110TH CONGRESS 1ST SESSION

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 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
- 4 (a) Short Title.—This Act may be cited as the
- 5 "Comprehensive Tuberculosis Elimination Act of 2007".
- 6 (b) Table of Contents for
- 7 this Act is as follows:
 - Sec. 1. Short title; table of contents.
 - Sec. 2. Findings.

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.

- 2 The Congress finds as follows:
- 3 (1) Each year approximately 9 million people
- become ill with active tuberculosis ("TB"), and 2
- 5 million of those people die. This is a direct result of
- 6 the disease having the ability to develop resistance
- 7 to treatments and to travel easily across borders.
- 8 (2) In 2005, there were 14,093 cases of active
- 9 TB reported in the United States. However, the de-
- cline 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.
- 13 (3) In addition to those with active TB, an esti-
- mated 10 to 15 million people in the United States
- have latent TB.

- 1 (4) The increasing occurrence of multidrug re2 sistant ("MDR") TB, including extensively drug re3 sistant ("XDR") TB—which is resistant to at least
 4 two main first-line drugs and additionally to three or
 5 more of the six classes of second-line drugs—raises
 6 concerns of a future epidemic of virtually untreat7 able 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 1 CONTROL AND PREVENTION 2 **Subtitle A—National Program for** 3 **Elimination of Tuberculosis** 4 5 SEC. 101. NATIONAL PROGRAM. 6 Section 317E of the Public Health Service Act (42 7 U.S.C. 247b-6) is amended— 8 (1) by striking the heading for the section and 9 inserting the following: "NATIONAL PROGRAM FOR 10 ELIMINATION OF TUBERCULOSIS"; and 11 (2) by amending subsection (b) to read as fol-12 lows: 13 "(b) Research and Development; Demonstra-TION PROJECTS; EDUCATION AND TRAINING.—With respect to the prevention, control, and elimination of tuber-15 culosis, the Secretary may, directly or through grants to 16 public or nonprofit private entities, carry out the following: 17 18 "(1) Research, with priority given to research 19 and development concerning— "(A) clinical trials to evaluate the safety 20 21 and effectiveness of new drugs, diagnostics, and 22 vaccines for latent tuberculosis infection and ac-23 tive tuberculosis: 24 "(B) epidemiological studies of populations 25 at risk of tuberculosis; and

1	"(C) field studies to evaluate the effective-
2	ness of new drugs, diagnostics, and vaccines,
3	and evaluation of efforts to eliminate the dis-
4	ease.
5	"(2) Demonstration projects for—
6	"(A) the development of regional capabili-
7	ties to prevent, control and eliminate tuber-
8	culosis;
9	"(B) the intensification of efforts—
10	"(i) to prevent, detect, and treat tu-
11	berculosis among African Americans and
12	other United States-born populations with
13	documented health disparities; and
14	"(ii) to reduce or eliminate racial dis-
15	parities in the incidence of tuberculosis in
16	these populations;
17	"(C) the intensification of efforts to con-
18	trol tuberculosis along the United States-Mexico
19	border and among United States-Mexico bina-
20	tional populations;
21	"(D) the intensification of efforts to pre-
22	vent, detect, and treat tuberculosis among for-
23	eign-born persons who are in the United States;
24	and

1	"(E) collaboration with Immigration and
2	Customs Enforcement to identify and treat im-
3	migrants with active or latent tuberculosis in-
4	fection.
5	"(3) A public information and education pro-
6	gram.
7	"(4) Education, training and clinical skills im-
8	provement activities for health professionals, includ-
9	ing allied health personnel and emergency response
10	employees.
11	"(5) Provide support for the Tuberculosis
12	Trials Consortium, the Tuberculosis Epidemiologic
13	Studies Consortium, and Regional Training and
14	Medical Consultation Centers to carry out activities
15	under paragraphs (1) through (4).
16	"(6) Collaboration with international organiza-
17	tions and foreign countries in carrying out such ac-
18	tivities.".
19	Subtitle B—Interagency
20	Collaboration
21	SEC. 111. ADVISORY COUNCIL FOR ELIMINATION OF TU-
22	BERCULOSIS.
23	(a) In General.—Section 317E(f) of the Public
24	Health Service Act (42 U.S.C. 247b–6(f)) is amended—

