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# Global Tuberculosis: Background and Issues for Congress

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Tuberculosis (TB) is one of the most widespread infectious diseases in the world, infecting 10 million people in 2020. Congress has recognized TB as an important global health issue and a potential threat to global health security. Although TB is curable, approximately 1.5 million TB-related deaths occur each year. Globally, new TB infection rates declined between 2015 and 2020. Global health observers anticipate new data to assess the extent to which interruptions in TB services during the COVID-19 pandemic affected TB control; for example between 2019 and 2020, global TB deaths increased by 5.6%. Members may debate appropriate funding levels and optimum strategies for addressing the continued challenge of global TB control during the remainder of the 117<sup>th</sup> Congress.

The United States Agency for International Development (USAID) and the U.S. Centers for Disease Control and Prevention (CDC) work closely with a range of multilateral partners to respond to the threat of TB, including the Global Fund to Fight AIDS, TB, and Malaria (the Global Fund), the largest multilateral actor in the TB space, and the World Health Organization (WHO), among others. National governments also play a key role in controlling TB within their own borders. Domestic government expenditures in middle-income countries with high TB burdens, such as Brazil, Russia, India, and China (BRICS), fund 97% of their domestic spending on TB control and account for a large portion of TB spending worldwide.

As the world has grappled with the secondary public health effects of the COVID-19 pandemic, Congress has increased its focus on TB in the context of global health security, building on prior efforts to address global TB control. For example, through the American Rescue Plan Act (P.L. 117-2), Congress appropriated \$3.5 billion to the Global Fund to mitigate the effects of the COVID-19 pandemic on TB, HIV/AIDS, and malaria. From FY2017 to FY2022, appropriations for bilateral TB control increased from \$246.2 million to \$370.0 million. In addition, Congress expanded support for bilateral TB programs, appropriating funds to the CDC for global TB control programs for the first time in FY2020.

In the remainder of the 117<sup>th</sup> Congress, Members may consider the following with regard to TB:

- U.S. contributions to the Global Fund,
- TB control after the COVID-19 pandemic, and
- the relationship between TB control, pandemic preparedness, and global health security.

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## Background

In 2020, tuberculosis (TB) was the number one infectious disease killer globally. Congress has intensified its focus on TB since then, partly in response to increasing TB deaths and interruptions in TB control during COVID-19 pandemic (see the “TB and COVID-19” **text box** below). This report provides background on global TB disease trends; describes how the disease is prevented, diagnosed, and treated; examines U.S. government funding and responses; and presents related issues for Congress.

TB is caused by a bacterium called mycobacterium tuberculosis.<sup>1</sup> The disease most often affects the lungs. When an infected person coughs, sneezes, or spits, the bacterium spreads through the air and can be inhaled by others.<sup>2</sup> TB transmission is preventable with active screening and rapid treatment, as well as physical distancing to prevent microbial spread through shared air, and is curable by antibiotics, but it causes 1.5 million deaths annually and is linked to numerous other social and health challenges globally.

TB is considered a disease of poverty. Research shows that the poorer a community is, the more likely individuals within it are to be infected with TB bacterium.<sup>3</sup> Poor access to basic health services, malnutrition, and inadequate living conditions (e.g., crowding, poor ventilation) are risk factors for the spread of TB.<sup>4</sup> According to the World Health Organization (WHO), over 90% of TB cases and deaths are in low- and lower-middle-income countries (see **Figure 1**).<sup>5</sup> According to WHO, globally in 2020 (the most recent year for which data are available)<sup>6</sup>

- 1.5 million people died from TB;
- 10 million people fell ill with TB;<sup>7</sup>
- 30 countries accounted for 86% of new TB cases, and half of those countries were in Africa;<sup>8</sup>
- almost 1.9 million people developed drug-resistant TB (DR-TB) and two in three people with DR-TB could not access effective treatment;<sup>9</sup> and

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<sup>1</sup> WHO, *Tuberculosis*, Key Facts, October 14, 2021.

<sup>2</sup> *Ibid.*

<sup>3</sup> WHO, *UN General Assembly High-Level Meeting on Ending TB*, Meeting Report, September 26, 2018.

<sup>4</sup> Matthew J. Saunders and Carlton A. Evans, “Fighting Poverty to Prevent Tuberculosis,” *The Lancet: Infectious Diseases*, vol. 16, no. 4 (April 2016). Devra M. Barter, Stephen O. Agboola, Megan B. Murray, et al., “Tuberculosis and Poverty: The Contribution of Patient Costs in Sub-Saharan Africa – A Systematic Review,” *BMC Public Health*, November 14, 2012. A. Siroka, I. Law, J. Macinko, et al., “The Effects of Household Poverty on Tuberculosis,” *The International Journal of Tuberculosis and Lung Disease*, vol. 20, no. 12 (December 1, 2016).

<sup>5</sup> WHO, *Tuberculosis*, Key Facts, October 14, 2021.

<sup>6</sup> WHO, *Global Tuberculosis Report 2021*, Geneva, Switzerland, 2021.

