To create incentives for private sector research related to developing vaccines against widespread diseases and ensure that such vaccines are affordable and widely distributed.

IN THE SENATE OF THE UNITED STATES

MARCH 1, 2000

Mr. KERRY (for himself, Mr. FRIST, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Foreign Relations

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Vaccines for the New Millennium Act of 2000”.

SEC. 2. FINDINGS.

Congress finds the following:
(1) Vaccines are among the most cost-effective weapons in the arsenal of modern medicine to stop the spread of contagious diseases and strengthen an individual’s immune system to resist a wide range of infectious diseases, and vaccines offer a relatively inexpensive means of lowering a society’s overall cost of medical care.

(2) Every year, up to 3,000,000 children’s lives are saved as the result of early childhood immunizations. But almost 3,000,000 more lives worldwide are lost from diseases that could be prevented with existing vaccines.

(3) Today, 1 in 4 children do not receive the 6 basic vaccinations: polio, diptheria, whooping cough, tetanus, measles, and tuberculosis. The proportion of children immunized against these 6 diseases has declined in recent years, from approximately 80 percent in 1990 to 74 percent in 1998.

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

(5) As well as the challenges of increasing access to existing vaccines, there are additional challenges for research and development of new vaccines.
Over 5,000,000 people die annually from HIV, tuberculosis, and malaria. Vaccines against these infectious diseases are urgently needed.

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

(7) While an estimated $2,000,000,000 is spent annually on research for AIDS treatment, much of it by the private sector, the total global research and development for preventive HIV vaccines is substantially less, perhaps as little as $300,000,000, and of the amount spent on lifesaving vaccine research, only a fraction is financed by private sector drug manufacturers.

(8) Between 7,000,000 and 8,000,000 individuals develop active tuberculosis every year and 2,000,000 to 3,000,000 individuals die from tuberculosis each year, with tuberculosis accounting for more than ¼ of all preventable adult deaths in developing countries. An individual is newly infected
with tuberculosis every second, and someone dies of tuberculosis every 10 seconds.

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

(10) While additional public funds for basic research are critical in the effort to find vaccines for HIV, malaria, and tuberculosis, equally important is a concerted effort by private sector drug manufacturers to find vaccines for these 3 major infectious diseases.

(11) Additional, targeted public subsidies for private sector lifesaving vaccine research and development are justified on the basis that achieving effective and affordable vaccines for HIV, malaria, and tuberculosis will yield public benefits beyond those benefits captured by the manufacturer.

SEC. 3. UNIVERSAL EARLY CHILDHOOD IMMUNIZATIONS.

Section 104(c)(3) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)(3)) is amended in the fourth sentence by striking “the protection of” and all that fol-
laws through “1991” and inserting “the universal protec-
tion of all children from immunizable diseases by Decem-
ber 31, 2009”.

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

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

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

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

(b) REPORT.—The President shall include in the July
1 report submitted to Congress under section 305(b)(1)
of the Foreign Assistance Act of 1961 (22 U.S.C.
2226(b)(1)) for fiscal years 2001 and 2002 a report on
the effectiveness of the Global Alliance for Vaccines and
Immunizations in meeting the goals of—

(1) improving access to sustainable immunization services;

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

(3) accelerating the development and introduction of new vaccines and technologies;

(4) accelerating research and development efforts for vaccines needed primarily in developing
countries; and

(5) making immunization coverage a centerpiece in international development efforts.

SEC. 5. CREDIT FOR MEDICAL RESEARCH RELATED TO DEVELOPING VACCINES AGAINST WIDESPREAD DISEASES.

(a) In General.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business related credits) is amended by adding at the end the following new section:
“SEC. 45D. CREDIT FOR MEDICAL RESEARCH RELATED TO 
DEVELOPING VACCINES AGAINST WIDE-
SPREAD DISEASES.

“(a) GENERAL RULE.—For purposes of section 38, 
the vaccine research credit determined under this section 
for the taxable year is an amount equal to 50 percent of 
the excess (if any) of—

“(1) the qualified vaccine research expenses for 
the taxable year, over 
“(2) the base amount.

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

“(1) QUALIFIED VACCINE RESEARCH EXPENSES.—

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

“(B) MODIFICATIONS.—For purposes of 
subparagraph (A), subsection (b) of section 41 
shall be applied—
“(i) by substituting ‘vaccine research’ for ‘qualified research’ each place it appears in paragraphs (2) and (3) of such subsection, and

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

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

“(2) VACCINE RESEARCH.—

“(A) IN GENERAL.—The term ‘vaccine research’ means research to develop vaccines and microbicides for—

“(i) malaria,

“(ii) tuberculosis,

“(iii) HIV, or

“(iv) any infectious disease (of a single etiology) that is determined by the Secretary of Health and Human Services (after consultation with the Director of the Center for Disease Control and Prevention
and the Administrator of the United States
Agency for International Development) to
cause the deaths of over 1,000,000 people
worldwide each year.

