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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 SENATE OF THE UNITED STATES

JUNE 16, 2021

Mr. SCOTT of South Carolina (for himself and Ms. ROSEN) introduced the following bill; which was read twice and referred to the Committee on Finance

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Manufacturing API,
5 Drugs, and Excipients in America Act” or the “MADE
6 in America Act”.

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

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

- Sec. 1. Short title.
Sec. 2. Table of contents.

TITLE I—HEALTH PROVISIONS

- Sec. 101. Report to Congress on barriers to domestic manufacturing of medical products.
Sec. 102. Enhance intra-agency coordination and public health assessment with regard to compliance activities.
Sec. 103. Reporting of mutual recognition agreements for inspections and review activities.
Sec. 104. Enhancing transparency of drug facility inspection timelines.
Sec. 105. Advanced manufacturing technologies program.

TITLE II—TAX INCENTIVES TO INCREASE DOMESTIC
PHARMACEUTICAL AND MEDICAL DEVICE PRODUCTION

- Sec. 201. Credit for pharmaceutical and medical device production activities in distressed zones.

3 **TITLE I—HEALTH PROVISIONS**

4 **SEC. 101. REPORT TO CONGRESS ON BARRIERS TO DOMES-**
5 **TIC MANUFACTURING OF MEDICAL PROD-**
6 **UCTS.**

7 (a) REPORT.—Not later than 6 months after the date
8 of enactment of this Act, the Secretary of Health and
9 Human Services, the Secretary of the Treasury, the Sec-
10 retary of Commerce, and the United States Trade Rep-
11 resentative (collectively referred to in this section as the
12 “Secretaries”) shall submit to the Committee on Health,
13 Education, Labor, and Pensions of the Senate and the
14 Committee on Energy and Commerce of the House of
15 Representatives a report on barriers to domestic manufac-
16 turing of active pharmaceutical ingredients, finished drug

1 products, and devices that are imported from outside of
2 the United States.

3 (b) CONTENTS.—Such report shall—

4 (1) identify factors that limit or otherwise dis-
5 courage the domestic manufacturing of active phar-
6 maceutical ingredients, drugs, and devices that are
7 currently imported from outside of the United
8 States, including any Federal, State, local, or Tribal
9 laws that hinder domestic manufacturing opportuni-
10 ties; and

11 (2) recommend specific strategies to overcome
12 the challenges identified under paragraph (1), in-
13 cluding strategies—

14 (A) to develop effective incentives for do-
15 mestic manufacturing; and

16 (B) to make changes to laws or regulations
17 that hinder domestic manufacturing opportuni-
18 ties.

19 (c) CONSULTATION.—In preparing the report under
20 subsection (a), the Secretaries shall consult with—

21 (1) the Food and Drug Administration, the
22 Centers for Medicare & Medicaid Services, the De-
23 partment of Defense, the Department of State, the
24 Department of Veterans Affairs, the Department of

1 Justice, and any other Federal agencies as appro-
2 priate; and

3 (2) relevant stakeholders, including drug, de-
4 vice, and active pharmaceutical ingredient manufac-
5 turers, and other entities, as appropriate.

6 (d) DEFINITION.—In this section, the term “active
7 pharmaceutical ingredient” has the meaning given to such
8 term in section 207.1 of title 21, Code of Federal Regula-
9 tions (or any successor regulations).

10 (e) PUBLICATION.—The Secretary shall make the re-
11 port under subsection (a) available on the public website
12 of the Department of Health and Human Services.

13 **SEC. 102. ENHANCE INTRA-AGENCY COORDINATION AND**
14 **PUBLIC HEALTH ASSESSMENT WITH REGARD**
15 **TO COMPLIANCE ACTIVITIES.**

16 (a) COORDINATION.—Section 506D of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 356d) is
18 amended by adding at the end the following:

19 “(g) COORDINATION.—The Secretary shall ensure
20 timely and effective internal coordination and alignment
21 among the field investigators of the Food and Drug Ad-
22 ministration and the staff of the Center for Drug Evalua-
23 tion and Research’s Office of Compliance and Drug Short-
24 age Program regarding the reviews of reports shared pur-

1 suant to section 704(b)(2), and any feedback or corrective
2 or preventive actions in response to such reports.”.

