

110TH CONGRESS
1ST SESSION

S. 569

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 13, 2007

Mr. LUGAR introduced the following bill; which was read twice and referred
to the Committee on Foreign Relations

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 Fu-
5 ture Act of 2007”.

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 Foreign Affairs of the House of Rep-
 7 resentatives.

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) GAVI ALLIANCE.—The term “GAVI Alli-
 17 ance” means the public-private partnership launched
 18 in 2000 for the purpose of saving the lives of chil-
 19 dren and protecting the health of all people through
 20 the widespread use of vaccines.

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

- 23 (A) HIV/AIDS;
- 24 (B) malaria;
- 25 (C) tuberculosis; or

1 (D) any infectious disease that, according
2 to the World Health Organization, afflicts over
3 1,000,000 people and causes more than
4 250,000 deaths each year in developing coun-
5 tries.

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 an inexpensive and effec-
12 tive public health intervention that has had a pro-
13 found life-saving impact around the world.

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) Other, less well-known neglected diseases,
4 such as pneumococcal disease, lymphatic filariasis,
5 leptospirosis, leprosy, and onchocerciasis, result in
6 severe health consequences for individuals afflicted
7 with them, such as anemia, blindness, malnutrition
8 and impaired childhood growth and development. In
9 addition, these diseases result in lost productivity in
10 developing countries costing in the billions of dollars.

11 (5) Infants, children, and adolescents are
12 among the populations hardest hit by AIDS, ma-
13 laria, and many other neglected diseases. Nearly
14 11,000,000 children under age 5 die each year due
15 to these diseases, primarily in developing countries.
16 Existing and future vaccines that target children
17 could prevent more than 2,500,000 of these illnesses
18 and deaths.

19 (6) The devastating impact of neglected dis-
20 eases in developing countries threatens the political
21 and economic stability of these countries and con-
22 stitutes a threat to United States economic and se-
23 curity interests.

24 (7) Of more than \$100,000,000,000 spent on
25 health research and development across the world,

1 only \$6,000,000,000 is spent each year on diseases
2 that are specific to developing countries, most of
3 which is from public and philanthropic sources.

4 (8) Despite the devastating impact these and
5 other diseases have on developing countries, it is es-
6 timated that only 10 percent of the world's research
7 and development on health is targeted on diseases
8 affecting 90 percent of the world's population.

9 (9) Because the developing country market is
10 small and unpredictable, there is an insufficient pri-
11 vate sector investment in research for vaccines for
12 neglected diseases that disproportionately affect pop-
13 ulations in developing countries.

14 (10) Creating a broad range of economic incen-
15 tives to increase private sector research on neglected
16 diseases is critical to the development of vaccines for
17 neglected diseases.

18 (11) In recognition of the need for more eco-
19 nomic incentives to encourage private sector invest-
20 ment in vaccines for neglected diseases, an inter-
21 national group of health, technical, and economic ex-
22 perts has developed a framework for an advance
23 market commitment pilot program for pneumococcal
24 vaccines. Pneumococcal disease, a cause of pneu-
25 monia and meningitis, kills 1,600,000 people every

1 year, an estimated 1,000,000 of whom are children
2 under age 5. This pilot program will seek to stimu-
3 late investments to develop and produce pneumo-
4 coccal vaccines that could prevent between 500,000
5 and 700,000 deaths by the year 2020.

6 (12) On February 9, 2007, 5 countries, Britain,
7 Canada, Italy, Norway, and Russia, together with
8 the Bill and Melinda Gates Foundation, pledged,
9 under a plan called an Advance Market Commit-
10 ment, to purchase pneumococcal vaccines now under
11 development. Together, these countries and the Bill
12 and Melinda Gates Foundation have committed
13 \$1,500,000,000 for this program. Experts believe
14 that this initiative could accelerate by a decade the
15 widespread use of such a vaccine in the developing
16 world and could prevent the deaths of an estimated
17 5,400,000 children by 2030.

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

20 It is the sense of Congress that—

21 (1) the President should continue to encourage
22 efforts to support the Global HIV Vaccine Enter-
23 prise, a virtual consortium of scientists and organi-
24 zations committed to accelerating the development of
25 an effective HIV vaccine;

1 (2) the United States should work with the
2 Global Fund to Fight AIDS, Tuberculosis and Ma-
3 laria, the Joint United Nations Programme on HIV/
4 AIDS (“UNAIDS”), the World Health Organiza-
5 tion, the International AIDS Vaccine Initiative, the
6 GAVI Alliance, and the World Bank to ensure that
7 all countries heavily affected by the HIV/AIDS pan-
8 demic have national AIDS vaccine plans;

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

18 (4) the United States should support the devel-
19 opment of effective vaccines for infants, children,
20 and adolescents as early as is medically and ethically
21 appropriate, in order to avoid significant delays in
22 the availability of pediatric vaccines at the cost of
23 thousands of lives;

24 (5) the United States should continue sup-
25 porting the work of the GAVI Alliance and the Glob-

1 al Fund for Children’s Vaccines as appropriate and
 2 effective vehicles to purchase and distribute vaccines
 3 for neglected diseases at an affordable price once
 4 such vaccines are discovered in order to distribute
 5 them to the developing world;

6 (6) the United States should work with others
 7 in the international community to address the mul-
 8 tiple obstacles to the development of vaccines for ne-
 9 glected diseases including scientific barriers, insuffi-
 10 cient economic incentives, protracted regulatory pro-
 11 cedures, lack of delivery systems for products once
 12 developed, liability risks, and intellectual property
 13 rights; and

14 (7) the United States should contribute to the
 15 pilot Advance Market Commitment for pneumococcal
 16 vaccines launched in Rome on February 9, 2007,
 17 which could prevent some 500,000 to 700,000 child
 18 deaths by the year 2020 and an estimated 5,400,000
 19 child deaths by 2030.

