I

117TH CONGRESS
2D SESSION

H. R. 8654

To prevent, treat, and cure tuberculosis globally.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 5, 2022

Mr. BERA (for himself and Ms. SALAZAR) introduced the following bill; which was referred to the Committee on Foreign Affairs

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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 2022''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Tuberculosis (referred to in the Act as ''TB'') is a preventable, treatable, and curable disease, yet more than 25 years after the World Health Organization declared it to be a public health emergency and called on countries to make scaling up TB

control a priority, TB remains a deadly health threat.

(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 and existing tools must be developed and scaled-up.

(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. According to the World Health Organization, global detection dropped by 18 percent between 2019 and 2020 and an estimated 1,300,000 fewer people were diagnosed and enrolled on TB treatment, and in some countries

case notifications dropped by up to 41 percent, setting progress back by up to 12 years.

(5) Failure to properly diagnose and treat TB can lead to death and can exacerbate antimicrobial resistance, a key contributor to rising cases of multidrug-resistant TB and extensively drug-resistant TB, and increasing the probability of the introduction of resistant TB into new geographic areas.

(6) 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.

(7) With sufficient resourcing, TB program expertise, infection control, laboratory capacity, active case finding and contact investigation can serve as platforms for respiratory pandemic response against existing and new infectious respiratory disease without disrupting ongoing TB programs and activities.

(8) Globally, only about ½ of the $13,000,000,000 required annually, as outlined in the Stop TB Partnership's Global Plan to End TB, is currently available.

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

(A) signed a Political Declaration to accelerate progress against TB, including through commitments to increase funding for TB prevention, diagnosis, treatment and research and development programs, and ambitious goals to successfully treat 40,000,000 people with active TB 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.

(10) The United States Government continues to be a lead funder of global TB research and development, contributing 44 percent of the total

$915,000,000 in global funding in 2020, and can catalyze more investments from other countries.

(11) Working with governments and partners around the world, USAID's TB programming has saved 66,000,000 lives, demonstrating the effectiveness of United States programs and activities.

(12) On September 26, 2018, the USAID Administrator announced a new performance-based Global Accelerator to End TB, aimed at catalyzing investments to meet the treatment target set by the United Nations High-Level Meeting, further demonstrating the critical role that United States leadership and assistance plays in the fight to eliminate TB.

(13) 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:

"SEC. 104B. ASSISTANCE TO COMBAT TUBERCULOSIS.

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

''(1) The continuing challenge of the international spread of tuberculosis (referred to in this section as 'TB'), and the deadly impact of TB's continued existence constitutes a continuing challenge.

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

''(3) Effectively resourced TB programs can serve as a critical platform for preventing and responding to future infectious respiratory disease pandemics.

''(b) POLICY.—

''(1) It is a major objective of the foreign assistance program of the United States to help end the TB pandemic through accelerated actions to support the diagnosis and treatment of all adults and children with all forms of TB, and to prevent new TB infections from occurring.

''(2) In countries in which the United States Government has established foreign assistance programs under this Act, particularly in countries with the highest burden of TB and other countries with high rates of infection and transmission of TB, it is the policy of the United States to—

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

"(i) reduce by 95 percent TB deaths by 2035;

"(ii) reduce by 90 percent the TB incidence rate by 2035; and

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

"(B) continue to support the Stop TB Partnership's Global Plan to End TB 2018–2022, and successor plans, as appropriate, including by providing support for—

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

"(ii) expanding diagnosis and treatment in line with the goals established by the Political Declaration of the High-Level Meeting of the General Assembly on the Fight Against Tuberculosis, including—

"(I) successfully treating 40,000,000 people with active TB by 2023 including 3,500,000 children, and 1,500,000 people with drug-resistant TB; and

"(II) 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 TB, and 6,000,000 people living with HIV, by 2023;

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

"(iv) sustainable procurements of TB commodities to avoid interruptions in supply, the procurement of commodities of unknown quality, or payment of excessive commodity costs in countries impacted by TB; and

''(C) ensure, to the greatest extent practicable, that United States funding supports activities that simultaneously emphasize—

''(i) the development of comprehensive person-centered programs, including diagnosis, treatment, and prevention strategies to ensure that—

''(I) all people sick with TB receive quality diagnosis and treatment through active case finding; and

''(II) people at high risk for TB infection are found and treated with preventive therapies in a timely manner;

''(ii) robust TB infection control practices are implemented in all congregate settings, including hospitals and prisons;

''(iii) the deployment of diagnostic and treatment capacity—

''(I) in areas with the highest TB burdens; and

''(II) for highly at-risk and impoverished populations, including patient support services;

''(iv) program monitoring and evaluation based on critical TB indicators, including indicators relating to infection control, the numbers of patients accessing TB treatment and patient support services, and preventative therapy for those at risk, including all close contacts, and treatment outcomes for all forms of TB;

''(v) 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 TB active case finding, contact tracing, and patient support services;

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

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

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

''(II) improving current tools for diagnosis and treatment of TB; and

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

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

''(I) training health workers;

''(II) sensitizing policy makers;

''(III) requiring access and affordability provisions into all grants and funding agreements;

''(IV) support education and empowerment campaigns for TB patients regarding local TB services;

''(V) monitor barriers to accessing TB services; and

''(VI) increase support for patient-led and community-led TB outreach efforts; and

"(ix) 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 TB that was approved by the World Health Assembly in May 2014, and is described in The End TB Strategy: Global strategy and targets for TB 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 TB.

