117TH CONGRESS
1ST SESSION

S. 3386

To prevent, treat, and cure tuberculosis globally.

IN THE SENATE OF THE UNITED STATES

DECEMBER 14, 2021

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

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A BILL

To prevent, treat, and cure tuberculosis globally.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''End Tuberculosis Now Act of 2021''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) More than 25 years after the World Health Organization declared Tuberculosis (referred to in this Act as ''TB'') a public health emergency and called on countries to make scaling up tuberculosis control a priority, TB remains a deadly health

threat despite the fact that TB is a preventable, treatable, and curable disease.

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

(3) Over ⅓ 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 low- and 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.

(5) In May 2020, a modeling study conducted by the Stop Tuberculosis Partnership (referred to in this Act as the ''Stop TB Partnership'') in collaboration with the United States Agency for International Development (referred to in this Act as ''USAID'') and partners estimated that a 3-month global lockdown followed by a protracted 10-month restoration could lead to an additional 6,300,000 cases of TB between 2020 and 2025 and an additional 1,400,000 TB deaths during this period, causing a setback of at least 5 to 8 years in the fight 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.

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

the introduction of resistant TB into new geographic areas.

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

(9) With sufficient resourcing, TB program expertise, infection control, laboratory capacity, active case finding and contact investigation, can serve as a platform for respiratory pandemic response against existing and new infectious respiratory disease without such a response necessitating the disruption of ongoing TB programs and activities.

(10) Globally, only about ½ of the $13,000,000,000 required annually outlined in the Stop TB Partnership's Global Plan to End TB for tuberculosis prevention, diagnosis, and treatment is 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

the negative impacts of COVID–19, with a total annual gap of at least $8,000,000,000 for TB diagnosis, prevention, and treatment in such countries.

(12) On September 26, 2018, the United Nations convened the first High-Level Meeting of the General Assembly on the Fight Against Tuberculosis, at which 120 countries—

(A) signed a Political Declaration to accelerate progress against TB, including commitments to increase funding for TB control and research and development programs, and ambitious goals to successfully treat 40,000,000 people with tuberculosis and prevent at least 30,000,000 from becoming ill with TB between 2018 and 2022; and

(B) committed to ''ending the epidemic in all countries, and pledge[d] to provide leadership and to work together to accelerate our national and global collective actions, investments and innovations urgently to fight this preventable and treatable disease,'' as reflected in United Nations General Assembly Resolution A/RES/73/3.

(13) The United States Government continues 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.

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

(15) On September 26, 2018, the USAID Administrator announced a new performance-based Global Accelerator to End TB, aimed at catalyzing investments to meet the target set by the United Nations High-Level Meeting on tuberculosis of treating 40,000,000 people with the disease by 2022, further demonstrating the critical role that United States leadership and assistance plays in the fight to 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.

SEC. 3. UNITED STATES GOVERNMENT ACTIONS TO END TUBERCULOSIS.

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

"SECTION 104B. ASSISTANCE TO COMBAT TUBERCULOSIS.

"(a) FINDINGS.—Congress makes the following findings:

"(1) Congress recognizes the continuing challenge of the international spread of tuberculosis, and the deadly impact of the continued existence of TB.

"(2) Additional tools and resources are required to effectively diagnose, prevent, and treat tuberculosis.

"(3) Effectively resourced tuberculosis programs can serve as a critical platform for respiratory pandemic response against existing and new infectious respiratory disease.

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

burden of tuberculosis and other countries with high rates of tuberculosis, it is the policy of the United States—

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

"(A) to reduce by 95 percent tuberculosis deaths by 2035;

"(B) to reduce by 90 percent the tuberculosis incidence rate by 2035; and

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

"(2) to support the Stop TB Partnership's Global Plan to End TB 2018–2022, and any follow up plan, including support for—

"(A) developing and using innovative new technologies and therapies to increase active case finding to rapidly diagnose and treat children and adults with all forms of tuberculosis, alleviate suffering, and ensure tuberculosis treatment completion;

"(B) providing diagnosis and treatment with the goal of successfully treating 40,000,000 people with tuberculosis by 2022, including 3,500,000 children, and 1,500,000

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;

''(C) diagnosing and treating latent tuberculosis infection, in support of the global goal of providing preventive therapy to at least 30,000,000 people, including 4,000,000 children under 5 years of age, 20,000,000 household contacts of people affected by tuberculosis, and 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

''(E) sustainably procuring tuberculosis commodities to avoid interruptions in supply, the procurement of commodities of unknown quality, or payment of excessive commodity costs in countries impacted by tuberculosis; and

''(3) to ensure that United States funding supports activities that simultaneously emphasize—

