

107TH CONGRESS  
1ST SESSION

# H. R. 1504

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.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 4, 2001

Ms. PELOSI (for herself, Ms. DUNN, Mr. RANGEL, Mr. McDERMOTT, Mrs. MORELLA, Mrs. CHRISTENSEN, Mr. FOLEY, Mr. LEWIS of Georgia, Mr. TOWNS, Mr. DEUTSCH, Mr. SERRANO, Ms. WOOLSEY, Mr. JEFFERSON, Mr. FILNER, Mr. McNULTY, Ms. ROYBAL-ALLARD, Mr. LANTOS, Mr. ENGLISH, Mrs. THURMAN, Ms. DELAURO, Ms. MILLENDER-McDONALD, and Mr. WYNN) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committees on Energy and Commerce, and International Relations, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Vaccines for the New  
3 Millennium Act of 2001”.

4 **SEC. 2. CREDIT FOR MEDICAL RESEARCH RELATED TO DE-**  
5 **VELOPING VACCINES AGAINST WIDESPREAD**  
6 **DISEASES.**

7 (a) IN GENERAL.—Subpart D of part IV of sub-  
8 chapter A of chapter 1 of the Internal Revenue Code of  
9 1986 (relating to business related credits) is amended by  
10 adding at the end the following new section:

11 **“SEC. 45E. CREDIT FOR MEDICAL RESEARCH RELATED TO**  
12 **DEVELOPING VACCINES AGAINST WIDE-**  
13 **SPREAD DISEASES.**

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

19 “(b) QUALIFIED VACCINE RESEARCH EXPENSES.—  
20 For purposes of this section—

21 “(1) QUALIFIED VACCINE RESEARCH EX-  
22 PENSES.—

23 “(A) IN GENERAL.—Except as otherwise  
24 provided in this paragraph, the term ‘qualified  
25 vaccine research expenses’ means the amounts  
26 which are paid or incurred by the taxpayer dur-

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

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

9                   “(i) by substituting ‘vaccine research’  
10                   for ‘qualified research’ each place it ap-  
11                   pears in paragraphs (2) and (3) of such  
12                   subsection, and

13                   “(ii) by substituting ‘100 percent’ for  
14                   ‘65 percent’ in paragraph (3)(A) of such  
15                   subsection.

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

22           “(2) VACCINE RESEARCH.—The term ‘vaccine  
23           research’ means research to develop vaccines and  
24           microbicides for—

25                   “(A) malaria,

1 “(B) tuberculosis,

2 “(C) HIV, or

3 “(D) any infectious disease (of a single eti-  
4 ology) which, according to the World Health  
5 Organization, causes over 1,000,000 human  
6 deaths annually.

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

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

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

23 “(d) SPECIAL RULES.—

24 “(1) LIMITATIONS ON FOREIGN TESTING.—No  
25 credit shall be allowed under this section with re-

1 spect to any vaccine research (other than human  
2 clinical testing) conducted outside the United States.

3 “(2) PRE-CLINICAL RESEARCH.—No credit shall  
4 be allowed under this section for pre-clinical re-  
5 search unless such research is pursuant to a re-  
6 search plan an abstract of which has been filed with  
7 the Secretary before the beginning of such year. The  
8 Secretary, in consultation with the Secretary of  
9 Health and Human Services, shall prescribe regula-  
10 tions specifying the requirements for such plans and  
11 procedures for filing under this paragraph.

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

16 “(4) ELECTION.—This section (other than sub-  
17 section (e)) shall apply to any taxpayer for any tax-  
18 able year only if such taxpayer elects to have this  
19 section apply for such taxable year.

20 “(e) CREDIT TO BE REFUNDABLE FOR CERTAIN  
21 TAXPAYERS.—

22 “(1) IN GENERAL.—In the case of an electing  
23 qualified taxpayer—

24 “(A) the credit under this section shall be  
25 determined without regard to section 38(c), and

1           “(B) the credit so determined be allowed  
2           under subpart C.

3           “(2) ELECTING QUALIFIED TAXPAYER.—For  
4           purposes of this subsection, the term ‘electing quali-  
5           fied taxpayer’ means, with respect to any taxable  
6           year, any domestic C corporation if—

7           “(A) the aggregate gross assets of such  
8           corporation throughout such taxable year are  
9           \$500,000,000 or less,

10           “(B) the net income tax (as defined in sec-  
11           tion 38(c)) of such corporation is zero for such  
12           taxable year and the 2 preceding taxable year,

13           “(C) as of the close of the taxable year, the  
14           corporation is not under the jurisdiction of a  
15           court in a title 11 or similar case (within the  
16           meaning of section 368(a)(3)(A)), and

17           “(D) the corporation elects the application  
18           of this subsection for such taxable year.

