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Realizing Returns on U.S. Government Investments in GeneXpert Diagnostic Technologies

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THE ISSUE:

Prohibitive pricing and lack of transparency regarding the cost of production of essential GeneXpert diagnostic tests. GeneXpert diagnostic tests are highly accurate, rapid molecular tests that enable decentralized, automated diagnostic testing to confirm the presence of COVID-19, tuberculosis (TB), HIV, viral hepatitis, and other diseases. The U.S.-based company Cepheid developed GeneXpert diagnostics with more than $252 million in public funding that came primarily from the U.S. government,[1] yet GeneXpert tests are marketed at unaffordable prices that limit access in the U.S. and in low- and middle-income countries (LMICs).[2,3] In addition to making significant investments in GeneXpert research and development (R&D), the U.S. government is also a major purchaser of GeneXpert tests for U.S. and LMIC markets. While the estimated cost of production for Cepheid is just $3-$5 per test,[4] tests are sold in the U.S. for $30-$60[5,6] and in LMICs for $10-$20,[7] many times Cepheid's estimated costs. Cepheid refuses to share its cost of production and continues marketing GeneXpert tests at prices that prohibit programs in the U.S. and LMICs from fully meeting their testing needs.[8]

WHAT TAG AND MSF ARE CALLING FOR:

The U.S. government should (1) engage Cepheid directly regarding the prohibitive pricing of GeneXpert tests and urge the company to publish production costs to promote transparency and public accountability, and enable fair and equitable pricing of U.S.-funded GeneXpert diagnostic technologies; (2) use Congressional investigative authority, such as the House Committee on Oversight and Reform, to hold Cepheid accountable for transparent, fair, and equitable pricing; and (3) take steps to mandate conditions that promote transparent, fair, and equitable pricing in future U.S. funding agreements that support the R&D of health technologies. TAG and MSF welcome U.S. government investments in R&D and procurement of new health technologies. However, we are concerned that the U.S. government is paying exorbitant prices for tests that taxpayer dollars were used to develop. While prohibitive prices limit access to these tests in the U.S. and LMICs, Cepheid's revenues continue growing exponentially (doubling in 2020).[9]

Why Focus on GeneXpert?

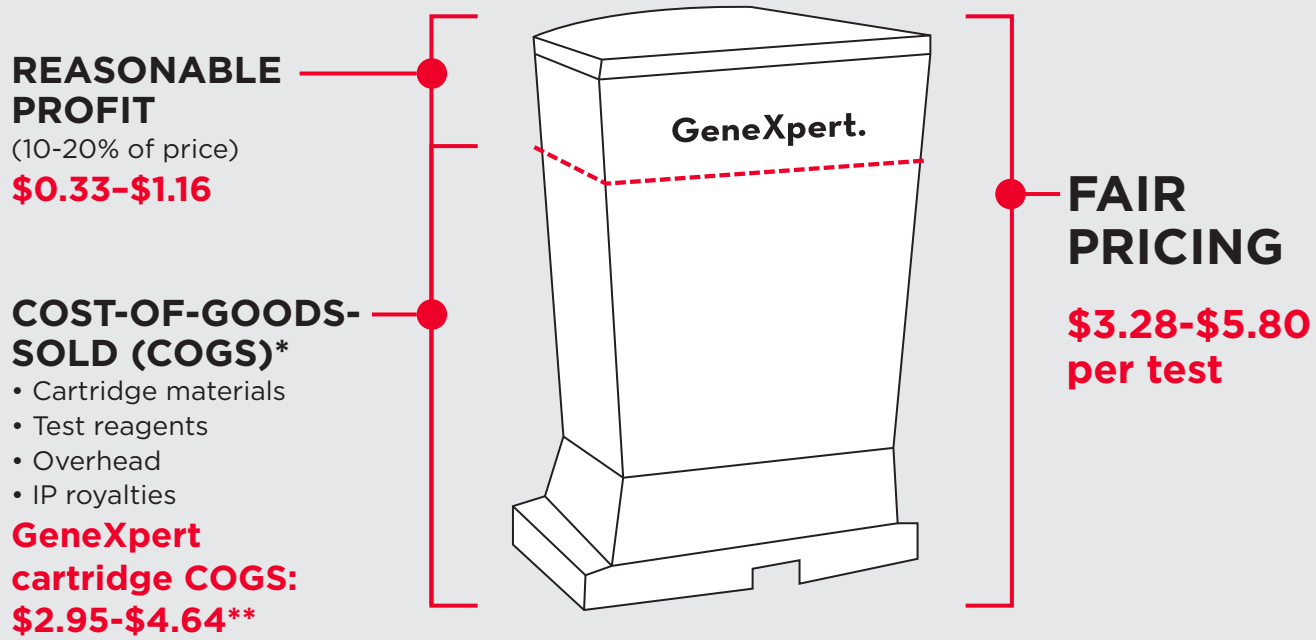
Accurate, rapid, and affordable diagnostics are an important gateway for patients to access proper treatment and care. In 2010 GeneXpert provided a breakthrough in diagnostic testing that enabled accurate rapid testing for TB, followed by similar tests for influenza, HIV, viral hepatitis, Ebola, COVID-19, and other diseases. These automated tests are particularly beneficial for LMICs because many district-level health centers in these countries do not have extensive laboratory infrastructure. More than 11,000 GeneXpert testing instruments have been placed in LMICs since 2010,[10] and nearly 5,000 instruments were in use in the U.S. at the start of 2020.[11] Following the onset of the COVID-19 pandemic, GeneXpert instruments were further scaled up in the U.S. to support rapid, decentralized confirmatory COVID-19 testing.

