

106TH CONGRESS  
2D SESSION

# H. R. 3812

To create incentives for private sector 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

MARCH 1, 2000

Ms. PELOSI (for herself, Mr. LANTOS, Mr. INSLEE, Mr. HINCHEY, Mr. JEFFERSON, Mr. JACKSON of Illinois, Ms. WOOLSEY, Mr. MATSUI, Mrs. MORELLA, and Mr. ROMERO-BARCELO) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committees on International Relations, and Commerce, 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 create incentives for private sector 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. FINDINGS.**

2 Congress finds the following:

3 (1) Vaccines are among the most cost-effective  
4 weapons in the arsenal of modern medicine to stop  
5 the spread of contagious diseases and strengthen an  
6 individual's immune system to resist a wide range of  
7 infectious diseases, and vaccines offer a relatively in-  
8 expensive means of lowering a society's overall cost  
9 of medical care.

10 (2) Every year, up to 3,000,000 children's lives  
11 are saved as the result of early childhood immuniza-  
12 tions. But almost 3,000,000 more lives worldwide  
13 are lost from diseases that could be prevented with  
14 existing vaccines.

15 (3) Today, 1 in 4 children do not receive the 6  
16 basic vaccinations: polio, diphtheria, whooping cough,  
17 tetanus, measles, and tuberculosis. The proportion of  
18 children immunized against these 6 diseases has de-  
19 clined in recent years, from approximately 80 per-  
20 cent in 1990 to 74 percent in 1998.

21 (4) Safe, effective, and universal immunization  
22 is a means to end the tragedy of avoidable childhood  
23 deaths, and a means to improve the overall health,  
24 productivity, and security of society.

25 (5) As well as the challenges of increasing ac-  
26 cess to existing vaccines, there are additional chal-

1 lenges for research and development of new vaccines.  
2 Over 5,000,000 people die annually from HIV, tu-  
3 berculosis, and malaria. Vaccines against these in-  
4 fectious diseases are urgently needed.

5 (6) The spread of HIV is a human tragedy that  
6 is reversing previous gains in life expectancy and ex-  
7 acerbating poverty in developing countries. Over  
8 33,000,000 people are infected with HIV, and the  
9 disease will kill more than 2,500,000 people this  
10 year. More than 11,000,000 children worldwide have  
11 been orphaned by AIDS and 16,000 people become  
12 newly infected every day.

13 (7) While an estimated \$2,000,000,000 is spent  
14 annually on research for AIDS treatment, much of  
15 it by the private sector, the total global research and  
16 development for preventive HIV vaccines is substan-  
17 tially less, perhaps as little as \$300,000,000, and of  
18 the amount spent on lifesaving vaccine research,  
19 only a fraction is financed by private sector drug  
20 manufacturers.

21 (8) Between 7,000,000 and 8,000,000 individ-  
22 uals develop active tuberculosis every year and  
23 2,000,000 to 3,000,000 individuals die from tuber-  
24 culosis each year, with tuberculosis accounting for  
25 more than  $\frac{1}{4}$  of all preventable adult deaths in de-

1       veloping countries. An individual is newly infected  
2       with tuberculosis every second, and someone dies of  
3       tuberculosis every 10 seconds.

4               (9) Each year, 300,000,000 to 500,000,000 in-  
5       dividuals become ill with malaria, and approximately  
6       1,000,000 individuals die from the disease, exacting  
7       an enormous toll in lives, medical costs, and lost  
8       productivity. The majority of those who die from  
9       malaria are children under the age of 5. One person  
10      dies from malaria every 30 seconds.

11              (10) While additional public funds for basic re-  
12      search are critical in the effort to find vaccines for  
13      HIV, malaria, and tuberculosis, equally important is  
14      a concerted effort by private sector drug manufac-  
15      turers to find vaccines for these 3 major infectious  
16      diseases.

17              (11) Additional, targeted public subsidies for  
18      private sector lifesaving vaccine research and devel-  
19      opment are justified on the basis that achieving ef-  
20      fective and affordable vaccines for HIV, malaria,  
21      and tuberculosis will yield public benefits beyond  
22      those benefits captured by the manufacturer.

