

114TH CONGRESS
1ST SESSION

H. R. 3539

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

SEPTEMBER 17, 2015

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Reinvigorating Anti-
5 biotic and Diagnostic Innovation Act of 2015”.

6 **SEC. 2. CLINICAL TESTING EXPENSES FOR QUALIFIED IN-**
7 **FECTIONOUS DISEASE PRODUCTS.**

8 (a) IN GENERAL.—Subpart D of part IV of sub-
9 chapter A of chapter 1 of the Internal Revenue Code of

1 1986 is amended by adding at the end the following new
2 section:

3 **“SEC. 45S. CLINICAL TESTING EXPENSES FOR QUALIFIED**
4 **INFECTIOUS DISEASE PRODUCTS.**

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

10 “(b) QUALIFIED CLINICAL TESTING EXPENSES.—
11 For purposes of this section—

12 “(1) QUALIFIED CLINICAL TESTING EX-
13 PENSES.—

14 “(A) IN GENERAL.—Except as otherwise
15 provided in this paragraph, the term ‘qualified
16 clinical testing expenses’ means the amounts
17 which are paid or incurred by the taxpayer dur-
18 ing the taxable year which would be described
19 in subsection (b) of section 41 if such sub-
20 section were applied with the modifications set
21 forth in subparagraph (B).

22 “(B) MODIFICATIONS.—For purposes of
23 subparagraph (A), subsection (b) of section 41
24 shall be applied—

1 “(i) by substituting ‘clinical testing’
2 for ‘qualified research’ each place it ap-
3 pears in paragraphs (2) and (3) of such
4 subsection, and

5 “(ii) by substituting ‘100 percent’ for
6 ‘65 percent’ in paragraph (3)(A) of such
7 subsection.

8 “(C) EXCLUSION FOR AMOUNTS FUNDED
9 BY GRANTS, ETC.—The term ‘qualified clinical
10 testing expenses’ shall not include any amount
11 to the extent such amount is funded by any
12 grant, contract, or otherwise by another person
13 (or any governmental entity).

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

18 “(2) CLINICAL TESTING.—

19 “(A) IN GENERAL.—The term ‘clinical
20 testing’ means any human clinical testing—

21 “(i) which is carried out under an ex-
22 emption for a drug being tested as an anti-
23 biotic or antifungal drug under section
24 505(i) of the Federal Food, Drug, and

1 Cosmetic Act (or regulations issued under
2 such section),

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

10 “(iii) which is conducted by or on be-
11 half of the taxpayer to whom exemption
12 under section 505(i) of such Act is grant-
13 ed.

14 “(B) TESTING MUST BE RELATED TO USE
15 AS QUALIFIED INFECTIOUS DISEASE PROD-
16 UCT.—Human clinical testing shall be taken
17 into account under subparagraph (A) only to
18 the extent such testing is related to the use of
19 the drug as a qualified infectious disease prod-
20 uct.

21 “(c) COORDINATION WITH CREDIT FOR INCREASING
22 RESEARCH EXPENDITURES.—

23 “(1) IN GENERAL.—Except as provided in para-
24 graph (2), any qualified clinical testing expenses for
25 a taxable year to which an election under this sec-

1 tion applies shall not be taken into account for pur-
2 poses of determining the credit allowable under sec-
3 tion 41 for such taxable year.

4 “(2) EXPENSES INCLUDED IN DETERMINING
5 BASE PERIOD RESEARCH EXPENSES.—Any qualified
6 clinical testing expenses for any taxable year which
7 are qualified research expenses (within the meaning
8 of section 41(b)) shall be taken into account in de-
9 termining base period research expenses for pur-
10 poses of applying section 41 to subsequent taxable
11 years.

12 “(d) DEFINITIONS AND SPECIAL RULES.—

13 “(1) QUALIFIED INFECTIOUS DISEASE PROD-
14 UCT.—For purposes of this section, the term ‘quali-
15 fied infectious disease product’ means any drug or
16 biological product for human use that—

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

20 “(i) an antibacterial or antifungal re-
21 sistant pathogen (including novel or emerg-
22 ing infectious pathogens), or

23 “(ii) qualifying pathogens listed by
24 the Secretary of Health and Human Serv-
25 ices under section 505E(f) of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C.
2 351 et seq.), and

3 “(B) is intended to treat an infection for
4 which there is an unmet medical need as de-
5 fined by the Secretary of Health and Human
6 Services.

