117TH CONGRESS 1ST SESSION **S**.

To prevent, treat, and cure tuberculosis globally.

## IN THE SENATE OF THE UNITED STATES

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

## 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 2021".

## 6 SEC. 2. FINDINGS.

- 7 Congress makes the following findings:
- 8 (1) More than 25 years after the World Health 9 Organization declared Tuberculosis (referred to in 10 this Act as "TB") a public health emergency and 11 called on countries to make scaling up tuberculosis

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control a priority, TB remains a deadly health
 threat despite the fact that TB is a preventable,
 treatable, and curable disease.

4 (2) In 2019 alone, an estimated 10,000,000 5 people became ill with TB, 10 percent of whom were 6 children, and 1,400,000 of whom died. In order to 7 achieve by 2035 the goals of the Political Declara-8 tion of the High-Level Meeting of the General As-9 sembly on the Fight Against Tuberculosis, adopted 10 by the United Nations General Assembly October 11 10, 2018, and of the World Health Organization 12 End TB Strategy, adopted by the World Health As-13 sembly in 2014, new tools must be developed and 14 made available.

(3) Over <sup>1</sup>/<sub>3</sub> of people who become ill with TB
may be undiagnosed or misdiagnosed, resulting in
unnecessary illness, communicable infections, and increased mortality.

(4) Since March 2020, the COVID-19 pandemic has severely disrupted TB responses in lowand middle-income countries, stalling and reversing
years of progress made against TB, with detection
dropping by 50 percent and an estimated 1,000,000
fewer people will be diagnosed and enrolled on TB
treatment.

1 (5) In May 2020, a modeling study conducted 2 by the Stop Tuberculosis Partnership (referred to in 3 this Act as the "Stop TB Partnership") in collabo-4 ration with the United States Agency for Inter-5 national Development (referred to in this Act as 6 "USAID") and partners estimated that a 3-month 7 global lockdown followed by a protracted 10-month 8 restoration could lead to an additional 6,300,000 9 cases of TB between 2020 and 2025 and an addi-10 tional 1,400,000 TB deaths during this period, caus-11 ing a setback of at least 5 to 8 years in the fight 12 against TB.

(6) Findings released by the Stop TB Partnership on March 18, 2021, found that TB diagnosis
and enrolment on treatment in 2020 declined by an
estimated total of 1,000,000 cases in 9 countries
that collectively represent 60 percent of the global
TB caseload, pushing the TB response back to 2008
levels in terms of people diagnosed and treated.

20 (7) Failure to properly diagnose and treat TB
21 can lead to death and can exacerbate antimicrobial
22 resistance, a key contributor to rising cases of multi23 drug-resistant tuberculosis, and extensively drug-re24 sistant tuberculosis, and increasing the probability of

the introduction of resistant TB into new geographic
 areas.

3 (8) TB programs have played a central role in 4 responding to COVID-19, including through 5 leveraging the expertise of medical staff with exper-6 tise in TB and lung diseases, the repurposing of TB 7 hospitals, and the use of the TB rapid molecular 8 testing platforms and X-Ray equipment for multiple 9 purposes, including COVID–19.

10 (9) With sufficient resourcing, TB program ex-11 pertise, infection control, laboratory capacity, active 12 case finding and contact investigation, can serve as 13 platform for respiratory pandemic a response 14 against existing and new infectious respiratory dis-15 ease without such a response necessitating the dis-16 ruption of ongoing TB programs and activities.

17 (10)of Globally, about  $1/_{2}$ only the 18 \$13,000,000,000 required annually outlined in the 19 Stop TB Partnership's Global Plan to End TB for 20 tuberculosis prevention, diagnosis, and treatment is 21 currently available.

