

COMPREHENSIVE TUBERCULOSIS ELIMINATION ACT OF
2008

SEPTEMBER 23, 2008.—Committed to the Committee of the Whole House on the
State of the Union and ordered to be printed

Mr. DINGELL, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 1532]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (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, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Comprehensive Tuberculosis Elimination Act of 2008”.

(b) **TABLE OF CONTENTS.**—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—DEPARTMENT OF HEALTH AND HUMAN SERVICES IN COORDINATION WITH THE CENTERS FOR DISEASE CONTROL AND PREVENTION AND OTHER APPROPRIATE AGENCIES

Subtitle A—National Strategy for Combating and Eliminating Tuberculosis

Sec. 101. National strategy.

Subtitle B—Interagency Collaboration

Sec. 111. Advisory Council for Elimination of Tuberculosis and the Federal Tuberculosis Task Force .

Subtitle C—Evaluation of Public Health Authorities

Sec. 121. Evaluation of public health authorities.

Subtitle D—Authorization of Appropriations

Sec. 131. Authorizations of appropriations.

TITLE II—NATIONAL INSTITUTES OF HEALTH

Sec. 201. Research and development concerning tuberculosis.

TITLE I—DEPARTMENT OF HEALTH AND HUMAN SERVICES IN COORDINATION WITH THE CENTERS FOR DISEASE CONTROL AND PREVENTION AND OTHER APPROPRIATE AGENCIES

Subtitle A—National Strategy for Combating and Eliminating Tuberculosis

SEC. 101. NATIONAL STRATEGY.

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 STRATEGY FOR COMBATING AND ELIMINATING TUBERCULOSIS”;

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

“(b) **RESEARCH AND DEVELOPMENT; DEMONSTRATION PROJECTS; EDUCATION AND TRAINING.**—With respect to the prevention, treatment, 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 latent tuberculosis infection, strains of tuberculosis resistant to drugs, and research concerning cases of tuberculosis that affect certain populations at risk for tuberculosis.

“(2) Research and development and related activities to develop new tools for the elimination of tuberculosis, including drugs, diagnostics, vaccines, and public health interventions, such as directly observed therapy and non-pharmaceutical intervention, and methods to enhance detection and response to outbreaks of tuberculosis, including multidrug resistant tuberculosis. The Secretary is encouraged to give priority to programmatically relevant research so that new tools can be utilized in public health practice.

“(3) Demonstration projects for—

“(A) the development of regional capabilities to prevent, control, and eliminate tuberculosis and prevent multidrug resistant and extensively drug resistant strains of tuberculosis;

“(B) the intensification of efforts to reduce health disparities in the incidence of tuberculosis;

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

lations, including through expansion of the scope and number of programs that—

- “(i) detect and treat binational cases of tuberculosis; and
 - “(ii) treat high-risk cases of tuberculosis referred from Mexican health departments;
 - “(D) the intensification of efforts to prevent, detect, and treat tuberculosis among foreign-born persons who are in the United States;
 - “(E) the intensification of efforts to prevent, detect, and treat tuberculosis among populations and settings documented as having a high risk for tuberculosis; and
 - “(F) tuberculosis detection, control, and prevention.
- “(4) Public information and education activities.
- “(5) Education, training, clinical skills improvement activities, and workplace exposure prevention for health professionals, including allied health personnel and emergency response employees.
- “(6) Support of Centers to carry out activities under paragraphs (1) through (4).
- “(7) Collaboration with international organizations and foreign countries in carrying out such activities.
- “(8) Develop, enhance, and expand information technologies that support tuberculosis control including surveillance and database management systems with cross-jurisdictional capabilities, which shall conform to the standards and implementation specifications for such information technologies as recommended by the Secretary.”; and
- (3) in subsection (d), by adding at the end the following:
- “(3) DETERMINATION OF AMOUNT OF NONFEDERAL CONTRIBUTIONS.—
- “(A) PRIORITY.—In awarding grants under subsection (a) or (b), the Secretary shall give highest priority to an applicant that provides assurances that the applicant will contribute non-Federal funds to carry out activities under this section, which may be provided directly or through donations from public or private entities and may be in cash or in kind, including equipment or services.
- “(B) FEDERAL AMOUNTS NOT TO BE INCLUDED AS CONTRIBUTIONS.—Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of non-Federal contributions as described in subparagraph (A).”.

