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

Cc:        Thomas P. Joyce, Jr., President and Chief Executive Officer, Danaher  
William K. Daniel, II, Executive Vice President, Danaher  
Peter Farrell, Executive Vice President, Global Commercial Operations, Cepheid  
David H. Persing, Executive Vice President, Chief Medical and Technology Officer, Cepheid  
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Cristina H. Kepner, Board Member, Cepheid  
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Hollings C. Renton, Board Member, Cepheid  
Glenn D. Steele Jr., Board Member, Cepheid

OPEN LETTER: Time to Lower the Price of Xpert Cartridges to US$ 5  
21 October 2019

Dear Mr. Kocmond,

The GeneXpert system has revolutionized rapid, accurate testing for the diagnosis of tuberculosis (TB) since entering the market in 2010, and the World Health Organization (WHO) recommends Xpert MTB/RIF and Xpert MTB/RIF Ultra as the initial test for diagnosing TB.\textsuperscript{1,2} Yet in large part due to the high price of Xpert cartridges, most high TB-burden countries have not sufficiently scaled up their procurement and use of Xpert as the initial TB diagnostic test.\textsuperscript{3,4} Instead, they continue to rely on the significantly less accurate, but more affordable method of sputum smear microscopy, leading to gaps in TB diagnosis and rapid linkage to effective treatment.\textsuperscript{5} In order to improve the scale-up of Xpert tests to help close these gaps, Cepheid must reduce the price of Xpert MTB/RIF and Xpert MTB/RIF Ultra cartridges to US$ 5, inclusive of service and maintenance.

The undersigned organizations and individuals working to end the neglect of people with TB request that Cepheid reduce the price of Xpert cartridges to US$ 5 per test for the public sector. This price reduction would fairly reflect both the volume-based cost of manufacturing, and the significant public and philanthropic investments behind Xpert’s development and dissemination. Furthermore, it is essential that this price is inclusive of a comprehensive service and maintenance plan, as many high TB-burden countries cannot afford to purchase the extended warranties currently required for the service and maintenance of their GeneXpert systems.\textsuperscript{6}

This US$ 5 price point should also be available in the private sector, especially in high TB-burden countries, where a majority of TB patients seek care and shoulder costs personally.\textsuperscript{7} According to a 2017-2018 survey, people in several high TB-burden countries were being charged US$ 100 or more for an Xpert test.\textsuperscript{8} Making the US$ 5 price per test available to private sector purchasers will increase scale-
up, further expand the already high volumes of sales, and bring Cepheid closer to fulfilling its stated mission to “improve patient outcomes by enabling access to molecular diagnostic testing everywhere.”

The current public-sector price of US$ 9.98 per Xpert cartridge for high TB-burden countries was set in 2012, as a result of a buy-down agreement in which Unitaid, the United States government and the Bill & Melinda Gates Foundation paid Cepheid US$ 11.1 million to reduce the price of Xpert cartridges from US$ 16.86. Since 2012, the volumes of sales of Xpert tests increased dramatically from 1.3 million to nearly 12 million cartridges sold in 2018 to the public sector alone, which is expected to have resulted in significant manufacturing efficiencies and cost savings. According to an independent cost-of-goods analysis commissioned by Médecins Sans Frontières (MSF), at annual volumes of 10 million, Cepheid’s manufacturing cost per cartridge is estimated to be as low as US$ 3. Therefore, the US$ 5 price point would enable Cepheid to include a comprehensive service and maintenance plan as well as a reasonable margin of profit within the price per cartridge, while also meeting the WHO target product profile price of under US$ 6 for rapid molecular TB diagnostic tests. In light of the volumes of sales and the resulting efficiencies that can be expected with regard to the cost of goods, it is time for Cepheid to reduce the price of Xpert MTB/RIF and Xpert MTB/RIF Ultra tests to US$ 5.

Cepheid developed GeneXpert and its assays over the past two decades largely through public and philanthropic funding, which included an estimated US$ 120 million from the US Department of Defense, US$ 45 million from the US National Institutes of Health (NIH), and over US$ 20 million via the Foundation for Innovative New Diagnostics (FIND), with funding largely from the Bill & Melinda Gates Foundation. In 2010, Cepheid stated: “the Xpert MTB/RIF test truly represents what can be accomplished in a successful academic-public-private partnership.” It is now time for the public to receive a larger return on this investment. Xpert tests must be affordable and accessible to high TB-burden countries, to enable them to implement WHO recommendations and fully scale up the use of Xpert as the initial TB diagnostic test.

