AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 1532

OFFERED BY MR. GENE GREEN OF TEXAS

- 1 Strike all after the enacting clause and insert the fol-
- 2 lowing:
- 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 2008".
- 6 (b) Table of Contents for
- 7 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.

1	TITLE I—DEPARTMENT OF
2	HEALTH AND HUMAN SERV-
3	ICES IN COORDINATION WITH
4	THE CENTERS FOR DISEASE
5	CONTROL AND PREVENTION
6	AND OTHER APPROPRIATE
7	AGENCIES
8	Subtitle A-National Strategy for
9	Combating and Eliminating Tu-
10	berculosis
11	SEC. 101. NATIONAL STRATEGY.
12	Section 317E of the Public Health Service Act (42
13	U.S.C. 247b-6) is amended—
14	(1) by striking the heading for the section and
15	inserting the following: "NATIONAL STRATEGY FOR
16	COMBATING AND ELIMINATING TUBERCULOSIS";
17	(2) by amending subsection (b) to read as fol-
18	lows:
19	"(b) Research and Development; Demonstra-
20	TION PROJECTS; EDUCATION AND TRAINING.—With re-
21	spect to the prevention, treatment, control, and elimi-
22	nation of tuberculosis, the Secretary may, directly or
23	through grants to public or nonprofit private entities,
24	carry out the following:

1	"(1) Research, with priority given to research
2	and development concerning latent tuberculosis in-
3	fection, strains of tuberculosis resistant to drugs,
4	and research concerning cases of tuberculosis that
5	affect certain populations at risk for tuberculosis.
6	"(2) Research and development and related ac-
7	tivities to develop new tools for the elimination of tu-
8	berculosis, including drugs, diagnostics, vaccines,
9	and public health interventions, such as directly ob-
10	served therapy and non-pharmaceutical intervention,
11	and methods to enhance detection and response to
12	outbreaks of tuberculosis, including multidrug resist-
13	ant tuberculosis. The Secretary is encouraged to give
14	priority to programmatically relevant research so
15	that new tools can be utilized in public health prac-
16	tice.
17	"(3) Demonstration projects for—
18	"(A) the development of regional capabili-
19	ties to prevent, control, and eliminate tuber-
20	culosis and prevent multidrug resistant and ex-
21	tensively drug resistant strains of tuberculosis;
22	"(B) the intensification of efforts to reduce
23	health disparities in the incidence of tuber-
24	culosis;

1	"(C) the intensification of efforts to con-
2	trol tuberculosis along the United States-Mexico
3	border and among United States-Mexico bina-
4	tional populations, including through expansion
5	of the scope and number of programs that—
6	"(i) detect and treat binational cases
7	of tuberculosis; and
8	"(ii) treat high-risk cases of tuber-
9	culosis referred from Mexican health de-
10	partments;
11	"(D) the intensification of efforts to pre-
12	vent, detect, and treat tuberculosis among for-
13	eign-born persons who are in the United States;
14	"(E) the intensification of efforts to pre-
15	vent, detect, and treat tuberculosis among pop-
16	ulations and settings documented as having a
17	high risk for tuberculosis; and
18	"(F) tuberculosis detection, control, and
19	prevention.
20	"(4) Public information and education activi-
21	ties.
22	"(5) Education, training, clinical skills improve-
23	ment activities, and workplace exposure prevention
24	for health professionals, including allied health per-
25	sonnel and emergency response employees.

1	"(6) Support of Centers to carry out activities
2	under paragraphs (1) through (4).
3	"(7) Collaboration with international organiza-
4	tions and foreign countries in carrying out such ac-
5	tivities.
6	"(8) Develop, enhance, and expand information
7	technologies that support tuberculosis control includ-
8	ing surveillance and database management systems
9	with cross-jurisdictional capabilities, which shall con-
10	form to the standards and implementation specifica-
11	tions for such information technologies as rec-
12	ommended by the Secretary."; and
13	(3) in subsection (d), by adding at the end the
14	following:
15	"(3) Determination of amount of non-
16	FEDERAL CONTRIBUTIONS.—
17	"(A) Priority.—In awarding grants
18	under subsection (a) or (b), the Secretary shall
19	give highest priority to an applicant that pro-
20	vides assurances that the applicant will con-
21	tribute non-Federal funds to carry out activities
22	under this section, which may be provided di-
23	rectly or through donations from public or pri-
24	vate entities and may be in cash or in kind, in-
25	cluding equipment or services.

