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

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:
- 8 (1) Tuberculosis (referred to in the Act as
 9 "TB") is a preventable, treatable, and curable dis10 ease, yet more than 25 years after the World Health
 11 Organization declared it to be a public health emer12 gency and called on countries to make scaling up TB

- 1 control a priority, TB remains a deadly health 2 threat.
- 3 (2) In 2019 alone, an estimated 10,000,000 4 people became ill with TB, 10 percent of whom were 5 children, and 1,400,000 of whom died. In order to 6 achieve by 2035 the goals of the Political Declara-7 tion of the High-Level Meeting of the General As-8 sembly on the Fight Against Tuberculosis, adopted 9 by the United Nations General Assembly October 10 10, 2018, and of the World Health Organization 11 End TB Strategy, adopted by the World Health As-12 sembly in 2014, new and existing tools must be de-13 veloped and scaled-up.
 - (3) Over ½ 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

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- 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 multi-drug-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

- 1 \$915,000,000 in global funding in 2020, and can 2 catalyze more investments from other countries.
- 3 (11) Working with governments and partners 4 around the world, USAID's TB programming has 5 saved 66,000,000 lives, demonstrating the effective-6 ness of United States programs and activities.
- 7 (12) On September 26, 2018, the USAID Ad-8 ministrator announced a new performance-based 9 Global Accelerator to End TB, aimed at catalyzing 10 investments to meet the treatment target set by the 11 United Nations High-Level Meeting, further dem-12 onstrating the critical role that United States leader-13 ship and assistance plays in the fight to eliminate 14 TB.
- 15 (13) It is essential to ensure that efforts among
 16 United States Government agencies, partner nations,
 17 international organizations, nongovernmental organi18 zations, the private sector, and other actors are com19 plementary and not duplicative in order to achieve
 20 the goal of ending the TB epidemic in all countries.
- 21 SEC. 3. UNITED STATES GOVERNMENT ACTIONS TO END
- TUBERCULOSIS.
- 23 Section 104B of the Foreign Assistance Act of 1961
- 24 (22 U.S.C. 2151b-3) is amended to read as follows:

1 "SEC. 104B. ASSISTANCE TO COMBAT TUBERCULOSIS.

- 2 "(a) FINDINGS.—Congress makes the following find-3 ings:
- "(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.
- 8 "(2) Additional tools and resources are required 9 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.

14 "(b) Policy.—

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- "(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—

1	"(A) support the objectives of the World
2	Health Organization End TB Strategy, includ-
3	ing its goals to—
4	"(i) reduce by 95 percent TB deaths
5	by 2035;
6	"(ii) reduce by 90 percent the TB in-
7	cidence rate by 2035; and
8	"(iii) reduce by 100 percent the num-
9	ber of families facing catastrophic health
10	costs due to TB by 2035;
11	"(B) continue to support the Stop TB
12	Partnership's Global Plan to End TB 2018–
13	2022, and successor plans, as appropriate, in-
14	cluding by providing support for—
15	"(i) developing and using innovative
16	new technologies and therapies to increase
17	active case finding and rapidly diagnose
18	and treat children and adults with all
19	forms of TB, alleviate suffering, and en-
20	sure TB treatment completion;
21	"(ii) expanding diagnosis and treat-
22	ment in line with the goals established by
23	the Political Declaration of the High-Level
24	Meeting of the General Assembly on the
25	Fight Against Tuberculosis, including—

1	"(I) successfully treating
2	40,000,000 people with active TB by
3	2023 including 3,500,000 children,
4	and 1,500,000 people with drug-re-
5	sistant TB; and
6	"(II) diagnosing and treating la-
7	tent tuberculosis infection, in support
8	of the global goal of providing preven-
9	tive therapy to at least 30,000,000
10	people, including 4,000,000 children
11	under 5 years of age, 20,000,000
12	household contacts of people affected
13	by TB, and 6,000,000 people living
14	with HIV, by 2023;
15	"(iii) ensuring high quality TB care
16	by closing gaps in care cascades, imple-
17	menting continuous quality improvement
18	at all levels of care, and providing related
19	patient support; and
20	"(iv) sustainable procurements of TB
21	commodities to avoid interruptions in sup-
22	ply, the procurement of commodities of un-
23	known quality, or payment of excessive
24	commodity costs in countries impacted by
25	TB: and

