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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

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

Mr. CARTER of Georgia introduced the following bill; which was referred to the Committee on _____

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.

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 ''Manufacturing API, Drugs, and Excipients in America Act'' or the ''MADE in America Act''.

SEC. 2. CREDIT FOR PHARMACEUTICAL AND MEDICAL DEVICE PRODUCTION ACTIVITIES IN DISTRESSED ZONES.

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

''SEC. 45BB. DISTRESSED ZONE PHARMACEUTICAL AND MEDICAL DEVICE PRODUCTION CREDIT.

''(a) IN GENERAL.—For purposes of section 38, the distressed zone pharmaceutical and medical device production credit for the taxable year shall be an amount equal to the applicable percentage of the qualified production activity expenditures of the taxpayer for the taxable year.

''(b) APPLICABLE PERCENTAGE.—For purposes of this section—

''(1) IN GENERAL.—Except as provided in paragraph (2), the term 'applicable percentage' means 25 percent.

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

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

''(c) QUALIFIED PRODUCTION ACTIVITY EXPENDITURES.—For purposes of this section—

''(1) IN GENERAL.—The term 'qualified production activity expenditures' means—

''(A) wages paid or incurred to an employee of the taxpayer for services performed by such employee in the conduct of a qualified pharmaceutical or diagnostic medical device production business in a distressed zone (but only if the employee's principal place of employment is in a distressed zone), and

''(B) qualified pharmaceutical or medical device production expenditures.

''(2) QUALIFIED PHARMACEUTICAL OR MEDICAL DEVICE PRODUCTION BUSINESS.—

''(A) IN GENERAL.—The term 'qualified pharmaceutical or medical device production business' means the trade or business of producing qualified pharmaceuticals in commercial quantities.

''(B) QUALIFIED PHARMACEUTICALS.—

"(i) IN GENERAL.—The term 'qualified pharmaceuticals' means pharmaceuticals, active pharmaceutical ingredients, excipients, medical diagnostic devices, or personal protective equipment.

"(ii) PHARMACEUTICAL.—The term 'pharmaceuticals'—

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

"(II) includes a biological product (as defined in section 351 of the Public Health Service Act).

"(iii) ACTIVE PHARMACEUTICAL INGREDIENT.—The term 'active pharmaceutical ingredients' has the meaning given to such term in section 207.1 of title 21, Code of Federal Regulations (or any successor regulations).

"(iv) EXCIPIENT.—The term 'excipient'—

"(I) means any inactive ingredient that is intentionally added to a pharmaceutical that is not intended to exert therapeutic effects at the in-

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

''(II) includes any such filler, extenders, diluent, wetting agent, solvent, emulsifier, preservative, flavor, absorption enhancer, sustained release matrix, and coloring agent.

''(v) MEDICAL DIAGNOSTIC DEVICE.—The term 'medical diagnostic device' means any device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) intended for use in the diagnosis of disease or other conditions.

''(vi) PERSONAL PROTECTIVE EQUIPMENT.—The term 'personal protective equipment' means—

''(I) any device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) that is a face mask, filtering facepiece respirator, face shield, surgical mask, gown, other apparel, or glove that is intended for a medical purpose, and

''(II) any particulate filtering air purifying respiratory protective device

that is approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or successor regulations).

''(3) CERTAIN HEALTH PLAN EXPENSES TREATED AS WAGES.—

''(A) IN GENERAL.—The term 'wages' shall include so much of the eligible employer's qualified health plan expenses as are properly allocable to such wages.

''(B) QUALIFIED HEALTH PLAN EXPENSES.—For purposes of this paragraph, the term 'qualified health plan expenses' means amounts paid or incurred by the eligible employer to provide and maintain a group health plan (as defined in section 5000(b)(1)), but only to the extent that such amounts are excluded from the gross income of employees by reason of section 106(a) of such Code.

