United States House of Representatives Committee on Appropriations Subcommittee on Labor, Health and Human Services, and Education

Written Testimony for Fiscal Year 2020 for the U.S. Centers for Disease Control and Prevention (CDC)

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On behalf of the Tuberculosis Roundtable

On behalf of the Tuberculosis (TB) Roundtable coalition, we are pleased to submit this testimony to the House of Representatives Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education (LHHS) 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 valuable public health role of the Centers for Disease Control's (CDC) domestic TB elimination program within the National Center for HIV, Viral Hepatitis, STI, and Tuberculosis Prevention (NCHHSTP), which is currently funded at $142.2 million in FY 2019. **We submit this testimony to urge the Subcommittee to commit $195.7 million in FY 2020 to the domestic TB elimination program**. Increased resources are necessary to restore state TB program capacity, lost through years of flat funding and reductions in public health staffing, implement the *U.S. National Action Plan to Combat Multi-Drug Resistant (MDR) TB*, implement a national TB prevention program, address ongoing issues in the supply of TB therapeutics and products, and expand urgently needed research and development (R&D) for TB.

CDC's mandate is to protect Americans from public health threats at home and abroad. Yet its work on global TB is underfunded and is mostly transferred in through other accounts. **Accordingly, we also urge the Subcommittee to commit $21 million to CDC's Division of Global HIV and TB (DGHT)** to allow the agency to use its unique technical expertise to directly address the nexus between the global TB epidemic and the TB epidemic in the U.S. We request that this funding be provided not through the CDC's domestic TB elimination program, or out of that Division's funding, but rather through a new budget line for CDC's work in global TB. This direct funding stream and increase 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.

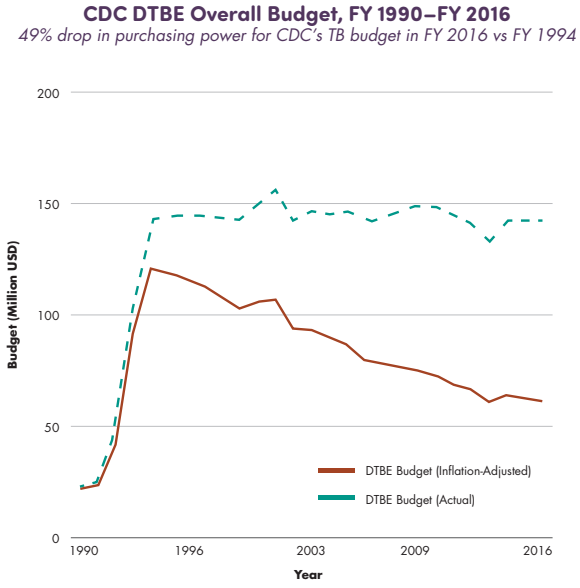
TB is an airborne disease, causing more deaths than any other single infectious disease agent globally. Over 10.0 million people worldwide fell ill with TB, resulting in 1.6 million deaths in

2017 alone.[1] In 2018, 9,029 people in the United States had TB but twenty-two states reported TB cases increases.[2] The CDC cautions that these data demonstrate that the incidence of TB is declining at a slower pace, dropping from a 4.7 percent annual decline from 2010 to 2014 to 1.3 percent from 2017 to 2018 and signal that we have reached the limit of what can be accomplished for TB elimination with our existing tools.[3] Four states — California, Florida, New York and Texas — continue to account for about half of the reported cases of TB in 2018.[4]

Drug-resistant TB (DR-TB), identified by CDC as a serious antibiotic resistant threat, poses a serious challenge to domestic TB control. Between 2005 and 2015, there were 1,195 cases of multidrug-resistant TB (MDR-TB), 31 cases of extensively drug-resistant TB (XDR-TB) reported in the U.S. and approximately, 10% of TB cases are mono-resistant, resistant to at least one TB medication. These data from the CDC illustrates that the goal of eliminating TB in the U.S. is unlikely to be achieved in the 21st century without an infusion of needed resources to scale-up prevention focusing on those at highest-risk for active TB disease, and advancing new public health tools to address DR-TB.

CDC's domestic TB program is our frontline defense against this deadly disease and its mission is to promote health and quality of life by carrying out public health activities in preventing, controlling, and eventually eliminating TB in the U.S. Approximately 50% of funding provided to the CDC's domestic program supports state and local TB programs, which carry out public health activities to eliminate TB within communities across the U.S. Furthermore, the domestic TB program also conducts programmatically-relevant research through its TB Trials Consortium (TBTC), to inform public health practices and create tools used by programs.

