

116TH CONGRESS
1ST SESSION

S. 2438

To prevent, treat, and cure tuberculosis globally.

IN THE SENATE OF THE UNITED STATES

AUGUST 1, 2019

Mr. MENENDEZ (for himself and Mr. YOUNG) introduced the following bill;
which was read twice and referred to the Committee on Foreign Relations

A BILL

To prevent, treat, and cure tuberculosis globally.

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 “End Tuberculosis Now
5 Act of 2019”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

8 (1) Tuberculosis is a preventable, treatable, and
9 curable airborne infection; however more than 25
10 years after the World Health Organization declared
11 tuberculosis a public health emergency and called on
12 countries to make scaling up tuberculosis control a

1 priority, tuberculosis still kills more people world-
2 wide than any other infectious disease, and is the
3 leading killer of people living with HIV/AIDS.

4 (2) In 2017, 10,000,000 people became ill with
5 tuberculosis, 10 percent of whom were children, and
6 1,600,000 people died from the disease. In order to
7 achieve the goals of the World Health Organization
8 End TB Strategy by 2035, new tools must be devel-
9 oped and made available.

10 (3) Over one-third of people who become ill with
11 tuberculosis may be undiagnosed, misdiagnosed, or
12 treated but not reported, resulting in unnecessary
13 illness, communicable infections, and increased mor-
14 tality.

15 (4) Failure to properly treat tuberculosis can
16 cause treatment failure and death, and exacerbates
17 antimicrobial resistance, increasing multi-drug-re-
18 sistant tuberculosis (MDR-TB) and extensively
19 drug-resistant tuberculosis (XDR-TB), which are
20 significantly costlier and more difficult to treat than
21 drug-sensitive tuberculosis and can also be trans-
22 mitted from person-to-person, increasing the likeli-
23 hood that drug-resistant tuberculosis will spread to
24 new geographic areas.

1 (5) Globally, only about half of the
2 \$13,000,000,000 required annually as outlined in
3 the Stop TB Partnership's Global Plan to End TB
4 for tuberculosis prevention, diagnosis, and treatment
5 is currently available.

6 (6) There is an annual \$1,300,000,000 gap in
7 funding needed for the development of vaccines, ad-
8 ditional rapid, point-of-care diagnostic tests, and
9 shorter, less toxic treatments which would facilitate
10 patient adherence to treatment regimens, reduce
11 program costs, and mitigate the growing threat of
12 drug-resistant tuberculosis. The United States Gov-
13 ernment continues to be a lead funder of global tu-
14 berculosis research and development, contributing 40
15 percent of the total \$772,000,000 in global funding
16 in 2017, and can catalyze more investments from
17 other countries.

18 (7) The rate of new cases of tuberculosis in
19 countries that receive United States bilateral assist-
20 ance for tuberculosis prevention, treatment, and con-
21 trol has fallen by one quarter since 2000 dem-
22 onstrating the effectiveness of United States pro-
23 grams and activities.

24 (8) In September 2018, United Nations Mem-
25 ber States in the first United National High Level

1 Meeting on Tuberculosis committed to “ending the
2 epidemic in all countries, and pledge[d] to provide
3 leadership and to work together to accelerate our na-
4 tional and global collective actions, investments, and
5 innovations urgently to fight this preventable and
6 treatable disease,” as reflected in United Nations
7 General Assembly Resolution A/RES/73/3.

8 (9) On September 26, 2018, the United Na-
9 tions convened the first High Level Meeting on Tu-
10 berculosis, where 120 countries signed a Political
11 Declaration to accelerate progress against tuber-
12 culosis, including commitments to increase funding
13 for tuberculosis control and research and develop-
14 ment programs, as well as ambitious goals to suc-
15 cessfully treat 40,000,000 people with tuberculosis
16 and prevent at least 30,000,000 from becoming ill
17 between 2018 and 2022.

