AMP Lawsuit Challenging FDA Final Rule on Medical Devices; Laboratory Tests

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Disclaimer

- AMP is providing this webinar for educational purposes only.
- If you need guidance or assistance with compliance with the FDA medical device regulations, AMP encourages you to seek out licensed counsel and/or certified regulatory affairs professionals.

Final Regulatory Change

Changes (in red) to 21 CFR 809.3

"In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and may also be biological products subject to section 351 of the Public Health Service Act, including when the manufacturer of these products is a laboratory."

Phase-Out Timeline

Stage 1: MDR, Correction and Removal Reporting, & Complaint file

May 6, 2025

Stage 2: Registration & Listing, Labeling, IDE

May 6, 2026

Stage 3: QSR, design controls, purchasing controls, acceptance activities, corrective and preventative actions, records requirements

May 6, 2027

Stage 4: Premarket approval required for high-risk IVDs

November 6, 2027

Stage 5: Premarket review required for all moderate and low risk IVDs; third party review allowed

May 6, 2028

MDUFA VI:
Negotiations begin

Late 2025-2026

MDUFA VI:
Performance goals and fees go into effect

Oct 1, 2027

For Stages 4 and 5, if completed application submitted, IVD may remain on the market while FDA completes review.

Continued Enforcement Discretion

Category of Test	Stage 1: MDR, Correction & Removal Reporting, Etc.	Stage 2: Registration & Listing, Labeling	Stage 3: QSR	Stage 4 & 5: Premarket Review
1976-Type LDTs: Includes LDTs involving (1) use of manual techniques (without automation) performed by laboratory personnel with specialized expertise; (2) use of components legally marketed for clinical use.	**Exempt**	**Exempt**	**Exempt**	**Exempt**
Human Leukocyte Antigen (HLA) LDTs for transplantation	**Exempt**	**Exempt**	**Exempt**	**Exempt**
Tests intended solely for forensic purposes	**Exempt**	**Exempt**	**Exempt**	**Exempt**
LDTs performed within the VHA or DoD	**Exempt**	**Exempt**	**Exempt**	**Exempt**

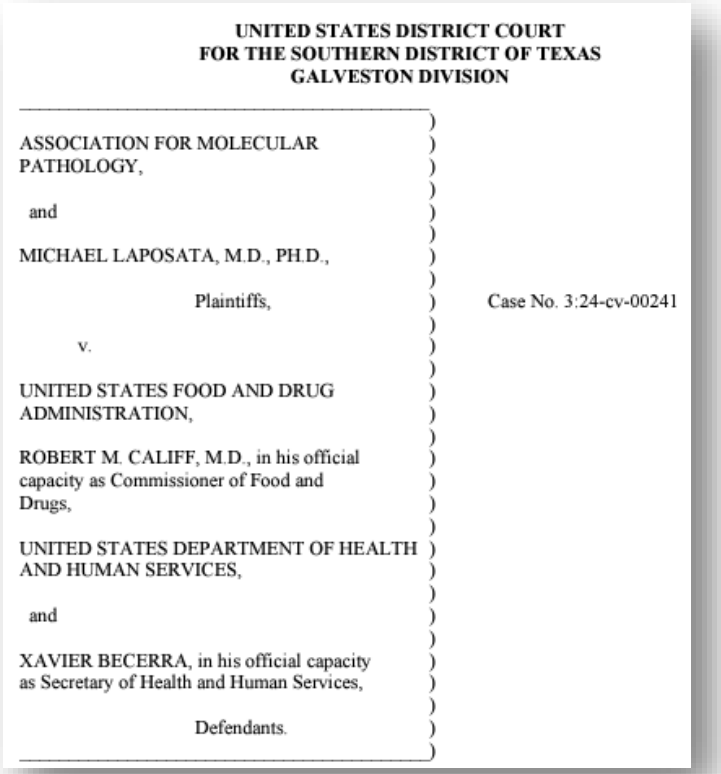
Continued Enforcement Discretion

Category of Test	Stage 1: MDR, Correction & Removal Reporting, Etc.	Stage 2: Registration & Listing, Labeling	Stage 3: QSR	Stage 4 & 5: Premarket Review
LDTs Approved by the NYS CLEP: Includes LDTs that are approved, conditionally approved, or within an approved exemption from full technical documentation	Required	Required	Required	**Exempt**
LDTs for unmet needs used in an integrated healthcare system	Required	Required	**Exempt**	**Exempt**
Currently marketed LDTs (prior to May 6, 2024)	Required	Required	**Exempt**	**Exempt**
Non-molecular antisera LDTs for rare red blood cell antigens	Required	Required	**Exempt**	**Exempt**