1	"(B) Federal amounts not to be in-
2	CLUDED AS CONTRIBUTIONS.—Amounts pro-
3	vided by the Federal Government, or services
4	assisted or subsidized to any significant extent
5	by the Federal Government, may not be in-
6	cluded in determining the amount of non-Fed-
7	eral contributions as described in subparagraph
8	(A).".
9	Subtitle B—Interagency
10	Collaboration
11	SEC. 111. ADVISORY COUNCIL FOR ELIMINATION OF TU-
12	BERCULOSIS AND THE FEDERAL TUBER-
13	CULOSIS TASK FORCE.
14	(a) In General.—Section 317E(f) of the Public
15	Health Service Act (42 U.S.C. 247b–6(f)) is amended—
16	(1) by redesignating paragraph (5) as para-
17	graph (6); and
18	(2) by striking paragraphs (2) through (4), and
19	inserting the following:
20	"(2) Duties.—The Council shall provide advice
21	and recommendations regarding the elimination of
22	tuberculosis to the Secretary. In addition, the Coun-
23	cil shall, with respect to eliminating such disease,
24	provide to the Secretary and other appropriate Fed-
25	eral officials advice on—

1	"(A) coordinating the activities of the De-
2	partment of Health and Human Services and
3	other Federal agencies that relate to the dis-
4	ease, including activities under subsection (b);
5	"(B) responding rapidly and effectively to
6	emerging issues in tuberculosis; and
7	"(C) efficiently utilizing the Federal re-
8	sources involved.
9	"(3) Comprehensive plan.—
10	"(A) In general.—In carrying out para-
11	graph (2), the Council shall make or update
12	recommendations on the development, revision,
13	and implementation of a comprehensive plan to
14	eliminate tuberculosis in the United States.
15	"(B) Consultation.—In carrying out
16	subparagraph (A), the Council may consult with
17	appropriate public and private entities, which
18	may, subject to the direction or discretion of
19	the Secretary, include—
20	"(i) individuals who are scientists,
21	physicians, laboratorians, and other health
22	professionals, who are not officers or em-
23	ployees of the Federal Government and
24	who represent the disciplines relevant to
25	tuberculosis elimination;

1	"(ii) members of public-private part-
2	nerships or private entities established to
3	address the elimination of tuberculosis;
4	"(iii) members of national and inter-
5	national nongovernmental organizations
6	whose purpose is to eliminate tuberculosis;
7	"(iv) members from the general public
8	who are knowledgeable with respect to tu-
9	berculosis elimination including individuals
10	who have or have had tuberculosis; and
11	"(v) scientists, physicians,
12	laboratorians, and other health profes-
13	sionals who reside in a foreign country
14	with a substantial incidence or prevalence
15	of tuberculosis, and who represent the spe-
16	cialties and disciplines relevant to the re-
17	search under consideration.
18	"(C) CERTAIN COMPONENTS OF PLAN.—In
19	carrying out subparagraph (A), the Council
20	shall, subject to the direction or discretion of
21	the Secretary—
22	"(i) consider recommendations for the
23	involvement of the United States in con-
24	tinuing global and cross-border tuber-
25	culosis control activities in countries where

1	a high incidence of tuberculosis directly af-
2	fects the United States; and
3	"(ii) review the extent to which
4	progress has been made toward eliminating
5	tuberculosis.
6	"(4) Biennial Report.—
7	"(A) In general.—The Council shall sub-
8	mit a biennial report to the Secretary, as deter-
9	mined necessary by the Secretary, on the activi-
10	ties carried under this section. Each such re-
11	port shall include the opinion of the Council on
12	the extent to which its recommendations re-
13	garding the elimination of tuberculosis have
14	been implemented, including with respect to—
15	"(i) activities under subsection (b);
16	and
17	"(ii) the national plan referred to in
18	paragraph (3).
19	"(B) Public.—The Secretary shall make
20	a report submitted under subparagraph (A)
21	public.
22	"(5) Composition.—The Council shall be com-
23	posed of—
24	"(A) ex officio representatives from the
25	Centers for Disease Control and Prevention, the