Subtitle B—Interagency Collaboration

SEC. 111. ADVISORY COUNCIL FOR ELIMINATION OF TUBERCULOSIS AND THE FEDERAL TUBERCULOSIS TASK FORCE.

(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. 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 Department of Health and Human Services and other Federal agencies that relate to the disease, including activities under subsection (b);

“(B) responding rapidly and effectively to emerging issues in tuberculosis; and

“(C) efficiently utilizing the Federal resources involved.

“(3) COMPREHENSIVE PLAN.—

“(A) IN GENERAL.—In carrying out paragraph (2), the Council shall make or update recommendations on the development, revision, and implementation of a comprehensive plan to eliminate tuberculosis in the United States.

“(B) CONSULTATION.—In carrying out subparagraph (A), the Council may consult with appropriate public and private entities, which may, subject to the direction or discretion of the Secretary, include—

- “(i) individuals who are scientists, physicians, laboratorians, 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 or private entities established to address the elimination of tuberculosis;

“(iii) members of national and international nongovernmental organizations whose purpose is to eliminate tuberculosis;

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

“(v) scientists, physicians, laboratorians, 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.

“(C) CERTAIN COMPONENTS OF PLAN.—In carrying out subparagraph (A), the Council shall, subject to the direction or discretion of the Secretary—

“(i) 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; and

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

“(4) BIENNIAL REPORT.—

“(A) IN GENERAL.—The Council shall submit a biennial report to the Secretary, as determined necessary by the Secretary, on the activities carried under this section. 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—

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

“(ii) the national plan referred to in paragraph (3).

“(B) PUBLIC.—The Secretary shall make a report submitted under subparagraph (A) public.

“(5) COMPOSITION.—The Council shall be composed of—

“(A) ex officio 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 officials;

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

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

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

(1) by redesignating subsection (g) as subsection (h); and

(2) by inserting after subsection (f) the following subsection:

“(g) FEDERAL TUBERCULOSIS TASK FORCE.—

“(1) DUTIES.—The Federal Tuberculosis Task Force (in this subsection referred to as the ‘Task Force’) shall provide to the Secretary and other appropriate Federal officials advice on research into new tools under subsection (b)(2), including advice regarding the efficient utilization of the Federal resources involved.

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

“(3) CONSULTATION.—In developing the comprehensive plan under paragraph (1), the Task Force shall consult with external parties including representatives from groups such as—

“(A) scientists, physicians, laboratorians, and other health professionals who represent the specialties and disciplines relevant to the research under consideration;

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

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

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

“(E) scientists, physicians, laboratorians, 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.”.

Subtitle C—Evaluation of Public Health Authorities

SEC. 121. EVALUATION OF PUBLIC HEALTH AUTHORITIES.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of the Comprehensive Tuberculosis Elimination Act of 2008, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report that evaluates and provides recommendations on changes needed to Federal and State public health authorities to address current disease containment challenges such as isolation and quarantine.

(b) CONTENTS OF EVALUATION.—The report described in subsection (a) shall include—

(1) an evaluation of the effectiveness of current policies to detain patients with active tuberculosis;

(2) an evaluation of whether Federal laws should be strengthened to expressly address the movement of individuals with active tuberculosis; and

(3) specific legislative recommendations for changes to Federal laws, if any.

(c) UPDATE OF QUARANTINE REGULATIONS.—Not later than 240 days after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to update the current interstate and foreign quarantine regulations found in parts 70 and 71 of title 42, Code of Federal Regulations.

