

# Association of Pathology Chairs

## Promoting Excellence In Academic Pathology

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Dear Dr. Bucshon:

This letter is provided in response to the request for public comments regarding the *Verifying Accurate, Leading-edge IVCT Development (VALID) Act* draft, released on December 6, 2018. As written, the proposed legislation would dramatically alter the federal regulatory oversight of in vitro diagnostic (IVD) development and manufacturing activities in the United States, placing all IVDs (including laboratory-developed tests) under FDA regulatory oversight as in vitro clinical tests (IVCTs).

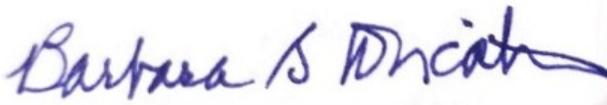
As pathology and laboratory medicine department chairs of academic medical centers and universities, we are committed to providing the best care possible to the patients we serve. We all believe in offering our patients the highest quality laboratory tests that are analytically and clinically validated while always focused on providing the best clinical care through our clinical colleagues. However, we are writing to express our profound concern regarding this proposed legislation and its unintended negative impact on clinical laboratory operations, diagnostic innovation, and its unintended yet negative effect on our ability to provide quality and innovative testing.

It is imperative that proposals for regulatory reform reflect the contribution and operational requirements of clinical laboratories and academic medical centers in supporting patient care through quality diagnostic testing and test development. Included below are essential concepts relevant to clinical laboratories and academic medical centers that should be considered in relation to VALID and/or future regulatory initiatives.

- *Regulations should not hinder innovation or discovery.* Clinical laboratories have served at the forefront of diagnostic advances, particularly in subspecialty care at academic medical centers and universities. Collaboration and partnership between clinical laboratory faculty, clinicians, and researchers in this setting has fostered tremendous innovation and diagnostic improvement, usually pre-dating any offering of FDA-cleared or approved alternatives. Such innovation lies at the heart of translational and personalized medicine. Regulation that is unduly burdensome to diagnostic innovation and/or translation into clinical laboratory assays would have a profoundly negative impact on patient care in our country.
- *Regulations should not limit the practice of pathology and laboratory medicine.* Clinical faculty in our departments fundamentally contribute to the diagnosis and management of patients through their respective board-certified specialties and subspecialties. While the VALID act states that the practice of medicine should not be limited, its description is far too narrow and does not acknowledge or protect the practice of pathology and laboratory medicine. These are the disciplines most closely aligned and familiar with in vitro diagnostic development and operation. Licensed medical professionals in anatomic and clinical pathology should not be restricted in applying medical judgement to their professional activities and assignments, nor should these medical activities be limited by any future, potential federal oversight over clinical laboratory test development.
- *Clinical laboratories are healthcare operations and not manufacturing facilities.* Regulatory oversight of clinical laboratories should be primarily aligned with existing CLIA-requirements where possible, such that these operations are not faced with duplicate layers of additional federal oversight. Regulations should also not hinder any necessary flexibility in test operation or modification that may be required to meet clinical practice needs of our associated healthcare providers and facilities
- *Regulations should not be overly burdensome as to prevent the continued offering of existing assays or future test development.* Clinical laboratories are already highly regulated. While all clinical laboratories in the U.S. are subject to regulatory requirements under CLIA, many laboratories may also be required to meet additional local, state, or third party regulatory and/or accreditation requirements. Additional federal oversight over test development, including user fees, submission fees, and documentation requirements for registration, submission, and notification could be a tipping point toward discontinuation of clinical test offerings and reluctance toward pursuing future test development. Additional layers of quality system requirements that are not closely aligned with CLIA could have a similar unintended effect.

In conclusion, the Association of Pathology Chairs (APC) is concerned that the VALID Act may have an unintended negative impact on clinical laboratory innovation, development, and operation, particularly in the academic medical center setting. We urge Congress and the FDA to work more closely with the academic clinical laboratory community, prior to advancing any future regulatory proposals. APC solely represents the interests of academic departments of pathology and laboratory medicine, and our members and faculty are available to provide such assistance.

Sincerely,

A handwritten signature in blue ink that reads "Barbara S. Ducatman". The signature is written in a cursive style with a long, sweeping tail on the final letter.

Barbara S. Ducatman, MD  
President