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

21 (a) FINDINGS.—Congress makes the following find-
 22 ings:

23 (1) Partnerships between governments and the
 24 private sector (including foundations, universities,
 25 corporations, community-based organizations, and

1 other nongovernmental organizations) are playing a
 2 critical role in the area of global health, particularly
 3 in the fight against neglected diseases, including
 4 HIV/AIDS, tuberculosis, and malaria.

5 (2) These public-private partnerships improve
 6 the delivery of health services in developing countries
 7 and accelerate research and development of vaccines
 8 and other preventive medical technologies essential
 9 to combating infectious diseases that disproportion-
 10 ately kill people in developing countries.

11 (3) These public-private partnerships maximize
 12 the unique capabilities of each sector while com-
 13 bining financial and other resources, scientific
 14 knowledge, and expertise toward common goals
 15 which cannot be achieved by either sector alone.

16 (4) Public-private partnerships such as the
 17 International AIDS Vaccine Initiative, PATH's Ma-
 18 laria Vaccine Initiative, and the Global TB Drug
 19 Facility are playing cutting edge roles in the efforts
 20 to develop vaccines for these diseases.

21 (5) Public-private partnerships serve as incen-
 22 tives to the research and development of vaccines for
 23 neglected diseases by providing biotechnology compa-
 24 nies, which often have no experience in developing
 25 countries, with technical assistance and on the

1 ground support for clinical trials of the vaccine
2 through the various stages of development.

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

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

10 (1) the sustainment and promotion of public-
11 private partnerships must be a central element of
12 the strategy pursued by the United States to create
13 effective incentives for the development of vaccines
14 and other preventive medical technologies for ne-
15 glected diseases debilitating the developing world;
16 and

17 (2) the United States Government should take
18 steps to address the obstacles to the development of
19 these technologies by increasing investment in re-
20 search and development and establishing market and
21 other incentives.

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 seek
10 to leverage resources from other countries and the
11 private sector;

12 (2) include the negotiation of advance market
13 commitments and other initiatives to create eco-
14 nomic incentives for the research, development, and
15 manufacturing of vaccines and microbicides for HIV/
16 AIDS, tuberculosis, malaria, and other neglected
17 diseases;

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

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

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

1 or the World Health Organization, or another entity;
2 and

3 (6) expand the purchase and delivery of existing
4 vaccines.

5 (b) REPORT.—Not later than 180 days after the date
6 of enactment of this Act, the President shall submit to
7 the appropriate congressional committees a report setting
8 forth the strategy described in subsection (a) and the steps
9 to implement such strategy.

10 **SEC. 7. ADVANCE MARKET COMMITMENTS.**

11 (a) PURPOSE.—The purpose of this section is to im-
12 prove global health by creating a competitive market for
13 future vaccines through advance market commitments.

14 (b) AUTHORITY TO NEGOTIATE.—

15 (1) IN GENERAL.—The Secretary of the Treas-
16 ury shall enter into negotiations with the appro-
17 priate officials of the World Bank, the International
18 Development Association, and the GAVI Alliance,
19 the member nations of such entities, and other inter-
20 ested parties for the purpose of establishing advance
21 market commitments to purchase vaccines and
22 microbicides to combat neglected diseases.

23 (2) REPORT.—Not later than 180 days after
24 the date of the enactment of this Act, the Secretary
25 shall submit to the appropriate congressional com-

1 mittees a report on the status of the negotiations to
2 create advance market commitments under this sec-
3 tion. This report may be submitted as part of the re-
4 port submitted under section 6(b).

5 (c) REQUIREMENTS.—The Secretary of the Treasury
6 shall work with the entities referred to in subsection (b)
7 to ensure that there is an international framework for the
8 establishment and implementation of advance market
9 commitments and that such commitments include—

10 (1) legally binding contracts for product pur-
11 chase that include a fair market price for a guaran-
12 teed number of treatments to ensure that the mar-
13 ket incentive is sufficient;

14 (2) clearly defined and transparent rules of
15 competition for qualified developers and suppliers of
16 the product;

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

19 (4) dispute settlement mechanisms; and

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

25 (d) AUTHORIZATION OF APPROPRIATIONS.—

1 (1) IN GENERAL.—There are authorized to be
2 appropriated such sums as may be necessary for
3 each of fiscal years 2009 through 2014 to fund an
4 advance market commitment pilot program for pneu-
5 mococcal vaccines.

6 (2) AVAILABILITY.—Amounts appropriated pur-
7 suant to this subsection shall remain available until
8 expended without fiscal year limitation.

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