August 19, 2020

Mr. Bill Gates
Bill and Melinda Gates Foundation
500 Fifth Avenue North
Seattle, WA 98109

Dear Mr. Gates,

I'm writing in response to your recent comments on COVID-19 testing, specifically regarding your proposal to withhold reimbursement for laboratories that do not meet a 72-hour turnaround time. Having raised the alarm about the potential devastation of a pandemic virus several years ago, you also recognize that the challenges facing the diagnostics community are unprecedented and extraordinary.

The American Clinical Laboratory Association (ACLA) is the national trade association representing leading clinical laboratories. The first COVID-19 tests available in the United States, beyond the CDC kits, were Laboratory Developed Tests (LDTs), and ACLA members were among the first to bring those tests to market. Today, ACLA member laboratories have performed more than 33 million molecular tests for COVID-19, tripling the number of tests performed each day in the span of three months.

ACLA laboratories have introduced a range of new tests and techniques to meet widespread patient need for COVID-19 testing, including the development of the first at-home specimen collection kits, the expanded use of specimen pooling and the launch of novel RNA extraction methods to speed up testing and reduce the amount of supplies needed to run each test. We share your belief that rapid clinical development and regulatory approval is critical as we work together to pioneer new tests and methods for the patients we serve.

Collectively, there has been significant progress in reducing turnaround times in recent weeks. Yet, we are acutely aware of the serious ramifications of this unprecedented virus. With the U.S. facing a staggering and growing death toll from COVID-19, some experts are understandably pushing drastic interventions to stop this global pandemic.

You have raised a critical and valid point, that prompt and timely delivery of test results best aides the pandemic response and patient care. It is with this exact goal in mind that ACLA member labs, diagnostic manufacturers and the laboratory community writ-large have invested so heavily in the research and innovation I have mentioned. However, slashing reimbursement for labs that fail to meet a three-day turnaround time, as you have proposed, will have an immediate chilling effect on the response and create barriers for laboratories to continue to meet the needs of patients in the pandemic. More fundamentally, this proposal fails to address the underlying factors driving extended turnaround time.

Here's why:

- Turnaround time is in large part a function of demand, which fluctuates based on the continued spread of the virus. Encouraging strict accordance to public health recommendations, including social distancing, in every community is the best way to address this problem. Further, clinicians order tests, not laboratories. If our goal is to better manage testing demand in the U.S., a better solution would be to encourage robust adherence to clear ordering guidelines for clinicians, a priority that ACLA has been calling for since our first meeting with the White House Coronavirus Task Force in early March.
- The global demand for testing supplies, including reagents and pipette tips, poses a major constraint to labs' ability to process tests in a timely manner. Indeed, the supply scarcity has periodically forced many labs to operate below capacity. Penalizing labs for lack of supply would do nothing to improve the supply chain.
- If forced to absorb the costs of tests performed, some laboratories will need to make difficult decisions about whether they can increase capacity or perform testing at all. We know that, for example, the initial low Medicare reimbursement rate was a barrier to entry for some laboratories early on in the crisis, as the cost to perform some tests was greater than the reimbursement level. Simply put, different testing platforms are more expensive to operate and increased reimbursement allowed some labs to bring COVID-19 testing online and helped others to further expand capacity. Notably, there was an immediate uptick in capacity following CMS's April decision to increase reimbursement for high-throughput PCR testing.
- While turnaround times have been significantly reduced, it's important that we clarify that a lab result that takes more than 72 hours after specimen pickup is not worthless. Each lab result produces knowledge to understand the disease, inform the pandemic response, allows exposed first responders and others to end self-quarantine and return to work and most importantly, helps to serve the patient. As labs respond to unpredictable fluctuations in demand, clinicians who order tests should encourage patients who believe they may have been exposed to self-isolate while awaiting results.

Supporting Innovation

Private sector laboratories, as you have correctly noted, were not able to bring tests to market until March, which limited our nation's ability to scale capacity in the early days of the pandemic. Yet, inexplicably, labs have been held to a different standard when it comes to federal support and investment. The $25 billion Congress designated for "testing" was broadly allocated for all testing-*related* activities (e.g. contact tracing), largely through the states. With limited exceptions to-date, academic, hospital and commercial labs have borne the cost and risk of capital investment and research to drastically expand capacity amidst a shifting coverage landscape where reimbursement is not guaranteed.

Pharmaceutical companies, on the other hand, have faced a drastically different set of standards for investment. For example, the federal government recently announced an agreement with a pharmaceutical company to pay $1.5 billion for 100 million doses of an unproven vaccine, on the hope that the vaccine will be effective. Your proposal is almost an inversion of this promise – responding to labs working to meet demand not with support, but with a penalty.

To better manage demand, we need to encourage every lab with the appropriate expertise to continue to increase COVID-19 testing capacity. Unfortunately, we believe the reimbursement penalties you propose will provide a disincentive to build the testing we need.

Since our first conversations with the CDC in mid-January, labs have been doing everything they can to develop and scale up accurate and reliable testing. We remain wholly focused on that vital mission and welcome the opportunity to discuss our path forward with you or your team in the near future.

Thank you for your continued attention to this critical issue and for your work improving the health of communities around the world.

Sincerely,

Julie Khani
President