Notwithstanding these benefits, high prices are limiting access to GeneXpert tests. Due to the high prices of GeneXpert TB tests, many LMICs and TB control programs in the U.S. continue to rely on less-expensive and less-accurate smear microscopy to test for TB,[12,13] a century-old technology capable of detecting only about 50% of people with TB[14] compared to 90% using GeneXpert.[15] To develop its COVID-19 test, Cepheid used open-source data and U.S. government funding from the Biomedical Advanced Research and Development Authority (BARDA),[16] and marketed the test for $30-$50[17] in the U.S. and $19.80 in LMICs.[18] High prices and insufficient allocation of COVID-19 tests by Cepheid limited the capacity of LMICs to scale up GeneXpert testing to meet demand, hindering the effectiveness of their responses to the COVID-19 pandemic.[19]

Why Call for Transparency and Fair Pricing?

An independent analysis found that it costs Cepheid between $2.95-$4.64 to manufacture each GeneXpert test cartridge at annual volumes of 10 million,[20] a threshold that was exceeded in 2017 for TB tests alone.[21] According to this estimate, Cepheid

FIGURE 1: Proposed COGS+ model for fair pricing of GeneXpert diagnostic tests



* COGS per test decrease as total volumes increase
** $2.95-$4.64 estimated COGS at volumes of 10 million tests per year[22]

sells GeneXpert TB tests with a 54-70% profit margin in LMICs ($10 per test) and a 90-95% profit margin in the U.S. ($50-$60 per test), and COVID-19 tests with a 75-85% profit margin in LMICs ($20 per test)* and an 85-94% profit margin in the U.S. ($30-$50 per test). Cepheid is projected to sell 45 million COVID-19 tests in 2021,[23] in addition to tests for other diseases. These volumes will further drive down Cepheid's cost of production. Based on these estimates, civil society organizations around the globe have requested that Cepheid transparently publish their cost-of-goods-sold (COGS), and price GeneXpert tests fairly and equitably according to a "COGS+" pricing model (COGS plus a reasonable 10-20% profit),[24] as was defined in the 2006 agreement between Cepheid and the Foundation for Innovative New Diagnostics (FIND).[25] Cepheid has refused, claiming that its COGS are a trade secret.[26] However, according to most definitions GeneXpert test COGS may not qualify as a trade secret because they are (1) generated with public funds; (2) not a source of independent economic value; (3) readily ascertainable; and (4) have already been shared with some public agencies.[27]

These substantial public investments stand in contrast to the lack of transparency and public accountability for fair and equitable pricing of GeneXpert tests, adding to the concern that the U.S. government has been paying twice for GeneXpert tests.

Transparency of GeneXpert COGS is essential for holding Cepheid accountable for fair and equitable pricing. The public sector invested at least $252 million in the R&D of GeneXpert technologies, $214 million of which came from the U.S. government in the form of government grants, tax credits, funding from the National Institutes of Health (NIH), small business grants, and early development at U.S. government labs.[28] The U.S. government, which is also one of Cepheid's largest customers, further invested in the roll-out of GeneXpert tests in the U.S. and LMICs. In 2012 the United States Agency for International Development (USAID) and the President's Emergency Plan for AIDS Relief (PEPFAR) contributed to the WHO and Unitaid-led buy-down that paid Cepheid $11.1 million to lower the price of GeneXpert TB tests to $9.98 per test for LMICs.[29] These substantial public investments

FIGURE 2: Timeline of U.S. government investment in the R&D and roll-out of GeneXpert technologies[31]

EARLY 1990S
Basic technologies for the GeneXpert system developed at Lawrence Livermore National Laboratory (University of California)

1995
Lawrence Livermore National Laboratory exclusively licenses basic technologies to newly founded Cepheid Inc.

1997-2000
U.S. Department of Defense commissions development of various iterations of the GeneXpert technology for military use