23 **SEC. 3. UNIVERSAL EARLY CHILDHOOD IMMUNIZATIONS.**

24       Section 104(c)(3) of the Foreign Assistance Act of  
25      1961 (22 U.S.C. 2151b(c)(3)) is amended in the fourth

1 sentence by striking “the protection of” and all that fol-  
2 lows through “1991” and inserting “the universal protec-  
3 tion of all children from immunizable diseases by Decem-  
4 ber 31, 2009”.

5 **SEC. 4. VOLUNTARY CONTRIBUTION TO GLOBAL ALLIANCE**  
6 **FOR VACCINES AND IMMUNIZATIONS AND**  
7 **INTERNATIONAL AIDS VACCINE INITIATIVE.**

8 (a) **AUTHORIZATION OF APPROPRIATIONS.**—Section  
9 302 of the Foreign Assistance Act of 1961 (22 U.S.C.  
10 2222) is amended by adding at the end the following:

11 “(j) In addition to amounts otherwise available under  
12 this section, there are authorized to be appropriated to  
13 the President for fiscal year 2001 an amount not in excess  
14 of \$50,000,000 and for fiscal year 2002 an amount not  
15 in excess of \$100,000,000 to be available only for United  
16 States contributions to the Global Alliance for Vaccines  
17 and Immunizations.

18 “(k) In addition to amounts otherwise available under  
19 this section, there are authorized to be appropriated to  
20 the President for fiscal year 2001 \$10,000,000 and for  
21 fiscal year 2002 \$20,000,000 to be available only for  
22 United States contributions to the International AIDS  
23 Vaccine Initiative.”.

24 (b) **REPORT.**—The President shall include in the July  
25 1 report submitted to Congress under section 305(b)(1)

1 of the Foreign Assistance Act of 1961 (22 U.S.C.  
2 2226(b)(1)) for fiscal years 2001 and 2002 a report on  
3 the effectiveness of the Global Alliance for Vaccines and  
4 Immunizations in meeting the goals of—

5 (1) improving access to sustainable immuniza-  
6 tion services;

7 (2) expanding the use of all existing, safe, and  
8 cost-effective vaccines where they address a public  
9 health problem;

10 (3) accelerating the development and introduc-  
11 tion of new vaccines and technologies;

12 (4) accelerating research and development ef-  
13 forts for vaccines needed primarily in developing  
14 countries; and

15 (5) making immunization coverage a center-  
16 piece in international development efforts.

17 **SEC. 5. CREDIT FOR MEDICAL RESEARCH RELATED TO DE-**  
18 **VELOPING VACCINES AGAINST WIDESPREAD**  
19 **DISEASES.**

20 (a) IN GENERAL.—Subpart D of part IV of sub-  
21 chapter A of chapter 1 of the Internal Revenue Code of  
22 1986 (relating to business related credits) is amended by  
23 adding at the end the following new section:

1 **“SEC. 45D. CREDIT FOR MEDICAL RESEARCH RELATED TO**  
2 **DEVELOPING VACCINES AGAINST WIDE-**  
3 **SPREAD DISEASES.**

4 “(a) GENERAL RULE.—For purposes of section 38,  
5 the vaccine research credit determined under this section  
6 for the taxable year is an amount equal to 30 percent of  
7 the qualified vaccine research expenses for the taxable  
8 year.

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

11 “(1) QUALIFIED VACCINE RESEARCH EX-  
12 PENSES.—

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

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

24 “(i) by substituting ‘vaccine research’  
25 for ‘qualified research’ each place it ap-

1                   pears in paragraphs (2) and (3) of such  
2                   subsection, and

3                   “(ii) by substituting ‘75 percent’ for  
4                   ‘65 percent’ in paragraph (3)(A) of such  
5                   subsection.

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

12                  “(2) VACCINE RESEARCH.—The term ‘vaccine  
13                  research’ means research to develop vaccines and  
14                  microbicides for—

15                         “(A) malaria,

16                         “(B) tuberculosis,

17                         “(C) HIV, or

18                         “(D) any infectious disease (of a single eti-  
19                         ology) which, according to the World Health  
20                         Organization, causes over 1,000,000 human  
21                         deaths annually.