1	National Institutes of Health, the United States
2	Agency for International Development, the
3	Agency for Healthcare Research and Quality,
4	the Health Resources and Services Administra-
5	tion, the United States-Mexico Border Health
6	Commission, and other Federal departments
7	and agencies that carry out significant activities
8	related to tuberculosis;
9	"(B) State and local tuberculosis control
10	and public health officials;
11	"(C) individuals who are scientists, physi-
12	cians, laboratorians, and other health profes-
13	sionals who represent disciplines relevant to tu-
14	berculosis elimination; and
15	"(D) members of national and inter-
16	national nongovernmental organizations estab-
17	lished to address the elimination of tuber-
18	culosis.".
19	(b) Rule of Construction Regarding Current
20	Membership.—With respect to the advisory council
21	under section 317E(f) of the Public Health Service Act,
22	the amendments made by subsection (a) may not be con-
23	strued as terminating the membership on such council of
24	any individual serving as such a member as of the day
25	before the date of the enactment of this Act.

1	(c) Federal Tuberculosis Task Force.—Section
2	317E of the Public Health Service Act (42 U.S.C. 247b-
3	6) is amended—
4	(1) by redesignating subsection (g) as sub-
5	section (h); and
6	(2) by inserting after subsection (f) the fol-
7	lowing subsection:
8	"(g) Federal Tuberculosis Task Force.—
9	"(1) Duties.—The Federal Tuberculosis Task
10	Force (in this subsection referred to as the 'Task
11	Force') shall provide to the Secretary and other ap-
12	propriate Federal officials advice on research into
13	new tools under subsection (b)(2), including advice
14	regarding the efficient utilization of the Federal re-
15	sources involved.
16	"(2) Comprehensive plan for New Tools
17	DEVELOPMENT.—In carrying out paragraph (1), the
18	Task Force shall make recommendations on the de-
19	velopment of a comprehensive plan for the creation
20	of new tools for the elimination of tuberculosis, in-
21	cluding drugs, diagnostics, and vaccines.
22	"(3) Consultation.—In developing the com-
23	prehensive plan under paragraph (1), the Task
24	Force shall consult with external parties including
25	representatives from groups such as—

1	"(A) scientists, physicians, laboratorians,
2	and other health professionals who represent
3	the specialties and disciplines relevant to the re-
4	search under consideration;
5	"(B) members from public-private partner-
6	ships, private entities, or foundations (or both)
7	engaged in activities relevant to research under
8	consideration;
9	"(C) members of national and inter-
10	national nongovernmental organizations estab-
11	lished to address tuberculosis elimination;
12	"(D) members from the general public who
13	are knowledgeable with respect to tuberculosis
14	including individuals who have or have had tu-
15	berculosis; and
16	"(E) scientists, physicians, laboratorians,
17	and other health professionals who reside in a
18	foreign country with a substantial incidence or
19	prevalence of tuberculosis, and who represent
20	the specialties and disciplines relevant to the re-
21	search under consideration.".

1 Subtitle C—Evaluation of Public

2 Health Authorities

3	SEC. 121. EVALUATION OF PUBLIC HEALTH AUTHORITIES.
4	(a) In General.—Not later than 180 days after the
5	date of enactment of the Comprehensive Tuberculosis
6	Elimination Act of 2008, the Secretary of Health and
7	Human Services shall prepare and submit to the appro-
8	priate committees of Congress a report that evaluates and
9	provides recommendations on changes needed to Federal
10	and State public health authorities to address current dis-
11	ease containment challenges such as isolation and quar-
12	antine.
13	(b) Contents of Evaluation.—The report de-
14	scribed in subsection (a) shall include—
15	(1) an evaluation of the effectiveness of current
16	policies to detain patients with active tuberculosis;
17	(2) an evaluation of whether Federal laws
18	should be strengthened to expressly address the
19	movement of individuals with active tuberculosis;
20	and
21	(3) specific legislative recommendations for
22	changes to Federal laws, if any.
23	(c) Update of Quarantine Regulations.—Not
24	later than 240 days after the date of enactment of this
25	Act, the Secretary of Health and Human Services shall