“(B) MICROBICIDE.—The term
‘microbicide’ means a substance used topically
for prevention from infection by an identified
pathogen.

“(C) VACCINE.—The term ‘vaccine’ means
a product using all or portions of the disease-
causing organism or nucleic acid sequences for
prevention from infection by an identified
pathogen.

“(c) BASE AMOUNT.—For purposes of this section,
the term ‘base amount’ means the amount which would
be determined for the taxable year under section 41(c)
(without regard to paragraph (4) thereof) if such sub-
section were applied by substituting ‘qualified vaccine re-
search expenses’ for ‘qualified research expenses’ each
place it appears.

“(d) COORDINATION WITH CREDIT FOR INCREASING
RESEARCH EXPENDITURES.—Any qualified vaccine re-
search expenses for a taxable year to which an election
under this section applies shall not be taken into account
for purposes of determining the credit allowable under section 41 for such taxable year.

“(e) Special Rules.—

“(1) Certain rules made applicable.—

Rules similar to the rules of paragraphs (1) and (2) of section 41(f) shall apply for purposes of this section.

“(2) Election.—This section (other than subsection (f)) shall apply to any taxpayer for any taxable year only if such taxpayer elects to have this section apply for such taxable year.

“(f) Shareholder Equity Investment Credit in Lieu of Research Credit.—

“(1) In general.—For purposes of section 38, the vaccine research credit determined under this section for the taxable year shall include an amount equal to 25 percent of the amount paid by the taxpayer to acquire qualified research stock in a corporation if—

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

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

“(2) QUALIFIED RESEARCH STOCK.—For purposes of paragraph (1), the term ‘qualified research stock’ means any stock in a C corporation—

“(A) which is originally issued after the date of the enactment of the Vaccine for the New Millennium Act of 2000,

“(B) which is acquired by the taxpayer at its original issue (directly or through an underwriter) in exchange for money or other property (not including stock), and

“(C) as of the date of issuance, such corporation meets the gross assets tests of subparagraphs (A) and (B) of section 1202(d)(1).”.

(b) INCLUSION IN GENERAL BUSINESS CREDIT.—

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

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

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

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

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

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

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

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

(d) DEDUCTION FOR UNUSED PORTION OF CREDIT.—Section 196(c) of the Internal Revenue Code of 1986 (defining qualified business credits) is amended by striking “and” at the end of paragraph (7), by striking the period at the end of paragraph (8) and inserting “, and”, and by adding at the end the following new paragraph:

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

(e) CLERICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

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

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

(g) DISTRIBUTION OF VACCINES DEVELOPED USING CREDIT.—It is the sense of Congress that if a tax credit
is allowed under section 45D of the Internal Revenue Code of 1986 to any corporation or shareholder of a corporation by reason of vaccine research expenses incurred by the corporation in the development of a vaccine, such corporation should certify to the Secretary of the Treasury that, within 1 year after that vaccine is first licensed, such corporation will establish a good faith plan to maximize international access to high quality and affordable vaccines.

(h) STUDY.—The Secretary of the Treasury, in consultation with the Institute of Medicine, shall conduct a study of the effectiveness of the credit under section 45D of the Internal Revenue Code of 1986 in stimulating vaccine research. Not later than the date which is 4 years after the date of the enactment of this Act, the Secretary shall submit to the Congress the results of such study together with any recommendations the Secretary may have to improve the effectiveness of such credit in stimulating vaccine research.

SEC. 6. CREDIT FOR CERTAIN SALES OF LIFESAVING VACCINES.

(a) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business related credits), as amended by section 5(a), is amended by adding at the end the following new section:
SEC. 45E. CREDIT FOR CERTAIN SALES OF LIFESAVING VACCINES.

(a) In General.—For purposes of section 38, the lifesaving vaccine sale credit determined under this section with respect to a taxpayer for the taxable year is an amount equal to the amount of qualified vaccine sales for the taxable year.

(b) Qualified Vaccine Sales.—For purposes of this section—

(1) In General.—The term ‘qualified vaccine sales’ means the aggregate amount paid to the taxpayer for a qualified sale.

(2) Qualified Sale.—

(A) In General.—The term ‘qualified sale’ means a sale of a qualified vaccine—

(i) to a nonprofit organization, governmental unit, or government of any foreign government, and

(ii) for distribution in a developing country.

(B) Developing Country.—For purposes of this paragraph, the term ‘developing country’ means a country which the International Bank for Reconstruction and Development (commonly referred to as the ‘World Bank Group’).
Bank’) determines to be a country with a lower middle income or less.

