Ruling Limits Lab Onus on Medical Necessity

Judge notes the case involved a well-known whistleblower who has sued labs in the past

CEO SUMMARY: A federal appeals court ruling has established a legal "safe harbor" for clinical laboratories, shifting the burden of proof in False Claims Act cases. By allowing labs to generally rely on physician orders as evidence of medical necessity, the decision provides a new defense against whistleblower litigation. The case in question centered on the necessity of PCR tests as ordered by providers.

In a decision that provides clarity for the diagnostic laboratory industry, the US Court of Appeals for the First Circuit has affirmed a lower court's dismissal of a high-stakes False Claims Act (FCA) lawsuit. The case, *United States ex rel. OMNI Healthcare Inc. v. MD Spine Solutions LLC (MD Labs)*, centered on the question of whether a clinical lab is responsible for justifying the medical necessity of a test ordered by a licensed physician.

The appellate court's ruling, issued in December 2025, established that laboratories can generally rely on a physician's order that a test is medically necessary for a patient.

For an industry that has long operated under the shadow of aggressive *qui tam* litigation regarding overutilization of tests, this decision creates a new "safe harbor" for medical necessity while defining the specific boundaries where that protection ends.

The First Circuit court determined "that clinical laboratories can generally rely on a physician's order as evidence that testing is reasonable and necessary," said healthcare attorney Danielle Tangorre, a partner at Robinson+Cole. "That's significant because labs bill for tests but do not treat patients. They rely on the physician's clinical judgment."

Tangorre was among the attorneys representing MD Labs in the appeals case.

Origins of the Dispute

The litigation began as a suit filed by OMNI Healthcare, a Florida-based healthcare company owned by Craig Deligdish, MD. Acting as the private whistleblower (formally known as a "relator"), OMNI

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alleged that MD Labs violated the FCA through billing practices for PCR-based urinary tract infection (UTI) testing.

A notable twist is that according to the appeals decision, Deligdish is well known as a pursuer of whistleblower complaints. "OMNI, by its own account, is a frequent flyer in the *qui tam* world, having recovered tens of millions of dollars on behalf of the government in other similar cases," wrote Circuit Judge O. Rogeriee Thompson.

Deligdish instructed OMNI's medical assistants to order PCR tests instead of traditional (and less expensive) bacterial urine culture test in the hopes of filing an FCA complaint against MD Labs—even if OMNI's physicians had requested the culture test, the court decision stated.

"OMNI initially brought a *qui tam* case involving both toxicology testing and PCR-based UTI infectious disease testing," Tangorre noted. "The government intervened only on the toxicology side, and MD Labs and its owners settled those allegations some time ago. The government declined to intervene on the UTI testing allegations, and that's when Robinson+Cole got involved on behalf of MD Labs."

Shifting the Burden of Proof

Following the government's declination, OMNI pursued the UTI allegations independently. There was extensive litigation involving discovery, experts, and depositions. Ultimately, MD Labs moved for summary judgment in 2024, arguing it did not knowingly submit false claims and that the tests were medically necessary.

A district court agreed and dismissed the case. When OMNI appealed, the First Circuit Court focused specifically on the intent required for a lab to be held liable for fraud. By ruling that a physician's order serves as sufficient evidence of medical necessity, the court fundamentally shifted the legal landscape for diagnostic laboratories.

"The court also clarified that if a lab relies on a physician's order, the burden shifts to the relator to show the lab should not have relied on it—for example, if the lab influenced or usurped the physician's decision-making," said Tangorre. "That's a major takeaway for laboratories."

'Red Flags' with Ordering

Despite the favorable ruling for clinical laboratories, the decision serves as a reminder that "blind reliance" on a physician's order is not the same as "willful blindness" to obvious fraud. Labs must still use their internal data to spot anomalies that could suggest a breakdown in the physician-lab relationship.

"Labs should watch their data for red flags—for example, identical test orders across all patients regardless of demographics or clinical history," Tangorre suggested. "There should be variation based on physician judgment."

If a lab sees that a specific clinic is ordering a full infectious disease PCR panel for 100% of its patients regardless of symptoms, the lab has a duty to investigate. In the MD Labs case, the court noted that physicians did not object to the testing, which supported the lab's defense.

"From MD Labs' perspective, they received a requisition for PCR UTI testing and ran it," Tangorre said. "But the case highlights that labs can still get pulled into investigations if they are not looking at underlying documentation."

Breaking Down Silos

To fully capitalize on the protections offered by the First Circuit Court's ruling, Tangorre argued that labs must change how they handle compliance internally. Risk management cannot be the sole responsibility of the legal department; it must be integrated into every facet of the business.

"Labs need to operate as a cohesive unit, not in silos," she said. "Whether it's accessioning, billing, or technical staff,

everyone should be asking: Does this make sense? Is the requisition appropriate? Does it reflect individualized physician decision-making?"

Technical staff and marketing teams also need to agree on how tests are presented. "Messaging across materials—websites, emails, sales outreach—should be accurate and consistent," Tangorre added. "Labs should ensure they have properly completed requisitions and, ideally, audit medical records periodically. That aligns with longstanding OIG compliance guidance and is becoming more important as scrutiny increases."

For the broader clinical laboratory community, the fact that this decision came from a circuit court carries significant weight. Circuit rulings are often cited by other courts across the country, providing a defensive blueprint for labs facing similar allegations through integrated compliance and a respect for the physician-patient relationship.

"It provides clarity on how courts view a lab's role in certifying medical necessity while relying on physicians," Tangorre explained. "It essentially gives labs guardrails: Labs can rely on physician orders, but here's where you can run into trouble."

As she concluded, "Organizations that operate cohesively and not in silos are in the best position to manage risk." TDR

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Whistleblower Litigation History of OMNI Healthcare Stretches Back at Least 11 Years

OMNI HEALTHCARE AND ITS OWNER, CRAIG DELIGDISH, MD, HAVE SERVED AS WHISTLEBLOWERS in multiple *qui tam* actions under the False Claims Act beyond the case against MD Labs detailed in this issue. While some of these cases resulted in substantial government recoveries, other filings have faced dismissals:

Millennium Health (2015): OMNI was one of several parties in a consolidated action against Millennium Health (formerly Millennium Laboratories). The case involved allegations that the lab billed Medicare for medically unnecessary urine drug and genetic testing. Millennium entered into a $256 million settlement with the Department of Justice (DOJ). The relators involved in the various suits received a combined share of approximately $30 million from the settlement proceeds, according to the DOJ.

US Oncology (2024): OMNI filed suit against US Oncology alleging the company improperly billed for "overfill" portions of injectable oncology medications. The case was dismissed by a district court, a decision later affirmed by the Second Circuit Court of Appeals, according to *Bloomberg Law*.

OPKO Health and BioReference Laboratories (2025): The DOJ reached a $704,349 agreement with these companies over allegations that BioReference billed Medicare and other federal healthcare programs for medically unnecessary blood tests, according to prior coverage in THE DARK REPORT. As a whistleblower in the case, OMNI received more than $112,000, which was 16% of the amount paid to the government. *(See "OPKO Settles Allegations of Fraudulent Billing," April 21, 2025.)*

North Brevard County Hospital District (2024–2026): OMNI initiated several suits against the North Brevard County Hospital District, operating as Parrish Medical Center, alleging violations of the Stark Law, the Anti-Kickback Statute, and the CARES Act. In January 2026, a federal judge for the Middle District of Florida dismissed the final federal claims with prejudice, according to *Florida Today*. Deligdish told *Florida Today* there are other cases pending against Parrish.