COLLEGE of AMERICAN PATHOLOGISTS

February 25, 2025

The Honorable Dan Crenshaw
U.S. House of Representatives
248 Cannon House Office Building
Washington, D.C. 20515

The Honorable Brad Finstad
U.S. House of Representatives
2418 Rayburn House Office Building
Washington, D.C. 20515

Dear Representatives Crenshaw and Finstad,

The College of American Pathologists (CAP) strongly supports H.R. 1463, the Freedom for Laboratory Innovation and Testing Act, legislation that would prohibit funding for the implementation, administration, or enforcement of the U.S. Food and Drug Administration's (FDA) final rule relating to "Medical Devices; Laboratory Developed Tests" (LDTs). The CAP shares your concerns regarding the onerous FDA LDT regulation because of its impact on patient access to critically important diagnostic tests as well as the extraordinary costs and burdens associated with its implementation that will hinder innovation and the development of LDTs.

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. As physicians specializing in the diagnosis of disease through laboratory methods, pathologists have a long track record of delivering high quality diagnostic services to patients and other physicians.

CAP members are concerned that the LDT rule will impact tens of thousands of safe and effective tests and result in pathologists no longer being able to offer local, high-quality tests. Such tests include: (1) in-house blood tests used to determine whether patients with non-small cell lung cancer could benefit from targeted therapies, (2) immunohistochemistry tests that assist in the diagnosis and classification of essentially all cancers, (3) tests to diagnose rare pediatric diseases, and (4) tests to monitor disease response to therapies. As a result, the rule would extensively delay diagnoses and treatment of many diseases for a full spectrum of patients.

We agree with your assessment, as noted in your February 21, 2025, letter to the Department of Health and Human Services Secretary Robert F. Kennedy Jr., that the rule has widespread apprehension and opposition. The rule has the potential to impact innovation, access to testing, research, and other economic areas. The CAP opposes the rule because it would reduce the number of highly accurate LDTs available to patients.

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The CAP appreciates your leadership on this issue. We look forward to working with you to support passage of H.R 1463. Please contact Michael Hurlbut at mhurlbu@cap.org if you have any questions or to coordinate efforts on this issue.

Sincerely,

Donald S. Karcher, MD, FCAP
President

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