We request Cepheid immediately reduce the price of Xpert tests to US$ 5, inclusive of service and maintenance. Before October 28th, we look forward to your response, which should articulate a plan for how Cepheid intends to lower the price of all Xpert cartridges to reflect the cost-of-goods efficiencies generated from the increased volumes of sales, as well as the public and philanthropic investments that supplemented the development of GeneXpert and the Xpert MTB/RIF and MTB/RIF Ultra assays. Please direct your response to David Branigan, David.Branigan@treatmentactiongroup.org.

Respectfully submitted,

David Branigan
TB Project Officer
Treatment Action Group
On behalf of the undersigned organizations and individuals
Organizational Endorsements:

ACTION, Global
Afrihealth Optonet Association (CSO Network), Nigeria
Alliance for Public Health (APH), Global
Asia Pacific Network of People Living with HIV (APN+)
Assam Network of Positive People (ANP+), India
Carmelo Hospital of Chokwe, Mozambique
Citizen News Service (CNS), India
Community and Family Aid Foundation, Ghana
Cultura LLC, United States
Dr. Uzo Adirieje Foundation (DUZAFOUND), Nigeria
Drug Resistant TB Scale Up Treatment Action Team (DR-TB STAT), Global
Eastern Africa National Networks of AIDS and Health Service Organisations (EANASO)
Epidemiological Laboratory for Research and Development, Sudan
Fondation Femme Plus, Democratic Republic of the Congo
Friends for International TB Relief (FIT), Germany/Vietnam
Global Alliance for Human Rights, India
Global Coalition of TB Activists, Global
Global Media Foundation, Ghana
Grupo de Ativistas em Tratamentos (GAT), Portugal/Europe
Health and Development Alliance (HEAD), Cambodia
Indian Network for People Living with HIV/AIDS (INP+), India
Institute for Research and Development, Ukraine
Interagency Coalition on AIDS and Development (ICAD), Global
International Council of AIDS Service Organizations (ICASO), Global
Jan Kalyankari Trust, Sanghmitra Group, India
Jointed Hands Welfare Organisation, Zimbabwe
Kenya AIDS NGOs Consortium, Kenya
Kwanhliziyonye Resource Care Center (KRCC), South Africa
LHL International Tuberculosis Foundation, Global
Love Life Society, Delhi, India
Médecins Sans Frontières (MSF), Global
Medical IMPACT, Mexico
National Coalition of People Living with HIV in India, India
National Empowerment Network of People living with HIV/AIDS in Kenya (NEPHAK), Kenya
National Tuberculosis Reference Laboratory (NTRL), Research Institute for Tropical Medicine, Philippines
Nelson Mandela TB HIV Community Information and Resource Center, Kenya
Network of Maharashtra People Living With HIV/AIDS (NMP+), India
Pamoja TB Group, Kenya
Partners In Health (PIH), Global
Peace and Life Enhancement Initiative International (PLEII), Nigeria
Radanan Ayar Association, Myanmar
REACH Ethiopia, Ethiopia
Respiratory Society of Kenya, Kenya
RESULTS Australia, Australia
RESULTS UK, United Kingdom
Romanian Angel Appeal Foundation, Romania
Russ Foundation, Madurai, India
Society for Conservation & Sustainability of Energy & Environment in Nigeria (SOCSEEN), Nigeria
TALAKU Community Based Organization, Kenya
Tamilnad Network of Positive People (TNPP+), India
TB Alert, United Kingdom
TB Proof, South Africa
The Reunion Project (TRP), United States
Touched by TB, India
Treatment Action Group (TAG), Global
U.S. People Living With HIV Caucus, United States
Vision Makers CBO, Kenya
Volunteer Health Services, Ethiopia
Volunteers for Development Nepal (VFDN), Nepal
World Vision India, India

