

116TH CONGRESS
2D SESSION

H. R. 6930

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

MAY 19, 2020

Mr. CARTER of Georgia (for himself, Mr. GRIFFITH, Mr. MCKINLEY, Mr. CRAWFORD, and Mr. SOTO) 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 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 of 2020” or the
4 “MADE in America Act of 2020”.

5 **SEC. 2. TABLE OF CONTENTS.**

6 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 and supplies.

Sec. 102. Enhance intraagency coordination and public health assessment with regard to compliance activities.

Sec. 103. Encouraging international harmonization.

Sec. 104. Mutual recognition agreements for inspections and review activities.

Sec. 105. Enhancing transparency of drug facility inspection timelines.

Sec. 106. 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.

7 **TITLE I—HEALTH PROVISIONS**

8 **SEC. 101. REPORT TO CONGRESS ON BARRIERS TO DOMES-**
9 **TIC MANUFACTURING OF MEDICAL PROD-**
10 **UCTS AND SUPPLIES.**

11 (a) REPORT.—Not later than January 1, 2021, the
12 Secretary of Health and Human Services (referred to in
13 this section as the “Secretary”) shall submit to the Com-
14 mittee on Energy and Commerce of the House of Rep-
15 resentatives and the Committee on Health, Education,
16 Labor, and Pensions of the Senate a report on barriers
17 to domestic manufacturing of active pharmaceutical ingre-

1 dients, drugs, and devices that are sourced or manufac-
2 tured outside of 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 sourced or manufactured outside of the
8 United States, including any Federal, State, local, or
9 Tribal laws and regulations that hinder domestic
10 manufacturing opportunities; 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 carrying out the report
20 under subsection (a), the Secretary 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 Commerce,
24 the Department of State, the Department of Vet-

(2) relevant stakeholders, including drug, device, and active pharmaceutical ingredient manufacturers, and other entities, as appropriate.

(d) DEFINITION.—In this section, the term “active pharmaceutical ingredient” has the meaning given to such term in section 207.1 of title 21, Code of Federal Regulations (and any successor regulations).

(e) PUBLICATION.—The Secretary shall make the report under subsection (a) available on the public website of the Department of Health and Human Services.

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

16 (a) BENEFIT/RISK FRAMEWORK.—

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1 risks to the public health, patient safety, the drug
2 supply and drug supply chain, and timely patient ac-
3 cess to drugs.”.

4 (2) ANNUAL REPORTING.—Subsection (b) of
5 section 704 of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 374) is amended by adding at
7 the end the following new paragraph:

8 “(3) On an annual basis, the Secretary shall prepare
9 a report on the utilization of the framework described in
10 paragraph (2) and post such report on the public website
11 of the Food and Drug Administration.”.

12 (3) APPLICABILITY.—The amendments made
13 by paragraphs (1) and (2) shall take effect on the
14 effective date described in section 3112 of the
15 CARES Act (Public Law 116–136), after executing
16 the amendments made by such section 3112, and
17 shall apply beginning on the date that is 1 year after
18 the date of enactment of this Act.

19 (b) PUBLIC MEETING.—The Secretary of Health and
20 Human Services shall publish in the Federal Register a
21 notice of a public meeting to be held no later than six
22 months after the date of enactment of this Act to discuss
23 and obtain input and recommendations from public stake-
24 holders, including patient advocates, consumers, regulated
25 industry, and health care providers, regarding the con-

1 tents of a benefit/risk framework described in section
2 704(b)(2) of the Federal Food, Drug, and Cosmetic Act,
3 as amended by subsection (a), that supports a safe, stable,
4 redundant drug supply chain.

5 (c) GUIDANCE.—The Secretary of Health and
6 Human Services shall—

7 (1) not later than one year after the date of en-
8 actment of this Act, issue draft guidance regarding
9 the goals and implementation of a benefit/risk
10 framework described in subsection (b); and

11 (2) not later than two years after such date of
12 enactment, issue final guidance with respect to the
13 implementation of such a framework.

