

106TH CONGRESS
2^D SESSION

H. R. 5219

To amend the Internal Revenue Code of 1986 to allow a credit against income tax for research related to developing vaccines against widespread diseases and ensure that such vaccines are affordable and widely distributed.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 20, 2000

Ms. PELOSI (for herself and Ms. DUNN) 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 income tax for research related to developing vaccines against widespread diseases and ensure that such vaccines are affordable and widely distributed.

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 “Vaccines for the New
5 Millennium Act of 2000”.

1 **SEC. 2. CREDIT FOR MEDICAL RESEARCH RELATED TO DE-**
2 **VELOPING VACCINES AGAINST WIDESPREAD**
3 **DISEASES.**

4 (a) IN GENERAL.—Subpart D of part IV of sub-
5 chapter A of chapter 1 of the Internal Revenue Code of
6 1986 (relating to business related credits) is amended by
7 adding at the end the following new section:

8 **“SEC. 45D. CREDIT FOR MEDICAL RESEARCH RELATED TO**
9 **DEVELOPING VACCINES AGAINST WIDE-**
10 **SPREAD DISEASES.**

11 “(a) GENERAL RULE.—For purposes of section 38,
12 the vaccine research credit determined under this section
13 for the taxable year is an amount equal to 30 percent of
14 the qualified vaccine research expenses for the taxable
15 year.

16 “(b) QUALIFIED VACCINE RESEARCH EXPENSES.—
17 For purposes of this section—

18 “(1) QUALIFIED VACCINE RESEARCH EX-
19 PENSES.—

20 “(A) IN GENERAL.—Except as otherwise
21 provided in this paragraph, the term ‘qualified
22 vaccine research expenses’ means—

23 “(i) vaccine clinical testing expenses,
24 and

1 “(ii) other vaccine research expenses
2 (to the extent not taken into account under
3 this clause for a prior taxable year).

4 “(B) LIMITATIONS ON OTHER VACCINE RE-
5 SEARCH EXPENSES.—

6 “(i) LIMITATION ON EXPENSES
7 TAKEN INTO ACCOUNT.—The amount of
8 other vaccine research expenses with re-
9 spect to any vaccine or microbicide which
10 may be taken into account under this sec-
11 tion for any taxable year shall not exceed
12 25 percent of the vaccine clinical testing
13 expenses with respect to such vaccine or
14 microbicide for such year.

15 “(ii) LIMITATION ON CREDIT.—The
16 amount of credit determined under this
17 section for any taxable year (determined
18 without regard to this clause) with respect
19 to other vaccine research expenses shall be
20 reduced by the amount of credit allowed in
21 any prior taxable year with respect to such
22 expenses under section 41.

23 “(2) VACCINE CLINICAL TESTING EXPENSES.—

24 “(A) IN GENERAL.—The term ‘vaccine
25 clinical testing expenses’ means the amounts

1 which are paid or incurred by the taxpayer dur-
2 ing the taxable year which would be described
3 in subsection (b) of section 41 if such sub-
4 section were applied with the modifications set
5 forth in subparagraph (B).

6 “(B) MODIFICATIONS; INCREASED INCEN-
7 TIVE FOR CONTRACT RESEARCH PAYMENTS FOR
8 COLLABORATIVE VACCINE CLINICAL TESTING
9 PROJECTS.—For purposes of subparagraph (A),
10 subsection (b) of section 41 shall be applied—

11 “(i) by substituting ‘vaccine clinical
12 testing’ for ‘qualified research’ each place
13 it appears in paragraphs (2) and (3) of
14 such subsection, and

15 “(ii) by substituting ‘100 percent’ for
16 ‘65 percent’ in paragraph (3)(A) of such
17 subsection.

18 “(C) VACCINE CLINICAL TESTING.—The
19 term ‘vaccine clinical testing’ means human
20 clinical testing which is related to the use of
21 any vaccine or microbicide referred to in para-
22 graph (3)(C) if—

23 “(i) in the case of human clinical test-
24 ing conducted in the United States, such

1 testing is approved by the Federal Food
2 and Drug Administration, or

3 “(ii) in the case of human clinical
4 testing conducted outside the United
5 States, such testing is approved by the
6 Federal Food and Drug Administration or
7 the appropriate authority of a county in-
8 cluded in the list under section 802(b)(1)
9 of the Federal Food, Drug, and Cosmetic
10 Act.

