

113TH CONGRESS
2D SESSION

H. R. 5835

To amend the Federal Food, Drug, and Cosmetic Act and 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

DECEMBER 10, 2014

Mr. GENE GREEN of Texas introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and 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.**

4 This Act may be cited as the “Comprehensive TB
5 Elimination Act of 2014”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1 (1) Each year approximately 9,000,000 people
2 become ill with active tuberculosis (TB), an airborne
3 infectious disease, and it is estimated that 1,500,000
4 of those people die, making TB the second leading
5 global infectious disease killer.

6 (2) There is a global underinvestment in quality
7 TB control, and in the research and development of
8 new drugs, diagnostics and a vaccine, as well as in
9 the relationship between TB and HIV/AIDS.

10 (3) The increasing occurrence of multi-drug re-
11 sistant (“MDR”) TB, including extensively drug re-
12 sistant (“XDR”) TB which is resistant to at least
13 two of the recommended first-line drugs and the rec-
14 ommended second-line medications, is a serious and
15 emerging global health problem.

16 (4) Cases of TB are reported annually in every
17 State within the United States, with a total of 9,582
18 cases of active TB reported in the United States in
19 2013.

20 (5) In addition to those with active TB, an esti-
21 mated 8,000,000 to 10,000,000 people in the United
22 States are infected with the TB bacteria.

23 (6) Drug-resistant TB poses a particular chal-
24 lenge to domestic TB control due to the high costs
25 of treatment and intensive health care resources re-

1 quired. Treatment costs for MDR TB range from
2 \$100,000 to \$300,000, which can cause a serious
3 strain on State public health budgets.

4 (7) In 2013, the United States experienced seri-
5 ous shortages of first- and second-line TB drugs and
6 biologics, including isoniazid, the first-line TB drug,
7 and tubersol, the biologic used in TB skin tests.

8 (8) New tools are urgently needed to more ef-
9 fectively prevent, diagnose, and treat TB. Within the
10 last 40 years, only one new TB drug has been devel-
11 oped and approved in the United States, and the
12 treatment regimen for MDR TB remains excessively
13 lengthy, toxic, and difficult for patients to tolerate.
14 The existing vaccine, which is not used in the United
15 States, confers no protection to adolescents and
16 adults, protecting only against pulmonary TB in in-
17 fants and children.

18 (9) The expertise in identifying, treating, and
19 preventing TB is within the Centers for Disease
20 Control and Prevention and the United States public
21 health system. The identification and preventive
22 treatment of the millions of people in the United
23 States with TB infection, representing the reservoir
24 of future active TB cases, is a key component of the
25 strategy to eliminate TB in the United States.

1 SEC. 3. FOOD AND DRUG ADMINISTRATION.

2 Clause (i) of section 506D(a)(1)(B) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 356d(a)(1)(B))
4 is amended to read as follows:

5 “(i) plans for enhanced interagency
6 and intra-agency coordination, communica-
7 tion, and decisionmaking, including by en-
8 suring coordination between the task force
9 established under this section and the Fed-
10 eral Tuberculosis Task Force under section
11 317E(g) of the Public Health Service Act
12 in the development and implementation of
13 strategies and systems to prevent and miti-
14 gate shortages of drugs used in connection
15 with tuberculosis;”.

16 SEC. 4. CENTERS FOR DISEASE CONTROL AND PREVEN-
17 TION; HEALTH RESOURCES AND SERVICES
18 ADMINISTRATION.

19 (a) PRIORITIZING PROGRAMS FOR HIGH-RISK POPU-
20 LATIONS, INCLUDING FOREIGN-BORN, HOMELESS, AND
21 UNINSURED POPULATIONS.—Subsection (a) of section
22 317E of the Public Health Service Act (42 U.S.C. 247b–
23 6) is amended—

24 (1) by striking “The Secretary” and inserting
25 the following:

26 “(1) GRANTS.—The Secretary”; and

1 (2) by adding at the end the following:

2 “(2) PRIORITY.—In making grants under this
3 subsection, the Secretary shall give priority to
4 awarding grants to State health departments pro-
5 posing to focus on the prevention, control, and elimi-
6 nation of tuberculosis in high-risk populations, in-
7 cluding foreign-born, homeless, and uninsured popu-
8 lations.”.