AMP Association for Molecular Pathology

Association for Molecular Pathology v. US Food and Drug Administration

- **Filing date:** August 19, 2024
- **Plaintiffs:** AMP & Dr. Michael Laposata
  - Dr. Laposata is a pathologist & AMP member
- **Location:**
  - Filed in Texas
  - Case will be heard in Eastern District Court



UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

ASSOCIATION FOR MOLECULAR PATHOLOGY,

and

MICHAEL LAPOSATA, M.D., PH.D.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

and

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,

Defendants.

Case No. 3:24-cv-00241

AMP's Complaint

- Congress chose not to grant FDA the authority to regulate LDTs as medical devices
  - Continues to deny FDA with regulatory authority (i.e., did not pass various pieces of legislation including VALID)
- **Instead, Congress passed CLIA**
- CLIA regulations ensure the quality of laboratories, their personnel, and the assays they perform
- CMS's regulations expressly authorize laboratories to (1) develop and perform LDTs that have not been cleared or approved by FDA and (2) to modify IVDs

AMP's Complaint

- LDTs are not products that are commercially distributed
- LDTs are protocols in medical practice
  - The final rule guts the practice of medicine exemption
- The harm of the final rule to laboratory professionals/patients/economy would be significant
  - up to $113.86 billion in one-time compliance costs & up to $14.31 billion in annual recurring costs
  - Laboratory consolidation; harms to small businesses
  - Significant negative impact on innovation, patient access, and supply chains

Supporting Materials: Declarations

Michael Laposata, MD PhD

12. It also will transform the practice of pathology, to the detriment of my own patients and millions of others. The very purpose of my profession and of my life's work is to improve my patients' health outcomes by diagnosing conditions after symptomatic presentation; identifying risk factors that can help us prevent symptoms from ever presenting; and ensuring that, once a patient is diagnosed or identified as being at risk, they can receive appropriate therapy. The Final Rule jeopardizes each part of my medical practice.

Rather than developing laboratory procedures based solely on patient need, as I currently do, my clinical decisionmaking will be subject to considerations of economic feasibility and regulatory burden. That is antithetical to my practice of medicine, my profession, and my values.

Supporting Materials: Declarations

Karen Kaul, MD, PhD

11. I am trained, board certified, and licensed clinically to perform this work, and am personally and professionally responsible for the accuracy and performance of these assays—just as other physicians are responsible for the clinical care of their patients.

22. All in all, the LDT Rule is already directly, immediately, and adversely affecting me, my colleagues, and thousands of other pathologists and laboratory professionals by fundamentally transforming the way we have been practicing medicine for decades—all under the duress of threatened criminal prosecution. And perhaps most important of all, it will severely harm our patients, by curtailing access to cutting-edge personalized medical care, stifling the innovation and adaptability at the heart of CLIA, impeding our ability to provide vital consultation to our physician colleagues, and delaying life-saving diagnostic services and patient treatment.

Supporting Materials: Declarations

Eric Konnick, MD, MS

13. The Final Rule's consequences will be devastating, both for me personally and for my patients. Given the extraordinary costs needed to comply with the FDA's new requirements for LDTs and the FDA's direct threats of criminal prosecution, I already have suspended the development and/or modification of numerous LDTs that were undergoing development and validation—in some cases for many years—because the extraordinary economic and compliance burdens imposed by the Final Rule will make it cost-prohibitive to pursue FDA clearance or approval for those LDTs. This has been particularly heart-breaking for me and my colleagues in the academic medical center context, where we frequently developed LDTs for rare cancers and other diseases or conditions even though the broader market demand for such procedures is highly limited and developing these procedures could not be commercially justified from a strict

