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H. R. 1840

To amend the Internal Revenue Code of 1986 to allow a credit against tax for clinical testing expenses for qualified infectious disease drugs and rapid diagnostic tests.

IN THE HOUSE OF REPRESENTATIVES

MARCH 30, 2017

Mr. PAULSEN (for himself, Mr. THOMPSON of California, Mr. GENE GREEN of Texas, Mr. WALZ, Mr. RUSH, and Mr. SHIMKUS) introduced the following bill; which was referred to the Committee on Ways and Means

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A BILL

To amend the Internal Revenue Code of 1986 to allow a credit against tax for clinical testing expenses for qualified infectious disease drugs and rapid diagnostic tests.

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 ''Reinvigorating Antibiotic and Diagnostic Innovation Act of 2017''.

SEC. 2. CLINICAL TESTING EXPENSES FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.

(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. 45S. CLINICAL TESTING EXPENSES FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.

"(a) GENERAL RULE.—For purposes of section 38, the qualified infectious disease product credit determined under this section for the taxable year is an amount equal to 50 percent of the qualified clinical testing expenses for the taxable year.

"(b) QUALIFIED CLINICAL TESTING EXPENSES.—For purposes of this section—

"(1) QUALIFIED CLINICAL TESTING EXPENSES.—

"(A) IN GENERAL.—Except as otherwise provided in this paragraph, the term 'qualified clinical testing expenses' means the amounts which are paid or incurred by the taxpayer during the taxable year which would be described in subsection (b) of section 41 if such subsection were applied with the modifications set forth in subparagraph (B).

"(B) MODIFICATIONS.—For purposes of subparagraph (A), subsection (b) of section 41 shall be applied—

"(i) by substituting 'clinical testing' for 'qualified research' each place it appears in paragraphs (2) and (3) of such subsection, and

"(ii) by substituting '100 percent' for '65 percent' in paragraph (3)(A) of such subsection.

"(C) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The term 'qualified clinical testing expenses' shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise by another person (or any governmental entity).

"(D) SPECIAL RULE.—For purposes of this paragraph, section 41 shall be deemed to remain in effect for periods after enactment of this section.

"(2) CLINICAL TESTING.—

"(A) IN GENERAL.—The term 'clinical testing' means any human clinical testing—

"(i) which is carried out under an exemption for a drug being tested as an antibiotic or antifungal drug under section 505(i) of the Federal Food, Drug, and

Cosmetic Act (or regulations issued under such section),

"(ii) which occurs before the date on which an application with respect to such drug is approved under section 505(b) of such Act or, if the drug is a biological product, before the date on which a license for such drug is issued under section 351 of the Public Health Service Act, and

"(iii) which is conducted by or on behalf of the taxpayer to whom exemption under section 505(i) of such Act is granted.

"(B) TESTING MUST BE RELATED TO USE AS QUALIFIED INFECTIOUS DISEASE PRODUCT.—Human clinical testing shall be taken into account under subparagraph (A) only to the extent such testing is related to the use of the drug as a qualified infectious disease product.

"(c) COORDINATION WITH CREDIT FOR INCREASING RESEARCH EXPENDITURES.—

"(1) IN GENERAL.—Except as provided in paragraph (2), any qualified clinical testing expenses for a taxable year to which an election under this sec-

tion applies shall not be taken into account for purposes of determining the credit allowable under section 41 for such taxable year.

''(2) EXPENSES INCLUDED IN DETERMINING BASE PERIOD RESEARCH EXPENSES.—Any qualified clinical testing expenses for any taxable year which are qualified research expenses (within the meaning of section 41(b)) shall be taken into account in determining base period research expenses for purposes of applying section 41 to subsequent taxable years.

''(d) DEFINITIONS AND SPECIAL RULES.—

''(1) QUALIFIED INFECTIOUS DISEASE PRODUCT.—For purposes of this section, the term 'qualified infectious disease product' means any drug or biological product for human use that—

''(A) is intended to treat a serious or life-threatening infection, including those caused by—

''(i) an antibacterial or antifungal resistant pathogen (including novel or emerging infectious pathogens), or

''(ii) qualifying pathogens listed by the Secretary of Health and Human Services under section 505E(f) of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), and

"(B) is intended to treat an infection for which there is an unmet medical need as defined by the Secretary of Health and Human Services.

