**

14 “(a) IN GENERAL.—For purposes of section 38, the
15 distressed zone pharmaceutical and medical device produc-
16 tion credit for the taxable year shall be an amount equal
17 to the applicable percentage of the qualified production ac-
18 tivity expenditures of the taxpayer for the taxable year.

19 “(b) APPLICABLE PERCENTAGE.—For purposes of
20 this section—

21 “(1) IN GENERAL.—Except as provided in para-
22 graph (2), the term ‘applicable percentage’ means
23 25 percent.

24 “(2) INCREASED AMOUNT WHERE EMPLOYEES
25 RESIDE IN DISTRESSED ZONE.—In the case of any
26 qualified pharmaceutical or medical device produc-

1 tion business a substantial portion of the employees
2 of which reside in a distressed zone, the applicable
3 percentage shall be 30 percent.

4 “(c) QUALIFIED PRODUCTION ACTIVITY EXPENDI-
5 TURES.—For purposes of this section—

6 “(1) IN GENERAL.—The term ‘qualified produc-
7 tion activity expenditures’ means—

8 “(A) wages paid or incurred to an em-
9 ployee of the taxpayer for services performed by
10 such employee in the conduct of a qualified
11 pharmaceutical or diagnostic medical device
12 production business in a distressed zone (but
13 only if the employee’s principal place of employ-
14 ment is in a distressed zone), and

15 “(B) qualified pharmaceutical or medical
16 device production expenditures.

17 “(2) QUALIFIED PHARMACEUTICAL OR MEDICAL
18 DEVICE PRODUCTION BUSINESS.—

19 “(A) IN GENERAL.—The term ‘qualified
20 pharmaceutical or medical device production
21 business’ means the trade or business of pro-
22 ducing qualified pharmaceuticals in commercial
23 quantities.

24 “(B) QUALIFIED PHARMACEUTICALS.—

1 “(i) IN GENERAL.—The term ‘quali-
2 fied pharmaceuticals’ means pharma-
3 ceuticals, active pharmaceutical ingredi-
4 ents, excipients, medical diagnostic devices,
5 or personal protective equipment.

6 “(ii) PHARMACEUTICAL.—The term
7 ‘pharmaceuticals’—

8 “(I) means any drug (as defined
9 in section 201 of the Federal Food,
10 Drug, and Cosmetic Act), and

11 “(II) includes a biological prod-
12 uct (as defined in section 351 of the
13 Public Health Service Act).

14 “(iii) ACTIVE PHARMACEUTICAL IN-
15 GREDIENT.—The term ‘active pharma-
16 ceutical ingredients’ has the meaning given
17 to such term in section 207.1 of title 21,
18 Code of Federal Regulations (or any suc-
19 cessor regulations).

20 “(iv) EXCIPIENT.—The term ‘excip-
21 ient’—

22 “(I) means any inactive ingre-
23 dient that is intentionally added to a
24 pharmaceutical that is not intended to
25 exert therapeutic effects at the in-

1 tended dosage, other than by acting to
2 improve product delivery, and

3 “(II) includes any such filler, ex-
4 tenders, diluent, wetting agent, sol-
5 vent, emulsifier, preservative, flavor,
6 absorption enhancer, sustained release
7 matrix, and coloring agent.

8 “(v) MEDICAL DIAGNOSTIC DEVICE.—

9 The term ‘medical diagnostic device’ means
10 any device (as defined in section 201(h) of
11 the Federal Food, Drug, and Cosmetic
12 Act) intended for use in the diagnosis of
13 disease or other conditions.

14 “(vi) PERSONAL PROTECTIVE EQUIP-
15 MENT.—The term ‘personal protective
16 equipment’ means—

17 “(I) any device (as defined in
18 section 201(h) of the Federal Food,
19 Drug, and Cosmetic Act) that is a
20 face mask, filtering facepiece res-
21 pirator, face shield, surgical mask,
22 gown, other apparel, or glove that is
23 intended for a medical purpose, and

24 “(II) any particulate filtering air
25 purifying respiratory protective device

1 that is approved by the National In-
2 stitute for Occupational Safety and
3 Health under part 84 of title 42, Code
4 of Federal Regulations (or successor
5 regulations).

