November 20, 2024

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

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

Subject: Revocation of FDA's May 6, 2024 rule on LDTs

Dear Ms. McMahon and Mr. Lutnick:

The Association for Diagnostics & Laboratory Medicine (ADLM) congratulates President-elect Donald J. Trump on his election as our nation's Chief Executive. During his earlier administration, we worked closely with his staff during the COVID pandemic, serving on National Testing Implementation Forum, offering insights and guidance on how to address testing issues. We look forward to working with the President-elect and his staff again.

ADLM wants to bring to your attention a rule promulgated by the Food and Drug Administration (FDA), which will have far-reaching effects on the ability of clinical laboratories to provide vital testing to patients, particularly children and those living in rural areas. On May 6th, the FDA issued a final rule (Docket No. FDA-2023-N-2177) that extends its oversight to laboratory developed tests (LDTs), which are already regulated by the Centers for Medicare and Medicaid services (CMS) under the longstanding CLIA regulations. This final rule represents an administrative overreach beyond what Congress intended, duplicates existing federal regulations, and adds new expenses to clinical laboratories. We encourage you to repeal the final rule.

Association for Diagnostics & Laboratory Medicine (ADLM) urges you to revoke this costly and duplicative rule and permit Congress to address this issue as part of CLIA modernization.

This rule, if implemented, would regulate laboratories, including hospital laboratories, that develop LDTs as if they are medical device manufacturers, failing to recognize the difference between the two sectors - manufacturers develop and sell their devices to anyone, whereas laboratories only develop LDTs for their patients at the request of an ordering physician. It was this process that allowed laboratories to develop the LDTs that were vital to addressing the COVID crisis.

During President-elect Trump's first term, HHS prevented the FDA from advancing this LDT policy. In fact, after his election in 2016, the agency revoked guidance to oversee LDTs stating it would leave the issue to Congress. When Congress refused to give the FDA explicit authority in 2022 over LDTs, the agency claimed it already had such authority and fast-tracked a final rule to make sure it was promulgated before the 2024 election.

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ADLM is concerned that if this rule is implemented it will:

- Hinder the development of new LDTs, which are critical to advancing care;
- Significantly increase the administrative and compliance costs associated with LDT testing, thus forcing laboratories to reduce or eliminate LDTs from their test menu; and
- Duplicate existing federal regulation that already governs the development and use of LDTs.

To this day, the FDA still has not demonstrated that there is a problem to fix - the data provided by the agency is limited and of questionable value. Revoking this rule, which lacks statutory authority, would preserve patient access to these tests, while giving Congress the opportunity to explore the issue and determine whether changes are needed.

We look forward to working with you on this important issue. If you have any questions, please email Vince Stine, PhD, ADLM's Senior Director of Government and Global Affairs, at vstine@myadlm.org, Or Evan Fortman, MPA, ADLM's Manager of Government Affairs at efortman@myadlm.org.

Sincerely,

Anthony A. Killeen, MD, MSc, PhD
President, ADLM