

109TH CONGRESS
1ST SESSION

H. R. 3781

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 14, 2005

Mr. VISCLOSKY introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committees on International Relations, Energy and Commerce, Small Business, and Financial Services, 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

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:

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

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

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

15 (4) HIV/AIDS.—The term “HIV/AIDS” has
16 the meaning given the term in section 104A(g) of
17 the Foreign Assistance Act of 1961 (22 U.S.C.
18 2151b–2).

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

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

3 (A) HIV/AIDS;

4 (B) malaria;

5 (C) tuberculosis; or

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

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

13 **SEC. 3. FINDINGS.**

14 Congress makes the following findings:

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

18 (2) During the 20th century, global immuniza-
19 tion efforts have successfully led to the eradication
20 of smallpox and the elimination of polio from the
21 Western Hemisphere, Europe, and most of Asia.
22 Vaccines for diseases such as measles and tetanus
23 have dramatically reduced childhood mortality world-
24 wide, and vaccines for diseases such as influenza,

1 pneumonia, and hepatitis help prevent sickness and
2 death of adults as well as children.

3 (3) According to the World Health Organiza-
4 tion, combined, AIDS, tuberculosis, and malaria kill
5 more than 5,000,000 people a year, most of whom
6 are in the developing world, yet there are no vac-
7 cines for these diseases.

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

12 (5) Economic disincentives result in little pri-
13 vate sector investment in vaccines for neglected dis-
14 eases, a situation which disproportionately affects
15 populations in developing countries.

16 (6) Of more than \$100,000,000,000 spent on
17 health research and development across the world,
18 only \$6,000,000,000 is spent each year on diseases
19 that are specific to developing countries, most of
20 which is from public and philanthropic sources.

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

1 (8) Providing a broad range of economic incen-
2 tives to increase private sector research on neglected
3 diseases, including increased public and private sec-
4 tor funding for research and development, guaran-
5 teed markets, tax credits, and improved regulatory
6 procedures would increase the number of products in
7 development and the likelihood of finding effective
8 vaccines for such diseases.

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

11 It is the sense of Congress that—

12 (1) the President should continue to encourage
13 efforts to support the Global HIV Vaccine Enter-
14 prise, a virtual consortium of scientists and organi-
15 zations committed to accelerating the development of
16 an effective HIV vaccine;

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

1 (3) the United States should support and en-
2 courage the carrying out of the agreements of the
3 Group of 8 made at the 2005 Summit at Gleneagles,
4 Scotland, to increase direct investment and create
5 market incentives, including through public-private
6 partnerships and advance market commitments, to
7 complement public research in the development of
8 vaccines, microbicides, and drugs for HIV/AIDS,
9 malaria, tuberculosis, and other neglected diseases;

10 (4) the United States should support testing of
11 promising vaccines in infants, children, and adoles-
12 cents as early as is medically and ethically appro-
13 priate, in order to avoid significant delays in the
14 availability of pediatric vaccines at the cost of thou-
15 sands of lives;

16 (5) the United States should continue sup-
17 porting the work of the Global Alliance for Vaccines
18 and Immunizations and the Global Fund for Chil-
19 dren's Vaccines as appropriate and effective vehicles
20 to purchase and distribute vaccines for neglected dis-
21 eases at an affordable price once such vaccines are
22 discovered in order to distribute them to the devel-
23 oping world; and

24 (6) the United States should work with others
25 in the international community to address the mul-

1 multiple obstacles to the development of vaccines for ne-
2 glected diseases including scientific barriers, insuffi-
3 cient economic incentives, protracted regulatory pro-
4 cedures, lack of delivery systems for products once
5 developed, liability risks, and intellectual property
6 rights.

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

8 (a) FINDINGS.—Congress makes the following find-
9 ings:

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

19 (2) Public-private sector partnerships increase
20 local and international capacities to improve the de-
21 livery of health services in developing countries and
22 to accelerate research and development of vaccines
23 and other preventive medical technologies essential
24 to combating infectious diseases that disproportion-
25 ately kill people in developing countries.

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

6 (4) Public-private partnerships such as the
7 International AIDS Vaccine Initiative, the Malaria
8 Vaccine Initiative, and the Global TB Drug Facility
9 are playing cutting edge roles in the efforts to de-
10 velop vaccines for these diseases.

