118TH CONGRESS
1ST SESSION

S. _____

To rescue domestic medical product manufacturing activity by providing incentives in economically distressed areas of the United States and its possessions.

IN THE SENATE OF THE UNITED STATES

Mr. RUBIO introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To rescue domestic medical product manufacturing activity by providing incentives in economically distressed areas of the United States and its possessions.

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 ''Medical Manufacturing, Economic Development, and Sustainability Act of 2023'' or the ''MMEDS Act of 2023''.

SEC. 2. ECONOMICALLY DISTRESSED ZONES.

(a) IN GENERAL.—Chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subchapter:

"Subchapter AA—Medical Product Manufacturing in Economically Distressed Zones

"SUBCHAPTER AA—MEDICAL PRODUCT MANUFACTURING IN ECONOMICALLY DISTRESSED ZONES

"SEC. 1400AA–1. MEDICAL PRODUCT MANUFACTURING IN ECONOMICALLY DISTRESSED ZONE CREDIT.

"(a) ALLOWANCE OF CREDIT.—There shall be allowed as a credit against the tax imposed by subtitle A for the taxable year an amount equal to 40 percent of the sum of—

"(1) the aggregate amount of the taxpayer's medical product manufacturing economically distressed zone wages for such taxable year,

"(2) the allocable employee fringe benefit expenses of the taxpayer for such taxable year, and

"(3) the depreciation and amortization allowances of the taxpayer for the taxable year with respect to qualified medical product manufacturing facility property.

''(b) DENIAL OF DOUBLE BENEFIT.—Any wages or other expenses taken into account in determining the credit under this section may not be taken into account in determining the credit under sections 41, and any other provision determined by the Secretary to be substantially similar.

''(c) DEFINITIONS AND SPECIAL RULES.—For purposes of this section—

''(1) ECONOMICALLY DISTRESSED ZONE WAGES.—

''(A) IN GENERAL.—The term 'economically distressed zone wages' means amounts paid or incurred for wages during the taxable year which are—

''(i) in connection with the active conduct of a trade or business of the taxpayer, and

''(ii) paid or incurred for an employee the principal place of employment of whom is in a qualified medical product manufacturing facility of such taxpayer.

''(B) LIMITATION ON AMOUNT OF WAGES TAKEN INTO ACCOUNT.—

''(i) IN GENERAL.—The amount of wages which may be taken into account

under subparagraph (A) with respect to any employee for any taxable year shall not exceed the contribution and benefit base determined under section 230 of the Social Security Act for the calendar year in which such taxable year begins.

''(ii) TREATMENT OF PART-TIME EMPLOYEES, ETC.—If—

''(I) any employee is not employed by the taxpayer on a substantially full-time basis at all times during the taxable year, or

''(II) the principal place of employment of any employee is not within an economically distressed zone at all times during the taxable year,

the limitation applicable under clause (i) with respect to such employee shall be the appropriate portion (as determined by the Secretary) of the limitation which would otherwise be in effect under clause (i).

''(C) TREATMENT OF CERTAIN EMPLOYEES.—The term 'economically distressed zone wages' shall not include any wages paid to employees who are assigned by the employer to

perform services for another person, unless the principal trade or business of the employer is to make employees available for temporary periods to other persons in return for compensation.

''(D) WAGES.—For purposes of this paragraph, the term 'wages' shall not include any amounts which are allocable employee fringe benefit expenses.

''(2) ALLOCABLE EMPLOYEE FRINGE BENEFIT EXPENSES.—

''(A) IN GENERAL.—The term 'allocable employee fringe benefit expenses' means the aggregate amount allowable as a deduction under this chapter to the taxpayer for the taxable year for the following amounts which are allocable to employment in a qualified medical product manufacturing facility:

''(i) Employer contributions under a stock bonus, pension, profit-sharing, or annuity plan.

''(ii) Employer-provided coverage under any accident or health plan for employees.

''(iii) The cost of life or disability insurance provided to employees.

''(B) ALLOCATION.—For purposes of subparagraph (A), an amount shall be treated as allocable to a qualified medical product manufacturing facility only if such amount is with respect to employment of an individual for services provided, and the principal place of employment of whom is, in such facility.

''(3) QUALIFIED MEDICAL PRODUCT MANUFACTURING FACILITY.—The term 'qualified medical product manufacturing facility' means any facility that—

''(A) researches and develops or produces medical products or essential components of medical products, and

''(B) is located within an economically distressed zone.

