

Manager's Substitute Amendment

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.**S. 3386**

To prevent, treat, and cure tuberculosis globally.

Referred to the Committee on Foreign Relations of the
Senate and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by Mr. MENENDEZ

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “End Tuberculosis Now
5 Act of 2022”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

8 (1) Tuberculosis (referred to in the Act as
9 “TB”) is a preventable, treatable, and curable dis-
10 ease, yet more than 25 years after the World Health
11 Organization declared it to be a public health emer-
12 gency and called on countries to make scaling up TB

1 control a priority, TB remains a deadly health
2 threat.

3 (2) In 2021 alone, an estimated 10,600,000
4 people became ill with TB, 11 percent of whom were
5 children, and an estimated 1,600,000 of these people
6 died from the illness. In order to achieve by 2035
7 the goals of the Political Declaration of the High-
8 Level Meeting of the General Assembly on the Fight
9 Against Tuberculosis, adopted by the United Na-
10 tions General Assembly October 10, 2018, and of
11 the World Health Organization End TB Strategy,
12 adopted by the World Health Assembly in 2014, new
13 and existing tools must be developed and scaled-up.

14 (3) More than $\frac{1}{3}$ of people who become ill with
15 TB may be undiagnosed or misdiagnosed, resulting
16 in unnecessary illness, communicable infections, and
17 increased mortality.

18 (4) Since March 2020, the COVID-19 pan-
19 demic has severely disrupted TB responses in low-
20 and middle-income countries, stalling and reversing
21 years of progress made against TB. According to the
22 World Health Organization, from 2019 to 2020—

23 (A) global detection of TB dropped by 18
24 percent;

1 (B) an estimated 1,300,000 fewer people
2 were diagnosed and enrolled on TB treatment;
3 and

4 (C) in some countries, TB case notifica-
5 tions dropped by up to 41 percent, setting
6 progress back by up to 12 years.

7 (5) Failure to properly diagnose and treat TB
8 can lead to death, can exacerbate antimicrobial re-
9 sistance (a key contributor to rising cases of multi-
10 drug-resistant TB and extensively drug-resistant
11 TB), and can increase the probability of the intro-
12 duction of resistant TB into new geographic areas.

13 (6) TB programs have played a central role in
14 responding to COVID-19, including through
15 leveraging the expertise of medical staff with exper-
16 tise in TB and lung diseases, the repurposing of TB
17 hospitals, and the use of the TB rapid molecular
18 testing platforms and x-ray equipment for multiple
19 purposes, including the treatment of COVID-19.

20 (7) With sufficient resourcing, TB program ex-
21 pertise, infection control, laboratory capacity, active
22 case finding, and contact investigation can serve as
23 platforms for respiratory pandemic response against
24 existing and new infectious respiratory disease with-
25 out disrupting ongoing TB programs and activities.

1 (8) Globally, only about $\frac{1}{2}$ of the
2 \$13,000,000,000 required annually, as outlined in
3 the Stop TB Partnership’s Global Plan to End TB,
4 is currently available.

5 (9) According to estimates by the Global Fund
6 for AIDS, Tuberculosis, and Malaria, an additional
7 \$3,500,000,000 was needed during 2021 for TB
8 programs in eligible countries in order to recover
9 from the negative impacts of COVID–19.

10 (10) On September 26, 2018, the United Na-
11 tions convened the first High-Level Meeting of the
12 General Assembly on the Fight Against Tuber-
13 culosis, during which 120 countries—

14 (A) signed a Political Declaration to accel-
15 erate progress against TB, including through
16 commitments to increase funding for TB pre-
17 vention, diagnosis, treatment, and research and
18 development programs, and to set ambitious
19 goals to successfully treat 40,000,000 people
20 with active TB and prevent at least 30,000,000
21 from becoming ill with TB between 2018 and
22 2022; and

23 (B) committed to “ending the epidemic in
24 all countries, and pledge[d] to provide leader-
25 ship and to work together to accelerate our na-

1 tional and global collective actions, investments
2 and innovations urgently to fight this prevent-
3 able and treatable disease”, as reflected in
4 United Nations General Assembly Resolution
5 73/3.