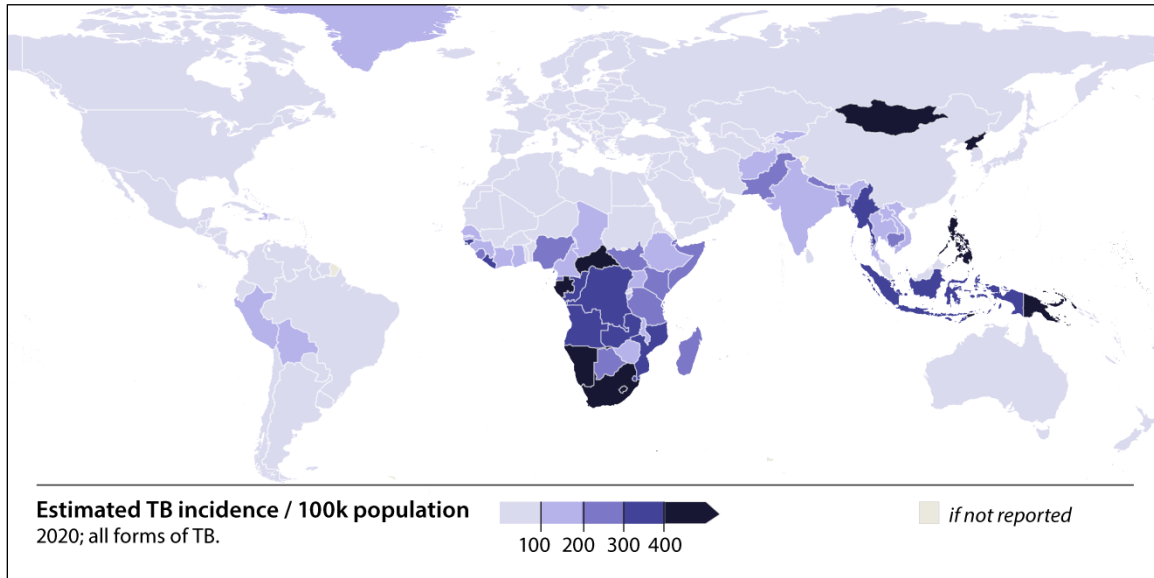
<sup>7</sup> *Ibid.*

<sup>8</sup> *Ibid.* The 30 high-burden countries are Angola, Bangladesh, Brazil, Central African Republic, China, Congo, Democratic People’s Republic of Korea, Democratic Republic of the Congo, Ethiopia, Gabon, India, Indonesia, Kenya, Lesotho, Liberia, Mongolia, Mozambique, Myanmar, Namibia, Nigeria, Pakistan, Papua New Guinea, the Philippines, Sierra Leone, South Africa, Thailand, Uganda, Tanzania, Vietnam, and Zambia.

<sup>9</sup> According to WHO, TB is typically treated by a standard six-month course of four antibiotics. Common drugs include rifampicin and isoniazid. In some cases, the TB bacteria does not respond to these first-line drugs and is known as Drug Resistant-TB. In these cases, the Drug Resistant-TB must be treated with second-line drugs, which include levofloxacin, moxifloxacin, bedaquiline, delamanid, and linezolid.

- roughly 50% of households affected by TB faced TB-related expenses they could not afford.<sup>10</sup>

**Figure 1. Global TB Incidence, 2020**  
(Cases per 100,000 population)



**Source:** WHO, *Global Tuberculosis Report 2021*, October 14, 2021.

**Notes:** Incidence refers to the occurrence of new cases of a disease or injury in a population over a specified period of time.

**Diagnosis and Treatment.** According to some experts, the cost of diagnosing and treating TB in many countries is often a barrier to care.<sup>11</sup> This cost barrier can adversely affect treatment adherence, contributing to increased morbidity (illness) and mortality (death) from the disease, as well as possible drug resistance. TB is generally diagnosed using either rapid molecular tests, sputum smear microscopy (a diagnostic test of phlegm for TB bacteria), or culture-based methods.<sup>12</sup> Many countries rely on the second method because it is the least expensive. Sputum smear microscopy has been shown to detect about half of all TB cases and cannot detect DR-TB, Rifampicin-TB (RR-TB, which is resistant to the first-line TB drug Rifampicin), or MDR-TB (Multi-Drug Resistant TB, which is resistant to treatment with two frontline drugs and emerges because of mismanagement of TB treatment and person-to-person transmission).<sup>13</sup> Detection of DR-TB strains is more expensive; it requires bacteriological confirmation of TB along with tests for the drug resistance itself (using rapid molecular tests, culture methods, or sequencing

<sup>10</sup> Ibid. According to WHO, many households affected by TB face “catastrophic costs,” including income loss resulting from direct and indirect expenses, that exceed a specific threshold of a household’s annual income.

<sup>11</sup> See, for example, Kerri Viney, Tauhidul Islam, and Nguyen Binh Hoa, “The Financial Burden of Tuberculosis for Patients in the Western-Pacific Region,” *Tropical Medicine: Infectious Diseases*, vol. 4, no. 2 (June 4, 2019). According to researchers, other factors that affect treatment adherence include “lack of knowledge, stigma and lack of social support, drug side effects and long treatment duration.” See, for example, Frezghi Hidray Gebreweld, Meron Mehari Kifle, Fitsum Eyob Gebremichael, et al., “Factors influencing adherence to tuberculosis treatment in Asmara, Eritrea: a qualitative study,” *Journal of Health and Population Nutrition*, vol. 37, no. 1 (January 5, 2018).

<sup>12</sup> WHO, *Tuberculosis*, Key Facts, October 14, 2021.

<sup>13</sup> Ibid. MDR-TB is TB that is resistant to treatment with isoniazid (the second most vital drug) and rifampicin.

technologies).<sup>14</sup> Several donors, including the United States, are providing support for countries to purchase GeneXpert (a real-time molecular TB test that detects the DNA in TB bacteria) to increase DR-TB detection. The Global Fund asserts that “the need continues to be bigger than the resources available.”<sup>15</sup>

TB treatment regimens vary depending on an individual’s type of TB infection. Drug-susceptible TB is treated by a four- to six-month course of four antimicrobial drugs. The majority of cases are curable if medicines are available and patients adhere to the treatment regimen. DR-TB antibiotic treatment lasts from 9 to 20 months and includes counselling and monitoring for adverse events. TB monitoring may include hospitalization for varying amounts of time, which may further burden health systems and complicate treatment adherence. While some DR-TB cases respond to treatment, many DR-TB (and MDR-TB cases) do not respond to existing medications, resulting in fewer treatment options and higher death rates.<sup>16</sup> Roughly 59% of MDR-TB cases are successfully treated versus 85% of cases susceptible to treatment with first-line drugs.<sup>17</sup>

TB transmission is primarily prevented through isolation of active TB cases. According to experts, approximately 1.7 billion people worldwide have latent TB, meaning that they are infected with the disease but cannot infect others because it is not actively causing illness in their bodies.<sup>18</sup> About 5%-10% of people with latent TB will develop active TB over their lifetimes. Some health experts promote issuing one course of TB treatment to people with latent TB to prevent them from developing active TB and possibly spreading it to their close contacts and community.<sup>19</sup> The Bacille Calmette-Guerin (BCG) vaccine, the only existing TB vaccine, can prevent TB infection in infants and small children but is not effective in adults.<sup>20</sup>

**DR-TB, MDR-TB and XDR-TB.** According to the WHO, almost 1.9 million people develop DR-TB every year and DR-TB causes one-third of antimicrobial resistance (AMR)-related deaths annually.<sup>21</sup> MDR-TB is also a significant issue.<sup>22</sup> Extensively drug resistant TB (XDR-TB) is a more rare form of MDR-TB, representing 8.5% of MDR-TB cases, that is resistant to treatment with more potent front-line drugs and second-line drugs, leaving patients with less effective treatment options.<sup>23</sup>

## Global Efforts to Address TB

In 2014, all WHO Member States, including the United States, adopted the WHO End TB Strategy, which aims to reduce TB incidence and deaths by 80% and 90%, respectively, and to eliminate catastrophic costs for TB-affected households by 2030.<sup>24</sup> In 2015, United Nations

<sup>14</sup> WHO, *Global Tuberculosis Report 2021*, Geneva, Switzerland.

