

February 28, 2023

To: Peter Farrell
Executive Vice President, Global Commercial Operations
Cepheid
Sunnyvale, CA, USA

Cc: Rainer M. Blair
President and Chief Executive Officer
Danaher
Washington, D.C., USA

Rachel O'Shea
Vice President, Global Access
Cepheid
Maurens-Scopont, France

Open Letter: Urgent action necessary to improve equitable access to GeneXpert tuberculosis diagnostics and achieve 1/4/6x24

Dear Mr. Farrell,

As a coalition of civil society activists, public health leaders, and researchers acting in solidarity with communities affected by tuberculosis (TB), we are writing to share information about the [1/4/6x24 Campaign](#) and to request Cepheid's urgent contribution to the Campaign through actions necessary to improve equitable access to GeneXpert diagnostics.

The 1/4/6x24 Campaign's name comes from its central demand: that countries and other duty bearers, including pharmaceutical and diagnostics companies, take action to improve access to the shortest available regimens recommended by the World Health Organization (WHO) – one month or once-weekly for TB prevention, four months for drug-sensitive TB, and six months for drug-resistant TB (DR-TB) – by the end of 2024. Stellar medical developments in the form of newer drugs and regimens have the potential to bridge the unmet medical needs of people with TB but improving access to these regimens depends on improving access to sensitive and specific molecular diagnostics for the detection of TB and drug resistance.

In 2021, 4.2 million people (40%) estimated to have TB were missed by the health system. This diagnostic gap is an access issue: less than 25% of people in need of TB testing had access to a rapid molecular test for TB. And of the estimated 450,000 people who developed DR-TB, just one in three received follow-on drug susceptibility testing and were linked to DR-TB treatment. This significant gap in access to rapid molecular testing for TB and drug resistance stands as one of the largest shortfalls in the global TB response today, and contributed to the rise in TB incidence between 2020 and 2021 and the rise in TB mortality between 2019 and 2021 (from 1.4 to 1.6 million people) for the first time in two decades.[1] Increased investment in the research and development of better TB diagnostics (e.g., rapid, non-sputum based tests designed for community settings) and in scaling up the implementation of available molecular diagnostic testing is urgently needed. Alongside this investment, available rapid molecular diagnostics must be made more affordable and accessible in low- and middle-income countries (LMICs).

Since the WHO first recommended GeneXpert TB tests more than a decade ago, Cepheid's annual sales volumes of GeneXpert tests across diseases rose from approximately one million in 2011 to more than 60 million in 2022.[2] Despite the significant manufacturing efficiencies resulting from this increase in volumes, Cepheid maintained high prices for tests and instruments, refusing to pass any of its cost savings on to national TB programs and private healthcare providers in LMICs.[3] In 2020, Cepheid doubled its revenue from US\$1 billion to \$2 billion,[4] and Danaher (Cepheid's parent company) reported a gross profit margin of 56 percent and paid no income taxes to the U.S. government.[5,6] In 2021, Cepheid's profits continued to climb, with revenues reaching \$2.88 billion.[7] Despite repeated calls from the Time for \$5 Coalition¹ for transparent and equitable pricing of GeneXpert tests and instruments and for reliable and sufficient service and maintenance, Cepheid has refused to adequately respond to these demands or to take action necessary to lower prices and improve access to GeneXpert testing in LMICs.[8] This lack of accountability to the public stands in contrast to the significant public funding amounting to (at minimum) \$252 million invested in the research and development of GeneXpert technology, including the base technology and several GeneXpert tests, which helped to establish Cepheid into the company it is today.[9]

We urge Cepheid to reconsider its approach to engaging civil society and the broader public, and to take urgent actions necessary to bring about affordable, equitable, and expanded access to GeneXpert testing in support of the 1/4/6x24 Campaign. Improving rates of rapid molecular testing and diagnosis of TB and DR-TB is critically needed so that all people with TB can access the shortest-available regimens for TB prevention and treatment by the end of 2024. In the context of a rapidly evolving TB diagnostics landscape with increasing competition, we request that Cepheid play a leadership role among diagnostics companies by supporting the 1/4/6x24 Campaign and making the following commitments:

To support access to one month or once-weekly preventive treatment (“1”):

- Introduce Xpert MTB-HR (with potential use as a triage test or test for detecting progression of TB infection to active disease) into the market at the price of \$5 in accordance with the Médecins Sans Frontières (MSF) analysis, which found it costs Cepheid less than \$5 to manufacture one GeneXpert test,[10] and provide full transparency of the cost-of-goods-sold (COGS).

