**ASSOCIATION FOR MOLECULAR PATHOLOGY**

*Providing global expertise in molecular testing that drives patient care*

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

May 12, 2025

Russell T. Vought
Director
Office of Management and Budget
Executive Office of the President
725 17th Street NW
Washington, DC 20503

Dear Director Vought,

Thank you for the opportunity to respond to the Office of Management and Budget (OMB) Request for Information (RFI) soliciting ideas for deregulation. The Association for Molecular Pathology (AMP) recommends that the government rescind 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). AMP is an international medical and professional association representing approximately 3,100 physicians, doctoral scientists, and medical technologists involved with laboratory testing based on knowledge derived from molecular biology, microbiology, genetics, and genomics. Our membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry. The FDA's final rule on LDTs would treat our members, i.e. health professionals, as manufacturers and the medical procedures and services they provide as medical devices. This would not only interfere with the practice of medicine and reduce patient access to life-saving laboratory testing, but also dramatically slow innovation in diagnostics and precision medicine more broadly.

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

***FDA is Acting Arbitrarily and Capriciously***

By issuing the rule during the last administration, the FDA has acted arbitrarily and capriciously to impose its regulations upon laboratory services, treating them as medical devices and healthcare providers as manufacturers. It would subject LDTs to costly and slow premarket review and inappropriate or duplicative requirements pertaining to package labeling, manufacturing quality

[1] https://www.federalregister.gov/documents/2024/05/06/2024-08935/medical-devices-laboratory-developed-tests

control, and product recall. These requirements are ill-suited for laboratory services, which are dynamic processes that rely upon expertise-driven oversight and analysis that factor in patient needs and evolving and variable clinical contexts. Moreover, the implementation of the rule is an upheaval of the current successful and efficient 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. This program is cost-effective and leverages 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.

***FDA's Final Rule is Costly and Burdensome***

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*.[2] Over the next twenty years, FDA projects total costs associated with the rule will range from $12.57 billion to $78.99 billion.[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. This financial burden will force laboratories to prioritize economic viability over patient care, undermining the ability to quickly adapt 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 innovative LDTs. Alternatively, many will 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.

***FDA's Final Rule Violates Executive Order # 14219***

AMP believes that the FDA's final rule on LDTs is in direct conflict with President Trump's recent Executive Order on Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative.[4] 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, the healthcare

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

[3] Ibid.

[4] Ibid.

system, and industry, and will likely result in a massive consolidation of clinical laboratories and tests, threatening patient access and chilling the development of lifesaving innovations. Further, the FDA's final rule on LDTs is in direct conflict with statutory authority granted by the Food and Drug Cosmetic Act (FDCA) and the Clinical Laboratory Improvement Amendments (CLIA).

The disruption to innovation in diagnostics and the practice of laboratory medicine was evident during 2020 as the country developed countermeasures to diagnose COVID-19. After the public health emergency declaration, FDA asserted its position over LDTs, requiring that all receive emergency use authorization from the FDA prior to being used clinically. This action halted testing in the US[5] and thankfully, the Trump Administration revoked the FDA's authority over LDTs enabling clinical laboratories to rapidly deploy much needed testing throughout the country.[6] If the FDA's final rule on LDTs were to be implemented, similar consequences would be experienced with testing for all clinical indications and the entire healthcare system would face limited testing options.

***FDA Exceeded its Statutory Authority***

AMP believes that the FDCA does not give FDA authority over LDTs and that Congress enacted CLIA to provide oversight over clinical laboratory services. The rule would be so damaging to our members' professional practice and the patients they serve, that AMP filed a lawsuit challenging the rule. I am proud to report that on March 31, 2025, U.S. District Court Judge Sean D. Jordan issued a ruling vacating the final rule. As part of his opinion, he wrote:

> *Although the FDCA's text alone is enough to conclude that FDA lacks authority to regulate laboratory-developed test services as medical "devices," see supra Part IV.B, the broader statutory framework of the FDCA and CLIA, and the historical underpinnings of these laws, reinforces the conclusion that the final rule attempts to assert authority over professional medical services that FDA lacks.*[7]

The HHS General Counsel in President Trump's first term, Congress, and U.S. District Court Judge Jordan all concur that the FDA's final rule on LDTs is not only a costly, damaging regulation, but that it is a dramatic agency overreach from its statutory authority. Therefore, in alignment with the recent Executive Order focused on deregulation, we strongly urge you to instruct the FDA 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 within CLIA that fosters innovation and supports patient care.

Sincerely,

Jane S. Gibson, PhD

President, Association for Molecular Pathology

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[5] https://www.nytimes.com/2020/03/10/us/coronavirus-testing-delays.html

[6] https://www.fiercebiotech.com/medtech/trump-administration-revokes-fda-authority-over-lab-developed-tests-including-some-covid-19

[7] Civil No. 4:24-CV-824–SDJ, Association for Molecular Pathology et al. v. US Food and Drug Administration et al, Memorandum Opinion and Order