1	(1) by redesignating paragraph (5) as para-
2	graph (6); and
3	(2) by striking paragraphs (2) through (4), and
4	inserting the following:
5	"(2) Duties.—The Council shall provide advice
6	and recommendations regarding the elimination of
7	tuberculosis to the Secretary, the Assistant Sec-
8	retary for Health, and the Director of the Centers
9	for Disease Control and Prevention. In addition, the
10	Council shall, with respect to eliminating such dis-
11	ease, provide to the Secretary and other appropriate
12	Federal officials advice on—
13	"(A) coordinating the activities of the Pub-
14	lic Health Service and other Federal agencies
15	that relate to the disease, including activities
16	under subsection (b); and
17	"(B) efficiently utilizing the Federal re-
18	sources involved.
19	"(3) National Plan.—
20	"(A) In general.—In carrying out para-
21	graph (2), the Council shall make recommenda-
22	tions on the development, revision, and imple-
23	mentation of a national plan to eliminate tuber-
24	culosis in the United States.

1	"(B) Consultation.—In carrying out
2	subparagraph (A), the Council shall consult
3	with public and private entities, including—
4	"(i) individuals who are scientists,
5	physicians, and other health professionals,
6	who are not officers or employees of the
7	Federal Government and who represent the
8	disciplines relevant to tuberculosis elimi-
9	nation;
10	"(ii) members of public-private part-
11	nerships established to address the elimi-
12	nation of tuberculosis;
13	"(iii) members of national and inter-
14	national nongovernmental organizations es-
15	tablished to address tuberculosis elimi-
16	nation; and
17	"(iv) members from the general public
18	who are knowledgeable with respect to tu-
19	berculosis elimination including individuals
20	who have or have had tuberculosis.
21	"(C) CERTAIN COMPONENTS OF PLAN.—In
22	carrying out subparagraph (A), the Council
23	shall—

1	"(i) consider the recommendations of
2	the Institute of Medicine regarding the
3	elimination of tuberculosis;
4	"(ii) consider recommendations for
5	the involvement of the United States in
6	continuing global and cross-border tuber-
7	culosis control activities in countries where
8	a high incidence of tuberculosis directly af-
9	fects the United States such as Mexico;
10	and
11	"(iii) review the extent to which
12	progress has been made toward eliminating
13	tuberculosis.
14	"(4) Annual Report.—The Council shall an-
15	nually submit to Congress and the Secretary a re-
16	port on the activities carried under this section,
17	other than subsection (g). Each such report shall in-
18	clude the opinion of the Council on the extent to
19	which its recommendations regarding the elimination
20	of tuberculosis have been implemented, including
21	with respect to—
22	"(A) activities under subsection (b); and
23	"(B) the national plan referred to in para-
24	graph (3).

1	"(5) Composition.—The Council shall be com-
2	posed of—
3	"(A) representatives from the Centers for
4	Disease Control and Prevention, the National
5	Institutes of Health, the United States Agency
6	for International Development, the Agency for
7	Healthcare Research and Quality, the Health
8	Resources and Services Administration, the
9	United States-Mexico Border Health Commis-
10	sion, and other Federal departments and agen-
11	cies that carry out significant activities related
12	to tuberculosis;
13	"(B) State and local tuberculosis control
14	and public health and officials;
15	"(C) individuals who are scientists, physi-
16	cians, laboratorians, and other health profes-
17	sionals who represent disciplines relevant to tu-
18	berculosis elimination;
19	"(D) members of national and inter-
20	national nongovernmental organizations estab-
21	lished to address the elimination of tuberculosis
22	and
23	"(E) members from the general public who
24	are knowledgeable with respect to the elimi-