6 (11) The United States Government continues
7 to be a lead funder of global TB research and devel-
8 opment, contributing 44 percent of the total
9 \$915,000,000 in global funding in 2020, and can
10 catalyze more investments from other countries.

11 (12) Working with governments and partners
12 around the world, USAID’s TB programming has
13 saved an estimated 66,000,000 lives, demonstrating
14 the effectiveness of United States programs and ac-
15 tivities against the illness.

16 (13) On September 26, 2018, the USAID Ad-
17 ministrator announced a new performance-based
18 Global Accelerator to End TB, aimed at catalyzing
19 investments to meet the treatment target set by the
20 United Nations High-Level Meeting, further dem-
21 onstrating the critical role that United States leader-
22 ship and assistance plays in the fight to eliminate
23 TB.

24 (14) It is essential to ensure that efforts among
25 United States Government agencies, partner nations,

1 international organizations, nongovernmental organi-
2 zations, the private sector, and other actors are com-
3 plementary and not duplicative in order to achieve
4 the goal of ending the TB epidemic in all countries.

5 **SEC. 3. UNITED STATES GOVERNMENT ACTIONS TO END**
6 **TUBERCULOSIS.**

7 Section 104B of the Foreign Assistance Act of 1961
8 (22 U.S.C. 2151b–3) is amended to read as follows:

9 **“SEC. 104B. ASSISTANCE TO COMBAT TUBERCULOSIS.**

10 **“(a) FINDINGS.—**Congress makes the following find-
11 ings:

12 **“(1)** The international spread of tuberculosis
13 (referred to in this section as ‘TB’) and the deadly
14 impact of TB’s continued existence constitutes a
15 continuing challenge.

16 **“(2)** Additional tools and resources are required
17 to effectively diagnose, prevent, and treat TB.

18 **“(3)** Effectively resourced TB programs can
19 serve as a critical platform for preventing and re-
20 sponding to future infectious respiratory disease
21 pandemics.

22 **“(b) POLICY.—**

23 **“(1) IN GENERAL.—**It is a major objective of
24 the foreign assistance program of the United States

1 to help end the TB public health emergency through
2 accelerated actions—

3 “(A) to support the diagnosis and treat-
4 ment of all adults and children with all forms
5 of TB; and

6 “(B) to prevent new TB infections from
7 occurring.

8 “(2) SUPPORT FOR GLOBAL PLANS AND OBJEC-
9 TIVES.—In countries in which the United States
10 Government has established foreign assistance pro-
11 grams under this Act, particularly in countries with
12 the highest burden of TB and other countries with
13 high rates of infection and transmission of TB, it is
14 the policy of the United States—

15 “(A) to support the objectives of the World
16 Health Organization End TB Strategy, includ-
17 ing its goals—

18 “(i) to reduce TB deaths by 95 per-
19 cent by 2035;

20 “(ii) to reduce the TB incidence rate
21 by 90 percent by 2035; and

22 “(iii) to reduce the number of families
23 facing catastrophic health costs due to TB
24 by 100 percent by 2035;

1 “(B) to support the Stop TB Partnership’s
2 Global Plan to End TB 2023–2030, including
3 by providing support for—

4 “(i) developing and using innovative
5 new technologies and therapies to increase
6 active case finding and rapidly diagnose
7 and treat children and adults with all
8 forms of TB, alleviate suffering, and en-
9 sure TB treatment completion;

10 “(ii) expanding diagnosis and treat-
11 ment in line with the goals established by
12 the Political Declaration of the High-Level
13 Meeting of the General Assembly on the
14 Fight Against Tuberculosis, including—

15 “(I) successfully treating
16 40,000,000 people with active TB by
17 2023, including 3,500,000 children,
18 and 1,500,000 people with drug-re-
19 sistant TB; and

20 “(II) diagnosing and treating la-
21 tent tuberculosis infection, in support
22 of the global goal of providing preven-
23 tive therapy to at least 30,000,000
24 people by 2023, including 4,000,000
25 children younger than 5 years of age,

1 20,000,000 household contacts of peo-
2 ple affected by TB, and 6,000,000
3 people living with HIV;