"(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 TB drugs and diagnostics.

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

''(6) STOP TUBERCULOSIS PARTNERSHIP.—The term 'Stop Tuberculosis Partnership' means the partnership of 1,600 organizations (including international and technical organizations, government programs, research and funding agencies, foundations, nongovernmental organizations, civil society and community groups, and the private sector), donors including the United States, high TB burden countries, multilateral agencies, and nongovernmental and technical agencies, which is governed by the Stop TB Partnership Coordinating Board and hosted by a United Nations entity, committed to short- and long-term measures required to control and eventually eliminate TB as a public health problem in the world.

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

''(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 TB.

''(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 TB programs to detect, cure, and prevent all forms of TB globally for the period between 2023 and 2030 that are 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 TB 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 TB worldwide, particularly to reduce the incidence of, and mortality from, all forms of drug-resistant TB;

''(B) ensure United States programs and activities focus on finding individuals with active TB disease and provide quality diagnosis and treatment, and reaching those at high risk with preventive therapy; and

''(C) ensure coordination among relevant United States Government agencies, including the Department of State, 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 TB activities to ensure accountability and transparency, reduce duplication of efforts and ensure appropriate integration and coordination of TB 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 TB programs to increase diagnosis and treatment of everyone who is sick with TB, and ensuring such individuals have access to quality diagnosis and treatment;

''(2) direct, high-quality integrated services for all forms of TB, as described by the World Health Organization, which call for the coordination of active case finding, treatment of all forms of TB disease and infection, patient support, and TB prevention;

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

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

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

''(6) the Stop Tuberculosis Partnership's Global Drug Facility, and the Global Alliance for Tuber-

culosis Drug Development, and other organizations promoting the development of new products and drugs for TB; and

''(7) ensuring TB 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 PARTNERSHIP.—In carrying out this section, the President, acting through the Administrator of the United States Agency for International Development, is authorized to provide resources to the World Health Organization and the Stop Tuberculosis Partnership to improve the capacity of countries with high burdens or rates of TB 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, and, to leverage the contributions of other donors for such activities.

''(i) ANNUAL REPORT ON TB 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 commit-

tees that describes United States foreign assistance to control TB and the impact of such efforts, including—

''(1) the number of individuals with active TB 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 TB control programs;

''(3) the numbers of people trained by the United States Government in TB 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 TB control programs;

''(5) a description of the collaboration and coordination of United States anti-TB 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 offices and agencies, including the Centers for Disease Control and Prevention and the Office of the Global AIDS Coordinator, for the purposes of combating TB;

''(7) the constraints on implementation of programs posed by health workforce shortages, health system limitations, other challenges to 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 the provision of TB services, and research; and

''(9) for each country, and when practicable, each project site receiving bilateral United States assistance for the purpose of TB prevention, treatment, and control—

''(A) a description of progress toward the adoption and implementation of the most recent

World Health Organization guidelines to improve diagnosis, treatment, and prevention of TB for adults and children, disaggregated by sex, including the proportion of health facilities that have adopted the latest World Health Organization guidelines on strengthening monitoring systems and preventative, diagnostic, and therapeutic methods, including the use of rapid diagnostic tests and orally administered TB treatment regimens;

''(B) the number of individuals screened for TB disease and the number evaluated for TB infection using active case finding outside of health facilities;

''(C) the number of individuals with active TB disease that were diagnosed and treated, including the rate of treatment completion and the number receiving patient support;

''(D) the number of adults and children, including people with HIV and close contacts, who are evaluated for TB infection, the number of adults and children started on treatment for TB infection, and the number of adults and children completing such treatment,

disaggregated by sex and, as possible, income or wealth quintile;

''(E) the establishment of effective TB infection control in all relevant congregant settings, including hospitals, clinics, and prisons;

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

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

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

''(G) a description of progress to expand diagnosis, prevention, and treatment for all forms of TB, including in pregnant women, children, and 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;

''(H) the rate of successful completion of TB treatment for adults and children, disaggregated by sex, and the number of indi-

viduals receiving support for treatment completion;

''(I) 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, factors impeding scale up of such treatment, and a description of progress to expand community-based MDR–TB care;

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

''(K) the proportion of health facilities with specimen referral linkages to quality diagnostic networks, including established testing sites and reference labs, to ensure maximum access and referral for second line drug resistance testing, and a description of the turnaround time for test results;

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

''(M) a description of how supported activities are coordinated with—

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

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

''(N) 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 TB, including whether there has been the development and implementation of a comprehensive plan to ensure TB activities recover from diversion of resources, the continued use of bidirectional TB–COVID testing, and progress on increased diagnosis and treatment of active TB.

''(j) ANNUAL REPORT ON TB RESEARCH AND DEVELOPMENT.—The President, acting through the Administrator of the United States Agency for International Development, and in coordination with the National Institutes of Health, the Centers for Disease Control and Pre-

vention, 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 TB 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 2022, and every 5 years thereafter until 2035, the Comptroller General of the United States shall submit a report to the appropriate congressional committees that evaluates the performance and impact on TB 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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