Subtitle D—Authorization of Appropriations

SEC. 131. AUTHORIZATIONS OF APPROPRIATIONS.

Section 317E of the Public Health Service Act, as amended by section 111(c) of this Act, is amended by striking subsection (h) and inserting the following:

“(h) AUTHORIZATION OF APPROPRIATIONS.—

“(1) GENERAL PROGRAM.—

“(A) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated \$300,000,000 for fiscal year 2009, \$315,000,000 for fiscal year 2010, \$330,750,000 for fiscal year 2011, \$347,287,500 for fiscal year 2012, and \$364,651,900 for fiscal year 2013.

“(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, State, political subdivision of a State, or other public entity in which there is, relative to other areas, a substantial number of cases of tuberculosis, multidrug resistant tuberculosis, or extensively drug resistant tuberculosis or a substantial rate of increase in such cases.

“(C) PRIORITY.—In allocating amounts appropriated under subparagraph (A), 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 a portion of 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 and case complexity in the respective geographic area and may consider other factors relevant to tuberculosis in such area.

“(iii) NO CHANGE TO FORMULA REQUIRED.—This subparagraph does not require the Secretary to modify the formula that was used by the Secretary to distribute funds to grantees under subsection (a) for fiscal year 2009.

“(2) LIMITATION.—The authorization of appropriations established in paragraph (1) for a fiscal year is effective only if the amount appropriated under such paragraph for such year equals or exceeds the amount appropriated to carry out this section for fiscal year 2009.”

TITLE II—NATIONAL INSTITUTES OF HEALTH

SEC. 201. RESEARCH AND DEVELOPMENT CONCERNING TUBERCULOSIS.

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 National Institutes of Health may expand, intensify, and coordinate research and development and related activities of the Institutes with respect to tuberculosis including activities toward the goal of eliminating such disease.

“(b) CERTAIN ACTIVITIES.—Activities under subsection (a) may include—

“(1) enhancing basic and clinical research on tuberculosis, including drug resistant tuberculosis;

“(2) expanding research on the relationship between such disease and the human immunodeficiency virus; and

“(3) developing new tools for the elimination of tuberculosis, including public health interventions and methods to enhance detection and response to outbreaks of tuberculosis, including multidrug resistant tuberculosis.”

PURPOSE AND SUMMARY

The purpose of H.R. 1532, the Comprehensive Tuberculosis Elimination Act of 2008, is to amend the Public Health Service Act with respect to making progress toward the goal of eliminating tuberculosis, and for other purposes.

BACKGROUND AND NEED FOR LEGISLATION

Tuberculosis (TB), a chronic bacterial infection, continues to be a worldwide problem. Tuberculosis is spread through the air when an infected person coughs, sneezes, or speaks. It usually infects the lungs; however, it can also damage other parts of the body. Nearly 2 billion people, including 10 to 15 million in the United States, are infected and approximately 8 million new cases and 1.6 million tuberculosis deaths are reported globally each year. Tuberculosis causes more deaths than any other infectious disease caused by a single microorganism. Tuberculosis is the leading cause of death among the 40 million people living with human immunodeficiency virus (HIV), approximately one-third of whom are co-infected with TB.

An emerging public health concern is the increase in the number of cases of multidrug-resistant tuberculosis, a form of the disease that is resistant to several of the standard therapeutic drugs. Recently, there has also been an increase in the number of cases of extensively drug-resistant tuberculosis, which is resistant to four or more standard drugs.

