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United States Senate  
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The Honorable Richard Burr  
Ranking Member  
Senate Committee on Health,  
Education, Labor and Pensions  
United States Senate  
Washington, DC 20510

May 22, 2022

**RE: Comment on Title VIII: Advancing Regulation of Cosmetics, Dietary Supplements and In Vitro Clinical Tests, Subtitle C In vitro clinical tests**

Dear Chair Murray and Ranking Member Burr:

On behalf of the Infectious Diseases Society of America (IDSAs), thank you for the opportunity to provide comments on the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act of 2022. IDSAs represents over 12,000 infectious diseases physicians, scientists and other public health and health care providers specializing in the prevention, diagnosis and treatment of infectious diseases. Our comments focus on TITLE VIII: Advancing Regulation of Cosmetics, Dietary Supplements and In Vitro Clinical Tests, Subtitle C In vitro clinical tests. Infectious diseases physicians rely upon commercial and laboratory developed tests, typically used in combination with comprehensive clinical assessments, to diagnose infectious diseases and support the management of complex patients. Ensuring continued patient access to high quality testing is essential.

IDSAs appreciates that the Committee has incorporated some of our prior feedback on the VALID Act into Subtitle C of Title VIII of FDASLA. However, we are concerned that some of the provisions in this Subtitle would dramatically curtail patient access to testing and halt innovation at academic clinical laboratories, which fill critical gaps in commercially available testing. We strongly urge the Committee incorporate our recommendations below to help prevent a significant loss of infectious diseases testing capacity. **Our highest priority recommendations are: 1) waive user fees for tests developed for institutional use by academic medical centers and hospital laboratories; and 2) permit tests for infectious or contagious diseases to qualify for the humanitarian test exemption.**

**Top Priorities**

**Sec. 829. Resources.** IDSAs strongly recommends that the financial burden of user fees be waived for in vitro clinical tests (IVCTs) developed for institutional use by academic medical centers and hospital laboratories. The fees associated with the FDA premarket approval process are likely to force academic medical centers and hospital laboratories to undertake an unaffordable and inappropriately burdensome process for which they could not recoup the costs, particularly for tests intended

exclusively for in-house or reference laboratory (versus commercial) use. As a result, many of these tests would not be performed or would be outsourced, delaying results and negatively impacting patient outcomes. Denoted by the use of brackets in the FDASLA discussion draft, we recognize that a final decision to impose user fees for IVCTs may not have been made yet. Therefore, if user fees are established in this area, we strongly urge you to provide this exemption as it is critical for qualified academic medical centers and hospital laboratories.

**Recommendation:** We urge you to waive user fees under this Subtitle for academic medical center laboratories and other hospital-based clinical laboratories developing IVCTs for institutional use through the [FDA Small Business Determination Program](#) or a similar model.

**Rationale:** We recognize that the Agency already has a program to assist small business device manufacturers by waiving or reducing key user fees. Ensuring that academic medical centers and other hospital-based clinical laboratories developing IVCTs for institutional use are exempt from user fees is critical to maintain patient access to high quality testing.

**Sec. 587C(a)(3). Humanitarian Test Exemption.** IDSA supports the language (p. 174, lines 13-19) allowing tests used for a diagnostic purpose for a disease or condition that affects not more than 10,000 individuals in the US per year to qualify for the humanitarian test exemption. The threshold of disease prevalence is a much clearer, more clinically meaningful threshold that will be much more straightforward to implement than previously proposed language that relied upon the number of times a test would be used (which is difficult to predict and less clinically useful).

However, IDSA is deeply concerned that the discussion draft includes bracketed language (p. 175, lines 4-9) that would prevent tests for contagious diseases to qualify for the humanitarian test exemption, as this language would nullify the previously discussed improvement to this section. The presumed rationale for excluding contagious diseases from the exemption is to ensure that these tests are well validated due to the potential for false negatives. However, infectious diseases tests are already rigorously validated and, more importantly, do not serve as the sole source of clinical decision-making, which greatly reduces the risks associated with erroneous results. There is already a dearth of commercially available tests for rare infectious diseases and excluding tests for infectious diseases from this exemption will dramatically limit the ability of academic clinical laboratories to develop these tests, greatly reducing patient testing access.

**Recommendation:** Strike bracketed language (p. 175, lines 4-9) that would prevent tests for contagious diseases from qualifying for the humanitarian test exemption.

**Rationale:** Tests for infectious diseases are not inherently higher risk than other tests, particularly because they are typically not used as the sole source of clinical decision-making.

## **Additional Comments**

**Sec. 587C(a)(4) Custom Tests and Low Volume Tests.** IDSA appreciates that the discussion draft (p. 176, lines 7-8) would allow the Secretary to increase the threshold beyond 5 tests under certain circumstances for laboratories that meet the requirements to perform high complexity testing (p. 176, lines 13-23). Unfortunately, IDSA members are unable to identify a circumstance in which a laboratory would develop or run only 5 infectious diseases tests.

**Recommendation:** We continue to urge you to increase this threshold to 500 tests to provide greater clarity and certainty for laboratories and physicians.

**Sec. 587F Regulatory Pathway Designation.** IDSA thanks the Committee for clarifying that first-of-a-kind tests may be low, moderate, or high risk, and that low-risk tests would be exempt from pre-market review. IDSA is also pleased to see that first-of-a-kind tests may be eligible for technology certification. IDSA also greatly appreciates that cross-referenced tests are no longer included in the discussion draft, and, as such, a cross-referenced test would be independently evaluated based on the tenets of the bill as to its risk level and not categorically placed in a high-risk tier. The changes to this section will be helpful in preserving patient access to testing and allowing innovation.

**Sec. 587I Registration and Listing.** IDSA supports the concept of “grandfathering” all tests in clinical use prior to the legislation’s enactment and lifting the requirement for premarket review for these tests. This approach will limit unnecessary upheaval and interruptions in patient access to testing. However, we remain concerned that under the transition provisions within section 825, the Secretary is authorized to require registration and listing under 587J as early as October 1, 2024. This abbreviated timeframe will pose an unreasonable burden on academic and hospital-based laboratories, who do not have dedicated regulatory staff for these tasks. IDSA recommends that this provision be amended to require registration of grandfathered tests within 3 years (i.e., October 1, 2025). This would still provide sufficient time for the FDA to review this information prior to the full implementation of the provisions (i.e., October 1, 2027).

**Recommendation:** On page 119, line 15, strike “1 year” and insert “3 years”

IDSA thanks you for your consideration of our feedback. Should you have any questions, please contact Amanda Jezek, IDSA senior vice president for public policy and government relations at [ajezek@idsociety.org](mailto:ajezek@idsociety.org).

Sincerely,



Daniel P. McQuillen, MD, FIDSA  
President, IDSA