"(2) SPECIAL LIMITATION ON FOREIGN TESTING.—

"(A) IN GENERAL.—No credit shall be allowed under this section with respect to any clinical testing conducted outside the United States unless—

"(i) such testing is conducted outside the United States because there is an insufficient testing population in the United States, and

"(ii) such testing is conducted by a United States person or by any other person who is not related to the taxpayer to whom exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act is granted.

"(B) INSUFFICIENT TESTING POPULATION.—For purposes of this section, the testing population in the United States is insuffi-

cient if there are not within the United States the number of available and appropriate human subjects needed to produce reliable and timely data from the clinical investigation.

''(3) CERTAIN RULES MADE APPLICABLE.—Rules similar to the rules of paragraphs (1) and (2) of section 41(f) shall apply for purposes of this section.

''(4) ELECTION.—This section shall apply to any taxpayer for any taxable year only if such taxpayer elects (at such time and in such manner as the Secretary may by regulations prescribe) to have this section apply for such taxable year.

''(e) TRANSFERABILITY.—

''(1) IN GENERAL.—Any taxpayer holding a credit under this section may transfer for valuable consideration unused but otherwise allowable credit for use by a qualified pharmaceutical research taxpayer. A taxpayer that transfers any amount of credit under this section shall file a notification of such transfer to the Secretary in accordance with procedures and forms prescribed by the Secretary.

''(2) USE OF TRANSFERRED CREDIT.—Any qualified pharmaceutical research taxpayer that receives credit that has been transferred shall use such

credit for the taxable year in which the transfer occurred. Any unused amounts of such credit may be carried back or forward to other taxable years in accordance with section 39.

''(3) DEFINITION OF QUALIFIED PHARMACEUTICAL RESEARCH TAXPAYER.—For purposes of this section, the term 'qualified pharmaceutical research taxpayer' means any domestic corporation the primary mission of which is pharmaceutical research or development.''.

(b) MADE PART OF BUSINESS CREDIT.—Section 38(b) of such Code is amended by striking ''plus'' at the end of paragraph (35), by striking the period at the end of paragraph (36) and inserting '', plus'', and by adding at the end the following new paragraph:

''(37) the qualified infectious disease product credit determined under section 45S(a).''.

(c) CLERICAL AMENDMENTS.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of such Code is amended by adding at the end the following new item:

''Sec. 45S. Clinical testing expenses for qualified infectious disease products.''.

(d) EFFECTIVE DATE.—The amendment made by this section shall apply to amounts paid or incurred after the date of the enactment of this Act.

SEC. 3. CLINICAL TESTING EXPENSES FOR RAPID INFECTIOUS DISEASES DIAGNOSTIC TESTS.

(a) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986, as amended by section 2, is amended by adding at the end the following new section:

"SEC. 45T. CLINICAL TESTING EXPENSES FOR RAPID INFECTIOUS DISEASES DIAGNOSTIC TESTS.

''(a) GENERAL RULE.—For purposes of section 38, the credit determined under this section for the taxable year is an amount equal to 50 percent of the qualified clinical testing expenses for the taxable year.

''(b) QUALIFIED CLINICAL TESTING EXPENSES.—For purposes of this section—

''(1) QUALIFIED CLINICAL TESTING EXPENSES.—

''(A) IN GENERAL.—Except as otherwise provided in this paragraph, the term 'qualified clinical testing expenses' means the amounts which are paid or incurred by the taxpayer during the taxable year which would be described in subsection (b) of section 41 if such subsection were applied with the modifications set forth in subparagraph (B).

''(B) MODIFICATIONS.—For purposes of subparagraph (A), subsection (b) of section 41 shall be applied—

''(i) by substituting 'clinical testing' for 'qualified research' each place it appears in paragraphs (2) and (3) of such subsection, and

''(ii) by substituting '100 percent' for '65 percent' in paragraph (3)(A) of such subsection.

''(C) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The term 'qualified clinical testing expenses' shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise by another person (or any governmental entity).

''(D) SPECIAL RULE.—For purposes of this paragraph, section 41 shall be deemed to remain in effect for periods after enactment of this section.

''(2) CLINICAL TESTING.—

''(A) IN GENERAL.—The term 'clinical testing' means any human clinical testing—

''(i) which is carried out under an exemption for a device being tested under

section 520(g) of the Federal Food, Drug, and Cosmetic Act (or regulations issued under such section),

"(ii) which is related only to such use as a qualified rapid infectious diseases diagnostic test,

"(iii) which occurs before the date on which an application with respect to such device receives premarket approval, if required, under section 515 of such Act, or receives clearance, if required, under section 510(k) of such Act, and

"(iv) which is conducted by or on behalf of the taxpayer to whom the exemption under section 520(g) of such Act was granted.

