July 6, 2022

The Honorable Chuck Schumer
Majority Leader
United States Senate
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
317 Russell Senate Office Building
Washington, DC 20510

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
1236 Longworth House Office Building
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
2468 Rayburn House Office Building
Washington, DC 20515

Dear Majority Leader Schumer, Minority Leader McConnell, Speaker Pelosi, and Minority Leader McCarthy,

We write to you today to express our significant concerns with the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2022 and request that you provide additional and sufficient time to resolve these concerns prior to advancing this legislation as part of the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act. The undersigned organizations represent a diverse and broad community of healthcare professionals, patient advocates, industry organizations, medical institutions, and pathology departments who practice laboratory medicine, provide clinical testing services, and deliver high quality care to patients throughout the US.

We recognize that the user fee reauthorization offers a fast moving legislative vehicle; however, since this proposal dramatically modifies the current regulatory framework for an entire category of medical services, it's critical that this is done right to protect patient access to innovative diagnostics. **As such, we respectfully request that you allow time for further refinement of the VALID Act and do not rush this very flawed, problematic legislation through the user fee reauthorization legislative process.**

In 2019, bipartisan, bicameral sponsors of the VALID Act in concert with staff from your Committee and the Energy and Commerce Committee held a series of two hour roundtable discussions with stakeholders and officials from the Food and Drug Administration (FDA) on draft legislative language that was ultimately introduced as the VALID Act of 2020. Since then, stakeholders, including many on this letter, have provided extensive written comments on each iteration of the legislation, met with your offices and the bill's sponsors numerous times, participated in staff briefings, and most recently, responded to dozens of written questions from your staff circulated to stakeholders this past winter. Given this immense and active engagement over the past four years, we were very dismayed to see that the VALID Act of 2022 failed to incorporate most of our recommendations, even the most significant.

To illustrate our concerns, the current discussion draft failed to resolve these key areas:

1. *Stifling innovation and constricting patient access to care.*

While each of our organizations hold specific positions, we are unified in our view that the VALID Act of 2022 creates an onerous and complex system that would radically alter the way that laboratory testing is regulated to the detriment of patient care. The VALID framework would be costly as laboratories would be subject to user fees and need to finance the internal FDA compliance activities that would be required. This would force many laboratories, especially community laboratories, to consolidate their testing menu which would disrupt localized patient care and minimize the innovative efforts at our most prestigious institutions. While we appreciate that the laboratory developed testing services offered today would be grandfathered, the utility of these tests would diminish over time as the VALID Act puts overly restrictive constraints on how they can be modified. Further, testing consolidation away from academic and other laboratories would result in a reduction in training opportunities for an already strained laboratory workforce. Unfortunately, the laboratory workforce shortages were a significant barrier for this country's ability to respond to the COVID-19 pandemic and we are greatly concerned about the potential impact the VALID Act would have on patient care in the decades to come

2. *Duplication with and lack of modernization of the Clinical Laboratory Improvement Amendments (CLIA).*

The VALID Act's provisions on quality systems, adverse event reporting, and laboratory inspections duplicate requirements that laboratories already comply with under the federally administered CLIA program. The bill also references terms and aspects of the current medical device regulations that are not translatable to laboratory developed testing services. Simply directing the Secretary to avoid duplication as is written in the VALID Act of 2022 is insufficient, especially when other aspects of the legislation call for requirements and activities that lead to duplicative and unnecessary regulatory burden. Further, many stakeholders acknowledged the need to modernize the CLIA program implemented more than thirty years ago. Any update to the oversight of laboratory testing is incomplete and potentially duplicative without considering updates to CLIA.

3. *Preemption of state requirements.*

Many stakeholders actively participate in validity and quality review programs such as those administered by the New York State Department of Health (NYSDOH). The NYSDOH program in particular has successfully incorporated the concept of reviewing certain testing services into their assessment of the quality of a laboratory's operations and its personnel which has resulted in a harmonious and effective approach to regulating laboratory practice. As such, stakeholders have encouraged the Committee to recognize the value of such programs, prevent duplication with state efforts, and apply lessons learned. The VALID Act of 2022 fails to incorporate any of these recommendations and instead allows states with programs in place

prior to 2022 to continue their programs only if their requirements match those of the FDA. Further, as developers will still need to comply with both the FDA requirements and those state requirements, this will create unavoidable duplication as drafted.