1	nation of tuberculosis, including individuals who
2	have or have had tuberculosis.".
3	(b) Rule of Construction Regarding Current
4	Membership.—With respect to the advisory council
5	under section 317E(f) of the Public Health Service Act,
6	the amendments made by subsection (a) may not be con-
7	strued as terminating the membership on such council of
8	any individual serving as such a member as of the day
9	before the date of the enactment of this Act.
10	Subtitle C—New Tools for
11	Tuberculosis Elimination
12	SEC. 121. NEW TOOLS.
13	Section 317E of the Public Health Service Act (42
14	U.S.C. 247b-6) is amended—
15	(1) by redesignating subsection (g) as sub-
16	section (h); and
17	(2) by inserting after subsection (f) the fol-
18	lowing subsection:
19	"(g) New Tools for Elimination of Tuber-
20	CULOSIS.—
21	"(1) Research and Development on drugs,
22	DIAGNOSTICS, VACCINES, AND PUBLIC HEALTH
23	INTERVENTIONS.—The Secretary, acting through
24	the Director of the Centers for Disease Control and
25	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—

1	"(i) scientists, physicians, and other
2	health professionals and who represent the
3	specialties and disciplines relevant to the
4	research under consideration;
5	"(ii) members from public-private
6	partnerships or foundations (or both) en-
7	gaged in research relevant to research
8	under consideration;
9	"(iii) members of national and inter-
10	national nongovernmental organizations es-
11	tablished to address tuberculosis elimi-
12	nation;
13	"(iv) members from the general public
14	who are knowledgeable with respect to tu-
15	berculosis, including individuals who have
16	or have had tuberculosis; and
17	"(v) scientists, physicians, and other
18	health professionals who reside in a foreign
19	country with a substantial incidence or
20	prevalence of tuberculosis, and who rep-
21	resent the specialties and disciplines rel-
22	evant to the research under consideration.
23	"(3) Grants and contracts.—The Secretary
24	shall carry out paragraph (1) directly and through

1	awards of grants, cooperative agreements, and con-
2	tracts to public and private entities, including—
3	"(A) public-private partnerships;
4	"(B) academic institutions, including insti-
5	tutions of higher education;
6	"(C) research institutions; and
7	"(D) the Tuberculosis Trials Consortium
8	and the Tuberculosis Epidemiologic Studies
9	Consortium.".
10	Subtitle D—Authorizations of
11	Appropriations
12	SEC. 131. AUTHORIZATIONS OF APPROPRIATIONS.
13	Section 317E of the Public Health Service Act, as
14	amended by section 121(1) of this Act, is amended by
15	amending subsection (h) to read as follows:
16	"(h) Authorization of Appropriations.—
17	"(1) General Program.—
18	"(A) In general.—For the purpose of
19	carrying out this section, other than subsection
20	(g), there are authorized to be appropriated
21	\$528,000,000 for fiscal year 2008, and such
22	sums as may be necessary for each of the fiscal
23	years 2009 through 2012.
24	"(B) Reservation for emergency
25	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

1	of tuberculosis morbidity in the respective
2	geographic area and may consider other
3	factors relevant to tuberculosis in such
4	area.
5	"(iii) No change to formula re-
6	QUIRED.—This subparagraph does not re-
7	quire the Secretary to modify the formula
8	that was used by the Secretary to dis-
9	tribute funds to grantees under subsection
10	(a) for fiscal year 2007.
11	"(2) New tools.—
12	"(A) In general.—For the purpose of
13	carrying out subsection (g), there are author-
14	ized to be appropriated \$100,000,000 for fiscal
15	year 2008, and such sums as may be necessary
16	for each of the fiscal years 2009 through 2012.
17	"(B) Limitation.—The authorization of
18	appropriations established in subparagraph (A)
19	for a fiscal year is effective only if the amount
20	appropriated under paragraph (1) for such year
21	equals or exceeds the amount appropriated to

carry out this section for fiscal year 2007.".

