COLLEGE of AMERICAN PATHOLOGISTS

November 19, 2024

Linda McMahon, Co-chair
Howard Lutnick, Co-chair
Transition Team, President-elect Donald J. Trump

Re: Federal regulation of laboratory-developed tests

Dear Co-chairs McMahon and Lutnick,

On behalf of the members of the College of American Pathologists (CAP), we congratulate President-elect Donald J. Trump on his victory in the 2024 presidential election. We look forward to working with the Trump Administration on policy and regulatory issues impacting the delivery of high-quality diagnostic services to patients. At this time, the CAP's highest priority concern relates to the Food and Drug Administration's (FDA's) proposed regulation of laboratory-developed tests (LDTs). The CAP urges the Trump Administration to rescind the regulation and work with Congress to enact legislation to establish a regulatory framework at the FDA uniquely tailored to diagnostic tests.

We are concerned about the final version of the FDA rule for several reasons – most importantly – because of its impact on patient access to critically important diagnostic tests. We are also concerned about the timeline for implementation and the unsustainable costs that will hinder the development of LDTs. Pathologists and laboratories fear these regulatory restrictions from the FDA will make it difficult for laboratories to continue to develop and provide LDTs and, thus, impair and delay the diagnosis of disease and treatment of patients.

The CAP's position on LDTs is guided by what is in the best interest of patients. Many patient advocates strongly support FDA oversight of LDTs because of medical decisions being made based on the results of LDTs, as well as the risks associated with some extraordinarily complex LDTs the quality of which is difficult to impossible to independently verify. The CAP has sought to focus FDA oversight on those high-risk LDTs, while allowing lower-risk tests to meet significantly more limited oversight requirements. Striking such a balance would protect patients and allow innovative tests to continue to be developed under an oversight framework that is the least burdensome for laboratories.

For over a decade, the CAP has advocated for the adoption of a new statutory framework for LDT regulation that would enhance patient safety, maintain quality laboratory testing, and promote innovation without creating unnecessary regulatory burdens on pathologists, clinical laboratories, and other professionals involved in laboratory testing. Most recently, the CAP has supported proposed legislation, the Verifying Accurate Leading-edge IVCT Development Act of 2023, H.R. 2369 (the VALID Act), which would create a three-tiered risk-based system, expressly authorizing FDA to regulate high-risk LDTs, while leveraging existing structures to improve and promote patient safety.

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At the same time, the CAP has opposed proposals that would vest CMS with exclusive jurisdiction over LDTs. CMS currently oversees laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). However, CLIA does not regulate the scientific principles behind, or the clinical validity of, laboratory tests and the CMS does not have the expertise to ensure these tests work clinically. Rather than expanding CMS's oversight under CLIA, the CAP believes that a proper framework for LDT regulation in the future would involve both FDA and CMS. Under such a framework, Congress would allocate authority between the agencies, considering FDA's expertise in ensuring the effectiveness and safety of highly complex tests and CMS's expertise in overseeing general laboratory operations.

Through CLIA, CMS establishes the quality standards for all laboratory testing to help ensure the accuracy, reliability, and timeliness of patient test results. CLIA needs periodic targeted regulatory updates to keep pace with recent technology – not a broad, disruptive legislative overhaul that would threaten patient access to clinical laboratory tests. Re-opening CLIA legislatively could have far-reaching and unintended consequences that could undermine the framework under which all clinical laboratory testing is done in the U.S. In particular, CLIA modernization legislation could have a disastrous effect on community laboratories and those serving rural areas where new unfunded mandates and regulatory burdens could threaten to close laboratories.

The College of American Pathologists (CAP) is the world's largest organization of Board-certified pathologists and the leading provider of laboratory accreditation and proficiency testing programs. Founded in 1946, the CAP represents licensed, Board-certified physicians, with over 18,000 members who specialize in diagnosing the causes and effects of disease through laboratory methods. They practice clinical and/or anatomic pathology in community hospitals, independent laboratories, academic medical centers, and federal and state health facilities.

We appreciate your attention to this important issue. We look forward to working with the Trump Administration on this and many other important issues impacting the delivery of high-quality diagnostic services to patients. We welcome your questions or request to discuss this issue. Please contact Kristin McDonald, the CAP's Vice President for Advocacy and Policy, at kmcdona@cap.org or 202.354.7120 to arrange a meeting time.

Sincerely,

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

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