

Loper Bright Renews Interest in the VALID Act

A recent Supreme Court decision in *Loper Bright Enterprises v. Raimondo* has significant implications for the regulation of laboratory-developed tests (LDTs) by the U.S. Food and Drug Administration (FDA). The ruling overturned the long-standing Chevron doctrine, which previously required courts to defer to federal agencies' interpretation of ambiguous statutes. This decision may impact ongoing legal challenges to the FDA's final rule on regulating LDTs as devices, notably by the American Clinical Laboratory Association and the Association for Molecular Pathology.

Implications for FDA Authority

Historically, the FDA's authority to regulate LDTs has been unclear, as LDTs fall under the jurisdiction of the Centers for Medicare & Medicaid Services (CMS) via the Clinical Laboratory Improvement Amendments (CLIA), not the FDA. However, the FDA's new rule redefines LDTs as medical devices, thus extending its regulatory authority. In the past, courts would likely have deferred to the FDA's interpretation, but under the *Loper Bright* ruling, courts must now independently evaluate the agency's authority.

The VALID Act as a Legislative Solution

The *Loper Bright* decision has renewed interest in the Verifying Accurate Leading-edge IVCT Development (VALID) Act, which seeks to provide clear regulatory authority to the FDA over LDTs, creating a new category called In Vitro Clinical Tests (IVCTs). The VALID Act would replace the current framework for medical devices with a system that better aligns with the unique nature of clinical tests. It proposes a risk-based approach to regulation, offering exemptions for low-risk tests and a streamlined review process for moderate-risk tests.

Impact Moving Forward

While the FDA continues to push forward with its rulemaking efforts, the *Loper Bright* decision may encourage Congress to pass the VALID Act, providing a definitive resolution to the debate over FDA's regulatory authority over LDTs. This legislation would eliminate the current ambiguities and establish a clear framework for future oversight of clinical laboratory tests.

APS will continue monitoring this evolving legal landscape, as any changes in FDA regulation could directly impact laboratory billing and compliance practices. If you have any questions, please contact your Practice Manager.