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Introduction

Chairman Smith, Ranking Member Bass and members of the Subcommittee, thank you for inviting me to testify on the U.S. Agency for International Development (USAID) response to the tuberculosis (TB) epidemic in southern Africa and globally.

As South Africa Minister of Health Aaron Motsoaledi has so aptly said of death by tuberculosis "[it] happens very slowly, maybe in a corner somewhere, in an isolated hospital ward, with nobody watching, so it doesn't evoke any emotion. Maybe that's what's at play around the entire world."

For more than 20 years, the U.S. Government (USG) has been a leader in the global effort to increase access to TB diagnosis, treatment, prevention and care, particularly in countries with the highest burden of disease. Thanks to the generosity of the American people and the strong support of the U.S. Congress, USAID is the largest bilateral donor in the fight against TB. We work in partnership with national TB programs (NTPs) in Ministries of Health (MoHs), the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), the World Health Organization (WHO), the Stop TB Partnership, technical assistance organizations, civil society including faith-based organizations, as well as affected people and communities. USAID has driven and funded interventions, tools, and technologies that have helped save 53 million lives from 2000 to 2016. Our efforts to build partnerships with national governments, multilateral organizations, and departments and agencies across the US Government have developed and strengthened country capacity to end the TB epidemic around the world.

TB has long been an issue of particular concern for me. Twenty years ago, I was privileged to play a key role in the creation of USAID's TB program. During my tenure as head of the USAID's Infectious Disease Division, the USAID TB program grew to be a major component of USAID's health portfolio. I was also heavily engaged in the creation of the Global Drug Facility (GDF) and the Stop TB Partnership, a unique international organization comprised of 1,500 partners dedicated to work collectively to end TB.

U.S. Government collaborative efforts to end TB globally

The U.S. Government's global TB strategy leverages interagency strengths and innovations to endeavor to reach every person with TB, cure those in need of treatment, and prevent the spread of the disease and new infections.

The vital collaboration and complementary efforts across the USG are reflected in our shared successes through the implementation of the U.S. Government Global TB Strategy (2015-2019) and the National Action Plan for Combating Multidrug-Resistant TB (2016-2020) as we work together to save lives and protect America's global health security. The U.S. Government

Global TB Strategy outlines clear roles and responsibilities for each federal partner. Among them, USAID leads international TB efforts to increase access to high quality, person-centered diagnosis, treatment, and care for TB and multidrug-resistant (MDR) TB. The Office of the Global AIDS Coordinator leads international HIV/AIDS efforts, including TB/HIV. The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), works domestically and globally on TB, including through PEPFAR, on research, surveillance, diagnostic and laboratory capacity, and treatment. The National Institutes of Health (NIH), specifically the National Institute of Allergy and Infectious Diseases (NIAID), also within HHS, conducts biomedical TB research that informs the overall TB effort; and the Department of Defense supports TB diagnosis and operational research through international laboratories. With the U.S. Government as the largest contributor to the Global Fund, combined with USAID's bilateral efforts, resources dedicated to TB/HIV coinfection efforts through the President's Emergency Plan for AIDS Relief (PEPFAR), and NIH and CDC investments in research, the U.S. is by far the leader in work to end TB worldwide.

The National Action Plan promotes greater coordination to reduce the domestic and global risk of MDR-TB; increases the American public's awareness of the threats posed by the disease; and serves as a call to action to all stakeholders on this worldwide concern. Similar to the U.S. Government Global TB Strategy, the three goals of the National Action Plan are implemented through a collaborative effort by multiple U.S. Government departments and agencies, with USAID leading the second goal of improving international capacity and collaboration to combat MDR-TB.

USAID leads U.S. Government global TB efforts through its support for high-quality diagnosis, treatment, prevention, and care services for millions of people with TB and at risk for TB and MDR-TB. The Agency bilateral TB program works with MoHs in 22 high-burden countries including Malawi, Mozambique, South Africa, Zambia, and Zimbabwe in southern Africa to produce sustainable results. USAID investments in TB save lives by improving the capacity of NTPs to introduce and expand access to new tools and high-quality TB services. In addition to USAID's bilateral programming, the Agency supports an additional 32 countries through targeted technical assistance and support for Global Fund grants including Angola, Botswana, Lesotho, Madagascar, Namibia, and Swaziland in southern Africa. In all, the Agency provides focused assistance to 54 countries, including 11 in southern Africa, to optimize implementation of country-owned and led national TB programs.