TB was once the leading cause of death in the U.S., but significant boosting of funding and reorganization of CDC's domestic TB elimination program aligned resources and research to address escalating outbreaks of DR-TB occurring among vulnerable communities in the 1980's. In part to increases in funding, the domestic TB program has been tremendously successful in lowering rates with strengthened control and prevention strategies over time. This is a public health success story, and illustration of the critical importance of adequate and appropriate funding to strengthen and sustain public health work. However, the domestic TB program has essentially received flat funding since FY 2012, which has resulted in stagnant numbers



[1] World Health Organization. Global Health Observatory Data – tuberculosis. https://www.who.int/gho/tb/en/
[2] Talwar A, Tsang CA, Price SF, et al. Tuberculosis — United States, 2018. MMWR Morb Mortal Wkly Rep 2019;68:257–262. DOI: http://dx.doi.org/10.15585/mmwr.mm6811a2.
[3] Ibid
[4] Ibid

of TB cases and rates in the past three years, a slowing annual decline of incidence, and the rise of deadlier drug-resistant forms of TB. When accounting for inflation (see chart) using the Biomedical Research and Development Price Index (BRDI) - which calculates how much the cost of conducting research and public health activities must change each year to maintain purchasing power - between FY 1994 and FY 2016, CDC's domestic TB program budget in constant dollars according to BRDI declined by more than 49%.[5] This gap only continues to grow if funding increases goes neglected, making it difficult for TB programs to be prepared for this evolving infectious threat. Further erosion of funding will only result in erosion of our successes led by our state and local programs, and new funding increases are needed to sustain programs to overcome the challenge of eliminating TB in the U.S.

Further compounding budgetary challenges and stagnation of resources, have been infrastructural issues related to aging public health tools in the form of inadequate treatments, diagnostics and vaccines that are available to combat TB, and disruptions in supply of current tools. Current treatments for DR-TB treatment regimens can involve 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. Additionally, a history of acute TB drug shortages in the U.S. due to unstable market conditions have had severe public health consequences, limiting efforts to address outbreaks and challenging efforts to cure those diagnosed with TB. The drugs used for treatment regimens are often prone to shortages and in the event of interruptions in our nation's TB drug supply, persons with TB disease may lapse and TB can spread. Treatment interruptions, or regimens that contains too few drugs, can foster drug-resistance. Additionally, treatment costs for patients with TB disease increases as drug resistance escalates. While the rate of TB cases may seem low, direct treatment costs in the U.S. average $19,000 to treat a single case of drug-susceptible TB (DS-TB), $164,000 for MDR-TB and upwards of $526,000 to treat XDR-TB. Much of these resources come at the expense of already strained TB program budgets.[6]

A modest and strategic investment in FY 2020 to strengthen the CDC's domestic TB elimination program's ability to carry out its core functions will put our nation on the path to achieving true TB elimination, cost-effectively. An estimated 13 million people in the U.S. have TB infection and investing TB prevention provides incredible value. In one analysis, during 1992–2014, 368,184 incident TB cases were reported, and cases decreased by two thirds during that period through the strategic implementation of various TB prevention and control measures.[7] Modeling during this time indicates that the societal benefits of averted TB cases ranged from $3.1 to $14.5 billion.[8] Another analysis finds a $43 return on investment for every dollar spent on reducing TB.[9] With a nominal increase to the domestic TB program to scale-up targeted prevention efforts

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[5] Treatment Action Group. Securing a Tuberculosis-Free Future through the Visionary Research of the CDC's Tuberculosis Trials Consortium. January 2018, http://www.treatmentactiongroup.org/sites/default/files/crag_tbtc_brief_1_10_18.pdf

[6] U.S. Centers for Disease Control and Prevention. The Costly Burden of Drug-Resistant TB in the U.S. https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/costly-burden-dr-tb-508.pdf

[7] Castro KG, Marks SM, Chen MP, et al. Estimating tuberculosis cases and their economic costs averted in the United States over the past two decades. *Int J Tuberc Lung Dis*. 2016;20(7):926–933. doi:10.5588/ijtld.15.1001

[8] Ibid

[9] The Economist. The economics of optimism. January 2015 https://www.economist.com/finance-and-economics/2015/01/22/the-economics-of-optimism

among the 13 million with TB infection, future cases of active cases can be successfully averted with significant savings to the public health system. Furthermore, a groundbreaking TB preventative therapy, called 3HP, has drastically cut down treatment from 9 months of daily treatment to 3 months of once-weekly treatment was developed through TBTC. Scaling-up this homegrown treatment innovation through TB programs in a nationwide prevention effort ensures the practical implementation of effective taxpayer-funded technologies like 3HP among those who are most vulnerable to TB, expands access to the benefits of this science, and get us even closer to full elimination.

Additional resources for the domestic TB elimination program can also help address issues of drug supply – an ongoing national problem – and contribute to solving the unique challenges of a fragmented market for TB products. Among the solutions considered could be emulating the successful Global Drug Facility (GDF) an efficient centralized/pooled procurement model that was built through U.S. taxpayer support that could be implemented stateside to stabilize the market and mitigate shortfalls in the domestic supply for TB products. With a relatively nominal investment in FY 2020, the HHS Supply Service Center at Perry Point, Maryland, which currently administers a small stockpile of TB drugs and serves domestic TB programs by filling gaps in the supply could be further strengthened and inventory expanded to meet demand by programs for these important, yet vulnerable, public health products.

