

Calendar No. 526107TH CONGRESS
2^D SESSION**S. 1115****[Report No. 107-227]**

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

IN THE SENATE OF THE UNITED STATES

JUNE 27, 2001

Mr. KENNEDY (for himself, Mr. STEVENS, Mr. INOUE, Mrs. HUTCHISON, Mr. CORZINE, Mr. TORRICELLI, Ms. LANDRIEU, Mr. BINGAMAN, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 26, 2002

Reported by Mr. KENNEDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]**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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Comprehensive Tuber-
3 culosis Elimination Act of 2001”.

4 **TITLE I—PREVENTIVE HEALTH**
5 **SERVICES**

6 **SEC. 101. ADVISORY COUNCIL FOR THE ELIMINATION OF**
7 **TUBERCULOSIS.**

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

10 (1) by redesignating paragraph (5) as para-
11 graph (6);

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

14 “(2) DUTIES.—For the purpose of making
15 progress toward the goal of eliminating tuberculosis,
16 the Council shall provide to the Secretary and other
17 appropriate Federal officials advice on coordinating
18 the activities of the Public Health Service and other
19 Federal agencies that relate to such disease and on
20 efficiently utilizing the Federal resources involved.

21 “(3) NATIONAL PLAN.—In carrying out para-
22 graph (2), the Council, in consultation with appro-
23 priate public and private entities, shall make rec-
24 ommendations on the development and implementa-
25 tion of a national plan to eliminate tuberculosis in

1 the United States. In carrying out this paragraph,
2 the Council shall—

3 “(A) consider the recommendations of the
4 Institute of Medicine regarding the elimination
5 of tuberculosis;

6 “(B) address the development and applica-
7 tion of new technologies; and

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

10 “(4) GLOBAL ACTIVITIES.—In carrying out
11 paragraph (2), the Council, in consultation with ap-
12 propriate public and private entities, shall make rec-
13 ommendations for the development and implementa-
14 tion of a plan to guide the involvement of the United
15 States in global tuberculosis-control activities, in-
16 cluding recommendations regarding policies, strate-
17 gies, objectives, and priorities. Such recommenda-
18 tions for the plan shall have a focus on high inci-
19 dence countries and on access to a comprehensive
20 package of tuberculosis control measures, as defined
21 by the World Health Organization directly observed
22 treatment, short course strategy (commonly known
23 as DOTS).

24 “(5) COMPOSITION.—The Council shall be com-
25 posed of—

1 “(A) representatives from the Centers for
 2 Disease Control and Prevention, the National
 3 Institutes of Health, the Agency for Healthcare
 4 Research and Quality, the U.S.-Mexico Border
 5 Health Commission, and other Federal depart-
 6 ments and agencies that carry out significant
 7 activities relating to tuberculosis; and

8 “(B) members appointed from among indi-
 9 viduals who are not officers or employees of the
 10 Federal Government.”; and

11 (3) by adding at the end the following:

12 “(7) APPLICABILITY OF FACA.—The Council
 13 shall be subject to the Federal Advisory Committee
 14 Act (5 U.S.C. App.).”.

15 **TITLE II—CENTERS FOR DIS-**
 16 **EASE CONTROL AND PREVEN-**
 17 **TION**

18 **SEC. 201. NATIONAL PROGRAM FOR TUBERCULOSIS ELIMI-**
 19 **NATION.**

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

22 (1) by striking the heading for the section and
 23 inserting the following:

1 immigrants with active or latent tuberculosis in-
2 fection.

3 ~~“(3) Public information and education pro-~~
4 ~~grams.~~

5 ~~“(4) Education, training and clinical skills im-~~
6 ~~provement activities for health professionals, includ-~~
7 ~~ing allied health personnel.~~

8 ~~“(5) Support of model centers to carry out ac-~~
9 ~~tivities under paragraphs (2) through (4).~~

10 ~~“(6) Collaboration with international organiza-~~
11 ~~tions and foreign countries in carrying out such ac-~~
12 ~~tivities, including coordinating activities through the~~
13 ~~Advisory Council for the Elimination of Tubercu-~~
14 ~~losis.”; and~~

15 ~~(3) by striking subsection (g) and inserting the~~
16 ~~following:~~

17 ~~“(g) REPORTS.—The Secretary, acting through the~~
18 ~~Director of the Centers for Disease Control and Preven-~~
19 ~~tion and in consultation with the Advisory Council for the~~
20 ~~Elimination of Tuberculosis, shall biennially prepare and~~
21 ~~submit to the Committee on Health, Education, Labor,~~
22 ~~and Pensions of the Senate and the Committee on Energy~~
23 ~~and Commerce of the House of Representatives, a report~~
24 ~~on the activities carried out under this section. Each re-~~
25 ~~port shall include the opinion of the Council on the extent~~

1 to which the recommendations of the Institute of Medicine
2 regarding tuberculosis have been implemented.”; and

3 “(h) **AUTHORIZATION OF APPROPRIATIONS.**—For the
4 purpose of carrying out this section, there are authorized
5 to be appropriated \$528,000,000 for fiscal year 2002, and
6 such sums as may be necessary for each of the fiscal years
7 2003 through 2006.”.

