

TO: Mr. Peter Sands, Global Fund to Fight AIDS, TB, and Malaria
Dr. Tedros Adhanom Ghebreyesus, World Health Organization
Dr. Catharina Boehme, World Health Organization
Dr. Sergio Carmona, FIND
Dr. Philippe Duneton, Unitaid
Mr. Ira Magaziner, CHAI
Ms. Etleva Kadilli, UNICEF
Dr. Olusoji Adeyi, World Bank
Ms. Adriana Costa, World Bank
Dr. Emilio Emini, Bill & Melinda Gates Foundation
Dr. John Nkengasong, Africa CDC
Dr. Benjamin Djoudalbaye, African Union
Mr. Nqobile Ndlovu, African Society for Laboratory Medicine
Honorable Zweli Mkhize, National Department of Health, South Africa
Honorable Rajesh Bhushan, Ministry of Health and Family Welfare, India
Honorable Eduardo Pazuello, Ministry of Health, Brazil
Honorable Mutahi Kagwe, Ministry of Health, Kenya
Mr. Balram Bhargava, Indian Council of Medical Research
Dr. Jarbas Barbosa, PAHO
Ms. Gloria D. Steele, USAID
Global Fund Members of the Board
Unitaid Members of the Board
ACT-A Facilitation Council Members
ACT-A Diagnostics Pillar and Diagnostics Consortium Members
Integrated Diagnostics Consortium Members

CC: Mr. Warren C. Kocmond, President and Chief Operating Officer, Cepheid
Mr. Philippe Jacon, President, Global Access, Cepheid

1 April 2021

Dear Colleagues,

On 25 February 2021, 108 civil society organizations sent an open letter to Cepheid requesting that the company increase access to Xpert SARS-CoV-2 tests in low- and middle-income countries (LMICs) by committing a greater proportion of Cepheid's manufacturing capacity to LMICs and by lowering the prices of Xpert tests for SARS-CoV-2 and other diseases to \$5 per test.

The requests from the 108 civil society organizations to Cepheid are motivated by and based on:

- (1) the inequitable global distribution of Xpert SARS-CoV-2 test supply during the COVID-19 pandemic, with less than 15% of the company's total supply allocated to LMICs—which over the past decade invested in scaling up Cepheid's GeneXpert instruments for the

diagnosis of tuberculosis (TB) and other diseases, but now do not have sufficient access to Xpert SARS-CoV-2 tests;^{1,2}

- (2) the only publicly available independent cost-of-goods-sold (COGS) analysis of Xpert cartridges which shows that while Cepheid charges between \$10 (TB) to \$20 (SARS-CoV-2, Ebola) per Xpert test for LMICs, it likely costs Cepheid between \$3 to \$5 to manufacture each Xpert test across diseases at volumes over 10 million tests annually,³ with the likelihood of even lower production costs given that Cepheid sold 9 million SARS-CoV-2 tests in Q4 of 2020 alone, and the company's response to civil society specifically mentions unprecedented high sales volumes of the TB and virology cartridges in 2020;^{2,4}
- (3) Cepheid surpassed \$2 billion in annual revenue in 2020, representing 100% growth over 2019, largely through sales of Xpert SARS-CoV-2 tests. Given this and the 35% increase in GeneXpert instrument sales during 2020 from the previous year, overcharging LMICs \$19.80 per test is just exploitative behavior;² and
- (4) a forthcoming peer-reviewed manuscript reporting that at least \$252 million in public funds were invested in the research and development of GeneXpert technologies, including \$4.7 million from the U.S. Biomedical Advanced Research and Development Authority (BARDA) to Cepheid to develop the Xpert SARS-CoV-2 assays,⁵ which amounts to a massive public subsidy that Cepheid used to initially establish itself as a company and more recently to double its revenues.