<sup>15</sup> Ibid.

<sup>16</sup> The Global Fund, *Focus on Drug-resistant Tuberculosis* (Geneva: The Global Fund, 2019).

<sup>17</sup> Ibid.

<sup>18</sup> Rein M.G.J. Houben and Peter J. Dodd, “The Global Burden of Latent Tuberculosis Infection: A Re-estimation Using Mathematical Modelling,” *PLoS Medicine*, vol. 13, no. 10 (October 13, 2016).

<sup>19</sup> WHO, *Latent tuberculosis infection*, The End TB Strategy, 2015.

<sup>20</sup> Ibid.

<sup>21</sup> WHO, *Global Tuberculosis Report 2021*, Geneva, Switzerland.

<sup>22</sup> WHO, *Tuberculosis: Multidrug-resistant tuberculosis (MDR-TB)*, 2018.

<sup>23</sup> Centers for Disease Control and Prevention, *Fact Sheet: Multidrug Resistant Tuberculosis*, May 4, 2016.

<sup>24</sup> WHO, *End TB Strategy*, 2014. According to WHO, “catastrophic costs” include income loss and direct and indirect expenses that exceed a specific threshold of a household’s annual income.

(U.N.) Member States adopted the Sustainable Development Goals (SDGs), which called for an end to the TB epidemic by 2030 (see **Table 1**).<sup>25</sup> Following a 2018 inaugural UN General Assembly (UNGA) High Level Meeting on TB, countries committed to specific targets for resource mobilization, research, prevention, care, and treatment (such as personal protective equipment, high-flow ventilation, and contact tracing). These commitments focused on improving the availability, affordability, and quality of health care services for TB patients, as well as their access to affordable treatments, generic drugs, and digital health technologies (such as telehealth services) (see **Figure 2**). More recently, in August 2020, WHO Member States adopted the *Global Strategy for TB Research and Innovation*, which outlines a plan to increase financial investments in TB research and innovation, improve global data sharing, and promote equitable access to the benefits of research.<sup>26</sup>

**Table 1. Global TB Targets**

Sustainable Development Goals (SDGs), End TB Strategy and the UN High-Level Meeting on TB Political Declaration

<b>SDG Target 3.3</b>	By 2023 end the epidemics of AIDS, TB, malaria, and neglected tropical diseases, and combat hepatitis, water-borne diseases, and other communicable diseases.
<b>WHO End TB Strategy</b>	<ul style="list-style-type: none"> <li>• 80% reduction in the TB incidence rate (new and relapse cases per 100,000 population per year) by 2030, compared with 2015-2020 milestone: 20% reduction; 2025 milestone: 50% reduction.</li> <li>• 90% reduction in the annual number of TB deaths by 2030, compared with 2015-2020 milestone: 35% reduction; 2025 milestone: 75% reduction.</li> <li>• No households affected by TB face catastrophic costs by 2020.</li> </ul>
<b>UN High-Level Meeting on TB, 2018</b>	<ul style="list-style-type: none"> <li>• 40 million people treated for TB from 2018 to 2022, including               <ul style="list-style-type: none"> <li>• 3.5 million children</li> <li>• 1.5 million people with DR-TB, including 115,000 children.</li> </ul> </li> <li>• At least 30 million people provided with TB preventive treatment from 2018 to 2022, including               <ul style="list-style-type: none"> <li>• 6 million people living with HIV</li> <li>• 4 million children aged under five years and 20 million people in other age groups who are household contacts of people affected by TB.</li> </ul> </li> <li>• Funding of at least \$13 billion per year for universal access to TB prevention, diagnosis, treatment, and care by 2022.</li> <li>• Funding of at least \$2 billion per year for TB research from 2018 to 2022.</li> </ul>

**Source:** WHO, *Global Tuberculosis Report 2021*, Geneva, Switzerland, 2021.

According to WHO, the SDG and End TB Strategy targets cannot be met without intensified research and innovation. Priorities include developing

- vaccines to lower the risk of TB infection,
- new therapies to reduce the risk that some 2 billion people with latent TB might develop active TB,
- rapid diagnostic tests for use at the point of care, and

<sup>25</sup> Under SDG 3.3.2. For more information, see <https://sdgs.un.org/goals>.

<sup>26</sup> WHO, *Member States adopt the Global Strategy for TB Research and Innovation at 73<sup>rd</sup> World Health Assembly*, August 10, 2020. WHO, *A Draft Global Strategy for Tuberculosis Research and Innovation*, May 8, 2020.

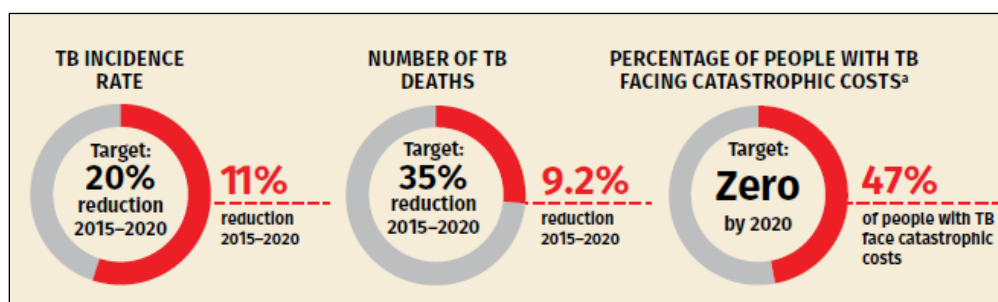
- simpler, shorter TB regimens.<sup>27</sup>

## Advances in Global TB Control

In the past several years, some countries have experienced declines in TB deaths by reaching more people with treatment and advancing infection prevention and control efforts, among other actions (see **Figure 2**). According to WHO, seven countries classified as having a high TB burden reportedly achieved the 2020 milestone of a 35% reduction in the absolute number of TB deaths from 2015 to 2020.<sup>28</sup> Nine countries classified as having a high TB burden achieved the 2020 milestone of a 20% reduction in TB incidence rate between 2015 and 2020.<sup>29</sup>

Other advances include progress in research and development for TB treatment options. In 2012, new drugs became available to treat TB, the first time in 40 years that new medicines were approved to treat the disease, shortening some treatment regimens from a four to six month period to three months.<sup>30</sup> These changes appear likely to improve treatment adherence and reduce the amount of time an individual is infectious to others.