To support access to four-month treatment regimens for drug-sensitive TB (“4”):

- Reduce the price of Xpert MTB/RIF Ultra from \$9.98 to \$5 in accordance with the above-cited MSF analysis and provide full transparency of the COGS.
- Standardize and offer the option of transparent and equitable all-inclusive pricing agreements that include instrument placement and AccessCare service and maintenance monitored by key performance indicators (KPIs) for all GeneXpert instruments and tests across diseases, and for all high-burden LMICs irrespective of volumes.
- Ensure sufficient manufacturing of GeneXpert TB tests to prevent supply shortages, as occurred with Xpert MTB/RIF Ultra in 2022,[11] and expand manufacturing operations in LMICs including through technology transfer to local manufacturers to promote sustainable supply and scale-up.

¹ Since 2019, the Time for \$5 Coalition has called on the diagnostics corporation Cepheid to drop the price of its GeneXpert tests to US\$5 a test so that many more people can get access to fast and accurate disease diagnosis.[3] The Time for \$5 Coalition is composed of more than 150 civil society organizations across the globe working to improve access to GeneXpert instruments and tests across diseases. The \$5 ask is based on publicly available evidence of Cepheid's cost of production of Xpert tests.[10]

To support access to six-month treatment regimens for drug-resistant TB (“6”):

- Reduce the price of Xpert MTB/XDR, which tests for resistance to isoniazid and fluoroquinolones, from \$19.80 to \$5 in accordance with the above-cited MSF analysis and provide full transparency of the COGS.
- Replace 6-color modules and instruments with 10-color modules and instruments as part of routine service and maintenance at no additional charge.
- Invest in the research and development of rapid molecular testing for resistance to bedaquiline and incorporate these resistance targets into a future version of the Xpert MTB/XDR cartridge.

The undersigned community and civil society organizations, which include members of the 1/4/6x24 Campaign Coalition and the Time for \$5 Coalition, call on Cepheid to publicly announce before World TB Day, 24 March 2023, its commitment to the above-listed actions necessary to improve equitable access to GeneXpert diagnostics in support of the 1/4/6x24 Campaign. Taking these actions will demonstrate Cepheid’s commitment to its stated mission “to improve patient outcomes by enabling access to molecular diagnostic testing everywhere.” We would like to request a meeting to discuss these issues with you and look forward to your written response to our requests no later than March 15, 2023.

Sincerely,

Access to Rights and Knowledge (ARK) Foundation, India
Action TB India
Advocacy Core Team, Zimbabwe
Advocacy Network Africa (AdNetA)
Affected Community Delegation of Stop TB Partnership
Africa TB Digest
Albergue Las Memorias Asociación Civil, México
Amba TB Association
Americas TB Coalition
ARTB, México
Bolo Didi, India
Cancer Alliance, South Africa
Center for HIV, TB, Malaria Prevention and Elimination Studies, Africa
Charitable Organization “100 PERCENT LIFE”, Ukraine
Coalition of Women Living with HIV and AIDS (COWLHA), Malawi
COLTMR CI (Collectif des Organisations de Lutte contre la Tuberculose et les Maladies Respiratoires en Côte d’Ivoire)
Curarse en Salud AC, México
Empower India
Ethiopian TB Association
Dandora Community AIDS Support Association (DACASA), Kenya
Fantasy Soccer Academy (FSA), Kenya
Global Coalition of TB Advocates (GCTA)
Global Network of People Living with HIV (GNP+)
Global TB Community Advisory Board (TB CAB)
Global TB Prevention and Elimination Justice
Grupo de Amigos con VIH A.C., México
ICHANGE, Côte d’Ivoire

International Treatment Preparedness Coalition (ITPC)
IRD Global
Jointed Hands Welfare Organisation, Zimbabwe
Joyful Hope Resource Platform Center, Kenya
Lean on Me Foundation, Kenya
Leona Foundation, Kenya
Makueni Community Based Organizations Consortium, Kenya
Mask Ethiopia
Matahari Global Solutions
Médecins Sans Frontières Access Campaign
Medical Impact
Migrant Human Rights Defenders
Most At Risk Populations' Society, Uganda
Movimiento CUS AC, México
Observatorio Social de Tuberculosis México
Partners In Health
Persaudaraan Korban NAPZA Indonesia (PKNI)/ Indonesia Network of People Who Use Drugs
PF "Answer", Kazakhstan
POP TB Indonesia
Rainbow Family Support and Advocacy-Africa (RaFaSA)
REACH India
Rekat Peduli Indonesia
Results Canada
Sankalp Rehabilitation Trust, India
SDG Brigade India
Sentinel Project on Pediatric Drug-Resistant Tuberculosis
Sikkim Drug Users' Forum, India
Situka Alliance Initiative Uganda
SMIT (Society of Moldova Against TB) NGO
Stop TB Canada
Stop TB Partnership-Kenya
Survivors Against TB, India
TB and Forced Migration
TB Europe Coalition
TB People Canada
TB People Ukraine
TB Proof
TB Public Private Mix (PPM) Learning Network
TB Watch
TB Women Global
The Global Nature Network Group
Treatment Action Group
Volunteer Health Services, Ethiopia
World Health Partners
Wote Youth Development Projects CBO, Kenya

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