3 (b) REPORTING.—Section 506C–1(a)(2) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 356c–
5 1(a)(2)) is amended to read as follows:

6 “(2)(A) describes the communication between
7 the field investigators of the Food and Drug Admin-
8 istration and the staff of the Center for Drug Eval-
9 uation and Research’s Office of Compliance and
10 Drug Shortage Program, including the Food and
11 Drug Administration’s procedures for enabling and
12 ensuring such communication;

13 “(B) provides the number of reports described
14 in section 704(b)(2) that were required to be sent to
15 the appropriate offices of the Food and Drug Ad-
16 ministration with expertise regarding drug shortage
17 and the number of such reports that were sent; and

18 “(C) describes the adoption and utilization of
19 the approach described in section 506D(g);”.

20 (c) APPLICABILITY.—

21 (1) SUBSECTION (a).—The amendment made
22 by subsection (a) shall apply beginning on the date
23 of enactment of this Act.

24 (2) SUBSECTION (b).—The amendment made
25 by subsection (b) shall apply beginning on the date

1 that is 1 year after the date of enactment of this
2 Act.

3 **SEC. 103. REPORTING OF MUTUAL RECOGNITION AGREE-**
4 **MENTS FOR INSPECTIONS AND REVIEW AC-**
5 **TIVITIES.**

6 (a) IN GENERAL.—Not later than the end of calendar
7 year 2020, and annually thereafter, the Secretary of
8 Health and Human Services (referred to in this section
9 as the “Secretary”) shall publish a report on the public
10 website of the Food and Drug Administration on the utili-
11 zation of agreements entered into pursuant to section 809
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 384e) or otherwise entered into by the Secretary to recog-
14 nize inspections between drug regulatory authorities
15 across countries and international regions with analogous
16 review criteria to the Food and Drug Administration, such
17 as the Pharmaceutical Inspection Co-Operation Scheme,
18 the Mutual Recognition Agreement with the European
19 Union, and the Australia-Canada-Singapore-Switzerland
20 Consortium, in the previous fiscal year.

21 (b) CONTENT.—The report under subsection (a) shall
22 include each of the following:

23 (1) The total number of establishments that are
24 registered under section 510(i) of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 360(i)), and of

1 such establishments, the number in each region of
2 interest.

3 (2) The total number of inspections conducted
4 as described in subparagraphs (A) and (B) of para-
5 graph (5) at establishments described in paragraph
6 (1).

7 (3) Of the inspections described in paragraph
8 (2), the total number of inspections in each of region
9 of interest.

10 (4) Of the inspections in each region of interest
11 reported pursuant to paragraph (3), the number of
12 inspections in each FDA inspection category.

13 (5) Of the number of inspections reported
14 under each of paragraphs (3) and (4)—

15 (A) the number of inspections which have
16 been conducted pursuant to an agreement or
17 other recognition described in subsection (a);
18 and

19 (B) the number of inspections which have
20 been conducted by employees or contractors of
21 the Food and Drug Administration.

22 (c) DEFINITIONS.—In this subsection:

23 (1) FDA INSPECTION CATEGORY.—The term
24 “FDA inspection category” means the following in-
25 spection categories:

1 (A) Inspections to support approvals of
2 changes to the manufacturing process of drugs
3 approved under section 505 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 355)
5 or section 351 of the Public Health Service Act
6 (42 U.S.C. 262).

7 (B) Good manufacturing practice surveil-
8 lance inspections.

9 (C) For-cause inspections.

10 (2) REGION OF INTEREST.—The term “region
11 of interest” means China, India, the European
12 Union, and any other geographic region as the Sec-
13 retary determines appropriate.