**Figure 2. Progress:WHO End TB Strategy**  
2015-2020



**Source:** WHO, *Global Tuberculosis Report 2021*, Geneva, Switzerland.

**Notes:** Graphic indicates progress toward 2020 milestones; red coloring indicates how far along toward the 2020 target, as of publication of WHO's Global Tuberculosis Report.

## Challenges in Global TB Control

Several issues have impeded international efforts to end the TB epidemic.<sup>31</sup> Such challenges include limited funding for research and development of TB vaccines, treatments, and other medical tools and devices; the difficulty that low- and middle-income countries (LMICs) face in accessing quality medicines; and the expense and effort of treatment and diagnosis of MDR-TB.

<sup>27</sup> As of March 2022, there were 22 drugs and 14 vaccine candidates in clinical trials.

<sup>28</sup> These are Kenya, Mozambique, Myanmar, Russia, Sierra Leone, Tanzania, and Vietnam. WHO, *Global Tuberculosis Report 2021*, Geneva, Switzerland, p. 12.

<sup>29</sup> These are Cambodia, Ethiopia, Kenya, Myanmar, Namibia, Russia, South Africa, Tanzania, and Zimbabwe. WHO, *Global Tuberculosis Report 2021*, Geneva, Switzerland, p. 13.

<sup>30</sup> WHO, *WHO Consolidated Guidelines on Tuberculosis*, 2020.

<sup>31</sup> According to the CDC, an epidemic is defined as an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area. For more information, see <https://www.cdc.gov/csels/dsepd/ss1978/glossary.html>.



Further, some experts estimate that the COVID-19 pandemic has set back global TB control efforts by as much as a decade (see the “TB and COVID-19” **text box** below).

**Access to Affordable, Quality Medicines and Diagnostic Tools.** Individuals in LMICs often struggle to access proven tuberculosis medicines and diagnostic tools at affordable prices. For example, one study found that up to 70% of patients in Southeast Asia faced “catastrophic costs” related to their TB care.<sup>32</sup> According to researchers, “a global pandemic” of low quality and counterfeit medicines is also negatively affecting the fight against TB and other infectious diseases.<sup>33</sup> Many LMICs lack the health systems and regulatory infrastructure to support the use of TB drugs and treatments and/or to detect fraudulent treatments.<sup>34</sup> Health experts view the use of counterfeit drugs as especially problematic because it jeopardizes patient safety, leads to treatment failure, increases antimicrobial resistance and TB transmission rates, and lowers confidence in health systems.<sup>35</sup>

**Global Donor Funding.** Annual global funding for TB control has doubled since 2006, but it remains short of WHO global funding goals. In 2020, approximately \$5.3 billion was committed globally for TB prevention, diagnosis, treatment, and care—less than half of the \$13 billion annually WHO and partners had estimated in 2018 would be needed for TB control by 2022.<sup>36</sup> In 2018, global funding for TB research reached \$906 million, roughly 45% of the \$2 billion WHO members and other stakeholders committed to spend annually on research and development from 2018 through 2022.

Roughly 85% of funds raised by WHO and partners were provided by national governments for TB programs in their countries. Middle- and upper-middle-income countries with large TB burdens, such as Brazil, Russia, India, China, and South Africa (BRICS), accounted for 57% of all global TB funding. Whereas the BRICS funded 97% of their domestic TB programs in 2020, international donors funded roughly 53% of TB programs in the 25 high TB burden countries in the same year.<sup>37</sup>

### TB and COVID-19

Global health experts have raised concerns about monitoring, reporting, and tracking TB amidst the COVID-19 pandemic. According to experts, TB reporting has dropped in many countries during the pandemic because of its disruptive effect on health systems and capacity rather than actual decreases in TB prevalence.<sup>38</sup> According to

<sup>32</sup> Kerri Viney, Tauhidul Islam, and Nguyen Binh Hoa, “The Financial Burden of Tuberculosis for Patients in the Western-Pacific Region,” *Tropical Medicine Infectious Disease*, vol. 4, no. 2 (2019). For example, one analysis from Indonesia found that unsuccessful treatment outcomes for patients experiencing catastrophic costs were two to three times higher than those who could afford to pay for treatment without experiencing catastrophic costs. Ahmad Fuady, Tanja Houweling, Muchtaruddin Mansyur, et al., “Catastrophic costs due to tuberculosis worsen treatment outcomes: a prospective cohort study in Indonesia,” *Transactions of the Royal Society of Tropical Medicine & Hygiene*, vol. 114, no. 9 (June 8, 2020).

<sup>33</sup> Gaurvika M.L. Nayyar, Amir Attaran, John P. Clark, et al., “Responding to the Pandemic of Falsified Medicines,” *American Journal of Tropical Medicine and Hygiene*, vol. 92, no. 6 (June 2015).

<sup>34</sup> According to WHO, pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine/vaccine-related problem. See more at <https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance>.

<sup>35</sup> R. Bate, P. Jensen, K. Hess, et al., “Substandard and falsified anti-tuberculosis drugs: a preliminary field analysis,” *The International Journal of Tuberculosis and Lung Disease*, vol. 17, no. 3 (March 2013).

<sup>36</sup> WHO, *Global Tuberculosis Report 2020*, Geneva, Switzerland, 2021.

<sup>37</sup> Ibid.

<sup>38</sup> Madhukar Pai, Teresa Kasaeva, and Soumya Swaminathan, “COVID-19’s Devastating Effect on Tuberculosis Care - A Path to Recovery,” *The New England Journal of Medicine*, January 5, 2022.

