

Administration Declines to Appeal FDA LDT Rule

After a federal judge struck down the Food and Drug Administration's (FDA) [Final Rule](#) on the regulation of Laboratory Developed Tests (LDTs) as medical devices on March 31st, the deadline for the Administration to appeal the ruling passed on May 31st. Passage of this deadline without the U.S. Department of Justice appealing the ruling represents a significant victory for ASHI and other clinical laboratory stakeholders across the country who have advocated against FDA regulation of LDTs for years. While the Administration has declined to appeal the ruling, the future of LDT regulation remains an open question, and ASHI is earnestly working to ensure our members are intimately involved and have an impactful voice in future policy debates. To that end, ASHI is working to determine whether the Administration plans to take any additional action with respect to LDT regulation and continues to engage with Congress regarding the possibility of future legislative initiatives now that defense of the FDA LDT Final Rule has been abandoned.

On June 5th, the Health Resources and Services Administration [announced](#) the new 34-member Board of Directors for the Organ Procurement and Transplantation Network (OPTN), including ASHI President Dr. Cathi Murphey's election as the Histocompatibility Representative. The newly elected Board of Directors will officially began their terms on July 1, 2025.

ASHI remains concerned over the Administration's decision to eliminate the Clinical Laboratory Improvements Advisory Committee (CLIAC) as part of the restructuring of the Department of Health and Human Services (HHS). CLIAC plays a critical role in advising the HHS secretary on issues related to clinical laboratory quality and laboratory medicine as well as specific questions related to possible revision of the Clinical Laboratory Improvement Amendments (CLIA) standards. ASHI recognizes the tremendous value CLIAC has added for decades and is exploring advocacy options to urge its reinstatement.