(Original Signature of Member)

116TH CONGRESS
2D 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 of 2020'' or the ''MADE in America Act of 2020''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

TITLE I—HEALTH PROVISIONS

SEC. 101. REPORT TO CONGRESS ON BARRIERS TO DOMESTIC MANUFACTURING OF MEDICAL PRODUCTS AND SUPPLIES.

(a) REPORT.—Not later than January 1, 2021, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on barriers to domestic manufacturing of active pharmaceutical ingre-

dients, drugs, and devices that are sourced or manufactured outside of the United States.

(b) CONTENTS.—Such report shall—

(1) identify factors that limit or otherwise discourage the domestic manufacturing of active pharmaceutical ingredients, drugs, and devices that are currently sourced or manufactured outside of the United States, including any Federal, State, local, or Tribal laws and regulations that hinder domestic manufacturing opportunities; and

(2) recommend specific strategies to overcome the challenges identified under paragraph (1), including strategies—

(A) to develop effective incentives for domestic manufacturing; and

(B) to make changes to laws or regulations that hinder domestic manufacturing opportunities.

(c) CONSULTATION.—In carrying out the report under subsection (a), the Secretary shall consult with—

(1) the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Department of Defense, the Department of Commerce, the Department of State, the Department of Vet-

erans Affairs, the Department of Justice, and any other Federal agencies as appropriate; and

(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.

SEC. 102. ENHANCE INTRAAGENCY COORDINATION AND PUBLIC HEALTH ASSESSMENT WITH REGARD TO COMPLIANCE ACTIVITIES.

(a) BENEFIT/RISK FRAMEWORK.—

(1) IN GENERAL.—Paragraph (2) of section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(b)) is amended by adding at the end the following: ''The Secretary shall ensure timely and effective coordination among such offices regarding the reviews of such report and the alignment of any feedback regarding such report, and any corrective or preventive actions in response to such report, after consideration of the benefits and

risks to the public health, patient safety, the drug supply and drug supply chain, and timely patient access to drugs.''.

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

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

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

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

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

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

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

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

SEC. 103. ENCOURAGING INTERNATIONAL HARMONIZATION.

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

(1) the consistency with which the International Conference on Harmonisation (in this section referred to as ''ICH'') guidelines on good manufacturing practices, including ICH Guidelines Q8–11, are being implemented by drug regulatory authorities across countries and international regions;

(2) whether domestic active pharmaceutical ingredient manufacturers (including any such contract manufacturers) are provided sufficient opportunity to participate with regulatory authorities in the development of guidelines prior to implementation;

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

(A) inefficiencies in drug manufacturing;

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

(C) the most common areas of divergence between ICH guidelines and regulatory standards and requirements by drug regulatory authorities across countries and international regions that, if rectified, may reduce the inefficiencies and incompatibilities identified pursuant to subparagraphs (A) and (B).

(b) INTERNATIONAL TRAINING PROGRAM.—Not later than two years after the date of enactment of this Act, informed by the needs identified in the report issued pursuant to subsection (a), the Secretary of Health and Human Services, in conjunction with drug regulatory authorities across countries and international regions and

the ICH, shall develop and implement a training program for drug regulatory authorities across countries and international regions to promote consistent application of and reduce divergence from ICH guidelines on good manufacturing practices.

SEC. 104. MUTUAL RECOGNITION AGREEMENTS FOR INSPECTIONS AND REVIEW ACTIVITIES.

(a) MUTUAL RECOGNITION OF INSPECTIONS.—Pursuant to section 809 of the Federal Food, Drug and Cosmetics Act (21 U.S.C. 384e), the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall establish or expand initiatives for mutual sharing of review and inspection criteria between drug regulatory authorities across countries and international regions, such as through the Pharmaceutical Cooperation Inspection Scheme, the Mutual Recognition Agreement with the European Union, and the Australia-Canada-Singapore-Switzerland Consortium, to—

(1) reduce the potential for duplicative regulatory evaluation of medical products regulated by the Food and Drug Administration; and

(2) more constructively allocate appropriations to the Food and Drug Administration, including those attributable to user fees, to harmonized regulatory processes.