4 “(iii) ensuring high-quality TB care
5 by closing gaps in care cascades, imple-
6 menting continuous quality improvement
7 at all levels of care, and providing related
8 patient support; and

9 “(iv) sustainable procurements of TB
10 commodities to avoid interruptions in sup-
11 ply, the procurement of commodities of un-
12 known quality, or payment of excessive
13 commodity costs in countries impacted by
14 TB;

15 “(C) ensure, to the greatest extent prac-
16 ticable, that United States funding supports ac-
17 tivities that simultaneously emphasize—

18 “(i) the development of comprehensive
19 person-centered programs, including diag-
20 nosis, treatment, and prevention strategies
21 to ensure that—

22 “(I) all people sick with TB re-
23 ceive quality diagnosis and treatment
24 through active case finding; and

1 come available, and increased support for
2 training frontline health care workers to
3 support expanded TB active case finding,
4 contact tracing, and patient support serv-
5 ices;

6 “(vi) coordination with domestic agen-
7 cies and organizations to support an ag-
8 gressive research agenda to develop vac-
9 cines as well as new tools to diagnose,
10 treat, and prevent TB globally;

11 “(vii) linkages with the private sector
12 on—

13 “(I) research and development of
14 a vaccine, and on new tools for diag-
15 nosis and treatment of TB;

16 “(II) improving current tools for
17 diagnosis and treatment of TB, in-
18 cluding telehealth solutions for pre-
19 vention and treatment; and

20 “(III) training healthcare profes-
21 sionals on use of the newest and most
22 effective diagnostic and therapeutic
23 tools;

1 “(viii) the reduction of barriers to
2 care, including stigma and treatment and
3 diagnosis costs, including through—

4 “(I) training health workers;

5 “(II) sensitizing policy makers;

6 “(III) requiring that all relevant
7 grants and funding agreements in-
8 clude access and affordability provi-
9 sions;

10 “(IV) supporting education and
11 empowerment campaigns for TB pa-
12 tients regarding local TB services;

13 “(V) monitoring barriers to ac-
14 cessing TB services; and

15 “(VI) increasing support for pa-
16 tient-led and community-led TB out-
17 reach efforts; and

18 “(ix) support for country-level, sus-
19 tainable accountability mechanisms and ca-
20 pacity to measure progress and ensure that
21 commitments made by governments and
22 relevant stakeholders are met.

23 “(c) DEFINITIONS.—In this section:

24 “(1) APPROPRIATE CONGRESSIONAL COMMIT-
25 TEES.—The term ‘appropriate congressional com-

1 mittees’ means the Committee on Foreign Relations
2 of the Senate and the Committee on Foreign Affairs
3 of the House of Representatives.

4 “(2) END TB STRATEGY.—The term ‘End TB
5 Strategy’ means the strategy to eliminate TB that
6 was approved by the World Health Assembly in May
7 2014, and is described in ‘The End TB Strategy:
8 Global Strategy and Targets for Tuberculosis Pre-
9 vention, Care and Control After 2015’.

10 “(3) GLOBAL ALLIANCE FOR TUBERCULOSIS
11 DRUG DEVELOPMENT.—The term ‘Global Alliance
12 for Tuberculosis Drug Development’ means the pub-
13 lic-private partnership that bring together leaders in
14 health, science, philanthropy, and private industry to
15 devise new approaches to TB.

16 “(4) GLOBAL TUBERCULOSIS DRUG FACIL-
17 ITY.—The term ‘Global Tuberculosis Drug Facility’
18 means the initiative of the Stop Tuberculosis Part-
19 nership to increase access to the most advanced, af-
20 fordable, quality-assured TB drugs and diagnostics.

21 “(5) MDR–TB.—The term ‘MDR–TB’ means
22 multi-drug-resistant TB.

23 “(6) STOP TUBERCULOSIS PARTNERSHIP.—The
24 term ‘Stop Tuberculosis Partnership’ means the
25 partnership of 1,600 organizations (including inter-

1 national and technical organizations, government
2 programs, research and funding agencies, founda-
3 tions, nongovernmental organizations, civil society
4 and community groups, and the private sector), do-
5 nors, including the United States, high TB burden
6 countries, multilateral agencies, and nongovern-
7 mental and technical agencies, which is governed by
8 the Stop TB Partnership Coordinating Board and
9 hosted by a United Nations entity, committed to
10 short- and long-term measures required to control
11 and eventually eliminate TB as a public health prob-
12 lem in the world.

