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UNITED TO END TUBERCULOSIS: KEY ASKS FOR THE U.S. FROM TB STAKEHOLDERS AND COMMUNITIES

PREAMBLE

Tuberculosis (TB) remains the leading infectious killer worldwide, despite being both preventable and curable. We can end TB as a health threat both inside and outside of the U.S. with increased leadership, commitment, and investments. The U.S. has committed to eliminating TB, yet progress in reducing the number of new cases is extremely slow both in the U.S. and globally; in fact, 23 U.S. states saw a rise in TB in 2017.

Years of flat funding for U.S. domestic and global TB programming and research—which means effectively decreased funding after adjusting for inflation—threatens progress towards TB elimination. The U.S. must sustain and expand these investments across a range of key agencies to accelerate the TB response and mitigate this rapidly evolving epidemic with new public health tools.

TB is becoming increasingly resistant to the few antibiotics that we have with which to treat it. Globally, drug-resistant TB is currently the single-largest driver of deaths to an antimicrobial-resistant (AMR) threat. More than 100 countries have reported cases of extensively drug-resistant TB (XDR-TB) since it was first documented in 2006. If we allow the status quo to continue, we risk the emergence and spread of an incurable airborne disease. Ensuring adequate investments to strengthen health systems at home and abroad is crucial. A country's rate of TB is a key indicator of the strength of its health system. By supporting global and domestic efforts to bringing public health infrastructure to the 21st century, we can strengthen the domestic response, as well as support pandemic preparedness.

As elimination of TB in the U.S. is inextricably linked with global efforts, it is deeply in the U.S. government's interest that this High-Level Meeting succeed. The U.S. must work closely with high-burden and other countries to ensure that commitments include strong and measurable targets. Additionally, the U.S. must make strategic investments and policy decisions to eliminate TB within its own borders.

We urge U.S. leadership to leverage the United Nations High-Level Meeting on TB in September 2018 as an opportunity to protect Americans from TB by ending the epidemic at home and abroad.

In keeping with the Key Asks prepared for the High-Level Meeting, U.S.-based TB stakeholders and communities call on U.S. government leadership to take the following priority actions to accelerate progress toward ending TB, both domestically and globally:

1. REACH ALL PEOPLE BY CLOSING THE GAPS ON TB DIAGNOSIS, TREATMENT, AND PREVENTION

DOMESTIC

- Support the U.S. Centers for Disease Control and Prevention (CDC) in implementing a Prevention Initiative to intensify efforts to diagnose and treat TB infection. Current domestic TB funding is inadequate to achieve elimination. This Prevention Initiative includes scaling up TB infection testing among high-risk populations, implementing shorter treatment options developed by U.S.-funded research, and supporting a national surveillance system.
- Work cross-agency to improve screening and diagnosis outreach capacity in key vulnerable populations, including people with HIV, incarcerated individuals, people who are homeless, foreign-born individuals, and at-risk children and pregnant women.
- Rectify inadequate funding and cuts through increasing resources (via CDC and state/local funds) for state and local TB programs to provide the full continuum of care, that is:
 - Conducting active case finding (proactively identifying those sick with TB, consistent with best practices)
 - Screening people at high risk for TB and linking at-risk individuals to treatment and prevention options.
- Fully fund and implement the *U.S. National Action Plan for Combating Multidrug-Resistant Tuberculosis (MDR-TB)*, including sustained and sufficient funding to maintain a stable reserve of TB products, are required.
- Address frequent stock-outs and high costs for tools to combat TB in the U.S. through developing and implementing novel models of procurement for TB commodities to secure consistent supplies, equitable access, lower prices, and create a more stable market.

GLOBAL

- Maintain and increase TB-specific funding for the U.S. Agency for International Development (USAID), the President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund, and the CDC's Division of Global HIV and TB.
- Support the scale up of evidence-based interventions (for example, TB-LAM testing, rapid molecular tests, bedaquiline, delamanid, and rifapentine-based prevention therapy).
- For scale-up of the response to MDR-TB, ensure funding is adequate to, at minimum, reach the targets in the *U.S. National Action Plan for Combating MDR-TB*, including for treatment.