(11) An estimated additional \$3,500,000,000
will be needed during 2021 for TB programs in
countries eligible for Global Fund for AIDS, Tuberculosis, and Malaria programming to recover from

1	the negative impacts of COVID–19, with a total an-
2	nual gap of at least \$8,000,000,000 for TB diag-
3	nosis, prevention, and treatment in such countries.
4	(12) On September 26, 2018, the United Na-
5	tions convened the first High-Level Meeting of the
6	General Assembly on the Fight Against Tuber-
7	culosis, at which 120 countries—
8	(A) signed a Political Declaration to accel-
9	erate progress against TB, including commit-
10	ments to increase funding for TB control and
11	research and development programs, and ambi-
12	tious goals to successfully treat 40,000,000 peo-
13	ple with tuberculosis and prevent at least
14	30,000,000 from becoming ill with TB between
15	2018 and 2022; and
16	(B) committed to "ending the epidemic in
17	all countries, and pledge[d] to provide leader-
18	ship and to work together to accelerate our na-
19	tional and global collective actions, investments
20	and innovations urgently to fight this prevent-
21	able and treatable disease," as reflected in
22	United Nations General Assembly Resolution A/
23	RES/73/3.
24	(13) The United States Government continues
25	to be a lead funder of global TB research and devel-

opment, contributing 44 percent of the total
 \$901,000,000 in global funding in 2019, and can
 catalyze more investments from other countries.

4 (14) Working with governments and partners
5 around the world, the TB efforts by USAID have
6 saved 60,000,000 lives, demonstrating the effective7 ness of United States programs and activities.

8 (15) On September 26, 2018, the USAID Ad-9 ministrator announced a new performance-based 10 Global Accelerator to End TB, aimed at catalyzing 11 investments to meet the target set by the United 12 Nations High-Level Meeting on tuberculosis of treat-13 ing 40,000,000 people with the disease by 2022, fur-14 ther demonstrating the critical role that United 15 States leadership and assistance plays in the fight to 16 eliminate TB.

(16) It is essential to ensure that efforts among
United States Government agencies, partner nations,
international organizations, nongovernmental organizations, the private sector, and other actors are complementary and not duplicative in order to achieve
the goal of ending the TB epidemic in all countries.

## 7 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) is amended to read as follows: 5 "SECTION 104B. ASSISTANCE TO COMBAT TUBERCULOSIS. 6 "(a) FINDINGS.—Congress makes the following find-7 ings: 8 "(1) Congress recognizes the continuing chal-9 lenge of the international spread of tuberculosis, and the deadly impact of the continued existence of TB. 10 11 "(2) Additional tools and resources are required 12 to effectively diagnose, prevent, and treat tuber-13 culosis. 14 "(3) Effectively resourced tuberculosis pro-

14 (3) Effectively resourced tuberculosis pro15 grams can serve as a critical platform for respiratory
16 pandemic response against existing and new infec17 tious respiratory disease.

18 "(b) POLICY.—It is a major objective of the foreign 19 assistance program of the United States to help end the 20 global tuberculosis pandemic through actions to support 21 the diagnosis and treatment of all adults and children with 22 all forms of tuberculosis, and to prevent new tuberculosis 23 infections in adults and children. In all countries in which 24 the United States Government has established develop-25 ment programs, particularly in countries with the highest

1	burden of tuberculosis and other countries with high rates
2	of tuberculosis, it is the policy of the United States—
3	"(1) to support the objectives of the World
4	Health Organization End TB Strategy, including
5	goals—
6	"(A) to reduce by 95 percent tuberculosis
7	deaths by 2035;
8	"(B) to reduce by 90 percent the tuber-
9	culosis incidence rate by 2035; and
10	((C) to reduce by 100 percent the number
11	of families facing catastrophic health costs due
12	to tuberculosis by 2035;
13	"(2) to support the Stop TB Partnership's
14	Global Plan to End TB 2018–2022, and any follow
15	up plan, including support for—
16	"(A) developing and using innovative new
17	technologies and therapies to increase active
18	case finding to rapidly diagnose and treat chil-
19	dren and adults with all forms of tuberculosis,
20	alleviate suffering, and ensure tuberculosis
21	treatment completion;
22	"(B) providing diagnosis and treatment
23	with the goal of successfully treating
24	40,000,000 people with tuberculosis by $2022$ ,
25	including 3,500,000 children, and 1,500,000

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people with drug-resistant tuberculosis in support of the target set by the Political Declaration of the High-Level Meeting of the General Assembly on the Fight Against Tuberculosis;

