

109TH CONGRESS
1ST SESSION

S. 1698

To accelerate efforts to develop vaccines for diseases primarily affecting developing countries and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 14, 2005

Mr. KERRY (for himself and Mr. LUGAR) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To accelerate efforts to develop vaccines for diseases primarily affecting developing countries and for other purposes.

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 2005”.

6 **SEC. 2. DEFINITIONS.**

7 In this Act:

8 (1) AIDS.—The term “AIDS” has the meaning
9 given the term in section 104A(g) of the Foreign As-
10 sistance Act of 1961 (22 U.S.C. 2151b–2).

1 (2) APPROPRIATE CONGRESSIONAL COMMIT-
2 TEES.—The term “appropriate congressional com-
3 mittees” means the Committee on Appropriations
4 and the Committee on Foreign Relations of the Sen-
5 ate and the Committee on Appropriations and the
6 Committee on International Relations of the House
7 of Representatives.

8 (3) DEVELOPING COUNTRY.—The term “devel-
9 oping country” means a country that the World
10 Bank determines to be a country with a lower mid-
11 dle income or less.

12 (4) HIV/AIDS.—The term “HIV/AIDS” has
13 the meaning given the term in section 104A(g) of
14 the Foreign Assistance Act of 1961 (22 U.S.C.
15 2151b–2).

16 (5) GLOBAL ALLIANCE FOR VACCINES AND IM-
17 MUNIZATIONS.—The term “Global Alliance for Vac-
18 cines and Immunizations” means the public-private
19 partnership launched in 2000 for the purpose of sav-
20 ing the lives of children and protecting the health of
21 all people through the widespread use of vaccines.

22 (6) NEGLECTED DISEASE.—The term “ne-
23 glected disease” means—

24 (A) HIV/AIDS;

25 (B) malaria;

1 (C) tuberculosis; or

2 (D) any infectious disease (of a single eti-
3 ology), which, according to the World Health
4 Organization, causes more than 1,000,000
5 deaths each year in developing countries.

6 (7) WORLD BANK.—The term “World Bank”
7 means the International Bank for Reconstruction
8 and Development.

9 **SEC. 3. FINDINGS.**

10 Congress makes the following findings:

11 (1) Immunization is cheap, reliable, and effec-
12 tive, and has made a profound impact on global
13 health, in both rich and poor countries.

14 (2) During the 20th century, global immuniza-
15 tion efforts have successfully led to the eradication
16 of smallpox and the elimination of polio from the
17 Western Hemisphere, Europe, and most of Asia.
18 Vaccines for diseases such as measles and tetanus
19 have dramatically reduced childhood mortality world-
20 wide, and vaccines for diseases such as influenza,
21 pneumonia, and hepatitis help prevent sickness and
22 death of adults as well as children.

23 (3) According to the World Health Organiza-
24 tion, combined, AIDS, tuberculosis, and malaria kill
25 more than 5,000,000 people a year, most of whom

1 are in the developing world, yet there are no vac-
2 cines for these diseases.

3 (4) It is estimated that just 10 percent of the
4 world's research and development on health is tar-
5 geted on diseases affecting 90 percent of the world's
6 population.

7 (5) Economic disincentives result in little pri-
8 vate sector investment in vaccines for neglected dis-
9 eases, a situation which disproportionately affects
10 populations in developing countries.

11 (6) Of more than \$100,000,000,000 spent on
12 health research and development across the world,
13 only \$6,000,000,000 is spent each year on diseases
14 that are specific to developing countries, most of
15 which is from public and philanthropic sources.

16 (7) Infants, children, and adolescents are
17 among the populations hardest hit by AIDS and ma-
18 laria, but they are at risk of being left behind in the
19 search for effective vaccines against such diseases.

20 (8) Providing a broad range of economic incen-
21 tives to increase private sector research on neglected
22 diseases, including increased public and private sec-
23 tor funding for research and development, guaran-
24 teed markets, tax credits, and improved regulatory
25 procedures would increase the number of products in

1 development and the likelihood of finding effective
2 vaccines for such diseases.

