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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

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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. 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.

(a) REPORT.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services, the Secretary of the Treasury, the Secretary of Commerce, and the United States Trade Representative (collectively referred to in this section as the ''Secretaries'') shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on barriers to domestic manufacturing of active pharmaceutical ingredients, finished drug

products, and devices that are imported from 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 imported from outside of the United States, including any Federal, State, local, or Tribal laws 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 preparing the report under subsection (a), the Secretaries shall consult with—

(1) the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Department of Defense, the Department of State, the Department of Veterans 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 (or 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 INTRA-AGENCY COORDINATION AND PUBLIC HEALTH ASSESSMENT WITH REGARD TO COMPLIANCE ACTIVITIES.

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

''(g) COORDINATION.—The Secretary shall ensure timely and effective internal coordination and alignment among the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program regarding the reviews of reports shared pur-

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

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

''(2)(A) describes the communication between the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program, including the Food and Drug Administration's procedures for enabling and ensuring such communication;

''(B) provides the number of reports described in section 704(b)(2) that were required to be sent to the appropriate offices of the Food and Drug Administration with expertise regarding drug shortage and the number of such reports that were sent; and

''(C) describes the adoption and utilization of the approach described in section 506D(g);''.

(c) APPLICABILITY.—

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

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

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

SEC. 103. REPORTING OF MUTUAL RECOGNITION AGREEMENTS FOR INSPECTIONS AND REVIEW ACTIVITIES.

(a) IN GENERAL.—Not later than the end of calendar year 2020, and annually thereafter, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall publish a report on the public website of the Food and Drug Administration on the utilization of agreements entered into pursuant to section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e) or otherwise entered into by the Secretary to recognize inspections between drug regulatory authorities across countries and international regions with analogous review criteria to the Food and Drug Administration, such as the Pharmaceutical Inspection Co-Operation Scheme, the Mutual Recognition Agreement with the European Union, and the Australia-Canada-Singapore-Switzerland Consortium, in the previous fiscal year.

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

(1) 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(i)), and of

such establishments, the number in each region of interest.

(2) The total number of inspections conducted as described in subparagraphs (A) and (B) of paragraph (5) at establishments described in paragraph (1).

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

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

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

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

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

(c) DEFINITIONS.—In this subsection:

(1) FDA INSPECTION CATEGORY.—The term ''FDA inspection category'' means the following inspection categories:

(A) Inspections to support approvals of changes to the manufacturing process of drugs approved 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).

(B) Good manufacturing practice surveillance inspections.

(C) For-cause inspections.

(2) REGION OF INTEREST.—The term ''region of interest'' means China, India, the European Union, and any other geographic region as the Secretary determines appropriate.

SEC. 104. 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, including inspections that are 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, including—

''(A) the median time for drugs described in section 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 section 704(b) of such Act (21 U.S.C. 374(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 actions indicated to address the conditions or practices observed during an inspection.

''(4) The number of facilities that were unable to implement requested corrective or preventive actions following a report pursuant to such section 704(b), resulting in a withhold recommendation, including the number of such times for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).''.

SEC. 105. 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, the Secretary shall continue in effect the programs to facilitate the development and

review of an application under subsection (b) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act for a drug or biological product that is manufactured using one of more advanced manufacturing technologies that have been designated in accordance with subsection (b).

''(b) DESIGNATION.—The Secretary shall designate a method of manufacturing or development of a drug or biological product as an advanced manufacturing technology under this section if it incorporates a novel technology or uses an established technique or technology in a novel way that—

''(1) enhances drug quality; or

''(2) improves the flexibility, robustness, or efficiency of the manufacturing process to—

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

''(B) reduce premarket development time; or

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

''(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 an 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, holding meetings between the sponsor of the application and appropriate Food and Drug Administration staff throughout the development of the drug of biological product using such advanced manufacturing technology.

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

''(1) PACKAGE.—A person who seeks designation of an advanced manufacturing technology under this section shall submit to the Secretary a package of scientific evidence supporting the implementation of the advanced manufacturing technology in a particular context-of-use. The Secretary shall assist with the development of such package by—

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

''(B) 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.

''(2) EVALUATION.—Within 90 days of receiving a package under paragraph (1), 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 DESIGNATION.—Upon designation of an advanced manufacturing technology, the holder of the advanced manufacturing technology designation, or a person the advanced manufacturing technology designation holder authorizes, may rely upon the advanced manufacturing technology for use across multiple manufacturing or 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 not later than 1 year after the date of enactment of the Manufacturing API, Drugs, and Excipients in America Act, to discuss and obtain input and recommendations from stakeholders regarding the goals and scope of, and a suit-

able 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, 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, 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 programs 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 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 production 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 amount 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—

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

''(2) 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.

''(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 expenditures 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 45U,''.

(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 45U(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 45U(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 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.

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