

False Claims Act decisions to know from Q3 2023

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Below are noteworthy False Claims Act (FCA) decisions from the third quarter of 2023.

The main issues in the cases are:

- (1) **Materiality.** The Fourth Circuit held that a pharmacist's efforts to falsify patient eligibility showed the eligibility requirements were material.
- (2) **Government investigation period.** The Fifth Circuit cut in half a government jury verdict because of the government's lengthy investigation.
- (3) **Damages in procurement cases.** The Ninth Circuit limited damages in a government procurement case, holding that penalties should be based on the number of invoices, not items and that the government had to prove lost value in the goods it received.
- (4) **Anti-Kickback Statute (AKS) causation standard.** Two District of Massachusetts courts split on the causation standard to apply for Anti-Kickback Statute-based FCA claims.

Further discussion on these cases is below.

Fourth Circuit holds misstatements about Medicaid eligibility could be material, even if eligibility requirements were unlawful

*United States v. Walgreen Co.*¹

On August 15, the Fourth Circuit revived a FCA lawsuit against Walgreens, finding that Walgreens's certifications of Medicaid eligibility were material to the government's decision to pay for certain drugs. This case stems from the 2016 admission by a Walgreens pharmacy manager that she falsified lab results and forms to make it appear that patients were eligible for Medicaid coverage of expensive hepatitis C drugs so that they could receive them.

Following the criminal proceedings against her, the United States and Virginia sued Walgreens, alleging it falsely certified that Medicaid patients met Virginia's eligibility requirements for the drugs.

The U.S. District Court for the Western District of Virginia dismissed the government's complaint in 2021, holding that Walgreens's certifications about the patients were not material under the FCA as a matter of law because Virginia's prior authorization requirement violated the Medicaid Act's prohibition on cost-based controls for needed drugs. Thus, the pharmacy manager's false statements "should not have so influenced the decision-making" about reimbursement.

The Fourth Circuit reversed, holding that the legality of the eligibility requirements was not relevant to the issue of FCA materiality. All that mattered was that Walgreens's admittedly false statements *did* influence the government's decision-making and thus were material under the Supreme Court's decision in *Escobar*. The Fourth Circuit reasoned, "Allowing Walgreens to avoid liability by challenging Virginia's eligibility criteria only after getting caught would hinder the [FCA's] purpose of holding fraudsters accountable."

Fifth Circuit slashes jury verdict based on statute of limitations after lengthy sealed investigation

*United States v. Corporate Management, Inc.*²

Repeated extensions of the seal period³ and long-running investigations have become common in FCA cases. In August, the government saw the repercussions of conducting an eight-year investigation before finally intervening in the case when the Fifth Circuit cut by more than half a jury verdict in favor of the government based on the FCA's statute of limitations.

In 2007, the relator sued a hospital and its management for over-billing the government for work not performed. Over the course of its investigation, the government sought over a dozen extensions of the seal period and eventually intervened in 2015, alleging fraud from 2002 to 2013. In 2020, the jury returned a verdict in the government's favor, awarding nearly \$11 million in single damages.

On appeal, the defendants argued that the FCA's six-year statute of limitations barred the government's claims from before 2009 and that the government's complaint in intervention did not relate back to the relator's complaint because it alleged different misconduct. The Fifth Circuit agreed.

Applying the statute of limitations to discredit claims from more than six years before the complaint in intervention, the Fifth Circuit reduced the jury's judgment to under \$4.6 million. The Fifth Circuit also rejected the government's argument that the FCA's tolling provision could save the pre-2009 claims, holding that the government knew, or at least should have known, of its claims earlier based on representations it made in a sealed memorandum supporting a seal extension.

The Fifth Circuit admonished the government for its "inexcusable" "incessant delay in intervening" and "gamesmanship." This case may serve as a warning that some courts' patience is wearing thin with repeated requests for seal extensions and slow investigations.

Ninth Circuit limits statutory penalties and damages in procurement fraud cases

*U.S. ex rel. Hendrix v. J-M Manufacturing Co.*⁴

The Ninth Circuit also issued a ruling limiting the government's recovery after a jury trial, this time in FCA cases alleging false claims in the government procurement context. Our additional coverage of this case is here.⁵

The relator alleged that a government contractor sold PVC pipe to the government despite knowing that the pipe did not comply with industry standards. In the liability phase of the trial, the jury held that each of the defendant's claims was false. In the damages phase of trial, after the jury was unable to reach a verdict, the U.S. District Court for the Central District of California granted judgment as a matter of law to the defendant on actual damages and awarded one statutory penalty per project.

On appeal, the Ninth Circuit limited both statutory penalties and actual damages. First, the Ninth Circuit rejected the plaintiffs' request to award a penalty for each piece of PVC pipe sold instead of one for each project. Rulings like this are particularly important in cases where the value of a product or service is low, but the volume is large, potentially resulting in massive statutory penalties that can raise Eighth Amendment concerns for defendants.

Second, the Ninth Circuit affirmed that the government was not entitled to recover the entire amount it spent on the PVC pipe in the absence of evidence of the true value of the pipe delivered or that the PVC pipe failed to operate as promised and was not returned.

District court applies but-for causation standard in one kickback case — but not another — as circuit split develops

*United States v. Teva Pharmaceuticals USA, Inc.*⁶

*United States v. Regeneron Pharmaceuticals*⁷

The 2010 amendments to the AKS provide that a claim for payment "that includes items or services **resulting from** a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the

FCA]."⁸ The Third, Sixth, and Eighth Circuits have weighed in on how to interpret the "resulting from" language, applying two different standards. District courts have likewise interpreted the "resulting from" language differently — in this case, within the same jurisdiction.

In July, one federal district judge for the U.S. District Court for the District of Massachusetts granted partial summary judgment to the government in its case against Teva Pharmaceuticals, alleging kickbacks in the form of unlawful co-pay subsidies for one of Teva's drugs. Siding with the Third Circuit's 2018 decision in *U.S. ex rel. Greenfield v. Medco Health Solutions*, the court held that the government could prove its FCA claim with just a "sufficient causal connection" between an alleged AKS violation and an allegedly false claim for payment.

Two months later, in the government's case against Regeneron, the manufacturer of the drug Eylea, a different federal judge in Massachusetts applied a but-for causation standard to the link the government must show between an AKS violation and a claim for payment. The court relied on the Sixth and Eighth Circuits' decisions in *U.S. ex rel. Martin v. Hathaway* and *U.S. ex rel. Cairns v. D.S. Medical LLC*, and rejected the Third Circuit's reasoning.

The decision in *Teva* has been certified for interlocutory appeal, so the First Circuit may soon weigh in on the developing circuit split. You can read our full analysis of these two Massachusetts cases here.⁹

Notes

¹ 78 F.4th 87 (4th Cir. 2023).

² 78 F.4th 727 (5th Cir. 2023).

³ <https://bit.ly/3FBsnyG>

⁴ 76 F.4th 1164 (9th Cir. 2023).

⁵ <https://bit.ly/3siKITz>

⁶ 2023 WL 4565105 (D. Mass. July 14, 2023).

⁷ 2023 WL 6296393 (D. Mass. Sept. 27, 2023).

⁸ 42 U.S.C. § 1320a-7b(g) (emphasis added).

⁹ <https://bit.ly/3QcCKhy>

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