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.

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 Future Act of 2007”.

SEC. 2. DEFINITIONS.

In this Act:

(1) AIDS.—The term “AIDS” has the meaning given the term in section 104A(g) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2).
(2) APPROPRIATE CONGRESSIONAL COMMITTEEES.—The term “appropriate congressional committees” means the Committee on Appropriations and the Committee on Foreign Relations of the Senate and the Committee on Appropriations and the Committee on Foreign Affairs of the House of Representatives.

(3) DEVELOPING COUNTRY.—The term “developing country” means a country that the World Bank determines to be a country with a lower middle income or less.

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

(5) GAVI ALLIANCE.—The term “GAVI Alliance” means the public-private partnership launched in 2000 for the purpose of saving the lives of children and protecting the health of all people through the widespread use of vaccines.

(6) NEGLECTED DISEASE.—The term “neglected disease” means—

(A) HIV/AIDS;

(B) malaria;

(C) tuberculosis; or
any infectious disease that, according to the World Health Organization, afflicts over 1,000,000 people and causes more than 250,000 deaths each year in developing countries.

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

SEC. 3. FINDINGS.

Congress makes the following findings:

(1) Immunization is an inexpensive and effective public health intervention that has had a profound life-saving impact around the world.

(2) During the 20th century, global immunization efforts have successfully led to the eradication of smallpox and the elimination of polio from the Western Hemisphere, Europe, and most of Asia. Vaccines for diseases such as measles and tetanus have dramatically reduced childhood mortality worldwide, and vaccines for diseases such as influenza, pneumonia, and hepatitis help prevent sickness and death of adults as well as children.

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

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

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

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

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

(8) Despite the devastating impact these and other diseases have on developing countries, it is estimated that only 10 percent of the world’s research and development on health is targeted on diseases affecting 90 percent of the world’s population.

(9) Because the developing country market is small and unpredictable, there is an insufficient private sector investment in research for vaccines for neglected diseases that disproportionately affect populations in developing countries.

(10) Creating a broad range of economic incentives to increase private sector research on neglected diseases is critical to the development of vaccines for neglected diseases.

(11) In recognition of the need for more economic incentives to encourage private sector investment in vaccines for neglected diseases, an international group of health, technical, and economic experts has developed a framework for an advance market commitment pilot program for pneumococcal vaccines. Pneumococcal disease, a cause of pneumonia and meningitis, kills 1,600,000 people every
year, an estimated 1,000,000 of whom are children under age 5. This pilot program will seek to stimulate investments to develop and produce pneumococcal vaccines that could prevent between 500,000 and 700,000 deaths by the year 2020.

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

SEC. 4. SENSE OF CONGRESS ON SUPPORT FOR NEGLECTED DISEASES.

It is the sense of Congress that—

(1) the President should continue to encourage efforts to support the Global HIV Vaccine Enterprise, a virtual consortium of scientists and organizations committed to accelerating the development of an effective HIV vaccine;
(2) the United States should work with the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Joint United Nations Programme on HIV/AIDS (‘‘UNAIDS’’), the World Health Organization, the International AIDS Vaccine Initiative, the GAVI Alliance, and the World Bank to ensure that all countries heavily affected by the HIV/AIDS pandemic have national AIDS vaccine plans;

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

(4) the United States should support the development of effective vaccines for infants, children, and adolescents as early as is medically and ethically appropriate, in order to avoid significant delays in the availability of pediatric vaccines at the cost of thousands of lives;

(5) the United States should continue supporting the work of the GAVI Alliance and the Glob-
al Fund for Children’s Vaccines as appropriate and
effective vehicles to purchase and distribute vaccines
for neglected diseases at an affordable price once
such vaccines are discovered in order to distribute
them to the developing world;

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

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

SEC. 5. PUBLIC-PRIVATE PARTNERSHIPS.

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

(1) Partnerships between governments and the
private sector (including foundations, universities,
corporations, community-based organizations, and
other nongovernmental organizations) are playing a critical role in the area of global health, particularly in the fight against neglected diseases, including HIV/AIDS, tuberculosis, and malaria.

(2) These public-private partnerships improve the delivery of health services in developing countries and accelerate research and development of vaccines and other preventive medical technologies essential to combating infectious diseases that disproportionately kill people in developing countries.

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

(4) Public-private partnerships such as the International AIDS Vaccine Initiative, PATH’s Malaria Vaccine Initiative, and the Global TB Drug Facility are playing cutting edge roles in the efforts to develop vaccines for these diseases.

(5) Public-private partnerships serve as incentives to the research and development of vaccines for neglected diseases by providing biotechnology companies, which often have no experience in developing countries, with technical assistance and on the
ground support for clinical trials of the vaccine through the various stages of development.

(6) Sustaining existing public-private partnerships and building new ones where needed are essential to the success of the efforts by the United States and others in the international community to find a cure for these and other neglected diseases.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

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

(2) the United States Government should take steps to address the obstacles to the development of these technologies by increasing investment in research and development and establishing market and other incentives.
SEC. 6. COMPREHENSIVE STRATEGY FOR ACCELERATING
THE DEVELOPMENT OF VACCINES FOR NE-
GLECTED DISEASES.

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

   (1) expand public-private partnerships and seek
to leverage resources from other countries and the
private sector;

   (2) include the negotiation of advance market
commitments and other initiatives to create eco-

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

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

   (5) address the issue of regulatory approval of
such vaccines and microbicides, whether through the
Commissioner of the Food and Drug Administration,
or the World Health Organization, or another entity;
and

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

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

SEC. 7. ADVANCE MARKET COMMITMENTS.

(a) PURPOSE.—The purpose of this section is to improve global health by creating a competitive market for future vaccines through advance market commitments.

(b) AUTHORITY TO NEGOTIATE.—

(1) IN GENERAL.—The Secretary of the Treasury shall enter into negotiations with the appropriate officials of the World Bank, the International Development Association, and the GAVI Alliance, the member nations of such entities, and other interested parties for the purpose of establishing advance market commitments to purchase vaccines and microbicides to combat neglected diseases.

(2) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall submit to the appropriate congressional com-
mittees a report on the status of the negotiations to create advance market commitments under this section. This report may be submitted as part of the report submitted under section 6(b).

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

(1) legally binding contracts for product purchase that include a fair market price for a guaranteed number of treatments to ensure that the market incentive is sufficient;

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

(3) clearly defined requirements for eligible vaccines to ensure that they are safe and effective;

(4) dispute settlement mechanisms; and

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

(d) AUTHORIZATION OF APPROPRIATIONS.—
(1) **IN GENERAL.**—There are authorized to be appropriated such sums as may be necessary for each of fiscal years 2009 through 2014 to fund an advance market commitment pilot program for pneumococcal vaccines.

(2) **AVAILABILITY.**—Amounts appropriated pursuant to this subsection shall remain available until expended without fiscal year limitation.