1	promulgate regulations to update the current interstate
2	and foreign quarantine regulations found in parts 70 and
3	71 of title 42, Code of Federal Regulations.
4	Subtitle D—Authorization of
5	Appropriations
6	SEC. 131. AUTHORIZATIONS OF APPROPRIATIONS.
7	Section 317E of the Public Health Service Act, as
8	amended by section 111(c) of this Act, is amended by
9	striking subsection (h) and inserting the following:
10	"(h) Authorization of Appropriations.—
11	"(1) General program.—
12	"(A) In general.—For the purpose of
13	carrying out this section, there are authorized
14	to be appropriated \$300,000,000 for fiscal year
15	2009, $$315,000,000$ for fiscal year 2010 ,
16	\$330,750,000 for fiscal year 2011,
17	\$347,287,500 for fiscal year 2012, and
18	\$364,651,900 for fiscal year 2013.
19	"(B) Reservation for emergency
20	GRANTS.—Of the amounts appropriated under
21	subparagraph (A) for a fiscal year, the Sec-
22	retary may reserve not more than 25 percent
23	for emergency grants under subsection (a) for
24	any geographic area, State, political subdivision
25	of a State, or other public entity in which there

1	is, relative to other areas, a substantial number
2	of cases of tuberculosis, multidrug resistant tu-
3	berculosis, or extensively drug resistant tuber-
4	culosis or a substantial rate of increase in such
5	cases.
6	"(C) Priority.—In allocating amounts
7	appropriated under subparagraph (A), the Sec-
8	retary shall give priority to allocating such
9	amounts for grants under subsection (a).
10	"(D) Allocation of funds.—
11	"(i) Requirement of formula.—Of
12	the amounts appropriated under subpara-
13	graph (A), not reserved under subpara-
14	graph (B), and allocated by the Secretary
15	for grants under subsection (a), the Sec-
16	retary shall distribute a portion of such
17	amounts to grantees under subsection (a)
18	on the basis of a formula.
19	"(ii) Relevant factors.—The for-
20	mula developed by the Secretary under
21	clause (i) shall take into account the level
22	of tuberculosis morbidity and case com-
23	plexity in the respective geographic area
24	and may consider other factors relevant to
25	tuberculosis in such area.

1	"(iii) No change to formula re-
2	QUIRED.—This subparagraph does not re-
3	quire the Secretary to modify the formula
4	that was used by the Secretary to dis-
5	tribute funds to grantees under subsection
6	(a) for fiscal year 2009.
7	"(2) Limitation.—The authorization of appro-
8	priations established in paragraph (1) for a fiscal
9	year is effective only if the amount appropriated
10	under such paragraph for such year equals or ex-
11	ceeds the amount appropriated to carry out this sec-
12	tion for fiscal year 2009.".
13	TITLE II—NATIONAL INSTITUTES
13 14	OF HEALTH
14	OF HEALTH
14 15	OF HEALTH SEC. 201. RESEARCH AND DEVELOPMENT CONCERNING TU-
14 15 16 17	OF HEALTH SEC. 201. RESEARCH AND DEVELOPMENT CONCERNING TU- BERCULOSIS.
14 15 16 17	OF HEALTH SEC. 201. RESEARCH AND DEVELOPMENT CONCERNING TU- BERCULOSIS. Subpart 2 of part C of title IV of the Public Health
14 15 16 17	OF HEALTH SEC. 201. RESEARCH AND DEVELOPMENT CONCERNING TU- BERCULOSIS. Subpart 2 of part C of title IV of the Public Health Service Act (42 U.S.C. 285b et seq.) is amended by insert-
114 115 116 117 118	OF HEALTH SEC. 201. RESEARCH AND DEVELOPMENT CONCERNING TU- BERCULOSIS. 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:
114 115 116 117 118 119 220	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.
14 15 16 17 18 19 20 21	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 In-
14 15 16 17 18 19 20 21	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

1	"(b) CERTAIN ACTIVITIES.—Activities under sub-
2	section (a) may include—
3	"(1) enhancing basic and clinical research on
4	tuberculosis, including drug resistant tuberculosis;
5	"(2) expanding research on the relationship be-
6	tween such disease and the human immunodeficiency
7	virus; and
8	"(3) developing new tools for the elimination of
9	tuberculosis, including public health interventions
10	and methods to enhance detection and response to
11	outbreaks of tuberculosis, including multidrug resist-
12	ant tuberculosis.".