''(C) ALLOCATION RULES.—For purposes of this paragraph, qualified health plan expenses shall be allocated to qualified wages in such manner as the Secretary may prescribe. Except as otherwise provided by the Secretary,

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

''(4) QUALIFIED PHARMACEUTICAL OR MEDICAL DEVICE PRODUCTION EXPENDITURES.—

''(A) DEFINITION.—The term 'qualified pharmaceutical or medical device production expenditures' means amounts paid or incurred (whether or not chargeable to capital account) for qualified property used in the conduct of a qualified pharmaceutical or medical device production business in a distressed zone (but only if the primary use of such property is in a distressed zone).

''(B) QUALIFIED PROPERTY.—

''(i) IN GENERAL.—The term 'qualified property' means any tangible personal property (other than a building or its structural components) used in the conduct of a qualified pharmaceutical or medical device production business in a distressed zone (but only if the primary use of such property is in a distressed zone).

''(ii) EXCEPTION.—Such term shall not include any property described in section 50(b) (determined as if the United States included Puerto Rico).

''(d) DISTRESSED ZONE.—For purposes of this section, the term 'distressed zone' means a population census tract which—

''(1) has been designated as a qualified opportunity zone under section 1400Z–1, and

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

''(e) SPECIAL RULES.—

''(1) APPLICATION TO UNITED STATES SHAREHOLDERS OF CONTROLLED FOREIGN CORPORATIONS.—

''(A) IN GENERAL.—In the case of a domestic corporation that is a United States shareholder of a qualified controlled foreign corporation, the credit under subsection (a) (determined without regard to this paragraph) shall be increased by an amount equal to 30 percent of the corporation's pro rata share (determined under rules similar to the rules of section 951(a)(2)) of qualified production activity ex-

penditures of such controlled foreign corporation for the taxable year of the qualified controlled foreign corporation ending with or within the taxable year of the domestic corporation.

''(B) QUALIFIED CORPORATION.—For purposes of subparagraph (A), the term 'qualified controlled foreign corporation' means, for any taxable year, a controlled foreign corporation which does not have gross income that is effectively connected with the conduct of a trade or business within the United States for such taxable year.

''(2) REDUCTION IN BASIS.—If a credit is determined under this section with respect to any property by reason of any qualified production activity expenditures described in subsection (b)(1)(B), the basis of such property shall be reduced by the amount of the credit so determined.

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

''(f) RECAPTURE.—

''(1) IN GENERAL.—If, during any taxable year, property take into account under subsection (c)(1)(B) is disposed of, or otherwise ceases to be used by the taxpayer in the active trade or business of producing qualified pharmaceuticals in commercial quantities, before the close of the recapture period, then the tax under this chapter for such taxable year shall be increased by the recapture percentage of the aggregate decrease in the credits allowed under section 38 for all prior taxable years which would have resulted solely from reducing to zero any credit determined under this section with respect to such property.

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

''(3) APPLICATION TO UNITED STATES SHAREHOLDERS.—In the case of any taxpayer to whom a credit is allowed by reason of subsection (e)(1), paragraph (1) shall be applied by substituting 'the controlled foreign corporation with respect to which the taxpayer is a United States shareholder' for 'the taxpayer'.

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

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

''(x) the credit determined under section 45BB,''.

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

''(II) the credit allowed under section 38 for the taxable year which is properly allocable to the distressed zone pharmaceutical and medical device production credit determined under section 45BB(a), plus''.

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

''(i) DISTRESSED ZONE PHARMACEUTICAL AND MEDICAL DEVICE PRODUCTION CREDIT.—No deduction shall be allowed for that portion of the qualified production activity expenditures (as defined in section 45BB(b)) otherwise allowable as a deduction for the taxable year which is equal to the amount of the distressed zone pharmaceutical and medical device production credit determined for such taxable year under section 45BB(a).''.

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

''(42) the distressed zone pharmaceutical and medical device production credit determined under section 45BB(a).''.

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

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

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