11 “(3) OTHER VACCINE RESEARCH EXPENSES.—

12 “(A) IN GENERAL.—The term ‘other vac-
13 cine research expenses’ means the amounts
14 (other than for vaccine clinical testing) which
15 are paid or incurred by the taxpayer during the
16 taxable year or any prior taxable year which
17 would be described in subsection (b) of section
18 41 if such subsection were applied with the
19 modifications set forth in subparagraph (B).

20 “(B) MODIFICATIONS; INCREASED INCEN-
21 TIVE FOR CONTRACT RESEARCH PAYMENTS FOR
22 COLLABORATIVE VACCINE RESEARCH
23 PROJECTS.—For purposes of subparagraph (A),
24 subsection (b) of section 41 shall be applied—

1 “(i) by substituting ‘vaccine research’
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) VACCINE RESEARCH.—

9 “(i) IN GENERAL.—The term ‘vaccine
10 research’ means research to develop vac-
11 cines and microbicides for—

12 “(I) malaria,

13 “(II) tuberculosis,

14 “(III) HIV, or

15 “(IV) any infectious disease (of a
16 single etiology) that is determined by
17 the Secretary of Health and Human
18 Services (after consultation with the
19 Director of the Center for Disease
20 Control and Prevention and the Ad-
21 ministrator of the United States
22 Agency for International Develop-
23 ment) to cause the deaths of over
24 1,000,000 people worldwide each year.

1 “(ii) MICROBICIDE.—The term
2 ‘microbicide’ means a substance used topi-
3 cally for prevention from infection by an
4 identified pathogen.

5 “(iii) VACCINE.—The term ‘vaccine’
6 means a product using all or portions of
7 the disease-causing organism or nucleic
8 acid sequences for prevention from infec-
9 tion by an identified pathogen.

10 “(D) ORDERING RULES.—For purposes of
11 paragraph (1)(B)(ii)—

12 “(i) other vaccine research expenses
13 shall be taken into account first from the
14 taxable year for which the credit under this
15 section is being determined and then from
16 earlier taxable years beginning with the
17 most recent prior year, and

18 “(ii) credit shall be treated as allowed
19 under section 41 with respect to any ex-
20 pense to the extent of the amount that the
21 credit under section 41 would have been
22 reduced but for such expense.

23 “(4) EXCLUSION FOR AMOUNTS FUNDED BY
24 GRANTS, ETC.—The term ‘qualified vaccine research
25 expenses’ shall not include any amount to the extent

1 such amount is funded by any grant, contract, or
2 otherwise by another person (or any governmental
3 entity).

4 “(c) COORDINATION WITH CREDIT FOR INCREASING
5 RESEARCH EXPENDITURES.—

6 “(1) IN GENERAL.—Except as provided in para-
7 graph (2), any qualified vaccine research expenses
8 for a taxable year to which an election under this
9 section applies shall not be taken into account for
10 purposes of determining the credit allowable under
11 section 41 for such taxable year.

12 “(2) EXPENSES INCLUDED IN DETERMINING
13 BASE PERIOD RESEARCH EXPENSES.—Any qualified
14 vaccine research expenses for any taxable year which
15 are qualified research expenses (within the meaning
16 of section 41(b)) shall be taken into account in de-
17 termining base period research expenses for pur-
18 poses of applying section 41 to subsequent taxable
19 years.

20 “(d) SPECIAL RULES.—

21 “(1) DENIAL OF CREDIT FOR CERTAIN FOR-
22 EIGN CLINICAL TESTING AND RESEARCH.—

23 “(A) IN GENERAL.—Except as provided in
24 subparagraph (B), no credit shall be allowed
25 under this section with respect to any clinical

1 testing or research conducted outside the
2 United States.

3 “(B) CERTAIN FOREIGN CLINICAL TESTING
4 ELIGIBLE FOR CREDIT.—Subparagraph (A)
5 shall not apply to human clinical testing con-
6 ducted outside the United States if the Director
7 of the Centers for Disease Control and Preven-
8 tion determines that there is an insufficient
9 testing population in the United States.

10 “(C) SPECIAL LIMITATION FOR CORPORA-
11 TIONS TO WHICH SECTION 936 APPLIES.—No
12 credit shall be allowed under this section with
13 respect to any activities conducted by a cor-
14 poration to which an election under section 936
15 applies.

