H. R. 1532

To amend the Public Health Service Act with respect to making progress toward the goal of eliminating tuberculosis, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 15, 2007

Mr. GENE GREEN of Texas (for himself, Mrs. WILSON of New Mexico, and Ms. BALDWIN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act with respect to making progress toward the goal of eliminating tuberculosis, 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
4 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
5 (a) SHORT TITLE.—This Act may be cited as the
6 “Comprehensive Tuberculosis Elimination Act of 2007”.
7 (b) TABLE OF CONTENTS.—The table of contents for
8 this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings.

TITLE I—CENTERS FOR DISEASE CONTROL AND PREVENTION
Subtitle A—National Program for Elimination of Tuberculosis

Sec. 101. National program.

Subtitle B—Interagency Collaboration

Sec. 111. Advisory council for elimination of tuberculosis.

Subtitle C—New Tools for Tuberculosis Elimination

Sec. 121. New tools.

Subtitle D—Authorizations of Appropriations

Sec. 131. Authorizations of appropriations.

TITLE II—NATIONAL INSTITUTES OF HEALTH

Sec. 201. Activities of National Heart, Lung, and Blood Institute.
Sec. 202. Activities of National institute of Allergy and Infectious Diseases.
Sec. 203. John E. Fogarty International Center for Advanced Study in the Health Sciences.
Sec. 204. Loan repayment programs regarding research on tuberculosis.
Sec. 205. Authorization of appropriations.

1 SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Each year approximately 9 million people become ill with active tuberculosis (“TB”), and 2 million of those people die. This is a direct result of the disease having the ability to develop resistance to treatments and to travel easily across borders.

(2) In 2005, there were 14,093 cases of active TB reported in the United States. However, the decline of 3.8 percent in the national TB case rate from 2004 to 2005 was one of the smallest declines in more than a decade.

(3) In addition to those with active TB, an estimated 10 to 15 million people in the United States have latent TB.
(4) The increasing occurrence of multidrug resistant (‘‘MDR’’) TB, including extensively drug resistant (‘‘XDR’’) TB—which is resistant to at least two main first-line drugs and additionally to three or more of the six classes of second-line drugs—raises concerns of a future epidemic of virtually untreatable TB.

(5) The Centers for Disease Control and Prevention is increasingly relied upon globally for its expertise and technical assistance in global tuberculosis preparedness and outbreak response capacity to identify and investigate outbreaks of multidrug resistant and extensively drug resistant TB.

(6) New tools are needed to more effectively prevent, diagnose, and treat TB. The standard method of diagnosing TB is over 100 years old, and fails to adequately detect TB in children and those co-infected with HIV/AIDS. The newest class of anti-TB drug is 40 years old, while rates of multidrug resistant TB are rising globally.
TITLE I—CENTERS FOR DISEASE CONTROL AND PREVENTION
Subtitle A—National Program for Elimination of Tuberculosis

SEC. 101. NATIONAL PROGRAM.

Section 317E of the Public Health Service Act (42 U.S.C. 247b–6) is amended—

(1) by striking the heading for the section and inserting the following: “NATIONAL PROGRAM FOR ELIMINATION OF TUBERCULOSIS”; and

(2) by amending subsection (b) to read as follows:

“(b) RESEARCH AND DEVELOPMENT; DEMONSTRATION PROJECTS; EDUCATION AND TRAINING.—With respect to the prevention, control, and elimination of tuberculosis, the Secretary may, directly or through grants to public or nonprofit private entities, carry out the following:

“(1) Research, with priority given to research and development concerning—

“(A) clinical trials to evaluate the safety and effectiveness of new drugs, diagnostics, and vaccines for latent tuberculosis infection and active tuberculosis;

“(B) epidemiological studies of populations at risk of tuberculosis; and
“(C) field studies to evaluate the effectiveness of new drugs, diagnostics, and vaccines, and evaluation of efforts to eliminate the disease.

“(2) Demonstration projects for—

“(A) the development of regional capabilities to prevent, control and eliminate tuberculosis;

“(B) the intensification of efforts—

“(i) to prevent, detect, and treat tuberculosis among African Americans and other United States-born populations with documented health disparities; and

“(ii) to reduce or eliminate racial disparities in the incidence of tuberculosis in these populations;

“(C) the intensification of efforts to control tuberculosis along the United States-Mexico border and among United States-Mexico binational populations;

“(D) the intensification of efforts to prevent, detect, and treat tuberculosis among foreign-born persons who are in the United States; and
“(E) collaboration with Immigration and Customs Enforcement to identify and treat immigrants with active or latent tuberculosis infection.