5 "(C) diagnosing and treating latent tuber-6 culosis infection, in support of the global goal 7 of providing preventive therapy to at least 8 30,000,000 people, including 4,000,000 children 9 under 5 years of age, 20,000,000 household 10 contacts of people affected by tuberculosis, and 11 6,000,000 people living with HIV, by 2022;

"(D) ensuring high quality tuberculosis
care by closing gaps in care cascades, implementing continuous quality improvement at all
levels of care, and providing patient support;
and

17 "(E) sustainably procuring tuberculosis
18 commodities to avoid interruptions in supply,
19 the procurement of commodities of unknown
20 quality, or payment of excessive commodity
21 costs in countries impacted by tuberculosis;

22 "(3) to ensure that United States funding sup23 ports activities that simultaneously emphasize—

24 "(A) the development of comprehensive25 person-centered programs, including diagnosis,

1	treatment, and prevention strategies to ensure
2	that—
3	"(i) all people sick with tuberculosis
4	receive quality diagnosis and treatment
5	through active case finding; and
6	"(ii) people at high risk for tuber-
7	culosis infection are found and treated
8	with preventive therapies in a timely man-
9	ner;
10	"(B) robust tuberculosis infection control
11	practices are implemented in all congregate set-
12	tings, including hospitals and prisons;
13	"(C) the deployment of diagnostic and
14	treatment capacity—
15	"(i) in areas with the highest tuber-
16	culosis burdens; and
17	"(ii) for highly at-risk and impover-
18	ished populations, including patient sup-
19	port;
20	"(D) program monitoring and evaluation
21	based on critical tuberculosis indicators, includ-
22	ing indicators relating to infection control, the
23	numbers of patients accessing tuberculosis
24	treatment, along with patient support services,
25	and preventative therapy for those at risk, in-

1	cluding all close contacts, and treatment out-
2	comes for all forms of tuberculosis;
3	"(E) training and engagement of health
4	care workers on the use of new diagnostic tools
5	and therapies as they become available, and in-
6	creased support for training frontline health
7	care workers to support expanded tuberculosis
8	active case finding, contact tracing and patient
9	support;
10	"(F) coordination with domestic agencies
11	and organizations on an aggressive research
12	agenda to develop vaccines as well as new tools
13	to diagnose, treat, and prevent tuberculosis
14	globally;
15	"(G) linkages with the private sector on—
16	"(i) research and development of a
17	vaccine, and on new tools for diagnosis and
18	treatment of tuberculosis;
19	"(ii) improving current tools for diag-
20	nosis and treatment of tuberculosis; and
21	"(iii) training healthcare professionals
22	on use of the newest and most effective di-
23	agnostic and therapeutic tools;

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1	"(H) the reduction of barriers to care, in-
2	cluding stigma and treatment and diagnosis
3	costs, through—
4	"(i) training for health workers;
5	"(ii) sensitizing of policy makers;
6	"(iii) requirements for access and af-
7	fordability provisions in all grants and
8	funding agreements;
9	"(iv) education and empowerment
10	campaigns for tuberculosis patients regard-
11	ing local tuberculosis services;
12	"(v) monitoring barriers to accessing
13	tuberculosis services; and
14	"(vi) increased support for patient-led
15	and community-led tuberculosis outreach
16	efforts;
17	((I) support for country-level, sustainable
18	accountability mechanisms and capacity to
19	measure progress and ensure that commitments
20	made by governments and relevant stakeholders
21	are met.
22	"(c) DEFINITIONS.—In this section:
23	"(1) Appropriate congressional commit-
24	TEES.—The term 'appropriate congressional com-
25	mittees' means the Committee on Foreign Relations

1	of the Senate and the Committee on Foreign Affairs
2	of the House of Representatives.

"(2) END TB STRATEGY.—The term 'End TB
Strategy' means the strategy to eliminate tuberculosis that was approved by the World Health Assembly in May 2014, and is described in The End
TB Strategy: Global strategy and targets for tuberculosis prevention, care and control after 2015.