11 (5) Public-private partnerships serve as incen-
12 tives to the research and development of vaccines for
13 neglected diseases by providing biotechnology compa-
14 nies, which often have no experience in developing
15 countries, with technical assistance and on the
16 ground support for clinical trials of the vaccine
17 through the various stages of development.

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

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

1 (1) the sustainment and promotion of public-
2 private partnerships must be a central element of
3 the strategy pursued by the United States to create
4 effective incentives for the development of vaccines
5 and other preventive medical technologies for ne-
6 glected diseases debilitating the developing world;
7 and

8 (2) the United States government should take
9 steps to address the obstacles to the development of
10 these technologies by increasing investment in re-
11 search and development and establishing market and
12 other incentives.

13 (c) POLICY.—It is the policy of the United States to
14 accelerate research and development for vaccines and
15 microbicides for neglected diseases by substantially in-
16 creasing funding for public-private partnerships that in-
17 vest directly in research, such as the International AIDS
18 Vaccine Initiative, the Malaria Vaccine Initiative, and the
19 Global TB Drug Facility, and for partnerships such as
20 the Vaccine Fund that incentivize the development of new
21 vaccines by purchase existing vaccines.

1 **SEC. 6. COMPREHENSIVE STRATEGY FOR ACCELERATING**
2 **THE DEVELOPMENT OF VACCINES FOR NE-**
3 **GLECTED DISEASES.**

4 (a) REQUIREMENT FOR STRATEGY.—The President
5 shall establish a comprehensive strategy to accelerate ef-
6 forts to develop vaccines and microbicides for neglected
7 diseases such as HIV/AIDS, malaria, and tuberculosis.
8 Such strategy shall—

9 (1) expand public-private partnerships and the
10 leveraging of resources from other countries and the
11 private sector;

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

16 (3) include the negotiation of advanced market
17 commitments;

18 (4) address intellectual property issues sur-
19 rounding the development of vaccines and
20 microbicides for neglected diseases;

21 (5) maximize United States capabilities to sup-
22 port clinical trials of vaccines and microbicides in
23 developing countries;

24 (6) address the issue of regulatory approval of
25 such vaccines, whether through the Commissioner of
26 the Food and Drug Administration, or the World

1 Health Organization or another internally-recognized
2 and agreed upon entity;

3 (7) expand the purchase and delivery of existing
4 vaccines; and

5 (8) address the challenges of delivering vaccines
6 in developing countries in advance so as to minimize
7 historical delays in access once vaccines are avail-
8 able.

9 (b) REPORT.—Not later than 270 days after the date
10 of enactment of this Act, the President shall submit to
11 the appropriate congressional committees a report setting
12 forth the strategy described in subsection (a) and the steps
13 to implement such strategy.

14 **SEC. 7. ADVANCED MARKET COMMITMENTS.**

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

20 (b) AUTHORITY TO NEGOTIATE.—

21 (1) IN GENERAL.—The Secretary of the Treas-
22 ury shall enter into negotiations with the appro-
23 priate officials of the World Bank, the International
24 Development Association, and Global Alliance for
25 Vaccines and Immunizations, the member nations of

1 such entities, and other interested parties for the
2 purpose of establishing advanced market commit-
3 ments to purchase vaccines and microbicides to com-
4 bat neglected diseases.

5 (2) REPORT.—Not later than 180 days after
6 the date of the enactment of this Act, the Secretary
7 shall submit to the appropriate congressional com-
8 mittees a report on the status of the negotiations to
9 create advanced market commitments under this
10 section.

11 (c) REQUIREMENTS.—The Secretary of the Treasury
12 shall work with the entities referred to in subsection (b)
13 to ensure that there is an international framework for the
14 establishment and implementation of advanced market
15 commitments and that such commitments include—

16 (1) legally binding contracts for product pur-
17 chase that include a fair market price for a guaran-
18 teed number of treatments to ensure that the mar-
19 ket incentive is sufficient;

20 (2) clearly defined and transparent rules of
21 competition for qualified developers and suppliers of
22 the product;

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

25 (4) dispute settlement mechanisms; and

1 (5) sufficient flexibility to enable the contracts
2 to be adjusted in accord with new information re-
3 lated to projected market size and other factors
4 while still maintaining the purchase commitment at
5 a fair price.