“(3) A public information and education program.

“(4) Education, training and clinical skills improvement activities for health professionals, including allied health personnel and emergency response employees.

“(5) Provide support for the Tuberculosis Trials Consortium, the Tuberculosis Epidemiologic Studies Consortium, and Regional Training and Medical Consultation Centers to carry out activities under paragraphs (1) through (4).

“(6) Collaboration with international organizations and foreign countries in carrying out such activities.”.

Subtitle B—Interagency Collaboration

SEC. 111. ADVISORY COUNCIL FOR ELIMINATION OF TUBERCULOSIS.

(a) In General.—Section 317E(f) of the Public Health Service Act (42 U.S.C. 247b–6(f)) is amended—
(1) by redesignating paragraph (5) as paragraph (6); and

(2) by striking paragraphs (2) through (4), and inserting the following:

“(2) DUTIES.—The Council shall provide advice and recommendations regarding the elimination of tuberculosis to the Secretary, the Assistant Secretary for Health, and the Director of the Centers for Disease Control and Prevention. In addition, the Council shall, with respect to eliminating such disease, provide to the Secretary and other appropriate Federal officials advice on—

“(A) coordinating the activities of the Public Health Service and other Federal agencies that relate to the disease, including activities under subsection (b); and

“(B) efficiently utilizing the Federal resources involved.

“(3) NATIONAL PLAN.—

“(A) IN GENERAL.—In carrying out paragraph (2), the Council shall make recommendations on the development, revision, and implementation of a national plan to eliminate tuberculosis in the United States.
“(B) CONSULTATION.—In carrying out subparagraph (A), the Council shall consult with public and private entities, including—

“(i) individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the Federal Government and who represent the disciplines relevant to tuberculosis elimination;

“(ii) members of public-private partnerships established to address the elimination of tuberculosis;

“(iii) members of national and international nongovernmental organizations established to address tuberculosis elimination; and

“(iv) members from the general public who are knowledgeable with respect to tuberculosis elimination including individuals who have or have had tuberculosis.

“(C) CERTAIN COMPONENTS OF PLAN.—In carrying out subparagraph (A), the Council shall—
“(i) consider the recommendations of the Institute of Medicine regarding the elimination of tuberculosis;

“(ii) consider recommendations for the involvement of the United States in continuing global and cross-border tuberculosis control activities in countries where a high incidence of tuberculosis directly affects the United States such as Mexico; and

“(iii) review the extent to which progress has been made toward eliminating tuberculosis.

“(4) ANNUAL REPORT.—The Council shall annually submit to Congress and the Secretary a report on the activities carried under this section, other than subsection (g). Each such report shall include the opinion of the Council on the extent to which its recommendations regarding the elimination of tuberculosis have been implemented, including with respect to—

“(A) activities under subsection (b); and

“(B) the national plan referred to in paragraph (3).
“(5) COMPOSITION.—The Council shall be composed of—

“(A) representatives from the Centers for Disease Control and Prevention, the National Institutes of Health, the United States Agency for International Development, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the United States-Mexico Border Health Commission, and other Federal departments and agencies that carry out significant activities related to tuberculosis;

“(B) State and local tuberculosis control and public health and officials;

“(C) individuals who are scientists, physicians, laboratorians, and other health professionals who represent disciplines relevant to tuberculosis elimination;

“(D) members of national and international nongovernmental organizations established to address the elimination of tuberculosis; and

“(E) members from the general public who are knowledgeable with respect to the elimi-
nation of tuberculosis, including individuals who
have or have had tuberculosis.”.

(b) Rule of Construction Regarding Current
Membership.—With respect to the advisory council
under section 317E(f) of the Public Health Service Act,
the amendments made by subsection (a) may not be con-
strued as terminating the membership on such council of
any individual serving as such a member as of the day
before the date of the enactment of this Act.

Subtitle C—New Tools for
Tuberculosis Elimination

SEC. 121. NEW TOOLS.