7 “(2) SPECIAL LIMITATION ON FOREIGN TEST-
8 ING.—

9 “(A) IN GENERAL.—No credit shall be al-
10 lowed under this section with respect to any
11 clinical testing conducted outside the United
12 States unless—

13 “(i) such testing is conducted outside
14 the United States because there is an in-
15 sufficient testing population in the United
16 States, and

17 “(ii) such testing is conducted by a
18 United States person or by any other per-
19 son who is not related to the taxpayer to
20 whom exemption under section 505(i) of
21 the Federal Food, Drug, and Cosmetic Act
22 is granted.

23 “(B) INSUFFICIENT TESTING POPU-
24 LATION.—For purposes of this section, the test-
25 ing population in the United States is insuffi-

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

5 “(3) CERTAIN RULES MADE APPLICABLE.—
6 Rules similar to the rules of paragraphs (1) and (2)
7 of section 41(f) shall apply for purposes of this sec-
8 tion.

9 “(4) ELECTION.—This section shall apply to
10 any taxpayer for any taxable year only if such tax-
11 payer elects (at such time and in such manner as
12 the Secretary may by regulations prescribe) to have
13 this section apply for such taxable year.

14 “(e) TRANSFERABILITY.—

15 “(1) IN GENERAL.—Any taxpayer holding a
16 credit under this section may transfer for valuable
17 consideration unused but otherwise allowable credit
18 for use by a qualified pharmaceutical research tax-
19 payer. A taxpayer that transfers any amount of
20 credit under this section shall file a notification of
21 such transfer to the Secretary in accordance with
22 procedures and forms prescribed by the Secretary.

23 “(2) USE OF TRANSFERRED CREDIT.—Any
24 qualified pharmaceutical research taxpayer that re-
25 ceives credit that has been transferred shall use such

1 credit for the taxable year in which the transfer oc-
2 curred. Any unused amounts of such credit may be
3 carried back or forward to other taxable years in ac-
4 cordance with section 39.

5 “(3) DEFINITION OF QUALIFIED PHARMA-
6 CEUTICAL RESEARCH TAXPAYER.—For purposes of
7 this section, the term ‘qualified pharmaceutical re-
8 search taxpayer’ means any domestic corporation the
9 primary mission of which is pharmaceutical research
10 or development.”.

11 (b) MADE PART OF BUSINESS CREDIT.—Section
12 38(b) of such Code is amended by striking “plus” at the
13 end of paragraph (35), by striking the period at the end
14 of paragraph (36) and inserting “, plus”, and by adding
15 at the end the following new paragraph:

16 “(37) the qualified infectious disease product
17 credit determined under section 45S(a).”.

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

“45S. Clinical testing expenses for qualified infectious disease products.”.

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

1 **SEC. 3. CLINICAL TESTING EXPENSES FOR RAPID INFEC-**
2 **TIOUS DISEASES DIAGNOSTIC TESTS.**

3 (a) IN GENERAL.—Subpart D of part IV of sub-
4 chapter A of chapter 1 of the Internal Revenue Code of
5 1986, as amended by section 2, is amended by adding at
6 the end the following new section:

7 **“SEC. 45T. CLINICAL TESTING EXPENSES FOR RAPID IN-**
8 **FECTIONOUS DISEASES DIAGNOSTIC TESTS.**

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

13 “(b) QUALIFIED CLINICAL TESTING EXPENSES.—
14 For purposes of this section—

15 “(1) QUALIFIED CLINICAL TESTING EX-
16 PENSES.—

17 “(A) IN GENERAL.—Except as otherwise
18 provided in this paragraph, the term ‘qualified
19 clinical testing expenses’ means the amounts
20 which are paid or incurred by the taxpayer dur-
21 ing the taxable year which would be described
22 in subsection (b) of section 41 if such sub-
23 section were applied with the modifications set
24 forth in subparagraph (B).

1 “(B) MODIFICATIONS.—For purposes of
2 subparagraph (A), subsection (b) of section 41
3 shall be applied—

4 “(i) by substituting ‘clinical testing’
5 for ‘qualified research’ each place it ap-
6 pears in paragraphs (2) and (3) of such
7 subsection, and

8 “(ii) by substituting ‘100 percent’ for
9 ‘65 percent’ in paragraph (3)(A) of such
10 subsection.

11 “(C) EXCLUSION FOR AMOUNTS FUNDED
12 BY GRANTS, ETC.—The term ‘qualified clinical
13 testing expenses’ shall not include any amount
14 to the extent such amount is funded by any
15 grant, contract, or otherwise by another person
16 (or any governmental entity).