13 “(7) XDR-TB.—The term ‘XDR-TB’ means
14 extensively drug-resistant TB.

15 “(d) AUTHORIZATION.—To carry out this section, the
16 President is authorized, consistent with section 104(c), to
17 furnish assistance, on such terms and conditions as the
18 President may determine, for the prevention, treatment,
19 control, and elimination of TB.

20 “(e) GOALS.—In consultation with the appropriate
21 congressional committees, the President shall establish
22 goals, based on the policy and indicators described in sub-
23 section (b), for—

24 “(1) United States TB programs to detect,
25 cure, and prevent all forms of TB globally for the

1 period between 2023 and 2030 that are aligned with
2 the End TB Strategy’s 2030 targets and the
3 USAID’s Global Tuberculosis (TB) Strategy 2023-
4 2030; and

5 “(2) updating the National Action Plan for
6 Combating Multidrug-Resistant Tuberculosis.

7 “(f) COORDINATION.—

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

15 “(2) BILATERAL ASSISTANCE.—In providing bi-
16 lateral assistance under this section, the President,
17 acting through the Administrator of the United
18 States Agency for International Development,
19 shall—

20 “(A) catalyze support for research and de-
21 velopment of new tools to prevent, diagnose,
22 treat, and control TB worldwide, particularly to
23 reduce the incidence of, and mortality from, all
24 forms of drug-resistant TB;

1 “(B) ensure United States programs and
2 activities focus on finding individuals with ac-
3 tive TB disease and provide quality diagnosis
4 and treatment, including through digital health
5 solutions, and reaching those at high risk with
6 preventive therapy; and

7 “(C) ensure coordination among relevant
8 United States Government agencies, including
9 the Department of State, the Centers for Dis-
10 ease Control and Prevention, the National In-
11 stitutes of Health, the Biomedical Advanced
12 Research and Development Authority, the Food
13 and Drug Administration, the National Science
14 Foundation, the Department of Defense
15 (through its Congressionally Directed Medical
16 Research Programs), and other relevant Fed-
17 eral departments and agencies that engage in
18 international TB activities—

19 “(i) to ensure accountability and
20 transparency;

21 “(ii) to reduce duplication of efforts;
22 and

23 “(iii) to ensure appropriate integra-
24 tion and coordination of TB services into

1 other United States-supported health pro-
2 grams.

3 “(g) PRIORITY TO END TB STRATEGY.—In fur-
4 nishing assistance under subsection (d), the President
5 shall prioritize—

6 “(1) building and strengthening TB pro-
7 grams—

8 “(A) to increase the diagnosis and treat-
9 ment of everyone who is sick with TB; and

10 “(B) to ensure that such individuals have
11 access to quality diagnosis and treatment;

12 “(2) direct, high-quality integrated services for
13 all forms of TB, as described by the World Health
14 Organization, which call for the coordination of ac-
15 tive case finding, treatment of all forms of TB dis-
16 ease and infection, patient support, and TB preven-
17 tion;

18 “(3) treating individuals co-infected with HIV
19 and other co-morbidities, and other individuals with
20 TB who may be at risk of stigma;

21 “(4) strengthening the capacity of health sys-
22 tems to detect, prevent, and treat TB, including
23 MDR-TB and XDR-TB, as described in the latest
24 international guidance related to TB;

1 “(5) researching and developing innovative
2 diagnostics, drug therapies, and vaccines, and pro-
3 gram-based research;

4 “(6) support for the Stop Tuberculosis Partner-
5 ship’s Global Drug Facility, the Global Alliance for
6 Tuberculosis Drug Development, and other organiza-
7 tions promoting the development of new products
8 and drugs for TB; and

9 “(7) ensuring that TB programs can serve as
10 key platforms for supporting national respiratory
11 pandemic response against existing and new infec-
12 tious respiratory disease.