Global TB situation

TB is the leading infectious cause of death, ninth leading cause of all deaths worldwide, and the most common cause of death in people with HIV. Each day, more than 4,600 individuals die of this curable disease, culminating in 1.7 million deaths each year--for context, that's more than twice the size of the population of the Chairman's congressional district in New Jersey. In 2016, approximately 10.4 million people developed TB, including 3.7 million women and 1 million children. Worldwide, more than two billion people are infected with *Mycobacterium tuberculosis*, the bacterium that causes TB. Those at greatest risk of developing active TB disease are those with compromised immune systems, including HIV, diabetes, and malnutrition. The disease predominantly affects the poorest and most vulnerable, with about 95 percent of TB deaths occurring in low- and middle- income countries. The majority of the global TB burden is in Asia. More than 55 percent of all TB cases are found in India, Indonesia, China, Pakistan, and the Philippines. If we don't solve TB in these countries, we cannot end TB.

Every year, about 60 percent of individuals with active TB disease are officially reported as

diagnosed and initiated on treatment. The remaining "missing" 40 percent--4.1 million people--do not receive services that meet international standards, which can lead to significant morbidity, drug-resistant (DR) TB, and even death. Unfortunately, the longer people with active TB disease remain untreated, whether it is drug-susceptible (DS) or DR, the more likely they are to spread the disease, infecting their families and communities. People with active TB disease can infect up to 10 to 15 other people over the course of a year.

Africa's estimated 2.6 million annual cases of TB comprise 25 percent of the world's TB burden. In Africa, the TB mortality rate in both those who are HIV-negative and people living with HIV (PLHIV) is, respectively, more than two and six times higher than the global average. The TB epidemic in the African region, as in other regions, is driven by a variety of factors, including weak health systems, but is exacerbated by the high prevalence of HIV, particularly in southern Africa.

TB is the leading killer of PLHIV, accounting for 40 percent of all HIV deaths worldwide. In 2016, almost 400,000 of the one million people with HIV-associated TB died of TB. As one of PEPFAR's main implementers, USAID works to make sure that countries receiving both PEPFAR funds and TB funds are coordinated, to ensure that patients have access to quality services for TB and HIV regardless of where they receive their care

USAID's bilateral TB program is working with countries to make certain every TB patient is being tested for HIV. In 2016, 82 percent of TB patients in the Africa region had a documented HIV test. PEPFAR data indicate that about half of eligible patients on antiretroviral treatment (ART) were screened for TB in 2017. Screening for active TB disease among PLHIV is important not only to identify individuals who would benefit from TB treatment for active disease, but because it can also identify individuals who would benefit from TB preventive therapy (TPT), which can greatly reduce the risk of developing active TB disease. When TPT is used as an adjunct to HIV treatment, the risk of active TB disease in PLHIV can be reduced by up to 90 percent. Screening for TB among PLHIV and scaling up TPT requires a strengthened and more focused response.

While HIV has the greatest impact on the TB epidemic in Africa, DR-TB is a major public health concern globally. DR-TB threatens to reverse progress made in combating the TB epidemic throughout the world. Experts have determined that by 2050, 75 million people will lose their lives to DR-TB and that the disease could cost the global economy $17 trillion.

Weak TB programs contribute to the development and spread of DR-TB which, like DS-TB, is transmitted through the air from person to person. MDR-TB, a form of TB that is resistant to two of the most efficacious medicines used to treat DS-TB, is present in every country in the world; extensively drug-resistant (XDR) TB, which is resistant to even more drugs, has been reported in more than 100 countries. In 2016, there were an estimated 600,000 cases of MDR-TB worldwide, accounting for more than four percent of all new TB cases; 93,000 (16%) were in Africa.

Despite the continuing and devastating impact of TB around the globe, considerable progress is being made. Since 2000, the TB mortality rate decreased by about 37 percent and the incidence rate declined by about 19 percent. Recent innovations have dramatically expanded our ability to rapidly diagnose all forms of TB and provide appropriate, life-saving treatment and care to those in need.

