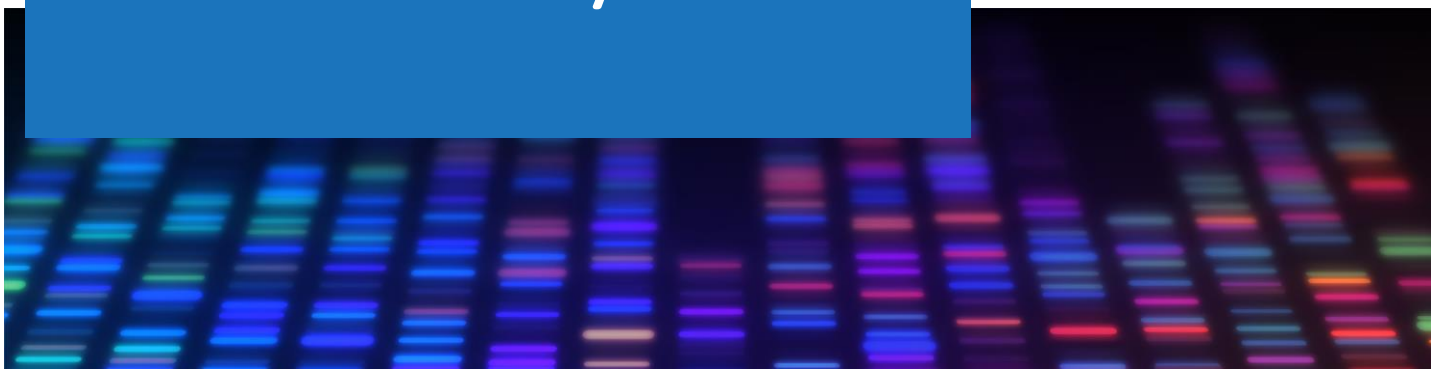
PCG Laboratory News

Issue 4: July 2024



COURT UPDATES REGARDING LDT

Fisheries and petroleum companies may soon have a significant impact on laboratories across the country. The U. S. Supreme Court (SCOTUS) recently published a ruling (June 2024) that may pave the path to delaying or reversing the FDA's Final Rule on LDTs.

A New Jersey fishing company sued the U. S. Secretary of Commerce (Gina Raimondo) over the financial responsibility of fishing monitors (*Loper Bright Enterprises v. Raimondo*). The case made its way to SCOTUS and on June 28, in a 6-3 ruling, SCOTUS overturned a 40-year-old case ("*Chevron doctrine*"), which gave deference to federal agencies in the executive branch, such as the FDA. *Chevron* allowed the FDA to interpret ambiguous legislation passed by Congress, giving such agencies increased regulatory powers. SCOTUS opined that the **courts** should interpret ambiguous legislation, not the executive branch.

The SCOTUS ruling opens a pathway for a lawsuit filed in May 2024 in an eastern Texas federal court, *American Clinical Laboratory Association (ACLA) et al v. U.S. Food and Drug Administration*. Using the *Loper* decision, the ACLA is petitioning the federal court to vacate and set aside the Final Rule regulations. The ACLA feels the FDA has overstepped its powers by attempting to regulate LDTs. The ACLA is also challenging whether LDTs are a laboratory service compared to a regulated device.

On the heels of the SCOTUS ruling, Senator Bill Cassidy, MD (R-LA), penned a 5-page letter on June 30, 2024, to FDA Commissioner Robert Califf, MD, arguing the FDA does not possess the ability to create regulations. Sen. Cassidy requested the FDA to respond to a series of questions regarding whether the FDA intends to comply with the *Loper* ruling. Specifically, Sen. Cassidy asked how the FDA will use the *Loper* decision to guide FDA's actions related to the LDT Final Rule. Sen. Cassidy requested answers by July 19, 2024.

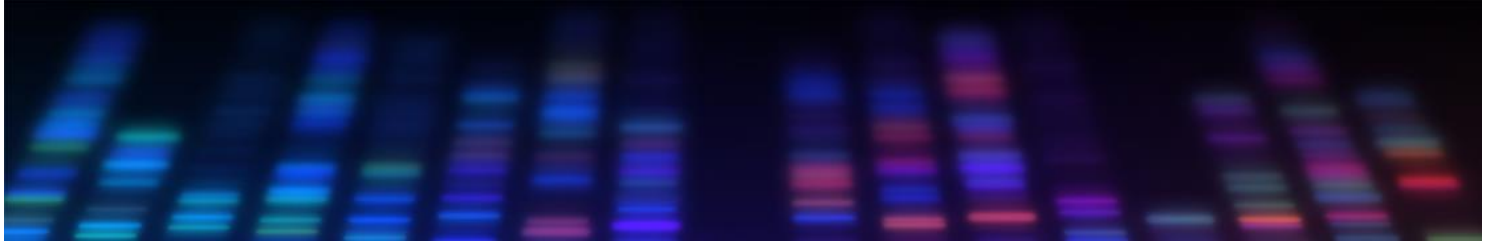
Stay tuned as these cases proceed.

FDA LDT FINAL RULE

Tasks to do NOW!

While the courts and Congress sort things out, laboratories should continue to prepare for Final Rule implementation. Stage 1 compliance is expected by May 6, 2025. Here is a list of items to do now in 2024:

- **Itemize your LDT assays** – list any test that is being used "off label" or modified from an FDA-approved assay. Body fluid chemistry tests will be the most common LDT in every laboratory. Include the date the assay was placed in use.
- **Assemble your FDU** (formally designated unit) for handling complaints (Stage 1 requirement)
- **Create policies** and procedures for handling complaints (Stage 1 requirement)



CONGRESS WEIGHING IN ON LDT

Appropriations bill may stop LDT Final Rule in its tracks.

If money speaks louder than words, then Congress is starting to yell. On July 10, 2024, The United States House of Representatives Appropriations Committee voted 29-26 to forward a budgeting bill to the full House. The bill includes Fiscal Year 2025 funding for the Food & Drug Administration.

In a single paragraph on page 84 of the 166-page document, the House Appropriations Committee ordered the FDA to suspend the LDT Final Rule and partner with Congress to pass legislation (i.e., VALID Act) that would modernize the regulatory approach for LDTs. As reported by Healthcaredive.com on July 15, 2024, the directive is tied to $3.5 billion in appropriations for next year.

The bill also declared how the LDT Final Rule is an extraordinary shift in regulatory process and would disrupt American healthcare by limiting patient access to LDTs.

Congress has been working on a bipartisan and bicameral bill since 2018, known as the Verifying Accurate Leading-edge IVCT Development (VALID) Act. The Act has stalled in Congress but the recent action by the FDA may breathe life back into the bill. The VALID Act would provide legislative regulations specifically for LDTs.

The Appropriations Committee funding bill is expected to be voted on by both Congressional chambers prior to the end of the current fiscal year (September 30, 2024). Until final approval, laboratories should continue to prepare for the FDA LDT Final Rule.

> ***"The Committee directs the FDA to suspend its efforts to implement the rule."***
> *U.S. House Appropriations Committee, July 10, 2024*

Purchase Consulting Group, LLC

Braintree, MA 02184

https://labconsultingpartners.com/

mbiskup@purchaseconsultinggroup.com

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