6 “(3) CERTAIN HEALTH PLAN EXPENSES TREAT-
7 ED AS WAGES.—

8 “(A) IN GENERAL.—The term ‘wages’
9 shall include so much of the eligible employer’s
10 qualified health plan expenses as are properly
11 allocable to such wages.

12 “(B) QUALIFIED HEALTH PLAN EX-
13 PENSES.—For purposes of this paragraph, the
14 term ‘qualified health plan expenses’ means
15 amounts paid or incurred by the eligible em-
16 ployer to provide and maintain a group health
17 plan (as defined in section 5000(b)(1)), but
18 only to the extent that such amounts are ex-
19 cluded from the gross income of employees by
20 reason of section 106(a) of such Code.

21 “(C) ALLOCATION RULES.—For purposes
22 of this paragraph, qualified health plan ex-
23 penses shall be allocated to qualified wages in
24 such manner as the Secretary may prescribe.
25 Except as otherwise provided by the Secretary,

1 such allocation shall be treated as properly
2 made if made on the basis of being pro rata
3 among employees and pro rata on the basis of
4 periods of coverage (relative to the periods to
5 which such wages relate).

6 “(4) QUALIFIED PHARMACEUTICAL OR MEDICAL
7 DEVICE PRODUCTION EXPENDITURES.—

8 “(A) DEFINITION.—The term ‘qualified
9 pharmaceutical or medical device production ex-
10 penditures’ means amounts paid or incurred
11 (whether or not chargeable to capital account)
12 for qualified property used in the conduct of a
13 qualified pharmaceutical or medical device pro-
14 duction business in a distressed zone (but only
15 if the primary use of such property is in a dis-
16 tressed zone).

17 “(B) QUALIFIED PROPERTY.—

18 “(i) IN GENERAL.—The term ‘quali-
19 fied property’ means any tangible personal
20 property (other than a building or its
21 structural components) used in the conduct
22 of a qualified pharmaceutical or medical
23 device production business in a distressed
24 zone (but only if the primary use of such
25 property is in a distressed zone).

1 “(ii) EXCEPTION.—Such term shall
2 not include any property described in sec-
3 tion 50(b) (determined as if the United
4 States included Puerto Rico).

5 “(d) DISTRESSED ZONE.—For purposes of this sec-
6 tion, the term ‘distressed zone’ means a population census
7 tract which—

8 “(1) has been designated as a qualified oppor-
9 tunity zone under section 1400Z–1, and

10 “(2) has a poverty rate in excess of 30 percent
11 for the calendar year prior to the calendar year that
12 includes the date of enactment of this section.

13 “(e) SPECIAL RULES.—

14 “(1) APPLICATION TO UNITED STATES SHARE-
15 HOLDERS OF CONTROLLED FOREIGN CORPORA-
16 TIONS.—

17 “(A) IN GENERAL.—In the case of a do-
18 mestic corporation that is a United States
19 shareholder of a qualified controlled foreign cor-
20 poration, the credit under subsection (a) (deter-
21 mined without regard to this paragraph) shall
22 be increased by an amount equal to 30 percent
23 of the corporation’s pro rata share (determined
24 under rules similar to the rules of section
25 951(a)(2)) of qualified production activity ex-

1 penditures of such controlled foreign corpora-
2 tion for the taxable year of the qualified con-
3 trolled foreign corporation ending with or with-
4 in the taxable year of the domestic corporation.

5 “(B) QUALIFIED CORPORATION.—For pur-
6 poses of subparagraph (A), the term ‘qualified
7 controlled foreign corporation’ means, for any
8 taxable year, a controlled foreign corporation
9 which does not have gross income that is effec-
10 tively connected with the conduct of a trade or
11 business within the United States for such tax-
12 able year.

13 “(2) REDUCTION IN BASIS.—If a credit is de-
14 termined under this section with respect to any
15 property by reason of any qualified production activ-
16 ity expenditures described in subsection (b)(1)(B),
17 the basis of such property shall be reduced by the
18 amount of the credit so determined.