14 **SEC. 103. ENCOURAGING INTERNATIONAL HARMONI-**
15 **ZATION.**

16 (a) GAO STUDY.—Not later than one year after the
17 date of enactment of this Act, the Comptroller General
18 of the United States shall issue a report evaluating—

19 (1) the consistency with which the International
20 Conference on Harmonisation (in this section re-
21 ferred to as “ICH”) guidelines on good manufac-
22 turing practices, including ICH Guidelines Q8–11,
23 are being implemented by drug regulatory authori-
24 ties across countries and international regions;

1 (2) whether domestic active pharmaceutical in-
2 ingredient manufacturers (including any such contract
3 manufacturers) are provided sufficient opportunity
4 to participate with regulatory authorities in the de-
5 velopment of guidelines prior to implementation;

6 (3) whether divergence from ICH guidelines or
7 differing regulatory standards or requirements by
8 drug regulatory authorities across countries and
9 international regions creates—

10 (A) inefficiencies in drug manufacturing;

11 (B) incompatible requirements that can
12 contribute to or exacerbate drug shortages; and

13 (C) the most common areas of divergence
14 between ICH guidelines and regulatory stand-
15 ards and requirements by drug regulatory au-
16 thorities across countries and international re-
17 gions that, if rectified, may reduce the ineffi-
18 ciencies and incompatibilities identified pursu-
19 ant to subparagraphs (A) and (B).

20 (b) INTERNATIONAL TRAINING PROGRAM.—Not later
21 than two years after the date of enactment of this Act,
22 informed by the needs identified in the report issued pur-
23 suant to subsection (a), the Secretary of Health and
24 Human Services, in conjunction with drug regulatory au-
25 thorities across countries and international regions and

1 the ICH, shall develop and implement a training program
2 for drug regulatory authorities across countries and inter-
3 national regions to promote consistent application of and
4 reduce divergence from ICH guidelines on good manufac-
5 turing practices.

6 **SEC. 104. MUTUAL RECOGNITION AGREEMENTS FOR IN-**
7 **SPECTIONS AND REVIEW ACTIVITIES.**

8 (a) **MUTUAL RECOGNITION OF INSPECTIONS.**—Pur-
9 suant to section 809 of the Federal Food, Drug and Cos-
10 metics Act (21 U.S.C. 384e), the Secretary of Health and
11 Human Services (in this section referred to as the “Sec-
12 retary”) shall establish or expand initiatives for mutual
13 sharing of review and inspection criteria between drug reg-
14 ulatory authorities across countries and international re-
15 gions, such as through the Pharmaceutical Cooperation
16 Inspection Scheme, the Mutual Recognition Agreement
17 with the European Union, and the Australia-Canada-
18 Singapore-Switzerland Consortium, to—

19 (1) reduce the potential for duplicative regu-
20 latory evaluation of medical products regulated by
21 the Food and Drug Administration; and

22 (2) more constructively allocate appropriations
23 to the Food and Drug Administration, including
24 those attributable to user fees, to harmonized regu-
25 latory processes.

1 (b) ADDITIONAL COUNTRIES, REGIONS, AND EVAL-
2 UATION.—In carrying out subsection (a), the Secretary
3 may expand the initiatives to include—

4 (1) additional countries and geographic regions
5 with established and competent regulatory frame-
6 works; and

7 (2) additional types of regulatory evaluation, in-
8 cluding with respect to—

9 (A) good manufacturing practice inspec-
10 tions; and

11 (B) approval of changes to the manufac-
12 turing of drugs for which an approval or licen-
13 sure is in effect under section 505 of the Fed-
14 eral Food, Drug, and Cosmetic Act (21 U.S.C.
15 355) or section 351 of the Public Health Serv-
16 ice Act (42 U.S.C. 262).

17 (c) IMPLEMENTATION FRAMEWORK.—

18 (1) PUBLICATION.—Not later than one year
19 after the date of enactment of this Act, the Sec-
20 retary shall publish an implementation framework
21 for the agreements to share review and inspection
22 criteria under subsection (a) on the public website of
23 the Food and Drug Administration.

24 (2) CONTENTS.—The implementation frame-
25 work under this subsection shall—

1 (A) include the timeline for establishing or
2 expanding initiatives described in subsection
3 (a);

4 (B) describe additional types of regulatory
5 processes that will become subject to such ini-
6 tiatives;

7 (C) specify the countries and geographic
8 regions where such initiatives will be established
9 or expanded; and

10 (D) identify additional opportunities and
11 challenges for expanding mutual recognition
12 agreements in drug and biologic regulation.

13 (d) ANNUAL REPORTING.—

14 (1) IN GENERAL.—Not later than the end of
15 calendar year 2020 and annually thereafter, the Sec-
16 retary shall publish a report on the public website of
17 the Food and Drug Administration on the utilization
18 of agreements described in subsection (c)(1) in the
19 previous fiscal year.

20 (2) CONTENTS.—The report under paragraph
21 (1) shall include each of the following:

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

1 States, and of these establishments, the number
2 in each region of interest.

3 (B) The total number of inspections con-
4 ducted at establishments described in subpara-
5 graph (A).

