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

CC:
Mr. Philippe Jacon, Senior Vice President, Global Access, Cepheid
Mr. Peter Sands, Global Fund to Fight AIDS, Tuberculosis and Malaria
Dr. Tedros Adhanom Ghebreyesus, World Health Organization (WHO)
Dr. Tereza Kasaeva, WHO
Dr. Meg Doherty, WHO
Dr. Catharina Boehme, WHO
Dr. Philippe Duneton, Unitaid
Mr. William Rodriguez, Foundation for Innovative New Diagnostics (FIND)
Mr. Ira Magaziner, Clinton Health Access Initiative (CHAI)
Ms. Etleva Kadilli, United Nations Children's Fund (UNICEF)
Ms. Adriana Costa, World Bank
Dr. John Nkengasong, Africa Centres for Disease Control and Prevention (Africa CDC)
Dr. Benjamin Djoudalbaye, African Union
Mr. Nqobile Ndlovu, African Society for Laboratory Medicine (ASLM)
Honorable Zweli Mkhize, National Department of Health, South Africa
Honorable Rajesh Bhushan, Ministry of Health and Family Welfare, India
Honorable Marcelo Queiroga, Ministry of Health, Brazil
Honorable Mutahi Kagwe, Ministry of Health, Kenya
Mr. Balram Bhargava, Indian Council of Medical Research
Dr. Jarbas Barbosa, Pan American Health Organization (PAHO)
Ms. Gloria D. Steele, United States Agency for International Development (USAID)
Dr. Lucica Ditiu, Stop TB Partnership
Dr. Angeli Achrekar, U.S. President's Emergency Plan for AIDS Relief (PEPFAR)
Dr. Shannon Hader, The Joint United Nations Programme on HIV/AIDS (UNAIDS)
Dr. Chip Lyons, The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)
Eminence Peter Kodwo Appiah Cardinal Turkson, Prefect of the Vatican’s Dicastery for the Promotion of Integral Human Development
Monsignor Robert J. Vitillo, General Secretary, International Catholic Migration Commission; Attaché for Health, Permanent Observer Mission of the Holy See to the UN in Geneva
Global Fund Members of the Board
Unitaid Members of the Board
Access to COVID-19 Tools (ACT) Accelerator Facilitation Council Members
ACT Accelerator Diagnostics Pillar and Diagnostics Consortium Members
Integrated Diagnostics Consortium Members

14 October 2021

Time for $5 Coalition Urges Cepheid to Reinstate Plans to Launch GeneXpert Omni

Dear Mr. Kocmond,

The Time for $5 Coalition, comprising over 150 civil society organizations representing affected communities in high-burden countries around the globe, is deeply concerned about the decision from Cepheid to cancel commercialization of the portable point-of-care GeneXpert Omni testing instrument. Communities affected by TB, HIV, HCV, and other diseases have been waiting since 2015 for the launch of Omni to improve access to point-of-care rapid molecular testing. During this time extensive public funds and resources have been invested in the research and development and trialing of Omni.[1] Yet, Cepheid has decided to cancel commercialization of Omni without explanation, mitigation plans, or consideration of the impact of this decision on affected communities.

As early as July 2015, Cepheid announced at the American Association for Clinical Chemistry annual meeting the development of GeneXpert Omni, a single-module point-of-care testing instrument that is battery-powered, dust- and temperature-resistant, and portable, to overcome the shortcomings of the existing GeneXpert instrument for community-based testing.[2] The instrument was planned to be launched in 2016 but has been ever delayed since then. Cepheid was acquired by Danaher in 2016 for $4 billion, and in 2018 Danaher CEO Thomas Joyce announced an expected 2018 launch date for Omni at the JP Morgan Healthcare conference.[3] Because the Omni launch was again delayed, Cepheid announced in 2018 an interim solution with the GeneXpert Edge instrument, a battery-operated single-module GeneXpert instrument but with less portability and adaptability for decentralized testing compared to Omni.[4] At the 2020 High-Level Dialogue to Assess Progress on and Intensify Commitment to Scaling Up Diagnosis and Treatment of Pediatric HIV and TB in Children Living with HIV, Philippe Jacon, Cepheid's Senior Vice President, Global Access, reiterated Cepheid's commitment to support further decentralization of testing through the release of the portable GeneXpert Omni instrument in 2021 in a limited set of countries, with broader market release in 2022 (commitment 53).[5]

