



COLLEGE of AMERICAN PATHOLOGISTS

February 14, 2025

Secretary Robert F. Kennedy, Jr.
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Kennedy,

On behalf of the members of the College of American Pathologists (CAP), we congratulate you on your confirmation as the Secretary of the Department of Health and Human Services. We look forward to working with the Trump Administration on policy and regulatory issues impacting the delivery of high-quality diagnostic services to patients. 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 deliver high quality diagnostic services to patients and other physicians. For almost 80 years, the CAP has been the advocate for pathologists, patients, and the public when it comes to improving laboratory quality and assuring that patients receive the right test, at the right time, and with the right result.

We look forward to working with the Trump Administration to reduce regulatory burdens, make government more efficient and improve our nation's health. To that end, the CAP urges the Trump Administration to rescind the Food and Drug Administration's (FDA's) proposed regulation of laboratory-developed tests (LDTs) and work with Congress to enact legislation establishing a regulatory framework uniquely tailored for LDTs. We are concerned about the FDA rule for several reasons – most importantly because of its impact on patient access to critically important diagnostic tests, the timeline for implementation, it may not address the intent of improving patient safety, and the unsustainable costs to laboratories that will hinder the development of LDTs.

We request a meeting with you to discuss this important issue, and the CAP's other priority items included in our attached memorandum. We look forward to working with the Trump Administration on important issues impacting the delivery of high-quality diagnostic services to patients.

Sincerely,

Donald Karcher, MD, FCAP
President, College of American Pathologists