

United States Senate Committee on Appropriations Subcommittee on State and Foreign Operations and Related Programs

Written Testimony for Fiscal Year 2020 for the U.S. Department of State, U.S. Agency for International Development (USAID), Global Tuberculosis Program

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On behalf of the Tuberculosis Roundtable

The Tuberculosis (TB) Roundtable coalition is pleased to submit this testimony to the Senate Committee on Appropriations, Subcommittee on State, Foreign Operations and Related Programs (SFOPS) for consideration in fiscal year (FY) 2020 appropriations. The TB Roundtable is comprised of organizations focused on federal advocacy for the domestic and global elimination of TB. Specifically, we seek to make the subcommittee aware of the critical global health security role undertaken by the United States Agency for International Development (USAID) TB Program, which is currently funded at \$302 million in FY 2019. We are pleased to see increases made to this program over the past two years, and by the House SFOPS appropriations subcommittee for FY 2020, and we submit this testimony to urge the Subcommittee to build on this momentum and support USAID's TB Program at a level of \$400 million in FY 2020 to further safeguard our nation's health against this infectious disease threat by fully implementing the *U.S. National Action Plan to Combat MDR-TB*, expanding treatment to those with TB who are undiagnosed and therefore infectious (i.e., "missing" cases), and expanding research and development (R&D) for needed tools to counter drug-resistant (DR-TB) forms of TB.

TB is an airborne disease, causing more deaths than any other single infectious disease agent globally. Over 10.0 million people worldwide fell ill with TB, resulting in 1.6 million deaths in 2017 alone.¹ Furthermore, TB is the world's third leading cause of death among women of reproductive age. An estimated 1 million children are suffering from the disease. TB is also the leading infectious killer of people living with HIV (PLHIV) globally contributing to 300,000 deaths among those with TB/HIV co-infection.² Nearly 4 million TB cases are still being missed annually, which is allowing the disease to continue spreading.³

Every economic-impact assessment conducted for TB has shown that the costs of the epidemic to national and global economies are far higher than the expenditures needed to end the epidemic. Most recently, in 2017, KPMG assessed that failing to end the TB epidemic led to a cost of \$616

¹ World Health Organization. Global Health Observatory Data – tuberculosis. <https://www.who.int/gho/tb/en/>

² Ibid.

³ Daniel P Chin, Christy L Hanson; Finding the Missing Tuberculosis Patients, *The Journal of Infectious Diseases*, Volume 216, Issue suppl_7, 6 November 2017, Pages S675–S678, <https://doi.org/10.1093/infdis/jix368>

billion to the global economy from 2000-2015, and the disease will be responsible for an additional \$1 trillion in lost economic output by 2030 if the status quo continues.⁴

Equally concerning, TB is the leading contributor to antimicrobial resistance (AMR) in the world. A third of the deaths to AMR are due to DR-TB. Globally, every year there are about 500,000 new people with multi-drug-resistant TB (MDR-TB)—TB resistant to multiple antibiotics—but only 10 percent of these individuals are being identified and successfully treated.⁵ In fact, further compounding the problem of DR-TB and its low cure rate is the ineffectiveness of current tools used in the diagnosis, treatment, and prevention of all forms of TB. The MDR treatment regimen that most highly-burdened countries rely on involves 250 injections and 15,000 pills over at least a two-year period, and side effects often ranging to permanent hearing loss, nerve damage, depression, kidney complications, and other issues. USAID's TB Program has made notable success in assisting countries to detect, diagnose, treat and prevent DR-TB. The *U.S. National Action Plan to Combat MDR-TB*, released in 2015, provides a comprehensive framework to address MDR-TB, but additional funding is required for its full implementation.

