AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

Empowering rheumatology professionals to excel in their specialty

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December 4, 2023

Jeffrey Shuren, MD, JD
Director
Center for Devices and Radiological Health
Food and Drug Administration
U.S. Department of Health and Human Services

Submitted electronically via regulations.gov

RE: [FDA-2023-N-2177] Medical Devices; Laboratory Developed Tests

Dear Director Shuren,

The American College of Rheumatology (ACR), representing over 8,500 rheumatologists and interprofessional team members, appreciates the opportunity to comment on the Laboratory Developed Test (LDT) proposed rule published in the *Federal Register* on October 3, 2023. We appreciate the delicate balance in regulating laboratory developed tests to allow for innovation while ensuring safety.

Rheumatologists and rheumatology professionals provide ongoing care for patients with complex chronic and acute conditions requiring specialized expertise. Early and appropriate treatment by rheumatologists and rheumatology professionals can control disease activity and prevent or slow disease progression, improve patient outcomes, and reduce the need for costly surgical or interventional procedures. The improved outcome enables our patients to continue to be more productive than they would have been without timely treatment.

LDTs are vital for rheumatologists and rheumatology interprofessional team members to diagnose and treat patients suffering from rheumatic diseases. The ACR firmly believes patients must have "access to reliable and patient-centered laboratory testing to optimize the diagnosis and monitoring of patients with conditions diagnosed and treated by rheumatologists."[1]

The in vitro diagnostic test landscape has changed dramatically since the Medical Device Amendments of 1976 was implemented. While we recognize and support the need for a shift in the regulatory oversight of these valuable tests to reflect better technical advancements, this oversight should not impede the innovation of future testing due to cumbersome regulatory requirements. The unintended consequences of the proposed four-year implementation timeline may create significant barriers to access to care as the LDTs will be required to go through significant regulatory

[1] American College of Rheumatology. (2023, November). *Clinical Laboratory Access & Optimization*. American College of Rheumatology Position Statement. https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/blt12127ac986aa2b47/acr-position-statement-clinical-laboratory-access-optimization.pdf

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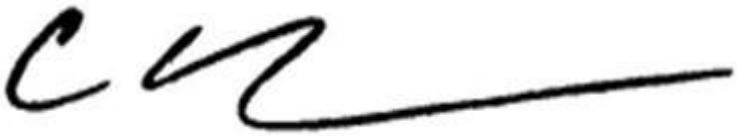
requirements that may halt the availability to our patients. We urge the Food and Drug Administration (FDA) to work with stakeholders to understand better any barriers to care that increased regulatory requirements may have on patients accessing tests that assist in diagnosing and treating diseases, particularly rheumatic diseases.

The ACR appreciates the delicate balance needed to ensure the safety and effectiveness of LDTs while allowing for innovation to diagnose and treat complex diseases. During ongoing discussions, the ACR welcomes the opportunity to be a resource to the FDA. Please contact Amanda Grimm Wiegrefe, MScHSRA, Director of Regulatory Affairs, at awiegrefe@rheumatology.org should you have any questions or need clarification.

Sincerely,



Christopher Phillips, MD
Chair, ACR Committee on Rheumatologic Care