September 23, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Secretary Azar:

The American Association for Clinical Chemistry (AACC), American College of Medical Genetics and Genomics (ACMG), and Association for Molecular Pathology (AMP) represent physicians, doctoral scientists, medical technologists, and other laboratory professionals dedicated to delivering high quality medical care by providing patients and their treating healthcare provider with vital information gleaned, in part, from laboratory testing services. We support the U.S. Department of Health and Human Services (HHS)'s decision to rescind all guidance and other informal documents and communications concerning premarket review of laboratory developed testing procedures (LDPs). We commend the Department for providing greater clarity on this issue and eliminating duplicative regulatory requirements for LDPs.

We agree that the Food and Drug Administration (FDA) must employ formal notice and comment rulemaking, as specified under the Administrative Procedures Act, before seeking to impose any new and significant regulatory requirements on clinical laboratories, hospitals, and health care providers.[1] The laboratory community first raised this issue in 2014 when the FDA issued draft guidance that would extend agency oversight to LDPs—duplicating existing Clinical Laboratory Improvement Amendments (CLIA) regulations promulgated by the Centers for Medicaid & Medicare Services (CMS).[2]

The HHS FAQ document on LDPs accurately details the requirements clinical laboratories must meet to perform these tests, such as validating the test within its clinical context, passing regular inspections and proficiency testing, adopting a robust quality management system, and employing appropriately licensed or credentialed laboratory personnel. We are confident that a CLIA-based regulatory system will continue to ensure that patients are given high quality health information to inform not only care related to COVID-19, but also cancer, rare diseases, other infectious diseases, and more.

Once again, thank you for providing clarity and streamlining regulatory requirements for the many healthcare professionals that depend on and use laboratory developed testing procedures in their clinical practice. If you have questions, please contact Vince Stine, PhD at VStine@aacc.org, Michelle McClure, PhD at mmcclure@acmg.net or Tara Burke, PhD at tburke@amp.org.

Sincerely,

American Association for Clinical Chemistry
American College of Medical Genetics and Genomics
Association for Molecular Pathology

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[1] The undersigned organizations do not waive their legal claim that the FDA lacks the statutory authority to regulate laboratory developed testing services, to the extent that it is established that the FDA does have such authority, all of the undersigned are unanimous that the overwhelming weight of legal authority dictates that any proposed new requirements must be issued through notice and comment rulemaking.

[2] https://www.amp.org/AMP/assets/File/position-statements/2014/Sign On Letter FDA Rulemaking.pdf