AMERICAN COLLEGE of RHEUMATOLOGY
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April 3, 2024

The Honorable Bill Cassidy, MD
Ranking Member, Health, Education, Labor & Pensions Committee
455 Dirksen Senate Office Building
Washington, D.C. 20510

Submitted electronically via diagnostics@help.senate.gov

Dear Senator Cassidy:

On behalf of the 8,500 American College of Rheumatology (ACR) members, I write to provide comments in response to your Request for Information on the Food and Drug Administration's (FDA) proposed regulatory approach to clinical diagnostics. The ACR appreciates the opportunity to provide our feedback on the value that laboratory developed tests (LDT) bring to the high quality of care we provide our patients. More specifically, we welcome the opportunity to share our expertise regarding the potential impact that the FDA's proposed changes to the LDT regulatory framework will have on our ability to provide care to the 50 million Americans with rheumatic diseases.

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. The ACR offers responses to the following questions:

FDA Regulatory Framework for Diagnostics

Do the proposed reforms to the FDA's device framework warrant the establishment of a new regulatory pathway specific to diagnostics? If yes, what are the principles that should guide such a new framework, as it would be applied to diagnostics currently subject to FDA premarket review?

LDTs play a central role in the practice of rheumatology. The ACR supports access to reliable and patient-centered laboratory testing to optimize the diagnosis and monitoring of patients with conditions diagnosed and treated by rheumatologists. Formal diagnostic and classification criteria, as well as clinical practice, rely on routine laboratory tests (such as complete blood counts and chemistry panels) and specialized tests (such as autoantibody and genetic tests for autoinflammatory conditions). LDTs are also used as prognostic markers to monitor response to treatment, as adjuncts to assess disease activity, to predict the risk of toxicity of treatments, and to monitor the toxicity of medications. In some instances, measurement of drug levels or anti-drug antibodies may help to adjust the choice or dose of a medication.

However, while the ACR strongly advocates for patients to have quick and easy access to diagnostic treatments, we also recognize that LDTs have become ubiquitous in healthcare settings and that the development of accurate and clinically meaningful LDTs is crucial to supporting advances in rheumatological care. As such, we recognize that LDTs need appropriate regulatory scrutiny. However, we strongly caution that the FDA's proposed four-year implementation timeline may create regulatory uncertainty and thus impede the innovation of future testing and create significant barriers to access to care.

The ACR encourages legislators and regulators to consider that patient care can be negatively impacted not just by unsafe and inaccurate LDTs, but also by the lack of availability of LDTs that could positively impact patients with existing medical needs. A goal of legislative and regulatory efforts is to identify an optimal balance to protect patient safety and not deny access to diagnostic services due to cost, process, and/or timing issues associated with LDT submissions and reviews. We urge the FDA and lawmakers to work with the ACR and other stakeholders to better understand any barriers to care that increased regulatory requirements may have on patients accessing tests that assist in diagnosing and treating diseases, particularly rheumatic diseases. Specifically, we strongly encourage the FDA to continue applying enforcement discretion to LDTs developed in academic or non-profit labs that perform local and national tests, as well as LDTs that only impact a small footprint of patients.[1] We also encourage the FDA to apply enforcement discretion to novel, pre-market LDTs that show encouraging results in clinical trials and are uniquely offered to patients by a small handful of labs.

In conclusion, LDTs are a vital tool in our fight against the complex and often devastating rheumatic diseases facing our patients and their families. As such, we look forward to working with you and other members of Congress to explore ways in which regulation and legislation can adequately ensure that patients are not denied access to safe and effective LDTs. Please contact Colby Tiner, M.A., Manager of Regulatory Affairs, at ctiner@rheumatology.org with any questions you may have.

Sincerely,

Christopher Phillips, MD
Chair, Committee on Rheumatologic Care
American College of Rheumatology

[1] https://omrf.org/research-faculty/core-facilities/clinical-immunology-laboratory/