''(4) QUALIFIED MEDICAL PRODUCT MANUFACTURING FACILITY PROPERTY.—The term 'qualified medical product manufacturing facility property' means any property originally used in (or consisting of) a qualified medical product manufacturing facility if such property is directly connected to the research, development, or production of a medical product.

"(5) MEDICAL PRODUCT; ESSENTIAL COMPONENT.—

"(A) MEDICAL PRODUCT.—The term 'medical product' means—

"(i) a drug that—

"(I) is a prescription drug subject to regulation 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) is subject to regulation under section 802 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 382), or

"(III) is described in section 201(jj) of such Act (21 U.S.C. 321(jj)), or

"(ii) a device, as defined in section 201(h) of such Act (21 U.S.C. 321(h)).

"(B) ESSENTIAL COMPONENT.—The term 'essential component' means, with respect to a medical product—

"(i) an active pharmaceutical ingredient, or

"(ii) a protein, antibody, enzyme, hormone, or other organic material that is an active ingredient in a biological product.

"(6) AGGREGATION RULES.—

"(A) IN GENERAL.—For purposes of this section, members of an affiliated group shall be treated as a single taxpayer.

"(B) AFFILIATED GROUP.—The term 'affiliated group' means an affiliated group (as defined in section 1504(a), determined without regard to section 1504(b)(3)) one or more members of which are engaged in the active conduct of a trade or business within an economically distressed zone.

"SEC. 1400AA–2. CREDIT FOR ECONOMICALLY DISTRESSED ZONE PRODUCTS AND SERVICES ACQUIRED BY DOMESTIC MEDICAL PRODUCT MANUFACTURERS.

"(a) ALLOWANCE OF CREDIT.—In the case of an eligible medical product manufacturer, there shall be allowed as a credit against the tax imposed by subtitle A for the taxable year an amount equal to the applicable percentage of the aggregate amounts paid or incurred by the taxpayer during such taxable year for qualified products or services.

''(b) APPLICABLE PERCENTAGE.—For purposes of this section, the term applicable percentage means—

''(1) 30 percent in the case of amounts paid or incurred to persons not described in paragraph (2) or (3), and

''(2) 5 percent in the case of amounts paid or incurred to a related person.

''(c) ELIGIBLE MEDICAL PRODUCT MANUFACTURER.—For purposes of this section, the term 'eligible medical product manufacturer' means any person in the trade or business of producing medical products in the United States.

''(d) QUALIFIED PRODUCT OR SERVICE.—For purposes of this section, the term 'qualified product or service' means—

''(1) any product which is produced in an economically distressed zone and which is integrated into a medical product produced by the taxpayer, and

''(2) any service which is provided in an economically distressed zone and which is necessary to the production of a medical product by the taxpayer (including packaging).

''(e) RELATED PERSONS.—For purposes of this section, persons shall be treated as related to each other if

such persons would be treated as a single employer under the regulations prescribed under section 52(b).

''(f) OTHER TERMS.—Terms used in this section which are also used in section 1400AA–1 shall have the same meaning as when used in such section.

''SEC. 1400AA–3. SPECIAL RULES TO SECURE THE NATIONAL SUPPLY CHAIN.

''(a) IN GENERAL.—In the case of a qualified repatriated pharmaceutical manufacturing facility, section 1400AA–1(a) shall be applied by substituting '60 percent' for '40 percent'.

''(b) ELECTION TO EXPENSE IN LIEU OF TAX CREDIT FOR DEPRECIATION.—In the case of a taxpayer which elects (at such time and in such manner as the Secretary may provide) the application of this subsection with respect to any qualified repatriated medical product manufacturing facility or qualified population health product manufacturing facility—

''(1) section 1400AA–1(a)(3) shall not apply with respect to any qualified medical product manufacturing facility property with respect to such facility, and

''(2) for purposes of section 168(k)—

''(A) such property shall be treated as qualified property, and

''(B) the applicable percentage with respect to such property shall be 100 percent.

''(c) QUALIFIED REPATRIATED MEDICAL PRODUCT MANUFACTURING FACILITY.—For purposes of this section, the term 'qualified repatriated medical product manufacturing facility' means any qualified medical product manufacturing facility (as defined in section 1400AA–1) the production of which was moved to an economically distressed zone from a foreign country that the United States Trade Representative has determined could pose a risk to the national supply chain because of political or social factors.