13 “(h) ASSISTANCE FOR THE WORLD HEALTH ORGA-
14 NIZATION AND THE STOP TUBERCULOSIS PARTNER-
15 SHIP.—In carrying out this section, the President, acting
16 through the Administrator of the United States Agency
17 for International Development, is authorized—

18 “(1) to provide resources to the World Health
19 Organization and the Stop Tuberculosis Partnership
20 to improve the capacity of countries with high bur-
21 dens or rates of TB and other affected countries to
22 implement the End TB Strategy, the Stop TB Glob-
23 al Plan to End TB, their own national strategies
24 and plans, other global efforts to control MDR-TB
25 and XDR-TB; and

1 “(2) to leverage the contributions of other do-
2 nors for the activities described in paragraph (1).

3 “(i) ANNUAL REPORT ON TB ACTIVITIES.—Not later
4 than December 15 of each year until the earlier of the
5 date on which the goals specified in subsection (b)(2)(A)
6 are met or the last day of 2035, the President shall submit
7 an annual report to the appropriate congressional commit-
8 tees that describes United States foreign assistance to
9 control TB and the impact of such efforts, including—

10 “(1) the number of individuals with active TB
11 disease that were diagnosed and treated, including
12 the rate of treatment completion and the number re-
13 ceiving patient support;

14 “(2) the number of persons with MDR–TB and
15 XDR–TB that were diagnosed and treated, includ-
16 ing the rate of completion, in countries receiving
17 United States bilateral foreign assistance for TB
18 control programs;

19 “(3) the number of people trained by the
20 United States Government in TB surveillance and
21 control;

22 “(4) the number of individuals with active TB
23 disease identified as a result of engagement with the
24 private sector and other nongovernmental partners

1 in countries receiving United States bilateral foreign
2 assistance for TB control programs;

3 “(5) a description of the collaboration and co-
4 ordination of United States anti-TB efforts with the
5 World Health Organization, the Stop TB Partner-
6 ship, the Global Fund to Fight AIDS, Tuberculosis
7 and Malaria, and other major public and private en-
8 tities;

9 “(6) a description of the collaboration and co-
10 ordination among the United States Agency for
11 International Development and other United States
12 departments and agencies, including the Centers for
13 Disease Control and Prevention and the Office of
14 the Global AIDS Coordinator, for the purposes of
15 combating TB;

16 “(7) the constraints on implementation of pro-
17 grams posed by health workforce shortages, health
18 system limitations, barriers to digital health imple-
19 mentation, other challenges to successful implemen-
20 tation, and strategies to address such constraints;

21 “(8) a breakdown of expenditures for patient
22 services supporting TB diagnosis, treatment, and
23 prevention, including procurement of drugs and
24 other commodities, drug management, training in di-
25 agnosis and treatment, health systems strengthening

1 that directly impacts the provision of TB services,
2 and research; and

3 “(9) for each country, and when practicable,
4 each project site receiving bilateral United States as-
5 sistance for the purpose of TB prevention, treat-
6 ment, and control—

7 “(A) a description of progress toward the
8 adoption and implementation of the most recent
9 World Health Organization guidelines to im-
10 prove diagnosis, treatment, and prevention of
11 TB for adults and children, disaggregated by
12 sex, including the proportion of health facilities
13 that have adopted the latest World Health Or-
14 ganization guidelines on strengthening moni-
15 toring systems and preventative, diagnostic, and
16 therapeutic methods, including the use of rapid
17 diagnostic tests and orally administered TB
18 treatment regimens;

19 “(B) the number of individuals screened
20 for TB disease and the number evaluated for
21 TB infection using active case finding outside
22 of health facilities;

23 “(C) the number of individuals with active
24 TB disease that were diagnosed and treated, in-

1 including the rate of treatment completion and
2 the number receiving patient support;

3 “(D) the number of adults and children,
4 including people with HIV and close contacts,
5 who are evaluated for TB infection, the number
6 of adults and children started on treatment for
7 TB infection, and the number of adults and
8 children completing such treatment,
9 disaggregated by sex and, as possible, income or
10 wealth quintile;