WHO, global reporting of TB incidence declined by 21% between 2019 and 2020, with much larger reductions in some high TB burden countries, including India, Indonesia, the Philippines, and South Africa.<sup>39</sup> Detection of TB has also declined, with at least 1.2 million fewer people having been tested and diagnosed with TB from January to August 2021. After increasing from 2016 to 2019, due to improved surveillance, among other factors, the number of case notifications (whereby TB-positive individuals are notified of their status, so they may begin treatment and take infection prevention and control measures) also declined precipitously (see **Figure 3**). Experts warn that reduced TB detection presents numerous risks, including increasing spread of the disease, since one person with untreated active TB can transmit the infection to about 10 to 15 others over the course of 12 months.<sup>40</sup>

Some of the resources used to fight TB (labs, testing machines, health care workers) have reportedly been diverted to respond to COVID-19, resulting in

- disruptions to diagnostic services and medicine,<sup>41</sup>
- a 60% decrease in the provision of the BCG vaccine to newborns,<sup>42</sup>
- a reduction in TB treatment coverage (from 72% in 2019 to 59% in 2020), and
- a 5.6% increase in TB deaths between 2019 and 2020, returning TB-related deaths to 2017 levels.

The increase in deaths between 2019 and 2020 represented the first time since 2010 that TB deaths increased.<sup>43</sup> Furthermore, WHO estimated that, due to COVID-19, between 2020 and 2025, an additional 1 million people might develop TB. Four countries (India, Indonesia, the Philippines, and South Africa), which account for 44% of all TB cases worldwide, had already reported large drops in TB diagnoses between January and June 2020, which TB experts attributed largely to challenges relating to COVID-19. Evidence from January 2021 suggests that people with TB face a higher risk of developing severe or fatal cases of COVID-19, and that a latent TB infection may be activated by COVID-19 infection.<sup>44</sup>

To mitigate health service disruptions, WHO recommended that countries expand the use of digital technologies for remote advice and support, and reduce the need for health facility visits by prioritizing home-based treatment and providing one-month supplies of TB treatments.<sup>45</sup> Some countries have had success with these methods; however, other countries, particularly low-income countries, have faced challenges (e.g., providing access to appropriate digital technology).

<sup>39</sup> WHO, *Global Tuberculosis Report 2020*, Geneva, Switzerland, 2021. The largest relative annual reductions in TB case notifications between 2019 and 2020 were in Gabon (80%), the Philippines (37%), Lesotho (35%), Indonesia (31%), and India (25%).

<sup>40</sup> The Global Fund, *Focus on Drug-resistant Tuberculosis* (Geneva: The Global Fund, 2019).

<sup>41</sup> HIV Learning Network, “Supporting TB Preventive Therapy for Clients Accessing DSD During COVID-19,” webinar presented on May 26, 2020, [https://cquin.icap.columbia.edu/wp-content/uploads/2020/05/TPT-DSD-COVID-26May\\_Master-deck\\_English\\_low-rest.pdf](https://cquin.icap.columbia.edu/wp-content/uploads/2020/05/TPT-DSD-COVID-26May_Master-deck_English_low-rest.pdf).

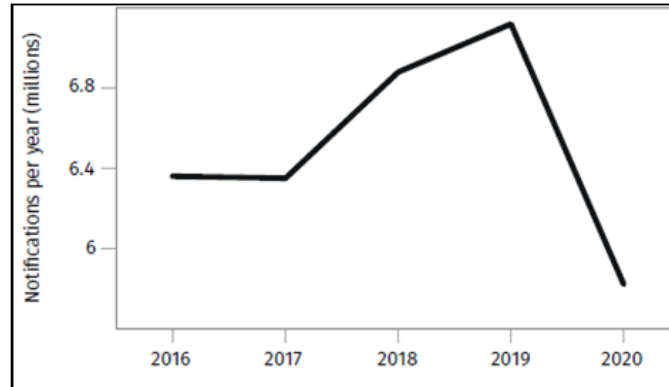
<sup>42</sup> H. Namkoong, N. Horita, and R. Ebina-Shibuya, “Concern over a Covid-19 Related BCG Shortage,” *The Union*, April 22, 2020.

<sup>43</sup> WHO, *Global Tuberculosis Report 2021*, Geneva, Switzerland, 2021.

<sup>44</sup> Mohammed Kayat, Hanan Fan, and Yusuf Vali, “COVID-19 promoting the development of active tuberculosis in a patient with latent tuberculosis infection: A case report,” *Respiratory Medicine Case Report*, January 20, 2021.

<sup>45</sup> WHO, *COVID-19: Considerations for tuberculosis (TB) care*, WHO Information Note, May 12, 2020.

**Figure 3. Global Trend in Case Notifications of People Newly Diagnosed with TB 2016-2020**



**Source:** WHO, *Global Tuberculosis Report 2021*, Geneva, Switzerland, 2021.

**Notes:** Notifications per year, in millions.

## Global TB Programs

### Bilateral Programs

The U.S. government funds global TB efforts partly by providing bilateral foreign assistance and technical guidance to countries to support TB control. These efforts are guided by the U.S. Government Global TB Strategy 2015-2019 and WHO’s End TB Strategy.<sup>46</sup> The U.S. Government Global TB Strategy supports countries with the highest TB and DR-TB burdens, leveraging interagency strengths and supporting multilateral and global programs, policies, and research for TB prevention, care, and treatment.<sup>47</sup> USAID and CDC have primary responsibility for implementing the U.S. government strategy.

Although Congress appropriates funds for global TB control only to USAID and CDC, other U.S. agencies may contribute to the efforts through their own budgets. The National Institute of Allergy and Infectious Diseases (NIAID), for example, funded the international Phase III trial through which the first successful short-course treatment regimen for drug-susceptible TB was developed.<sup>48</sup>

**USAID** is the lead agency on bilateral global TB control activities. The agency provides bilateral assistance to 23 countries with high TB burdens and targeted technical assistance in an additional 32 countries.<sup>49</sup> USAID TB programs also support efforts to expand the availability of new MDR-TB drugs and regimens and to invest in clinical trials to aid those efforts.<sup>50</sup> The USAID TB

<sup>46</sup> U.S. Government, *Global Tuberculosis Strategy*, 2015-2019. WHO, *The End TB Strategy*, 2014.

<sup>47</sup> U.S. Government, *Global Tuberculosis Strategy*, 2015-2019.

