

110TH CONGRESS
1ST SESSION

S. 2351

To amend the Internal Revenue Code of 1986 to provide a tax credit for medical research related to developing qualified infectious disease products.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 14, 2007

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

A BILL

To amend the Internal Revenue Code of 1986 to provide a tax credit for medical research related to developing qualified infectious disease products.

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. TAX CREDIT FOR MEDICAL RESEARCH RE-**
4 **LATED TO DEVELOPING QUALIFIED INFEC-**
5 **TIOUS DISEASE PRODUCTS.**

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 (relating to business-related credits) is amended by
9 adding at the end the following new section:

1 **“SEC. 450. CREDIT FOR MEDICAL RESEARCH RELATED TO**
 2 **DEVELOPING QUALIFIED INFECTIOUS DIS-**
 3 **EASE PRODUCTS.**

4 “(a) GENERAL RULE.—For purposes of section 38,
 5 the infectious disease research credit determined under
 6 this section for the taxable year is an amount equal to
 7 50 percent of the qualified infectious disease research ex-
 8 penses for the taxable year.

9 “(b) QUALIFIED INFECTIOUS DISEASE RESEARCH
 10 EXPENSES.—For purposes of this section—

11 “(1) QUALIFIED INFECTIOUS DISEASE RE-
 12 SEARCH EXPENSES.—Except as otherwise provided
 13 in this subsection, the term ‘qualified infectious dis-
 14 ease research expenses’ means the amounts which
 15 are paid or incurred by the taxpayer during the tax-
 16 able year with respect to any research and develop-
 17 ment of any qualified infectious disease product
 18 which would be described in subsection (b) of section
 19 41 if such subsection were applied with the modifica-
 20 tions set forth in paragraph (2).

21 “(2) MODIFICATIONS; INCREASED INCENTIVE
 22 FOR CONTRACT RESEARCH PAYMENTS.—For pur-
 23 poses of paragraph (1), subsection (b) of section 41
 24 shall be applied—

25 “(A) by substituting ‘qualified infectious
 26 disease research’ for ‘qualified research’ each

1 place it appears in paragraphs (2) and (3) of
2 such subsection, and

3 “(B) by substituting ‘100 percent’ for ‘65
4 percent’ in paragraph (3)(A) of such sub-
5 section.

6 “(3) EXCLUSION FOR AMOUNTS FUNDED BY
7 GRANTS, ETC.—The term ‘qualified infectious dis-
8 ease research expenses’ shall not include any amount
9 to the extent such amount is funded by any grant,
10 contract, or otherwise by another person (or any
11 governmental entity).

12 “(4) QUALIFIED INFECTIOUS DISEASE RE-
13 SEARCH.—The term ‘qualified infectious disease re-
14 search’ means qualified research (as defined in sec-
15 tion 41(d)) which relates to the development of a
16 qualified infectious disease product, except that
17 qualified infectious disease research shall include ex-
18 penses related to re-formulating existing qualified in-
19 fectionous disease products.

20 “(5) QUALIFIED INFECTIOUS DISEASE PROD-
21 UCT.—

22 “(A) IN GENERAL.—The term ‘qualified
23 infectious disease product’ means any antibiotic
24 drug, antiviral, diagnostic test, biological prod-
25 uct, or vaccine that is developed for the purpose

1 of treating, detecting, preventing, or identifying
2 a qualifying pathogen.

3 “(B) QUALIFYING ANTIBIOTIC DRUG AND
4 ANTIVIRAL FORMULATIONS.—To qualify as a
5 qualified infectious disease product under sub-
6 paragraph (A), any antibiotic drug or antiviral
7 shall be in a formulation for which the Sec-
8 retary of Health and Human Services, after
9 consulting with infectious diseases clinicians
10 and appropriate professional associations, has
11 determined there is a significant medical need.

12 “(6) OTHER DEFINITIONS.—

13 “(A) ANTIBIOTIC DRUG.—The term ‘anti-
14 biotic drug’ has the meaning given to that term
15 in section 201 of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 321).

17 “(B) ANTIVIRAL.—The term ‘antiviral’
18 means a drug or biological product intended for
19 human use that impedes the reproduction of a
20 virus.

21 “(C) BIOLOGICAL PRODUCT.—The term
22 ‘biological product’ has the meaning given to
23 that term in section 351 of the Public Health
24 Service Act (42 U.S.C. 262).

1 “(D) DEVICE.—The term ‘device’ has the
2 meaning given to that term in section 201 of
3 the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 321).

5 “(E) DIAGNOSTIC TEST.—The term ‘diag-
6 nostic test’ means a device or product used to
7 detect the presence, concentration, or character-
8 istics of an infectious human disease.