3 **SEC. 4. SENSE OF CONGRESS ON SUPPORT FOR NE-**
4 **GLECTED DISEASES.**

5 It is the sense of Congress that—

6 (1) the President should continue to encourage
7 efforts to support the Global HIV Vaccine Enter-
8 prise, a virtual consortium of scientists and organi-
9 zations committed to accelerating the development of
10 an effective HIV vaccine;

11 (2) the United States should work with the
12 Global Fund to Fight AIDS, Tuberculosis and Ma-
13 laria, the Joint United Nations Programme on HIV/
14 AIDS (“UNAIDS”), the World Health Organiza-
15 tion, the International AIDS Vaccine Initiative, and
16 the World Bank to ensure that all countries heavily
17 affected by the HIV/AIDS pandemic have national
18 AIDS vaccine plans;

19 (3) the United States should support and en-
20 courage the carrying out of the agreements of the
21 Group of 8 made at the 2005 Summit at Gleneagles,
22 Scotland, to increase direct investment and create
23 market incentives, including through public-private
24 partnerships and advance market commitments, to
25 complement public research in the development of

1 vaccines, microbicides, and drugs for HIV/AIDS,
2 malaria, tuberculosis, and other neglected diseases;

3 (4) the United States should support testing of
4 promising vaccines in infants, children, and adoles-
5 cents as early as is medically and ethically appro-
6 priate, in order to avoid significant delays in the
7 availability of pediatric vaccines at the cost of thou-
8 sands of lives;

9 (5) the United States should continue sup-
10 porting the work of the Global Alliance for Vaccines
11 and Immunizations and the Global Fund for Chil-
12 dren's Vaccines as appropriate and effective vehicles
13 to purchase and distribute vaccines for neglected dis-
14 eases at an affordable price once such vaccines are
15 discovered in order to distribute them to the devel-
16 oping world; and

17 (6) the United States should work with others
18 in the international community to address the mul-
19 tiple obstacles to the development of vaccines for ne-
20 glected diseases including scientific barriers, insuffi-
21 cient economic incentives, protracted regulatory pro-
22 cedures, lack of delivery systems for products once
23 developed, liability risks, and intellectual property
24 rights.

1 **SEC. 5. PUBLIC-PRIVATE PARTNERSHIPS.**

2 (a) FINDINGS.—Congress makes the following find-
3 ings:

4 (1) Creative partnerships between governments
5 and organizations in the private sector (including
6 foundations, universities, corporations including
7 pharmaceutical companies and biotechnology firms,
8 community-based organizations and other non-
9 governmental organizations) are playing a critical
10 role in the area of global health, particularly in the
11 fight against neglected diseases, including HIV/
12 AIDS, tuberculosis, and malaria.

13 (2) Public-private sector partnerships increase
14 local and international capacities to improve the de-
15 livery of health services in developing countries and
16 to accelerate research and development of vaccines
17 and other preventive medical technologies essential
18 to combating infectious diseases that disproportion-
19 ately kill people in developing countries.

20 (3) These partnerships maximize the unique ca-
21 pabilities of each sector while combining financial
22 and other resources, scientific knowledge, and exper-
23 tise toward common goals which cannot be achieved
24 by either sector alone.

25 (4) Public-private partnerships such as the
26 International AIDS Vaccine Initiative, the Malaria

1 Vaccine Initiative, and the Global TB Drug Facility
2 are playing cutting edge roles in the efforts to de-
3 velop vaccines for these diseases.

4 (5) Public-private partnerships serve as incen-
5 tives to the research and development of vaccines for
6 neglected diseases by providing biotechnology compa-
7 nies, which often have no experience in developing
8 countries, with technical assistance and on the
9 ground support for clinical trials of the vaccine
10 through the various stages of development.

11 (6) Sustaining existing public-private partner-
12 ships and building new ones where needed are essen-
13 tial to the success of the efforts by the United States
14 and others in the international community to find a
15 cure for these and other neglected diseases.