USAID response to the global TB situation

USAID works in most of the countries with the highest burdens of TB, MDR-TB, and TB/HIV to strengthen health systems and increase country capacity to provide high-quality TB services. Since 2000, our contributions have helped priority countries achieve an almost 40 percent decrease in TB-related mortality and a 20 percent decrease in TB incidence. USAID has helped provide high-quality TB treatment for almost 6 million TB patients, including almost 150,000 MDR-TB patients, in just the last two years. Over the past 20 years, USAID investments have also improved international and national TB surveillance systems, which have enabled better targeting of interventions at the global and country level, and identified trends in TB and MDR-TB which have informed policies, research, and response.

USAID has been a catalyst for investment and change in high burden TB countries. Over 80 percent of funding to support the TB response is financed through national domestic resources. With the majority of the world's TB cases in middle income countries, and with the limited international TB resources available, USAID has played a critical role in accelerating and enhancing the TB response in supported countries by influencing national and subnational clinical and technical policies and guidelines to improve the quality of care and introduce new approaches and tools, and has helped ensure coordination to maximize efforts. The Agency continues to work with governments and major partners to mobilize domestic resources and drive quality improvements for sustainable, multisectoral, person-centered TB programs.

The Agency's commitment to a person-centered approach requires a multisectoral response that includes ministries and sectors other than those directly related to health care. For example, USAID engages Ministries of Labor to reach manufacturers and workers, Ministries of Education to reach teachers and children, correctional agencies to reach prisoners and guards, faith-based and community organizations to reach families and communities, and the corporate sector to reach companies ranging from mining enterprises to the pharmaceutical industry and private health care providers. At the country level, USAID works with NTPs and local partners to scale up and accelerate implementation of the following tools and approaches:

Person-centered care: To improve quality of care and TB outcomes, USAID works with a range of organizations to ensure services are tailored to the needs of individuals and their communities. TB care has evolved to embrace a human rights approach that is focused on meeting the individual needs of each person so that they are able to access timely, quality diagnosis, care, and treatment in a supportive environment that is based on respect for patient autonomy, physical comfort, and psychosocial support. Individuals receiving TB treatment face months of therapy; those requiring treatment for DR-TB not only face months of therapy but toxic and often painful regimens. Person-centered care has been shown to reduce stigma, and increase patient satisfaction as well as treatment adherence. USAID has pioneered country- and population-specific interventions in all priority countries.

Public-private partnerships: USAID continues to leverage American innovation and leadership in an effort to scale up new tools to improve the quality of diagnosis and treatment. In a joint effort with Johnson and Johnson, the Agency has introduced bedaquiline, the first new TB drug approved by the Food and Drug Administration (FDA) in more than 50 years. More than 25,000 treatment courses are now available in more than 70 countries to treat people with DR-TB. USAID led the successful effort that resulted in rapid global introduction and scale-up of this new drug regimen. In addition, USAID has been instrumental in the introduction of the shortened MDR-TB treatment regimen (which can reduce the duration of treatment by more than 50 percent, from at least 20 months to 9 months) in all priority countries. Some USAID

countries with intensified support are enrolling almost 80 percent of those eligible on the regimen, improving treatment outcomes and saving precious resources. USAID is also partnering with diagnostic companies such as Cepheid and Becton Dickinson to expand access to quality rapid testing for TB and DR-TB. In FY 2016, USAID reduced the number of "missing" TB cases by 10 percent in priority countries by strengthening screening and the diagnostic network, to find people earlier so that they can initiate treatment more rapidly, not only improving the health of these individuals, but decreasing transmission to others.

Preventing the development of active TB disease: USAID programs work to prevent both the transmission of TB from one person to another, and the progression from latent TB infection (LTBI) to active TB disease in those who become infected. Access to early diagnosis and quality treatment is one of the best ways to prevent the transmission of active TB disease, as well as the development of MDR-TB. In addition, TPT, a critical intervention, particularly for contacts of individuals with active TB disease and PLHIV, is being expanded in countries.

Engaging the private health sector: USAID partners with the private sector and affected communities to expand their engagement in the delivery of TB services. Across our bilateral TB programs, USAID enables providers outside the government system, such as faith-based organizations, to care for patients as recommended by national guidelines, and to facilitate their inclusion in local planning activities. For example, Ethiopia established a new public-private platform within the Federal Ministry of Health to improve the provision of TB care. Through USAID technical support, facility standards were finalized and health facility inspectors trained, and a learning community for private health businesses was created. In India, USAID trained a group of private providers in an urban population of West Bengal to provide quality TB services. Although this urban population represented only 15 percent of the total population of West Bengal, the project was able to double the TB cases detected by the private sector in the state.

