ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

6120 Executive Boulevard, Suite 700, Rockville, Maryland, 20852

25 February 2025

Robert F. Kennedy Jr.
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Kennedy:

On behalf of the Association for Molecular Pathology, I am writing to bring to your attention a very expensive and problematic final rule[1] recently finalized by the U.S. Food and Drug Administration (FDA) that imposes existing medical device regulations on laboratory developed testing procedures (LDTs). This harmful and wasteful rule was hastily developed and finalized during the last Administration and marks a significant shift in how hundreds of thousands of LDTs are regulated, with far-reaching impacts on patients, healthcare providers, and laboratories. The rule has exorbitant costs to the government and the healthcare system and will likely result in increased costs to patients and a massive consolidation of clinical laboratories and tests, threatening patient access and diminishing the development of lifesaving innovations. Further, the rule is in direct conflict with statutory authority granted by the Food and Drug Cosmetic Act and the Clinical Laboratory Improvement Amendments (CLIA). For these reasons and, in light of the recent Executive Order on Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative[2], we strongly urge you to rescind this rule.

During President Trump's first term, the Department of Health and Human Services (HHS) blocked the FDA from moving forward with its planned policy to move oversight and authority of LDTs from the HHS CLIA program to the FDA. The FDA then withdrew its guidance for regulating LDTs, stating that it would defer to Congress on the matter. When Congress declined to grant the FDA explicit authority over LDTs in 2022, the agency asserted that it already possessed the necessary authority and expedited the finalization of a rule to ensure its implementation before the 2024 election.

LDTs are professional clinical testing services used as part of the care for patients provided by highly-trained physicians and doctoral professionals in hospitals, academic, public health, and dedicated clinical laboratories. They are not commercially manufactured and marketed, but rather are professional services designed, developed, validated, performed, and interpreted by board-

[1] https://www.federalregister.gov/documents/2024/05/06/2024-08935/medical-devices-laboratory-developed-tests
[2] https://www.whitehouse.gov/presidential-actions/2025/02/ensuring-lawful-governance-and-implementing-the-presidents-department-of-government-efficiency-regulatory-initiative/?source=email

certified professionals in a single laboratory. LDTs are often created in response to unmet clinical needs and are instrumental for disease prevention, early and precise diagnosis, or monitoring and guidance of patient treatment, including for cancer, cardiovascular disease, pediatric illnesses, infectious diseases, and more.

By issuing the rule, the FDA has acted arbitrarily and capriciously to impose its regulations upon laboratory services, treating them as medical devices and healthcare providers as manufacturers. The rule will subject LDTs to costly and slow premarket review and inappropriate or duplicative requirements pertaining to package labeling, manufacturing quality control, and product recall. These requirements are ill-suited for laboratory services, which are validated processes that rely upon expertise-driven oversight and analysis that factors in patient needs and evolving and variable clinical contexts. Moreover, the implementation of the rule is an upheaval of the lang-standing, successful regulatory approach through the Clinical Laboratory Improvement Amendments (CLIA) program administered by the Centers for Medicare and Medicaid Services (CMS), which focuses on continual quality assurance, personnel qualifications, and testing accuracy, ensuring patient safety without the inappropriate constraints of medical device regulations. CLIA is cost-effective and uses the significant expertise of third-party organizations, who are involved in accrediting and inspecting laboratories as well as conducting proficiency testing multiple times a year for each laboratory.

If the FDA's final rule is not rescinded, it will drastically impact patient care and innovation and raise costs. FDA itself estimates that the total recurring costs to the agency and laboratories across the nation could be $4.54 billion *each year*.[3] This enormous number highlights the financial burden of the rule, and unfortunately, it is likely a significant underestimation of the impact. Moreover, according to FDA's own estimates, over 90% of affected laboratories are small businesses. Most clinical laboratories offering LDTs are estimated to have average annual receipts of roughly $4 million—comparable to the cost of a *single* premarket review submission. In other words, taking even a single LDT through the premarket review pathway at the FDA is unsustainable for the vast majority of clinical laboratories. This financial burden will force laboratories to prioritize economic viability over patient care, undermining the ability to quickly adapt clinical testing methods to the latest scientific advances. Many laboratory professionals will be forced to stop providing patients with cutting-edge medical care and abandon ongoing efforts to develop necessary and innovative LDTs. Alternatively, many laboratories may have to declare bankruptcy trying to comply with FDA's new mandates—leading to significant job losses in the pathology profession, driving future doctors into other fields, reducing training opportunities, and further exacerbating the ongoing shortage of pathologists in the United States. This is not the future we envision for a field so crucial to medical care, prevention, disease screening, and response to infectious disease outbreaks.

In summary, AMP is deeply concerned that the FDA's rule is not the right path forward as it threatens the stability of the laboratory sector and its workforce. AMP and other concerned stakeholders request a meeting with Secretary Kennedy to discuss this issue in further detail. We maintain that FDA does not have the statutory authority to regulate LDTs as medical devices under

[3] https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/laboratory-developed-tests-regulatory-impact-analysis-final-rule

the Federal Food, Drug, and Cosmetic Act. Therefore, in alignment with the recent Executive Order, we strongly urge you to instruct the FDA to delay implementation of the final rule, consider rulemaking to rescind the rule in its entirety, and work with your colleagues in Congress, in collaboration with the laboratory community, to craft a modernized framework that fosters innovation and supports patient care.

Sincerely,

Jane S. Gibson, PhD

President, Association for Molecular Pathology

CC:

Joel Zinberg, Special Assistant to the President for Health Care and Deregulation Economic Policy for National Economic Council

Rachel Riley, Senior Advisor, Assistant Secretary for Administration, the Department of Health and Human Services

Department of Government Efficiency