16 (b) SENSE OF CONGRESS.—It is the sense of Con-
17 gress that—

18 (1) the sustainment and promotion of public-
19 private partnerships must be a central element of
20 the strategy pursued by the United States to create
21 effective incentives for the development of vaccines
22 and other preventive medical technologies for ne-
23 glected diseases debilitating the developing world;
24 and

1 (2) the United States Government should take
2 steps to address the obstacles to the development of
3 these technologies by increasing investment in re-
4 search and development and establishing market and
5 other incentives.

6 (c) POLICY.—It is the policy of the United States to
7 accelerate research and development for vaccines and
8 microbicides for neglected diseases by substantially in-
9 creasing funding for public-private partnerships that in-
10 vest directly in research, such as the International AIDS
11 Vaccine Initiative, the Malaria Vaccine Initiative, and the
12 Global TB Drug Facility, and for partnerships such as
13 the Vaccine Fund that incentivize the development of new
14 vaccines by purchase existing vaccines.

15 **SEC. 6. COMPREHENSIVE STRATEGY FOR ACCELERATING**
16 **THE DEVELOPMENT OF VACCINES FOR NE-**
17 **GLECTED DISEASES.**

18 (a) REQUIREMENT FOR STRATEGY.—The President
19 shall establish a comprehensive strategy to accelerate ef-
20 forts to develop vaccines and microbicides for neglected
21 diseases such as HIV/AIDS, malaria, and tuberculosis.
22 Such strategy shall—

23 (1) expand public-private partnerships and the
24 leveraging of resources from other countries and the
25 private sector;

1 (2) include initiatives to create economic incen-
2 tives for the research, development, and manufac-
3 turing of vaccines for HIV/AIDS, tuberculosis, ma-
4 laria, and other neglected diseases;

5 (3) include the negotiation of advanced market
6 commitments;

7 (4) address intellectual property issues sur-
8 rounding the development of vaccines and
9 microbicides for neglected diseases;

10 (5) maximize United States capabilities to sup-
11 port clinical trials of vaccines and microbicides in
12 developing countries;

13 (6) address the issue of regulatory approval of
14 such vaccines, whether through the Commissioner of
15 the Food and Drug Administration, or the World
16 Health Organization or another internally-recognized
17 and agreed upon entity;

18 (7) expand the purchase and delivery of existing
19 vaccines; and

20 (8) address the challenges of delivering vaccines
21 in developing countries in advance so as to minimize
22 historical delays in access once vaccines are avail-
23 able.

24 (b) REPORT.—Not later than 270 days after the date
25 of enactment of this Act, the President shall submit to

1 the appropriate congressional committees a report setting
2 forth the strategy described in subsection (a) and the steps
3 to implement such strategy.

4 **SEC. 7. ADVANCED MARKET COMMITMENTS.**

5 (a) PURPOSE.—The purpose of this section is to cre-
6 ate incentives for the private sector to invest in research,
7 development, and manufacturing of vaccines for neglected
8 diseases by creating a competitive market for future vac-
9 cines through advanced market commitments.

10 (b) AUTHORITY TO NEGOTIATE.—

11 (1) IN GENERAL.—The Secretary of the Treas-
12 ury shall enter into negotiations with the appro-
13 priate officials of the World Bank, the International
14 Development Association, and Global Alliance for
15 Vaccines and Immunizations, the member nations of
16 such entities, and other interested parties for the
17 purpose of establishing advanced market commit-
18 ments to purchase vaccines and microbicides to com-
19 bat neglected diseases.

20 (2) REPORT.—Not later than 180 days after
21 the date of the enactment of this Act, the Secretary
22 shall submit to the appropriate congressional com-
23 mittees a report on the status of the negotiations to
24 create advanced market commitments under this
25 section.

1 (c) REQUIREMENTS.—The Secretary of the Treasury
2 shall work with the entities referred to in subsection (b)
3 to ensure that there is an international framework for the
4 establishment and implementation of advanced market
5 commitments and that such commitments include—

6 (1) legally binding contracts for product pur-
7 chase that include a fair market price for a guaran-
8 teed number of treatments to ensure that the mar-
9 ket incentive is sufficient;

10 (2) clearly defined and transparent rules of
11 competition for qualified developers and suppliers of
12 the product;

13 (3) clearly defined requirements for eligible vac-
14 cines to ensure that they are safe and effective;

15 (4) dispute settlement mechanisms; and

16 (5) sufficient flexibility to enable the contracts
17 to be adjusted in accord with new information re-
18 lated to projected market size and other factors
19 while still maintaining the purchase commitment at
20 a fair price.

