

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
Philippe Jacon, Senior Vice President, Global Access, Cepheid
Martin Colla, Director, Global Access, Cepheid
Cristina H. Kepner, Board Member, Cepheid
Robert J. Easton, Board Member, Cepheid
Thomas L. Gutshall, Board Member, Cepheid
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

6 January 2020

Dear Mr. Kocmond,

We acknowledge your response, which regrettably did not meet the expectations of the 156 undersigned organizations and individuals. **We reiterate our request for you to respond with a detailed plan for how Cepheid will lower the price of Xpert MTB/RIF and Xpert MTB/RIF Ultra tuberculosis (TB) tests to US\$5, and include in this price the cost of service and maintenance. We additionally request that you articulate how Cepheid will lower the price of all GeneXpert tests, including those for HIV, hepatitis B and C, human papillomavirus (HPV), and other sexually transmitted infections (STIs), and include in this lower price the cost of service and maintenance.**

In 2018, Xpert TB cartridge sales volumes reached nearly 12 million cartridges sold to High Burden Developing Countries (HBDCs) alone.¹ Given the current high volumes of sales and resulting manufacturing efficiencies and cost savings, we know Cepheid can do better than \$9.98 per cartridge for TB tests. This price is comparable to the earlier FIND-negotiated price of \$10.72 for volumes of just 3.7 million annually,² **one third** of what they are today,³ and **one eighth** of what they would be if Xpert MTB/RIF and Xpert MTB/RIF Ultra were being used according to World Health Organization recommendations, as the initial TB test for all.^{4,5}

According to an independent cost of goods (COGS) analysis commissioned by Médecins Sans Frontières (MSF), the estimated cost to produce Xpert MTB/RIF and Xpert MTB/RIF Ultra cartridges at volumes of 1 million cartridges per year was estimated to be \$8.63 and \$8.82, respectively.⁶ When modeled at annual volumes of 10 million, the estimated cost dropped to \$4.64 per cartridge, including royalties on two patents. Presuming that these patents have expired, at annual volumes of 10 million the cost of producing each Xpert cartridge is estimated to be as low as \$3 (see: <https://msfaccess.org/time-for-5>).⁷

In your response, you mentioned Cepheid's investments related to HIV, hepatitis B and C, HPV, and other STIs. Under the HBDC concessional pricing program, viral tests are currently priced at \$14.90 per cartridge, while STI test cartridges are priced at \$16.20 for chlamydia and gonorrhea, and \$19.00 for *Trichomonas vaginalis*.⁸ Yet the COGS analysis found that there is no significant cost distinction to warrant a higher price: it found that the basic materials to construct the bacterial and viral cartridges are the same.⁹ Similar to Xpert tests for TB, the sales volumes for Cepheid's other assays are expected to continue to rise, particularly the HIV viral load tests,¹⁰ as well as the tests for HPV and other STIs.^{11,12} Since all of these assays are manufactured on the same production line, and all contribute to manufacturing efficiencies,¹³ a comparable price reduction across all GeneXpert assays that includes the cost of service and maintenance is a reasonable request.

In 2011, Cepheid stated that "[t]he single most influential factor impacting the price of the test going forward is test volume. Higher annual test volume will directly translate into lower overall production costs and result in a lower ExWorks price to the HBDC Market."¹⁴ Higher annual test volumes have arrived; it's time that the global public share the benefits of Cepheid's lower production costs.

By January 21st, the 156 undersigned organizations and individuals look forward to your response, which should directly address the evidence presented in this correspondence, and articulate how Cepheid will lower the price of TB test cartridges to \$5, as well as how Cepheid will lower the price of all GeneXpert assays, inclusive of service and maintenance. Please direct your response to David Branigan, David.Branigan@treatmentactiongroup.org.