6 (C) Of the inspections described in sub-
7 paragraph (B), the total number of inspections
8 in each of region of interest.

9 (D) Of the inspections in each region of in-
10 terest reported pursuant to subparagraph (C),
11 the number of inspections in each FDA inspec-
12 tion category.

13 (E) Of the number of inspections reported
14 under each of subparagraphs (B), (C), and
15 (D)—

16 (i) the number of inspections which
17 have been conducted pursuant to an agree-
18 ment described in subsection (c)(1); and

19 (ii) the number of inspections which
20 have been conducted by employees or other
21 agents of the Food and Drug Administra-
22 tion.

23 (3) DEFINITIONS.—In this subsection:

24 (A) The term “region of interest” refers to
25 China, India, the European Union, and any

1 other geographic region as determined appro-
2 priate by the Secretary.

3 (B) The term “FDA inspection category”
4 means refers to the following inspection cat-
5 egories:

6 (i) Inspections to support an approval
7 of a drug under section 505 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C.
9 355) or section 351 of the Public Health
10 Service Act (42 U.S.C. 262).

11 (ii) Good manufacturing practice in-
12 spections.

13 (iii) For-cause inspections.

14 **SEC. 105. 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 necessary for approval
23 of a drug under subsection (c) or (j) of section 505 of
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 355), approval of a device under section 515 of such Act

1 (21 U.S.C. 360e), or clearance of a device under section
2 510(k) of such Act (21 U.S.C. 360(k)) that were con-
3 ducted during the previous calendar year. Such informa-
4 tion 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, and the median time from the beginning
9 of an inspection to the issuance of a report pursuant
10 to section 704(b) of the Federal Food, Drug, and
11 Cosmetic Act (21 U.S.C. 374(b)), including—

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

15 “(B) the median time for drugs described
16 in section 506C(a) of such Act (21 U.S.C.
17 356c(a)) only; and

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

21 “(2) The median time from the issuance of a
22 report pursuant to such section 704(b) to the send-
23 ing of a warning letter, issuance of an import alert,
24 or holding of a regulatory meeting for inspections
25 for which the Secretary concluded that regulatory or

1 enforcement action was indicated, including the me-
2 dian time for each category of drugs listed in sub-
3 paragraphs (A) through (C) of paragraph (1).

4 “(3) The median time from the sending of a
5 warning letter, issuance of an import alert, or hold-
6 ing of a regulatory meeting to resolution of the regu-
7 latory or enforcement action indicated for inspec-
8 tions for which the Secretary concluded that such
9 action was indicated.

10 “(4) The number of times that a facility was
11 issued a report pursuant to such section 704(b) and
12 approval of an application was delayed due to the
13 issuance of a withhold recommendation, including
14 the number of such times for each category of drugs
15 listed in subparagraphs (A) through (C) of para-
16 graph (1).”.

17 **SEC. 106. ADVANCED MANUFACTURING TECHNOLOGIES**
18 **PROGRAM.**

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

22 **“SEC. 524B. ADVANCED MANUFACTURING TECHNOLOGIES**
23 **PROGRAM.**

24 “(a) IN GENERAL.—Not later than 1 year after the
25 date of enactment of the Manufacturing API, Drugs, and

1 Excipients in America Act of 2020, the Secretary shall
2 continue in effect the program to evaluate new drug manu-
3 facturing technologies that are included in an application,
4 or supplement to an application, for a drug under sub-
5 section (b) or (j) of section 505 of this Act or for a biologi-
6 cal product submitted under subsection (a) or (k) of sec-
7 tion 351 of the Public Health Service Act.

8 “(b) DESIGNATION.—The Secretary shall designate a
9 method of manufacturing a drug as an advanced manufac-
10 turing technology under this section if the drug manufac-
11 turer demonstrates that such technology is likely to—

12 “(1) prevent or resolve a drug shortage;

13 “(2) maintain an adequate supply of critical
14 medications for national emergencies; or

15 “(3) promote the adoption of innovative ap-
16 proaches to drug product design and manufacturing.

17 “(c) CONSULTATION.—If the Secretary designates a
18 method of manufacturing as an advanced manufacturing
19 technology under this section, the Secretary shall take ac-
20 tions to expedite the development and implementation of
21 such method of manufacture for purposes of approval of
22 the application under subsection (c) or (j) of section 505
23 of this Act or subsection (a) or (k) of section 351 of the
24 Public Health Service Act, which may include, as appro-
25 priate—

1 “(1) holding meetings between the sponsor of
2 the application and appropriate Food and Drug Ad-
3 ministration staff throughout the development of the
4 technology;

5 “(2) providing timely advice to, and interactive
6 communication with, the sponsor regarding the de-
7 velopment of the technology; and

8 “(3) involving senior managers and experienced
9 staff of the Food and Drug Administration, as ap-
10 propriate, in a collaborative, cross-disciplinary review
11 of the method of manufacturing.