9 (b) GRANTS FOR COORDINATION OF PROGRAMS AND
10 SERVICES FOR PREVENTION, DIAGNOSIS, AND TREAT-
11 MENT.—

12 (1) GRANTS.—Section 317E of the Public
13 Health Service Act (42 U.S.C. 247b–6) is amend-
14 ed—

15 (A) by redesignating subsections (c)
16 through (h) as subsections (d) through (i), re-
17 spectively; and

18 (B) by inserting after subsection (b) the
19 following:

20 “(c) GRANTS FOR COORDINATION OF PROGRAMS AND
21 SERVICES FOR PREVENTION, DIAGNOSIS, AND TREAT-
22 MENT.—

23 “(1) GRANTS.—The Secretary, acting through
24 the Administrator of the Health Resources and Serv-
25 ices Administration, may award grants to State and

1 local governments and Federally qualified health
 2 centers for coordinating the programs and services
 3 of such governments and centers to ensure timely
 4 and appropriate prevention, diagnosis, and treat-
 5 ment of tuberculosis.

6 “(2) DEFINITION.—In this subsection, the term
 7 ‘Federally qualified health center’ has the meaning
 8 given to such term in section 1861(aa) of the Social
 9 Security Act.”.

10 (2) CONFORMING CHANGES.—Section 317E of
 11 the Public Health Service Act (42 U.S.C. 247b–6)
 12 is amended—

13 (A) in subsections (d), (e)(1), (e)(3)(A),
 14 and (f)(1), as redesignated, by striking “sub-
 15 section (a) or (b)” each place it appears and in-
 16 serting “subsection (a), (b), or (c)”; and

17 (B) in subsection (e)(3)(A), as redesign-
 18 nated, by inserting “(subject to subsection
 19 (a)(2))” after “highest priority”.

20 (c) FEDERAL TUBERCULOSIS TASK FORCE.—Para-
 21 graph (1) of section 317E(h) of the Public Health Service
 22 Act (42 U.S.C. 247b–6(g)), as redesignated, is amended
 23 to read as follows:

24 “(1) DUTIES.—The Federal Tuberculosis Task
 25 Force (in this subsection referred to as the ‘Task

1 Force’) shall provide to the Secretary and other ap-
 2 propriate Federal officials advice on—

3 “(A) research into new tools under sub-
 4 section (b)(2) and ensuring access to such new
 5 tools; and

6 “(B) the development and implementation
 7 of strategies and systems to prevent and miti-
 8 gate shortages of drugs used in connection with
 9 tuberculosis.”.

10 (d) REAUTHORIZATION OF NATIONAL STRATEGY FOR
 11 COMBATING AND ELIMINATING TUBERCULOSIS.—Section
 12 317E(i)(1)(A) of the Public Health Service Act (42 U.S.C.
 13 247b–6(h)(1)(A)) is amended by striking “\$243,101,250
 14 for fiscal year 2013” and inserting “\$243,101,250 for
 15 each of fiscal years 2013 through 2019”.

16 **SEC. 5. NATIONAL INSTITUTES OF HEALTH.**

17 Paragraph (1) of section 424C(b) of the Public
 18 Health Service Act (42 U.S.C. 285b–7c(b)) is amended
 19 to read as follows:

20 “(1) enhancing basic, clinical, and operational
 21 research on tuberculosis, including with respect to—

22 “(A) drug resistant tuberculosis;

23 “(B) infection with, and the progression of,
 24 tuberculosis; and

1 “(C) pediatric tuberculosis;”.

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