14 **SEC. 104. ENHANCING TRANSPARENCY OF DRUG FACILITY**
15 **INSPECTION TIMELINES.**

16 Section 902 of the FDA Reauthorization Act of 2017
17 (21 U.S.C. 355 note) is amended to read as follows:

18 **“SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

19 “Not later than March 1 of each year, the Secretary
20 of Health and Human Services shall post on the public
21 website of the Food and Drug Administration information
22 related to inspections of facilities, including inspections
23 that are necessary for approval of a drug under subsection
24 (c) or (j) of section 505 of the Federal Food, Drug, and
25 Cosmetic Act (21 U.S.C. 355), approval of a device under

1 section 515 of such Act (21 U.S.C. 360e), or clearance
2 of a device under section 510(k) of such Act (21 U.S.C.
3 360(k)) that were conducted during the previous calendar
4 year. Such information shall include the following:

5 “(1) The median time following a request from
6 staff of the Food and Drug Administration review-
7 ing an application or report to the beginning of the
8 inspection, including—

9 “(A) the median time for drugs described
10 in section 505(j)(11)(A)(i) of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C.
12 355(j)(11)(A)(i));

13 “(B) the median time for drugs described
14 in section 506C(a) of such Act (21 U.S.C.
15 356c(a)) only; and

16 “(C) the median time for drugs on the
17 drug shortage list in effect under section 506E
18 of such Act (21 U.S.C. 356f).

19 “(2) The median time from the issuance of a
20 report pursuant to section 704(b) of such Act (21
21 U.S.C. 374(b)) to the sending of a warning letter,
22 issuance of an import alert, or holding of a regu-
23 latory meeting for inspections for which the Sec-
24 retary concluded that regulatory or enforcement ac-
25 tion was indicated, including the median time for

1 each category of drugs listed in subparagraphs (A)
2 through (C) of paragraph (1).

3 “(3) The median time from the sending of a
4 warning letter, issuance of an import alert, or hold-
5 ing of a regulatory meeting to resolution of the ac-
6 tions indicated to address the conditions or practices
7 observed during an inspection.

8 “(4) The number of facilities that were unable
9 to implement requested corrective or preventive ac-
10 tions following a report pursuant to such section
11 704(b), resulting in a withhold recommendation, in-
12 cluding the number of such times for each category
13 of drugs listed in subparagraphs (A) through (C) of
14 paragraph (1).”.

15 **SEC. 105. ADVANCED MANUFACTURING TECHNOLOGIES**
16 **PROGRAM.**

17 Subchapter A of chapter V of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
19 ed by adding at the end the following:

20 **“SEC. 524B. ADVANCED MANUFACTURING TECHNOLOGIES**
21 **PROGRAM.**

22 “(a) IN GENERAL.—Not later than 1 year after the
23 date of enactment of the Manufacturing API, Drugs, and
24 Excipients in America Act, the Secretary shall continue
25 in effect the programs to facilitate the development and

1 review of an application under subsection (b) or (j) of sec-
2 tion 505 of this Act or subsection (a) or (k) of section
3 351 of the Public Health Service Act for a drug or biologi-
4 cal product that is manufactured using one of more ad-
5 vanced manufacturing technologies that have been des-
6 ignated in accordance with subsection (b).

7 “(b) DESIGNATION.—The Secretary shall designate a
8 method of manufacturing or development of a drug or bio-
9 logical product as an advanced manufacturing technology
10 under this section if it incorporates a novel technology or
11 uses an established technique or technology in a novel way
12 that—

13 “(1) enhances drug quality; or

14 “(2) improves the flexibility, robustness, or effi-
15 ciency of the manufacturing process to—

16 “(A) prevent or resolve a drug shortage;

17 “(B) reduce premarket development time;

18 or

19 “(C) increase the supply of drugs described
20 in paragraph (1) or (2) of section 506C(a) for
21 national emergencies.

22 “(c) CONSULTATION.—If the Secretary designates a
23 method of manufacturing as an advanced manufacturing
24 technology under this section, the Secretary shall take ac-
25 tions to expedite the development and implementation of

1 such method of manufacture for purposes of approval of
2 an application under subsection (c) or (j) of section 505
3 of this Act or subsection (a) or (k) of section 351 of the
4 Public Health Service Act, which may include, as appro-
5 priate, holding meetings between the sponsor of the appli-
6 cation and appropriate Food and Drug Administration
7 staff throughout the development of the drug of biological
8 product using such advanced manufacturing technology.