19 “(3) COORDINATION WITH OTHER CREDITS.—
20 Any qualified production activity expenditures taken
21 into account in determining the amount of the credit
22 under subsection (a) shall not be taken into account
23 in determining a credit under any other provision of
24 this chapter.

25 “(f) RECAPTURE.—

1 “(1) IN GENERAL.—If, during any taxable year,
2 property taken into account under subsection
3 (e)(1)(B) is disposed of, or otherwise ceases to be
4 used by the taxpayer in the active trade or business
5 of producing qualified pharmaceuticals in commer-
6 cial quantities, before the close of the recapture pe-
7 riod, then the tax under this chapter for such tax-
8 able year shall be increased by the recapture per-
9 centage of the aggregate decrease in the credits al-
10 lowed under section 38 for all prior taxable years
11 which would have resulted solely from reducing to
12 zero any credit determined under this section with
13 respect to such property.

14 “(2) RECAPTURE PERCENTAGE.—For purposes
15 of subparagraph (A), the recapture percentage shall
16 be determined in the same manner as under section
17 50(a)(1)(B).

18 “(3) APPLICATION TO UNITED STATES SHARE-
19 HOLDERS.—In the case of any taxpayer to whom a
20 credit is allowed by reason of subsection (e)(1),
21 paragraph (1) shall be applied by substituting ‘the
22 controlled foreign corporation with respect to which
23 the taxpayer is a United States shareholder’ for ‘the
24 taxpayer’.

1 “(4) APPLICATION OF OTHER RULES.—For
2 purposes of this paragraph, rules similar to the rules
3 of paragraphs (3), (4), and (5) (other than subpara-
4 graph (A) thereof) of section 50(a)(1) shall apply.”.

5 (b) CREDIT ALLOWED AGAINST ALTERNATIVE MIN-
6 IMUM TAX.—Section 38(c)(4)(B) of such Code is amended
7 by redesignating clauses (x), (xi), and (xii) as clauses (xi),
8 (xii), and (xiii), respectively, and by inserting after clause
9 (ix) the following new clause:

10 “(x) the credit determined under sec-
11 tion 45BB,”.

12 (c) CREDIT ALLOWED AGAINST BASE EROSION
13 ANTI-ABUSE TAX.—Section 59A(b)(1)(B)(ii) of such
14 Code is amended by striking “plus” at the end of sub-
15 clause (I), by redesignating subclause (II) as subclause
16 (III), and by inserting after subclause (I) (as so amended)
17 the following new subclause:

18 “(II) the credit allowed under
19 section 38 for the taxable year which
20 is properly allocable to the distressed
21 zone pharmaceutical and medical de-
22 vice production credit determined
23 under section 45BB(a), plus”.

1 (d) DENIAL OF DEDUCTION.—Section 280C of such
2 Code is amended by adding at the end the following new
3 subsection:

4 “(i) DISTRESSED ZONE PHARMACEUTICAL AND
5 MEDICAL DEVICE PRODUCTION CREDIT.—No deduction
6 shall be allowed for that portion of the qualified produc-
7 tion activity expenditures (as defined in section 45BB(b))
8 otherwise allowable as a deduction for the taxable year
9 which is equal to the amount of the distressed zone phar-
10 maceutical and medical device production credit deter-
11 mined for such taxable year under section 45BB(a).”.

12 (e) PART OF GENERAL BUSINESS CREDIT.—Section
13 38(b) of such Code is amended by striking “plus” at the
14 end of paragraph (40), by striking the period at the end
15 of paragraph (41) and inserting “, plus”, and by adding
16 at the end the following new paragraph:

17 “(42) the distressed zone pharmaceutical and
18 medical device production credit determined under
19 section 45BB(a).”.

20 (f) CLERICAL AMENDMENT.—The table of sections
21 for subpart D of part IV of subchapter A of chapter 1
22 is amended by adding at the end the following new item:

“Sec. 45BB. Distressed zone pharmaceutical and medical device production
credit.”.

1 (g) EFFECTIVE DATE.—The amendments made by
2 this section shall apply to amounts paid or incurred after
3 the date of the enactment of this Act.

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