21 (d) TRUST FUND.—

22 (1) AUTHORITY TO ESTABLISH.—On the date
23 that the Secretary of the Treasury determines that
24 a vaccine to combat a neglected disease is available
25 for purchase, the Secretary shall establish in the

1 Treasury of the United States a fund to be known
2 as the Lifesaving Vaccine Purchase Fund consisting
3 of amounts appropriated pursuant to paragraph (4).

4 (2) INVESTMENT OF FUND.—Amounts in such
5 Fund shall be invested in accordance with section
6 9702 of title 31, United States Code, and any inter-
7 est on, and proceeds from any such investment shall
8 be credited to and become part of the Fund.

9 (3) USE OF FUND.—The Secretary is author-
10 ized to expend amounts in such Fund for the pur-
11 chase of a vaccine to combat a neglected disease
12 pursuant to an advanced market commitment under-
13 taken on behalf of the Government of the United
14 States.

15 (4) AUTHORITY TO ACCEPT CONTRIBUTIONS.—
16 The President may accept and use in furtherance of
17 the purposes of this Act contributions from non-
18 governmental organizations, international health
19 agencies, the United Nations, the Global Fund to
20 Fight AIDS, Tuberculosis and Malaria, private non-
21 profit organizations that are organized to support
22 public health research and programs, and any other
23 organizations willing to contribute to the Lifesaving
24 Vaccine Purchase Fund.

25 (5) APPROPRIATIONS.—

1 (A) IN GENERAL.—For each fiscal year be-
 2 ginning after the date that the Secretary deter-
 3 mines that a vaccine to combat a neglected dis-
 4 ease is available for purchase, there are author-
 5 ized to be appropriated out of any funds in the
 6 Treasury not otherwise appropriated such sums
 7 as may be necessary to carry out the purposes
 8 of such Fund.

9 (B) TRANSFER OF FUNDS.—The Secretary
 10 shall transfer the amount appropriated under
 11 paragraph (1) for a fiscal year to such Fund.

12 (C) AVAILABILITY.—Amounts appro-
 13 priated pursuant to this paragraph shall remain
 14 available until expended without fiscal year lim-
 15 itation.

16 **SEC. 8. CREDIT FOR MEDICAL RESEARCH RELATED TO DE-**
 17 **VELOPING VACCINES AGAINST NEGLECTED**
 18 **DISEASES.**

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

1 **“SEC. 45J. CREDIT FOR MEDICAL RESEARCH RELATED TO**
 2 **DEVELOPING VACCINES FOR NEGLECTED**
 3 **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; INCREASED INCEN-
 22 TIVE FOR CONTRACT RESEARCH PAYMENTS.—
 23 For purposes of subparagraph (A), subsection
 24 (b) of section 41 shall be applied—

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

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

3 “(ii) by substituting ‘100 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) HIV/AIDS (as that term is defined in
16 section 104A(g) of the Foreign Assistance Act
17 of 1961 (22 U.S.C. 21516–2)),

18 “(B) malaria,

19 “(C) tuberculosis, or

20 “(D) any infectious disease (of a single eti-
21 ology) which, according to the World Health
22 Organization, causes more than 1,000,000
23 human deaths each year in developing coun-
24 tries.

1 “(c) COORDINATION WITH CREDIT FOR INCREASING
2 RESEARCH EXPENDITURES.—

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

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

17 “(d) SPECIAL RULES.—

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

22 “(2) PRE-CLINICAL RESEARCH.—No credit shall
23 be allowed under this section for pre-clinical re-
24 search unless such research is pursuant to a re-
25 search plan an abstract of which has been filed with

1 the Secretary before the beginning of such year. The
 2 Secretary, in consultation with the Secretary of
 3 Health and Human Services, shall prescribe regula-
 4 tions specifying the requirements for such plans and
 5 procedures for filing under this paragraph.