9 “(F) DRUG.—The term ‘drug’ has the
10 meaning given to that term in section 201 of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 321).

13 “(G) QUALIFYING PATHOGEN.—The term
14 ‘qualifying pathogen’ means—

15 “(i) methicillin-resistant staphy-
16 lococcus aureus,

17 “(ii) life-threatening gram negative
18 bacteria, such as *Escherichia coli* (*E. coli*),
19 *Acinetobacter*, *Klebsiella* species, and
20 *Pseudomonas aeruginosa*,

21 “(iii) extensively drug resistant tuber-
22 culosis (XDR–TB), or

23 “(iv) any other infectious pathogen
24 identified for purposes of this section by
25 the Secretary of Health and Human Serv-

1 ices, in concurrence with infectious disease
 2 clinicians and appropriate professional as-
 3 sociations, as a significant threat to public
 4 health because of drug resistance or other
 5 factors (or likely to become such a threat).

6 “(H) VACCINE.—The term ‘vaccine’ means
 7 a vaccine intended for human use.

8 “(c) COORDINATION WITH CREDIT FOR INCREASING
 9 RESEARCH EXPENDITURES.—

10 “(1) IN GENERAL.—Except as provided in para-
 11 graph (2), any qualified infectious disease research
 12 expenses for a taxable year to which an election
 13 under this section applies shall not be taken into ac-
 14 count for purposes of determining the credit allow-
 15 able under section 41 for such taxable year.

16 “(2) EXPENSES INCLUDED IN DETERMINING
 17 BASE PERIOD RESEARCH EXPENSES.—Any qualified
 18 infectious disease research expenses for any taxable
 19 year which are qualified research expenses (within
 20 the meaning of section 41(b)) shall be taken into ac-
 21 count in determining base period research expenses
 22 for purposes of applying section 41 to subsequent
 23 taxable years.

24 “(d) SPECIAL RULES.—

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

5 “(2) COORDINATION WITH CREDIT FOR CLIN-
 6 ICAL TESTING EXPENSES FOR CERTAIN DRUGS FOR
 7 RARE DISEASES.—Any qualified infectious disease
 8 research expenses for a taxable year to which an
 9 election under this section applies shall not be taken
 10 into account for purposes of determining the credit
 11 allowable under section 45C for such taxable year.

12 “(3) 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) TERMINATION.—This section shall not apply to
 18 taxable years beginning after December 31, 2012.”.

19 (b) INCLUSION IN GENERAL BUSINESS CREDIT.—
 20 Section 38(b) of the Internal Revenue Code of 1986 is
 21 amended by striking “plus” at the end of paragraph (30),
 22 by striking the period at the end of paragraph (31) and
 23 inserting “, plus”, and by adding at the end the following
 24 new paragraph:

1 “(32) the infectious disease research credit de-
 2 termined under section 45O.”.

3 (c) DENIAL OF DOUBLE BENEFIT.—Section 280C of
 4 the Internal Revenue Code of 1986 (relating to certain
 5 expenses for which credits are allowable) is amended by
 6 adding at the end the following new subsection:

7 “(f) CREDIT FOR QUALIFIED INFECTIOUS DISEASE
 8 RESEARCH EXPENSES.—

9 “(1) IN GENERAL.—No deduction shall be al-
 10 lowed for that portion of the qualified infectious dis-
 11 ease research expenses (as defined in section
 12 45O(b)) otherwise allowable as a deduction for the
 13 taxable year which is equal to the amount of the
 14 credit determined for such taxable year under sec-
 15 tion 45O(a).

16 “(2) CERTAIN RULES TO APPLY.—Rules similar
 17 to the rules of paragraphs (2), (3), and (4) of sub-
 18 section (c) shall apply for purposes of this sub-
 19 section.”.

20 (d) DEDUCTION FOR UNUSED PORTION OF CRED-
 21 IT.—Section 196(c) of the Internal Revenue Code of 1986
 22 (defining qualified business credits) is amended by strik-
 23 ing “and” at the end of paragraph (12), by striking the
 24 period at the end of paragraph (13) and inserting “, and”,
 25 and by adding at the end the following new paragraph:

1 “(14) the infectious disease research credit de-
 2 termined under section 45O(a) (other than such
 3 credit determined under the rules of section
 4 280C(e)(2)).”.

5 (e) TECHNICAL AMENDMENT.—The table of sections
 6 for subpart D of part IV of subchapter A of chapter 1
 7 of the Internal Revenue Code of 1986 is amended by add-
 8 ing at the end the following new item:

 “Sec. 45O. Credit for medical research related to developing qualified infectious
 disease products.”.

9 (f) EFFECTIVE DATE.—The amendments made by
 10 this section shall apply to taxable years beginning after
 11 December 31, 2007.

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