6 (d) TRUST FUND.—

7 (1) AUTHORITY TO ESTABLISH.—On the date
8 that the Secretary of the Treasury determines that
9 a vaccine to combat a neglected disease is available
10 for purchase, the Secretary shall establish in the
11 Treasury of the United States a fund to be known
12 as the Lifesaving Vaccine Purchase Fund consisting
13 of amounts appropriated pursuant to paragraph (4).

14 (2) INVESTMENT OF FUND.—Amounts in such
15 Fund shall be invested in accordance with section
16 9702 of title 31, United States Code, and any inter-
17 est on, and proceeds from any such investment shall
18 be credited to and become part of the Fund.

19 (3) USE OF FUND.—The Secretary is author-
20 ized to expend amounts in such Fund for the pur-
21 chase of a vaccine to combat a neglected disease
22 pursuant to an advanced market commitment under-
23 taken on behalf of the Government of the United
24 States.

1 (4) AUTHORITY TO ACCEPT CONTRIBUTIONS.—

2 The President may accept and use in furtherance of
3 the purposes of this Act contributions from non-
4 governmental organizations, international health
5 agencies, the United Nations, the Global Fund to
6 Fight AIDS, Tuberculosis and Malaria, private non-
7 profit organizations that are organized to support
8 public health research and programs, and any other
9 organizations willing to contribute to the Lifesaving
10 Vaccine Purchase Fund.

11 (5) APPROPRIATIONS.—

12 (A) IN GENERAL.—For each fiscal year be-
13 ginning after the date that the Secretary deter-
14 mines that a vaccine to combat a neglected dis-
15 ease is available for purchase, there are author-
16 ized to be appropriated out of any funds in the
17 Treasury not otherwise appropriated such sums
18 as may be necessary to carry out the purposes
19 of such Fund.

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

23 (C) AVAILABILITY.—Amounts appro-
24 priated pursuant to this paragraph shall remain

1 available until expended without fiscal year lim-
2 itation.

3 **SEC. 8. CREDIT FOR MEDICAL RESEARCH RELATED TO DE-**
4 **VELOPING VACCINES AGAINST NEGLECTED**
5 **DISEASES.**

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

10 **“SEC. 45J. CREDIT FOR MEDICAL RESEARCH RELATED TO**
11 **DEVELOPING VACCINES FOR NEGLECTED**
12 **DISEASES.**

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

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

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

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

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

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

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

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

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

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

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

4 “(B) malaria,

5 “(C) tuberculosis, or

6 “(D) any infectious disease (of a single eti-
7 ology) which, according to the World Health
8 Organization, causes more than 1,000,000
9 human deaths each year in developing coun-
10 tries.

11 “(c) COORDINATION WITH CREDIT FOR INCREASING
12 RESEARCH EXPENDITURES.—

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

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

1 poses of applying section 41 to subsequent taxable
2 years.

3 “(d) SPECIAL RULES.—

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

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

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

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

1 “(e) CREDIT TO BE REFUNDABLE FOR CERTAIN
2 TAXPAYERS.—

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

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

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

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

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

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

19 “(C) as of the close of the taxable year, the
20 corporation is not under the jurisdiction of a
21 court in a title 11 or similar case (within the
22 meaning of section 368(a)(3)(A)),

23 “(D) the corporation provides such assur-
24 ances as the Secretary requires that, not later
25 than 2 taxable years after the taxable year in

1 which the taxpayer receives any refund of a
2 credit under this subsection, the taxpayer will
3 make an amount of qualified vaccine research
4 expenses equal to the amount of such refund,
5 and

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

8 “(3) AGGREGATE GROSS ASSETS.—Aggregate
9 gross assets shall be determined in the same manner
10 as such assets are determined under section
11 1202(d).

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

18 “(5) SPECIAL RULES.—

19 “(A) RECAPTURE OF CREDIT.—The Sec-
20 retary shall promulgate such regulations as nec-
21 essary and appropriate to provide for the recap-
22 ture of any credit allowed under this subsection
23 in cases where the taxpayer fails to make the
24 expenditures described in paragraph (2)(D).

