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False Claims Act decisions and settlements to know from Q4 2021

By Scott Gallisdorfer, Esq., Bass, Berry & Sims PLC*

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The final months of 2021 saw a flurry of noteworthy False Claims Act (FCA) activity. Among other developments, appellate courts issued important decisions concerning materiality, the government's qui tam dismissal authority, and the application of the Eighth Amendment's Excessive Fines Clause.

The fourth quarter also brought news of several significant settlements, including a group of eight- and nine-figure resolutions of alleged Anti-Kickback Statute violations by pharmaceutical manufacturers and the latest example of a private equity firm paying a substantial sum to resolve FCA allegations leveled against one of its portfolio companies.

In October, the Sixth Circuit issued a notable decision limiting what may constitute an adverse employment action to support a claim under the FCA's anti-retaliation provision.

This post summarizes key developments from the year's final quarter and identifies important takeaways for healthcare providers and government contractors.

Key fourth quarter appellate decisions addressed materiality, the government's dismissal authority, excessive fines, and whistleblower retaliation claims

Materiality

Five years[1] after the Supreme Court's decision in *Universal Health Services v. U.S. ex rel. Escobar*, the FCA's materiality element continues to be a key factor driving the resolution of FCA litigation.

The fourth quarter of 2021 was no exception, as circuit courts issued at least two important rulings addressing materiality:

- *In S. ex rel. Foreman v. AECOM*, the Second Circuit carefully analyzed several of the non-exclusive Escobar materiality factors, reaching mixed conclusions about their weight and the direction they cut. On balance, however, the Second Circuit held that the district court had correctly dismissed all but one of the relator's FCA claims because the overall picture suggested that the alleged violations of contractual recordkeeping requirements at issue "were not plausibly material to the government's payment decision." While some courts have begun to analyze materiality in a "holistic" fashion, Foreman serves as an important reminder that even a more "holistic" analysis may still prove fatal to a relator's claims — including at the motion-to-dismiss stage.
- *In S. ex rel. Prose v. Molina Healthcare of Illinois*, the Seventh Circuit reversed a district court's dismissal of FCA claims on materiality grounds. The Seventh Circuit rejected the defendant's "barebones assertion" that the government was aware of the material facts underlying the alleged violations of skilled nursing facility regulations yet had continued to pay the defendant's claims anyway. Highlighting the difficulty often facing defendants who lack access to the facts concerning the government's payment decisions, the court noted that an analysis of the defendant's materiality defense was "better saved for a later stage" because no one could yet "say what the government did and did not know." Importantly, however, the court left open the possibility that the defendant's materiality defense could prevail on summary judgment.

Government dismissal authority

The end of 2021 also brought yet another entrant to the recent run of cases[2] addressing what the government must show to affirmatively dismiss a qui tam action over a relator's objection. In *U.S. ex rel. Polansky v. Executive Health Services*, the Third Circuit affirmed the district court's decision to grant the government's motion to dismiss an FCA action alleging that the defendant had assisted hospitals in billing claims as inpatient services that should have been billed as outpatient.

While the Third Circuit concluded that the government must first formally intervene before it may seek to dismiss a qui tam action against the wishes of a relator, it joined all other circuits that have addressed the issue in holding that the government's burden for justifying such a dismissal is not especially demanding.

While other circuits have disagreed on the precise contours of the required showing (and at least one, the D.C. Circuit, requires no showing at all) — the Third Circuit agreed with the Seventh Circuit

that Federal Rule of Civil Procedure 41(a) supplies the appropriate governing standard.

Because, in this instance, the government moved to dismiss **after** the defendant had answered the complaint, the Third Circuit determined that dismissal was appropriate only after first satisfying itself that the exercise of the government's dismissal authority was for a "proper" purpose and was not an abuse of the government's discretion. Given the "litigation costs" that the suit imposed on the government, its decision to dismiss easily passed that test. The Third Circuit's holding in *Polansky* tends to confirm that most courts are likely to evaluate government requests to dismiss qui tam actions with a high degree of deference — even well into discovery. (*NB:* In another recent decision addressing this issue, the First Circuit joined the D.C. Circuit by holding that the government's dismissal authority is essentially unfettered).

Excessive fines

As we have previously covered,[3] in December, the Eleventh Circuit issued an important decision through which it became the first federal court of appeals to hold that the Eighth Amendment's Excessive Fines Clause applies to monetary judgments in declined FCA cases.

In that case, *U.S. ex rel. Yates v. Pinellas Hematology & Oncology, P.A.*, a jury awarded only $755 in actual damages to the United States based on the defendant's submission of claims to Medicare that falsely represented certain diagnostic tests had been performed at appropriately certified testing locations. Nonetheless, because nearly 300 individual claims were at issue, applying the FCA's per-claim penalty provision (in this case, $5,500 per claim) resulted in the entry of a total judgment of nearly $1.2 million.

On appeal, the Eleventh Circuit first joined several other circuits in holding that "FCA monetary awards are fines for the purposes of the Excessive Fines Clause." It then clarified that the same conclusion remains true in **declined** cases because such monetary awards are still fines "imposed by the United States" even when the government is not an active participant in the litigation.

Nonetheless, the court ultimately upheld the judgment against the defendant, reasoning that it was not excessive due to the repeated fraud, the defendant's degree of scienter, and the harm inflicted on the government. Still, the Eleventh Circuit's decision provides a potential avenue of relief for defendants in future declined cases who face the prospect of civil monetary penalties far in excess of actual damages.