18 (10) On September 26, 2018, the Administrator
19 for the United States Agency for International De-
20 velopment (USAID) announced a new business
21 model to support the fight to end tuberculosis (TB).
22 Through \$30,000,000 in funding and a new per-
23 formance-based Global Accelerator to End TB,
24 USAID will catalyze investments to meet the target
25 set by the United Nations High-Level Meeting on

1 tuberculosis of treating 40,000,000 people with the
2 disease by 2022. The Accelerator will increase sup-
3 port to governments and local partners as part of a
4 multisectoral approach to ending tuberculosis.

5 (11) It is essential that existing funding for tu-
6 berculosis programs be allocated prudently, and with
7 an emphasis on coordination, to ensure that efforts
8 among United States agencies, partner nations,
9 international organizations, nongovernmental organi-
10 zations, both faith-based and non-faith-based, the
11 private sector and other actors are complementary
12 and not duplicative. Improved data on tuberculosis,
13 access to services, accountability, and program qual-
14 ity can help ensure funding gets to where it is most
15 needed.

16 (12) If progress does not accelerate, the global
17 tuberculosis epidemic, particularly increasing cases
18 of MDR-TB and XDR-TB, where many cases are
19 not curable and vastly more costly to treat, could
20 erase decades of progress in global efforts to end
21 both tuberculosis and HIV/AIDS, much of which has
22 been achieved with United States investment.

1 **SEC. 3. UNITED STATES GOVERNMENT ACTIONS TO END**
2 **TUBERCULOSIS.**

3 Section 104B of the Foreign Assistance Act of 1961
4 (22 U.S.C. 2151b–3(g)) is amended by striking sub-
5 sections (a) through (h) and inserting the following new
6 subsections:

7 “(a) FINDINGS.—Congress makes the following find-
8 ings:

9 “(1) Congress recognizes the continuing chal-
10 lenge of the international tuberculosis epidemic and
11 the deadly impact of its continued existence.

12 “(2) The means exist to detect, treat, prevent,
13 and cure tuberculosis to a large extent, but not
14 enough to ensure ending it, due to inadequate means
15 of diagnosis, prevention, and treatment.

16 “(3) Absent accelerated efforts to address tu-
17 berculosis and increased domestic mobilization of re-
18 sources from high-burden tuberculosis countries, tar-
19 gets set forth in the End TB Strategy will not be
20 met.

21 “(b) POLICY.—It is a major objective of the foreign
22 assistance program of the United States to help end the
23 global tuberculosis epidemic through actions to diagnose
24 and treat all adults and children with all forms of tuber-
25 culosis, including tuberculosis infection, and to prevent
26 new tuberculosis infections in adults and children. In all

1 countries in which the United States Government has es-
2 tablished development programs, particularly in countries
3 with the highest burden of tuberculosis and other coun-
4 tries with high rates of tuberculosis, it is the policy of the
5 United States to—

6 “(1) support the objectives of the World Health
7 Organization End TB Strategy, including goals to—

8 “(A) reduce by 95 percent tuberculosis
9 deaths by 2035;

10 “(B) reduce by 90 percent the tuberculosis
11 incidence rate by 2035; and

12 “(C) reduce by 100 percent the number of
13 families facing catastrophic health costs due to
14 tuberculosis by 2035;

15 “(2) support the Stop TB Partnership’s Global
16 Plan to End TB 2016–2020, including support
17 for—

18 “(A) development and use of innovative
19 new technologies and therapies to increase ac-
20 tive case finding to rapidly diagnose and treat
21 children and adults with all forms of tuber-
22 culosis, alleviate suffering, and ensure tuber-
23 culosis treatment completion;

24 “(B) the diagnosis and treatment of latent
25 tuberculosis infection, in support of the global

1 goal of providing preventive therapy to at least
2 30,000,000 people, including 4,000,000 children
3 under five years of age, 20,000,000 household
4 contacts of people affected by tuberculosis, and
5 6,000,000 people living with HIV, by 2022;