9 "(3) GLOBAL ALLIANCE FOR TUBERCULOSIS
10 DRUG DEVELOPMENT.—The term 'Global Alliance
11 for Tuberculosis Drug Development' means the pub12 lic-private partnership that bring together leaders in
13 health, science, philanthropy, and private industry to
14 devise new approaches to tuberculosis.

15 "(4) GLOBAL TUBERCULOSIS DRUG FACIL16 ITY.—The term 'Global Tuberculosis Drug Facility'
17 means the initiative of the Stop Tuberculosis Part18 nership to increase access to the most advanced, af19 fordable, quality-assured tuberculosis drugs and
20 diagnostics.

21 "(5) MDR–TB.—The term 'MDR–TB' means
22 multi-drug-resistant tuberculosis.

23 "(6) STOP TUBERCULOSIS PARTNERSHIP.—The
24 term 'Stop Tuberculosis Partnership' means the
25 partnership of the United Nations Office for Project

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Services, donors including the United States, high
 tuberculosis burden countries, multilateral agencies,
 and nongovernmental and technical agencies com mitted to short- and long-term measures required to
 control and eventually eliminate tuberculosis as a
 public health problem in the world.

7 "(7) XDR-TB.—The term 'XDR-TB' means
8 extensively drug-resistant tuberculosis

9 "(d) AUTHORIZATION.—To carry out this section, the 10 President is authorized, consistent with section 104(c), to 11 furnish assistance, on such terms and conditions as the 12 President may determine, for the prevention, treatment, 13 control, and elimination of tuberculosis.

14 "(e) GOALS.—In consultation with the appropriate 15 congressional committees, the President shall establish goals, based on the policy and indicators described in sub-16 17 section (b), for United States tuberculosis programs to detect, cure and prevent all forms of tuberculosis globally 18 for the period between 2023 and 2030 that is aligned with 19 the End TB Strategy's 2030 targets, by updating the 20 21 United States Government Tuberculosis Strategy (2015– 22 2019) and the National Action Plan for Combating 23 Multidrug-Resistant Tuberculosis.

24 "(f) COORDINATION.—

1 "(1) IN GENERAL.—In carrying out this sec-2 tion, the President shall coordinate with the World 3 Health Organization, the Stop TB Partnership, the 4 Global Fund to Fight AIDS, Tuberculosis, and Ma-5 laria, and other organizations with respect to the de-6 velopment and implementation of a comprehensive 7 global tuberculosis response program. "(2) BILATERAL ASSISTANCE.—In providing bi-8 9 lateral assistance under this section, the President, 10 acting through the Administrator of the United 11 States Agency for International Development, 12 shall— "(A) catalyze support for research and de-13 14 velopment of new tools to prevent, diagnose, 15 treat, and control tuberculosis worldwide, par-16 ticularly to reduce the incidence of, and mor-17 tality from, all forms of drug-resistant tuber-18 culosis; 19 "(B) ensure United States programs and 20 activities aimed at reaching those infected with 21 tuberculosis provide quality diagnosis and treat-22 ment, and reach those at high risk with preven-23 tive therapy; and

24 "(C) ensure coordination among relevant
25 United States Government agencies, including

1 the Centers for Disease Control and Prevention, 2 the National Institutes of Health, the Bio-3 medical Advanced Research and Development 4 Authority, the Food and Drug Administration, 5 the National Science Foundation, the Depart-6 ment of Defense (through its Congressionally 7 Directed Medical Research Program), and other 8 Federal agencies that engage in international 9 tuberculosis activities to ensure accountability 10 and transparency, reduce duplication of efforts 11 and ensure appropriate integration and coordi-12 nation of tuberculosis services into other United 13 States-supported health programs.