Whistleblower retaliation

Finally, in October, the Sixth Circuit issued a notable decision limiting what may constitute an adverse employment action to support a claim under the FCA's anti-retaliation provision. In *El-Khalil v. Usen*, the Sixth Circuit affirmed the district court's grant of summary judgment in favor of a defendant medical center, holding that a negative recommendation as to the renewal of the plaintiff physician's medical staff privileges was not by itself the kind of "adverse" action contemplated by the statute.

The court offered two reasons for this conclusion: first, the physician did not have privileges before the recommendation was issued, so there was no significant change to his employment status; and second, the medical staff's governing body still retained the ultimate discretion to approve or deny the plaintiff's application for privileges.

In early October, three pharmaceutical manufacturers paid settlements of eight and nine figures to resolve FCA allegations related to price-fixing for certain generic drugs.

The Sixth Circuit's decision serves as an important reminder to courts and would-be plaintiffs that, when it comes to proving a retaliation claim, not just **any** supposedly negative employment action will suffice.

Kickback and private equity issues, among others, drove significant fourth quarter settlements

The last quarter of 2021 also brought a raft of settlement activity; below, we summarize those likely to be of particular interest to healthcare providers and government contractors — including several settlements by hospitals and health systems, as well as the latest FCA settlement involving a private equity firm.

- In a series of early October settlements, three pharmaceutical manufacturers paid[4] settlements of eight and nine figures (**$213 million**, **$183 million**, and **$49 million**, respectively) to resolve FCA allegations related to price-fixing for certain generic drugs. The government alleged that the manufacturers paid and received compensation prohibited by the Anti-Kickback Statute in connection with agreements on price, supply, and customer allocation, resulting in higher drug prices for federal healthcare programs and beneficiaries.
- On October 14, H.I.G. Growth Partners, LLC, a private equity firm, agreed[5] to pay nearly **$20 million** to resolve FCA claims based on allegations that the firm: (1) knew a mental health clinic it owned and operated employed individuals who were unlicensed or unqualified to perform services billed to Medicaid; and (2) failed to adopt recommendations that would have brought the clinic into compliance. Two of the clinic's former executives agreed to pay an additional **$5 million** toward the settlement, and the clinic previously reached a settlement of its own. According to the Massachusetts Attorney General's Office, the resolution is the "largest publicly disclosed government health care fraud settlement in the nation involving private equity oversight of health care providers, as well as the largest amount a private equity company itself has agreed to pay to resolve fraud allegations involving healthcare portfolio companies."

- On November 1, Geisinger Community Health Services agreed[6] to pay more than **$18.5 million** to resolve self-disclosed FCA allegations that it submitted claims to Medicare for home health and hospice services that violated rules and regulations regarding certification of terminal illness, patient election of hospice care, and physician face-to-face encounters with home health patients. Notably, the government's press release specifically commended Geisinger for proactively disclosing the conduct to the U.S. Attorney's Office.
- On November 8, Arthrex Inc., a medical device manufacturer, agreed[7] to pay **$16 million** to resolve FCA allegations that it paid kickbacks to an orthopedic surgeon in the form of sham royalty payments for the surgeon's contributions to the development of its products. According to the government, the payments were intended to induce the surgeon's use and recommendation of the products. The company entered a five-year corporate integrity agreement with HHS-OIG as part of the resolution.
- On November 9, various anesthesia providers and several Georgia outpatient surgery centers, along with associated individuals, agreed[8] to pay more than **$28 million** to resolve FCA allegations that they billed for services tainted by kickbacks, in violation of the Anti-Kickback Statute. The anesthesia providers allegedly made payments for drugs, supplies, equipment, and labor and provided free staffing for a number of the surgery centers, all to induce the surgery centers to name them the exclusive anesthesia providers for the centers.
- On December 2, Flower Mound Hospital Partners LLC agreed[9] to pay **$18.2 million** to resolve FCA allegations that it repurchased shares from physician-owners and resold the shares to younger physicians, violating the Anti-Kickback Statute and Stark Law. In determining which physicians could purchase the shares and how many would be made available, the hospital allegedly considered the volume or value of their referrals.

Several of the issues addressed in this post are covered in more depth in our recently released 10th annual Healthcare Fraud & Abuse Review.[10] Continue to watch this space for future quarterly updates on key FCA cases and settlements in 2022.

Notes

[1] https://bit.ly/3iejmA7

[2] https://bit.ly/3N0psSM

[3] https://bit.ly/3qhkW8O

[4] https://bit.ly/3CRsJz8

[5] https://bit.ly/3N2x732

[6] https://bit.ly/3lxSvd7

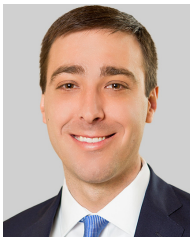
[7] https://bit.ly/3tZEnUA

[8] https://bit.ly/3tiopFN

[9] https://bit.ly/3qfNiA1

[10] https://bit.ly/3JofgRL

About the author



Scott Gallisdorfer is a member of **Bass, Berry & Sims** in Nashville, Tennessee. He focuses his practice on complex litigation and government and internal investigations, with an emphasis on matters related to the health care industry. Gallisdorfer has significant experience in False Claims Act litigation and health care fraud and abuse investigations, including civil and criminal investigations by the Department of Justice, the Department of Health and Human Services Office of Inspector General and other federal and state regulators. He can be reached at scott.gallisdorfer@bassberry.com. This article was originally published Feb. 28, 2022, on the firm's website. Republished with permission.

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