6 “(C) steps to ensure high-quality tuber-
7 culosis care by closing gaps in care cascades,
8 implementing continuous quality improvement
9 at all levels of care, and providing patient sup-
10 port; and

11 “(D) sustainable procurement of tuber-
12 culosis commodities, to avoid interruptions in
13 supply, procurement of commodities of un-
14 known quality, or payment of excessive com-
15 modity costs in countries impacted by tuber-
16 culosis;

17 “(3) ensure United States funding supports ac-
18 tivities that simultaneously emphasize—

19 “(A) the development of comprehensive
20 person-centered programs which include diag-
21 nosis, treatment, and prevention strategies to
22 ensure that those at high risk for infection are
23 found and treated with preventive therapies in
24 a timely manner;

1 “(B) robust tuberculosis infection control
2 practices in all congregate settings, including
3 hospitals and prisons;

4 “(C) the deployment of diagnostic and
5 treatment capacity in areas with the highest tu-
6 berculosis burdens, as well as for highly at-risk
7 and impoverished populations, including patient
8 support;

9 “(D) program monitoring and evaluation
10 based on critical tuberculosis indicators, includ-
11 ing infection control, the numbers of patients
12 accessing tuberculosis treatment, along with pa-
13 tient support, and preventative therapy for
14 those at risk, including all close contacts, as
15 well as treatment completion for all forms of tu-
16 berculosis;

17 “(E) training health care workers on the
18 use of new diagnostic tools and therapies as
19 they become available;

20 “(F) coordination with domestic agencies
21 on an aggressive research agenda to develop
22 vaccines as well as new tools to diagnose, treat,
23 and prevent tuberculosis globally;

24 “(G) linkages with the private sector on
25 improved diagnosis and treatment of tuber-

1 culosis, training for healthcare professionals on
 2 use of the most effective diagnostic and thera-
 3 peutic tools, and research in the areas of vac-
 4 cine development as well as the development of
 5 therapeutics and diagnostic tools;

6 “(H) efforts to address barriers to patients
 7 seeking care including stigma and costs related
 8 to diagnosis and treatment;

9 “(I) efforts to address human rights-re-
 10 lated barriers to tuberculosis services, includ-
 11 ing—

12 “(i) training health workers;

13 “(ii) sensitizing policy makers;

14 “(iii) legal literacy and patient em-
 15 powerment campaigns;

16 “(iv) strengthening legal services; and

17 “(v) monitoring laws and policies; and

18 “(J) the establishment of independent ac-
 19 countability mechanisms and inclusive country
 20 level systems to measure progress and ensure
 21 that commitments made by governments and
 22 relevant stakeholders are met.

23 “(c) AUTHORIZATION.—To carry out this section and
 24 consistent with section 104(c), the President is authorized
 25 to furnish assistance, on such terms and conditions as the

1 President may determine, for the prevention, treatment,
2 control, and elimination of tuberculosis.

3 “(d) GOALS.—In consultation with the appropriate
4 congressional committees, the President shall establish
5 new goals for United States efforts, based on the policy
6 and indicators described in subsection (b), to reach, cure,
7 and prevent all forms of tuberculosis globally over the 5-
8 year period following the date of the enactment of this
9 subsection by updating the United States Government Tu-
10 berculosis Strategy (2015–2019) and the National Action
11 Plan for Combatting Multidrug-Resistant Tuberculosis.

12 “(e) COORDINATION.—

13 “(1) IN GENERAL.—In carrying out this sec-
14 tion, the President shall coordinate with the World
15 Health Organization, the Stop TB Partnership, the
16 Global Fund to Fight AIDS, Tuberculosis, and Ma-
17 laria, and other organizations with respect to the de-
18 velopment and implementation of a comprehensive
19 tuberculosis response program.