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

21 “(2) CLINICAL TESTING.—

22 “(A) IN GENERAL.—The term ‘clinical
23 testing’ means any human clinical testing—

24 “(i) which is carried out under an ex-
25 emption for a device being tested under

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

4 “(ii) which is related only to such use
5 as a qualified rapid infectious diseases di-
6 agnostic test,

7 “(iii) which occurs before the date on
8 which an application with respect to such
9 device receives premarket approval, if re-
10 quired, under section 515 of such Act, or
11 receives clearance, if required, under sec-
12 tion 510(k) of such Act, and

13 “(iv) which is conducted by or on be-
14 half of the taxpayer to whom the exemp-
15 tion under section 520(g) of such Act was
16 granted.

17 “(c) COORDINATION WITH CREDIT FOR INCREASING
18 RESEARCH EXPENDITURES.—

19 “(1) IN GENERAL.—Except as provided in para-
20 graph (2), any qualified clinical testing expenses for
21 a taxable year to which an election under this sec-
22 tion applies shall not be taken into account for pur-
23 poses of determining the credit allowable under sec-
24 tion 41 for such taxable year.

1 “(2) EXPENSES INCLUDED IN DETERMINING
2 BASE PERIOD RESEARCH EXPENSES.—Any qualified
3 clinical testing expenses for any taxable year which
4 are qualified research expenses (within the meaning
5 of section 41(b)) shall be taken into account in de-
6 termining base period research expenses for pur-
7 poses of applying section 41 to subsequent taxable
8 years.

9 “(d) DEFINITIONS AND SPECIAL RULES.—

10 “(1) QUALIFIED RAPID INFECTIOUS DISEASES
11 DIAGNOSTIC TEST.—For purposes of this section,
12 the term ‘qualified rapid infectious diseases diag-
13 nostic test’ means an in-vitro diagnostic (IVD) de-
14 vice that provides results in less than four hours and
15 that is used to identify or detect the presence, con-
16 centration, or characteristics of a serious or life-
17 threatening infection, including those caused by (1)
18 an antibacterial or antifungal resistant pathogen, in-
19 cluding novel or emerging infectious pathogens or
20 (2) qualifying pathogens listed by the Secretary of
21 Health and Human Services under Chapter V (21
22 U.S.C. 351 et seq.) section 505E(f).

23 “(2) SPECIAL LIMITATION ON FOREIGN TEST-
24 ING.—

1 “(A) IN GENERAL.—No credit shall be al-
2 lowed under this section with respect to any
3 clinical testing conducted outside the United
4 States unless—

5 “(i) such testing is conducted outside
6 the United States because there is an in-
7 sufficient testing population in the United
8 States, and

9 “(ii) such testing is conducted by a
10 United States person or by any other per-
11 son who is not related to the taxpayer to
12 whom the exemption under section 520(g)
13 of Federal Food, Drug, and Cosmetic Act
14 was granted.

15 “(B) INSUFFICIENT TESTING POPU-
16 LATION.—For purposes of this section, the test-
17 ing population in the United States is insuffi-
18 cient if there are not within the United States
19 the number of available and appropriate human
20 subjects needed to produce reliable and timely
21 data from the clinical investigation.

22 “(3) CERTAIN RULES MADE APPLICABLE.—
23 Rules similar to the rules of paragraphs (1) and (2)
24 of section 41(f) shall apply for purposes of this sec-
25 tion.

1 “(4) ELECTION.—This section shall apply to
2 any taxpayer for any taxable year only if such tax-
3 payer elects (at such time and in such manner as
4 the Secretary may by regulations prescribe) to have
5 this section apply for such taxable year.

6 “(e) TRANSFERABILITY.—

7 “(1) IN GENERAL.—Any taxpayer holding a
8 credit under this section may transfer for valuable
9 consideration unused but otherwise allowable credit
10 for use by a qualified diagnostics research taxpayer.
11 A taxpayer that transfers any amount of credit
12 under this section shall file a notification of such
13 transfer to the Secretary in accordance with proce-
14 dures and forms prescribed by the Secretary.

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

22 “(3) DEFINITION OF QUALIFIED DIAGNOSTICS
23 RESEARCH TAXPAYER.—For purposes of this sec-
24 tion, the term ‘qualified diagnostics research tax-

1 payer’ means any domestic corporation that de-
2 rives—

3 “(A) any gross income from research or
4 development on diagnostic tests used to identify
5 or detect the presence, concentration or charac-
6 teristics of a serious or life-threatening infec-
7 tious disease or pathogen; or

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

13 “(C) more than 50 percent of its gross in-
14 come from activities related to health care.”.

15 (b) MADE PART OF BUSINESS CREDIT.—Section
16 38(b) of such Code, as amended by section 2, is amended
17 by striking “plus” at the end of paragraph (36), by strik-
18 ing the period at the end of paragraph (37) and inserting
19 “, plus”, and by adding at the end the following new para-
20 graph:

21 “(38) the credit determined under section
22 45T(a).”.

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

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

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

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

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