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

20 “(3) ELECTION.—This section shall apply to
21 any taxpayer for any taxable year only if such tax-
22 payer elects to have this section apply for such tax-
23 able year.”

24 (b) INCLUSION IN GENERAL BUSINESS CREDIT.—

1 (1) IN GENERAL.—Section 38(b) of such Code
2 is amended by striking “plus” at the end of para-
3 graph (11), by striking the period at the end of
4 paragraph (12) and inserting “, plus”, and by add-
5 ing at the end the following new paragraph:

6 “(13) the vaccine research credit determined
7 under section 45D.”.

8 (2) TRANSITION RULE.—Section 39(d) of such
9 Code is amended by adding at the end the following
10 new paragraph:

11 “(9) NO CARRYBACK OF SECTION 45D CREDIT
12 BEFORE ENACTMENT.—No portion of the unused
13 business credit for any taxable year which is attrib-
14 utable to the vaccine research credit determined
15 under section 45D may be carried back to a taxable
16 year ending before the date of the enactment of sec-
17 tion 45D.”.

18 (c) DENIAL OF DOUBLE BENEFIT.—Section 280C of
19 such Code is amended by adding at the end the following
20 new subsection:

21 “(d) CREDIT FOR QUALIFIED VACCINE RESEARCH
22 EXPENSES.—

23 “(1) IN GENERAL.—No deduction shall be al-
24 lowed for that portion of the qualified vaccine re-
25 search expenses (as defined in section 45D(b)) oth-

1 erwise allowable as a deduction for the taxable year
2 which is equal to the amount of the credit deter-
3 mined for such taxable year under section 45D(a).

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

8 (d) DEDUCTION FOR UNUSED PORTION OF CRED-
9 IT.—Section 196(c) of such Code (defining qualified busi-
10 ness credits) is amended by striking “and” at the end of
11 paragraph (7), by striking the period at the end of para-
12 graph (8) and inserting “, and”, and by adding at the
13 end the following new paragraph:

14 “(9) the vaccine research credit determined
15 under section 45D(a) (other than such credit deter-
16 mined under the rules of section 280C(d)(2)).”.

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

“Sec. 45D. Credit for medical research related to developing vac-
cines against widespread diseases.”.

21 (f) EFFECTIVE DATE.—The amendments made by
22 this section shall apply to expenses paid or incurred after
23 December 31, 2000, in taxable years ending after such
24 date.

1 (g) DISTRIBUTION OF VACCINES DEVELOPED USING
2 CREDIT.—It is the sense of the Congress that if credit
3 is allowed under section 45D of the Internal Revenue Code
4 of 1986 to any corporation or shareholder of a corporation
5 by reason of vaccine research expenses incurred by the
6 corporation in the development of a vaccine, such corpora-
7 tion should certify to the Secretary of the Treasury that,
8 within 1 year after that vaccine is first licensed, such cor-
9 poration will establish a good faith plan utilizing tech-
10 nology transfer, differential pricing, in-country produc-
11 tion, or other mechanisms to maximize international ac-
12 cess to high quality and affordable vaccines. The preceding
13 sentence shall not be construed to waive rights to set
14 prices, patent ownership, or confidentiality of privileged
15 information.

16 (h) STUDY.—The Institute of Medicine shall conduct
17 a study of the effectiveness of the credit under section 45D
18 of the Internal Revenue Code of 1986 in stimulating vac-
19 cine research. Not later than the date which is 5 years
20 after the date of the enactment of this Act, the Institute
21 of Medicine shall submit to the Congress the results of
22 such study together with any recommendations it may
23 have to improve the effectiveness of such credit in stimu-
24 lating vaccine research.

1 **SEC. 3. CREDIT FOR CERTAIN SALES OF LIFESAVING VAC-**
2 **CINES.**

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

7 **“SEC. 45E. CREDIT FOR CERTAIN SALES OF LIFESAVING**
8 **VACCINES.**

9 “(a) IN GENERAL.—For purposes of section 38, the
10 lifesaving vaccine sale credit determined under this section
11 with respect to a taxpayer for the taxable year is an
12 amount equal to the amount of qualified vaccine sales for
13 the taxable year.

14 “(b) QUALIFIED VACCINE SALES.—For purposes of
15 this section—

16 “(1) IN GENERAL.—The term ‘qualified vaccine
17 sales’ means the aggregate amount paid to the tax-
18 payer for a qualified sale.