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

24                         “(1) IN GENERAL.—Except as provided in para-  
25                         graph (2), any qualified vaccine research expenses

1 for a taxable year to which an election under this  
2 section applies shall not be taken into account for  
3 purposes of determining the credit allowable under  
4 section 41 for such taxable year.

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

13 “(d) SPECIAL RULES.—

14 “(1) LIMITATIONS ON FOREIGN TESTING.—No  
15 credit shall be allowed under this section with re-  
16 spect to any vaccine research (other than human  
17 clinical testing) conducted outside the United States.

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

22 “(3) ELECTION.—This section (other than sub-  
23 section (e)) shall apply to any taxpayer for any tax-  
24 able year only if such taxpayer elects to have this  
25 section apply for such taxable year.

1       “(e) SHAREHOLDER EQUITY INVESTMENT CREDIT  
2 IN LIEU OF RESEARCH CREDIT.—

3           “(1) IN GENERAL.—For purposes of section 38,  
4 the vaccine research credit determined under this  
5 section for the taxable year shall include an amount  
6 equal to 20 percent of the amount paid by the tax-  
7 payer to acquire qualified research stock in a cor-  
8 poration if—

9           “(A) the amount received by the corpora-  
10 tion for such stock is used within 18 months  
11 after the amount is received to pay qualified  
12 vaccine research expenses of the corporation for  
13 which a credit would (but for subparagraph (B)  
14 and subsection (d)(3)) be determined under this  
15 section, and

16           “(B) the corporation waives its right to the  
17 credit determined under this section for the  
18 qualified vaccine research expenses which are  
19 paid with such amount.

20           “(2) QUALIFIED RESEARCH STOCK.—For pur-  
21 poses of paragraph (1), the term ‘qualified research  
22 stock’ means any stock in a C corporation—

23           “(A) which is originally issued after the  
24 date of the enactment of the Lifesaving Vaccine  
25 Technology Act of 1999,

1           “(B) which is acquired by the taxpayer at  
2           its original issue (directly or through an under-  
3           writer) in exchange for money or other property  
4           (not including stock), and

5           “(C) as of the date of issuance, such cor-  
6           poration meets the gross assets tests of sub-  
7           paragraphs (A) and (B) of section 1202(d)(1).”

8           (b) INCLUSION IN GENERAL BUSINESS CREDIT.—

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

14                 “(13) the vaccine research credit determined  
15                 under section 45D.”.

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

19                 “(9) NO CARRYBACK OF SECTION 45D CREDIT  
20                 BEFORE ENACTMENT.—No portion of the unused  
21                 business credit for any taxable year which is attrib-  
22                 utable to the vaccine research credit determined  
23                 under section 45D may be carried back to a taxable  
24                 year ending before the date of the enactment of sec-  
25                 tion 45D.”.

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

4 “(d) CREDIT FOR QUALIFIED VACCINE RESEARCH  
5 EXPENSES.—

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

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

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

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

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

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

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

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

23 (h) STUDY.—The Institute of Medicine shall conduct  
24 a study of the effectiveness of the credit under section 45D

1 of the Internal Revenue Code of 1986 in stimulating vac-  
2 cine research. Not later than the date which is 5 years  
3 after the date of the enactment of this Act, the Institute  
4 of Medicine shall submit to the Congress the results of  
5 such study together with any recommendations it may  
6 have to improve the effectiveness of such credit in stimu-  
7 lating vaccine research.

8 **SEC. 6. CREDIT FOR CERTAIN SALES OF LIFESAVING VAC-**  
9 **CINES.**

10 (a) IN GENERAL.—Subpart D of part IV of sub-  
11 chapter A of chapter 1 of the Internal Revenue Code of  
12 1986 (relating to business related credits), as amended by  
13 section 5(a), is amended by adding at the end the fol-  
14 lowing new section:

15 **“SEC. 45E. CREDIT FOR CERTAIN SALES OF LIFESAVING**  
16 **VACCINES.**

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

22 “(b) QUALIFIED VACCINE SALES.—For purposes of  
23 this section—

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

4           “(2) QUALIFIED SALE.—

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

7           “(i) to a nonprofit organization, gov-  
8 ernmental unit, or government of any for-  
9 eign government, and

10           “(ii) for distribution in a developing  
11 country.