The valuable public health, programmatic and technical assistance, and essential R&D roles of USAID's TB Program in countering, containing, and eliminating the world's leading infectious killer cannot go understated. USAID's in-country programs have led to declining incidence across 23 countries with bilateral USAID TB funding, with rates dropping by 19 percent since 2000 and 3 percent from 2014 to 2015—more than double the average global rate of 1.4 percent reported by WHO in 2016.⁶ USAID continues to be a leading implementer of the Xpert diagnostic, which diagnoses TB, including indication of DR-TB, within 90 minutes. USAID provides essential training and monitoring and evaluation systems for optimizing the use of this system, which is increasing TB detection rates globally. USAID's bilateral assistance supports countries in developing strong applications to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), facilitates grant implementation, and improves the management of DR-TB— helping countries to leverage their resources to maximize impact. USAID resources are also stabilizing an extremely fragile market for TB products by bringing down the cost of and expanding access to TB medications through direct support for the Global Drug Facility (GDF) and MDR-TB Financing, helping countries to avoid dangerous treatment interruptions and to effectively use new drugs.⁷

USAID also has notable successes in TB research—from development to access—which must be accelerated to develop shorter treatment regimens, rapid and affordable diagnostic tests, and an effective vaccine, as well as to ensure their timely deployment and uptake. In the past few years, we have seen the development of a rapid TB diagnostic that can identify MDR-TB, and two new

⁴ KPMG. Global Economic Impact of Tuberculosis. 2017, <https://big.assets.huffingtonpost.com/GlobalEconomicImpactTB.pdf>

⁵ Curry International Tuberculosis Center. Drug-Resistant Tuberculosis: A Survival Guide for Clinicians, 3rd edition. 2016, https://www.currytbcenter.ucsf.edu/sites/default/files/tb_sg3_book.pdf

⁶ U.S. Agency for International Development. End the Tuberculosis Epidemic – Fiscal Year 2015 Report on Foreign Assistance for Tuberculosis. https://www.usaid.gov/sites/default/files/documents/1864/USAID-TB-Annual-Report_FY_2015_508.pdf

⁷ Stop TB Partnership. What is the Global Drug Facility? <http://www.stoptb.org/gdf/whatis/default.asp>

antibiotics—bedaquiline and delamanid—offer new hope to patients. More recently, USAID has been crucial in financing the trial that has led to an expected FDA approval of another new drug, pretomanid, that will add to our arsenal of public health tools.⁸ USAID assistance has been crucial to getting these life-saving drugs like bedaquiline and other quality-assured products to all patients in need through the GDF.

Given the momentum, the next 5 years are crucial to advance emerging research innovations. Clinical research undertaken through USAID support has significantly shortened treatment for MDR-TB, with continued treatment advances and improved outcomes anticipated. USAID could play a vital research role in advancing a promising experimental TB vaccine candidate, following encouraging phase 2b results.⁹ Recognizing the importance of pivotal research at the UN High-Level Meeting on TB in 2018, national governments around the world are now committed to mobilizing resources to meet a globally accepted fair-share target of contributing 0.1% of gross expenditure in R&D towards TB to overcome a \$1.3 billion annual funding gap.¹⁰ The U.S. government is the world's leading funder of TB R&D at \$313.5 million, of which \$34 million is contributed by USAID, making the agency the fourth largest TB R&D funder globally.¹¹ However, to capitalize on USAID's successful research agenda and for the U.S. to reach its own 0.1% funding target, an additional \$131 million split among several agencies such as USAID is needed.¹² Doing so will allow the U.S. to continue to lead on the research and implementation of new tools for TB by leveraging its research expertise at USAID and other federally-funded research institutions. Continuing to support TB R&D at USAID and other agencies within the U.S. government can catalyze other national governments to make similar commitments.

The funding trend of USAID's TB Program has been largely flat for several years, with a boost in FY 2018 by \$20 million and in FY 2019 by \$41 million, pushing total funding from \$241 million to \$302 million. We thank the subcommittee for its support for the program with this additional funding. However, with new political commitments to ending TB being made internationally, the advent of new tools and need to support ongoing research, USAID's TB Program is now in a strategic position to build on its global leadership role in FY 2020. With increased robust funding, USAID could ambitiously fast-track progress through TB control and prevention scaleup and accelerate the development and implementation of shorter, less toxic treatments, which would facilitate greater patient adherence to treatment regimens, reduce program costs, and thereby mitigate the growing threat of DR-TB. With increased support USAID could consider resuming direct technical assistance for TB to countries in the Western Hemisphere. Critically, increasing USAID's TB Program funding will facilitate full

⁸ TB Alliance. TB Medicine Pretomanid Enters Regulatory Review Process in the United States. March 9, 2019, <https://www.tballiance.org/news/pretomanid-enters-FDA-review>