12 “(d) EVALUATION OF AN ADVANCED MANUFAC-
13 TURING TECHNOLOGY.—

14 “(1) PACKAGE.—A sponsor who receives des-
15 ignation of an advanced manufacturing technology
16 under this section shall provide the Secretary with a
17 package of scientific evidence supporting the imple-
18 mentation of the advanced manufacturing technology
19 in a particular context-of-use.

20 “(2) EVALUATION.—Within 90 days of receiv-
21 ing the package, the Secretary shall determine
22 whether a designated advanced manufacturing tech-
23 nology is validated for the proposed context of use
24 based on the scientific merit the supporting evidence
25 provided by the sponsor.

1 “(3) EFFECT OF APPROVAL.—Upon approval,
2 the same sponsor may rely upon the advanced man-
3 ufacturing technology for use across multiple manu-
4 facturing product lines within the same context-of-
5 use without having to re-submit data to the Sec-
6 retary validating the underlying technology.

7 “(e) IMPLEMENTATION AND REPORTING.—

8 “(1) PUBLIC MEETING.—The Secretary shall
9 publish in the Federal Register a notice of a public
10 meeting to be held no later than 1 year after the
11 date of enactment of the Manufacturing API,
12 Drugs, and Excipients in America Act of 2020 to
13 discuss and obtain input and recommendations from
14 stakeholders regarding the goals and scope of, and
15 a suitable framework and procedures and require-
16 ments for, the program under this section.

17 “(2) PROGRAM GUIDANCE.—The Secretary
18 shall—

19 “(A) not later than 1 year after the date
20 of enactment of the Manufacturing API, Drugs,
21 and Excipients in America Act of 2020, issue
22 draft guidance regarding the goals and imple-
23 mentation of the program under this section;
24 and

“(B) not later than 2 years after the date of enactment of the Manufacturing API, Drugs, and Excipients in America Act of 2020, issue final guidance with respect to the implementation of such program.

“(3) REPORT.—The Secretary shall make available on the public website of the Food and Drug Administration an annual report on the progress of the program under this section.”.

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.

(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. 45U. 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

1 to 30 percent of the qualified production activity expendi-
2 tures of the taxpayer for the taxable year.

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

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

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

14 “(B) amounts paid or incurred for any
15 tangible personal property (whether or not oth-
16 erwise properly chargeable to capital account)
17 used in the conduct of a qualified pharma-
18 ceutical or medical device production business
19 in a distressed zone (but only if the primary use
20 of such property is in a distressed zone).

21 “(2) QUALIFIED PHARMACEUTICAL OR MEDICAL
22 DEVICE PRODUCTION BUSINESS.—

23 “(A) IN GENERAL.—The term ‘qualified
24 pharmaceutical or medical device production
25 business’ means the trade or business of pro-

1 ducing pharmaceuticals, excipients, active phar-
2 maceutical ingredients, medical diagnostic de-
3 vices, or personal protective equipment.

4 “(B) ACTIVE PHARMACEUTICAL INGRE-
5 DIENT.—The term ‘active pharmaceutical ingre-
6 dients’ has the meaning given to such term in
7 section 207.1 of title 21, Code of Federal Regu-
8 lations (and any successor regulations).

9 “(C) EXCIPIENT.—The term ‘excipient’—

10 “(i) means any inactive ingredient
11 that is intentionally added to a pharma-
12 ceutical that is not intended to exert thera-
13 peutic effects at the intended dosage, other
14 than by acting to improve product delivery;
15 and

16 “(ii) includes any such filler, extend-
17 ers, diluent, wetting agent, solvent, emulsi-
18 fier, preservative, flavor, absorption
19 enhancer, sustained release matrix, and
20 coloring agent.

21 “(D) MEDICAL DIAGNOSTIC DEVICE.—The
22 term ‘medical diagnostic device’ means any de-
23 vice (as defined in section 201(h) of the Federal
24 Food, Drug, and Cosmetic Act) intended for

1 use in the diagnosis of disease or other condi-
2 tions.