Cepheid's most recent decision to cancel commercialization of Omni adds insult to injury. For more than a decade, high prices of GeneXpert instruments and tests, and unaffordable and inadequate service and maintenance plans, have stood in the way of scaling up countries' testing services for TB and other diseases.[6] The decision by Cepheid to cancel the launch of Omni adds to the general failure of the corporation to improve access to GeneXpert technology. Despite rising volumes and skyrocketing profits,[7] Cepheid continues to charge low- and middle-income countries at least double what it costs the corporation to produce GeneXpert TB tests, and at least triple for HIV and COVID-19 tests, based on publicly available cost of goods data.[8] In addition to being unaffordable for many countries, the current GeneXpert instruments fail to close the TB testing gap because of the laboratory infrastructure required, meaning that the test is available only at the district or central hospital level. Many

people with TB never reach this level of care, and diagnosis with the WHO-recommended GeneXpert test remains elusive for most people. In 2019, just 33% of people with TB received a rapid molecular test,[i] despite the WHO recommendation since 2013 to use rapid molecular tests as the initial test for all people being evaluated for TB.[9,10] The lack of access to rapid molecular testing closer to the point of care translates to a shortfall in reaching the 2018 UN High Level Meeting TB target of providing diagnosis and treatment to 40 million people with TB from 2018 to 2022;[11] in 2018 and 2019, only 14.1 million people with TB were diagnosed and treated.[9]

Cepheid's decision to cancel the launch of the point-of-care Omni instrument will leave many people with TB, HIV, HCV, and COVID-19 without access to diagnosis and proper care, and carelessly squander the public resources and time that have supported the development and evaluation of the Omni technology between 2015 and today. The public sector invested at least $252M in the research and development of GeneXpert technology, with significant additional investments in the global roll-out of this technology over the past decade.[12] Cepheid as a corporation has been built off public funding. It's time for the public to receive a return on this investment through improved access to GeneXpert testing at the point of care and through equitable pricing of GeneXpert tests reflecting the cost of production plus a reasonable 10-20% profit.[13]

As representatives of global civil society and affected communities, **the Time for $5 Coalition urges Cepheid to reverse its decision by reinstating plans to commercialize GeneXpert Omni**, and we again reiterate our request for Cepheid to reduce the price of GeneXpert tests to $5, inclusive of service and maintenance, across diseases.[14,15] More affordable testing in communities closer to the point of care with instruments such as Omni, combined with adequate service and maintenance plans, will be crucial to close the TB testing gap. Taking these actions will show the world that Cepheid is committed to progress to end TB, HIV, HCV, COVID-19, and other diseases.

By COB Thursday, October 28th, the Time for $5 Coalition looks forward to Cepheid's response, which should be directed to david.branigan@treatmentactiongroup.org.

Sincerely,

David Branigan on behalf of the Time for $5 Coalition

[i] According to the WHO Global Tuberculosis Report 2020, in 2019, just 57% of people with pulmonary TB were bacteriologically confirmed, and of those, just 58% received a rapid molecular test.

About the Time for $5 Coalition

The Time for $5 Coalition is comprised of more than 150 civil society organizations working across countries and diseases to improve access to rapid diagnostic testing. Since 2019, the civil society Time for $5 Coalition has demanded that Cepheid lower the price of GeneXpert tests to $5 per test across diseases, inclusive of service and maintenance,[13] based on the available evidence of Cepheid's cost of production of GeneXpert tests.[8] In 2021, the Coalition called on Cepheid to improve access to COVID-19 tests in low- and middle-income countries (LMICs) by lowering the price of the tests and increasing the volumes available to LMICs.[14] Cepheid has continued to refuse to reduce the prices of GeneXpert tests to $5 per test for LMICs, to overcharge the global public for these essential tests, and to prioritize making profit over saving lives.

References

[1] U.S. Army Contracting Command. Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 17-03, Sub-Objective 17-07 Ceiling Increase Modification for "The GeneXpert Omni: A Man-Portable Diagnostic Testing Device for the DoD Government". U.S. Department of Defense. 2020 September 14. https://www.hhs.gov/sites/default/files/technical-direction-letter-expanded-diagnostic-testing-device-project-cepheid.pdf.