''SEC. 1400AA–4. DESIGNATION OF ECONOMICALLY DISTRESSED ZONES.

''(a) IN GENERAL.—For purposes of this subchapter, the term 'economically distressed zone' means any population census tract within the United States which—

''(1) has a poverty rate of not less than 35 percent for each of the 5 most recent calendar years for which information is available, or

''(2) satisfies each of the following requirements:

''(A) The census tract has pervasive poverty, unemployment, low labor force participation, and general distress measured as a pro-

longed period of economic decline measured by real gross national product.

''(B) The census tract has a poverty rate of not less than 30 percent for each of the 5 most recent calendar years for which information is available.

''(C) The census tract has been designated as such by the Secretary and the Secretary of Commerce pursuant to an application under subsection (b).

''(b) APPLICATION FOR DESIGNATION.—

''(1) IN GENERAL.—An application for designation as an economically distressed zone may be filed by a State or local government in which the population census tract to which the application applies is located.

''(2) REQUIREMENTS.—Such application shall include a strategic plan for accomplishing the purposes of this subchapter, which—

''(A) describes the coordinated economic, human, community, and physical development plan and related activities proposed for the nominated area,

''(B) describes the process by which the affected community is a full partner in the proc-

ess of developing and implementing the plan and the extent to which local institutions and organizations have contributed to the planning process,

''(C) identifies the amount of State, local, and private resources that will be available in the nominated area and the private/public partnerships to be used, which may include participation by, and cooperation with, universities, medical centers, and other private and public entities,

''(D) identifies the funding requested under any Federal program in support of the proposed economic, human, community, and physical development and related activities,

''(E) identifies baselines, methods, and benchmarks for measuring the success of carrying out the strategic plan, including the extent to which poor persons and families will be empowered to become economically self-sufficient, and

''(F) does not include any action to assist any establishment in relocating from one area outside the nominated area to the nominated area, except that assistance for the expansion of

an existing business entity through the establishment of a new branch, affiliate, or subsidiary is permitted if—

"(i) the establishment of the new branch, affiliate, or subsidiary will not result in a decrease in employment in the area of original location or in any other area where the existing business entity conducts business operations,

"(ii) there is no reason to believe that the new branch, affiliate, or subsidiary is being established with the intention of closing down the operations of the existing business entity in the area of its original location or in any other area where the existing business entity conducts business operation, and

"(iii) includes such other information as may be required by the Secretary and the Secretary of Commerce.

"(c) PERIOD FOR WHICH DESIGNATIONS ARE IN EFFECT.—Designation as an economically distressed zone may be made at any time during the 10-year period beginning on the date of the enactment of this section, and shall remain in effect with respect to such zone during the 15-

year period beginning on the date of such designation. Economically distressed zones described in subsection (a)(1) shall take effect on the date of the enactment of this Act and shall remain in effect during the 15-year period beginning on such date.

''(d) TERRITORIES AND POSSESSIONS.—The term 'United States' includes the 50 States, the District of Columbia, and the territories and possessions of the United States.

''(e) REGULATIONS.—The Secretary shall issue such regulations or other guidance as may be necessary or appropriate to carry out the purposes of this section, including—

''(1) not later than 30 days after the date of the enactment of this section, a list of the population census tracts described in subsection (a)(1), and

''(2) not later than 60 days after the date of the enactment of this section, regulations or other guidance regarding the designation of population census tracts described in subsection (a)(2).''.

(b) CLERICAL AMENDMENT.—The table of subchapters for chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

''SUBCHAPTER AA—MEDICAL PRODUCT MANUFACTURING IN ECONOMICALLY DISTRESSED ZONES''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2022.

SEC. 3. REPORT ON NEED FOR INCENTIVIZING DEVELOPMENT OF THERAPIES.

Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall examine and report to the Congress on—

(1) the extent to which the health of aging individuals in the United States, African Americans, Hispanics, Native Americans, veterans, or other vulnerable populations in the United States has been disproportionately harmed by the COVID–19 pandemic and prior epidemics and pandemics;

(2) the therapies currently available, and whether there is a need for additional innovation and development to produce therapies, to reduce the exposure of vulnerable populations in the United States to risk of disproportionate harm in epidemics and pandemics; and

(3) whether the Secretary recommends providing the same incentives for the development and marketing of therapies described in paragraph (2) as is provided under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) with respect to

qualified infectious disease products designated under section 505E(d) of such Act (21 U.S.C. 355f(d)).