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September 16, 2020

The Honorable Alex Azar
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Seeking clarification on the definition of Laboratory Developed Tests (LDTs) per HHS Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of LDTs

Dear Secretary Azar:

The Infectious Diseases Society of America (IDSAs) appreciates the August 19, 2020 U.S. Department of Health and Human Services (HHS) announcement that the Food and Drug Administration (FDA), which recognizes the importance of innovation and patient access to high-quality lifesaving testing, will not require premarket review of laboratory developed tests (LDTs) without notice-and-comment rulemaking. We write to offer comments that we hope can guide future policymaking in this area and strike the appropriate balance between the flexibility necessary for innovation and the regulation necessary to ensure high quality of tests.

It is critical that all laboratories developing and performing diagnostic testing have the appropriate expertise and equipment to develop valid tests and deliver the accurate and reliable results that patients and clinicians depend on. The HHS rescission announcement raises questions about the scope of the term “laboratory developed test” – and thus, which tests require FDA review – as well as the applicability of postmarket requirements such as Quality System Regulation, Medical Device Reporting, and labelling requirements.

Given that modern laboratory networks and health systems often operate with multiple locations, IDSAs recommends a facility-based approach for tests developed by clinical laboratories that would ensure that all LDTs were appropriately subject to either Clinical Laboratory Improvement Amendments (CLIA) or FDA requirements. In this paradigm, LDTs would be defined as:

Tests developed by CLIA-certified laboratories meeting the requirements for high-complexity testing to be used in a single laboratory or a network of related laboratories (such as public health and hospital systems), and by reference laboratories that provide testing for local hospitals and physician practices.

As a key source of diagnostic quality and innovation, LDTs play a critical role in our healthcare system, especially during a pandemic. These tests are often developed to address unmet clinical needs and are critical tools in the fight against infectious

diseases and emerging outbreaks. In the case of COVID-19, many of the first widely available tests in the U.S. were LDTs.

IDSA has [long maintained](#) that proposed models for FDA oversight of LDTs would impede test development and compromise patient access to lifesaving testing. Infectious diseases (ID) LDTs are primarily developed to address unmet medical needs and to improve care for the patients in local and regional health systems. The regulatory process initially imposed by FDA early in the COVID-19 pandemic impeded the ability of ID experts practicing at academic medical center, reference, and community health system laboratories across the country to design, validate, and offer high-quality LDTs for use in patient care. The agency's modification of its LDT authorization requirements following concerted stakeholder input was a welcome revision that allowed COVID-19 LDTs to be rapidly developed and deployed.

We also maintain that it is inappropriate to hold tests developed and used by not-for-profit clinical laboratories to the same requirements as tests developed and marketed commercially, given the very different ways in which the tests are developed and used. The fees and requirements associated with the FDA premarket approval processes would force academic medical centers and hospital laboratories to undertake an unaffordable and inappropriately burdensome process for which they could not recoup the costs. Even the clinical laboratories that offer reference testing via LDTs are not selling a commercial kit to an outside laboratory, but rather providing a medically necessary diagnostic testing service to their hospital populations. As a result, many of these tests would not be performed, or would be outsourced to larger reference laboratories, delaying results and negatively impacting patient care – often the difference between life and death in infectious disease treatment. In the case of a pandemic, decreased testing capacity and longer turnaround times also hamper isolation and contact tracing—key strategies for reducing transmission.

IDSA acknowledges the complexity of diagnostics regulation in a rapidly innovating field and recognizes the potential risks posed by LDTs where a single test may determine the course of treatment (e.g., oncology). Early testing backlogs triggered by onerous FDA regulatory requirements and difficulty validating the CDC test highlight the importance of taking the time to balance regulatory impacts with the need for patient access to rapid, lifesaving tests.

This pandemic has demanded a real-time assessment of the current diagnostics regulatory framework and illustrated the consequences of not having rapidly available adequate testing in managing infectious diseases. IDSA urges HHS and Congress to work with appropriate scientific and public health experts across academia, government, and industry to analyze the LDT landscape and the impacts of potential legislation. Our member experts stand ready to assist in these efforts.

We appreciate your close attention to these important and complex issues and thank you for the opportunity to contribute to the development of appropriate policies to spur innovation and protect patient access to high-quality diagnostic testing.

Sincerely,



Thomas M. File, Jr., MD, MSc, FIDSA
President, IDSA