<sup>48</sup> According to NIAID, the results indicate that “a four-month daily treatment regimen containing high-dose, or ‘optimized,’ rifapentine with moxifloxacin is as safe and effective as the existing standard six-month daily regimen at curing drug-susceptible tuberculosis (TB) disease.” For more information, see <https://www.niaid.nih.gov/news-events/landmark-tb-trial-identifies-shorter-course-treatment-regimen>.

<sup>49</sup> USAID, *Accelerating Action to End TB Fact Sheet*, October 2020. USAID, *Combating Multidrug-Resistant Tuberculosis: Year Four of the National Action Plan*, April 7, 2021.

<sup>50</sup> USAID, *Accelerating Action to End TB Fact Sheet*, October 2020. USAID, *Combating Multidrug-Resistant*

program, dubbed the Global Accelerator to End TB, works with governments, civil society, and the private sector to reach WHO End TB Strategy and U.N. High Level Meeting targets, laid out in October 2018, of diagnosing an additional 40 million people and enrolling them in TB treatment by the end of 2022, as well as meeting the goals laid out in the U.S. Government Global TB Strategy.<sup>51</sup> USAID reports that the agency and its implementing partners have helped countries achieve (or surpass) several of the Global Accelerator to End TB targets, which are to

- reduce TB incidence by 25% compared with 2015 levels,
- maintain treatment success rates of 90% for individuals with drug-susceptible TB,
- boost the cumulative number of patients started on DR-TB treatment,
- successfully treat at least 13 million TB patients, and
- provide anti-retroviral therapy (ART) for all TB-HIV infected patients.<sup>52</sup>

It is unclear whether USAID intends to update these targets in response to the COVID-19 pandemic or to update the U.S. Government TB strategy.

CDC provides technical support for tuberculosis-related surveillance, laboratory strengthening, and public health capacity development efforts worldwide.<sup>53</sup> CDC leads the TB Clinical Trials Consortium, a group of researchers from U.S. and international public health departments, academic medical centers, and Veterans Affairs medical centers that works to expand and integrate TB research into TB care and programs.<sup>54</sup> CDC subject matter experts partner with country ministries of health and seek to enhance the technical capacity of multilateral partnerships, including with WHO and the Global Fund.<sup>55</sup> CDC's strategic priorities are to accelerate the global response to HIV-associated TB, support the global epidemic response to TB in high-burden countries, strengthen surveillance and laboratory systems and the use of strategic information to optimize performance of TB programs, and provide and develop leadership to contribute to the global public goods needed to end TB.

## Multilateral Programs

The **World Health Organization**, the United Nations specialized agency that directs and coordinates health efforts within the U.N. system, provides funding, technical support, and strategic guidance as part of its Global Tuberculosis Program.<sup>56</sup> For example, WHO has established the Technical Advisory Group on Tuberculosis Diagnostics and Laboratory Strengthening to provide countries with expert scientific guidance on TB diagnostic methods and other health system-strengthening activities deemed vital to TB control efforts.<sup>57</sup> WHO also advises Member States on health communications, strengthening public-private partnerships for

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*Tuberculosis: Year Four of the National Action Plan*, April 7, 2021.

<sup>51</sup> USAID, *What We Do: Tuberculosis*, June 4, 2021.

<sup>52</sup> U.S. Government, *Global Tuberculosis Strategy*, 2015-2019. This strategy was released in 2015.

<sup>53</sup> CDC Tuberculosis Presentation to CRS, October 2021.

<sup>54</sup> For more information on the TB Clinical Trials Consortium, see <https://www.cdc.gov/tb/topic/research/tbct/default.htm>.

<sup>55</sup> CDC Tuberculosis Presentation to CRS, October 2021. CDC, *CDC Global Health: What CDC Is Doing*, September 15, 2017.

<sup>56</sup> WHO, *Global Tuberculosis Programme*, 2022.

<sup>57</sup> WHO, *Technical Advisory Group on Tuberculosis Diagnostics and Laboratory Strengthening*, 2022.

TB care and coordinating an international knowledge sharing platform for training and continuing education of health care providers.

Since its establishment, the **Global Fund** has become one of the world’s largest donors supporting global TB control. (This report focuses on Global Fund efforts to fight TB; a discussion of Global Fund malaria and HIV/AIDS programs is outside the scope of this report.) In 2020, the Global Fund provided 77% of all international financing for TB programs and supported TB treatment for 4.7 million people worldwide.<sup>58</sup> Roughly 18% of the Global Fund’s budget is allocated to TB control (50% goes to fighting HIV/AIDS and 32% to eliminating malaria).<sup>59</sup> Some observers have questioned why TB control receives the smallest share of Global Fund financing.<sup>60</sup> The Global Fund states that the funding balance between the three diseases allows the organization to allocate funds most effectively, according to which countries have the highest disease burdens and the lowest economic capacity.<sup>61</sup>

## Global TB Funding

### Bilateral Global TB Funding

The U.S. government is the largest bilateral donor to global TB control programs. In the past five years, Congress has increased appropriations for bilateral TB aid from \$246.2 million in FY2017 to \$371.1 million in FY2022 (see **Table 2**). In FY2020, Congress, citing the threat of global TB, including to domestic TB control and prevention, provided the Centers for Disease Control and Prevention with a first-time appropriation for global TB control efforts.<sup>62</sup>

**Table 2. U.S. TB Foreign Assistance, FY2017-FY2022**

(current \$ millions)

	<b>FY2017 Enacted</b>	<b>FY2018 Enacted</b>	<b>FY2019 Enacted</b>	<b>FY2020 Enacted</b>	<b>FY2021 Enacted</b>	<b>FY2022 Enacted</b>	<b>FY2023 Requested</b>
USAID	246.2	261.0	302.0	310.0	319.0	371.1	350.0
CDC	0	0	0	7.2	9.2	9.2	9.2

**Sources:** Created by CRS, from U.S. Department of State, *Congressional Budget Justifications for Foreign Operations: FY2018-FY2023*; appropriations legislation; and engagement with USAID and CDC legislative affairs staff.

**Notes:** Excludes emergency appropriations and rescissions. According to CDC, requests for global tuberculosis control funds did not begin until FY2020.

<sup>58</sup> The Global Fund, *Results Report 2021*, 2021.

<sup>59</sup> Ibid.

