ACMG
American College of Medical Genetics and Genomics
Translating Genes Into Health®

May 22, 2022

The Honorable Patty Murray
Chair, Senate Committee on Health, Education, Labor, and Pensions
154 Russell Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member, Senate Committee on Health, Education, Labor, and Pensions
217 Russell Senate Office Building
Washington, DC 20510

RE: The Food and Drug Administration Safety and Landmark Advancements Act of 2022 Discussion Draft, Title VIII: The Verifying Accurate Leading-edge IVCT Development Act of 2022

Dear Chairwoman Murray and Ranking Member Burr:

The American College of Medical Genetics and Genomics (ACMG) appreciates the opportunity to provide feedback on the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act of 2022 discussion draft. Specifically, we want to provide feedback on Title VIII, the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2022.

The ACMG is the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics, and the only medical specialty society in the US that represents the full spectrum of medical genetics disciplines in a single organization. The ACMG is the largest membership organization specifically for medical geneticists, providing education, resources and a voice for more than 2,500 clinical and laboratory geneticists, genetic counselors and other healthcare professionals, nearly 80% of whom are board certified in the medical genetics specialties. ACMG's mission is to improve health through the clinical and laboratory practice of medical genetics as well as through advocacy, education and clinical research,

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and to guide the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health.

ACMG has long been committed to supporting the development of high-quality genetic and genomic tests that are both analytically and clinically valid, as demonstrated by our development and ongoing maintenance of expert-reviewed technical standards and guidelines, disease-specific standards and guidelines, clinical practice resources, and supporting policy statements. We are uniquely positioned on this topic as we represent both clinical laboratory professionals who develop tests and direct clinical testing laboratories, as well as physicians and other healthcare professionals who order and rely on these tests to diagnose and care for patients.

For several years, the ACMG and numerous other healthcare professional organizations have expressed serious concerns about the VALID Act and its potential harmful impact on clinical testing laboratories and patient access to clinical testing throughout the US. These issues have not been addressed in the discussion draft text of the VALID Act of 2022, and we are deeply concerned that the legislation will have significant unintended negative consequences if enacted as currently written. Even more concerning, by including the VALID Act in the fast-moving FDASLA Act, there will not be adequate time to address the numerous stakeholder concerns and ensure that patient access to clinical testing is not negatively impacted. This is evidenced by the 5-day timeframe allotted for stakeholders to review and comment on the new proposed language of this complicated 260-page bill.

As currently written, the VALID Act would impose significant unnecessary burdens on clinical testing laboratories that would result in decreased test offerings, reduced flexibility to meet unique patient needs, and possibly even closure of smaller academic laboratories. This is contradictory to the goals of precision medicine and ultimately will harm patient care. It is imperative that Congress take the time to fully evaluate the impacts of such legislation and revise it such that patient needs are prioritized. **Therefore, we strongly urge you to consider the VALID Act independently of the FDASLA Act so that appropriate review and stakeholder engagement can occur.**

ACMG welcomes the opportunity to continue to engage further on these concerns and work with Congress and other stakeholders to develop additional exemptions

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and modifications to the VALID Act that will improve clinical testing without harming our ability to provide timely and personalized care to patients. We also urge you to take into consideration the existing regulatory framework for clinical testing laboratories and how it could be modernized to address concerns in a way that does not negatively impact our vital clinical testing laboratories, which serve to train most of the country's workforce in pathology and laboratory medicine.

For additional questions or discussion, please contact Dr. Michelle McClure, ACMG Director of Public Policy, at mmcclure@acmg.net.

Sincerely,

Marc Williams, MD, FACMG
President
American College of Medical Genetics and Genomics

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