"(c) COORDINATION WITH CREDIT FOR INCREASING RESEARCH EXPENDITURES.—

"(1) IN GENERAL.—Except as provided in paragraph (2), any qualified clinical testing expenses for a taxable year to which an election under this section applies shall not be taken into account for purposes of determining the credit allowable under section 41 for such taxable year.

''(2) EXPENSES INCLUDED IN DETERMINING BASE PERIOD RESEARCH EXPENSES.—Any qualified clinical testing expenses for any taxable year which are qualified research expenses (within the meaning of section 41(b)) shall be taken into account in determining base period research expenses for purposes of applying section 41 to subsequent taxable years.

''(d) DEFINITIONS AND SPECIAL RULES.—

''(1) QUALIFIED RAPID INFECTIOUS DISEASES DIAGNOSTIC TEST.—For purposes of this section, the term 'qualified rapid infectious diseases diagnostic test' means an in-vitro diagnostic (IVD) device that provides results in less than four hours and that is used to identify or detect the presence, concentration, or characteristics of a serious or life-threatening infection, including those caused by (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or (2) qualifying pathogens listed by the Secretary of Health and Human Services under Chapter V (21 U.S.C. 351 et seq.) section 505E(f).

''(2) SPECIAL LIMITATION ON FOREIGN TESTING.—

"(A) IN GENERAL.—No credit shall be allowed under this section with respect to any clinical testing conducted outside the United States unless—

"(i) such testing is conducted outside the United States because there is an insufficient testing population in the United States, and

"(ii) such testing is conducted by a United States person or by any other person who is not related to the taxpayer to whom the exemption under section 520(g) of Federal Food, Drug, and Cosmetic Act was granted.

"(B) INSUFFICIENT TESTING POPULATION.—For purposes of this section, the testing population in the United States is insufficient if there are not within the United States the number of available and appropriate human subjects needed to produce reliable and timely data from the clinical investigation.

"(3) CERTAIN RULES MADE APPLICABLE.—Rules similar to the rules of paragraphs (1) and (2) of section 41(f) shall apply for purposes of this section.

''(4) ELECTION.—This section shall apply to any taxpayer for any taxable year only if such taxpayer elects (at such time and in such manner as the Secretary may by regulations prescribe) to have this section apply for such taxable year.

''(e) TRANSFERABILITY.—

''(1) IN GENERAL.—Any taxpayer holding a credit under this section may transfer for valuable consideration unused but otherwise allowable credit for use by a qualified diagnostics research taxpayer. A taxpayer that transfers any amount of credit under this section shall file a notification of such transfer to the Secretary in accordance with procedures and forms prescribed by the Secretary.

''(2) USE OF TRANSFERRED CREDIT.—Any qualified diagnostics research taxpayer that receives credit that has been transferred shall use such credit for the taxable year in which the transfer occurred. Any unused amounts of such credit may be carried back or forward to other taxable years in accordance with section 39.

''(3) DEFINITION OF QUALIFIED DIAGNOSTICS RESEARCH TAXPAYER.—For purposes of this section, the term 'qualified diagnostics research tax-

payer' means any domestic corporation that derives—

"(A) any gross income from research or development on diagnostic tests used to identify or detect the presence, concentration or characteristics of a serious or life-threatening infectious disease or pathogen; or

"(B) any gross income from research or development on qualified infectious disease products within the meaning given to such term in section 505E(g) of the Federal, Food, Drug, and Cosmetic Act; or

"(C) more than 50 percent of its gross income from activities related to health care.".

(b) MADE PART OF BUSINESS CREDIT.—Section 38(b) of such Code, as amended by section 2, is amended by striking "plus" at the end of paragraph (36), by striking the period at the end of paragraph (37) and inserting ", plus", and by adding at the end the following new paragraph:

"(38) the credit determined under section 45T(a).".

(c) CLERICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1

of such Code, as amended by section 2, is amended by adding at the end the following new item:

"Sec. 45T. Clinical testing expenses for rapid infectious diseases diagnostic tests.".

(d) EFFECTIVE DATE.—The amendment made by this section shall apply to amounts paid or incurred after the date of the enactment of this Act.

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