20 “(2) BILATERAL ASSISTANCE.—In providing bi-
21 lateral assistance under this section, the President,
22 acting through the Administrator of the United
23 States Agency for International Development,
24 shall—

1 “(A) coordinate and catalyze intensified
2 international tuberculosis research and develop-
3 ment, prevention, diagnosis, treatment, and
4 control efforts, particularly to reduce the inci-
5 dence of, and mortality from, all forms of drug
6 resistant tuberculosis; and

7 “(B) ensure coordination among relevant
8 United States Government agencies and pro-
9 grams, including the Centers for Disease Con-
10 trol and Prevention, the National Institutes of
11 Health, the Biomedical Advanced Research and
12 Development Authority, the Food and Drug Ad-
13 ministration, the National Science Foundation,
14 the Department of Defense Congressionally Di-
15 rected Medical Research Program, and the
16 President’s Emergency Plan for AIDS Relief
17 (PEPFAR), that engage in international tuber-
18 culosis activities to ensure accountability and
19 transparency, reduce duplication of efforts, en-
20 sure equitable shares in domestic expenditure
21 and advancement on research and development,
22 and ensure appropriate integration and coordi-
23 nation of tuberculosis services into other United
24 States-supported health programs.

1 “(f) PRIORITY TO END TB STRATEGY.—In fur-
2 nishing assistance under subsection (b), the President
3 shall give priority to—

4 “(1) direct, high-quality services for all forms of
5 tuberculosis described in international policies and
6 guidelines, with a preference for programs that im-
7 plement a coordinated package of active case find-
8 ing, treatment of all forms of tuberculosis disease
9 and infection, patient support and tuberculosis pre-
10 vention;

11 “(2) individuals infected with both tuberculosis
12 and HIV, and other co-morbidities, treatment for in-
13 dividuals with MDR–TB, XDR–TB, strengthening
14 of health systems, use of the latest International
15 Standards for Tuberculosis Care by all providers,
16 and empowering individuals with tuberculosis;

17 “(3) enabling and promoting tuberculosis re-
18 search to develop innovative new diagnostics, drug
19 therapies, and vaccines, and program-based oper-
20 ational research; and

21 “(4) funding for the Stop Tuberculosis Partner-
22 ship’s Global Drug Facility the Stop Tuberculosis
23 Partnership, and the Global Alliance for Tuber-
24 culosis Drug Development.

1 “(g) ASSISTANCE FOR THE WORLD HEALTH ORGA-
 2 NIZATION AND THE STOP TUBERCULOSIS PARTNER-
 3 SHIP.—In carrying out this section, the President, acting
 4 through the Administrator of the United States Agency
 5 for International Development, is authorized to provide in-
 6 creased resources to the World Health Organization and
 7 the Stop Tuberculosis Partnership to improve the capacity
 8 of countries with high rates of tuberculosis and other af-
 9 fected countries to implement the Stop Tuberculosis Strat-
 10 egy and specific strategies related to addressing MDR-
 11 TB and XDR-TB.

12 “(h) ANNUAL REPORT ON TUBERCULOSIS ACTIVI-
 13 TIES.—The President shall submit an annual report to
 14 Congress that describes the impact of United States for-
 15 eign assistance on efforts to control tuberculosis, includ-
 16 ing—

17 “(1) the number of people with active tuber-
 18 culosis and the number with tuberculosis infection
 19 diagnosed and treated, including the rate of treat-
 20 ment completion and the number receiving patient
 21 support, in countries receiving United States bilat-
 22 eral foreign assistance for tuberculosis control pur-
 23 poses;

24 “(2) the number of persons who have been di-
 25 agnosed and started treatment for MDR-TB and

1 XDR–TB in countries receiving United States bilat-
2 eral foreign assistance for tuberculosis control pro-
3 grams;

4 “(3) a description of the collaboration and co-
5 ordination of United States anti-tuberculosis efforts
6 with the World Health Organization, the Global
7 Fund, and other major public and private entities;

