



Better health through
laboratory medicine.

February 14, 2022

The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Ranking Member McMorris Rodgers,

The American Association for Clinical Chemistry (AACCC) supports your efforts to ensure that expectant mothers have access to safe and reliable testing. AACCC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACCC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world. We are committed to safeguarding that laboratory testing serves the needs of patients and their caregivers.

In your recent letter to the Secretary of the Department of Health and Human Services (HHS) Xavier Becerra, you requested the Secretary's insights into issues regarding the prenatal testing concerns expressed in the January 1, 2022, New York Times article, "*When They Warn of Rare Disorders, These Prenatal Tests Are Usually Wrong.*" We agree that the report raised important topics of concern and areas in need of further government investigation and action, and we appreciate your commitment to examining these issues.

Unfortunately, the article included several inaccuracies pertaining to testing in general; conflating screening and diagnostic tests. Screening tests are not meant to indicate that a person has a disease or disorder; rather, they are intended to indicate whether a patient has an increased risk for the disease or disorder and, therefore, a need for further testing.

The authors repeatedly reference screening and diagnostic tests without making a clear distinction between these differing types of tests and their purposes. It is only after a diagnostic test that a clinician can determine whether a patient has a particular condition. The value of screening tests is that they can significantly decrease the number of patients who need to undergo diagnostic tests, thus reducing both healthcare costs and patient risk and discomfort.

The New York Times article asserts that the large number of "false positives" associated with prenatal screens indicates that the screening tests themselves are faulty. This assertion reflects the authors' misunderstanding of how screening tests are designed and what they are intended to do, rather than a flaw in the tests themselves.

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AACC agrees that women – and indeed all patients – should have the knowledge they need to make fully informed health decisions. What is needed is better education for all healthcare providers, and improved provider-patient communications. Any clinician ordering a screening test should clearly understand, and be able to explain, the strengths and limitations of such a test, so that a patient can make an educated decision as to whether or not to undergo additional testing.

Similarly, we agree with the assertion that a laboratory developing a new “first-of-kind” test method should publish its findings in a peer-reviewed scientific journal and/or present a paper at a scientific meeting, thus allowing their peers to critically evaluate and verify the performance and claims of the test. Information sharing is a core principle of AACC’s membership and our annual scientific meeting. Additionally, we believe that clinical validity is essential for any test being used in patient care.

Congress has created a mechanism for addressing many of the issues raised in this article. In 1988, President Reagan signed into law the bipartisan Clinical Laboratory Improvement Amendments (CLIA) which set forth requirements for regulating the clinical laboratories that perform these tests. The statute also created an advisory committee – the Clinical Laboratory Improvement Advisory Committee (CLIAC) -- to update and refine these standards.

CLIAC is currently considering modifications to the existing regulations. AACC believes this advisory panel is the ideal venue for discussing many of the matters raised in the article. We urge you to contact CDC, which staffs the committee, and recommend that they examine the issues surrounding prenatal tests and whether additional oversight is necessary and if so to develop approaches to address the challenges within existing regulatory frameworks. AACC looks forward to working with you to ensure that patients continue to have access to safe and accurate testing.

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

Sincerely,

A handwritten signature in black ink, appearing to read "S. R. Master".

Stephen R. Master, MD, PhD
President, AACC