A May 2000 Institute for Medicine (IOM) report entitled “Ending Neglect: The Elimination of Tuberculosis in the U.S.” found that the resurgence of tuberculosis in the late 1980s and early 1990s was largely due to Federal funding reductions. According to the Centers for Disease Control and Prevention (CDC), however, inten-

sive efforts brought the disease under control again and the Nation is back on track toward its goal of eliminating tuberculosis. In 2006, the lowest number of U.S. cases (13,779) was reported. Since the 1992 TB resurgence peak in the United States, the number of TB cases reported annually has decreased by 48 percent. In addition, the case rate is the lowest ever, at 4.6 cases per 100,000 people. Yet, the high global burden of disease, coupled with continued problems of drug-resistant strains and a failure to develop better tools for TB control, threaten our ability to eliminate TB in the U.S. and hamper efforts to control TB globally as the decreasing trend in the annual case rate has slowed from an annual average decline of 6.6 percent for 1993 through 2002 to an annual average decline of 3.1 percent for 2003 through 2006.

The IOM report also stated that proper funding, the organization of prevention and control activities, and the research and development of new tools could eliminate tuberculosis as a public health problem in the U.S. As a result, research aimed at the diagnosis, treatment, and prevention of all forms of tuberculosis and the care of infected individuals continues to be of interest to Congress.

HEARINGS

No hearings were held in connection with H.R. 1532.

COMMITTEE CONSIDERATION

On Wednesday, September 17, 2008, the full Committee met in open markup session and ordered H.R. 1532 favorably reported to the House, amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. No record votes were taken on amendments or in connection with ordering H.R. 1532 reported to the House. A motion by Mr. Dingell to order H.R. 1532 favorably reported to the House, amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Regarding clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the oversight findings of the Committee regarding H.R. 1532 are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of H.R. 1532 is to amend the Public Health Service Act to (1) reauthorize and modify a grant program for the prevention, treatment, control, and elimination of tuberculosis; (2) create a new Federal Tuberculosis Task Force; and (3) encourage the Director of the National Institutes of Health (NIH) to expand, intensify, and coordinate research and development and related activities with respect to tuberculosis, including activities related to the goal of eliminating the disease.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX
EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1532 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARKS AND TAX AND TARIFF BENEFITS

Regarding compliance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 1532 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate on H.R. 1532 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate on H.R. 1532 provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 22, 2008.

Hon. JOHN D. DINGELL,
*Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1532, the Comprehensive Tuberculosis Elimination Act of 2008.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Jamease Kowalczyk.

Sincerely,

ROBERT A. SUNSHINE
(For Peter R. Orszag, Director).

Enclosure.

H.R. 1532—Comprehensive Tuberculosis Elimination Act of 2008

H.R. 1532 would authorize the Secretary of Health and Human Services to conduct planning, research, and development activities to detect, treat, and eliminate tuberculosis, and to provide grants to public or nonprofit entities to carry out related research and development activities. The bill also would direct the Secretary to issue updated regulations regarding quarantine for communicable diseases.

The bill would authorize the appropriation of \$300 million for fiscal year 2009 and about \$1.7 billion for the 2009–2013 period. Based on past spending for similar activities, CBO estimates that implementing H.R. 1532 would cost \$111 million in 2009 and about \$1.3 billion over the 2009–2013 period, assuming the appropriation

of authorized amounts. Enacting H.R. 1532 would have no effect on direct spending or receipts. Costs of the legislation fall within budget function 550 (health).

| | By fiscal year, in millions of dollars— | | | | | 2009– 2013 |
|--|---|------|------|------|------|---------------|
| | 2009 | 2010 | 2011 | 2012 | 2013 | |
| CHANGES IN SPENDING SUBJECT TO APPROPRIATION | | | | | | |
| Authorization Level | 300 | 315 | 331 | 347 | 365 | 1,658 |
| Estimated Outlays | 111 | 253 | 302 | 327 | 347 | 1,340 |

H.R. 1532 contains no intergovernmental or private-sector mandates as defined in Unfunded Mandates Reform Act.