Management of drugs and commodities: USAID continues to be a major supporter of the GDF. The GDF is a pooled procurement mechanism that provides a package of services, including technical assistance in TB drug management and monitoring of drug use, as well as procurement of high-quality TB drugs at low cost. As the largest supplier of TB medicines and diagnostics, GDF ensures the availability, affordability and quality of TB medicines. Since 2012, GDF interventions have led to a price reduction in MDR-TB treatment regimens by more than 60 percent and several individual drugs by 70 percent. Earlier this year, the GDF announced 28 newly signed agreements with manufacturers for 83 products that will result in additional savings of approximately $31 million. The price reductions are particularly valuable to high-burden, middle-income countries such as South Africa and India, as it is imperative that they realize high returns on their domestic investments, ensuring increased and continued self-reliance.

Monitoring and Evaluation: USAID provides global technical leadership and country-level support to improve the collection, analysis, and use of TB data to inform policies and programs and customize interventions to those most at risk for TB. Timely, accurate, and complete data are required for NTPs to make strategic decisions and prioritize services. In addition, the Agency provides technical assistance to support the development of global guidance and the implementation of TB prevalence surveys, drug resistance surveys, and quality service assessments. For example, the recent prevalence survey in Kenya showed prevalence was three times higher in males than females. Not only do males have a higher disease burden, but they are also two times more likely to be missed. The survey also revealed that in Kenya, the highest prevalence age group among women was 65 and over. This survey provided essential data that

is being used to inform evidence-based, tailored TB programming.

Research and Innovation: USAID's research portfolio has been a key component of its TB program since inception. In close cooperation with USG partners, the Agency supports late-stage research studies and ensures the uptake of early-stage research supported by departments and agencies. Our research focuses on improving the treatment of DS-TB and MDR-TB, preventing progression from infection to disease as well as transmission from person to person, and building capacity to conduct operational research that improves the performance of TB programs. One of the studies currently supported by USAID is the Standardized Treatment REgimen of Anti-tuberculosis drugs for patients with Multi-drug resistant Tuberculosis (STREAM) study, the first rigorously conducted global trial to test new drug regimens for the treatment of MDR-TB that are that are less than half as long as the current regimen (6-9 vs 20-24 months), eliminate the need for painful injections, and do not cause debilitating conditions such as loss of hearing and psychosis.

Looking ahead

USAID is committed to accelerating progress toward ending tuberculosis. The Agency continues to mobilize increased commitments and funding from high-burden countries and other donors in support of this goal. The United Nations High-Level Meeting on TB (UNHLM) later this year will provide a much needed opportunity to support these objectives and bring global attention to a disease that, despite its horrific impact, is all too often ignored or unseen. It is critical we continue to maximize existing resources and leverage additional resources to build self-reliant TB responses. The first UNHLM on TB in September this year will provide an historic opportunity to galvanize the political commitment needed to step up the battle against TB and put the world and individual countries on the path to ending the epidemic. With increased political commitment, we will have the opportunity to accelerate action on TB, prioritizing domestic resource mobilization, increased early diagnosis and treatment of TB and DR-TB, person-centered care, rapid development and introduction of new tools through collaborative research efforts, and furthering of private sector partnerships.

USAID will continue its work with other USG departments and agencies to maximize our investments by leveraging the collective resources of partner governments as well as other key stakeholders. In particular, the Agency will continue to expand person-centered approaches to TB services; active detection by reaching out to contacts of TB patients; scaling up TB services in coordination with HIV programs; expanding engagement with the private sector including private practitioners and faith-based organizations; and forging partnerships with the corporate sector. In addition, the Agency will continue to advance novel approaches and evidence-based interventions to inform global policy guidelines and improve programs.

USAID remains committed to ending TB. Administrator Mark Green has declared TB, "a fight we can win" and has actively engaged to bring greater attention and resources to the issue. The Agency has been successfully implementing the USG's Global TB Strategy and looks forward to continuing to build upon these achievements.

Thank you again to Chairman Smith, Ranking Member Bass, and the members of the Subcommittee for calling this timely hearing. We stand at a critical juncture in the road between the path of ending the epidemic and letting the disease continue to kill more people than any other infectious disease each year. With your support, we can help the world take the right path, and end TB.