8 “(4) a description of the collaboration and co-
9 ordination among the United States Agency for
10 International Development and other United States
11 agencies, including the Centers for Disease Control
12 and the Office of the Global AIDS Coordinator, for
13 the purposes of combatting tuberculosis;

14 “(5) the constraints on implementation of pro-
15 grams posed by health workforce shortages, health
16 system limitations, and other capacities;

17 “(6) the numbers of people trained by the
18 United States Government in tuberculosis surveil-
19 lance and control;

20 “(7) a breakdown of expenditures for direct pa-
21 tient tuberculosis services, drugs and other commod-
22 ities, drug management, training in diagnosis and
23 treatment, health systems strengthening, research,
24 and support costs; and

1 “(8) for each country receiving bilateral United
2 States assistance for the purpose of tuberculosis pre-
3 vention, treatment, and control—

4 “(A) a description of progress to adopt and
5 implement the most recent World Health Orga-
6 nization guidelines to improve diagnosis, treat-
7 ment, and prevention of tuberculosis for adults
8 and children, disaggregated by sex, including
9 the proportion of health facilities which have
10 adopted the latest WHO guidelines on strength-
11 ening surveillance systems and preventative, di-
12 agnostic, and therapeutic methods, including
13 the use of rapid diagnostic tests and orally ad-
14 ministered TB treatment regimens;

15 “(B) the rate of tuberculosis incidence for
16 adults and children, disaggregated by sex, and
17 a description of progress in implementing meas-
18 ures to reduce incidence, including the number
19 of adults and children receiving tuberculosis
20 preventive therapy, including people with HIV
21 and all close contacts, disaggregated by sex,
22 and the establishment of effective tuberculosis
23 infection control in all congregant settings, in-
24 cluding hospitals, clinics, and prisons;

1 “(C) a description of progress to expand
 2 diagnosis, prevention, and treatment for all
 3 forms of tuberculosis, including in pregnant
 4 women, children, and other high-risk groups
 5 who are vulnerable or in vulnerable situations,
 6 such as migrants, prisoners, miners, and others
 7 exposed to silica, and people living with HIV/
 8 AIDS, disaggregated by sex;

9 “(D) the rate of successful completion of
 10 tuberculosis treatment for adults and children,
 11 disaggregated by sex, and the number of pa-
 12 tients receiving support for treatment comple-
 13 tion;

14 “(E) the number of people, disaggregated
 15 by sex, receiving treatment for MDR–TB, the
 16 proportion of those treated with the latest regi-
 17 mens endorsed by the World Health Organiza-
 18 tion, any factors impeding scale up of such
 19 treatment, and a description of progress to ex-
 20 pand community-based MDR–TB care;

21 “(F) a description of tuberculosis com-
 22 modity procurement challenges, including short-
 23 ages, stockouts, or failed tenders for tuber-
 24 culosis drugs or other commodities;

1 “(G) the proportion of health facilities with
 2 specimen referral linkages to GeneXpert testing
 3 sites, and to reference labs for second line drug
 4 resistance testing, and a description of the
 5 turnaround time for test results;

6 “(H) the number of people trained by the
 7 United States Government to deliver high-qual-
 8 ity tuberculosis surveillance, laboratory services,
 9 prevention, treatment, and care;

10 “(I) a description of activities that serve to
 11 coordinate and leverage countries’ domestic re-
 12 sources, including development of plans, proce-
 13 dures, and disease estimates that support effec-
 14 tive use of resources from the Global Fund to
 15 Fight AIDS, Tuberculosis, and Malaria; and

16 “(J) the full text of any Statement of
 17 Partnership agreed to by the ministry of health
 18 and the United States Agency for International
 19 Development to establish a shared framework
 20 combatting tuberculosis.