1 “(B) EXCLUSION OF CERTAIN QUALIFIED
2 VACCINE RESEARCH EXPENSES.—For purposes
3 of determining the credit under this section for
4 a taxable year, the qualified vaccine research
5 expenses taken into account for such taxable
6 year shall not include an amount paid or in-
7 curred during such taxable year equal to the
8 amount described in paragraph (2)(D) (and not
9 already taken into account under this subpara-
10 graph for a previous taxable year).”.

11 (b) INCLUSION IN GENERAL BUSINESS CREDIT.—
12 Section 38(b) of the Internal Revenue Code of 1986 is
13 amended by striking “plus” at the end of paragraph (18),
14 by striking the period at the end of paragraph (19) and
15 inserting “, plus”, and by adding at the end the following
16 new paragraph:

17 “(20) the vaccine research credit determined
18 under section 45J.”.

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

22 “(e) CREDIT FOR QUALIFIED VACCINE RESEARCH
23 EXPENSES.—

24 “(1) IN GENERAL.—No deduction shall be al-
25 lowed for that portion of the qualified vaccine re-

1 search expenses (as defined in section 45J(b)) other-
 2 wise allowable as a deduction for the taxable year
 3 which is equal to the amount of the credit deter-
 4 mined for such taxable year under section 45J(a).

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

9 (d) DEDUCTION FOR UNUSED PORTION OF CRED-
 10 IT.—Section 196(c) of the Internal Revenue Code of 1986
 11 (defining qualified business credits) is amended by strik-
 12 ing “and” at the end of paragraph (11), by striking the
 13 period at the end of paragraph (12) and inserting “, and”,
 14 and by adding at the end the following new paragraph:

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

18 (e) TECHNICAL AMENDMENTS.—

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

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

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

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

4 (g) STUDY.—

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

10 (2) REPORT.—Not later than the date that is
11 5 years after the date of the enactment of this Act,
12 the National Institutes of Health shall submit to
13 Congress the results of the study conducted under
14 paragraph (1), together with recommendations (if
15 any) to improve the effectiveness of such credit in
16 stimulating vaccine research.

17 **SEC. 9. CREDIT FOR CERTAIN SALES OF LIFESAVING VAC-**
18 **CINES.**

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), as amended by
22 section 4, is amended by adding at the end the following
23 new section:

1 **“SEC. 45K. CREDIT FOR CERTAIN SALES OF LIFESAVING**
2 **VACCINES.**

3 “(a) IN GENERAL.—For purposes of section 38, the
4 lifesaving vaccine sale credit determined under this section
5 with respect to a taxpayer for the taxable year is an
6 amount equal to the amount of qualified vaccine sales for
7 the taxable year.

8 “(b) QUALIFIED VACCINE SALES.—For purposes of
9 this section—

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

13 “(2) QUALIFIED SALE.—

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

16 “(i) to a nonprofit organization or to
17 a government of any foreign country (or
18 instrumentality of such a government), and

19 “(ii) for distribution in a developing
20 country.

21 “(B) DEVELOPING COUNTRY.—For pur-
22 poses of this paragraph, the term ‘developing
23 country’ means a country which the Secretary
24 determines to be a country with a lower middle
25 income or less (as such term is used by the

1 International Bank for Reconstruction and De-
2 velopment).

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

5 “(A) which is described in section
6 45J(b)(2), and

7 “(B) which is approved as a new drug
8 after the date of the enactment of this para-
9 graph by—

10 “(i) the Food and Drug Administra-
11 tion,

12 “(ii) the World Health Organization,
13 or

14 “(iii) the appropriate authority of a
15 country included in the list under section
16 802(b)(1) of the Federal Food, Drug, and
17 Cosmetic Act.

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

23 “(d) NATIONAL LIMITATION ON AMOUNT OF CRED-
24 ITS.—

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

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

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

8 “(2) ALLOCATION OF LIMITATION.—

9 “(A) IN GENERAL.—The limitation amount
10 under paragraph (1) shall be allocated for any
11 calendar year by the Administrator of the
12 United States Agency for International Devel-
13 opment (referred to in this section as the ‘Ad-
14 ministrators’) among organizations with an ap-
15 plication approved by the Administrator in ac-
16 cordance with subparagraph (B).

