

August 29, 2023

Ms. Shalanda Young
Director
Office of Management and Budget
Executive Office of the President
Washington, DC 20503

Mr. Richard Revesz
Administrator
Office of Information and Regulatory Affairs, OMB
Executive Office of the President
Washington, DC 20503

Dear Ms. Young and Mr. Revesz,

On behalf of the American Society for Microbiology (ASM) and the Infectious Diseases Society of America (IDSA) we are writing to share our strong concerns about efforts to change the way laboratory-developed tests (LDTs) are regulated and to offer our expertise about the unique factors impacting infectious diseases (ID) testing. A regulatory pathway to oversee LDTs must be designed for these tests and with the clinical realities of how LDTs are widely used in ID testing in mind. We urge you to take the time necessary to work closely with us and other relevant professional societies to ensure that changes meant to improve patient safety do not produce unintended consequences.

The significant regulatory and financial burden of potential new rules/user fees on clinical microbiology laboratories and laboratory professionals focused on ID testing poses a threat to patient access to high quality, timely ID testing. This threat could result in harm to patient outcomes and public health. ASM and IDSA believe that ensuring accuracy of diagnostic tests is essential to patient safety and high-quality patient care. However, new regulations, if not designed with the input of ID clinicians and medical microbiologists, could result in the opposite outcome and severely limit access to ID testing, furthering health inequity. In particular, a regulatory framework with user fees and major reporting requirements, which may be appropriate for large, for-profit commercial enterprises given the worldwide populations they serve, would be completely untenable for smaller, non-profit clinical labs where many ID LDTs are developed, such as those serving academic medical centers and community hospital networks. These labs are already highly regulated through other means, such as accreditation by the College of American Pathologists. Any potential additional regulatory requirements must account for these laboratories' unique needs and avoid placing an undue burden on these understaffed and under-resourced laboratories that are vital to the healthcare ecosystem.

LDTs are widely used by ID physicians and clinical microbiology laboratories for the diagnosis and monitoring of myriad infectious diseases, and changes in their regulation will have far-reaching implications for patients and the clinicians and labs that serve them. For example, clinicians rely upon commercial tests and LDTs, typically used in combination with comprehensive clinical assessments, to diagnose infectious diseases and support the management of complex patients. Without timely proper identification of a pathogen, an ineffective or otherwise inappropriate antimicrobial may be prescribed for a patient, with the added danger of increasing antimicrobial resistance.

LDTs in ID also play an important role when testing for uncommon infections and emerging new pathogens, and when testing special patient populations such as infants/children and immunocompromised individuals. For less common infectious diseases, there are often a limited number of FDA approved assays and limited approved specimen types for testing. Sometimes there are none at all. For these patient populations to receive the correct diagnosis and applicable treatment, LDTs are often the only option. Adding additional, unnecessary and costly regulatory hurdles could delay or even eliminate the availability of these important diagnostic tests. Rapid turnaround time is uniquely critical for

infectious diseases tests, underscoring the need to maintain onsite testing capabilities at academic medical centers, community health centers and other health care settings.

Lastly, new regulations at this time would cause further harm to a field that already is facing serious workforce shortages. Clinical microbiology laboratories were at the forefront of the SARS-CoV 2 pandemic response utilizing their expertise in LDTs. Many of these clinical microbiology laboratories are already under resourced, further limiting their ability to meet any new requirements for pre-market submission and approval. New regulations could potentially accelerate the consolidation of complex diagnostic testing to a limited number of institutions and commercial entities, which could have the unintended consequence of stifling innovation and reducing timely patient access to critical testing. The subsequent loss of expertise in LDTs could hamper our response to the next pandemic.

Thank you for your consideration of our views. We urge you to proceed with caution when considering regulatory changes that could hinder the ability of ID testing to continue to meet the diverse needs of patients, and the clinicians and clinical laboratories that support their care. We stand ready to work with you to ensure patient safety and patient care are not compromised. Please contact Mary Lee Watts, ASM Director of Federal Affairs at mwatts@asmusa.org or Eli Briggs, IDSA Director of Public Policy at ebriggs@idsociety.org if you have any questions.

Sincerely,



Virginia Miller, PhD
President, American Society for Microbiology



Carlos del Rio, MD, FIDSA
President, Infectious Diseases Society of America



Linoj Samuel, PhD, D(ABMM)
Chair, ASM Clinical and Public Health Microbiology Committee

Cc: Dr. Robert Califf, FDA Commissioner
Dr. Jeffrey Shuren, Director, FDA Center for Devices and Radiological Health