(b) ADDITIONAL COUNTRIES, REGIONS, AND EVALUATION.—In carrying out subsection (a), the Secretary may expand the initiatives to include—

(1) additional countries and geographic regions with established and competent regulatory frameworks; and

(2) additional types of regulatory evaluation, including with respect to—

(A) good manufacturing practice inspections; and

(B) approval of changes to the manufacturing of drugs for which an approval or licensure is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(c) IMPLEMENTATION FRAMEWORK.—

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

(2) CONTENTS.—The implementation framework under this subsection shall—

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

(B) describe additional types of regulatory processes that will become subject to such initiatives;

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

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

(d) ANNUAL REPORTING.—

(1) IN GENERAL.—Not later than the end of calendar year 2020 and annually thereafter, the Secretary shall publish a report on the public website of the Food and Drug Administration on the utilization of agreements described in subsection (c)(1) in the previous fiscal year.

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

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

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

(B) The total number of inspections conducted at establishments described in subparagraph (A).

(C) Of the inspections described in subparagraph (B), the total number of inspections in each of region of interest.

(D) Of the inspections in each region of interest reported pursuant to subparagraph (C), the number of inspections in each FDA inspection category.

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

(i) the number of inspections which have been conducted pursuant to an agreement described in subsection (c)(1); and

(ii) the number of inspections which have been conducted by employees or other agents of the Food and Drugs Administration.

(3) DEFINITIONS.—In this subsection:

(A) The term ''region of interest'' refers to China, India, the European Union, and any

other geographic region as determined appropriate by the Secretary.

(B) The term ''FDA inspection category'' means refers to the following inspection categories:

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

(ii) Good manufacturing practice inspections.

(iii) For-cause inspections.

SEC. 105. ENHANCING TRANSPARENCY OF DRUG FACILITY INSPECTION TIMELINES.

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

''SEC. 902. ANNUAL REPORT ON INSPECTIONS.

''Not later than March 1 of each year, the Secretary of Health and Human Services shall post on the public website of the Food and Drug Administration information related to inspections of facilities necessary for approval of a drug under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), approval of a device under section 515 of such Act

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

''(1) The median time following a request from staff of the Food and Drug Administration reviewing an application or report to the beginning of the inspection, and the median time from the beginning of an inspection to the issuance of a report pursuant to section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(b)), including—

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

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

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

''(2) The median time from the issuance of a report pursuant to such section 704(b) to the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting for inspections for which the Secretary concluded that regulatory or

enforcement action was indicated, including the median time for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).

''(3) The median time from the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting to resolution of the regulatory or enforcement action indicated for inspections for which the Secretary concluded that such action was indicated.

''(4) The number of times that a facility was issued a report pursuant to such section 704(b) and approval of an application was delayed due to the issuance of a withhold recommendation, including the number of such times for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).''.

SEC. 106. ADVANCED MANUFACTURING TECHNOLOGIES PROGRAM.

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

''SEC. 524B. ADVANCED MANUFACTURING TECHNOLOGIES PROGRAM.

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

Excipients in America Act of 2020, the Secretary shall continue in effect the program to evaluate new drug manufacturing technologies that are included in an application, or supplement to an application, for a drug under subsection (b) or (j) of section 505 of this Act or for a biological product submitted under subsection (a) or (k) of section 351 of the Public Health Service Act.

''(b) DESIGNATION.—The Secretary shall designate a method of manufacturing a drug as an advanced manufacturing technology under this section if the drug manufacturer demonstrates that such technology is likely to—

''(1) prevent or resolve a drug shortage;

''(2) maintain an adequate supply of critical medications for national emergencies; or

''(3) promote the adoption of innovative approaches to drug product design and manufacturing.

''(c) CONSULTATION.—If the Secretary designates a method of manufacturing as an advanced manufacturing technology under this section, the Secretary shall take actions to expedite the development and implementation of such method of manufacture for purposes of approval of the application under subsection (c) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act, which may include, as appropriate—

''(1) holding meetings between the sponsor of the application and appropriate Food and Drug Administration staff throughout the development of the technology;

''(2) providing timely advice to, and interactive communication with, the sponsor regarding the development of the technology; and

''(3) involving senior managers and experienced staff of the Food and Drug Administration, as appropriate, in a collaborative, cross-disciplinary review of the method of manufacturing.