17 “(B) APPLICATION FOR ALLOCATION.—
18 The Administrator shall prescribe the proce-
19 dures for an application for an allocation under
20 this subsection and the factors to be taken into
21 account in making such allocations. Such appli-
22 cations shall be made at such time and in such
23 form and manner as the Administrator shall
24 prescribe and shall include a detailed plan for
25 distribution of the vaccine.

1 “(3) CARRYOVER OF UNUSED LIMITATION.—If
 2 the limitation amount under paragraph (1) for any
 3 calendar year exceeds the aggregate amount allo-
 4 cated under paragraph (2), such limitation for the
 5 following calendar year shall be increased by the
 6 amount of such excess. No amount may be carried
 7 under the preceding sentence to any calendar year
 8 after 2024.

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

11 (b) INCLUSION IN GENERAL BUSINESS CREDIT.—
 12 Section 38(b) of the Internal Revenue Code of 1986 (relat-
 13 ing to current year business credit), as amended by section
 14 4(b), is amended by striking “plus” at the end of para-
 15 graph (19), by striking the period at the end of paragraph
 16 (20) and inserting “, plus”, and by adding at the end the
 17 following new paragraph:

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

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

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

1 (d) EFFECTIVE DATE.—The amendments made by
 2 this section shall apply to sales of vaccines after December
 3 31, 2005, in taxable years ending after such date.

4 **SEC. 10. SBIR AND STTR PROGRAM FUNDING FOR VACCINE**
 5 **DEVELOPMENT.**

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

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

11 “(1) SBIR EXPENDITURES.—Each agency re-
 12 quired to make expenditures under subsection (f)(1)
 13 or under subsection (n)(1), that is determined by the
 14 Administrator to have a mission related to global
 15 health or disease prevention shall expend with small
 16 business concerns, in addition to any amounts re-
 17 quired to be expended under subsections (f) and (n),
 18 not less than \$10,000,000 for fiscal year 2006 and
 19 each fiscal year thereafter, specifically in connection
 20 with SBIR and STTR programs which meet the re-
 21 quirements of this section, policy directives, and reg-
 22 ulations to carry out this section, to carry out the
 23 pilot program established under this subsection.

24 “(2) PILOT PROGRAM.—During the 4-year pe-
 25 riod beginning on the date of enactment of the Vac-

1 cines for the New Millennium Act of 2005, the Ad-
2 ministrator shall establish and carry out a program
3 to encourage the development of vaccines and
4 microbicides to combat a neglected disease, including
5 outreach activities to raise awareness of such pro-
6 gram.

7 “(3) ADMINISTRATIVE COSTS.—The limitations
8 in subsection (f)(2) and (n)(2) shall not apply to
9 agency expenditures under the pilot program estab-
10 lished under this subsection.

11 “(4) REPORT.—Six months before the date of
12 expiration of the pilot program established under
13 this subsection, the Administrator shall submit to
14 the Committee on Small Business and Entrepre-
15 neurship of the Senate and the Committee on Small
16 Business of the House of Representatives a report
17 containing an assessment of whether the pilot pro-
18 gram is meeting the objective of providing incentives
19 to small business concerns to research the develop-
20 ment of vaccines and microbicides to combat a ne-
21 glected disease, and an accounting of the expendi-
22 tures for the pilot program.

23 “(5) DEFINITIONS.—As used in this subsection
24 and subsection (j), the terms ‘neglected disease’ and
25 ‘developing country’ have the same meanings as in

1 section 2 of the Vaccines for the New Millennium
2 Act of 2005.”.

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

6 “(4) ADDITIONAL MODIFICATIONS FOR THE DE-
7 VELOPMENT OF VACCINES FOR A NEGLECTED DIS-
8 EASE.—Not later than 90 days after the date of en-
9 actment of the Vaccines for the New Millennium Act
10 of 2005, the Administrator shall modify the policy
11 directives issued pursuant to this subsection to en-
12 sure that agencies participating in the SBIR and
13 STTR programs develop an action plan for imple-
14 menting the pilot program for the development of
15 vaccines and microbicides to combat a neglected dis-
16 ease under subsection (x), including outreach to
17 raise awareness of the pilot program.”.

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