19           “(3) AGGREGATE GROSS ASSETS.—Aggregate  
20           gross assets shall be determined under section  
21           1202(d).

22           “(4) CONTROLLED GROUPS.—A corporation  
23           shall be treated as meeting the requirement of para-  
24           graph (2)(B) only if each person who is treated with  
25           such corporation as a single employer under sub-

1 sections (a) and (b) of section 52 also meets such re-  
2 quirement.”

3 (b) INCLUSION IN GENERAL BUSINESS CREDIT.—

4 (1) IN GENERAL.—Section 38(b) of such Code  
5 is amended by striking “plus” at the end of para-  
6 graph (12), by striking the period at the end of  
7 paragraph (13) and inserting “, plus”, and by add-  
8 ing at the end the following new paragraph:

9 “(14) the vaccine research credit determined  
10 under section 45E.”.

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

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

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

24 “(d) CREDIT FOR QUALIFIED VACCINE RESEARCH  
25 EXPENSES.—

1           “(1) IN GENERAL.—No deduction shall be al-  
2           lowed for that portion of the qualified vaccine re-  
3           search expenses (as defined in section 45E(b)) oth-  
4           erwise allowable as a deduction for the taxable year  
5           which is equal to the amount of the credit deter-  
6           mined for such taxable year under section 45E(a).

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

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

17                 “(10) the vaccine research credit determined  
18                 under section 45E(a) (other than such credit deter-  
19                 mined under the rules of section 280C(d)(2)).”.

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

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



1 (f) EFFECTIVE DATE.—The amendments made by  
2 this section shall apply to taxable years ending after the  
3 date of the enactment of this Act.

4 (g) STUDY.—The Institute of Medicine shall conduct  
5 a study of the degree to which the credit under section  
6 45E of the Internal Revenue Code of 1986 has stimulated  
7 vaccine research. Not later than the date which is 5 years  
8 after the date of the enactment of this Act, the Institute  
9 of Medicine shall submit to the Congress the results of  
10 such study together with any recommendations it may  
11 have to improve the effectiveness of such credit has stimu-  
12 lated vaccine research.

13 **SEC. 3. CREDIT FOR CERTAIN SALES OF LIFESAVING VAC-**  
14 **CINES.**

15 (a) IN GENERAL.—Subpart D of part IV of sub-  
16 chapter A of chapter 1 of the Internal Revenue Code of  
17 1986 (relating to business related credits) is amended by  
18 adding at the end the following new section:

19 **“SEC. 45F. CREDIT FOR CERTAIN SALES OF LIFESAVING**  
20 **VACCINES.**

21 “(a) IN GENERAL.—For purposes of section 38, the  
22 lifesaving vaccine sale credit determined under this section  
23 with respect to a taxpayer for the taxable year is an  
24 amount equal to the amount of qualified vaccine sales for  
25 the taxable year.

1       “(b) QUALIFIED VACCINE SALES.—For purposes of  
2 this section—

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

6           “(2) QUALIFIED SALE.—

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

9                   “(i) to a nonprofit organization or to  
10 a government of any foreign country (or  
11 instrumentality of such a government), and

12                   “(ii) for distribution in a developing  
13 country.

14           “(B) DEVELOPING COUNTRY.—For pur-  
15 poses of this paragraph, the term ‘developing  
16 country’ means a country which the Secretary  
17 determines to be a country with a lower middle  
18 income or less (as such term is used by the  
19 International Bank for Reconstruction and De-  
20 velopment).

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

23                   “(A) which is described in section  
24 45E(b)(3)(C), and

1           “(B) which is approved as a new drug  
2           after the date of the enactment of this para-  
3           graph by—

4                   “(i) the Food and Drug Administra-  
5                   tion,

6                   “(ii) the World Health Organization,  
7                   or

8                   “(iii) the appropriate authority of a  
9                   county included in the list under section  
10                  802(b)(1) of the Federal Food, Drug, and  
11                  Cosmetic Act.

12          “(c) LIMIT ON AMOUNT OF CREDIT.—The maximum  
13          amount of the credit allowable under subsection (a) with  
14          respect to a sale shall not exceed the portion of the limita-  
15          tion amount allocated under subsection (d) with respect  
16          to such sale.