Section 317E of the Public Health Service Act (42
U.S.C. 247b–6) is amended—

(1) by redesignating subsection (g) as sub-
section (h); and

(2) by inserting after subsection (f) the fol-
lowing subsection:

“(g) New Tools for Elimination of Tubercu-
losis.—

“(1) Research and development on drugs,

diagnostics, vaccines, and public health

interventions.—The Secretary, acting through

the Director of the Centers for Disease Control and

Prevention, shall expand, intensify, and coordinate
research and development and related activities of such Centers to develop new tools for the elimination of tuberculosis, including drugs, diagnostics, vaccines, and public health interventions.

“(2) FEDERAL TUBERCULOSIS TASK FORCE.—

“(A) DUTIES.—The Federal Tuberculosis Task Force (established in December 2001 as part of the Centers for Disease Control and Prevention) (in this subsection referred to as the ‘Task Force’) shall provide to the Secretary and other appropriate Federal officials advice on the implementation of paragraph (1), including advice regarding the efficient utilization of the Federal resources involved.

“(B) NATIONAL PLAN FOR NEW TOOLS DEVELOPMENT.—In carrying out paragraph (1), the Task Force shall make recommendations on the development of a national plan for the development of new tools for the elimination of tuberculosis, including drugs, diagnostics, and vaccines.

“(C) CONSULTATION.—In developing the national plan under paragraph (1), the Task Force shall consult with—
“(i) scientists, physicians, and other health professionals and who represent the specialties and disciplines relevant to the research under consideration;

“(ii) members from public-private partnerships or foundations (or both) engaged in research relevant to research under consideration;

“(iii) members of national and international nongovernmental organizations established to address tuberculosis elimination;

“(iv) members from the general public who are knowledgeable with respect to tuberculosis, including individuals who have or have had tuberculosis; and

“(v) scientists, physicians, and other health professionals who reside in a foreign country with a substantial incidence or prevalence of tuberculosis, and who represent the specialties and disciplines relevant to the research under consideration.

“(3) GRANTS AND CONTRACTS.—The Secretary shall carry out paragraph (1) directly and through
awards of grants, cooperative agreements, and contracts to public and private entities, including—

“(A) public-private partnerships;

“(B) academic institutions, including institutions of higher education;

“(C) research institutions; and

“(D) the Tuberculosis Trials Consortium and the Tuberculosis Epidemiologic Studies Consortium.”.

Subtitle D—Authorizations of Appropriations

SEC. 131. AUTHORIZATIONS OF APPROPRIATIONS.

Section 317E of the Public Health Service Act, as amended by section 121(1) of this Act, is amended by amending subsection (h) to read as follows:

“(h) Authorization of Appropriations.—

“(1) General Program.—

“(A) In general.—For the purpose of carrying out this section, other than subsection (g), there are authorized to be appropriated $528,000,000 for fiscal year 2008, and such sums as may be necessary for each of the fiscal years 2009 through 2012.

“(B) Reservation for Emergency Grants.—Of the amounts appropriated under
subparagraph (A) for a fiscal year, the Secretary may reserve not more than 25 percent for emergency grants under subsection (a) for any geographic area in which there is, relative to other areas, a substantial number of cases of tuberculosis, multidrug resistant tuberculosis, or extensively resistant tuberculosis or a substantial rate of increase in such cases.

“(C) PRIORITY.—In allocating amounts appropriated under subparagraph (A) and not reserved under subparagraph (B), the Secretary shall give priority to allocating such amounts for grants under subsection (a).

“(D) ALLOCATION OF FUNDS.—

“(i) REQUIREMENT OF FORMULA.—Of the amounts appropriated under subparagraph (A), not reserved under subparagraph (B), and allocated by the Secretary for grants under subsection (a), the Secretary shall distribute such amounts to grantees under subsection (a) on the basis of a formula.

“(ii) RELEVANT FACTORS.—The formula developed by the Secretary under clause (i) shall take into account the level
of tuberculosis morbidity in the respective
geographic area and may consider other
factors relevant to tuberculosis in such
area.

“(iii) NO CHANGE TO FORMULA RE-
QUIRED.—This subparagraph does not re-
quire the Secretary to modify the formula
that was used by the Secretary to dis-
tribute funds to grantees under subsection
(a) for fiscal year 2007.

“(2) NEW TOOLS.—

“(A) IN GENERAL.—For the purpose of
carrying out subsection (g), there are author-
ized to be appropriated $100,000,000 for fiscal
year 2008, and such sums as may be necessary
for each of the fiscal years 2009 through 2012.

