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AACC Press Releases

New Legislation Would Jeopardize Patient Access to Medical Tests Across the Board by Restricting Policy that Removed Barriers to Coronavirus Testing

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WASHINGTON – On March 5, U.S. House and Senate lawmakers introduced the VALID Act, which would give the Food and Drug Administration (FDA) new, expansive powers to regulate laboratory developed tests—tests that are already regulated by the Centers for Medicare and Medicaid Services (CMS) and are subject to stringent personnel, quality control, and proficiency testing requirements. This bill promotes duplicative, costly federal regulations for clinical laboratories that will result in decreased patient access to essential medical tests. AACC urges Congress not to act on this bill until its impact on healthcare can be thoroughly evaluated.

When the coronavirus was declared a public health emergency, all coronavirus tests had to receive emergency use authorization (EUA) from the FDA. This meant that CMS-certified labs, which are not typically subject to FDA oversight, now had to get prior approval from the FDA before introducing their coronavirus test. This administrative requirement created new, burdensome regulatory barriers that delayed laboratories from developing their COVID-19 test. If it had not been corrected, many of the labs that are responding today to the urgent need for testing would remain stymied by insurmountable regulatory hurdles.

In response to concerns from AACC and the clinical laboratory community, FDA amended its EUA requirements last week to allow all qualified labs to develop and perform coronavirus tests

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prior to obtaining an EUA, as long as they submit an EUA request to FDA within 15 days of the tests' launch. The lawmakers behind the VALID Act have stated that this bill would benefit patients by making permanent this decision by the FDA. However, the rest of the bill introduces new and redundant regulatory hurdles for labs to overcome when developing tests for numerous conditions that are not public health emergencies but are nonetheless critical in everyday patient care.

If this bill were to pass, it would mean new, duplicative regulation and cost-prohibitive user fees for labs developing non-public health emergency tests. It would prevent labs from performing these tests, and it would limit patients' access to testing. The single provision on public health emergencies touted by the bills' supporters does nothing to reverse the crippling effect the legislation would have on hospitals and smaller labs in day-to-day healthcare situations.

FDA's involvement in the regulation of laboratory-developed coronavirus tests caused significant, potentially harmful delays in containing this epidemic. It would have the same result across the healthcare system should the VALID Act become law.

"FDA's EUA requirements clearly deterred many AACC member laboratories from developing tests for coronavirus," said AACC President Dr. Carmen L. Wiley. "We support FDA's decision to ease the EUA requirements for coronavirus, as well as efforts to expand access to diagnostic testing during this and future public health emergencies. However, we are very concerned that the VALID Act would have the same prohibitive effect on all laboratory developed tests that EUA requirements had on coronavirus tests. We therefore urge Congress to resist the impulse to prematurely take up this bill during the current crisis, and to wait to address this legislation until its impact on patient care can be thoroughly assessed."

ABOUT AACC

Dedicated to achieving better health through laboratory medicine, AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of progressing laboratory science. Since 1948, AACC has worked to advance the common interests of the field, providing programs that advance scientific collaboration, knowledge, expertise, and innovation. For more information, visit www.aacc.org.