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

10 “(4) ELECTION.—This section (other than sub-
 11 section (e)) shall apply to any taxpayer for any tax-
 12 able year only if such taxpayer elects to have this
 13 section apply for such taxable year.

14 “(e) CREDIT TO BE REFUNDABLE FOR CERTAIN
 15 TAXPAYERS.—

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

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

20 “(B) the credit so determined shall be al-
 21 lowed as a credit under subpart C.

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

1 “(A) the aggregate gross assets of such
2 corporation at any time during such taxable
3 year are \$500,000,000 or less,

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

7 “(C) as of the close of the taxable year, the
8 corporation is not under the jurisdiction of a
9 court in a title 11 or similar case (within the
10 meaning of section 368(a)(3)(A)),

11 “(D) the corporation provides such assur-
12 ances as the Secretary requires that, not later
13 than 2 taxable years after the taxable year in
14 which the taxpayer receives any refund of a
15 credit under this subsection, the taxpayer will
16 make an amount of qualified vaccine research
17 expenses equal to the amount of such refund,
18 and

19 “(E) the corporation elects the application
20 of this subsection for such taxable year.

21 “(3) AGGREGATE GROSS ASSETS.—Aggregate
22 gross assets shall be determined in the same manner
23 as such assets are determined under section
24 1202(d).

1 “(4) CONTROLLED GROUPS.—A corporation
 2 shall be treated as meeting the requirement of para-
 3 graph (2)(B) only if each person who is treated with
 4 such corporation as a single employer under sub-
 5 sections (a) and (b) of section 52 also meets such re-
 6 quirement.

7 “(5) SPECIAL RULES.—

8 “(A) RECAPTURE OF CREDIT.—The Sec-
 9 retary shall promulgate such regulations as nec-
 10 essary and appropriate to provide for the recap-
 11 ture of any credit allowed under this subsection
 12 in cases where the taxpayer fails to make the
 13 expenditures described in paragraph (2)(D).

14 “(B) EXCLUSION OF CERTAIN QUALIFIED
 15 VACCINE RESEARCH EXPENSES.—For purposes
 16 of determining the credit under this section for
 17 a taxable year, the qualified vaccine research
 18 expenses taken into account for such taxable
 19 year shall not include an amount paid or in-
 20 curred during such taxable year equal to the
 21 amount described in paragraph (2)(D) (and not
 22 already taken into account under this subpara-
 23 graph for a previous taxable year).”.

24 (b) INCLUSION IN GENERAL BUSINESS CREDIT.—
 25 Section 38(b) of the Internal Revenue Code of 1986 is

1 amended by striking “plus” at the end of paragraph (18),
 2 by striking the period at the end of paragraph (19) and
 3 inserting “, plus”, and by adding at the end the following
 4 new paragraph:

5 “(20) the vaccine research credit determined
 6 under section 45J.”.

7 (c) DENIAL OF DOUBLE BENEFIT.—Section 280C of
 8 the Internal Revenue Code of 1986 is amended by adding
 9 at the end the following new subsection:

10 “(e) CREDIT FOR QUALIFIED VACCINE RESEARCH
 11 EXPENSES.—

12 “(1) IN GENERAL.—No deduction shall be al-
 13 lowed for that portion of the qualified vaccine re-
 14 search expenses (as defined in section 45J(b)) other-
 15 wise allowable as a deduction for the taxable year
 16 which is equal to the amount of the credit deter-
 17 mined for such taxable year under section 45J(a).

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

22 (d) DEDUCTION FOR UNUSED PORTION OF CRED-
 23 IT.—Section 196(c) of the Internal Revenue Code of 1986
 24 (defining qualified business credits) is amended by strik-
 25 ing “and” at the end of paragraph (11), by striking the

1 period at the end of paragraph (12) and inserting “, and”,
 2 and by adding at the end the following new paragraph:

3 “(13) the vaccine research credit determined
 4 under section 45J(a) (other than such credit deter-
 5 mined under the rules of section 280C(e)(2)).”.