12           “(B) DEVELOPING COUNTRY.—For pur-  
13 poses of this paragraph, the term ‘developing  
14 country’ means a country which the Inter-  
15 national Bank for Reconstruction and Develop-  
16 ment (commonly referred to as the ‘World  
17 Bank’) determines to be a country with a lower  
18 middle income or less.

19           “(3) QUALIFIED VACCINE.—The term ‘qualified  
20 vaccine’ means a vaccine (as defined in section  
21 4132(a)(2)) which is—

22           “(A) approved by the Food and Drug Ad-  
23 ministration as a new drug after the date of the  
24 enactment of this paragraph, and

25           “(B) used for—

1                   “(i) malaria,  
2                   “(ii) tuberculosis,  
3                   “(iii) HIV, or  
4                   “(iv) any infectious disease (of a sin-  
5                   gle etiology) that is determined by the Sec-  
6                   retary of Health and Human Services  
7                   (after consultation with the Director of the  
8                   Center for Disease Control and Prevention  
9                   and the United States Agency for Inter-  
10                  national Development) to cause the deaths  
11                  of over 1,000,000 people worldwide each  
12                  year.

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

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

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

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

1           “(B) \$125,000,000 for each of years 2007  
2 through 2010, and

3           “(C) zero after 2011.

4           “(2) ALLOCATION OF LIMITATION.—

5           “(A) IN GENERAL.—The limitation amount  
6 under paragraph (1) shall be allocated on a  
7 competitive basis for any calendar year by the  
8 Secretary (in consultation with the Adminis-  
9 trator of the United States Agency for Inter-  
10 national Development) among organizations  
11 with an approved application.

12           “(B) APPROVED APPLICATION.—For pur-  
13 poses of subparagraph (A), the term ‘approved  
14 application’ means an application which is ap-  
15 proved by the Administrator of the United  
16 States Agency for International Development  
17 with respect to a qualified sale made during the  
18 calendar year. Such application shall be made  
19 at such time and in such form and manner as  
20 the Administrator shall prescribe by regulation  
21 and shall include a detailed and cost-effective  
22 plan for distribution of the vaccine.

23           “(3) CARRYOVER OF UNUSED LIMITATION.—If  
24 the limitation amount under paragraph (1) for any  
25 calendar year exceeds the aggregate amount allo-

1 cated under paragraph (2), such limitation for the  
2 following calendar year shall be increased by the  
3 amount of such excess. The limitation amount shall  
4 remain available until expended.

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

7 (b) INCLUSION IN GENERAL BUSINESS CREDIT.—

8 (1) IN GENERAL.—Section 38(b) of the Internal  
9 Revenue Code of 1986 (relating to current year  
10 business credit), as amended by section 5(b)(1), is  
11 amended by striking “plus” at the end of paragraph  
12 (12), by striking the period at the end of paragraph  
13 (13) and inserting “, plus”, and by adding at the  
14 end the following new paragraph:

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

17 (2) TRANSITION RULE.—Section 39(d) of such  
18 Code (relating to transitional rules), as amended by  
19 section 5(b)(2), is amended by adding at the end the  
20 following new paragraph:

21 “(10) NO CARRYBACK OF SECTION 45E CREDIT  
22 BEFORE ENACTMENT.—No portion of the unused  
23 business credit for any taxable year which is attrib-  
24 utable to the lifesaving vaccine sale credit deter-  
25 mined under section 45E may be carried back to a

1 taxable year ending before the date of the enactment  
2 of section 45E.”.

3 (c) CLERICAL AMENDMENT.—The table of sections  
4 for subpart D of part IV of subchapter A of chapter 1  
5 of the Internal Revenue Code of 1986, as amended by sec-  
6 tion 5(e), is amended by adding at the end the following  
7 new item:

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

8 (d) EFFECTIVE DATE.—The amendments made by  
9 this section shall apply to sales of vaccines in taxable years  
10 beginning after December 31, 2000.