**Individual Endorsements:**
Amruta Soni, Bihar, India
Andrea von Delft, TB Proof, South Africa
Andrew Codlin, Friends for International TB Relief (FIT), Germany/Vietnam
Aparna Iyer, Mumbai, India
Arne von Delft, University of Cape Town & TB Proof, South Africa
Arumugam Sankar, India
Aschalew Ashagre, Ethiopian Thoracic Society (ETS), Addis Ababa, Ethiopia
Berlin Jose, Madurai, India
Bobby Khumanthem, New Delhi, India
Brijesh Dubey, Chairman of Global Alliance for Human Rights, India
Cecilia Coitinho Azevedo, MD, National Reference Laboratory, Uruguay
Challa Ruda, KNCV Tuberculosis Foundation, Addis Ababa, Ethiopia
Colleen Daniels, CD Global Consulting, Australia
Daisy David, HIV and TB survivor, Tamilnad Network of Positive People (TNPP+), India
Dr. Bobby John, New Delhi, India
Dr. Ramon Basilio, National TB Reference Lab, Philippines
Earl Mantes, Research Institute for Tropical Medicine, Manila, Philippines
Eddie Sistoso Jr., Research Institute for Tropical Medicine, Philippines
Edy Nacarapa, Carmelo Hospital of Chokwe, Mozambique
Elzsa Jade Tayactac, Technical Assistance Group, National Tuberculosis Reference Laboratory, Philippines
Endale Mengesha Goshu, Senior Laboratory Advisor, KNCV Tuberculosis Foundation, Addis Ababa, Ethiopia
Endy Fekadu, Volunteer Health Services, Ethiopia
Erick Okioma, Victory Post Test Group, Kenya
Ganesh Acharya, TB Activist, Mumbai, India
Grace Kahenya, Laboratory & Diagnostic Advisor, Philippines
Hari Shanker Singh, India
Jahnabi Goswami, Assam, India
Jennifer Furin, Harvard Medical School, United States
Jerry Amoah-Larbi, Ghana National TB Voice Network, Ghana
Josaphat Ambehi, Tuko Kazi Kapsabet, Kenya
Joyce Munala, Kenya
Kaartik Chauhan, IQVIA (formerly QuintilesIMS), New Delhi, India
Kamlesh, Kasbale, India
Kathleen England, Global Diagnostic Consultants, United States
Luan Vo, Friends for International TB Relief, Hanoi, Vietnam
Marco Tovar, Socios en Salud, Sucursal, Peru
Meera Hada, National Tuberculosis Center, Nepal
Mekdes Bekele, Health Worker, Addis Ababa, Ethiopia
Mildred Fernando-Pancho, Global Coalition of TB Activists (GCTA), Manila, Philippines
Mohammad Khakerah Rashidi, Global Health Systems Innovation (GHSI), Afghanistan
Mona Balani, HIV-TB Activist, India
Monette Faner, University of the Philippines, Manila, Philippines
Muluk Aseresa, Management Sciences for Health (MSH), Arlington, Virginia, United States
Mx Sachin Awasthy, Mumbai, India
Nelson Otwoma, National Empowerment Network of People living with HIV/AIDS in Kenya (NEPHAK), Kenya
Nikki James Francisco, Philippine Pediatric Society, Aklan, Philippines
Olanrewaju Oladimeji, University of Namibia, Walter Sisulu University, South Africa & University of Jos, Nigeria
Pardeep Kumar, Punjab, India
Peter Francis Raguindin, Philippines
Phindile Khumalo, Kwanhliziyonye Resource Care Center (KRCC), South Africa
Prabha Mahesh, Touched by TB, Maharashtra, India
Prashant Yende, India
Prof. Brian Citro, Northwestern Pritzker School of Law, United States
Rahab Mwaniki, Nairobi, Kenya
Rahul Dwivedi, Citizen News Service (CNS) Correspondent, India
Rajan Dahiwal, Beed, Maharashtra, TAG, India
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Rosa Herrera, Mexico
Shamim Mannan, Public Health Consultant, Delhi, India
Snehnansu Bhaduri, Global Human Rights Association (GHRA), India
Tara Rivera, Medical Center Manila, Philippines
Tarit Chakraborty, Bengal Network for People Living with HIV/AIDS (BNP+), India
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Thura Aung, Radanar Ayar Association, Myanmar
Vida Joyce Nodque-Binarao, Philippines
Waheedah Shabazz-El, The Reunion Project (TRP), United States
Zahedul Islam, Alliance for Public Health (APH), Kyiv, Ukraine
References


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15. Ibid.