In Cepheid's 13 March reply to civil society, the company did not provide any substantive information to address the evidence-based requests in the open letter calling for lower prices for Xpert tests and increased supply of Xpert SARS-CoV-2 tests for LMICs. Instead, Cepheid referred to their high and exorbitant Xpert test prices for LMICs as "compassionate" and implied that Cepheid's supply of Xpert SARS-CoV-2 tests for LMICs has been adequate. Meanwhile, GeneXpert technology was largely developed through public funding and Cepheid as a company was built off of the "markets" and the biospecimens of people with TB in LMICs. Cepheid's clear dismissal of the concerns and requests of the undersigned civil society and affected community organizations struggling for access to rapid molecular tests necessary to address the ongoing concurrent pandemics and public health crises presented by COVID-19, TB, HIV, HCV, and other diseases is disrespectful and unacceptable.

As we write to you now, members of the COVID-19 Diagnostics Consortium are negotiating with Cepheid for affordable prices and increased supply of Xpert SARS-CoV-2 tests to be committed to the Consortium for allocation to LMICs. Abbott has already reduced the price of its molecular test for COVID-19 from \$15 to \$10,⁶ because they have reached sufficient volumes of sales. In the past year Cepheid doubled its revenue from \$1 billion to \$2 billion largely through the sales of Xpert SARS-CoV-2 tests. Cepheid's volumes for Xpert SARS-CoV-2 tests alone are expected to exceed 36 million in 2021.² The only outcome acceptable to civil society is a reduced price of Xpert SARS-CoV-2 tests and an increased proportion of Cepheid's manufacturing capacity for Xpert SARS-CoV-2 tests committed to LMICs.

This type of behavior by Cepheid did not begin with COVID-19. Since 2010, Cepheid has held a monopoly on rapid molecular testing for TB, and the high prices across Xpert tests, GeneXpert instruments, and service and maintenance plans have prohibited the ability of countries to scale up and fully implement testing according to WHO recommendations.^{7,8} In 2013, the WHO recommended rapid molecular tests as the initial TB test for all; yet, in 2019 an estimated 30% of people with TB were not diagnosed or notified, and only 28% of people diagnosed with TB received rapid molecular testing as the initial test.⁹ In the context of COVID-19, testing for TB and other diseases has been even further set back.

To address these concurrent crises, the undersigned 142 organizations urgently appeal to you as leading health actors working to improve public health to:

(1) commit to apply collective leverage necessary to successfully negotiate higher supply volumes of Cepheid's Xpert SARS-CoV-2 tests for LMICs and lower prices for Xpert tests across diseases according to COGS-plus (COGS plus rational % of profit) and volume-based pricing structures, along with affordable and reliable service and maintenance plans and more affordable delivery models for GeneXpert instruments;

(2) commit to establishing a standardized methodology for determining COGS for diagnostics and appointing a normative body to undertake independent COGS evaluations, to update these evaluations with changing global sales volumes, and to make this information publicly available to procuring countries and funding agencies; and

(3) increase investments in the development and rollout of alternative rapid molecular testing platforms for LMICs to improve access to COVID-19, HIV, TB, HBV, and HCV diagnosis and promote competition that has been sorely missing over the past decade, especially in TB. Investments should be conditional on company commitment to COGS-plus and volume-based pricing and favorable terms of service and maintenance.

As representatives of global civil society and affected communities, we look forward to working with you to improve access to diagnostics, including most urgently through the application of collective will and leverage.

Sincerely,

Action Canada for Sexual Health and Rights, Canada
AIDS Access Foundation, Thailand
AIDS Action Baltimore, United States
AIDS and Rights Alliance for Southern Africa (ARASA), Namibia
Akbar Sumatera Barat Foundation, Indonesia
Alliance for Public Health, Ukraine
Americas TB Coalition, United States
APCASO, Asia-Pacific
APLA, United States