14 "(g) PRIORITY TO END TB STRATEGY.—In fur15 nishing assistance under subsection (d), the President
16 shall give priority to—

"(1) building and strengthening tuberculosis
programs to diagnose and treat all people sick with
TB, and ensuring everyone who is sick with tuberculosis have access to quality diagnosis and treatment;

"(2) direct, high-quality integrated services for
all forms of tuberculosis, as described by the World
Health Organization, which call for the coordination
of active case finding, treatment of all forms of tu-

1	berculosis disease and infection, patient support, and
2	tuberculosis prevention;
3	"(3) individuals co-infected with HIV and other
4	co-morbidities, and other individuals with tuber-
5	culosis who may be at risk of stigma;
6	"(4) strengthening the capacity of health sys-
7	tems to detect, prevent, and treat tuberculosis, in-
8	cluding MDR–TB and XDR–TB, as described in the
9	International Standards for Tuberculosis Care, and
10	the latest international guidance related to tuber-
11	culosis;
12	"(5) research and development of innovative
13	diagnostics, drug therapies, and vaccines, and pro-
14	gram-based operational research;
15	"(6) the Stop Tuberculosis Partnership's Global
16	Drug Facility, and the Global Alliance for Tuber-
17	culosis Drug Development, and other organizations
18	promoting the development of new products and
19	drugs for tuberculosis; and
20	"(7) ensuring tuberculosis programs can serve
21	as key platforms for supporting national respiratory
22	pandemic response against existing and new infec-
23	tious respiratory disease.
24	"(h) Assistance for the World Health Orga-
25	NIZATION AND THE STOP TUBERCULOSIS PARTNER-

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SHIP.—In carrying out this section, the President, acting 1 2 through the Administrator of the United States Agency 3 for International Development, is authorized to provide in-4 creased resources to the World Health Organization and 5 the Stop Tuberculosis Partnership to improve the capacity of countries with high burdens or rates of tuberculosis and 6 7 other affected countries to implement the End TB Strat-8 egy, the Stop TB Global Plan to End TB, their own na-9 tional strategies and plans, other global efforts to control 10 MDR–TB and XDR–TB.

11 "(i) ANNUAL REPORT ON TUBERCULOSIS ACTIVI-12 TIES.—Not later than December 15 of each year until the 13 goals specified in subsection (b)(1) are met, the President 14 shall submit an annual report to the appropriate congres-15 sional committees that describes United States foreign as-16 sistance to control tuberculosis and the impact of such ef-17 forts, including—

"(1) the number of individuals with active tuberculosis disease that were diagnosed and treated,
including the rate of treatment completion and the
number receiving patient support;

"(2) the number of persons with MDR–TB and
XDR–TB that were diagnosed and treated, including the rate of completion, in countries receiving

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United States bilateral foreign assistance for tuber culosis control programs;

3 "(3) the numbers of people trained by the
4 United States Government in tuberculosis surveil5 lance and control;

6 "(4) the number of individuals with active TB 7 disease identified as a result of engagement with the 8 private sector and other nongovernmental partners 9 in countries receiving United States bilateral foreign 10 assistance for tuberculosis control programs;

"(5) a description of the collaboration and coordination of United States anti-tuberculosis efforts
with the World Health Organization, the Stop TB
Partnership, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and other major public and
private entities;

"(6) a description of the collaboration and coordination among the United States Agency for
International Development and other United States
agencies, including the Centers for Disease Control
and Prevention and the Office of the Global AIDS
Coordinator, for the purposes of combating tuberculosis;

24 "(7) the constraints on implementation of pro-25 grams posed by health workforce shortages, health

system limitations, other components of successful
 implementation, and strategies to address such con straints;

4 "(8) a breakdown of expenditures for patient 5 services supporting TB diagnosis, treatment, and 6 prevention, including procurement of drugs and 7 other commodities, drug management, training in di-8 agnosis and treatment, health systems strengthening 9 that directly impacts provision of TB services, and 10 research; and

"(9) for each country receiving bilateral United
States assistance for the purpose of tuberculosis prevention, treatment, and control—

14 "(A) a description of progress to adopt and 15 implement the most recent World Health Orga-16 nization guidelines to improve diagnosis, treat-17 ment, and prevention of tuberculosis for adults 18 and children, disaggregated by sex, including 19 the proportion of health facilities that have 20 adopted the latest World Health Organization 21 guidelines on strengthening surveillance systems 22 and preventative, diagnostic, and therapeutic 23 methods, including the use of rapid diagnostic 24 tests and orally administered tuberculosis treat-25 ment regimens;