Lastly the research and development (R&D) role of the TBTC at the domestic TB elimination program in giving TB controllers the tools in countering, containing, and eliminating the world's leading infectious killer cannot go understated. TBTC research has had global implications, for example in the shortening of treatment, which have led to the changing treatment guidelines from the WHO to national programs in countries where TB is most endemic. In FY 2020, the TBTC researchers will engage in a re-competition process to devise an agenda for the next wave of programmatically-relevant research to eliminate TB. This is an opportunity to ensure the next 5 years advance emerging and innovative research we need in the form of new tools. 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 $18.3 million is contributed by CDC, making the agency the tenth largest TB R&D funder globally.[11] However, to capitalize on TBTC's expected re-competition to strengthen the 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 CDC 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 CDC coordinate with other federally-funded research institutions under LHHS, including the National Institute for Allergy and Infectious Diseases

[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

(NIAID) and the Biomedical Advance Research and Development Authority (BARDA), as well as the U.S. Agency for International Development (USAID). Continuing to support TB R&D at CDC and other agencies within the U.S. government can catalyze other national governments to make similar commitments.

With funding trends largely flat for a decade, FY 2020 represents a pivotal year to advance research and programming at the domestic TB elimination program, as well as DGHT, and move us towards TB elimination. We thank the subcommittee for its support for the program through sustained. However, with increased funding will go a long way to address multiple issues faced by resource strapped programs, including preparedness to counter DR-TB, addressing TB infection among the 13 million people in the U.S., and supporting R&D for new tools. The CDC's domestic program is now in a strategic position to build on its success and achieve true elimination within our borders. Critically, increasing the domestic TB program and DGHT's funding will facilitate their vital roles in the full implementation achievement of the goals and objectives set forth by the *U.S. National Action Plan to Combat MDR-TB* (see table).[13]

Goals of the National Action Plan (NAP)[13]
Actions taken in alignment with this National Action Plan will contribute to meeting the following domestic goals and objectives
Goal #1: Strengthen Domestic Capacity to Combat Multidrug-Resistant Tuberculosis

• *1. 1. Upgrade TB surveillance to ensure complete and accurate detection of drug-resistant TB*
• *1.2. Strengthen State and local capacity to prevent transmission of drug-resistant TB*
• *1.3. Ensure that patients with drug-resistant TB receive treatment until cured*
  ○ 1.3.1. Explore the potential use of a national TB stockpile to ensure the availability of TB medicines and screening tests
  ○ 1.3.2. Explore options for providing care for persons with MDR-TB or XDR-TB who do not have a medical home
  ○ 1.3.3. Improve completion of therapy for persons who travel in or out of the United States while on treatment for TB disease

Goal #3: Accelerate Basic and Applied Research and Development to Combat Multidrug-Resistant Tuberculosis

• *3.1. Increase options for preventing active TB, latent TB infection, and TB transmission*
  ○ 3.1.1. Advance research and development of novel vaccines
  ○ 3.1.2. Support the development of methodologies to prevent transmission and development of TB and MDR-TB
• *3.2. Improve the diagnosis of drug-resistant and drug-susceptible latent and active TB*
  ○ 3.2.1. Support the development of new tools and approaches for detection of drug-resistant TB
  ○ 3.2.2. Support research to identify biological markers to help detect latent TB and progression to active TB in children and adults
• *3.3. Improve treatment options for drug-susceptible and drug-resistant TB*
  ○ 3.3.1. Improve the use of existing TB drugs for treatment of drug-susceptible and drug-resistant TB
  ○ 3.3.2. Enhance knowledge to enable optimal and safe use of newly registered TB drugs
  ○ 3.3.3. Develop novel drugs and shorter regimens to treat drug-resistant TB and improve the selection of drug candidates for clinical trials
• *3.4. Increase capacity to conduct biomedical and clinical research on TB in TB-endemic countries*

In summary, we thank the subcommittee for its continued support for the domestic TB program at CDC. We fully acknowledge that the subcommittee has a difficult task in strategically appropriating funding within numerous agencies and programs under LHHS with this year's upcoming budget process. However, we urge you to leverage the programs and research that the domestic TB elimination program has pioneered by funding the CDC's domestic TB program at $195.7 million in FY 2020, and we urge the Subcommittee to commit $21 million to CDC's DGHT to allow the agency to use its unique technical expertise to directly address the nexus between the global TB epidemic and the TB epidemic in the U.S. This funding level will put the U.S. back on the path to eliminating TB and will position the U.S. as a global leader in the TB space.

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