2. TRANSFORM THE TB RESPONSE TO BE EQUITABLE, RIGHTS BASED, AND PEOPLE CENTERED

DOMESTIC

- Provide adequate funding for CDC and state and local health departments to collaborate with community organizations in providing culturally and linguistically competent outreach and care to vulnerable populations.
- Ensure non-discriminatory health, immigration, and other policies that encourage at-risk individuals to seek and stay in care and remove unnecessary barriers, for example:
 - oppose proposed changes to Public Charge definitions,
 - update TB screening policies for immigrants to promote use of rapid tests rather than delay entry to the U.S.,
 - rescind the request to add a citizenship question to the Census,
 - and support the availability of health care via the Affordable Care Act, Medicaid, emergency Medicaid, and other vital initiatives.
- Provide socio-economic support for TB patients and their families to promote rights and support retention in care.
- Close the Pediatric Research Equity Act loophole, which exempts TB drugs from pediatric research requirements and excludes children from benefitting from scientific progress.

- Take an active role in determining fair pricing for TB products, especially when public funding contributed to product development, to avoid the public paying twice, for example:
 - leverage public funding for access upfront through making public support for product development conditional upon access clauses regarding affordability, registration, and data and compound sharing;
 - support the use of “march-in rights,” under the Bayh-Dole Act, for publicly funded products that are not available or affordable.

GLOBAL

- Maintain and increase U.S. funding for global TB programming that prioritizes the provision of equitable, affordable, accessible services and care, particularly for vulnerable or marginalized populations, including socio-economic support for TB patients and their families.
- Ensure U.S. influence does not interfere with countries’ sovereignty in fair pricing or intellectual property decisions consistent with globally agreed upon provisions contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration on the TRIPS Agreement and Public Health.

3. ACCELERATE DEVELOPMENT OF ESSENTIAL NEW TOOLS TO END TB

DOMESTIC AND GLOBAL

- Protect and expand U.S. investment in TB research and development (R&D) from basic science through product development to implementation and health systems research, across key agencies (CDC, USAID, the National Institutes of Health [NIH], the National Science Foundation [NSF], the Food and Drug Administration [FDA], the Department of Defense [DOD], and the Biomedical Advanced Research and Development Authority [BARDA]).
- Ensure that research conducted by public funding is needs driven, evidence based, and guided by the principles of affordability, efficiency, equity, and collaboration, and interventions that are developed are subsequently registered and available in all affected countries.
- Given the market failure associated with the development of new tools for TB, support new incentive mechanisms to finance R&D in ways that do not rely on the proceeds of sales (through high prices or high volumes) to pay for R&D costs. This includes supporting innovative financing mechanisms for TB such as the Life Prize.

4. INVEST THE FUNDS NECESSARY TO END TB

DOMESTIC

- Ensure funding is adequate to implement and reach the goals outlined in the *U.S. National Action Plan for Combating MDR-TB*.
- Increase CDC Division of TB Elimination funding to \$195.7 million in FY19, and to \$260.0 million by 2023.
- Authorize the Comprehensive TB Elimination Act (CTEA) currently in Congress (S.2567, H.R. 5794).
- Protect and expand U.S. investment in TB R&D to meet the target of \$440 million per year.

GLOBAL

- Invest \$400 million in FY19 for USAID’s Global TB Program.
- Support and increase U.S. commitments to the Global Fund to \$1.35 billion, CDC Division of Global HIV and TB to \$21 million, and PEPFAR to \$5.16 billion to scale-up technologies and programs to eliminate TB.

5. COMMIT TO DECISIVE AND ACCOUNTABLE GLOBAL LEADERSHIP, INCLUDING REGULAR UN REPORTING AND REVIEW

DOMESTIC

- Require agencies to report to Congress on progress of Sustainable Development Goal (SDG) 3.3
- Ensure appropriate engagement with the House TB Elimination Caucus to advance discussions and ensure a high level of political commitment.

GLOBAL

- Transition plans and strategies for USAID, PEPFAR, and the Global Fund should adequately assess risk and national capacity to manage national TB programs, supply chains, surveillance systems, and expand health coverage. Health indicators should be considered on equal footing with economic indicators such as gross national income and country classification.
- Step-up and facilitate the convening of a Global TB Cabinet of Heads of State from high-burden TB countries.
- Support and encourage a follow-up meeting to the High-Level Meeting, to take place in 2023, and every five years thereafter, to ensure progress to ending TB.
- Ensure the High-Level Meeting includes a commitment by the UN Secretary-General to deliver an annual report on progress towards achieving the commitments made by the member states. This report must be supported by a fully independent review body that uses an evidence-based approach.