March 8, 2021

Rob Fairweather Acting Director Office of Management & Budget 725 17th Street, NW Washington, DC 20503

Dear Mr. Fairweather,

As you prepare the President's fiscal year (FY) 2022 budget, the undersigned organizations respectfully submit our updated recommendations on funding levels for global tuberculosis (TB) programs at the U.S. Agency for International Development (USAID) and the U.S. contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund).

The global TB pandemic, including the rapid spread of drug-resistant TB, poses a serious global security threat. To combat global TB, we recommend \$1 billion for USAID's global TB program, \$1.56 billion for the U.S. contribution to the Global Fund, and boosting the total funding for TB research and development (R&D) across key U.S. research institutions to at least \$444.5 million.

TB is the second highest global infectious killer after COVID-19, causing 1.5 million deaths in 2019. But in the high-burden TB countries where USAID and the Global Fund work, TB infections are still the leading disease killer and the TB programs are the first line of defense against airborne infectious diseases. It is clear the COVID-19 pandemic has only worsened the challenge of addressing TB as access to testing and treatment has plummeted, case notifications have dropped, and far more opportunities for TB transmission have gone unchecked. In a recent update, USAID reported one million fewer case notifications in 2020 as compared to 2019, a reflection of service interruptions that are estimated to set back the highest-burden countries by up to ten years in their fight to end TB. Worse yet, without sufficient funding and intervention, this trend will continue into 2021. This is particularly troubling as COVID-19 disease presents increased risks of morbidity and mortality for those with latent TB infection (LTBI) and active TB disease, especially in cases of pulmonary TB.

TB is also a leading cause of death among women of reproductive age in developing countries, and it is an under-recognized health problem in children. TB is the leading killer of people with HIV in sub-Saharan Africa and remains a life-threatening co-infection for those with other chronic diseases. Almost half a million people each year fall ill with multidrug-resistant TB (MDR-TB), but the World Health Organization (WHO) reports that fewer than 30 percent are being identified and treated.

Following the successful 2018 UN High-Level Meeting on TB, the first-ever for TB, the U.S. has a unique opportunity to provide global leadership toward ending the TB pandemic. With growing buy-in at the highest political level in key countries, USAID has an opportunity to do more to accelerate progress and catalyze other countries to invest in the fight against TB.

USAID's 2018 report on implementation of the *National Action Plan for Combating Multi-Drug Resistant TB* states that in 2017 the rate of expanding access to MDR-TB diagnosis and treatment "remained relatively unchanged," stipulating that "additional resources will be required" to reach further milestones. More funding would also strengthen the TB Global Drug Facility's role to stabilize a fragile market and ensure access to quality-assured TB products to diagnose and treat DR-TB, which will help avert further drug resistance and get us closer to meeting *NAP* goals.

In 2018, USAID launched a new business model called the "Global Accelerator to End Tuberculosis" to speed progress and build self-reliance through support for local organizations in priority countries. Investments in 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. According to USAID, the number of applications and strong demand for these locally managed grants far exceeded their current level of resources. Expanding this bilateral funding envelope could strengthen the community level response to TB and build additional early alert capacity against other airborne infectious diseases.

Additionally, the U.S. contribution to the Global Fund is a crucial way to leverage more global TB resources. The Global Fund provides 73 percent of international financing for TB programs worldwide. Since 2002, the number of deaths from TB has fallen 25 percent in countries where the Global Fund invests, and in 2019 alone, 5.7 million people were treated for TB in these countries. We recommend maintaining the \$1.56 billion for the U.S. contribution to the Global Fund. The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) also contributes to the fight against TB-HIV co-infection through its programs, and robust funding should be maintained.

In order to reach our global goals to end TB, we must invest in the development of new health technologies such as point-of-care diagnostics, new drugs, and vaccines through support to National Institute of Allergy and Infectious Diseases (NIAID), Centers for Disease Control and Prevention (CDC), USAID, Biomedical Advanced Research & Development Authority (BARDA), FDA, National Science Foundation (NSF), the Department of Defense's Congressionally Directed Medical Research Programs (CDMRP), as well as PEPFAR. USAID's continued support for late-stage clinical trials for new TB treatments is essential. The TB Trials Consortium (TBTC) at the Division for Tuberculosis Elimination (DTBE) continues to lead on critical research on latent tuberculosis infection (LTBI) treatment shortening, and recent funding interruptions to trial sites highlights the need for greater investment in this network. New, more effective vaccines that protect adolescents, adults, and infants from TB, are crucial to TB elimination efforts, yet investment in TB vaccine product development is severely lacking.

At the recent UN High Level Meeting, member states determined that \$2 billion would need to be invested in R&D annually in order to effectively end TB by 2030. If each country invested just 0.1 percent of gross domestic expenditure on R&D towards TB, we would reach that goal. The U.S. is currently 89 percent of the way towards its goal, and we have seen that even small increases in U.S. funding catalyze large increases from other countries. We recommend the U.S. government boost contributions to TB R&D across the aforementioned agencies to at least \$444.5 million to advance current and prospective technologies and tools in the pipeline.

We welcome the opportunity to work with you and your staff on efforts to halt the global TB pandemic and protect U.S. communities from this disease. Please contact Elizabeth Lovinger (elizabeth.lovinger@treatmentactiongroup.org) or Nuala Moore (nmoore@thoracic.org) if you have any questions or need more information.

Sincerely,

American Thoracic Society
Americas TB Coalition
Association for Professionals in Infection Control and Epidemiology
Dimagi, Inc.
Elizabeth Glaser Pediatric AIDS Foundation
Friends of the Global Fight Against AIDS, Tuberculosis, and Malaria
Fund for Global Health
Global Health Technologies Coalition
Harvard Medical School Center for Global Health Delivery
Health GAP (Global Access Project)
IAVI
Infectious Diseases Society of America
International Union Against Tuberculosis and Lung Disease (The Union)
Johnson & Johnson
Management Sciences for Health
Medical IMPACT
National Tuberculosis Controllers Association
Partners in Health
RESULTS
Stop TB USA
TB Alliance
Treatment Action Group
We Are TB