''(d) EVALUATION OF AN ADVANCED MANUFACTURING TECHNOLOGY.—

''(1) PACKAGE.—A sponsor who receives designation of an advanced manufacturing technology under this section shall provide the Secretary with a package of scientific evidence supporting the implementation of the advanced manufacturing technology in a particular context-of-use.

''(2) EVALUATION.—Within 90 days of receiving the package, the Secretary shall determine whether a designated advanced manufacturing technology is validated for the proposed context of use based on the scientific merit the supporting evidence provided by the sponsor.

''(3) EFFECT OF APPROVAL.—Upon approval, the same sponsor may rely upon the advanced manufacturing technology for use across multiple manufacturing product lines within the same context-of-use without having to re-submit data to the Secretary validating the underlying technology.

''(e) IMPLEMENTATION AND REPORTING.—

''(1) PUBLIC MEETING.—The Secretary shall publish in the Federal Register a notice of a public meeting to be held no later than 1 year after the date of enactment of the Manufacturing API, Drugs, and Excipients in America Act of 2020 to discuss and obtain input and recommendations from stakeholders regarding the goals and scope of, and a suitable framework and procedures and requirements for, the program under this section.

''(2) PROGRAM GUIDANCE.—The Secretary shall—

''(A) not later than 1 year after the date of enactment of the Manufacturing API, Drugs, and Excipients in America Act of 2020, issue draft guidance regarding the goals and implementation of the program under this section; 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

to 30 percent of the qualified production activity expenditures of the taxpayer for the taxable year.

''(b) 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), or

''(B) amounts paid or incurred for any tangible personal property (whether or not otherwise properly chargeable to capital account) 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).

''(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 pro-

ducing pharmaceuticals, excipients, active pharmaceutical ingredients, medical diagnostic devices, or personal protective equipment.

''(B) 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 (and any successor regulations).

''(C) 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 intended 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.

''(D) 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.

''(E) 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).

''(F) PHARMACEUTICAL.—The term 'pharmaceutical'—

''(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).

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

''(A) IN GENERAL.—For purposes of paragraph (1), 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) DISTRESSED ZONE.—The term 'distressed zone' means a population census tract—

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

''(B) which 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.

''(c) SPECIAL RULES.—

''(1) 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.

''(2) 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.

''(3) LIMITATION ON WAGES TAKEN INTO ACCOUNT.—The amount of wages taken into account under subsection (a) with respect to any employee shall not exceed an amount equal to the contribution and benefit base in effect under section 230 of the Social Security Act for the calendar year in which the taxable year begins.''.

(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 45U,''.

(c) SPECIAL RULE FOR CONTROLLED FOREIGN CORPORATIONS.—Section 960(d) of such Code is amended by adding at the end the following new paragraph:

''(4) SPECIAL FOR CONTROLLED FOREIGN CORPORATIONS WITH DISTRESSED ZONE PHARMACEUTICAL AND MEDICAL DEVICE EXPENDITURES.—The amount of foreign taxes deemed paid by a domestic corporation under paragraph (1) (determined without regard to this paragraph) shall be increased by an amount equal to the lesser of—

''(A) the excess of—

"(i) the amount calculated with respect to such corporation under paragraph (1) (determined without regard to this paragraph and by substituting '100 percent' for '80 percent'), over

"(ii) the amount calculated with respect to such corporation under paragraph (1) (determined without regard to this paragraph), or

"(B) an amount equal to 15 percent of the qualified production activity expenditures (as defined in section 45U(b)(1)) of the controlled foreign corporation for the taxable year of the foreign corporation ending in or with the taxable year of the domestic corporation.".

(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 45U(b)) otherwise allowable as a deduction for the taxable year which is equal to the amount of the distressed zone phar-

maceutical and medical device production credit determined for such taxable year under section 45U(a).''.

(e) PART OF GENERAL BUSINESS CREDIT.—Section 38(b) of such Code 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 by adding at the end the following new paragraph:

''(34) the distressed zone pharmaceutical and medical device production credit determined under section 45U(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. 45U. 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.