⁹ STAT. Experimental TB vaccine shows promise in clinical trials. September 2018, <https://www.statnews.com/2018/09/28/experimental-tb-vaccine-clinical-trials/>

¹⁰ Treatment Action Group. Investing in R&D to End TB: A Global Priority. November 2017, http://treatmentactiongroup.org/sites/default/files/Funding%20target%20brief_final_31Oct.pdf

¹¹ Treatment Action Group. Tuberculosis Research Funding Trends 2005-2017. December 2018. http://www.treatmentactiongroup.org/sites/default/files/tb_funding_2018_final.pdf

¹² Treatment Action Group. Closing the Gap in Tuberculosis Research Funding: Actions for U.S. Congress. February 2019, http://www.treatmentactiongroup.org/sites/default/files/TAG_GERD_brief_leg_v5.pdf

implementation achievement of the goals and targets set forth by the *U.S. National Action Plan to Combat MDR-TB*¹³:

USAID TB Program’s expansive presence and assistance in high-burden countries such as Ethiopia, India, Mozambique, Nigeria, South Africa, Ukraine, and Vietnam significantly strengthens our nation’s global health security against TB and places us closer to these targets. USAID is uniquely positioned to help countries overcome challenges in case-finding and assist in linking the “missing” 4 million to care and treatment. The program’s

| Targets of the National Action Plan (NAP) ¹³ | |
|---|--|
| <i>Actions taken in alignment with this National Action Plan will contribute to meeting the following domestic and global targets</i> | |
| Year | Target |
| 2016 | <ul style="list-style-type: none"> Initiate appropriate treatment in 25 percent of patients with MDR-TB in 10 countries with the highest burdens of MDR-TB. |
| 2018 | <ul style="list-style-type: none"> Initiate appropriate treatment in 35 percent of patients with MDR-TB in 10 countries with the highest burdens of MDR-TB. |
| 2020 | <ul style="list-style-type: none"> Reduce by 15 percent the number of cases of MDR-TB disease in the United States. Initiate appropriate treatment in 50 percent of patients with MDR-TB in 10 countries with the highest burdens of MDR-TB. Reduce global incidence by 25 percent compared to 2015 levels. Successfully treat 16 million TB patients in high-burden countries Achieve and maintain treatment success rates of 90 percent for individuals in high-burden countries with drug-susceptible TB |

Challenge TB initiative has shown remarkable success, by funding a broad range of community engagement activities that contribute to TB case-finding, care, and treatment.¹⁴

In 2018, USAID launched a new business model to speed up progress and build self-reliance, called the “Global Accelerator to End Tuberculosis;” and as a part of this USAID has launched a new mechanism to directly support local organizations in priority countries.¹⁵ Investments by the program into community engagement are a vital part of improving TB care and support at the local-level, by catalyzing collaboration with affected people, communities, and civil society organizations. However, additional funding support for the program is needed, without which we will fall short of reaching these goals as the infectious threat evolves and people continue to go missed.

In summary, we thank the subcommittee for its previous support for USAID’s TB Program in FY 2018 and FY 2019. We fully acknowledge that the subcommittee has a difficult task in strategically appropriating funding to U.S. foreign assistance and global health programs with this year’s upcoming budget process. But we urge the subcommittee to build on the progress that the USAID TB Program has pioneered by funding it at \$400 million. This funding level will save millions of lives here and place us on the path to global elimination of TB. Additionally, we strongly support wider global health community asks in maximizing contributions and funding levels for the Global Fund to \$1.56 billion and the President’s Emergency Plan for AIDS Relief (PEPFAR) to \$5.5 billion, both of which are crucial lifesaving programs that impact the health and well-being of people with TB everywhere.

¹³ White House. U.S. National Action Plan to Combat Multidrug-Resistant Tuberculosis. 2015.

¹⁴ U.S. Agency for International Development. Challenging TB Worldwide. <https://www.challengentb.org/about>

¹⁵ U.S. Agency of International Development. USAID Global Accelerator to End TB. <https://www.usaid.gov/what-we-do/global-health/tuberculosis/resources/news-and-updates/global-accelerator-end-tb>