8 **TITLE III—NATIONAL**
9 **INSTITUTES OF HEALTH**

10 **SEC. 301. ACTIVITIES OF NATIONAL HEART, LUNG, AND**
11 **BLOOD INSTITUTE.**

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

15 “**TUBERCULOSIS**

16 “**SEC. 424C. (a) IN GENERAL.**—The Director of the
17 Institute shall expand, intensify, and coordinate research
18 and related activities of the Institute with respect to tuber-
19 culosis, including activities toward the goal of eliminating
20 such disease.

21 “(b) **CERTAIN ACTIVITIES.**—Activities under sub-
22 section (a) shall include—

23 “(1) enhancing basic and clinical research on
24 tuberculosis; and

1 “(2) expanding research on the relationship be-
2 tween such disease and the human immunodeficiency
3 virus.

4 “(c) RESEARCH EDUCATION.—

5 “(1) TUBERCULOSIS ACADEMIC AWARDS.—The
6 Director of the Institute may provide awards to fac-
7 ulty of schools of medicine, nursing, or osteopathic
8 medicine for information and education programs,
9 including the development of curricula, to signifi-
10 cantly increase the opportunities for students and
11 for practicing providers to learn the principles and
12 practices of preventing, managing, and controlling
13 tuberculosis.

14 “(2) TUBERCULOSIS/PULMONARY INFECTION
15 AWARDS.—The Director of the Institute may provide
16 awards to support the career development of clini-
17 cally trained professionals who are committed to re-
18 search regarding pulmonary infections, including tu-
19 berculosis, by providing for supervised study and re-
20 search.

21 “(3) AUTHORIZATION OF APPROPRIATIONS.—

22 “(A) TUBERCULOSIS ACADEMIC
23 AWARDS.—For the purpose of carrying out
24 paragraph (1), there are authorized to be ap-
25 propriated \$5,000,000 for fiscal year 2002, and

1 such sums as may be necessary for each of the
2 fiscal years 2003 through 2006.

3 “(B) TUBERCULOSIS/PULMONARY INFECTION AWARDS.—For the purpose of carrying
4 out paragraph (2), there are authorized to be
5 appropriated \$5,000,000 for fiscal year 2002,
6 and such sums as may be necessary for each of
7 the fiscal years 2003 through 2006.”.

9 **SEC. 302. ACTIVITIES OF NATIONAL INSTITUTE OF AL-**
10 **LERGY AND INFECTIOUS DISEASES.**

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

13 (1) by redesignating subsection (b) as sub-
14 section (e);

15 (2) by inserting after subsection (a) the fol-
16 lowing subsection:

17 “(b) Activities under subsection (a) shall include ac-
18 tivities to develop a tuberculosis vaccine. Such activities
19 shall be carried out in accordance with the blueprint for
20 tuberculosis vaccine development described in the report
21 prepared pursuant to the workshop convened in March
22 1998 by the Advisory Council for Elimination of Tubercu-
23 losis; the Director of the National Vaccine Program;
24 and the Director of the Institute.”; and

1 (3) in subsection (c) (as so redesignated), in the
2 first sentence—

3 (A) by striking “and” after “1994,”; and

4 (B) by inserting before the period the fol-
5 lowing: “, \$240,000,000 for fiscal year 2002,
6 and such sums as may be necessary for each of
7 the fiscal years 2003 through 2006”.

8 **SEC. 303. JOHN E. FOGARTY INTERNATIONAL CENTER FOR**
9 **ADVANCED STUDY IN THE HEALTH**
10 **SCIENCES.**

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

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

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

18 (3) by adding at the end the following:

19 “(b) TUBERCULOSIS.—

20 “(1) IN GENERAL.—In carrying out subsection
21 (a) with respect to tuberculosis, the Center shall ex-
22 pand, intensify, and coordinate international activi-
23 ties of the Center for research and training. In par-
24 ticular, the Center shall expand its activities to in-

1 elude support for clinical, operational, and health
2 services research and training.

3 “(2) INTERNATIONAL TRAINING PROGRAM.—In
4 carrying out paragraph (1), the Center shall carry
5 out an international training program regarding tu-
6 berculosis. Such program shall be modeled after the
7 international training program carried out by the
8 Center with respect to the human immunodeficiency
9 virus.”.