11 **SEC. 7. LIFESAVING VACCINE PURCHASE FUND.**

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

13 (1) create incentives for private sector research  
14 into vaccines for HIV, malaria, tuberculosis, and  
15 other major infectious diseases; and

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

18 (b) DEFINITIONS.—In this section:

19 (1) DEVELOPING COUNTRY.—The term “devel-  
20 oping country” means a country which the Inter-  
21 national Bank for Reconstruction and Development  
22 (commonly referred to as the ‘World Bank’) deter-  
23 mines to be a country with a lower middle income  
24 or less.

1           (2) ELIGIBLE VACCINE.—The term “eligible  
2 vaccine” has the meaning given the term “qualified  
3 vaccine” in section 45E(b)(3) of the Internal Rev-  
4 enue Code of 1986.

5           (c) ESTABLISHMENT OF TRUST FUND.—There is es-  
6 tablished in the Treasury of the United States a trust fund  
7 to be known as the “Lifesaving Vaccine Purchase Fund”  
8 (in this section referred to as the “Fund”) consisting of  
9 amounts appropriated under subsection (f).

10          (d) INVESTMENT OF FUND.—Amounts in the Fund  
11 shall be invested in accordance with section 9702 of title  
12 31, United States Code, and any interest on, and proceeds  
13 from any such investment shall be credited to and become  
14 part of the Fund.

15          (e) USE OF FUND.—

16           (1) IN GENERAL.—The Secretary of the Treas-  
17 ury (in this section referred to as the “Secretary”)  
18 is authorized to expend amounts in the Fund for  
19 purchases of eligible vaccines. Such vaccines shall be  
20 distributed to developing countries.

21           (2) LIMITATION.—The Secretary shall not  
22 make expenditures from the Fund in excess of  
23 \$100,000,000 for any fiscal year.

24           (3) REGULATIONS.—The Secretary shall pro-  
25 mulgate such regulations as are necessary to carry

1 out the provisions of this subsection, including regu-  
2 lations regarding—

3 (A) the procedures for purchasing eligible  
4 vaccines, including pricing rules which take into  
5 account the seller's research and development  
6 and manufacturing costs and the desirability of  
7 the vaccine purchased, a funding formula estab-  
8 lishing a minimum price per dose, and min-  
9 imum technical requirements and a market test  
10 requirement for the eligible vaccine; and

11 (B) the distribution of eligible vaccines to  
12 developing countries under agreements between  
13 the United States Agency for International De-  
14 velopment and international organizations or  
15 recipient developing countries that provide  
16 for—

17 (i) consideration of the prevalence of  
18 the disease treated by the eligible vaccine  
19 in the recipient developing country;

20 (ii) consideration of the ability of the  
21 recipient country to effectively and safely  
22 deliver the vaccines; and

23 (iii) a required matching payment by  
24 the recipient developing country based on  
25 the per capita income of the country, in an

1 amount not in excess of 25 percent of the  
2 purchase price paid for such vaccine.

3 (4) CONSULTATION.—The Secretary shall pro-  
4 mulgate regulations under paragraph (3) after ex-  
5 tensive consultation with—

6 (A) the International Bank for Reconstruc-  
7 tion and Development (commonly referred to as  
8 the “World Bank”);

9 (B) the World Health Organization;

10 (C) the Secretary of Health and Human  
11 Services; and

12 (D) the Lifesaving Vaccine Advisory Com-  
13 mission.

14 (f) APPROPRIATIONS.—

15 (1) IN GENERAL.—Subject to paragraph (2),  
16 there are appropriated out of any funds in the  
17 Treasury not otherwise appropriated such sums as  
18 may be necessary to carry out the purposes of the  
19 Fund for each of 10 fiscal years beginning with the  
20 first fiscal year in which the Secretary makes an ex-  
21 penditure from the Fund.