<sup>60</sup> See, for example, Jenny Lei Ravelo, “Stop TB head: TB still the ‘Cinderella’ in Global Fund disease split,” November 17, 2021.

<sup>61</sup> The Global Fund, *Global Fund Board Approves New Strategy Placing People and Communities at Center to Lead Fight Against HIV, TB, Malaria, to Build Systems for Health, Equity and Strengthen Pandemic Preparedness*, November 10, 2021.

<sup>62</sup> U.S. Congress, House Committee on Appropriations, *Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2020*, Report of the Committee on Appropriations House of Representatives on H.R. 2740 Together With Minority Views, 116<sup>th</sup> Cong., 1<sup>st</sup> sess., May 15, 2019. See page 78, “The Committee provides an increase ... above the fiscal year 2019 program level for Global Tuberculosis activities. These funds are intended to supplement, not supplant, existing funding provided through a transfer from Tuberculosis in the HIV/AIDS, Viral Hepatitis, STD and TB Prevention account to Global Tuberculosis in the Global Health account.”

U.S. funding for infectious disease control is based on a variety of factors, including but not limited to disease mortality rates. Other factors determining funding levels may include potential of the disease threat to the United States, costs of treatment, and options for partnerships with multilateral organizations, other donor governments, and private stakeholders, such as foundations or corporations. Until 2020 (with the emergence of COVID-19), TB was the leading infectious disease killer, although other infectious diseases have generally received more funding from the U.S. government and other international donors.

## U.S. Contributions to the Global Fund

The U.S. government is the largest donor to the Global Fund, providing roughly \$1.56 billion annually. From FY2001 through FY2021, Congress appropriated \$22 billion for the Global Fund. In order to encourage other donors to contribute to the Global Fund, appropriations language prohibits U.S. contributions from exceeding one-third of all donor contributions.<sup>63</sup> The U.S. government cannot unilaterally determine how much funding the Global Fund allocates to each disease. In 2021, to mitigate the effects of the COVID-19 pandemic on TB and other infectious diseases such as HIV/AIDS and malaria, Congress appropriated \$3.5 billion to the Global Fund through the American Rescue Plan Act (P.L. 117-2), indicating congressional support for the Global Fund as a global health programs implementation mechanism.

## Issues for Congress

Many Members of Congress have shown consistent interest in TB control, including through raising appropriations to relevant federal and multilateral entities, introducing related legislation and resolutions, and conducting oversight hearings.<sup>64</sup> In the 117<sup>th</sup> Congress, Members may consider the following issues as they determine funding allocations and global health and development priorities.

### U.S. Contributions to the Global Fund

Members of Congress have long debated the relative mix and amount of U.S. bilateral and multilateral funding for TB interventions—and some have questioned in particular the relative importance of funding the Global Fund compared with bilateral funding mechanisms.<sup>65</sup>

Proponents of the Global Fund posit that this multilateral funding mechanism is best situated to deploy TB and other infectious disease interventions at large scale, and as such the best way to channel the bulk of U.S. support for TB controls.<sup>66</sup> Critics have questioned the efficiency and

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<sup>63</sup> The provision requiring that total U.S. contributions do not exceed 33% of total contributions was part of the initial PEPFAR authorization and has been maintained in subsequent reauthorizations. See language in P.L. 110-293 and P.L. 112-74.

<sup>64</sup> For example, see H.Res. 517, Supporting the Global Fund to Fight AIDS, TB, Malaria, and its Sixth Replenishment. U.S. Congress, House Committee on Appropriations, Subcommittee on State, Foreign Operations, and Related Programs, *Hearings Before a Subcommittee of the Committee on Appropriations*, 116<sup>th</sup> Cong., 2<sup>nd</sup> sess., February 27, 2020.

<sup>65</sup> See for instance, U.S. Congress, Senate Committee on Foreign Relations, *Fraud and Abuse of Global Fund Investments at Risk Without Greater Transparency*, committee print, 112<sup>th</sup> Cong., 1<sup>st</sup> sess., April 5, 2011.

<sup>66</sup> AVAC, Friends of the Global Fight Against AIDS, Tuberculosis and Malaria, Health GAP, Partners in Health, RESULTS and Treatment Action Group, *The Global Fund: A Foundation for Health Equity*, September 2021.

effectiveness of the Global Fund's grant-making processes, among other things, and have called for increased transparency and accountability.<sup>67</sup>

This policy debate continues through legislative activity in the 117<sup>th</sup> Congress. For example, S. 2297, introduced in June 2021, aims to “accelerate and enhance the United States international response to pandemics” (including TB) and leverage U.S. commitments to the Global Fund to increase public and private donations. Meanwhile, the FY2022 House committee report states, “oversight of the Global Fund remains a top priority, as well as continued support for an independent Office of the Inspector General.”<sup>68</sup>

As the Global Fund replenishment approaches in the second half of 2022, Congress may continue to take an interest in oversight of the Global Fund's operations, as well as appropriations and transparency regarding U.S. foreign assistance to the Global Fund.

## The Relationships Between TB Control, Pandemic Preparedness, and the Global Health Security Agenda

Legislative and executive emphasis on global health security and pandemic preparedness has intensified since 2019, with appropriations increasing for related efforts and the Biden Administration establishing new coordinating frameworks, such as the National Strategy for The COVID-19 Response and Pandemic Preparedness.<sup>69</sup> Some global health observers question whether TB control is sufficiently prioritized within the strategy and other global health security initiatives, such as the Global Health Security Agenda (GHSA).<sup>70</sup>

Some Members of Congress have introduced related legislation, such as the Global Health Security Act of 2021 (H.R. 391),<sup>71</sup> that would codify the GHSA,<sup>72</sup> establish a fund for global health security and pandemic preparedness, and increase coordination between bilateral and

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<sup>67</sup> Zhihao Chang, Violet Rusu, and Jillian C. Kohler, “The Global Fund: Why Anti-Corruption, Transparency and Accountability Matter,” *Globalization and Health*, vol. 17, no. 108 (2021). “The Global Fund in the Era of SDGs: Time to Rethink?,” *The Lancet Public Health*, January 2020. Anuj Kapilashrami and Johanna Hanefeld, “Meaningful Change or More of the Same? The Global Fund's New Funding Model and the Politics of HIV Scale-Up,” *Global Public Health*, vol. 9, no. 1 (2014), pp. 160-175.

