

October 7, 2020

Russell Vought
Director
Office of Management & Budget
725 17th Street, NW
Washington, DC 20503

Dear Mr. Vought:

As you prepare the President's fiscal year (FY) 2022 budget, the undersigned organizations respectfully submit our recommendations on funding levels for global and domestic tuberculosis (TB) programs at the U.S. Agency for International Development (USAID), Centers for Disease Control and Prevention (CDC), and the U.S. contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). The global TB pandemic, including drug-resistant TB, continues to pose a serious global security threat. TB remains the leading global infectious killer, with 1.5 million deaths annually, although COVID-19 may overtake it later this year.

In order to rapidly adapt and restore critical TB services and prevent a dangerous reversal of progress, we urge you to provide at least \$600 million in additional funds for the USAID TB Program, \$1.56 billion for the US contribution to the Global Fund, \$225 million for CDC's Division of TB Elimination (DTBE), \$21 million for global TB efforts at the CDC's Division of Global HIV and TB (DGHT), and boosting the total funding for TB research and development (R&D) across key U.S. research institutions to \$444.5 million.

The COVID-19 pandemic is having a major impact on individuals with TB and on TB programs, putting unprecedented pressure on the health workforce, infrastructure and resources globally, including in the U.S. Many high TB burden countries have reported substantial reductions in the diagnosis of TB, even after the relaxation of COVID-19 lockdowns, resulting in far fewer people starting treatment for the disease. [A new Civil Society survey](#) of people with TB, TB programs, healthcare workers, and researchers in the U.S. and in countries including India and Kenya showed the extent of the damage that COVID-19 has wrought upon the fight against TB. Respondents expressed concerns about the pandemic driving vulnerable populations into poverty and away from healthcare and about already modest budgets for TB response and research being redirected towards COVID-19, which could have lasting consequences for TB for many years to come. Shortages of some medications and overtaxed health personnel have also made it difficult to maintain treatment for existing patients or provide essential preventive therapy.

These challenges also extend to TB R&D, for which studies have been forced to assume delays and protocol modifications or find expensive solutions to keep trial participants safely engaged. According to recent modeling, the world could see an additional 6.3 million cases of TB, and an additional 1.4 million TB deaths, between 2020 and 2025, setting the fight against TB back 10 years or more.

Although considered a low-incidence country, every state within the U.S. continues to report TB disease and the rate of decline in cases is now stagnant, showing that we cannot make further progress towards eliminating TB in the U.S. without increasing our investment in our national and state and local TB and research and development programs. Twenty-three states reported TB case

increases in 2019. Drug-resistant TB poses a particular challenge to state and local public health budgets due to the high cost of treatment and intensive health care resources required. There are also an estimated 13 million people in the U.S. with latent TB infection (LTBI), the reservoir of future active TB cases.

The National Tuberculosis Controllers Association (NTCA) recently found that local and state TB programs have played a significant role in the public health response to COVID-19 by applying their expertise in addressing this airborne infection through contact tracing, surveillance, infection control, and isolation procedures to this new pandemic. However, NTCA also found in some counties and cities, TB clinics have closed, leading to a significant reduction in diagnosis and evaluation of this airborne disease and fewer contact investigations for active TB cases. And most TB programs around the country report that TB program staff, and TB hospital units have been moved to focus almost exclusively on the COVID-19 response. In addition, the COVID-19 emergency in the US, and its economic impact, has put enormous strain on state and local budgets that fund the majority of TB services, putting TB funding at risk.

We are concerned that this transfer of many TB program staff and resources away from urgent TB-related services is increasing the risk of greater transmission of TB infection and untreated active disease, posing a danger to communities. For example, officials at the New York City Department of Health have stated that while they have modified many TB services in response to the Covid-19 emergency, critical services may suffer. They report: “There is concern from doctors and nurses about missing early signs of adverse reactions to medication that can lead to serious complications or even death. We also worry about patients not completing treatment, and that delays in testing contacts could result in these individuals developing active TB. TB transmission may go undetected for prolonged periods.”

CDC is recognized globally for its expertise in TB identification, treatment and prevention. Yet its work on global TB is underfunded. Increasing CDC’s Division of Global HIV and TB funding to \$21 million would allow the agency to use its unique technical expertise to address the nexus between the global TB pandemic and the incidence of TB in the U.S. This funding would help strengthen TB elimination programs in highly burdened countries, focusing on countries contributing to the TB burden in the U.S. such as Mexico, Vietnam and the Philippines.