4. *Lack of clarity in the risk categorizations, definitions, eligibility criteria for technical certification, and other key aspects of the legislation.*

Lack of clarity in key aspects of the VALID Act of 2022 including the definitions of high, moderate, and low risk, create ambiguities that make it impossible to understand the implications of various provisions on laboratory medicine and patient care. Further, the criteria for the technical certification program are unclear as to the types of tests eligible for authorization under such an order. Even more concerning, terms previously defined in an earlier version of the VALID Act such as "well characterized" and "adverse event" have been removed from this version yet are still referenced in the legislation.

5. *Unpredictable regulatory process due to significant discretion given to the Secretary.*

Throughout the legislation, the text grants discretion to the Secretary creating an unpredictable regulatory process and ambiguities in the significance of the policy. This is especially problematic as stakeholders try to understand the implications for their laboratories and practices. For example, in the section on an abbreviated premarket review, the legislation says that developers will not need to provide raw data as part of their submission unless requested by the FDA. The requirement of providing raw data is a meaningful distinction between full premarket review and abbreviated premarket review, and yet the Secretary has the discretion in any instance to require that data. Additionally, in the grandfathering provision, the Secretary has the discretion to direct any grandfathered test for premarket review. This further creates confusion as laboratories determine which of their tests will be subject to review. There are dozens of instances in the legislation similar to these examples. We strongly urge the Committee to narrow the discretion so that stakeholders may better evaluate and understand the implications of this legislation.

6. *Subject matter experts, i.e. test developers, are unable to actively participate in the accreditation process.*

The VALID Act of 2022 prohibits test developers from becoming accredited third-party reviewers unless FDA waives this requirement, which is in sharp contrast to how the medical and scientific community usually act. These professionals are the subject matter experts most qualified to assess the validity of a diagnostic test and as such, their participation in these processes should not be left to the discretion of the Secretary or agency. This country has a long history of understanding the merits of and thus supporting scientific peer review and without such a system, FDA will greatly lack access expertise needed to regulate the tens of thousands laboratory developed testing services that are used in clinical care.

7. *FDA lacks adequate resources to meet these obligations.*

During the COVID-19 pandemic, the FDA was quickly overwhelmed by the volume of applications summitted for the emergency use authorization, so much so that they had to pause review of all other non-EUA applications. This meant delays to the review and subsequent access to potentially lifesaving tests such as for oncology indications. Even with the funding infusion from user fees, based on the experience during the pandemic, we are very much concerned that FDA will be unable to handle implementing and administering the VALID Act. In 2021, there were more than 160,000 individual genetic tests on the market and FDA could not handle the influx of 2133 emergency use authorization requests for COVID-19 from March 2020 – April 2021.

8. *The emergency use authorization (EUA) provision will create a similar crisis experienced in winter and spring 2020.*

At the onset of the pandemic, a contaminant in the only EUA-authorized test kit plus restrictions on clinical laboratories that prevented them from offering laboratory developed testing services without FDA review, led to a crisis in the United States in which we had no testing for COVID-19 for over one month. Guidance published on February 29, 2020 allowing the use of tests while laboratories awaited an EUA decision was critical for the country's response. Recognizing the importance of this guidance, the VALID Act of 2020 and the VALID Act of 2021 included EUA language that allowed a similar approach. It's unclear why this was removed in the VALID Act of 2022, and we encourage the Committee to allow for similar approach in which laboratories can quickly mobilize during a public health emergency.

These are just eight examples of instances in the VALID Act that need major overhaul to address the concerns stakeholders have shared countless times in writing and in meetings with the bill's sponsors and with Committee staff. Before advancing this legislation, we implore you to modify the legislation to reflect stakeholders' input and to do so in a timeframe that ensures that policy fosters patient safety and innovation instead of creating barriers and delays to access novel diagnostics.

For these reasons, the undersigned organizations request that you do not advance the VALID Act as part of the Food and Drug Administration Safety and Landmark Advancements Act and instead work with stakeholders to refine this legislation.