9 “(d) EVALUATION OF AN ADVANCED MANUFAC-
10 TURING TECHNOLOGY.—

11 “(1) PACKAGE.—A person who seeks designa-
12 tion of an advanced manufacturing technology under
13 this section shall submit to the Secretary a package
14 of scientific evidence supporting the implementation
15 of the advanced manufacturing technology in a par-
16 ticular context-of-use. The Secretary shall assist
17 with the development of such package by—

18 “(A) providing timely advice to, and inter-
19 active communication with, the sponsor regard-
20 ing the development of the technology; and

21 “(B) involving senior managers and experi-
22 enced staff of the Food and Drug Administra-
23 tion, as appropriate, in a collaborative, cross-
24 disciplinary review of the method of manufac-
25 turing.

1 “(2) EVALUATION.—Within 90 days of receiv-
2 ing a package under paragraph (1), the Secretary
3 shall determine whether a designated advanced man-
4 ufacturing technology is validated for the proposed
5 context of use based on the scientific merit the sup-
6 porting evidence provided by the sponsor.

7 “(3) EFFECT OF DESIGNATION.—Upon des-
8 ignation of an advanced manufacturing technology,
9 the holder of the advanced manufacturing technology
10 designation, or a person the advanced manufac-
11 turing technology designation holder authorizes, may
12 rely upon the advanced manufacturing technology
13 for use across multiple manufacturing or product
14 lines within the same context-of-use without having
15 to re-submit data to the Secretary validating the un-
16 derlying technology.

17 “(e) IMPLEMENTATION AND REPORTING.—

18 “(1) PUBLIC MEETING.—The Secretary shall
19 publish in the Federal Register a notice of a public
20 meeting, to be held not later than 1 year after the
21 date of enactment of the Manufacturing API,
22 Drugs, and Excipients in America Act, to discuss
23 and obtain input and recommendations from stake-
24 holders regarding the goals and scope of, and a suit-

1 able framework and procedures and requirements
2 for, the program under this section.

3 “(2) PROGRAM GUIDANCE.—The Secretary
4 shall—

5 “(A) not later than 1 year after the date
6 of enactment of the Manufacturing API, Drugs,
7 and Excipients in America Act, issue draft
8 guidance regarding the goals and implementa-
9 tion of the program under this section; and

10 “(B) not later than 2 years after the date
11 of enactment of the Manufacturing API, Drugs,
12 and Excipients in America Act, issue final guid-
13 ance with respect to the implementation of such
14 program.

15 “(3) REPORT.—The Secretary shall make avail-
16 able on the public website of the Food and Drug Ad-
17 ministration an annual report on the progress of the
18 programs under this section.”.

1 **TITLE II—TAX INCENTIVES TO**
2 **INCREASE DOMESTIC PHAR-**
3 **MACEUTICAL AND MEDICAL**
4 **DEVICE PRODUCTION**

5 **SEC. 201. CREDIT FOR PHARMACEUTICAL AND MEDICAL**
6 **DEVICE 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. 45U. DISTRESSED ZONE PHARMACEUTICAL AND MED-**
13 **ICAL 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

1 qualified pharmaceutical or medical device produc-
2 tion business a substantial portion of the employees
3 of which reside in a distressed zone, the applicable
4 percentage shall be 30 percent.

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

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

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

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

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

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

25 “(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 amount 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—

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

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

14 “(e) SPECIAL RULES.—

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

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

1 951(a)(2)) of qualified production activity ex-
2 penditures of such controlled foreign corpora-
3 tion for the taxable year of the qualified con-
4 trolled foreign corporation ending with or with-
5 in the taxable year of the domestic corporation.

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

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

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

1 “(f) RECAPTURE.—

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

15 “(2) RECAPTURE PERCENTAGE.—For purposes
16 of subparagraph (A), the recapture percentage shall
17 be determined in the same manner as under section
18 50(a)(1)(B).

19 “(3) APPLICATION TO UNITED STATES SHARE-
20 HOLDERS.—In the case of any taxpayer to whom a
21 credit is allowed by reason of subsection (e)(1),
22 paragraph (1) shall be applied by substituting ‘the
23 controlled foreign corporation with respect to which
24 the taxpayer is a United States shareholder’ for ‘the
25 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 45U,”.

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 45U(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 45U(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 45U(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 (32), by striking the period at the end
15 of paragraph (33) and inserting “, plus”, and by adding
16 at the end the following new paragraph:

17 “(34) the distressed zone pharmaceutical and
18 medical device production credit determined under
19 section 45U(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. 45U. Distressed zone pharmaceutical and medical device production cred-
it.”.

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.

○