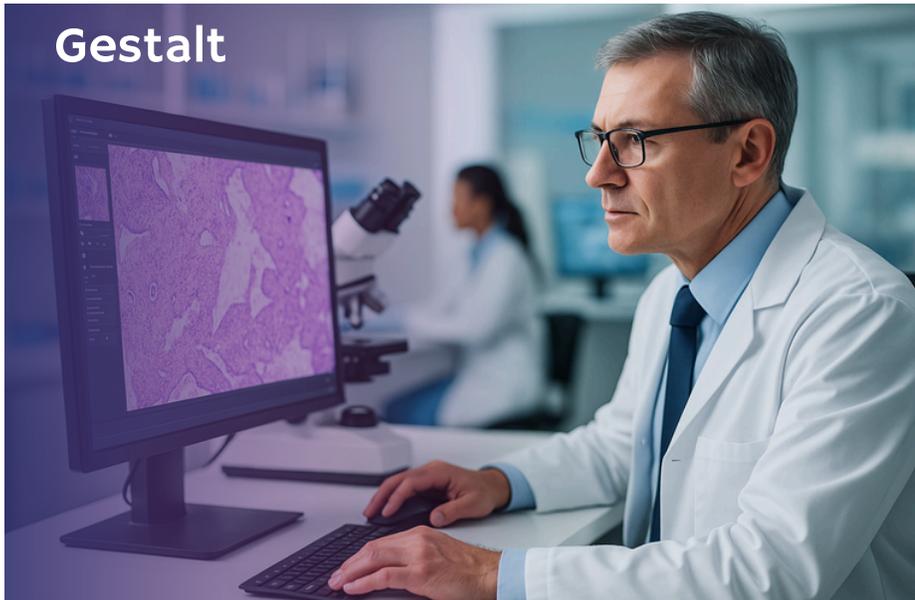


# DIGIPATH DISPATCH

Gestalt Company Newsletter



## WHAT THE DEMISE OF THE FDA'S LDT RULE MEANS FOR LABS

By Lisa-Jean Clifford

The recent court decision to vacate the FDA's final rule on Laboratory Developed Tests (LDTs) was expected — and it's a meaningful victory for pathology labs, clinicians, and the patients we all serve.

More than anything, this ruling safeguards what makes laboratory medicine dynamic: the ability to develop, implement, and adapt diagnostic tools quickly and responsibly. In no other area of medicine are physicians told which tools they must use to diagnose. This decision reinforces that pathologists — as board-certified physicians — must retain the authority to choose and validate the technologies that support their clinical expertise.

From an industry perspective, this shift has far-reaching implications. By reaffirming CLIA as the appropriate regulatory framework, labs can continue to pursue innovation without being slowed by unnecessary oversight that doesn't align with how diagnostic tools or supporting applications are developed or delivered. It clears the path for more rapid deployment of advanced tools — including digital pathology and AI — especially in complex, high-stakes settings where speed, accuracy, access and adaptability are critical.

(Continued on Page 2)

## Newsletter Highlights

A Message from the CEO

Industry Impact on LTD Ruling

Team Expansion

Leadership Growth

Gestalt in the News



Because Days Matter

## WHAT THE DEMISE OF THE FDA'S LDT RULE MEANS FOR LABS (CONTINUED)

But this freedom comes with shared responsibility. As a community, we must now ensure that autonomy does not come at the expense of rigor. Validation, transparency, training, and collaboration must remain non-negotiable. Regulatory relief doesn't mean a relaxation of standards — it means the opportunity to continue to define and uphold those standards ourselves.

At Gestalt, we're committed to being a trusted partner in that effort. Our PathFlow® platform is built for flexibility, scalability, and workflow precision — and our PathFlow® Education Module is designed to support labs in onboarding, proficiency testing, and training on their own terms. We remain steadfast in our belief that empowering pathologists — not restricting them — is how we improve diagnostics and, ultimately, patient care.

This is not just a legal outcome. It's a clear moment for a powerful statement — for pathologists to lead, for labs to innovate, and for all of us to raise the bar together.

-Lisa-Jean Clifford  
President

## IN THE NEWS: MILESTONES & INDUSTRY LEADERSHIP



### Gestalt Secures \$7.5M in Series A Funding

Gestalt recently closed a \$7.5 million Series A funding round to accelerate growth and advance our AI-powered digital pathology solutions. Led by Cowles Ventures, TVF Funds, Inland Imaging, KickStart, and regional angel investors, this investment fuels expanded market reach, enhanced AI capabilities within PathFlow®, and progress toward FDA clearance. It's a pivotal step in our mission to empower pathologists and improve diagnostic efficiency, accuracy, and patient care.

### Lisa-Jean Clifford Co-Authors AI Integration Framework

We're proud to share that Lisa-Jean Clifford, President of Gestalt, co-authored a peer-reviewed article in the Journal of Pathology Informatics titled A Framework for the Evaluation and Implementation of Artificial Intelligence Tools in Pathology. This publication offers critical guidance for safely and effectively integrating AI into diagnostic workflows.

Lisa-Jean's contribution reflects Gestalt's commitment to advancing responsible, scalable digital transformation.



## TEAM EXPANSION

At Gestalt, we believe that building the right team is essential to advancing our mission and shaping the future of digital pathology. As we continue to grow, we are intentionally expanding our leadership to include voices that bring fresh expertise, diverse perspectives, and a deep commitment to empowering pathologists and improving patient care.

The strength of our team fuels our ability to innovate, scale, and support the evolving needs of the labs and healthcare systems we serve. We're proud to highlight the leaders who are helping us drive this momentum forward.



**Lisa-Jean Clifford, President**

We're proud to recognize Lisa-Jean Clifford's promotion to President of Gestalt. A nationally respected voice in digital pathology and AI-driven diagnostics, Lisa-Jean brings deep industry expertise and a proven track record of leadership. Her vision and commitment continue to shape Gestalt's growth, innovation, and impact across the healthcare landscape.



**Dr. Renuka Kulkarni, Chief Medical Officer**

We're thrilled to welcome Dr. Renuka Kulkarni to Gestalt as Chief Medical Officer. A physician scientist with over 20 years of experience in surgical and digital pathology, Dr. Kulkarni brings deep clinical expertise and a passion for advancing diagnostic technology. Her leadership will help shape Gestalt's next generation of AI-powered solutions to better serve pathologists and patients worldwide.



**Steve Rector, Board Member**

We're excited to welcome the leadership and financial expertise of Mr. Steve Rector to our esteemed board of directors. As CFO and Managing Director at Cowles Company, Steve brings valuable experience in growth capital investments and financial strategy. He also serves on several corporate and nonprofit boards, contributing to organizations like Clearas Water Recovery, Ag Energy Solutions, Scorebook Live, and the Rypien Foundation.

## A Message from the CEO



At Gestalt, growth is never just about us—it's about the partnerships, people, and progress we build together. This newsletter celebrates that spirit: securing Series A funding, adding extraordinary leaders to our team, and contributing to the global conversation on AI in pathology.

As we look ahead, we're focused on listening, collaborating, and delivering solutions that meet the real-world needs of pathologists and healthcare systems. We're proud to walk this path alongside you.

Onward and upward.

*-DR*