[2] Johnson, Madeleine. Cepheid Introduces True Point-of-Care Molecular Platform at AACC Analyst Event [Internet]. GenomeWeb. 2015 July 27 [cited 2021 Oct 7]. https://www.genomeweb.com/pcr/cepheid-introduces-true-point-care-molecular-platform-aacc-analyst-event?_ga=2.244938437.1515707739.1632466390-465025916.1617026470%23.YU132I4zbIU#.YV97wxDMLUI.

[3] GenomeWeb. JPM Healthcare Day 2: Danaher, Exact Sciences, Agilent, DiaSorin, Bio-Rad, Hologic, More [Internet]. GenomeWeb. 2018 January 10 [cited 2021 Oct 7]. https://www.genomeweb.com/business-news/jpm-healthcare-day-2-danaher-exact-sciences-agilent-diasorin-bio-rad-hologic-more?_ga=2.183107174.1515707739.1632466390-465025916.1617026470#.YV96FRDMLUI.

[4] Johnson, Madeleine. Cepheid to Launch GeneXpert Edge for Decentralized Testing While Omni Remains Delayed [Internet]. 360Dx. 2018 July 19 [cited 2021 Oct 7]. https://www.360dx.com/pcr/cepheid-launch-genexpert-edge-decentralized-testing-while-omni-remains-delayed#.YV96gBDMLUJ.

[5] The Vatican Platform for High-Level Dialogues. ROME ACTION PLAN 2020. Rome: The Vatican Platform for High-Level Dialogues; 2020. https://7516e5c8-88e8-4634-85db-70d27ff1f169.filesusr.com/ugd/38bdff_0c8878ebb1e64b979a147255605d4d0c.pdf.

[6] 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? Glob Health Sci Pract. 2019 December 23;7(4):551-563. https://doi.org/10.9745/GHSP-D-19-00244.

[7] Ketchum K. Demand for Cepheid SARS-CoV-2 point-of-care tests expected to continue through 2022. 360DX [Internet]. 2021 Apr 22 [cited 2021 Oct 7]. https://www.360dx.com/covid-19/demand-cepheid-sars-cov-2-point-care-tests-expected-continue-through-2022#.YJFNO31KjUJ.

[8] Médecins Sans Frontières Access Campaign. Time for $5: GeneXpert diagnostic tests. Geneva: Médecins Sans Frontières Access Campaign; 2019. https://msfaccess.org/time-for-5.

[9] World Health Organization. Global tuberculosis report 2020. Geneva: World Health Organization; 2019. https://www.who.int/publications/i/item/9789240013131.

[10] World Health Organization. Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF assay for the diagnosis of pulmonary and extrapulmonary TB in adults and children: policy update. Geneva: World Health Organization; 2013. https://apps.who.int/iris/bitstream/handle/10665/112472/9789241506335_eng.pdf?sequence=1&isAllowed=y.

[11] United Nations General Assembly. Political Declaration of the UN General Assembly High-Level Meeting. New York: United Nations; 2018. https://www.who.int/tb/unhlmonTBDeclaration.pdf.

[12] Gotham D, McKenna L, Deborggraeve S, et al. Public investments in the development of GeneXpert molecular diagnostic technology. PLoS ONE. 2021 August 31;16(8): e0256883. https://doi.org/10.1371/journal.pone.0256883.

[13] Branigan, D. Realizing Returns on U.S. Government Investments in GeneXpert Diagnostic Technologies. New York: Treatment Action Group; 2021. https://www.treatmentactiongroup.org/publication/realizing-returns-on-u-s-government-investments-in-genexpert-diagnostic-technologies/.

[14] TB Online. Time to lower the price of Xpert cartridges to $5 [Internet]. 2020 Apr 4 [cited 2021 Oct 7]. https://www.tbonline.info/posts/2020/4/4/time-lower-price-xpert-cartridges-us-5/.

[15] TB Online. Advocates request Cepheid increase access to GeneXpert SARS-CoV-2 tests in LMICs [Internet]. 2021 Feb 25 [cited 2021 Oct 7]. https://www.tbonline.info/posts/2021/2/25/advocates-request-cepheid-increase-access-genexper/.