

November 21, 2024

Howard Lutnick, Co-Chair
President-elect Donald J. Trump's Transition
Team
Washington, DC

Linda McMahon, Co-Chair
President-elect Donald J. Trump's Transition
Team
Washington, DC

Submitted electronically

Dear Mr. Lutnick and Ms. McMahon,

The undersigned organizations — the American Clinical Laboratory Association (ACLA), the American Association of Bioanalysts and its division the National Independent Laboratory Association, the American Society for Clinical Pathology, the American Society for Microbiology, the Association for Diagnostics & Laboratory Medicine, and the Infectious Diseases Society of America — congratulate President-elect Trump and Vice President-elect Vance on their election victory. These organizations collectively represent the nation's leading clinical laboratories, laboratory directors, analysts, pathologists, and other physicians and laboratory professionals. We are committed to working with the new Administration and leadership in Congress to advance the delivery of essential diagnostic health information to patients and providers.

As you know, in May 2024, the US Food and Drug Administration (FDA) finalized a rule that imposes on clinical laboratories new regulations that threaten to undermine a critical pillar of our health care system. Specifically, FDA finalized a rule that subjects laboratory developed testing services — often referred to as “LDTs” — to new federal regulation by FDA as medical devices.¹ We urge the new Administration to withdraw this misguided and unlawful rule.

Subjecting laboratory developed testing services to medical device regulation is a clear example of regulatory overreach. Without statutory authority and ignoring the far-reaching damage the new regulations will cause, FDA chose to jam a new rule through the regulatory process in a matter of months, which is highly unusual for a rule of this significance. The new rule undermines laboratories and laboratory professionals and interferes with their ability to develop and offer innovative diagnostic services for patients. Numerous aspects of medical device law — from basic approval standards to labeling and quality system requirements — do not fit laboratory developed testing services. Furthermore, the costs of compliance with this new rule are causing and will continue to cause laboratories to divert resources from the development of the next generation of diagnostics for cancer, infectious disease, cardiovascular disease, neurology, and numerous other diseases and conditions, including rare diseases. The rule will reduce patient access to laboratory developed testing services, including diagnostics for which there is no existing alternative.

Laboratories have delivered groundbreaking innovations that shifted the standard of care for diagnosis and treatment of important diseases, and they have been the first to respond to emerging public health threats. Rather than credit laboratories with these contributions to public health, FDA chose to justify its action by disparaging laboratory developed testing services through cherry-picked studies and unconfirmed allegations in lawsuits and the media. It is

¹ See *Final Rule, Medical Devices; Laboratory Developed Tests*, 89 Fed. Reg. 37286 (May 6, 2024).

disappointing that FDA took this flawed, rushed, and unilateral approach. FDA's actions may undermine patient trust in laboratory testing, a cornerstone of our health care system.

Even putting aside the rule's many policy flaws, more fundamentally, the rule is illegal. Laboratory developed testing services are not devices, they are professional services. Congress assigned the regulation of clinical laboratories and the tests they develop to the Centers for Medicare and Medicaid Services (CMS), not FDA, under a different regulatory system. For these and other reasons, ACLA has been forced to file a lawsuit challenging this regulation in federal court, which is currently pending. See *ACLA v. Becerra*, Case No. 4:24-cv-479-SDJ (E.D. Tex). The other undersigned organizations joined together in an *amicus* brief in support of the ACLA lawsuit. ACLA's lawsuit is consistent with the memorandum issued by Robert Charrow, then-General Counsel of the Department of Health and Human Services, in June 2020, which recognized that laboratory developed tests are not "goods or commodities" but rather "clinical laboratory services" analogous to a "doctor's development and use of a medical procedure." That memorandum rejected many of the key premises on which FDA's rule relies and expressed significant doubts regarding FDA's authority to regulate laboratory developed testing services as devices.

Although it is our strong belief that the ACLA lawsuit will result in the rule being invalidated, FDA nevertheless should withdraw the rule. Withdrawing the rule would signal that FDA's prior characterization of laboratory testing services was inaccurate and help undo the damage that the final rule is causing. Moreover, given the timelines (coupled with FDA's failure to provide meaningful guidance on myriad implementation issues), laboratories are already being forced to divert scarce resources to comply with this misguided rule. Withdrawing the rule would align with the President-elect's pledge to reduce unnecessary and counterproductive regulatory burdens. An announcement by the new Administration that it does not intend to go forward with FDA's final rule would demonstrate the new Administration's commitment to a responsible regulatory approach and allow laboratories to focus fully on their highest priority – serving patients.

For these reasons, we respectfully request that on Day 1 the new Administration announce that it does not intend to enforce compliance with the final rule, and thereafter begin a regulatory process to formally withdraw the rule.

Thank you for your attention to this important matter. We would be pleased to meet with the Transition Team to discuss these issues further. Please feel free to contact Susan Van Meter, ACLA, at any time at svanmeter@acla.com or 202.637.4865.

Sincerely,

American Association of Bioanalysts,/ National Independent Laboratory Association

American Clinical Laboratory Association

American Society for Clinical Pathology

American Society for Microbiology

Association for Diagnostics & Laboratory Medicine

Infectious Diseases Society of America