COLLEGE of AMERICAN PATHOLOGISTS

November 20, 2024

The Honorable Chuck Schumer
Majority Leader
United States Senate
322 Hart SOB
Washington, DC 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
317 Russell SOB
Washington, DC 20510

The Honorable Mike Johnson
Speaker
United States House of Representatives
568 Cannon HOB
Washington, DC 20515

The Honorable Hakeen Jeffries
Minority Leader
United States House of Representatives
2433 Rayburn HOB
Washington, DC 20515

Dear Leader Schumer, Speaker Johnson, Minority Leaders McConnell and Jeffries,

As the end of the 118th Congress approaches, the College of American Pathologists (CAP) urges you to include legislation in an end-of-year package preventing the implementation of the U.S. Food and Drug Administration's (FDA) "Medical Devices; Laboratory Developed Tests" final rule.

The FDA's final rule, published on April 29, 2024, goes far beyond the necessary approach for federal oversight of LDTs. The CAP does not support the FDA moving forward with the rule's regulatory oversight plan. If enacted, the rule would reduce the number of highly accurate LDTs available to patients and further delay timely patient care.

Currently, the FDA regulates laboratory tests under the authority of the Food, Drug and Cosmetic Act Amendments of 1976 and intends, under the final rule, to regulate LDTs as "medical devices." Historically, the FDA has not regulated LDTs under its enforcement discretion policy because LDTs were created and performed manually by laboratory personnel. While the vast majority of LDTs are safe, well-characterized, and have been used for decades, some of these tests are complex and often marketed nationwide, requiring greater oversight by the FDA. Therefore, the CAP believes these changing circumstances necessitate proper but balanced oversight of LDTs.

For example, the CAP has heard from pathologists in Oregon operating a robust multidisciplinary lung cancer program that the final rule will force them to abandon (1) in-house blood tests used to determine whether patients with non-small cell lung cancer could benefit from targeted therapies and (2) immunohistochemistry tests that assist in the diagnosis and classification of essentially all cancers. The CAP's members explained that these restrictions would extensively delay diagnoses and treatment of cancers because tissue and blood samples would have to be sent out to large commercial laboratories capable of absorbing the final rule's immense compliance costs. Similarly, CAP members in Puerto Rico have noted that the final rule will require them to send samples to the mainland, delaying treatment and resulting in massive bills for patients. Those delays and

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increased health care costs will impair local laboratory operations and may cost some patients their lives.

Since 2009, the CAP has advocated for a reasonable and balanced regulatory framework that would ensure quality laboratory testing for patients and minimize the regulatory burden on laboratories while allowing for continued innovation in laboratory testing. The CAP supports (1) a three-tiered risk-based system, which would focus the FDA's resources on high-risk tests, while leveraging existing structures to improve and promote patient safety with lower-risk tests; (2) the use of mitigating measures for the further down-classification of test risk; and (3) exemptions for rare diseases and unmet clinical needs.

To that end, the CAP asks that legislation be passed, before the end of the year, to prevent implementation of this harmful rule. Congress must intervene to ensure regulatory certainty and avoid disruption of patient access to life saving and life preserving diagnostics. Thank you for your attention to this important issue, and please do not hesitate to contact Michael Hurlbut, mhurlbu@cap.org, for additional information.

Sincerely,

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President

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