6 (e) TECHNICAL AMENDMENTS.—

7 (1) Section 1324(b)(2) of title 31, United
 8 States Code, is amended by inserting “or from sec-
 9 tion 45J(e) of such Code,” after “1978,”.

10 (2) The table of sections for subpart D of part
 11 IV of subchapter A of chapter 1 of the Internal Rev-
 12 enue Code of 1986 is amended by adding at the end
 13 the following new item:

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

14 (f) EFFECTIVE DATE.—The amendments made by
 15 this section shall apply to taxable years beginning after
 16 December 31, 2005.

17 (g) STUDY.—

18 (1) IN GENERAL.—The National Institutes of
 19 Health shall conduct a study of the extent to which
 20 the credit under section 45J of the Internal Revenue
 21 Code of 1986, as added by subsection (a), has stim-
 22 ulated vaccine research.

23 (2) REPORT.—Not later than the date that is
 24 5 years after the date of the enactment of this Act,

1 the National Institutes of Health shall submit to
 2 Congress the results of the study conducted under
 3 paragraph (1), together with recommendations (if
 4 any) to improve the effectiveness of such credit in
 5 stimulating vaccine research.

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

8 (a) IN GENERAL.—Subpart D of part IV of sub-
 9 chapter A of chapter 1 of the Internal Revenue Code of
 10 1986 (relating to business related credits), as amended by
 11 section 4, is amended by adding at the end the following
 12 new section:

13 **“SEC. 45K. CREDIT FOR CERTAIN SALES OF LIFESAVING**
 14 **VACCINES.**

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

20 “(b) QUALIFIED VACCINE SALES.—For purposes of
 21 this section—

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

25 “(2) QUALIFIED SALE.—

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

3 “(i) to a nonprofit organization or to
4 a government of any foreign country (or
5 instrumentality of such a government), and

6 “(ii) for distribution in a developing
7 country.

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

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

17 “(A) which is described in section
18 45J(b)(2), and

19 “(B) which is approved as a new drug
20 after the date of the enactment of this para-
21 graph by—

22 “(i) the Food and Drug Administra-
23 tion,

24 “(ii) the World Health Organization,
25 or

1 “(iii) the appropriate authority of a
2 country included in the list under section
3 802(b)(1) of the Federal Food, Drug, and
4 Cosmetic Act.

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

10 “(d) NATIONAL LIMITATION ON AMOUNT OF CRED-
11 ITS.—

12 “(1) IN GENERAL.—Except as provided in para-
13 graph (3), there is a lifesaving vaccine sale credit
14 limitation amount for each calendar year equal to—

15 “(A) \$100,000,000 for each of years 2006
16 through 2010, and

17 “(B) \$125,000,000 for each of years 2011
18 through 2012.

19 “(2) ALLOCATION OF LIMITATION.—

20 “(A) IN GENERAL.—The limitation amount
21 under paragraph (1) shall be allocated for any
22 calendar year by the Administrator of the
23 United States Agency for International Devel-
24 opment (referred to in this section as the ‘Ad-
25 ministrator’) among organizations with an ap-

1 plication approved by the Administrator in ac-
2 cordance with subparagraph (B).

3 “(B) APPLICATION FOR ALLOCATION.—

4 The Administrator shall prescribe the proce-
5 dures for an application for an allocation under
6 this subsection and the factors to be taken into
7 account in making such allocations. Such appli-
8 cations shall be made at such time and in such
9 form and manner as the Administrator shall
10 prescribe and shall include a detailed plan for
11 distribution of the vaccine.

12 “(3) CARRYOVER OF UNUSED LIMITATION.—If

13 the limitation amount under paragraph (1) for any
14 calendar year exceeds the aggregate amount allo-
15 cated under paragraph (2), such limitation for the
16 following calendar year shall be increased by the
17 amount of such excess. No amount may be carried
18 under the preceding sentence to any calendar year
19 after 2024.