10 **SEC. 304. LOAN REPAYMENT PROGRAMS REGARDING RE-**
11 **SEARCH ON TUBERCULOSIS.**

12 Part G of title IV of the Public Health Service Act
13 (42 U.S.C. 288 et seq.) is amended—

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

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

18 “LOAN REPAYMENTS REGARDING RESEARCH ON
19 TUBERCULOSIS

20 “SEC. 487H. In carrying out sections 487C, 487E,
21 and 487F, the Secretary shall seek to ensure that, for fis-
22 cal year 2002 and subsequent fiscal years, a portion of
23 amounts appropriated to carry out such sections is re-
24 served for the purpose of entering into contracts under
25 which (in accordance with the section involved) individuals
26 will conduct research on tuberculosis.”.

1 *culosis in the United States. In carrying out this*
2 *paragraph, the Council shall—*

3 “(A) *consider the recommendations of the*
4 *Institute of Medicine regarding the elimination*
5 *of tuberculosis;*

6 “(B) *address the development and applica-*
7 *tion of new technologies; and*

8 “(C) *review the extent to which progress has*
9 *been made toward eliminating tuberculosis.*

10 “(4) *GLOBAL ACTIVITIES.—In carrying out*
11 *paragraph (2), the Council, in consultation with ap-*
12 *propriate public and private entities, shall make rec-*
13 *ommendations for the development and implementa-*
14 *tion of a plan to guide the involvement of the United*
15 *States in global and cross border tuberculosis-control*
16 *activities, including recommendations regarding poli-*
17 *cies, strategies, objectives, and priorities. Such rec-*
18 *ommendations for the plan shall have a focus on*
19 *countries where a high incidence of tuberculosis di-*
20 *rectly affects the United States, such as Mexico, and*
21 *on access to a comprehensive package of tuberculosis*
22 *control measures, as defined by the World Health Or-*
23 *ganization directly observed treatment, short course*
24 *strategy (commonly known as DOTS).*

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 In-*
5 *stitutes of Health, the Agency for Healthcare Re-*
6 *search and Quality, the Health Resources and*
7 *Services Administration, the U.S.-Mexico Border*
8 *Health Commission, and other Federal depart-*
9 *ments and agencies that carry out significant ac-*
10 *tivities relating to tuberculosis; and*

11 “(B) *members appointed from among indi-*
12 *viduals who are not officers or employees of the*
13 *Federal Government.*”.

14 ***TITLE II—CENTERS FOR DIS-***
15 ***EASE CONTROL AND PREVEN-***
16 ***TION***

17 ***SEC. 201. NATIONAL PROGRAM FOR TUBERCULOSIS ELIMI-***
18 ***NATION.***

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

21 (1) *by striking the heading for the section and*
22 *inserting the following:*

23 “*NATIONAL PROGRAM FOR TUBERCULOSIS ELIMINATION*”;

24 (2) *by amending subsection (b) to read as fol-*
25 *lows:*

1 “(b) *RESEARCH, DEMONSTRATION PROJECTS, EDU-*
2 *CATION, AND TRAINING.*—*With respect to the prevention,*
3 *control, and elimination of tuberculosis, the Secretary may,*
4 *directly or through grants to public or nonprofit private*
5 *entities, carry out the following:*

6 “(1) *Research, with priority given to research*
7 *concerning—*

8 “(A) *diagnosis and treatment of latent in-*
9 *fection of tuberculosis;*

10 “(B) *strains of tuberculosis resistant to*
11 *drugs;*

12 “(C) *cases of tuberculosis that affect certain*
13 *high-risk populations; and*

14 “(D) *clinical trials, including those con-*
15 *ducted through the Tuberculosis Trials Consor-*
16 *tium.*

17 “(2) *Demonstration projects, including for—*

18 “(A) *the development of regional capabili-*
19 *ties for the prevention, control, and elimination*
20 *of tuberculosis particularly in low-incidence re-*
21 *gions; and*

22 “(B) *collaboration with the Immigration*
23 *and Naturalization Service to identify and treat*
24 *immigrants with active or latent tuberculosis in-*
25 *fection.*

1 “(3) *Public information and education pro-*
2 *grams.*

3 “(4) *Education, training and clinical skills im-*
4 *provement activities for health professionals, includ-*
5 *ing allied health personnel.*

6 “(5) *Support of model centers to carry out ac-*
7 *tivities under paragraphs (2) through (4).*

8 “(6) *Collaboration with international organiza-*
9 *tions and foreign countries, including Mexico, in co-*
10 *ordination with the United States Agency for Inter-*
11 *national Development, in carrying out such activities,*
12 *including coordinating activities through the Advi-*
13 *sory Council for the Elimination of Tuberculosis.”;*
14 *and*

