Immune Deficiency Foundation

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June 7, 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

Dear Chairwoman Murray and Ranking Member Burr,

Thank you for the opportunity to provide feedback on the discussion draft of the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act, particularly Subtitle C of Title VIII, which includes the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2022. We write to you as leading immunologists who care for patients diagnosed with primary immunodeficiency (PI), a group of more than 450 rare, inherited disorders in which part of the immune system is absent or does not function properly.

We have significant concerns with the VALID Act of 2022; in particular, how shifting regulatory responsibility for laboratory developed tests (LDTs) from the Centers for Medicare & Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA) to the Food and Drug Administration (FDA) will affect patient access to testing for rare conditions like PI. This shift will also affect many states' newborn screening programs, which rely heavily on LDTs performed in state public health labs[i]. Our chief concerns:

1) The VALID Act will impose a significant financial and administrative burden on non-profit, academic, and hospital-associated clinical laboratories and state and local public health laboratories. Regardless of whether any particular test performed by a lab must undergo the proposed FDA pre-market approval process, labs will have to pay FDA user fees and register all of their LDTs with the FDA. These are new financial and administrative burdens for clinical labs that are already understaffed and overburdened due to the continuing COVID-19 pandemic. Such labs do not have dedicated regulatory staff. Many labs may choose to shut down further LDT development and may even cease to offer grandfathered LDT tests if they cannot meet the FDA registration requirements.

2) The FDA does not have the capacity to take over LDT regulation. Because the COVID-19 public health emergency triggered emergency use authorization (EUA), the FDA was suddenly responsible for authorizing LDTs for COVID-19 that would

have otherwise been accessible as soon as they were developed and validated[ii]. FDA had to put all other *in vitro* diagnostic reviews on hold to deal with the influx, and eventually allowed LDTs to be used while authorization was pending. While user fees from clinical labs will allow new staff to be hired, there is currently a labor shortage and FDA is not guaranteed to be able to find staff with the required expertise. In addition, a provision in an earlier version of the VALID Act that would have allowed LDTs to be used while undergoing FDA pre-market approval in select situations is no longer included in the bill.

3) **The test volume limitation for the humanitarian (i.e., rare disease) exemption discourages diagnostic testing for rare diseases.** The humanitarian exemption from FDA pre-market approval hinges on less than 10,000 tests being performed per year for a given LDT. This provision incentivizes limited use of LDTs when many rare diseases are under- or misdiagnosed. Because symptoms of rare diseases are not necessarily any more specific than other conditions, such patients may need extensive testing, including testing for multiple rare diseases, to be correctly diagnosed. Test volume is not an appropriate measure of whether an LDT has a rare disease indication.

4) **Under the VALID Act, LDTs would be regulated by both FDA and CMS under CLIA, creating a duplicate and unclear regulatory landscape.** In many places, such as the provision on laboratory inspection, the VALID Act duplicates regulations already in place under CLIA. Again, increasing the administrative burden on non-profit, academic, and hospital-associated clinical laboratories and state and local public health laboratories will limit their ability to offer any LDTs, even those exempt from pre-market approval.

In summary, we are concerned that the VALID Act of 2022 as it currently stands will not only prevent clinical laboratories from developing new LDTs for rare diseases and newborn screening but will cause these labs to cease offering LDTs that are currently available and crucial for rare disease diagnosis. Instead of working to correct diagnostic gaps, the VALID Act will decrease patient access to diagnostic tests, particularly for rare diseases.

We urge the Committee to remove the VALID Act as part of the Food and Drug Administration Safety and Landmark Advancements Act and to strengthen oversight of LDTs by updating CLIA rather than shifting the regulation of LDTs to the FDA.

Sincerely,

Kathleen Sullivan, MD, PhD, Chair
On behalf of the Medical Advisory Committee
Immune Deficiency Foundation

[i] https://www.frontiersin.org/articles/10.3389/fimmu.2020.577853/full
[ii] https://asm.org/Articles/Policy/2020/Amid-COVID-19,-ASM-Advocates-for-Changes-to-FDA-Em

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