''(A) the development of comprehensive person-centered programs, including diagnosis,

treatment, and prevention strategies to ensure that—

"(i) all people sick with tuberculosis receive quality diagnosis and treatment through active case finding; and

"(ii) people at high risk for tuberculosis infection are found and treated with preventive therapies in a timely manner;

"(B) robust tuberculosis infection control practices are implemented in all congregate settings, including hospitals and prisons;

"(C) the deployment of diagnostic and treatment capacity—

"(i) in areas with the highest tuberculosis burdens; and

"(ii) for highly at-risk and impoverished populations, including patient support;

"(D) program monitoring and evaluation based on critical tuberculosis indicators, including indicators relating to infection control, the numbers of patients accessing tuberculosis treatment, along with patient support services, and preventative therapy for those at risk, in-

cluding all close contacts, and treatment outcomes for all forms of tuberculosis;

''(E) training and engagement of health care workers on the use of new diagnostic tools and therapies as they become available, and increased support for training frontline health care workers to support expanded tuberculosis active case finding, contact tracing and patient support;

''(F) coordination with domestic agencies and organizations on an aggressive research agenda to develop vaccines as well as new tools to diagnose, treat, and prevent tuberculosis globally;

''(G) linkages with the private sector on—

''(i) research and development of a vaccine, and on new tools for diagnosis and treatment of tuberculosis;

''(ii) improving current tools for diagnosis and treatment of tuberculosis; and

''(iii) training healthcare professionals on use of the newest and most effective diagnostic and therapeutic tools;

''(H) the reduction of barriers to care, including stigma and treatment and diagnosis costs, through—

''(i) training for health workers;

''(ii) sensitizing of policy makers;

''(iii) requirements for access and affordability provisions in all grants and funding agreements;

''(iv) education and empowerment campaigns for tuberculosis patients regarding local tuberculosis services;

''(v) monitoring barriers to accessing tuberculosis services; and

''(vi) increased support for patient-led and community-led tuberculosis outreach efforts; and

''(I) support for country-level, sustainable accountability mechanisms and capacity to measure progress and ensure that commitments made by governments and relevant stakeholders are met.

''(c) DEFINITIONS.—In this section:

''(1) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term 'appropriate congressional committees' means the Committee on Foreign Relations

of the Senate and the Committee on Foreign Affairs 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.

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

''(4) GLOBAL TUBERCULOSIS DRUG FACILITY.—The term 'Global Tuberculosis Drug Facility' means the initiative of the Stop Tuberculosis Partnership to increase access to the most advanced, affordable, quality-assured tuberculosis drugs and diagnostics.

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

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

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

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

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

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

''(f) COORDINATION.—

''(1) IN GENERAL.—In carrying out this section, the President shall coordinate with the World Health Organization, the Stop TB Partnership, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and other organizations with respect to the development and implementation of a comprehensive global tuberculosis response program.

''(2) BILATERAL ASSISTANCE.—In providing bilateral assistance under this section, the President, acting through the Administrator of the United States Agency for International Development, shall—

''(A) catalyze support for research and development of new tools to prevent, diagnose, treat, and control tuberculosis worldwide, particularly to reduce the incidence of, and mortality from, all forms of drug-resistant tuberculosis;

''(B) ensure United States programs and activities aimed at reaching those infected with tuberculosis provide quality diagnosis and treatment, and reach those at high risk with preventive therapy; and

''(C) ensure coordination among relevant United States Government agencies, including

the Centers for Disease Control and Prevention, the National Institutes of Health, the Biomedical Advanced Research and Development Authority, the Food and Drug Administration, the National Science Foundation, the Department of Defense (through its Congressionally Directed Medical Research Program), and other Federal agencies that engage in international tuberculosis activities to ensure accountability and transparency, reduce duplication of efforts and ensure appropriate integration and coordination of tuberculosis services into other United States-supported health programs.

''(g) PRIORITY TO END TB STRATEGY.—In furnishing assistance under subsection (d), the President 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-

berculosis disease and infection, patient support, and tuberculosis prevention;

''(3) individuals co-infected with HIV and other co-morbidities, and other individuals with tuberculosis who may be at risk of stigma;

''(4) strengthening the capacity of health systems to detect, prevent, and treat tuberculosis, including MDR–TB and XDR–TB, as described in the International Standards for Tuberculosis Care, and the latest international guidance related to tuberculosis;

''(5) research and development of innovative diagnostics, drug therapies, and vaccines, and program-based operational research;

''(6) the Stop Tuberculosis Partnership's Global Drug Facility, and the Global Alliance for Tuberculosis Drug Development, and other organizations promoting the development of new products and drugs for tuberculosis; and

''(7) ensuring tuberculosis programs can serve as key platforms for supporting national respiratory pandemic response against existing and new infectious respiratory disease.