17          “(d) NATIONAL LIMITATION ON AMOUNT OF CRED-  
18          ITS.—

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

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

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

1           “(2) ALLOCATION OF LIMITATION.—The limita-  
2           tion amount under paragraph (1) shall be allocated  
3           for any calendar year by the Administrator of the  
4           United States Agency for International Development  
5           among organizations with an application approved  
6           by the Administrator. The Administrator shall pre-  
7           scribe the procedures for applications for an alloca-  
8           tion under this subsection and the factors to be  
9           taken into account in making such allocations. Such  
10          applications shall be made at such time and in such  
11          form and manner as the Administrator shall pre-  
12          scribe and shall include a detailed plan for distribu-  
13          tion of the vaccine.

14          “(3) CARRYOVER OF UNUSED LIMITATION.—If  
15          the limitation amount under paragraph (1) for any  
16          calendar year exceeds the aggregate amount allo-  
17          cated under paragraph (2), such limitation for the  
18          following calendar year shall be increased by the  
19          amount of such excess. No amount may be carried  
20          under the preceding sentence to any calendar year  
21          after 2020.

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

24          (b) INCLUSION IN GENERAL BUSINESS CREDIT.—

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

7           “(15) the lifesaving vaccine sale credit deter-  
8           mined under section 45F.”.

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

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

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

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

23          (d) EFFECTIVE DATE.—The amendments made by  
24          this section shall apply to sales of vaccines after December  
25          31, 2001, in taxable years ending after such date.

1 **SEC. 4. LIFESAVING VACCINE PURCHASE FUND.**

2 (a) PURPOSE.—It is the purpose of this section to—

3 (1) create incentives for private sector research  
4 into vaccines for HIV, malaria, tuberculosis, and  
5 other major infectious diseases; and

6 (2) ensure that vaccines for major infectious  
7 diseases are affordable and widely distributed.

8 (b) DEFINITIONS.—In this section:

9 (1) DEVELOPING COUNTRY.—The term “devel-  
10 oping country” means a country which the Inter-  
11 national Bank for Reconstruction and Development  
12 (commonly referred to as the ‘World Bank’) deter-  
13 mines to be a country with a lower middle income  
14 or less.

15 (2) ELIGIBLE VACCINE.—The term “eligible  
16 vaccine” has the meaning given the term “qualified  
17 vaccine” in section 45F(b)(3) of the Internal Rev-  
18 enue Code of 1986.

19 (c) ESTABLISHMENT OF FUND.—As of the date that  
20 the Secretary of the Treasury (in this section referred to  
21 as the “Secretary”) determines that any eligible vaccine  
22 is available for purchase, there is established in the Treas-  
23 ury of the United States a fund to be known as the “Life-  
24 saving Vaccine Purchase Fund” (in this section referred  
25 to as the “Fund”) consisting of amounts appropriated  
26 under subsection (f).

1 (d) INVESTMENT OF FUND.—Amounts in the Fund  
2 shall be invested in accordance with section 9702 of title  
3 31, United States Code, and any interest on, and proceeds  
4 from any such investment shall be credited to and become  
5 part of the Fund.

6 (e) USE OF FUND.—

7 (1) IN GENERAL.—The Secretary is authorized  
8 to expend amounts in the Fund for purchases of eli-  
9 gible vaccines. Such vaccines shall be distributed to  
10 developing countries.

11 (2) PURCHASE AND DISTRIBUTION OF VAC-  
12 CINES.—

13 (1) PURCHASE PRICES, ETC.—Vaccines pur-  
14 chased by the Fund—

15 (A) shall be made at prices which take into  
16 account the seller's research and development  
17 and manufacturing costs and the desirability of  
18 the vaccine purchased, and

19 (B) shall be made under a funding formula  
20 establishing a minimum price per dose and min-  
21 imum technical requirements and a market test  
22 requirement for the eligible vaccine.

23 (3) DISTRIBUTION.—Eligible vaccines pur-  
24 chased by the Fund shall be distributed to devel-  
25 oping countries under agreements between the

1 United States Agency for International Development  
2 and international organizations or recipient devel-  
3 oping countries that provide for—

4 (A) consideration of the prevalence of the  
5 disease treated by the eligible vaccine in the re-  
6 cipient developing country;

7 (B) consideration of the ability of the re-  
8 cipient country to effectively and safely deliver  
9 the vaccines; and

10 (C) a required matching payment by the  
11 recipient developing country based on the per  
12 capita income of the country, in an amount not  
13 in excess of 25 percent of the purchase price  
14 paid for such vaccine.

