



## COLLEGE of AMERICAN PATHOLOGISTS

---

April 16, 2025

The Honorable Martin A. Makary, MD, MPH  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Makary,

On behalf of the members of the College of American Pathologists (CAP), congratulations on becoming Commissioner of the Food and Drug Administration (FDA). We look forward to working with you to streamline federal regulation, while protecting the public's health and maintaining access to high-quality health care services across the health care continuum, i.e., prevention, diagnosis, treatment, palliation, and death. The CAP looks forward to continuing to work closely with FDA in several areas, including diagnostic devices, in vitro device approvals, medical device shortages, device labeling, digital pathology tools, and other topics affecting pathologists and laboratories.

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. Our members have extensive expertise in using the medical devices and products that the FDA reviews and monitors. Pathologists and laboratory professionals rely on the FDA's timely, evidence-based reviews to ensure that clinicians and patients have access to the right test for the right patient at the right time. We are eager to work with you to ensure that the FDA preserves its high-quality review and monitoring standards, especially during this time of transition.

The CAP serves as one of the largest laboratory accreditors and proficiency testers under the Clinical Laboratory Improvement Amendments (CLIA) regulations, which require compliance with requirements through a quality system approach for overall operations and administration of the clinical laboratory. The world's foremost experts and critical pathology thought leaders with special expertise in laboratory medicine donate thousands of volunteer hours each year to our organization. We are happy to bring this expertise to the FDA to collaborate in and contribute to your important work.

Pathologists serve as directors of complex CLIA-certified laboratories and research laboratories. They have responsibility for the selection, verification, integration, and monitoring of laboratory tests. Pathologists also play a critical role in surveillance and public health. The FDA's public health role is essential – particularly with the growing threats in our country from the measles, avian influenza, and other infectious diseases. We value your background and training as a physician and health care researcher. We believe you will use this training and experience to make evidence-based decisions at the FDA, as you seek to implement a more efficient and effective government.

We also want to draw your attention to the rapidly emerging role of artificial intelligence (AI) in the health care industry. The engagement of pathologists in AI-enabled laboratory services is essential. In their leadership role in clinical and anatomic pathology laboratories, pathologists develop, evaluate, deploy, and configure technology. As experienced clinicians, we ensure that technology improves patient diagnosis, and we work quickly to address any risks to patient safety that may arise. Through our federally certified CAP Accreditation and Proficiency Testing Programs, we rigorously review laboratories to ensure that they are delivering high-quality testing services. Transparent



## COLLEGE of AMERICAN PATHOLOGISTS

---

information from manufacturers of technology – especially that which involves AI – is vital to ensure that laboratories and CAP accreditors understand appropriate clinical use of these devices.

We look forward to working with you to ensure patient access to high-quality, evidence-based diagnostic testing and transparent information in AI technology. We would appreciate meeting with you to discuss these issues. Please contact Helena Duncan, Senior Director of Quality (hduncan@cap.org, 202-354-7131) to schedule a meeting.

Sincerely,

Donald S. Karcher, MD, FCAP  
President