The CBO staff contact for this estimate is Jamease Kowalczyk, who can be reached at 226–9010. This estimate was approved by Keith J. Fontenot, Deputy Assistant Director for Health and Human Resources, Budget Analysis Division.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates regarding H.R. 1532 prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act would be created by H.R. 1532.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for H.R. 1532 is provided in the provisions of Article I, section 8, clause 1, that relate to expending funds to provide for the general welfare of the United States.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that H.R. 1532 does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act of 1995.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title; table of contents

Section establishes the short title of the bill as the “Comprehensive Tuberculosis Elimination Act of 2008”, and also provides the table of contents.

Title I—Department of Health and Human Services in Coordination with the Centers for Disease Control and Prevention and Other Appropriate Agencies

Subtitle A—National Strategy for Combating and Eliminating Tuberculosis

Section 101. National strategy

Section 101 amends Section 317E of the Public Health Service Act (42 U.S.C. 247b–6) to strike the existing title and replace it with, “National Strategy for Combating and Eliminating Tuberculosis.”

In addition, section 101 states that, with respect to the prevention, treatment, control, and elimination of tuberculosis, the Secretary may, directly or through grants to public or nonprofit private entities, carry out additional activities including (1) research and development, with priority given to projects concerning latent tuberculosis infection, strains of tuberculosis resistant to drugs, and cases of tuberculosis that affect certain at-risk populations and (2) research and development and related activities concerning the development of new tools for the elimination of tuberculosis, such as directly observed therapy and non-pharmaceutical intervention and methods to enhance detection and response to outbreaks of tuberculosis. In doing so, the Secretary is encouraged to give priority to programmatically relevant research.

Section 101 states that demonstration projects shall be for the development of regional capabilities to prevent, control, and eliminate tuberculosis and prevent multidrug-resistant and extensively drug-resistant strains of tuberculosis. In addition, demonstration projects shall be for the intensification of efforts to reduce disparities in the incidence of tuberculosis among United States-Mexico bi-national populations and to control tuberculosis along the United States-Mexico border. Demonstration projects shall also be for the intensification of efforts to prevent, detect, and treat tuberculosis among foreign-born persons who are living in the United States and among other high-risk populations and settings.

Section 101 also requires that, with respect to the prevention, treatment, control, and elimination of tuberculosis, the Secretary may carry out activities relating to workplace exposure prevention for health professionals. The Secretary may also develop, enhance, and expand information technologies that support tuberculosis control such as surveillance and database management systems with cross-jurisdictional capabilities.

In awarding grants in this section, the Secretary shall give highest priority to an applicant that provides assurances that they will contribute non-Federal funds to carry out the activities. These non-Federal funds may be provided directly or through donations from public or private entities and may be in cash or in kind, including equipment and services. Finally, section 101 clarifies that amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of non-Federal contributions.

Subtitle B—Interagency Collaboration

Section 111. Advisory Council for Elimination of Tuberculosis and the Federal Tuberculosis Task Force

Section 111 amends section 317E(f) of the Public Health Service Act (42 U.S.C. 247b–6(f)) by modifying the structure and duties of the Advisory Council for the Elimination of Tuberculosis. Section 111 establishes both the composition of the Advisory Council and the specific duties for the Advisory Council, which include providing advice and recommendations regarding the elimination of tuberculosis to the Secretary. In addition, the Advisory Council shall provide advice on coordinating the activities of Federal agencies that relate to tuberculosis, respond rapidly and effectively to emerging issues relating to tuberculosis, and efficiently utilize the Federal resources involved.

Section 111 establishes a Comprehensive Plan which requires the Advisory Council to make or update recommendations on the development, revision, and implementation of a strategy to eliminate tuberculosis in the United States. In carrying out this task, the Advisory Council may consult with appropriate public and private entities, subject to the direction or discretion of the Secretary. In addition, the Advisory Council shall, subject to the discretion of the Secretary, consider recommendations for continuing the involvement of the United States in global and cross-border tuberculosis control activities in countries where a high incidence of tuberculosis directly affects the United States. The Advisory Council shall review the extent to which progress has been made toward eliminating tuberculosis with regard to these cross-border control activities.