15 (4) REGULATIONS.—The Secretary shall pro-  
16 mulgate such regulations as are necessary to carry  
17 out the provisions of this subsection.

18 (5) CONSULTATION.—The Secretary shall pro-  
19 mulgate regulations under paragraph (4) after ex-  
20 tensive consultation with—

21 (A) the International Bank for Reconstruc-  
22 tion and Development (commonly referred to as  
23 the “World Bank”);

24 (B) the World Health Organization;



1 (C) the Secretary of Health and Human  
2 Services; and

3 (D) the Lifesaving Vaccine Advisory Com-  
4 mission.

5 (f) APPROPRIATIONS.—

6 (1) IN GENERAL.—Subject to paragraph (2),  
7 there are appropriated out of any funds in the  
8 Treasury not otherwise appropriated such sums as  
9 may be necessary to carry out the purposes of the  
10 Fund for each of 10 fiscal years beginning with the  
11 first fiscal year after the date that the Secretary de-  
12 termines that any eligible vaccine is available for  
13 purchase by the Fund.

14 (2) TRANSFER TO FUND.—The Secretary shall  
15 transfer the amount appropriated under paragraph  
16 (1) for a fiscal year to the Fund.

17 (3) AVAILABILITY.—Amounts appropriated  
18 under this section shall remain available until ex-  
19 pended.

20 **SEC. 5. SENSES OF CONGRESS.**

21 It is the sense of Congress that:

22 (1) MANUFACTURING CAPACITY.—Delivery of  
23 vaccines to developing country populations is often  
24 delayed a decade or more after these products are li-  
25 censed for use in industrialized nations. This delay

1 is due partly to inadequate manufacturing capacity  
2 that limits supply of vaccines in the early years of  
3 their distribution. The public sector has a role to  
4 play in ensuring that manufacturing capacity for  
5 vaccines for the priority diseases referred to in sec-  
6 tion 45E(b)(2) of the Internal Revenue Code of  
7 1986 (as added by this Act) is sufficient to secure  
8 access to these vaccines simultaneously in industri-  
9 alized and developing countries. It is appropriate for  
10 the Federal government to consider a variety of  
11 mechanisms in order to ensure adequate manufac-  
12 turing capacity to meet this goal. These mechanisms  
13 may include loan programs, accelerated depreciation,  
14 revenue bonds, or infrastructure grants.

15 (2) DISTRIBUTION OF VACCINES DEVELOPED  
16 USING CREDIT.—Given the important goal of ensur-  
17 ing that all those in need, in both industrialized and  
18 developing countries, reap the benefits of any vac-  
19 cine or microbicide that is developed for HIV, tuber-  
20 culosis, or malaria, and acknowledging the impor-  
21 tance of intellectual property rights and the right of  
22 corporations and shareholders of corporations to set  
23 prices, retain patent ownership, and maintain con-  
24 fidentiality of privileged information, corporations  
25 and shareholders of corporations who elect to take

1 the credit under section 45E of the Internal Revenue  
2 Code of 1986 for research expenses incurred in the  
3 development of a vaccine or microbicide shall certify  
4 to the Secretary of the Treasury that, within 1 year  
5 after that vaccine or microbicide is first licensed,  
6 such corporation will establish a plan to maximize  
7 distribution of such vaccine or microbicide in the de-  
8 veloping world using such mechanisms as technology  
9 transfer, differential pricing, and in-country produc-  
10 tion where possible, or other mechanisms to maxi-  
11 mize international access to high quality and afford-  
12 able vaccines.

13 (3) CONTINUED SUPPORT OF GLOBAL EF-  
14 FORTS.—The Federal government should continue  
15 supporting the work of the Global Alliance for Vac-  
16 cines and Immunizations and the Global Fund for  
17 Children’s Vaccines as an appropriate and effective  
18 vehicle to purchase and distribute these vaccines at  
19 an affordable price once they are discovered in order  
20 to distribute them to the developing world, as it does  
21 with vaccines against hepatitis-B, haemophilus influ-  
22 enza, and yellow fever.

23 (4) TIERED PRICING.—Flexible or differential  
24 pricing for vaccines, providing lowered prices for the  
25 poorest countries, is one of several valid strategies to

- 1 accelerate the introduction of vaccines in developing
- 2 countries.