22 (2) LIMITATION.—The amount appropriated for  
23 any fiscal year under paragraph (1) may not exceed  
24 \$100,000,000.

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

4           (4) AVAILABILITY.—Amounts appropriated  
5 under this section shall remain available until ex-  
6 pended.

7 **SEC. 8. MULTILATERAL LIFESAVING VACCINE PURCHASE**  
8 **FUND.**

9           (a) NEGOTIATIONS.—The President should enter into  
10 negotiations with officials of foreign governments and  
11 other interested parties for the establishment of an inter-  
12 national vaccine purchase fund that would—

13           (1) accept contributions from governments of  
14 developed countries;

15           (2) use such contributions to purchase and dis-  
16 tribute in developing countries vaccines for—

17                   (A) malaria,

18                   (B) tuberculosis,

19                   (C) HIV, and

20                   (D) any infectious disease (of a single eti-  
21 ology) which causes the deaths of over  
22 1,000,000 people worldwide each year; and

23           (3) be a significant market incentive for private  
24 sector vaccine research.

1 (b) REPORT.—Not later than 1 year after the date  
2 of enactment of this Act, and annually thereafter, the  
3 President shall report to Congress on—

4 (1) the status of negotiations under subsection  
5 (a); and

6 (2) if such fund is established, any rec-  
7 ommendations for further action, including rec-  
8 ommendations regarding the Lifesaving Vaccine  
9 Purchase Fund established under section 7 of this  
10 Act.

11 **SEC. 9. LIFESAVING VACCINE ADVISORY COMMISSION TO**  
12 **OVERSEE AND EVALUATE PUBLIC PRIVATE**  
13 **VACCINE PARTNERSHIPS.**

14 (a) ESTABLISHMENT.—There is established a com-  
15 mission to be known as the “Lifesaving Vaccine Advisory  
16 Commission” (referred to in this section as the “Commis-  
17 sion”).

18 (b) MEMBERSHIP.—

19 (1) NUMBER AND APPOINTMENT.—

20 (A) IN GENERAL.—The Commission shall  
21 be composed of 12 members, appointed by the  
22 President, as follows:

23 (i) 6 individuals with experience and  
24 expertise in the pharmaceutical or bio-  
25 technology industry.

1 (ii) 6 individuals with experience and  
2 expertise in the medical, public health, or  
3 academic community.

4 The individuals appointed under this subpara-  
5 graph shall not be officers or employees of the  
6 Federal Government, except to the extent that  
7 they are considered to be such officers or em-  
8 ployees by virtue of their membership on the  
9 Commission.

10 (B) QUALIFICATIONS.—The members of  
11 the Commission appointed under subparagraph  
12 (A) should, as a group, achieve a balanced  
13 membership representing the Nation as a whole  
14 and balancing the concerns of the public health  
15 community with the concerns of the bio-  
16 technology and pharmaceutical industry.

17 (2) TIME OF APPOINTMENT.—Each member of  
18 the Commission shall be appointed not later than 90  
19 days after the date of enactment of this Act.

20 (3) TERMS.—Each member of the Commission  
21 shall be appointed for the life of the Commission.

22 (4) VACANCIES.—Any vacancy in the Commis-  
23 sion shall be filled in the same manner in which the  
24 original appointment was made.

25 (5) COMPENSATION.—

1 (A) PROHIBITION OF PAY.—Except as pro-  
2 vided in subparagraph (B), members of the  
3 Commission shall serve without pay.

4 (B) TRAVEL EXPENSES.—Each member of  
5 the Commission may receive travel expenses, in-  
6 cluding per diem in lieu of subsistence, in ac-  
7 cordance with sections 5702 and 5703 of title  
8 5, United States Code.

9 (6) QUORUM.—7 members of the Commission  
10 shall constitute a quorum.

11 (7) CHAIRPERSON.—The Commission shall se-  
12 lect one of the individuals appointed under para-  
13 graph (1) as the chairperson of the Commission.

14 (8) MEETINGS.—The Commission shall meet at  
15 the call of its chairperson or a majority of its mem-  
16 bers.