“(B) LIMITATION.—The authorization of
appropriations established in subparagraph (A)
for a fiscal year is effective only if the amount
appropriated under paragraph (1) for such year
equals or exceeds the amount appropriated to
carry out this section for fiscal year 2007.”.
TITLE II—NATIONAL INSTITUTES OF HEALTH

SEC. 201. ACTIVITIES OF NATIONAL HEART, LUNG, AND BLOOD INSTITUTE.

Subpart 2 of part C of title IV of the Public Health Service Act (42 U.S.C. 285b et seq.) is amended by inserting after section 424B the following section:

"SEC. 424C. TUBERCULOSIS.

"(a) In General.—The Director of the Institute shall expand, intensify, and coordinate research and development and related activities of the Institute with respect to tuberculosis, including activities toward the goal of eliminating such disease.

"(b) Certain Activities.—Activities under subsection (a) shall include—

"(1) enhancing basic and clinical research on tuberculosis; and

"(2) expanding research on the relationship between such disease and the human immunodeficiency virus.

"(c) Research Education.—

"(1) Tuberculosis Academic Awards.—The Director of the Institute may provide awards to faculty of schools of medicine or osteopathic medicine to assist such faculty in developing high quality cur-
ricula in such schools designed to significantly in-
crease the opportunities for interested individuals,
including students of the school and practicing phy-
sicians and nurses, to learn the principles and prac-
tices of preventing, managing, and controlling tuber-
culosis.

“(2) TUBERCULOSIS/PULMONARY INFECTION
AWARDS.—The Director of the Institute may provide
awards to support the career development of clini-
cally trained professionals who are committed to re-
search regarding pulmonary infections and tuber-
culosis by providing for supervised study and re-
search.”.

SEC. 202. ACTIVITIES OF NATIONAL INSTITUTE OF AL-
LERGY AND INFECTIOUS DISEASES.

Section 447A of the Public Health Service Act (42
U.S.C. 285f–2) is amended—

(1) by striking “In carrying out section 446”
and inserting“(a) In carrying out section 446”; and

(2) by inserting at the end the following:

“(b) Activities under subsection (a) shall include ac-
tivities to develop a tuberculosis vaccine. Such activities
shall be carried out in accordance with the blueprint for
tuberculosis vaccine development described in the report
prepared pursuant to the workshop convened in March
1998 by the Advisory Council for Elimination of Tuberculosis, the Director of the National Vaccine Program, and the Director of the Institute.”.

SEC. 203. JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES.

Section 482 of the Public Health Service Act (42 U.S.C. 287b) is amended—

1. by inserting “(a) IN GENERAL.—” before “The general purpose”;

2. in subsection (a) (as so designated), by inserting after “Health Sciences” the following: “(in this subpart referred to as the ‘Center’)”; and

3. by adding at the end the following subsection:

“(b) TUBERCULOSIS.—

“(1) IN GENERAL.—In carrying out subsection (a) with respect to tuberculosis, the Center shall expand, intensify, and coordinate international activities of the Center for research and training.

“(2) INTERNATIONAL TRAINING PROGRAM.—In carrying out paragraph (1), the Center shall carry out an international training program regarding tuberculosis. Such program shall be modeled after the international training program carried out by the
Center with respect to the human immunodeficiency
virus.”.

SEC. 204. LOAN REPAYMENT PROGRAMS REGARDING RE-
SEARCH ON TUBERCULOSIS.

Part G of title IV of the Public Health Service Act
(42 U.S.C. 288 et seq.) is amended—

(1) by redesignating the second section 487F as
section 487G; and

(2) by inserting after section 487G (as so re-
designated) the following section:

“LOAN REPAYMENTS REGARDING RESEARCH ON
TUBERCULOSIS

“Sec. 487H. In carrying out sections 487C, 487E,
and 487F, the Secretary shall seek to ensure that, for fis-
cal year 2008 and subsequent fiscal years, a portion of
amounts appropriated to carry out such sections is re-
served for the purpose of entering into contracts under
which (in accordance with the section involved) individuals
will conduct research on tuberculosis.”.

SEC. 205. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this title and the
amendments made by this title, there are authorized to
be appropriated such sums as may be necessary. Such au-
thorization of appropriations shall be in addition to the
authorization of appropriations established by section
402A(a) of the Public Health Service Act and any other authorization of appropriations available for such purpose.