Sincerely,

David Branigan
TB Project Officer
Treatment Action Group
On behalf of the 156 undersigned organizations and individuals

Organizational Endorsements:

AASRA for Community Transformation (ACTINDIA), India
Access to Rights and Knowledge (ARK) Foundation, India
ACT! AP, Asia Pacific
ACTION, Global
Active Help Organization (AHO), Pakistan
Afrihealth Optonet Association, Nigeria
Aids Counselling Trust (ACT), Zimbabwe
Alliance for Public Health, Ukraine / Global
Alliance Lanka, Nugegoda, Sri Lanka
Americas TB Coalition (ATBC), Latin America and the Caribbean
APCASO, Asia Pacific
Asha Parivar, India
Association Burkinabé d'Action Communautaire, ABAC, Burkina Faso
Association for Protection of Human Rights and Community Development (APHRICOD), Nigeria
Burundian Alliance for the Fight Against Tuberculosis and Leprosy (ABTL), Burundi
Canadian HIV/AIDS Legal Network, Global
Carmelo Hospital of Chokwe, Mozambique
Citizen News Service (CNS), India

Civil Society Movement Against Tuberculosis (CISMAT), Sierra Leone
Coalition PLUS, Global
Community and Family Aid Foundation, Ghana
Compañeros en Salud (CES), Chiapas, Mexico
Delhi Network of Positive People (DNP+), India
Dr Uzo Adirieje Foundation (DUZAFOUND), Nigeria
Drug Resistant TB Scale Up Treatment Action Team (DR-TB STAT), Global
Empower India, India
End Hep C SF, USA
Epicentre / Médecins Sans Frontières (MSF), Global
European AIDS Treatment Group (EATG), Europe
FACT, Zimbabwe
Georgia Harm Reduction Network, Georgia
Ghana National TB Voice Network, Ghana
Global Coalition of TB Activists (GCTA), Global
Global Media Foundation, Ghana
Global TB Community Advisory Board (TB CAB), Global
Grassroots Development and Empowerment Foundation, Nigeria
Health GAP (Global Access Project), Global
Hepatitis Education Project, Seattle, USA
Human Touch Foundation, Goa, India
INP+ (Indian Network For People Living With HIV/AIDS), India
INTILISH, Uzbekistan
ITPC Eastern Europe and Central Asia (ITPCru), Eastern Europe and Central Asia
ITPC South Asia, Delhi, India
Jointed Hands Welfare Organisation, Zimbabwe
KHANA, Cambodia
Lawyers Collective, India
League PLWHA, Moldova
LHL International Tuberculosis Foundation, Global
Maa Community Health Workers CBO, Kenya
Manicaland Network of Most at Risk Populations, Zimbabwe
Médecins Du Monde, Georgia
Médecins Sans Frontières (MSF), Global
Médecins Sans Frontières (MSF), Mozambique
Medical IMPACT, Global
Mongolian Tuberculosis Coalition, Mongolia
National Coalition of People Living with HIV in India (NCPIPLUS), India
National Empowerment Network of People Living with HIV/AIDS in Kenya (NEPHAK), Kenya
National TB Reference Lab, Philippines
Network of TB Champions, Kenya
Pamoja TB Group, Kenya
Pan-African Treatment Access Movement, Africa
Partners In Health (PIH), Global
PIVOT, Madagascar
plan:g Partnership for Global Health, Austria
Private Health Sector Project, Ethiopia
REACH, Ethiopia

RESULTS UK, United Kingdom
San Francisco Hepatitis C Task Force, USA
Sentinel Project on Pediatric Drug-Resistant TB, Global
Sikkim Drug Users' Forum, India
Society for Conservation and Sustainability of Energy and Environment in Nigeria (SOCSEEN), Nigeria
South African National AIDS Council (SANAC) Civil Society Forum, Access Chapter 2 (AC2), South Africa
Southern African Miners Association (SAMA), Southern Africa
STOPAIDS, United Kingdom
Swaziland Migrant Mineworkers Association (SWAMMIWA), Eswatini
TB Proof, Global
The Hepatitis C Mentor and Support Group (HCMMSG), USA
TINPSWALO Association - Vincentian Association to Fight AIDS and TB, Chokwe, Mozambique
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Volunteer Health Services, Ethiopia
Volunteers for Development Nepal (VFDN), Nepal
Women for Health, Georgia
Wote Youth Development Projects, Kenya
Yayasan Menara Agung, Indonesia

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Wondimu Adane, TB Program Officer, Addis Ababa, Ethiopia

References

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- ⁶ Cambridge Consultants/Médecins Sans Frontières (MSF). Cost of Goods and Manufacturing Analysis of GeneXpert Cartridges. 2019 March. Available from: https://msfaccess.org/sites/default/files/2019-12/2018%20COGS%20analysis%20of%20Xpert%20MTB_RIF%20Ultra%20cartridges.pdf.
- ⁷ Ibid.
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