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(Original Signature of Member)

115TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

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.

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IN THE HOUSE OF REPRESENTATIVES

Mr. PAULSEN introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**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 2017”.

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

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 is amended by adding at the end the following new  
6 section:

7   **“SEC. 45S. CLINICAL TESTING EXPENSES FOR QUALIFIED**  
8                   **INFECTIOUS DISEASE PRODUCTS.**

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

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

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

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

1 biotic or antifungal drug under section  
2 505(i) of the Federal Food, Drug, and  
3 Cosmetic Act (or regulations issued under  
4 such section),

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

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

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

23 “(c) COORDINATION WITH CREDIT FOR INCREASING  
24 RESEARCH EXPENDITURES.—

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

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

15      “(d) DEFINITIONS AND SPECIAL RULES.—

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

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

23           “(i) an antibacterial or antifungal re-  
24      sistant pathogen (including novel or emerg-  
25      ing infectious pathogens), or

1 “(ii) qualifying pathogens listed by  
2 the Secretary of Health and Human Serv-  
3 ices under section 505E(f) of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C.  
5 351 et seq.), and

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

10 “(2) SPECIAL LIMITATION ON FOREIGN TEST-  
11 ING.—

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

16 “(i) such testing is conducted outside  
17 the United States because there is an in-  
18 sufficient testing population in the United  
19 States, and

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

1                   “(B) INSUFFICIENT TESTING POPU-  
2                   LATION.—For purposes of this section, the test-  
3                   ing population in the United States is insuffi-  
4                   cient if there are not within the United States  
5                   the number of available and appropriate human  
6                   subjects needed to produce reliable and timely  
7                   data from the clinical investigation.

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

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

17                  “(e) TRANSFERABILITY.—

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

1           “(2) USE OF TRANSFERRED CREDIT.—Any  
2           qualified pharmaceutical research taxpayer that re-  
3           ceives credit that has been transferred shall use such  
4           credit for the taxable year in which the transfer oc-  
5           curred. Any unused amounts of such credit may be  
6           carried back or forward to other taxable years in ac-  
7           cordance with section 39.

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

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

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

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

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



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

4 **SEC. 3. CLINICAL TESTING EXPENSES FOR RAPID INFEC-**  
5 **TIOUS DISEASES DIAGNOSTIC TESTS.**

6 (a) IN GENERAL.—Subpart D of part IV of sub-  
7 chapter A of chapter 1 of the Internal Revenue Code of  
8 1986, as amended by section 2, is amended by adding at  
9 the end the following new section:

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

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

16 “(b) QUALIFIED CLINICAL TESTING EXPENSES.—  
17 For purposes of this section—

18 “(1) QUALIFIED CLINICAL TESTING EX-  
19 PENSES.—

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

1 section were applied with the modifications set  
2 forth in subparagraph (B).

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

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

10 “(ii) by substituting ‘100 percent’ for  
11 ‘65 percent’ in paragraph (3)(A) of such  
12 subsection.

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

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

23 “(2) CLINICAL TESTING.—

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

1 “(i) which is carried out under an ex-  
2 emption for a device being tested under  
3 section 520(g) of the Federal Food, Drug,  
4 and Cosmetic Act (or regulations issued  
5 under such section),

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

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

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

19 “(c) COORDINATION WITH CREDIT FOR INCREASING  
20 RESEARCH EXPENDITURES.—

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

1 poses of determining the credit allowable under sec-  
2 tion 41 for such taxable year.

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

11 “(d) DEFINITIONS AND SPECIAL RULES.—

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

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

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

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

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

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

24           “(3) CERTAIN RULES MADE APPLICABLE.—  
25           Rules similar to the rules of paragraphs (1) and (2)

1 of section 41(f) shall apply for purposes of this sec-  
2 tion.

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

8 “(e) TRANSFERABILITY.—

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

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

24 “(3) DEFINITION OF QUALIFIED DIAGNOSTICS  
25 RESEARCH TAXPAYER.—For purposes of this sec-

1       tion, the term ‘qualified diagnostics research tax-  
2       payer’ means any domestic corporation that de-  
3       rives—

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

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

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

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

22              “(38) the credit determined under section  
23      45T(a).”.

24      (c) CLERICAL AMENDMENT.—The table of sections  
25      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.