Claims for Relief

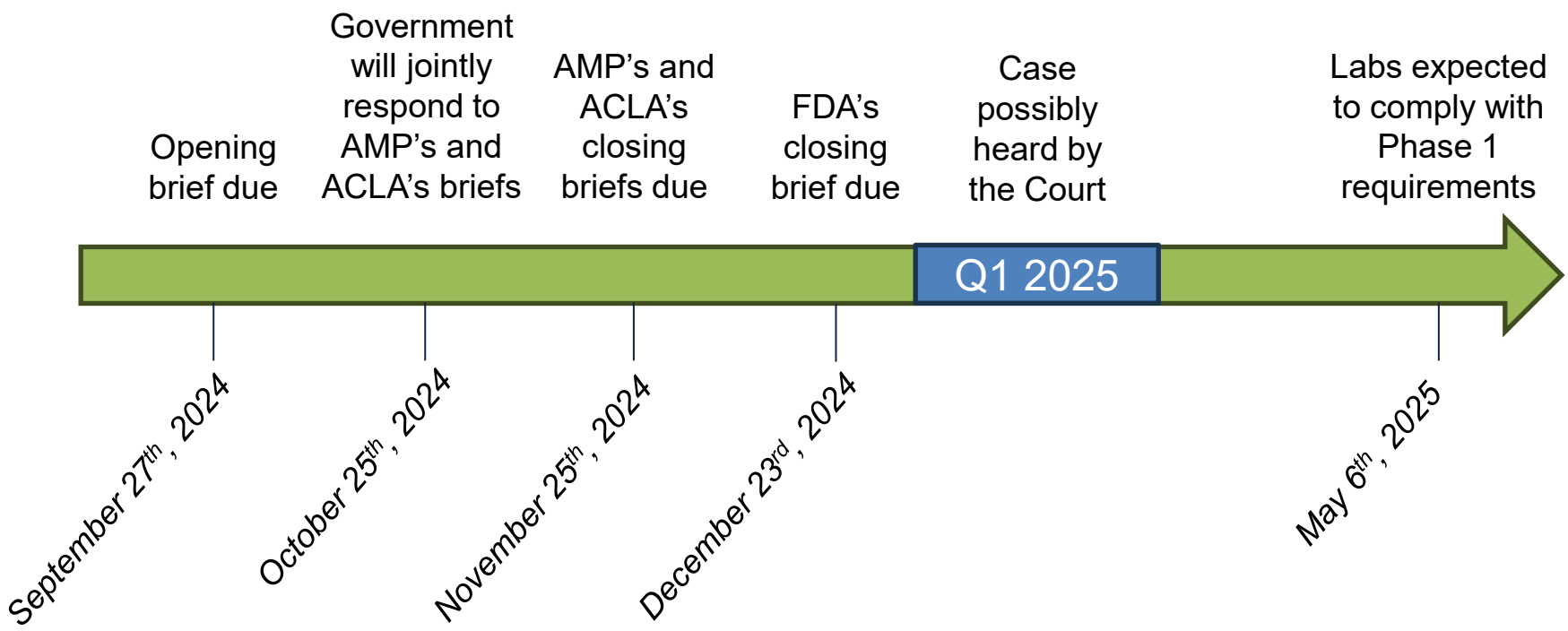
- The Administrative Procedure Act (APA) is a federal law that governs how federal agencies make and enforce rules, and how they interact with the public.
- FDA has violated the APA:
  - FDA's final rule is acting "not in accordance with the law"
  - FDA is acting in a way that is "arbitrary, capricious, [or] an abuse of discretion."

Request of the Court

- ***Declare*** the final rule is contrary to the law
- ***Vacate*** the final rule
- ***Enjoin*** FDA from taking any further action to enforce the rule

- After extensive consideration, AMP has not asked for a preliminary injunction

Tentative Timeline



AMP Survey on LDT Rule Impact

https://www.surveymonkey.com/r/AMP-FDARule

- **Goals**: Gain a better understanding of the impact of the FDA rule on clinical laboratory testing and operations, investigate laboratories' perceptions regarding future directions, & determine AMP resources that can be provided to assist members.
- **Audience**:
  - Lab directors; US-based labs; subject matter experts
  - Open to both AMP members and non-members

Questions?

Thank you!