<sup>68</sup> U.S. Congress, House Committee on Appropriations, *State, Foreign Operations, and Related Programs Appropriations Bill, 2022*, 117<sup>th</sup> Cong., 1<sup>st</sup> sess., July 6, 2021.

<sup>69</sup> The National Strategy for the COVID-19 Response and Pandemic Preparedness includes plans for “restoring the White House Directorate on Global Health Security and Biodefense ... surge the international COVID-19 public health and humanitarian response ... seek to strengthen ... multilateral initiatives, such as ... the Global Fund to Fight AIDS, Tuberculosis, and Malaria.” See <https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf>.

<sup>70</sup> The White House, *National Security Memorandum on United States Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness*, January 21, 2021, stated “United States international engagement to combat COVID-19 and advance global health security and biopreparedness is ... an urgent priority—to save lives, promote economic recovery, and develop resilience against future biological catastrophes. My Administration will treat epidemic and pandemic preparedness, health security, and global health as top national security priorities, and will work with other nations to combat COVID-19 and seek to create a world that is safe and secure from biological threats.” For more information, see <https://go.usa.gov/xermr>.

<sup>71</sup> H.R. 391 was passed by the House of Representatives on June 28, 2021.

<sup>72</sup> The U.S. government and the WHO launched the Global Health Security Agenda in 2014, a five-year (2014-2018) multilateral effort to accelerate International Health Regulations (2005) implementation, particularly in resource-poor countries lacking the capacity to adhere to the regulations. All annual appropriations for global pandemic preparedness count toward U.S. financial support for GHSA. For more information on GHSA, see CRS In Focus IF11461, *The Global Health Security Agenda (GHSA): 2020-2024*.

multilateral global health security efforts (including the Global Fund) to improve health systems resilience and build capacity to prevent, detect, and respond to infectious disease threats, including TB.<sup>73</sup> A 2020 White House report on U.S. implementation of GHSA, however, does not mention TB control—indicating a possible disconnect between the U.S. funding and strategy for TB control and broader pandemic preparedness initiatives.<sup>74</sup>

## TB Control After the COVID-19 Pandemic

Overall, the pandemic has had mixed effects on global TB control efforts. On one hand, the COVID-19 pandemic and its associated restrictions on physical movement and reduced staffing capacity have hindered TB diagnosis, treatment, and care in some countries. On the other hand, health system-strengthening investments through HIV/AIDS, Malaria, and TB programming have been leveraged for global COVID-19 pandemic response.<sup>75</sup>

Despite the short-term benefits of using TB response mechanisms to address the COVID-19 emergency,<sup>76</sup> some experts question whether this approach may have had the unintended consequence of limiting TB control efforts, while others caution against potential long-term misapplication of TB funds and health care worker resources for purposes other than TB control.<sup>77</sup>

In 2021, Congress enacted \$3.75 billion through the American Rescue Plan Act (P.L. 117-2) “to support programs for the prevention, treatment, and control of HIV/AIDS, TB and Malaria in order to prevent, prepare for, and respond to coronavirus, including to mitigate the impact on such programs from coronavirus and support recovery from the impacts of the coronavirus.” That total also included a \$3.5 billion one-time emergency contribution to the Global Fund, through which Congress routed roughly 93% of the funding.

As more global health funding and programming have been allocated for COVID-19 pandemic responses, Congress may consider the extent to which pandemic-centric funding might affect TB control in the future—and whether to disaggregate funding for TB control within pandemic response appropriations.

As Congress debates appropriations for global TB programs going forward, including the President’s FY2023 budget request for \$2 billion to the Global Fund, Members may consider the following elements, among others, of the relationship between COVID-19 and TB control:

- the extent to which COVID-19 will continue to affect progress made in combating TB and how U.S.-funded programs might adapt;

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<sup>73</sup> See, U.S. Congress, House Committee on Rules, H.Rept. 117-125, 117<sup>th</sup> Cong., September 21, 2021, pp. 349-355.

<sup>74</sup> The White House, *Strengthening Health Security Across the Globe: Progress and Impact of United States Government Investments in the Global Health Security Agenda: Annual Report 2020*.

<sup>75</sup> Catherine Tomlinson, *TB Investments Provide Returns in Combating Both TB and COVID-19*, Treatment Action Group, August 2020.

<sup>76</sup> For example, TB control platforms (e.g., mobile clinics) have reportedly been used to respond to COVID-19.

<sup>77</sup> Helena J. Chapman and Bienvenido A. Veras-Esteverez, “Lessons Learned During the COVID-19 Pandemic to Strengthen TB Infection Control: A Rapid Review,” *Global Health: Science and Practice*, vol. 9, no. 4 (December 2021). Catherine Tomlinson, *TB Investments Provide Returns in Combating Both TB and COVID-19*, Treatment Action Group, August 2020.



- whether or not TB control platforms (e.g., mobile clinics) will continue to be used to respond to COVID-19 in the long term, including through vaccination delivery and other health interventions for COVID-19; and<sup>78</sup>
- how to leverage lessons learned from COVID-19 to “address programmatic barriers in the clinical, social and economic management of TB disease, [including ones] created or exacerbated by the COVID-19 pandemic.”<sup>79</sup>

Congress may leverage its oversight or authorizing authority to weigh in on such questions, as it has done for bilateral HIV/AIDS and malaria control programs and funding. Congress has addressed similar questions for other infectious diseases through authorizing legislation. In 2003, for example, Congress enacted P.L. 108-25, establishing the President’s Emergency Plan for AIDS Relief, which specified that

[t]he President shall establish a comprehensive, integrated, five-year strategy to combat global HIV/AIDS that ... includes specific objectives, multisectoral approaches, and specific strategies to treat individuals infected with HIV/AIDS ... implement a tiered approach to direct delivery of care and treatment through a system based on central facilities augmented by expanding circles of local delivery of care and treatment through local systems and capacity.

Congress might consider exercising similar leverage of its oversight or authorizing authorities with regard to countering TB.

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<sup>78</sup> See, for example, J. Stephen Morrison and Katherine E. Bliss, *The Time Is Now for U.S. Global Leadership on Covid-19 Vaccines*, Center for Strategic and International Studies, April 14, 2021.

<sup>79</sup> WHO, *Compendium of TB/COVID-19 studies*, 2021.