Section 111 requires the Advisory Council to submit a biennial report to the Secretary, if the Secretary determines it necessary, on the activities carried out under this section. The report shall include the opinion of the Advisory Council on the extent to which its recommendations regarding the elimination of tuberculosis have been implemented. The Secretary shall make this report public.

Section 111 creates a Federal Tuberculosis Task Force. The Task Force is required to provide the Secretary, and other appropriate Federal officials, advice on research into new tools for the elimination of tuberculosis, including advice regarding the efficient utilization of the Federal resources involved. In carrying out these activities, the Task Force shall make recommendations on the development of a comprehensive plan for the creation of new tools for the elimination of tuberculosis, including drugs, diagnostics, and vaccines. In developing this comprehensive plan, the Task Force shall consult with external parties.

Subtitle C—Evaluation of Public Health Authorities

Section 121. Evaluation of public health authorities

Section 121 requires the HHS Secretary to prepare and submit a report to Congress, which evaluates and provides recommendations on changes needed to Federal and State public health authorities to address current disease containment challenges such as isolation and quarantine. The report shall include an evaluation of the effectiveness of current policies to detain patients with active

tuberculosis, an evaluation of whether Federal laws should be strengthened to expressly address the movement of individuals with active tuberculosis, and specific legislative recommendations for changes to Federal laws, if any. This report shall be submitted to Congress no later than 180 days after the date of enactment of this Act.

In addition, Section 121 requires the Secretary of HHS to promulgate regulations to update current interstate and foreign quarantine regulations within 240 days of the date of enactment of this Act.

Subtitle D—Authorization of Appropriations

Section 131. Authorization of appropriations

Section 131 amends section 317E of the Public Health Service Act to provide updated and modified authorization of appropriations. Section 131 authorizes to be appropriated \$300,000,000 for fiscal year 2009 with 5 percent increases per year for each of fiscal years 2010 through 2013. Of amounts appropriated for a fiscal year, the Secretary may reserve not more than 25 percent for emergency grants.

Title II—National Institutes of Health

Section 201. Research and development concerning tuberculosis

Section 201 amends Subpart 2 of part C of title IV of the Public Health Service Act (42 U.S.C. 285b et seq.) to include a new section which states that the Director of the National Institutes of Health (NIH) may expand, intensify, and coordinate research and development and related activities of the Institutes with respect to tuberculosis, including activities related to the goal of eliminating the disease. Such activities may include enhancing basic and clinical research on tuberculosis, expanding research on the relationship between tuberculosis and the human immunodeficiency virus, and developing new tools for the elimination of tuberculosis, including public health interventions and methods to enhance detection and response to outbreaks of tuberculosis.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * *

PART B—FEDERAL-STATE COOPERATION

* * * * *

【PREVENTIVE HEALTH SERVICES REGARDING TUBERCULOSIS】

NATIONAL STRATEGY FOR COMBATING AND ELIMINATING
TUBERCULOSIS

SEC. 317E. (a) * * *

【(b) RESEARCH, 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 concerning strains of tuberculosis resistant to drugs and research concerning cases of tuberculosis that affect certain populations.

【(2) Demonstration projects.

【(3) Public information and education programs.

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

【(5) Support of centers to carry out activities under paragraphs (1) through (4).

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

(b) *RESEARCH AND DEVELOPMENT; DEMONSTRATION PROJECTS; EDUCATION AND TRAINING.*—*With respect to the prevention, treatment, 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 latent tuberculosis infection, strains of tuberculosis resistant to drugs, and research concerning cases of tuberculosis that affect certain populations at risk for tuberculosis.*

(2) *Research and development and related activities to develop new tools for the elimination of tuberculosis, including drugs, diagnostics, vaccines, and public health interventions, such as directly observed therapy and non-pharmaceutical intervention, and methods to enhance detection and response to outbreaks of tuberculosis, including multidrug resistant tuberculosis. The Secretary is encouraged to give priority to programatically relevant research so that new tools can be utilized in public health practice.*

