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March 15, 2024

The Honorable Brett Guthrie  
Energy and Commerce Health Subcomm.  
Washington, DC 20515

The Honorable Anna Eshoo  
Energy and Commerce Health Subcomm.  
Washington, DC 20515

Dear Chairman Guthrie and Representative Eshoo:

On behalf of the Infectious Diseases Society of America (IDSA), thank you for convening the Energy and Commerce Health Subcommittee hearing on March 21 on laboratory-developed tests (LDTs). These tests are critically important in combination with comprehensive clinical assessments for expeditious diagnosis and management of infectious diseases (ID) in complex patients. **Our members have reported that if implemented as written, the proposed rule released last year by the Food and Drug Administration (FDA) would cause most hospital and health system laboratories to stop offering and developing LDTs because they lack the infrastructure, personnel and financial resources to meet the rule's requirements.**

IDSA is committed to ensuring the accuracy of and access to medical tests so that ID physicians have the best possible information for clinical practice. However, we are deeply concerned that the FDA proposed rule will dramatically curtail patient access to testing, with devastating outcomes for patients with serious infections. For many infectious diseases, LDTs are the only – or the most reliable – tests available to provide timely results, especially if the alternative is sending specimens to an external reference laboratory for testing. LDTs are used in a wide array of ID practice areas, including testing for organism identification, antimicrobial susceptibility, HIV and hepatitis viral drug resistance, tickborne diseases, fungal infections, sexually transmitted infections and respiratory infections.

IDSA urges FDA to delay LDT requirements associated with 510(k) premarket notification or premarket approval, quality system regulation and labeling until more complete data on LDTs are compiled and made publicly available. Further, IDSA asserts that if FDA ends enforcement discretion for LDTs, a risk-based approach to regulation should be developed using comprehensive data (to be gathered prior to implementation) on the existing use of LDTs, including any associated adverse events.

IDSA's complete comments in response to the FDA proposed rule on LDTs can be found [here](#). I am happy to provide further details about the importance of LDTs to the diagnosis, treatment and prevention of infectious diseases. Should you have any questions, please contact Eli Briggs, IDSA director of public policy, at [ebriggs@idsociety.org](mailto:ebriggs@idsociety.org).

Sincerely,



Steven K. Schmitt, MD, FIDSA, FACP  
President