''(h) ASSISTANCE FOR THE WORLD HEALTH ORGANIZATION AND THE STOP TUBERCULOSIS PARTNER-

SHIP.—In carrying out this section, the President, acting through the Administrator of the United States Agency for International Development, is authorized to provide increased resources to the World Health Organization and the Stop Tuberculosis Partnership to improve the capacity of countries with high burdens or rates of tuberculosis and other affected countries to implement the End TB Strategy, the Stop TB Global Plan to End TB, their own national strategies and plans, other global efforts to control MDR–TB and XDR–TB.

''(i) ANNUAL REPORT ON TUBERCULOSIS ACTIVITIES.—Not later than December 15 of each year until the goals specified in subsection (b)(1) are met, the President shall submit an annual report to the appropriate congressional committees that describes United States foreign assistance to control tuberculosis and the impact of such efforts, 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

United States bilateral foreign assistance for tuberculosis control programs;

''(3) the numbers of people trained by the United States Government in tuberculosis surveillance and control;

''(4) the number of individuals with active TB disease identified as a result of engagement with the private sector and other nongovernmental partners in countries receiving United States bilateral foreign 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;

''(7) the constraints on implementation of programs posed by health workforce shortages, health

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

''(8) a breakdown of expenditures for patient services supporting TB diagnosis, treatment, and prevention, including procurement of drugs and other commodities, drug management, training in diagnosis and treatment, health systems strengthening that directly impacts provision of TB services, and research; and

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

''(A) a description of progress to adopt and implement the most recent World Health Organization guidelines to improve diagnosis, treatment, and prevention of tuberculosis for adults and children, disaggregated by sex, including the proportion of health facilities that have adopted the latest World Health Organization guidelines on strengthening surveillance systems and preventative, diagnostic, and therapeutic methods, including the use of rapid diagnostic tests and orally administered tuberculosis treatment regimens;

''(B) the number of adults and children receiving tuberculosis preventive therapy, including people with HIV and all close contacts, disaggregated by sex and, as possible, income or wealth quintile, and the establishment of effective tuberculosis infection control in all relevant congregant settings, including hospitals, clinics, and prisons;

''(C) a description of progress in implementing measures to reduce tuberculosis incidence, including actions—

''(i) to expand active case finding and contact tracing to identify and reach vulnerable groups; and

''(ii) to expand tuberculosis preventive therapy, engagement of the private sector, and diagnostic capacity;

''(D) a description of progress to expand diagnosis, prevention, and treatment for all forms of tuberculosis, including in pregnant women, children, and other high-risk individuals and groups at greater risk of TB, including migrants, prisoners, miners, people exposed to silica, and people living with HIV/AIDS, disaggregated by sex;

''(E) the rate of successful completion of tuberculosis treatment for adults and children, disaggregated by sex, and the number of individuals receiving support for treatment completion;

''(F) the number of people, disaggregated by sex, receiving treatment for MDR–TB, the proportion of those treated with the latest regimens endorsed by the World Health Organization, any factors impeding scale up of such treatment, and a description of progress to expand community-based MDR–TB care;

''(G) a description of tuberculosis commodity procurement challenges, including shortages, stockouts, or failed tenders for tuberculosis drugs or other commodities;

''(H) the proportion of health facilities with specimen referral linkages to GeneXpert testing sites, and to reference labs for second line drug resistance testing, and a description of the turnaround time for test results;

''(I) the number of people trained by the United States Government to deliver high-quality tuberculosis surveillance, laboratory services, prevention, treatment, and care;

"(J) a description of how supported activities are coordinated with—

"(i) country national TB plans and strategies; and

"(ii) tuberculosis control efforts supported by the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and other international assistance funds, including in the areas of program development and implementation; and

"(K) for the first 3 years of the report required under this subsection, a section that describes the progress in recovering from the negative impact of COVID–19 on tuberculosis, including whether there has been the development and implementation of a comprehensive plan to ensure tuberculosis activities recover from diversion of resources, the continued use of bidirectional TB–COVID testing, and progress on increased diagnosis and treatment of active tuberculosis.

"(j) ANNUAL REPORT ON TUBERCULOSIS RESEARCH AND DEVELOPMENT.—The President, acting through the Administrator of the United States Agency for International Development, and in coordination with the Na-

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

''(1) describes current progress and challenges to the development of new tools for the purpose of 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

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

''(k) EVALUATION REPORT.—Not later than 2 years after the date of the enactment of the End Tuberculosis Now Act of 2021, and every 5 years thereafter until 2036, the Comptroller General of the United States shall submit a report to the appropriate congressional committees that evaluates the performance and impact on tuberculosis prevention, diagnosis, treatment, and care efforts that are supported by United States bilateral assistance funding,

including recommendations for improving such programs.''.

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