(3) *Demonstration projects for—*

(A) *the development of regional capabilities to prevent, control, and eliminate tuberculosis and prevent multidrug resistant and extensively drug resistant strains of tuberculosis;*

(B) *the intensification of efforts to reduce health disparities in the incidence of tuberculosis;*

(C) *the intensification of efforts to control tuberculosis along the United States-Mexico border and among United States-Mexico binational populations, including through expansion of the scope and number of programs that—*

(i) *detect and treat binational cases of tuberculosis;*

and

(ii) *treat high-risk cases of tuberculosis referred from Mexican health departments;*

(D) the intensification of efforts to prevent, detect, and treat tuberculosis among foreign-born persons who are in the United States;

(E) the intensification of efforts to prevent, detect, and treat tuberculosis among populations and settings documented as having a high risk for tuberculosis; and

(F) tuberculosis detection, control, and prevention.

(4) Public information and education activities.

(5) Education, training, clinical skills improvement activities, and workplace exposure prevention for health professionals, including allied health personnel and emergency response employees.

(6) Support of Centers to carry out activities under paragraphs (1) through (4).

(7) Collaboration with international organizations and foreign countries in carrying out such activities.

(8) Develop, enhance, and expand information technologies that support tuberculosis control including surveillance and database management systems with cross-jurisdictional capabilities, which shall conform to the standards and implementation specifications for such information technologies as recommended by the Secretary.

* * * * *

(d) APPLICATION FOR GRANT.—

(1) * * *

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(3) DETERMINATION OF AMOUNT OF NONFEDERAL CONTRIBUTIONS.—

(A) PRIORITY.—*In awarding grants under subsection (a) or (b), the Secretary shall give highest priority to an applicant that provides assurances that the applicant will contribute non-Federal funds to carry out activities under this section, which may be provided directly or through donations from public or private entities and may be in cash or in kind, including equipment or services.*

(B) FEDERAL AMOUNTS NOT TO BE INCLUDED AS CONTRIBUTIONS.—*Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of non-Federal contributions as described in subparagraph (A).*

* * * * *

(f) ADVISORY COUNCIL.—

(1) * * *

[(2) GENERAL 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.

[(3) CERTAIN ACTIVITIES.—With respect to the elimination of tuberculosis, the Council shall—

[(A) in making recommendations under paragraph (2), make recommendations regarding policies, strategies, objectives, and priorities;

[(B) address the development and application of new technologies; and

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

[(4) COMPOSITION.—The Secretary shall determine the size and composition of the Council, and the frequency and scope of official meetings of the Council.]

(2) *DUTIES.*—*The Council shall provide advice and recommendations regarding the elimination of tuberculosis to the Secretary. 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 Department of Health and Human Services and other Federal agencies that relate to the disease, including activities under subsection (b);*

(B) *responding rapidly and effectively to emerging issues in tuberculosis; and*

(C) *efficiently utilizing the Federal resources involved.*

(3) *COMPREHENSIVE PLAN.*—

(A) *IN GENERAL.*—*In carrying out paragraph (2), the Council shall make or update recommendations on the development, revision, and implementation of a comprehensive plan to eliminate tuberculosis in the United States.*

(B) *CONSULTATION.*—*In carrying out subparagraph (A), the Council may consult with appropriate public and private entities, which may, subject to the direction or discretion of the Secretary, include—*

(i) *individuals who are scientists, physicians, laboratorians, 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 or private entities established to address the elimination of tuberculosis;*

(iii) *members of national and international non-governmental organizations whose purpose is to eliminate tuberculosis;*

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

(v) *scientists, physicians, laboratorians, 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.*

(C) *CERTAIN COMPONENTS OF PLAN.*—*In carrying out subparagraph (A), the Council shall, subject to the direction or discretion of the Secretary—*

(i) *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; and

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

(4) BIENNIAL REPORT.—

(A) IN GENERAL.—*The Council shall submit a biennial report to the Secretary, as determined necessary by the Secretary, on the activities carried under this section. 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—*

(i) activities under subsection (b); and

(ii) the national plan referred to in paragraph (3).