3 “(E) PERSONAL PROTECTIVE EQUIP-
4 MENT.—The term ‘personal protective equip-
5 ment’ means—

6 “(i) any device (as defined in section
7 201(h) of the Federal Food, Drug, and
8 Cosmetic Act) that is a face mask, filtering
9 facepiece respirator, face shield, surgical
10 mask, gown, other apparel, or glove that is
11 intended for a medical purpose; and

12 “(ii) any particulate filtering air puri-
13 fying respiratory protective device that is
14 approved by the National Institute for Oc-
15 cupational Safety and Health under part
16 84 of title 42, Code of Federal Regulations
17 (or successor regulations).

18 “(F) PHARMACEUTICAL.—The term ‘phar-
19 maceutical’—

20 “(i) means any drug (as defined in
21 section 201 of the Federal Food, Drug,
22 and Cosmetic Act); and

23 “(ii) includes a biological product (as
24 defined in section 351 of the Public Health
25 Service Act).

1 “(3) CERTAIN HEALTH PLAN EXPENSES TREAT-
2 ED AS WAGES.—

3 “(A) IN GENERAL.—For purposes of para-
4 graph (1), the term ‘wages’ shall include so
5 much of the eligible employer’s qualified health
6 plan expenses as are properly allocable to such
7 wages.

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

17 “(C) ALLOCATION RULES.—For purposes
18 of this paragraph, qualified health plan ex-
19 penses shall be allocated to qualified wages in
20 such manner as the Secretary may prescribe.
21 Except as otherwise provided by the Secretary,
22 such allocation shall be treated as properly
23 made if made on the basis of being pro rata
24 among employees and pro rata on the basis of

1 periods of coverage (relative to the periods to
2 which such wages relate).

3 “(4) DISTRESSED ZONE.—The term ‘distressed
4 zone’ means a population census tract—

5 “(A) which has been designated as a quali-
6 fied opportunity zone under section 1400Z-1,
7 and

8 “(B) which has a poverty rate in excess of
9 30 percent for the calendar year prior to the
10 calendar year that includes the date of enact-
11 ment of this section.

12 “(c) SPECIAL RULES.—

13 “(1) 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 “(2) 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.

1 “(3) LIMITATION ON WAGES TAKEN INTO AC-
 2 COUNT.—The amount of wages taken into account
 3 under subsection (a) with respect to any employee
 4 shall not exceed an amount equal to the contribution
 5 and benefit base in effect under section 230 of the
 6 Social Security Act for the calendar year in which
 7 the taxable year begins.”.

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

13 “(x) the credit determined under sec-
 14 tion 45U,”.

15 (c) SPECIAL RULE FOR CONTROLLED FOREIGN COR-
 16 PORATIONS.—Section 960(d) of such Code is amended by
 17 adding at the end the following new paragraph:

18 “(4) SPECIAL FOR CONTROLLED FOREIGN COR-
 19 PORATIONS WITH DISTRESSED ZONE PHARMA-
 20 CEUTICAL AND MEDICAL DEVICE EXPENDITURES.—
 21 The amount of foreign taxes deemed paid by a do-
 22 mestic corporation under paragraph (1) (determined
 23 without regard to this paragraph) shall be increased
 24 by an amount equal to the lesser of—

25 “(A) the excess of—

1 “(i) the amount calculated with re-
2 spect to such corporation under paragraph
3 (1) (determined without regard to this
4 paragraph and by substituting ‘100 per-
5 cent’ for ‘80 percent’), over

6 “(ii) the amount calculated with re-
7 spect to such corporation under paragraph
8 (1) (determined without regard to this
9 paragraph), or

10 “(B) an amount equal to 15 percent of the
11 qualified production activity expenditures (as
12 defined in section 45U(b)(1)) of the controlled
13 foreign corporation for the taxable year of the
14 foreign corporation ending in or with the tax-
15 able year of the domestic corporation.”.

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

19 “(i) DISTRESSED ZONE PHARMACEUTICAL AND
20 MEDICAL DEVICE PRODUCTION CREDIT.—No deduction
21 shall be allowed for that portion of the qualified produc-
22 tion activity expenditures (as defined in section 45U(b))
23 otherwise allowable as a deduction for the taxable year
24 which is equal to the amount of the distressed zone phar-

1 maceutical and medical device production credit deter-
 2 mined for such taxable year under section 45U(a).”.

3 (e) PART OF GENERAL BUSINESS CREDIT.—Section
 4 38(b) of such Code is amended by striking “plus” at the
 5 end of paragraph (32), by striking the period at the end
 6 of paragraph (33) and inserting “, plus”, and by adding
 7 at the end the following new paragraph:

8 “(34) the distressed zone pharmaceutical and
 9 medical device production credit determined under
 10 section 45U(a).”.

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

“Sec. 45U. Distressed zone pharmaceutical and medical device production cred-
 it.”.

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

○