Sincerely,

20/20 GeneSystems, Inc.
Academy of Clinical Laboratory Physicians and Scientists
AdventHealth
Akron Children's Hospital
Alabama Clinics
Alphadera Labs
American Association for Clinical Chemistry

American College of Medical Genetics and Genomics
American Society for Clinical Pathology
American Society for Histocompatibility and Immunogenetics (ASHI)
American Society of Hematology
American Society of Transplantation
Amerimmune
Ananda Analytical Laboratories, LLC
ARUP Laboratories
Association for Creatine Deficiencies
Association for Molecular Pathology
Association for Pathology Informatics
Association of American Medical Colleges
Association of Organ Procurement Organizations
Association of Pathology Chairs
Atrium Health
Baylor Scott & White Health
Beutner Laboratories
BIOTAP Medical
Bluewater Dx
Cancer Advocacy Group of Louisiana
Cancer Genomics Consortium (CGC)
Capture Diagnostics
CardioPath, LLC
Cedars-Sinai
Children' s Mercy Kansas City
Children's Hospital Los Angeles
Clinical Immunology Society (CIS)
Coalition for Innovative Laboratory Testing
Columbia University Irving Medical Center
Compliance Medical
Damajha Systems (SDVOSB)
Dartmouth Health
Department of Pathology & Laboratory Medicine, University of California, Irvine
Department of Pathology & Laboratory Medicine, University of Miami School of Medicine
Department of Pathology and Laboratory Medicine, Hartford Hospital
Department of Pathology and Laboratory Medicine, Northwell Health
Department of Pathology and Laboratory Medicine, Perelman School of Medicine, University of Pennsylvania
Department of Pathology and Laboratory Medicine, University of Florida - Jacksonville
Department of Pathology and Laboratory Medicine, University of Louisville
Department of Pathology and Laboratory Medicine, University of North Carolina School of Medicine
Department of Pathology, Duke University
Department of Pathology, East Carolina University Brody School of Medicine

Department of Pathology, Texas Tech University Health Sciences Center, El Paso, Texas
Department of Pathology, University of Arizona College of Medicine Phoenix
Department of Pathology, University of Illinois at Chicago
Department of Pathology, University of Pittsburgh Medical Center
Department of Pathology. University of Alabama at Birmingham
Diaceutics, Inc.
Diamond Medical Laboratories
East Coast Clinical Consultants
Elina Labs, LLC
Emory Healthcare
Entvantage Diagnostics, Inc.
Everly Health
Gene By Gene
GeneDx
GeneMatters
Genetics Institute of America
Genome Medical, Inc.
Genomind
GenXys Health Care Systems Inc.
GoDx Inc
Gravity Diagnostics
Gravity Diagnostics
Harbor-UCLA Medical Center
Helix Op Co, LLC
ID Tech Molecular Laboratory
Invitae Corporation
IVD Logix LLC
Johns Hopkins Health System
Kaiser Permanente
KRAS Kickers
KSL Diagnostics Inc.
Laboratory Access and Benefits Coalition
Leading Edge Laboratory Consultants
Lighthouse Lab Services
Mass Spectrometry & Advances in the Clinical Lab (MSACL)
MD Rescue LLC
MD Revenue Partners
MED-US Consulting LLC
Medical Group Management Association
MLD Foundation
My Gene Counsel
National MPS Society
Nationwide Children's Hospital
Nebraska Medicine

NorthShore University HealthSystem
Northwest Pathology, P.S.
nuCARE Medical Solutions
NYU Langone Health
Ochsner Cancer Institute
Ochsner Precision Cancer Therapies Program
Olive View-UCLA Medical Center
Oregon Health & Science University
Pan-American Society for Clinical Virology (PASCV)
PathGroup
Pierian
Premier, Inc.
Progentec Diagnostics, Inc.
Pulmonary Pathology Society
Sapere Bio
Sema4
Teiko Bio, Inc.
Theralink Technolohies, Inc.
TriCore Reference Laboratories
UC Davis Health
UC San Diego Health
UCI Health
UCLA Health
University of California Health
University of California San Francisco
University of Chicago Medical Center
University of Cincinnati Health
University of Nebraska Medical Center (UNMC)
University of New Mexico
University of Rochester
University of Vermont Health Network
UVA Health
UW Health
UW Medicine
Vanderbilt University Medical Center
Virginia Commonwealth University
Weill Cornell Medicine
West Virginia University Health System