Asha Parivar, India
Ashwasti, India
Asia Pacific Network of People Living with HIV (APN+), Asia Pacific
Association Burkinabé d'Action Communautaire (ABAC), Burkina Faso
Association Nationale de Soutien aux Seropositifs et Malades du Sida, Burundi
AU-ECOSOCC Kenya National Chapter, Kenya
Brazilian National TB Community Advisory Board (CCAP TB Brasil), Brazil
Canadian Aboriginal AIDS Network, Canada
Canadian AIDS Society/Société canadienne du sida, Canada
Cancer Alliance, South Africa
Carmelo Hospital of Chokwe, Mozambique
CENTA, Tanzania
CHISA, Malawi
Citizen News Service (CNS), India
Coalición TB de las Americas, Uruguay
Coalition des organismes communautaires québécois de lutte contre le sida (COCQ-SIDA),
Canada
Coalition of People Fighting HIV/TB in Migori (COPFAM), Kenya
Coalition PLUS, Global
Community and Family Aid Foundation, Ghana
COVID Advocates Advisory Board (CAAB), Global
Cultura LLC, United States
Delhi Network of Positive People (DNP+), India
Disabled and HIV/AIDS Organization Lesotho (DHAOL), Lesotho
Dr Uzo Adirieje Foundation (DUZAFOUND), Nigeria
EMPOWER INDIA, India
End Hep C SF, United States
European AIDS Treatment Group (EATG), Belgium
Fountain of Hope CBO, Kenya
Fundación Grupo Efecto Positivo, Argentina
Fundación IFARMA, Colombia
Fundamental Human Rights & Rural Development Association (FHRRDA), Pakistan
Gaya Celebes Foundation Makassar, Indonesia
GIV (Grupo de Incentivo à Vida), Brazil
Global Coalition of TB Activists (GCTA), Global
Global Media Foundation, Ghana
Global Network of People Living with HIV (GNP+), Global
Global Tuberculosis Community Advisory Board (TB CAB), Global
Great-Lakes in Action for Peace and Sustainable Development (GLAPD), Democratic Republic of
the Congo
Grupo de Ativistas em Tratamentos (GAT), Portugal
Hawaii Health and Harm Reduction Center, United States
Health and Development Alliance (HEAD), Cambodia
Health GAP (Global Access Project), Global

Health Justice Initiative, South Africa
Health Options for Young Men on HIV/AIDS/STI (HOYMAS), Kenya
Health Poverty Action, United Kingdom
Hep Free Hawaii, United States
Hepatitis C Mentor and Support Group (HCMSG), United States
HIV Legal Network, Canada
Human Touch Foundation, India
IFARMA Foundation, Colombia
Ignite Your Destiny International, Kenya
Indigenous Women Empowerment Network, Ghana
Indonesia AIDS Coalition, Indonesia
Initiative for Health & Equity in Society, India
Institut de la société civile pour le VIH et la santé en Afrique Ouest et Centre, Senegal
Interagency Coalition on AIDS and Development, Canada
International Indigenous Working Group on HIV & AIDS, Canada
International Treatment Preparedness Coalition (ITPC), South Africa
ITPC-South Asia, South Asia
Janna Health Foundation, Nigeria
JAPETI (Jaringan Peduli TB Indonesia)/Indonesia TB Care Network, Indonesia
Jointed Hands Welfare Organisation, Zimbabwe
JSH Consulting, Germany
KANCO, Kenya
Kenya Treatment Access Movement (KETAM), Kenya
Khmer HIV/AIDS NGO Alliance (KHANA), Cambodia
Leona Foundation, Kenya
Leprosy and TB Relief Initiative (LTR), Nigeria
LHL International Tuberculosis Foundation, Norway
Malawi Network of Religious Leaders Living with or Personally Affected by HIV and AIDS
(MANERELA+), Malawi
Mambokaaje CBO, Kenya
Maryknoll Sisters, United States
Médecins Du Monde Mission in South Caucasus, Georgia
Médecins Sans Frontières - Access Campaign, Switzerland
Medical Impact, Kenya
Medical IMPACT, Mexico
Meera Foundation, India
Mikayi Dev Organization, Kenya
Moi County Referral Hospital, Kenya
Montefiore Medical Center, United States
Namibia Diverse Women's Association (NDWA), Namibia
National Coalition of People Living with HIV in India (NCPI Plus), India
Network of TB Champions, Kenya
NGO IRD, Ukraine
NGO RIEC "INTILISH", Uzbekistan

