

Mr. Warren C. Kocmond
President and Chief Operating Officer
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States

CC:

Mr. Philippe Jacon, President, Global Access, Cepheid
Mr. Peter Sands, Global Fund to Fight AIDS, TB, and Malaria
Dr. Tedros Adhanom Ghebreyesus, World Health Organization
Dr. Catharina Boehme, FIND
Dr. Philippe Duneton, Unitaid
Mr. Ira Magaziner, CHAI
Ms. Etleva Kadilli, UNICEF
Dr. Olusoji Adeyi, World Bank
Dr. Emilio Emini, Bill & Melinda Gates Foundation
Dr. John Nkengasong, Africa CDC
Dr. Benjamin Djoudalbaye, African Union
Mr. Ngobile 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

25 February 2021

Dear Mr. Kocmond,

The world is grappling with not only a devastating global COVID-19 pandemic but also inadequate access to affordable medical tools, including diagnostics. The 108 civil society organizations below are writing out of deep concern about the lack of access to Cepheid's GeneXpert SARS-CoV-2 tests in low- and middle-income countries (LMICs).

We are writing to request that Cepheid increase access to these tests by committing a greater proportion of its COVID-19 manufacturing capacity to LMICs and by lowering the price of its cartridges.

The COVID-19 Supply Chain System and Diagnostics Consortium was established in February 2020 at the request of the United Nations Secretary-General and the World Health Organization Director-General. The consortium, comprised of international public health and procurement agencies, works to secure adequate supply volumes and affordable prices of COVID-19 diagnostics for LMICs. It also coordinates procurement and equitable allocations across countries. We understand that Cepheid will again be asked by the Consortium to commit adequate volumes at an affordable price for LMICs for the next tranche of supply starting March 2021.

While wealthy nations have numerous options in terms of quality-assured COVID-19 reverse transcription-polymerase chain reaction (RT-PCR) testing assays to perform on a variety of platforms and instruments, Cepheid's GeneXpert SARS-CoV-2 test is critical for LMICs given the existing placement of Cepheid's GeneXpert instruments in these countries.

We are disappointed, therefore, that Cepheid has continued to undersupply LMICs through the Diagnostics Consortium. According to the latest COVID-19 Supply Chain System situation report (dated 25 January 2021),¹ Cepheid committed only two million COVID-19 tests over the last six months. In contrast, Cepheid sold nine million COVID-19 cartridges globally in the fourth quarter of 2020.² It is shameful that less than 15% of Cepheid's total production capacity is committed to the Diagnostics Consortium, which represents 144 low- and middle-income countries accounting for more than 80% of the global population. We urge Cepheid to commit greater volumes to the Diagnostics Consortium.

We also request a significant reduction of the price per GeneXpert SARS-CoV-2 cartridge for all LMICs from the current US\$19.80 down to \$5 per cartridge, based on available evidence that it costs Cepheid less than \$5 to produce the GeneXpert cartridges at volumes over 10 million annually.³ Based on the fact that Cepheid's global annual sales volume in 2021 will likely exceed 36 million COVID-19 tests,² in addition to sales volumes for other diseases, a price reduction is long overdue. Such a price reduction would also better reflect the \$4.7 million in public financial contributions from the U.S. government that went into the development of the GeneXpert SARS-CoV-2 tests.⁴

Cepheid surpassed \$2 billion in annual revenue in 2020,² representing 100% growth over the previous year, largely through sales of the SARS-CoV-2 GeneXpert tests. Given this and the 35% increase in instrument sales during 2020 from the previous year, countries' efforts to address the COVID-19 pandemic have more than helped recoup Cepheid's initial investments and start-up costs for the SARS-CoV-2 tests.

Too many countries that invested in Cepheid's instruments to address tuberculosis, HIV, and COVID-19 now cannot procure the necessary COVID-19 cartridges due to Cepheid's consistent undersupply of the Diagnostics Consortium. Cepheid should take urgent steps in the global fight against the COVID-19 pandemic by committing to supply the volumes requested through the Diagnostics Consortium and decreasing the price of its GeneXpert SARS-CoV-2 test to \$5 per cartridge. Furthermore, we would like to reiterate previous appeals from civil society and affected communities to Cepheid to decrease the price of its other GeneXpert tests, including for tuberculosis, HIV, HBV, and HCV, to \$5, inclusive of service and maintenance.⁵ This price better

reflects the cost of manufacturing and would allow LMICs to scale up GeneXpert testing for COVID-19 as well as other infectious diseases, and therefore save lives.

We look forward to Cepheid's response to this letter by Thursday, 11 March, which should be directed to david.branigan@treatmentactiongroup.org.

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
Alliance for Public Health, Ukraine
Americas TB Coalition, United States
APCASO, Asia-Pacific
APLA, United States
Asha Parivar, India
Asia Pacific Network of People Living with HIV (APN+), Asia Pacific
Association Nationale de Soutien aux Seropositifs et Malades du Sida, Burundi
AU-ECOSOCC Kenya National Chapter, Kenya
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
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
Fundación Grupo Efecto Positivo, Argentina
Fundación IFARMA, Colombia
Fundamental Human Rights & Rural Development Association (FHRRDA), Pakistan
Global Media Foundation, Ghana
Global Network of People Living with HIV (GNP+), Global
Global Tuberculosis Community Advisory Board (TB CAB), Global

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 Poverty Action, United Kingdom
Hep Free Hawaii, United States
Hepatitis C Mentor and Support Group (HCMMSG), United States
HIV Legal Network, Canada
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 Treatment Preparedness Coalition (ITPC), South Africa
ITPC-South Asia, South Asia
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, Mexico
Meera Foundation, India
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
Northwest Coalition for Responsible Investment, United States
Organisation for Health in Sustainable Development (OHISD), Cameroon
Pamoja TB Group, Kenya
Partners In Health, Global
Philippine Business for Social Progress, Philippines
Positive Malaysian Treatment Access & Advocacy Group (MTAAG+), Malaysia
Positive Women's Network USA, United States
Public Health Action, South Africa
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
Swaziland Migrant Mineworkers Association (SWAMMIWA), Eswatini
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
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 WHO. Procurement considerations for COVID-19 diagnostics. [Online]. 2021 Jan 25 [cited 2021 Feb 10]. Available from:

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. [Online]. 2021 Jan 28 [cited 2021 Feb 10]. Available from: <https://www.360dx.com/business-news/danaher-q4-revenues-39-percent#.YCbacNNKjUJ>

³ MSF. Time for five: GeneXpert diagnostic tests. [Online]. 2019 Dec [cited 2021 Feb 10]. Available from: <https://msfaccess.org/time-for-5>

⁴ US DHHS. BARDA's rapidly expanding COVID-19 medical countermeasure portfolio. [Online]. [cited 2021 Feb 10]. Available from: <https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx>

⁵ TB Online. Time to lower the price of Xpert cartridges to \$5. [Online]. 2020 April [cited 2021 Feb 10]. Available from: <http://tbonline.info/posts/2020/4/4/time-lowerprice-xpert-cartridges-us-5/>.