(B) PUBLIC.—*The Secretary shall make a report submitted under subparagraph (A) public.*

(5) COMPOSITION.—*The Council shall be composed of—*

(A) ex officio 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 officials;

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

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

[(5)] (6) STAFF, INFORMATION, AND OTHER ASSISTANCE.—The Secretary shall provide to the Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

[(g) FUNDING.—

[(1) IN GENERAL; ALLOCATION FOR EMERGENCY GRANTS.—

[(A)] For the purpose of making grants under subsection (a), there are authorized to be appropriated \$200,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2002.

[(B)] 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 or a substantial rate of increase in such cases.

[(2) RESEARCH, DEMONSTRATION PROJECTS, EDUCATION, AND TRAINING.—For the purpose of carrying out subsection (b), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 2002.]

(g) FEDERAL TUBERCULOSIS TASK FORCE.—

(1) *DUTIES.*—*The Federal Tuberculosis Task Force (in this subsection referred to as the “Task Force”) shall provide to the Secretary and other appropriate Federal officials advice on research into new tools under subsection (b)(2), including advice regarding the efficient utilization of the Federal resources involved.*

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

(3) *CONSULTATION.*—*In developing the comprehensive plan under paragraph (1), the Task Force shall consult with external parties including representatives from groups such as—*

(A) *scientists, physicians, laboratorians, and other health professionals who represent the specialties and disciplines relevant to the research under consideration;*

(B) *members from public-private partnerships, private entities, or foundations (or both) engaged in activities relevant to research under consideration;*

(C) *members of national and international nongovernmental organizations established to address tuberculosis elimination;*

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

(E) *scientists, physicians, laboratorians, 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.*

(h) *AUTHORIZATION OF APPROPRIATIONS.*—

(1) *GENERAL PROGRAM.*—

(A) *IN GENERAL.*—*For the purpose of carrying out this section, there are authorized to be appropriated \$300,000,000 for fiscal year 2009, \$315,000,000 for fiscal year 2010, \$330,750,000 for fiscal year 2011, \$347,287,500 for fiscal year 2012, and \$364,651,900 for fiscal year 2013.*

(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, State, political subdivision of a State, or other public entity in which there is, relative to other areas, a substantial number of cases of tuberculosis, multidrug resistant tuberculosis, or extensively drug resistant tuberculosis or a substantial rate of increase in such cases.*

(C) *PRIORITY.*—*In allocating amounts appropriated under subparagraph (A), 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 dis-*

tribute a portion of 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 and case complexity in the respective geographic area and may consider other factors relevant to tuberculosis in such area.

(iii) *NO CHANGE TO FORMULA REQUIRED.*—This subparagraph does not require the Secretary to modify the formula that was used by the Secretary to distribute funds to grantees under subsection (a) for fiscal year 2009.

(2) *LIMITATION.*—The authorization of appropriations established in paragraph (1) for a fiscal year is effective only if the amount appropriated under such paragraph for such year equals or exceeds the amount appropriated to carry out this section for fiscal year 2009.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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SEC. 424C. TUBERCULOSIS.

(a) *IN GENERAL.*—The Director of the National Institutes of Health may expand, intensify, and coordinate research and development and related activities of the Institutes with respect to tuberculosis including activities toward the goal of eliminating such disease.

(b) *CERTAIN ACTIVITIES.*—Activities under subsection (a) may include—

(1) enhancing basic and clinical research on tuberculosis, including drug resistant tuberculosis;

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

(3) developing new tools for the elimination of tuberculosis, including public health interventions and methods to enhance detection and response to outbreaks of tuberculosis, including multidrug resistant tuberculosis.

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