1	"(C) ensure, to the greatest extent prac-
2	ticable, that United States funding supports ac-
3	tivities that simultaneously emphasize—
4	"(i) the development of comprehensive
5	person-centered programs, including diag-
6	nosis, treatment, and prevention strategies
7	to ensure that—
8	"(I) all people sick with TB re-
9	ceive quality diagnosis and treatment
10	through active case finding; and
11	"(II) people at high risk for TB
12	infection are found and treated with
13	preventive therapies in a timely man-
14	ner;
15	"(ii) robust TB infection control prac-
16	tices are implemented in all congregate set-
17	tings, including hospitals and prisons;
18	"(iii) the deployment of diagnostic
19	and treatment capacity—
20	"(I) in areas with the highest TB
21	burdens; and
22	"(II) for highly at-risk and im-
23	poverished populations, including pa-
24	tient support services;

1	"(iv) program monitoring and evalua-
2	tion based on critical TB indicators, in-
3	cluding indicators relating to infection con-
4	trol, the numbers of patients accessing TB
5	treatment and patient support services,
6	and preventative therapy for those at risk,
7	including all close contacts, and treatment
8	outcomes for all forms of TB;
9	"(v) training and engagement of
10	health care workers on the use of new di-
11	agnostic tools and therapies as they be-
12	come available, and increased support for
13	training frontline health care workers to
14	support expanded TB active case finding,
15	contact tracing, and patient support serv-
16	ices;
17	"(vi) coordination with domestic agen-
18	cies and organizations to support an ag-
19	gressive research agenda to develop vac-
20	cines as well as new tools to diagnose,
21	treat, and prevent TB globally;
22	"(vii) linkages with the private sector
23	on—

1	"(I) research and development of
2	a vaccine, and on new tools for diag-
3	nosis and treatment of TB;
4	"(II) improving current tools for
5	diagnosis and treatment of TB; and
6	"(III) training healthcare profes-
7	sionals on use of the newest and most
8	effective diagnostic and therapeutic
9	tools;
10	"(viii) the reduction of barriers to
11	care, including stigma and treatment and
12	diagnosis costs, including through—
13	"(I) training health workers;
14	"(II) sensitizing policy makers;
15	"(III) requiring access and af-
16	fordability provisions into all grants
17	and funding agreements;
18	"(IV) support education and em-
19	powerment campaigns for TB patients
20	regarding local TB services;
21	"(V) monitor barriers to access-
22	ing TB services; and
23	"(VI) increase support for pa-
24	tient-led and community-led TB out-
25	reach efforts; and

1	"(ix) support for country-level, sus-
2	tainable accountability mechanisms and ca-
3	pacity to measure progress and ensure that
4	commitments made by governments and
5	relevant stakeholders are met.
6	"(c) Definitions.—In this section:
7	"(1) Appropriate congressional commit-
8	TEES.—The term 'appropriate congressional com-
9	mittees' means the Committee on Foreign Relations
10	of the Senate and the Committee on Foreign Affairs
11	of the House of Representatives.
12	"(2) End the strategy.—The term 'End TB
13	Strategy' means the strategy to eliminate TB that
14	was approved by the World Health Assembly in May
15	2014, and is described in The End TB Strategy:
16	Global strategy and targets for TB prevention, care
17	and control after 2015.
18	"(3) Global alliance for tuberculosis
19	DRUG DEVELOPMENT.—The term 'Global Alliance
20	for Tuberculosis Drug Development' means the pub-
21	lic-private partnership that bring together leaders in
22	health, science, philanthropy, and private industry to
23	devise new approaches to TB.
24	"(4) Global Tuberculosis drug facil-
25	ITY.—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.
- 4 "(5) MDR-TB.—The term 'MDR-TB' means 5 multi-drug-resistant TB.
- 6 "(6) Stop tuberculosis partnership.—The 7 term 'Stop Tuberculosis Partnership' means the 8 partnership of 1,600 organizations (including inter-9 national and technical organizations, government 10 programs, research and funding agencies, founda-11 tions, nongovernmental organizations, civil society 12 and community groups, and the private sector), do-13 nors including the United States, high TB burden 14 countries, multilateral agencies, and nongovern-15 mental and technical agencies, which is governed by 16 the Stop TB Partnership Coordinating Board and 17 hosted by a United Nations entity, committed to 18 short- and long-term measures required to control 19 and eventually eliminate TB as a public health prob-20 lem in the world.
- 21 "(7) XDR-TB.—The term 'XDR-TB' means
 22 extensively drug-resistant TB.
- 23 "(d) AUTHORIZATION.—To carry out this section, the 24 President is authorized, consistent with section 104(c), to
- 25 furnish assistance, on such terms and conditions as the