1	"(B) the number of adults and children re-
2	ceiving tuberculosis preventive therapy, includ-
3	ing people with HIV and all close contacts,
4	disaggregated by sex and, as possible, income or
5	wealth quintile, and the establishment of effec-
6	tive tuberculosis infection control in all relevant
7	congregant settings, including hospitals, clinics,
8	and prisons;
9	"(C) a description of progress in imple-
10	menting measures to reduce tuberculosis inci-
11	dence, including actions—
12	"(i) to expand active case finding and
13	contact tracing to identify and reach vul-
14	nerable groups; and
15	"(ii) to expand tuberculosis preventive
16	therapy, engagement of the private sector,
17	and diagnostic capacity;
18	"(D) a description of progress to expand
19	diagnosis, prevention, and treatment for all
20	forms of tuberculosis, including in pregnant
21	women, children, and other high-risk individuals
22	and groups at greater risk of TB, including mi-
23	grants, prisoners, miners, people exposed to sili-
24	ca, and people living with HIV/AIDS,
25	disaggregated by sex;

1	((E) the rate of successful completion of
2	tuberculosis treatment for adults and children,
3	disaggregated by sex, and the number of indi-
4	viduals receiving support for treatment comple-
5	tion;
6	"(F) the number of people, disaggregated
7	by sex, receiving treatment for MDR–TB, the
8	proportion of those treated with the latest regi-
9	mens endorsed by the World Health Organiza-
10	tion, any factors impeding scale up of such
11	treatment, and a description of progress to ex-
12	pand community-based MDR–TB care;
13	"(G) a description of tuberculosis com-
14	modity procurement challenges, including short-
15	ages, stockouts, or failed tenders for tuber-
16	culosis drugs or other commodities;
17	"(H) the proportion of health facilities
18	with specimen referral linkages to GeneXpert
19	testing sites, and to reference labs for second
20	line drug resistance testing, and a description
21	of the turnaround time for test results;
22	"(I) the number of people trained by the
23	United States Government to deliver high-qual-
24	ity tuberculosis surveillance, laboratory services,
25	prevention, treatment, and care;

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1	"(J) a description of how supported activi-
2	ties are coordinated with—
3	"(i) country national TB plans and
4	strategies; and
5	"(ii) tuberculosis control efforts sup-
6	ported by the Global Fund to Fight AIDS,
7	Tuberculosis, and Malaria, and other inter-
8	national assistance funds, including in the
9	areas of program development and imple-
10	mentation;
11	"(K) for the first 3 years of the report re-
12	quired under this subsection, a section that de-
13	scribes the progress in recovering from the neg-
14	ative impact of COVID–19 on tuberculosis, in-
15	cluding whether there has been the development
16	and implementation of a comprehensive plan to
17	ensure tuberculosis activities recover from di-
18	version of resources, the continued use of
19	bidirectional TB–COVID testing, and progress
20	on increased diagnosis and treatment of active
21	tuberculosis.
22	"(j) Annual Report on Tuberculosis Research
23	AND DEVELOPMENT.—The President, acting through the
24	Administrator of the United States Agency for Inter-
25	national Development, and in coordination with the Na-

tional Institutes of Health, the Centers for Disease Con trol and Prevention, the Biomedical Advanced Research
 and Development Authority, the Food and Drug Adminis tration, the National Science Foundation, and the Office
 of the Global AIDS Coordinator, shall submit an annual
 report to Congress that—

7 "(1) describes current progress and challenges
8 to the development of new tools for the purpose of
9 tuberculosis prevention, treatment, and control;

"(2) identifies critical gaps and emerging priorities for research and development, including for
rapid and point-of-care diagnostics, shortened treatments and prevention methods, and vaccines; and

14 "(3) describes research investments by type,15 funded entities, and level of investment.

16 "(k) EVALUATION REPORT.—Not later than 2 years 17 after the date of the enactment of the End Tuberculosis 18 Now Act of 2021, and every 5 years thereafter until 2036, 19 the Comptroller General of the United States shall submit 20a report to the appropriate congressional committees that 21 evaluates the performance and impact on tuberculosis pre-22 vention, diagnosis, treatment, and care efforts that are 23 supported by United States bilateral assistance funding, 24 including recommendations for improving such pro-25 grams.".