17 (c) DUTIES.—The Commission shall—

18 (1) review the progress of national and inter-  
19 national efforts to develop vaccines for—

20 (A) malaria;

21 (B) tuberculosis;

22 (C) HIV; and

23 (D) any infectious disease (of a single eti-  
24 ology) that is determined by the Secretary of  
25 Health and Human Services (after consultation

1 with the Director of the Center for Disease  
2 Control and Prevention and the Administrator  
3 of the United States Agency for International  
4 Development) to cause the deaths of over  
5 1,000,000 people worldwide each year;

6 (2) examine the merits of innovative financing  
7 mechanisms, such as tax incentives, purchase funds,  
8 patent exchanges, conditional research and develop-  
9 ment grants based on market pricing agreements,  
10 and other proposals that combine public subsidies  
11 with private sector research and development efforts,  
12 and

13 (3) develop consensus among industry and pub-  
14 lic health advocates on policy recommendations for  
15 ways the Federal Government can further advance  
16 public private partnerships, both nationally and  
17 internationally, in vaccine research and development,  
18 with a goal of finding effective and affordable vac-  
19 cines for the major infectious diseases of the world.

20 (d) STAFF AND SUPPORT SERVICES.—

21 (1) STAFF.—

22 (A) IN GENERAL.—The chairperson of the  
23 Commission may, without regard to civil service  
24 laws and regulations and after consultation  
25 with the Commission, appoint an executive di-

1 rector of the Commission and such other addi-  
2 tional personnel as may be necessary to enable  
3 the Commission to perform its duties.

4 (B) COMPENSATION.—The chairperson of  
5 the Commission may fix the compensation of  
6 the executive director and other personnel with-  
7 out regard to the provisions of chapter 51 and  
8 subchapter III of chapter 53 of title 5, United  
9 States Code, relating to classification of posi-  
10 tions and General Schedule pay rates, except  
11 that the rate of pay for the executive director  
12 and other personnel may not exceed the rate  
13 payable for level V of the Executive Schedule  
14 under section 5316 of such title.

15 (2) STAFF OF FEDERAL AGENCIES.—Upon re-  
16 quest by the chairperson of the Commission, the  
17 head of any Federal department or agency may de-  
18 tail, on a nonreimbursable basis, any of the per-  
19 sonnel of the department or agency to the Commis-  
20 sion to assist the Commission to carry out its duties  
21 under this Act.

22 (3) ADMINISTRATIVE SUPPORT SERVICES.—The  
23 Administrator of General Services shall provide to  
24 the Commission, on a reimbursable basis, any ad-

1       ministrative support services that are necessary to  
2       enable the Commission to carry out this Act.

3       (e) POWERS OF COMMISSION.—

4             (1) HEARINGS.—The Commission may hold  
5       such hearings, sit and act at such times and places,  
6       take such testimony, and receive such evidence as  
7       the Commission considers advisable to carry out the  
8       purposes of this section.

9             (2) INFORMATION FROM FEDERAL AGENCIES.—

10       The Commission may secure directly from any Fed-  
11       eral department or agency such information as the  
12       Commission considers necessary to carry out the  
13       provisions of this section. Upon request of the chair-  
14       person of the Commission, the head of such depart-  
15       ment or agency shall furnish such information to the  
16       Commission.

17             (3) MAILS.—The Commission may use the  
18       United States mails in the same manner and under  
19       the same conditions as any other Federal agency.

20       (f) FINAL REPORT.—Not later than 18 months after  
21       the date of enactment of this Act, the Commission shall  
22       submit to the President and Congress a final report. The  
23       final report shall contain—

24             (1) a summary of the activities of the Commis-  
25       sion;

1           (2) a final accounting of funds received and ex-  
2           pended by the Commission; and

3           (3) any findings and recommendations of the  
4           Commission which are supported by at least 9 mem-  
5           bers.

6 **SEC. 10. SENSE OF CONGRESS.**

7           It is the sense of Congress that flexible or differential  
8           pricing for vaccines, providing lowered prices for the poor-  
9           est countries, is one of several valid strategies to accelerate  
10          the introduction of vaccines in developing countries.

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