May 21, 2021

The Honorable Xavier Becerra
Secretary
United States Department of Health and Human Services
200 Independence, SW
Washington, DC 20201

Dear Secretary Becerra:

The American Association for Clinical Chemistry is a global scientific and medical professional organization that represents many of the front-line individuals who have been developing and overseeing COVID-19 testing for the past 14 months. When the initial COVID-19 test kits proved inadequate, our members created the laboratory developed tests (LDTs) needed to fill the critical void until newer and better test kits were developed.

One reason we were able to answer the call so quickly and effectively is that our laboratories routinely develop tests to assist physicians in diagnosing and treating their patients. While the lab medicine community has taken up this challenge during other public health emergencies, such as during the SARS and H1N1 crises, we more frequently develop LDTs during non-emergency times for situations in which there is no test available or when an existing Food and Drug Administration (FDA) approved or cleared test kit is not suitable for a particular purpose.

Unfortunately, there is much confusion in the media and among policymakers about LDTs. One mischaracterization is that these tests are unregulated. This is false. LDTs are stringently regulated by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA). Further, only a select number of the 260,000 laboratories in the United States are permitted to perform these tests (e.g., UCSF Medical Center, SF; Cedars-Sinai Medical Center, LA).

AACC is concerned that ongoing efforts to create a dual regulatory structure, which places laboratory services under both FDA and CMS oversight, will force many hospitals and other healthcare providers to discontinue these tests, thereby delaying physician access to timely, often vital patient information. Further, there is no evidence that a problem exists with these tests. When asked to assess the quality of LDTs, the FDA took two years to find 20 examples of tests that might be problematic, many of which were disproven. It is important to note that FDA approval or clearance does necessarily ensure high quality; many FDA approved or cleared tests are recalled for quality or accuracy problems.

AACC is open to reviewing and updating the current FDA medical device review process to align it more closely with the scientific and regulatory needs for in vitro diagnostic devices. It is important to the lab medicine community that IVDs are brought to market as quickly and safely as possible. Similarly, we are supportive of reassessing federal oversight of LDTs to identify and implement changes that can further improve their performance and assure they have been rigorously evaluated. However, AACC believes it is imperative that these two distinct methods for generating patient test results remain separate.

The creation of a one size fits all regulatory approach would likely harm, rather than improve patient care. Medical device manufacturers manufacture standardized machines and test kits that are marketed and sold to any healthcare provider. Clinical laboratories develop and perform LDTs only for their patients and are prohibited from selling their test to an outside entity. Further, laboratory directors must ensure these tests are scientifically valid or face severe sanctions.

AACC would like to meet with you and your staff to further discuss this issue. We support all efforts to improve the quality of laboratory testing. However, it is vital to remember that there are two distinct approaches, which have been in existence for more than 40 years that have served this country and our healthcare system well, particularly during the coronavirus pandemic. We look forward to working with you on this important issue.

If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,

David G. Grenache, PhD, D(ABCC)
President, AACC