Nils-Siama Organisation Kibera, Kenya
Northwest Coalition for Responsible Investment, United States
Organisation for Health in Sustainable Development (OHISD), Cameroon
Pamoja TB Group, Kenya
Pan African Positive Women's Coalition, Zimbabwe
Partners In Health, Global
Persaudaraan Korban NAPZA Bogor, Indonesia
Philippine Business for Social Progress, Philippines
Pont Sante Afrique ASBL/ONGD, Democratic Republic of the Congo
Positive Malaysian Treatment Access & Advocacy Group (MTAAG+), Malaysia
Positive Women's Network USA, United States
Public Health Action, South Africa
Rede Paulista de Controle Social da Tuberculose, Brazil
Romanian Association Against AIDS (ARAS), Romania
San Francisco AIDS Foundation, United States
San Francisco Hepatitis C Task Force, United States
Section 27, South Africa
Sikkim Drug Users' Forum, India
Sisters of Charity of Saint Elizabeth, United States
Sisters of St. Francis of Philadelphia, United States
Social Awareness Service Organisation, India
Socialist Party, India
Society for Women against AIDS in Africa (SWAA SENEGAL), Senegal
Southern African Programme on Access to Medicines and Diagnostics, South Africa
Sportsmenwomen Fighting HIV/TB in Kenya, Kenya
Survivors Organization, Kenya
Swaziland Migrant Mineworkers Association (SWAMMIWA), Eswatini
Tanzania Network for People who Use Drugs (TaNPUD), Tanzania
TB Patients Association SMIT (Society of Moldova against Tuberculosis), Republic of Moldova
TB Proof, South Africa
The Botswana Network on Ethics, Law & HIV/AIDS (BONELA), Botswana
The International Union Against TB and Lung Disease, France
The Sentinel Project on Pediatric Drug Resistant Tuberculosis, United States
Third World Network, Malaysia
TINPSWALO ASSOCIATION - Vicentian Association to Fight AIDS & TB, Mozambique
Treatment Action Group (TAG), United States
Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPCru), Russian
Federation
Trinity Health, United States
Tropical Logistics International Ltd., Kenya
Tunisian Center for Public Health, Tunisia
Urban Survivors Union, United States
Volunteers for Development Nepal (VFDN), Nepal
Walter Sisulu University, South Africa

Wote Youth Development Projects, Kenya
Yale University School of Public Health, United States
Yolse, Santé Publique et Innovation, Switzerland
Zimbabwe Civil Liberties and Drug Network, Zimbabwe
Zimbabwe Community Competence Trust, Zimbabwe

¹ World Health Organization. Procurement considerations for COVID-19 diagnostics. 2021 Jan 25. https://www.who.int/docs/default-source/coronaviruse/procurement-considerations-for-covid-19-diagnostics.pdf?sfvrsn=70a480ce_16.

² 360Dx. Danaher Q4 revenues up 39 percent. 2021 Jan 28. <https://www.360dx.com/businessnews/danaher-q4-revenues-39-percent#.YCbacNNKjUJ>.

³ MSF. Time for five: GeneXpert diagnostic tests. 2019 Dec. <https://msfaccess.org/time-for-5>.

⁴ Cepheid. Letter responding to the 25 February civil society open letter. 2021 March 13. https://www.tbonline.info/media/uploads/documents/tag_response_march2021.pdf.

⁵ BARDA. BARDA's rapidly expanding COVID-19 medical countermeasure portfolio. <https://medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx>.

⁶ World Health Organization. Emergency Global Supplies Catalogue (COVID-19). 2021 March 11. <https://www.who.int/publications/m/item/emergency-global-supply-chain-system-covid-19-catalogue>.

⁷ England K, Masini T, Fajardo E. Detecting tuberculosis: rapid tools but slow progress. *Public Health Action*. 2019 Sep 21; 9(3):80–3. <https://doi.org/10.5588/pha.19.0013>.

⁸ Piatek AS, Wells WA, Shen KC, Colvin CE. Realizing the “40 by 2022” commitment from the United Nations High-Level Meeting on the Fight to End Tuberculosis: what will it take to meet rapid diagnostic testing needs? *Global Health: Science and Practice*. 2019 Dec; 7(4):551–63. <https://doi.org/10.9745/GHSP-D-19-00244>.

⁹ World Health Organization. Global tuberculosis report 2020. Geneva: World Health Organization; 2020. <https://apps.who.int/iris/bitstream/handle/10665/336069/9789240013131-eng.pdf>.