11 “(E) the establishment of effective TB in-
12 fection control in all relevant congregant set-
13 tings, including hospitals, clinics, and prisons;

14 “(F) a description of progress in imple-
15 menting measures to reduce TB incidence, in-
16 cluding actions—

17 “(i) to expand active case finding and
18 contact tracing to reach vulnerable groups;
19 and

20 “(ii) to expand TB preventive ther-
21 apy, engagement of the private sector, and
22 diagnostic capacity;

23 “(G) a description of progress to expand
24 diagnosis, prevention, and treatment for all
25 forms of TB, including in pregnant women,

1 children, and individuals and groups at greater
2 risk of TB, including migrants, prisoners, min-
3 ers, people exposed to silica, and people living
4 with HIV/AIDS, disaggregated by sex;

5 “(H) the rate of successful completion of
6 TB treatment for adults and children,
7 disaggregated by sex, and the number of indi-
8 viduals receiving support for treatment comple-
9 tion;

10 “(I) the number of people, disaggregated
11 by sex, receiving treatment for MDR-TB, the
12 proportion of those treated with the latest regi-
13 mens endorsed by the World Health Organiza-
14 tion, factors impeding scale up of such treat-
15 ment, and a description of progress to expand
16 community-based MDR-TB care;

17 “(J) a description of TB commodity pro-
18 curement challenges, including shortages,
19 stockouts, or failed tenders for TB drugs or
20 other commodities;

21 “(K) the proportion of health facilities
22 with specimen referral linkages to quality diag-
23 nostic networks, including established testing
24 sites and reference labs, to ensure maximum ac-
25 cess and referral for second line drug resistance

1 testing, and a description of the turnaround
2 time for test results;

3 “(L) the number of people trained by the
4 United States Government to deliver high-quality
5 TB diagnostic, preventative, monitoring,
6 treatment, and care services;

7 “(M) a description of how supported activi-
8 ties are coordinated with—

9 “(i) country national TB plans and
10 strategies; and

11 “(ii) TB control efforts supported by
12 the Global Fund to Fight AIDS, Tuber-
13 culosis, and Malaria, and other inter-
14 national assistance programs and funds,
15 including in the areas of program develop-
16 ment and implementation; and

17 “(N) for the first 3 years of the report re-
18 quired under this subsection, a description of
19 the progress in recovering from the negative im-
20 pact of COVID–19 on TB, including—

21 “(i) whether there has been the devel-
22 opment and implementation of a com-
23 prehensive plan to recover TB activities
24 from diversion of resources;

1 “(ii) the continued use of bidirectional
2 TB–COVID testing; and

3 “(iii) progress on increased diagnosis
4 and treatment of active TB.

5 “(j) ANNUAL REPORT ON TB RESEARCH AND DE-
6 VELOPMENT.—The President, acting through the Admin-
7 istrator of the United States Agency for International De-
8 velopment, and in coordination with the National Insti-
9 tutes of Health, the Centers for Disease Control and Pre-
10 vention, the Biomedical Advanced Research and Develop-
11 ment Authority, the Food and Drug Administration, the
12 National Science Foundation, and the Office of the Global
13 AIDS Coordinator, shall submit an annual report to the
14 appropriate congressional committees that—

15 “(1) describes the current progress and chal-
16 lenges to the development of new tools for the pur-
17 pose of TB prevention, treatment, and control;

18 “(2) identifies critical gaps and emerging prior-
19 ities for research and development, including for
20 rapid and point-of-care diagnostics, shortened treat-
21 ments and prevention methods, telehealth solutions
22 for prevention and treatment, and vaccines; and

23 “(3) describes research investments by type,
24 funded entities, and level of investment.

1 “(k) EVALUATION REPORT.—Not later than 2 years
2 after the date of the enactment of the End Tuberculosis
3 Now Act of 2022, and every 5 years thereafter until the
4 last day of 2035, the Comptroller General of the United
5 States shall submit a report to the appropriate congres-
6 sional committees that evaluates the performance and im-
7 pact on TB prevention, diagnosis, treatment, and care ef-
8 forts that are supported by United States bilateral assist-
9 ance funding, including recommendations for improving
10 such programs.”.