July 12, 2022

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Chuck Schumer
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Kevin McCarthy
Republican Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Republican Leader
U.S. Senate
Washington, DC 20510

Dear Speaker Pelosi and Leaders Schumer, McConnell and McCarthy:

As leaders of academic health centers and systems providing innovative and personalized care for millions of Americans, we urge Congress not to include the VALID Act in the 2022 FDA user fee legislative package. The VALID Act in its current form remains a controversial proposal opposed by many stakeholders in the medical and laboratory sciences. While the Senate HELP Committee bill (S. 4348, FDASLA) incorporates the VALID Act, House-passed legislation (H.R. 7667, FDA22), approved by a vote of 392-28, has no corresponding section. As currently written, the VALID Act would greatly harm our institutions' efforts to offer cutting-edge new tests for patients and limit options for our care teams.

We wish to acknowledge how important it is for Congress to pass an FDA user fee package in a timely manner to ensure critical food and drug safety operations at the FDA are not disrupted. Furthermore, we applaud leadership of both the House Energy and Commerce Committee and Senate HELP Committee for their efforts to produce user fee bills that contain important policy reforms. Nevertheless, we are deeply concerned with the inclusion of a proposal that would significantly alter federal regulation of in vitro clinical tests (also often called laboratory developed tests, or LDTs) in the Senate HELP-reported bill. Our institutions work tirelessly to continuously improve the LDTs we use in support of whole patient care and stand ready to work with parties on a balanced path forward. While a well-intentioned attempt to ensure safety and clinical utility of medical tests, the VALID Act uses a broad ax rather than a scalpel in its approach and would produce numerous negative consequences to the nation's health care system:

> *Fewer New Tests, Less Innovation*—We believe the likely result of VALID will be that many hospital-based clinical labs will not be able to devote the required resources to develop and deploy LDTs subject to a complex FDA premarket review process. Under VALID, LDT test offering would require more financial resources, both to hire greater numbers of people to handle administrative requirements, as well as in FDA fees. Even hospital labs that continue to use LDTs under grandfathered status would face constraints on their ability to update and improve tests over time. The result will be a stifling of innovation to the determent of patients.

Care Delays—VALID would establish a time-consuming approval process for laboratory tests that could delay care and would be administratively challenging, especially given clinical labs will continue to be regulated under CLIA/CMS, as they are now. It is also unclear if the FDA is equipped with staffing and resources necessary to process an entirely new category of product reviews, and to do so on a timeline that will not entail months/years of delay before a new test reaches patients. Laboratory science evolves quickly, and it is not hard to envision scenarios where a test will become scientifically outdated and improved upon by the time FDA approves it. Moreover, the administrative burden of getting an LDT FDA approved would lead to fewer academic centers offering tests, and the need to ship samples to commercial labs also would lead to care delays.

Lab Consolidation, Weakened Public Health Preparedness—With fewer hospital-based labs developing LDTs, hospital labs would lose infrastructure, trained personnel and expertise in the developing and performing of specialty testing. The health care system would increasingly depend on a small number of large reference laboratories and commercially manufactured test kits. An overreliance on a few large actors could prove especially problematic during public health emergencies when testing needs escalate rapidly, and when there is an emergent need for many laboratories to work on a novel testing target (e.g. SARS-CoV-2).

Academic health centers are hubs of innovation. Discoveries made by our researchers and physician-scientists are transferred to every sector of health care and benefit patients around the globe. These innovations range from common tests including the Pap smear to the most complex genetic sequencing.

We and our institutions stand ready to work with congressional leaders on alternative approaches to enhance regulation of potentially high risk in vitro clinical tests and would welcome the relevant committees to hold hearings on this topic to further vet a range of policy ideas. In the meantime, we respectfully request Congress not to advance the VALID Act or ensure academic medical center clinical laboratories are exempted from its requirements (as advocated by several Senators during HELP Committee markup).

At a minimum, lessening the burden on academic labs by addressing several provisions in the FDASLA would make these new regulations less likely to decrease the number of available tests for patient care. The most onerous and resource-intensive aspects of FDASLA could be diminished without increased risk to patients or access to care by making the following changes applicable only to labs at academic health centers, or "academic clinical laboratories" (ACLs):

- Exclude ACLs from the requirement to proactively list all tests that are to be grandfathered. Instead, such labs should be prepared to present evidence of use of the test prior to enactment should a question arise about whether a test was properly included in this exemption. CLIA-certified labs already maintain Test menus in compliance with CLIA regulations that should fulfill requirement for test registry, thereby avoiding duplicative work.
- When a test developed and administered by an ACL is grandfathered, exempt from premarket review through a technology certification, or approved through premarket

review, changes to the specimen type, patient age range, reference range, or disease indication for the test should not be considered a modification and therefore not treated as a new test.

- Designate tests developed by an ACL as low-risk to acknowledge the risk-mitigating factors that arise from additional oversight, expertise, and integration into clinical care that ACLs demonstrate, aspects that are wholly different from commercial or reference labs.
- Expand custom/low volume tests exempt categories to include <100 tests annually (instead of five).

Thank you for your careful attention to this matter.

Sincerely,

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cc: The Honorable Patty Murray, Chair, Senate Health, Education, Labor, and Pensions Committee
The Honorable Richard Burr, Ranking Member, Senate Health, Education, Labor, and Pensions Committee
The Honorable Frank Pallone, Chair, House Energy and Commerce Committee
The Honorable Cathy McMorris Rodgers, Ranking Member, House Energy and Commerce Committee