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

“(A) approved by the Food and Drug Administration as a new drug after the date of the enactment of this paragraph, and

“(B) used for—

“(i) malaria,

“(ii) tuberculosis,

“(iii) HIV, or

“(iv) any infectious disease (of a single etiology) that is determined by the Secretary of Health and Human Services (after consultation with the Director of the Center for Disease Control and Prevention and the United States Agency for International Development) to cause the deaths of over 1,000,000 people worldwide each year.

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

“(d) NATIONAL LIMITATION ON AMOUNT OF CREDITS.—

“(1) IN GENERAL.—Except as provided in paragraph (3), there is a lifesaving vaccine sale credit for each calendar year equal to—

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

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

“(C) zero after 2011.

“(2) ALLOCATION OF LIMITATION.—

“(A) IN GENERAL.—The limitation amount under paragraph (1) shall be allocated on a competitive basis for any calendar year by the Secretary (in consultation with the Administrator of the United States Agency for International Development) among organizations with an approved application.

“(B) APPROVED APPLICATION.—For purposes of subparagraph (A), the term ‘approved application’ means an application which is approved by the Administrator of the United States Agency for International Development
with respect to a qualified sale made during the
calendar year. Such application shall be made
at such time and in such form and manner as
the Administrator shall prescribe by regulation
and shall include a detailed and cost-effective
plan for distribution of the vaccine.

“(3) Carryover of Unused Limitation.—If
the limitation amount under paragraph (1) for any
calendar year exceeds the aggregate amount allo-
cated under paragraph (2), such limitation for the
following calendar year shall be increased by the
amount of such excess. The limitation amount shall
remain available until expended.

“(e) Special Rules.—For purposes of this section,
rules similar to the rules of section 41(f)(2) shall apply.”.

(b) Inclusion in General Business Credit.—

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

“(14) the lifesaving vaccine sale credit deter-
mined under section 45E.”.
(2) TRANSITION RULE.—Section 39(d) of such Code (relating to transitional rules), as amended by section 5(b)(2), is amended by adding at the end the following new paragraph:

“(10) NO CARRYBACK OF SECTION 45E CREDIT BEFORE ENACTMENT.—No portion of the unused business credit for any taxable year which is attributable to the lifesaving vaccine sale credit determined under section 45E may be carried back to a taxable year ending before the date of the enactment of section 45E.”.

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

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

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

SEC. 7. LIFESAVING VACCINE PURCHASE FUND.

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

(1) create incentives for private sector research into vaccines for HIV, malaria, tuberculosis, and other major infectious diseases; and
(2) ensure that vaccines for major infectious
diseases are affordable and widely distributed.

(b) DEFINITIONS.—In this section:

(1) DEVELOPING COUNTRY.—The term “develop-
ing country” means a country which the Inter-
national Bank for Reconstruction and Development
(commonly referred to as the “World Bank”) deter-
mines to be a country with a lower middle income
or less.

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

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

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

(e) USE OF FUND.—
(1) **IN GENERAL.**—The Secretary of Treasury (in this section referred to as the “Secretary”) is authorized to expend amounts in the Fund for purchases of eligible vaccines. Such vaccines shall be distributed to developing countries.

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

(3) **REGULATIONS.**—The Secretary shall promulgate such regulations as are necessary to carry out the provisions of this subsection, including regulations regarding—

(A) the procedures for purchasing eligible vaccines, including pricing rules which take into account the seller’s research and development and manufacturing costs and the desirability of the vaccine purchased, a funding formula establishing a minimum price per dose, and minimum technical requirements and a market test requirement for the eligible vaccine; and

(B) the distribution of eligible vaccines to developing countries under agreements between the United States Agency for International Development and international organizations or
recipient developing countries that provide
for—

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

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

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

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

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

(B) the World Health Organization; and

(C) the Secretary of Health and Human
Services.

(f) APPROPRIATIONS.—

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

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

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

(4) AVAILABILITY.—Amounts appropriated under this section shall remain available until expended.

SEC. 8. MULTILATERAL LIFESAVING VACCINE PURCHASE FUND.

(a) NEGOTIATIONS.—The President should enter into negotiations with officials of foreign governments and other interested parties for the establishment of an international vaccine purchase fund that would—

(1) accept contributions from governments of developed countries;

(2) use such contributions to purchase and distribute in developing countries vaccines for—

(A) malaria,
(B) tuberculosis,
(C) HIV, and
(D) any infectious disease (of a single etiology) which causes the deaths of over 1,000,000 people worldwide each year; and
(3) be a significant market incentive for private sector vaccine research.

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

(1) the status of negotiations under subsection (a); and
(2) if such fund is established, any recommendations for further action, including recommendations regarding the Lifesaving Vaccine Purchase Fund established under section 7 of this Act.

SEC. 9. SENSE OF CONGRESS.

It is the sense of Congress that flexible or differential pricing for vaccines, providing lowered prices for the poorest countries, is one of several valid strategies to accelerate the introduction of vaccines in developing countries.