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

22 (b) INCLUSION IN GENERAL BUSINESS CREDIT.—

23 Section 38(b) of the Internal Revenue Code of 1986 (relat-
24 ing to current year business credit), as amended by section
25 4(b), is amended by striking “plus” at the end of para-

1 graph (19), by striking the period at the end of paragraph
 2 (20) and inserting “, plus”, and by adding at the end the
 3 following new paragraph:

4 “(21) the lifesaving vaccine sale credit deter-
 5 mined under section 45K.”.

6 (c) CLERICAL AMENDMENT.—The table of sections
 7 for subpart D of part IV of subchapter A of chapter 1
 8 of the Internal Revenue Code of 1986, as amended by sec-
 9 tion 2(c), is amended by adding at the end the following
 10 new item:

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

11 (d) EFFECTIVE DATE.—The amendments made by
 12 this section shall apply to sales of vaccines after December
 13 31, 2005, in taxable years ending after such date.

14 **SEC. 10. SBIR AND STTR PROGRAM FUNDING FOR VACCINE**
 15 **DEVELOPMENT.**

16 (a) PILOT PROGRAM.—Section 9 of the Small Busi-
 17 ness Act (15 U.S.C. 638) is amended by adding at the
 18 end the following:

19 “(x) REQUIRED EXPENDITURES FOR THE DEVELOP-
 20 MENT OF VACCINES FOR NEGLECTED DISEASES.—

21 “(1) SBIR EXPENDITURES.—Each agency re-
 22 quired to make expenditures under subsection (f)(1)
 23 or under subsection (n)(1), that is determined by the
 24 Administrator to have a mission related to global
 25 health or disease prevention shall expend with small

1 business concerns, in addition to any amounts re-
2 quired to be expended under subsections (f) and (n),
3 not less than \$10,000,000 for fiscal year 2006 and
4 each fiscal year thereafter, specifically in connection
5 with SBIR and STTR programs which meet the re-
6 quirements of this section, policy directives, and reg-
7 ulations to carry out this section, to carry out the
8 pilot program established under this subsection.

9 “(2) PILOT PROGRAM.—During the 4-year pe-
10 riod beginning on the date of enactment of the Vac-
11 cines for the New Millennium Act of 2005, the Ad-
12 ministrator shall establish and carry out a program
13 to encourage the development of vaccines and
14 microbicides to combat a neglected disease, including
15 outreach activities to raise awareness of such pro-
16 gram.

17 “(3) ADMINISTRATIVE COSTS.—The limitations
18 in subsection (f)(2) and (n)(2) shall not apply to
19 agency expenditures under the pilot program estab-
20 lished under this subsection.

21 “(4) REPORT.—Six months before the date of
22 expiration of the pilot program established under
23 this subsection, the Administrator shall submit to
24 the Committee on Small Business and Entrepre-
25 neurship of the Senate and the Committee on Small

1 Business of the House of Representatives a report
 2 containing an assessment of whether the pilot pro-
 3 gram is meeting the objective of providing incentives
 4 to small business concerns to research the develop-
 5 ment of vaccines and microbicides to combat a ne-
 6 glected disease, and an accounting of the expendi-
 7 tures for the pilot program.

8 “(5) DEFINITIONS.—As used in this subsection
 9 and subsection (j), the terms ‘neglected disease’ and
 10 ‘developing country’ have the same meanings as in
 11 section 2 of the Vaccines for the New Millennium
 12 Act of 2005.”.

13 (b) POLICY OBJECTIVES.—Section 9(j) of the Small
 14 Business Act (15 U.S.C. 638(j)) is amended by adding
 15 at the end the following:

16 “(4) ADDITIONAL MODIFICATIONS FOR THE DE-
 17 VELOPMENT OF VACCINES FOR A NEGLECTED DIS-
 18 EASE.—Not later than 90 days after the date of en-
 19 actment of the Vaccines for the New Millennium Act
 20 of 2005, the Administrator shall modify the policy
 21 directives issued pursuant to this subsection to en-
 22 sure that agencies participating in the SBIR and
 23 STTR programs develop an action plan for imple-
 24 menting the pilot program for the development of
 25 vaccines and microbicides to combat a neglected dis-

- 1 ease under subsection (x), including outreach to
- 2 raise awareness of the pilot program.”.

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