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TITLE II—NATIONAL INSTITUTES OF HEALTH 2 SEC. 201. ACTIVITIES OF NATIONAL HEART, LUNG, AND 4 **BLOOD INSTITUTE.** 5 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: 7 8 "SEC. 424C. TUBERCULOSIS. 9 "(a) In General.—The Director of the Institute 10 shall expand, intensify, and coordinate research and development and related activities of the Institute with respect 11 12 to tuberculosis, including activities toward the goal of 13 eliminating such disease. 14 "(b) CERTAIN ACTIVITIES.—Activities under subsection (a) shall include— 15 "(1) enhancing basic and clinical research on 16 17 tuberculosis; and "(2) expanding research on the relationship be-18 19 tween such disease and the human immunodeficiency 20 virus. 21 "(c) Research Education.— 22 "(1) Tuberculosis academic awards.—The 23 Director of the Institute may provide awards to fac-24 ulty of schools of medicine or osteopathic medicine

to assist such faculty in developing high quality cur-

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- 1 ricula in such schools designed to significantly in-
- 2 crease the opportunities for interested individuals,
- 3 including students of the school and practicing phy-
- 4 sicians and nurses, to learn the principles and prac-
- 5 tices of preventing, managing, and controlling tuber-
- 6 culosis.
- 7 "(2) Tuberculosis/Pulmonary infection
- 8 AWARDS.—The Director of the Institute may provide
- 9 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.".
- 14 SEC. 202. ACTIVITIES OF NATIONAL INSTITUTE OF AL-
- 15 LERGY AND INFECTIOUS DISEASES.
- Section 447A of the Public Health Service Act (42)
- 17 U.S.C. 285f-2) is amended—
- 18 (1) by striking "In carrying out section 446"
- and inserting "(a) In carrying out section 446"; and
- 20 (2) by inserting at the end the following:
- 21 "(b) Activities under subsection (a) shall include ac-
- 22 tivities to develop a tuberculosis vaccine. Such activities
- 23 shall be carried out in accordance with the blueprint for
- 24 tuberculosis vaccine development described in the report
- 25 prepared pursuant to the workshop convened in March

1	1998 by the Advisory Council for Elimination of Tuber-
2	culosis, the Director of the National Vaccine Program,
3	and the Director of the Institute.".
4	SEC. 203. JOHN E. FOGARTY INTERNATIONAL CENTER FOR
5	ADVANCED STUDY IN THE HEALTH
6	SCIENCES.
7	Section 482 of the Public Health Service Act (42
8	U.S.C. 287b) is amended—
9	(1) by inserting "(a) In General.—" before
10	"The general purpose";
11	(2) in subsection (a) (as so designated), by in-
12	serting after "Health Sciences" the following: "(in
13	this subpart referred to as the 'Center')"; and
14	(3) by adding at the end the following sub-
15	section:
16	"(b) Tuberculosis.—
17	"(1) In general.—In carrying out subsection
18	(a) with respect to tuberculosis, the Center shall ex-
19	pand, intensify, and coordinate international activi-
20	ties of the Center for research and training.
21	"(2) International training program.—In
22	carrying out paragraph (1), the Center shall carry
23	out an international training program regarding tu-
24	berculosis. Such program shall be modeled after the
25	international training program carried out by the

1	Center with respect to the human immunodeficiency
2	virus.''.
3	SEC. 204. LOAN REPAYMENT PROGRAMS REGARDING RE-
4	SEARCH ON TUBERCULOSIS.
5	Part G of title IV of the Public Health Service Act
6	(42 U.S.C. 288 et seq.) is amended—
7	(1) by redesignating the second section 487F as
8	section 487G; and
9	(2) by inserting after section 487G (as so re-
10	designated) the following section:
11	"LOAN REPAYMENTS REGARDING RESEARCH ON
12	TUBERCULOSIS
13	"Sec. 487H. In carrying out sections 487C, 487E,
14	and 487F, the Secretary shall seek to ensure that, for fis-
15	cal year 2008 and subsequent fiscal years, a portion of
16	amounts appropriated to carry out such sections is re-
17	served for the purpose of entering into contracts under
18	which (in accordance with the section involved) individuals
19	will conduct research on tuberculosis.".
20	SEC. 205. AUTHORIZATION OF APPROPRIATIONS.
21	For the purpose of carrying out this title and the
22	amendments made by this title, there are authorized to
23	be appropriated such sums as may be necessary. Such au-
24	thorization of appropriations shall be in addition to the
25	authorization of appropriations established by section

- 1 402A(a) of the Public Health Service Act and any other
- 2 authorization of appropriations available for such purpose.

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