The US must act now to help prevent a dangerous reversal of progress on TB. We urge the administration to propose an increase in USAID TB funding to \$600 million, to allow the agency to:

- **Expand the TB Local Organizations Network.** At the 2018 UN High-Level Meeting on TB, 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. Local organizations are also well-positioned to reach people affected by TB during COVID-related disruptions and restrictions on movement.

- **Support countries in faster implementation of innovations** that are proving crucial in the context of COVID-19. These include community-based screenings using portable diagnostics, bi-directional screening for TB and COVID-19, home delivery of TB medications with multi-month

dispensing, and telemedicine approaches to keep patients on track during the six to nine months of daily TB treatment.

- **Increase the scale of support to Priority Countries** that have a strong commitment to reaching the targets agreed to at the UN High level Meeting on TB in 2018. This assistance should cover screening for and treatment of TB infection among all close contacts as well as expanding social support to all patients, including nutrition, now even more critical given the impact of COVID-19 on access to food and income. It will also support countries in planning for and implementing Global Fund grants.
- **Add a limited number of countries with a significant TB burden to the list of Priority Countries.** For instance, the US should expand assistance to Latin America and the Caribbean to ensure access to the latest TB innovations, including among migrants and other vulnerable populations and in areas where services have been disrupted by COVID-19.
- **Double the U.S. contribution to the Global TB Drug Facility (GDF),** given the increased need in the context of COVID-19 for forecasting and market interventions to ensure an uninterrupted supply of TB medication. Such an increase would help GDF establish a “safety net” to assist countries experiencing failed tenders or other issues as they improve their procurement policies and laws under domestic financing; expand the number of countries where GDF can provide the full range of technical assistance; and support an expansion of GDF’s Flexible Procurement Fund to respond to emergencies by supporting pre-payment for TB commodities.
- **Expand USAID backing for TB research and development** to at least \$48.9 million per year. This includes greater support for product development partnerships and other public-private partnerships, academic researchers, and other research institutions and networks. At this pivotal time for the development and scale up of new diagnostic, treatment, and prevention options, including a promising TB vaccine candidate, USAID support would help get TB research back on track after COVID-related disruptions and help the U.S. meet its Fair Share target, setting an example for other countries.

Increased investment in TB research should be implemented across several agencies, through support to the National Institute of Allergy and Infectious Diseases (NIAID), CDC, USAID, Biomedical Advanced Research & Development Authority (BARDA), the Food and Drug Administration (FDA), National Science Foundation (NSF), the Department of Defense’s Congressionally Directed Medical Research Programs (CDMRP), as well as the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR). USAID’s continued support for late stage clinical trials for new TB treatments is essential. The TB Trials Consortium (TBTC) at DTBE continues to lead on critical research on LTBI treatment shortening. 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. 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. This is a conservative figure, based upon fair share estimates determined prior to COVID-19 and its related costs.

The U.S. contribution to the Global Fund is a crucial way to leverage more TB resources. The Fund provides more than 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 a funding level of \$1.56 billion for the US contribution to Global Fund, maintaining the level of funding from FY20 and allowing for maximum burden-sharing from other donors to the Global Fund. PEPFAR also contributes to the fight against TB-HIV co-infection through its programs, and robust funding should be maintained.

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 David Bryden (dbryden@results.org) or Nuala Moore (nmoore@thoracic.org) if you have any questions or need more information.

Sincerely,

American Association of Physicians of Indian Origin
American Lung Association
American Thoracic Society
Americas TB Coalition
Association for Professionals in Infection Control and Epidemiology
Association of Public Health Laboratories
Association of State and Territorial Health Officials
Elizabeth Glaser Pediatric AIDS Foundation
Friends of the Global Fight Against AIDS, TB and Malaria
Fund for Global Health
Georgia AIDS Coalition
Global Health Technologies Coalition
Health GAP
IAVI
Infectious Diseases Society of America
International Union Against Tuberculosis and Lung Disease
Management Sciences for Health
Medical IMPACT
National Alliance of State and Territorial AIDS Directors
National Association of County and City Health Officials
National Tuberculosis Controllers Association
Partners in Health
RESULTS
Stop TB USA
TB Alliance
TB Photovoice
Treatment Action Group
We Are TB
Zero TB Initiative