- 1 President may determine, for the prevention, treatment,
- 2 control, and elimination of TB.
- 3 "(e) Goals.—In consultation with the appropriate
- 4 congressional committees, the President shall establish
- 5 goals, based on the policy and indicators described in sub-
- 6 section (b), for United States TB programs to detect,
- 7 cure, and prevent all forms of TB globally for the period
- 8 between 2023 and 2030 that are aligned with the End
- 9 TB Strategy's 2030 targets, by updating the United
- 10 States Government Tuberculosis Strategy (2015–2019)
- 11 and the National Action Plan for Combating Multidrug-
- 12 Resistant Tuberculosis.
- 13 "(f) COORDINATION.—
- 14 "(1) In general.—In carrying out this sec-
- tion, the President shall coordinate with the World
- 16 Health Organization, the Stop TB Partnership, the
- 17 Global Fund to Fight AIDS, Tuberculosis, and Ma-
- laria, and other organizations with respect to the de-
- velopment and implementation of a comprehensive
- 20 global TB response program.
- 21 "(2) BILATERAL ASSISTANCE.—In providing bi-
- lateral assistance under this section, the President,
- acting through the Administrator of the United
- 24 States Agency for International Development,
- shall—

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"(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 ofDefense (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.

1	"(g) Priority To End TB Strategy.—In fur-
2	nishing assistance under subsection (d), the President
3	shall give priority to—
4	"(1) building and strengthening TB programs
5	to increase diagnosis and treatment of everyone who
6	is sick with TB, and ensuring such individuals have
7	access to quality diagnosis and treatment;
8	"(2) direct, high-quality integrated services for
9	all forms of TB, as described by the World Health
10	Organization, which call for the coordination of ac-
11	tive case finding, treatment of all forms of TB dis-
12	ease and infection, patient support, and TB preven-
13	tion;
14	"(3) individuals co-infected with HIV and other
15	co-morbidities, and other individuals with TB who
16	may be at risk of stigma;
17	"(4) strengthening the capacity of health sys-
18	tems to detect, prevent, and treat TB, including
19	MDR-TB and XDR-TB, as described in the latest
20	international guidance related to TB;
21	"(5) research and development of innovative
22	diagnostics, drug therapies, and vaccines, and pro-
23	gram-based research;
24	"(6) the Stop Tuberculosis Partnership's Global
25	Drug Facility, and the Global Alliance for Tuber-

- 1 culosis Drug Development, and other organizations
- 2 promoting the development of new products and
- drugs for TB; and
- 4 "(7) ensuring TB programs can serve as key
- 5 platforms for supporting national respiratory pan-
- 6 demic response against existing and new infectious
- 7 respiratory disease.
- 8 "(h) Assistance for the World Health Orga-
- 9 NIZATION AND THE STOP TUBERCULOSIS PARTNER-
- 10 Ship.—In carrying out this section, the President, acting
- 11 through the Administrator of the United States Agency
- 12 for International Development, is authorized to provide re-
- 13 sources to the World Health Organization and the Stop
- 14 Tuberculosis Partnership to improve the capacity of coun-
- 15 tries with high burdens or rates of TB and other affected
- 16 countries to implement the End TB Strategy, the Stop
- 17 TB Global Plan to End TB, their own national strategies
- 18 and plans, other global efforts to control MDR-TB and
- 19 XDR-TB, and, to leverage the contributions of other do-
- 20 nors for such activities.
- 21 "(i) Annual Report on TB Activities.—Not later
- 22 than December 15 of each year until the goals specified
- 23 in subsection (b)(1) are met, the President shall submit
- 24 an annual report to the appropriate congressional commit-

- 1 tees that describes United States foreign assistance to
 2 control TB and the impact of such efforts, including—
 3 "(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;
- 7 "(2) the number of persons with MDR-TB and 8 XDR-TB that were diagnosed and treated, includ-9 ing the rate of completion, in countries receiving 10 United States bilateral foreign assistance for TB 11 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:

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- 1 "(6) a description of the collaboration and co-2 ordination among the United States Agency for 3 International Development and other United States offices and agencies, including the Centers for Dis-4 5 ease Control and Prevention and the Office of the 6 Global AIDS Coordinator, for the purposes of com-7 bating TB; 8 "(7) the constraints on implementation of pro-9 grams posed by health workforce shortages, health 10 system limitations, other challenges to successful im-
 - "(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

plementation and strategies to address such con-

- "(9) for each country, and when practicable, each project site receiving bilateral United States assistance for the purpose of TB prevention, treatment, and control—
- 24 "(A) a description of progress toward the 25 adoption and implementation of the most recent

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straints;

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,

1	disaggregated by sex and, as possible, income or
2	wealth quintile;
3	"(E) the establishment of effective TB in-
4	fection control in all relevant congregant set-
5	tings, including hospitals, clinics, and prisons;
6	"(F) a description of progress in imple-
7	menting measures to reduce TB incidence, in-
8	cluding actions—
9	"(i) to expand active case finding and
10	contact tracing to reach vulnerable groups;
11	and
12	"(ii) to expand TB preventive ther-
13	apy, engagement of the private sector, and
14	diagnostic capacity;
15	"(G) a description of progress to expand
16	diagnosis, prevention, and treatment for all
17	forms of TB, including in pregnant women,
18	children, and individuals and groups at greater
19	risk of TB, including migrants, prisoners, min-
20	ers, people exposed to silica, and people living
21	with HIV/AIDS, disaggregated by sex;
22	"(H) the rate of successful completion of
23	TB treatment for adults and children,
24	disaggregated by sex, and the number of indi-

1	viduals receiving support for treatment comple-
2	tion;
3	"(I) the number of people, disaggregated
4	by sex, receiving treatment for MDR-TB, the
5	proportion of those treated with the latest regi-
6	mens endorsed by the World Health Organiza-
7	tion, factors impeding scale up of such treat
8	ment, and a description of progress to expand
9	community-based MDR-TB care;
10	"(J) a description of TB commodity pro-
11	curement challenges, including shortages
12	stockouts, or failed tenders for TB drugs or
13	other commodities;
14	"(K) the proportion of health facilities
15	with specimen referral linkages to quality diag-
16	nostic networks, including established testing
17	sites and reference labs, to ensure maximum ac-
18	cess and referral for second line drug resistance
19	testing, and a description of the turnaround
20	time for test results;
21	"(L) the number of people trained by the
22	United States Government to deliver high-qual-
23	ity TB diagnostic, preventative, monitoring

treatment, and care services;

1	"(M) a description of how supported activi-
2	ties are coordinated with—
3	"(i) country national TB plans and
4	strategies; and
5	"(ii) TB control efforts supported by
6	the Global Fund to Fight AIDS, Tuber-
7	culosis, and Malaria, and other inter-
8	national assistance programs and funds
9	including in the areas of program develop-
10	ment and implementation; and
11	"(N) 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 TB, including
15	whether there has been the development and
16	implementation of a comprehensive plan to en-
17	sure TB activities recover from diversion of re-
18	sources, the continued use of bidirectional TB-
19	COVID testing, and progress on increased diag-
20	nosis and treatment of active TB.
21	"(j) Annual Report on TB Research and De-
22	VELOPMENT.—The President, acting through the Admin-
23	istrator of the United States Agency for International De-
24	velopment, and in coordination with the National Insti-
25	tutes of Health, the Centers for Disease Control and Pre-

- 1 vention, the Biomedical Advanced Research and Develop-
- 2 ment Authority, the Food and Drug Administration, the
- 3 National Science Foundation, and the Office of the Global
- 4 AIDS Coordinator, shall submit an annual report to Con-
- 5 gress that—
- 6 "(1) describes current progress and challenges
- 7 to the development of new tools for the purpose of
- 8 TB prevention, treatment, and control;
- 9 "(2) identifies critical gaps and emerging prior-
- 10 ities for research and development, including for
- 11 rapid and point-of-care diagnostics, shortened treat-
- ments and prevention methods, and vaccines; and
- "(3) describes research investments by type,
- funded entities, and level of investment.
- 15 "(k) EVALUATION REPORT.—Not later than 2 years
- 16 after the date of the enactment of the End Tuberculosis
- 17 Now Act of 2022, and every 5 years thereafter until 2035,
- 18 the Comptroller General of the United States shall submit
- 19 a report to the appropriate congressional committees that
- 20 evaluates the performance and impact on TB prevention,
- 21 diagnosis, treatment, and care efforts that are supported
- 22 by United States bilateral assistance funding, including
- 23 recommendations for improving such programs.".