21 “(i) ANNUAL REPORT ON TUBERCULOSIS RESEARCH
 22 AND DEVELOPMENT.—The President, acting through the
 23 Administrator of the United States Agency for Inter-
 24 national Development, shall submit to Congress an annual
 25 report, to be prepared in coordination with the National

1 Institutes of Health, the Centers for Disease Control and
 2 Prevention, the Biomedical Advanced Research and Devel-
 3 opment Authority (BARDA), the Food and Drug Admin-
 4 istration, the National Science Foundation, the Depart-
 5 ment of Defense Congressionally Directed Medical Re-
 6 search Program, and the President’s Emergency Plan for
 7 AIDS Relief (PEPFAR)—

8 “(1) describing current progress and challenges
 9 to the development of new tools for the purpose of
 10 tuberculosis prevention, treatment, and control;

11 “(2) identifying critical gaps and emerging pri-
 12 orities for research and development, including for
 13 rapid and point-of-care diagnostics, shortened treat-
 14 ments and prevention methods, and vaccines; and

15 “(3) describing research investments by type,
 16 funded entities, and level of investment.

17 “(j) EVALUATION REPORT.—

18 “(1) IN GENERAL.—Not later than one year
 19 after the date of the enactment of this subsection,
 20 and every 5 years thereafter, the Comptroller Gen-
 21 eral of the United States shall submit to the Admin-
 22 istrator of the United States Agency for Inter-
 23 national Development and the appropriate congres-
 24 sional committees a report that evaluates the per-
 25 formance and impact on tuberculosis prevention, di-

1 agnosis, treatment, and care efforts that are sup-
 2 ported by United States bilateral assistance funding,
 3 including recommendations for improving such pro-
 4 grams.

5 “(2) FORM.—The report required under para-
 6 graph (1) shall be submitted in unclassified form,
 7 but may contain a classified annex if necessary.

8 “(3) PUBLIC AVAILABILITY.—The Comptroller
 9 General shall publish the unclassified portion of the
 10 report required under paragraph (1) on a publicly
 11 available website of the Government Accountability
 12 Office.

13 “(k) DEFINITIONS.—In this section:

14 “(1) APPROPRIATE CONGRESSIONAL COMMIT-
 15 TEES.—The term ‘appropriate congressional com-
 16 mittees’ means the Committee on Foreign Relations
 17 of the Senate and the Committee on Foreign Affairs
 18 of the House of Representatives.

19 “(2) GLOBAL ALLIANCE FOR TUBERCULOSIS
 20 DRUG DEVELOPMENT.—The term ‘Global Alliance
 21 for Tuberculosis Drug Development’ means the pub-
 22 lic-private partnership that bring together leaders in
 23 health, science, philanthropy, and private industry to
 24 devise new approaches to tuberculosis.

1 “(3) GLOBAL TUBERCULOSIS DRUG FACIL-
 2 ITY.—The term ‘Global Tuberculosis Drug Facility
 3 (GDF)’ means the initiative of the Stop Tuber-
 4 culosis Partnership to increase access to the most
 5 advanced, affordable, quality-assured tuberculosis
 6 drugs and diagnostics.

7 “(4) END TB STRATEGY.—The term ‘End TB
 8 Strategy’ means the strategy to eliminate tuber-
 9 culosis approved by the World Health Assembly in
 10 May 2014, which is described in The End TB Strat-
 11 egy: Global Strategy and Targets for Tuberculosis
 12 Prevention, Care and Control after 2015.

13 “(5) STOP TUBERCULOSIS PARTNERSHIP.—The
 14 term ‘Stop Tuberculosis Partnership’ means the
 15 partnership of the United Nations Office for Project
 16 Services, donors including the United States, high-
 17 burden tuberculosis countries, multilateral agencies,
 18 and nongovernmental and technical agencies com-
 19 mitted to short- and long-term measures required to
 20 control and eventually eliminate tuberculosis as a
 21 public health problem in the world.”.