19 “(2) QUALIFIED SALE.—

20 “(A) IN GENERAL.—The term ‘qualified
21 sale’ means a sale of a qualified vaccine—

22 “(i) to a nonprofit organization or to
23 a government of any foreign country (or
24 instrumentality of such a government), and

25 “(ii) for distribution in a developing
26 country.

1 “(B) DEVELOPING COUNTRY.—For pur-
2 poses of this paragraph, the term ‘developing
3 country’ means a country which the Secretary
4 determines to be a country with a lower middle
5 income or less (as such term is used by the
6 International Bank for Reconstruction and De-
7 velopment).

8 “(3) QUALIFIED VACCINE.—The term ‘qualified
9 vaccine’ means any vaccine and microbicide—

10 “(A) which is described in section
11 45D(b)(3)(C), and

12 “(B) which is approved as a new drug
13 after the date of the enactment of this para-
14 graph by—

15 “(i) the Food and Drug Administra-
16 tion,

17 “(ii) the World Health Organization,
18 or

19 “(iii) the appropriate authority of a
20 county included in the list under section
21 802(b)(1) of the Federal Food, Drug, and
22 Cosmetic Act.

23 “(c) LIMIT ON AMOUNT OF CREDIT.—The maximum
24 amount of the credit allowable under subsection (a) with
25 respect to a sale shall not exceed the portion of the limita-

1 tion amount allocated under subsection (d) with respect
2 to such sale.

3 “(d) NATIONAL LIMITATION ON AMOUNT OF CRED-
4 ITS.—

5 “(1) IN GENERAL.—Except as provided in para-
6 graph (3), there is a lifesaving vaccine sale credit for
7 each calendar year equal to—

8 “(A) \$100,000,000 for each of years 2002
9 through 2006, and

10 “(B) \$125,000,000 for each of years 2007
11 through 2010.

12 “(2) ALLOCATION OF LIMITATION.—The limita-
13 tion amount under paragraph (1) shall be allocated
14 for any calendar year by the Administrator of the
15 United States Agency for International Development
16 among organizations with an application approved
17 by the Administrator. The Administrator shall pre-
18 scribe the procedures for applications for an alloca-
19 tion under this subsection and the factors to be
20 taken into account in making such allocations. Such
21 applications shall be made at such time and in such
22 form and manner as the Administrator shall pre-
23 scribe and shall include a detailed plan for distribu-
24 tion of the vaccine.

1 “(3) CARRYOVER OF UNUSED LIMITATION.—If
2 the limitation amount under paragraph (1) for any
3 calendar year exceeds the aggregate amount allo-
4 cated under paragraph (2), such limitation for the
5 following calendar year shall be increased by the
6 amount of such excess. No amount may be carried
7 under the preceding sentence to any calendar year
8 after 2020.

9 “(e) SPECIAL RULES.—For purposes of this section,
10 rules similar to the rules of section 41(f)(2) shall apply.”

11 (b) INCLUSION IN GENERAL BUSINESS CREDIT.—

12 (1) IN GENERAL.—Section 38(b) of such Code
13 (relating to current year business credit) is amended
14 by striking “plus” at the end of paragraph (12), by
15 striking the period at the end of paragraph (13) and
16 inserting “, plus”, and by adding at the end the fol-
17 lowing new paragraph:

18 “(14) the lifesaving vaccine sale credit deter-
19 mined under section 45E.”.

20 (2) TRANSITION RULE.—Section 39(d) of such
21 Code (relating to transitional rules) is amended by
22 adding at the end the following new paragraph:

23 “(10) NO CARRYBACK OF SECTION 45E CREDIT
24 BEFORE ENACTMENT.—No portion of the unused
25 business credit for any taxable year which is attrib-

1 utable to the lifesaving vaccine sale credit deter-
2 mined under section 45E may be carried back to a
3 taxable year ending before the date of the enactment
4 of section 45E.”.

5 (c) CLERICAL AMENDMENT.—The table of sections
6 for subpart D of part IV of subchapter A of chapter 1
7 of such Code is amended by adding at the end the fol-
8 lowing new item:

 “Sec. 45E. Credit for certain sales of lifesaving vaccines.”.

9 (d) EFFECTIVE DATE.—The amendments made by
10 this section shall apply to sales of vaccines after December
11 31, 2001, in taxable years ending after such date.

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