2003
Following the 2001 anthrax attacks, U.S. government contracts Cepheid to develop a version of the GeneXpert technology that can detect anthrax spores in mail sorting facilities

2006
First GeneXpert diagnostic test approved for clinical use (group B Streptococcus). Non-profit organization FIND enters into agreement with Cepheid to co-develop a GeneXpert TB test, with much of the development done at the University of Medicine and Dentistry of New Jersey (UMDNJ)

2010
WHO endorses FIND-Cepheid-UMDNJ TB test

2011
FIND enters into agreements with Cepheid to co-develop an HIV viral load test and a GeneXpert remote calibration kit, with continued support from UMDNJ

2012
WHO, Unitaid, Bill & Melinda Gates Foundation, and the U.S. government pay Cepheid $11.1 million to buy-down the price of GeneXpert TB tests to $9.98 per test for LMICs

2018
By the end of 2018, 10,562 GeneXpert instruments and 45,979,570 GeneXpert TB tests had been procured in the public sector in LMICs, including through funding support from USAID, PEPFAR, and the Global Fund to Fight AIDS, Tuberculosis and Malaria

2020
U.S. BARDA commissions COVID-19 test development; an estimated 24 million cartridges were expected to be sold in the first year on the market

Adapted from timeline of GeneXpert technology development (Gotham D et al., PLOS ONE, Forthcoming 2021)

* At press time, Cepheid notified customers of its intention to reduce the price of COVID-19 tests to $14.90 per cartridge for LMICs, which falls far short of community demands and reflects a high 69-80% profit margin.

stand in contrast to the lack of transparency and public accountability for fair and equitable pricing of GeneXpert tests, adding to the concern that the U.S. government has been paying twice for GeneXpert tests. Despite rising volumes and inflating profit margins, Cepheid has not further reduced these test prices.[30] Due to Cepheid's unchecked profiteering and high prices, LMICs continue to be unable to fully scale up access to these essential diagnostics.

Danaher's profiteering comes at the expense of U.S. taxpayers, and reflects the company's prioritization of profit over enabling widespread access to affordable, scalable testing for TB, COVID-19, HIV, viral hepatitis, and other diseases.

The Cepheid story follows a common pattern for publicly funded health technologies—public sector funding underwrites R&D, and the finished technology is commercialized by a private sector company without accountability to ensure access for the public. When Cepheid was acquired by the U.S. corporation Danaher in 2016, CEO Tom Joyce described Cepheid's business model as one in which revenues are driven by the sale of test cartridges after initial large investments in the placement of GeneXpert instruments have already been made, providing a guaranteed returning customer base and ongoing source of revenue.[32] In 2020, Danaher touted a gross profit margin of 56%[33] and paid no federal income tax.[34] Danaher's profiteering comes at the expense of U.S. taxpayers, and reflects the company's prioritization of profit over enabling widespread access to affordable, scalable testing for TB, COVID-19, HIV, viral hepatitis, and other diseases.

How Can U.S. Policymakers Take Action?

The U.S. government, with its longstanding commitment to investing in the development and distribution of health technologies that address U.S. and global public health needs, is in a unique position to hold Cepheid accountable for transparent, fair, and equitable pricing of GeneXpert tests. The U.S. government invested heavily in the R&D of GeneXpert technology, amounting to at least $214 million in public investments.[35] Through its other contributions to the Global Fund to Fight AIDS, Tuberculosis and Malaria, and bilateral funding to other government programs via agencies such as USAID and PEPFAR, the U.S. government has substantially funded the roll-out of GeneXpert technologies and helped establish Cepheid's global footprint.[36] Meanwhile, lack of transparency and unaffordable prices of GeneXpert tests continue to limit access to GeneXpert testing in the U.S. and in LMICs.

Given the U.S. government's unique position and leverage, we call on the U.S. government to:

1. **Engage directly with Cepheid to urge the company to publicly disclose the cost of production of GeneXpert tests for purposes of transparency and public accountability for fair and equitable pricing;**

2. **Use Congressional investigative authority, such as the House Committee on Oversight and Reform, to compel Cepheid to transparently publish the cost of production of GeneXpert tests to facilitate public accountability for fair and equitable pricing; and**

3. **Work with stakeholders and civil society organizations to develop and implement reforms that mandate the inclusion of enforceable conditions that promote transparent, fair, and equitable pricing in future U.S. funding agreements for the research and development of health technologies.**

U.S. leadership on this issue would significantly advance both domestic and global efforts for equitable access to diagnostics and other health technologies and send a strong message that recipients of U.S. government funding for the R&D of health technologies will be held accountable to ensure public return on public investment.

The full list of references is available here: https://www.treatmentactiongroup.org/publication/realizing-returns-on-u-s-government-investments-in-genexpert-diagnostic-technologies