15 (3) *by striking subsection (g) and inserting the*
16 *following:*

17 “(g) *REPORTS.—The Secretary, acting through the Di-*
18 *rector of the Centers for Disease Control and Prevention*
19 *and in consultation with the Advisory Council for the*
20 *Elimination of Tuberculosis, shall biennially prepare and*
21 *submit to the Committee on Health, Education, Labor, and*
22 *Pensions of the Senate and the Committee on Energy and*
23 *Commerce of the House of Representatives, a report on the*
24 *activities carried out under this section. Each report shall*
25 *include the opinion of the Council on the extent to which*

1 *its recommendations under section 317E(f)(3) regarding tu-*
 2 *berculosis have been implemented.”; and*

3 “(h) *AUTHORIZATION OF APPROPRIATIONS.—For the*
 4 *purpose of carrying out this section, there are authorized*
 5 *to be appropriated \$235,000,000 for fiscal year 2003, and*
 6 *such sums as may be necessary for each of the fiscal years*
 7 *2004 through 2007.”.*

8 ***TITLE III—NATIONAL***
 9 ***INSTITUTES OF HEALTH***

10 ***SEC. 301. ACTIVITIES OF NATIONAL HEART, LUNG, AND***
 11 ***BLOOD INSTITUTE.***

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

15 ***“TUBERCULOSIS***

16 ***“SEC. 424C. (a) IN GENERAL.—The Director of the In-***
 17 ***stitute shall expand, intensify, and coordinate research and***
 18 ***related activities of the Institute with respect to the treat-***
 19 ***ment, diagnosis, and prevention of tuberculosis,***
 20 ***including—***

21 ***“(1) basic and clinical research on tuberculosis;***
 22 ***and***

23 ***“(2) research on the relationship between tuber-***
 24 ***culosis and the human immunodeficiency virus.***

25 ***“(b) RESEARCH EDUCATION.—***

1 “(1) *TUBERCULOSIS ACADEMIC AWARDS.*—*The*
2 *Director of the Institute may award grants to institu-*
3 *tions for the development and support of programs of*
4 *core curricula for training clinical investigators, in-*
5 *cluding medical, nursing, or osteopathic students, in*
6 *the principles and practices of preventing, managing,*
7 *and controlling tuberculosis in patients.*

8 “(2) *TUBERCULOSIS/PULMONARY INFECTION*
9 *AWARDS.*—*The Director of the Institute may provide*
10 *awards to support the research of trained profes-*
11 *sionals into the basic biological processes and mecha-*
12 *nisms involved in tuberculosis, as well as research*
13 *into the development of new diagnostic techniques and*
14 *treatments.*

15 “(3) *AUTHORIZATION OF APPROPRIATIONS.*—*For*
16 *the purpose of carrying out this subsection, there are*
17 *authorized to be appropriated \$10,000,000 for fiscal*
18 *year 2003, and such sums as may be necessary for*
19 *each of the fiscal years 2004 through 2007.”.*

20 **SEC. 302. ACTIVITIES OF NATIONAL INSTITUTE OF ALLERGY**
21 **AND INFECTIOUS DISEASES.**

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

24 (1) *by redesignating subsection (b) as subsection*
25 *(c);*

1 (2) *by inserting after subsection (a) the following*
 2 *subsection:*

3 “(b) *Activities under subsection (a) may include ac-*
 4 *tivities to develop a tuberculosis vaccine. The recommenda-*
 5 *tions contained within the Blueprint for Tuberculosis Vac-*
 6 *cine Development, described in the report prepared pursu-*
 7 *ant to the workshop convened in March 1998 by the Direc-*
 8 *tor of the Institute, shall be taken into consideration.”; and*

9 (3) *in subsection (c) (as so redesignated), in the*
 10 *first sentence—*

11 (A) *by striking “and” after “1994,”; and*

12 (B) *by inserting before the period the fol-*
 13 *lowing: “, \$136,000,000 for fiscal year 2003,*
 14 *\$162,000,000 for fiscal year 2004, and such sums*
 15 *as may be necessary for each of the fiscal years*
 16 *2005 through 2007”.*

17 **SEC. 303. JOHN E. FOGARTY INTERNATIONAL CENTER FOR**
 18 **ADVANCED STUDY IN THE HEALTH SCIENCES.**

19 (a) *IN GENERAL.—With respect to tuberculosis, the*
 20 *John E. Fogarty International Center for Advanced Study*
 21 *in the Health Sciences shall expand, intensify, and coordi-*
 22 *nate international activities of the Center for research and*
 23 *training. In particular, the Center shall expand its activi-*
 24 *ties to include support for clinical, operational, and health*
 25 *services research and training.*

1 **(b) INTERNATIONAL TRAINING PROGRAM.**—*In car-*
2 *rying out subsection (a), the Center shall carry out an*
3 *international training program regarding tuberculosis.*
4 *Such program shall be modeled after the international*
5 *training program carried out by the Center with respect*
6 *to the human immunodeficiency virus.*

Calendar No. 526

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[Report No. 107-227]

A BILL

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JULY 26, 2002

Reported with an amendment