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Top False Claims Act Developments of 2023

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The Department of Justice (DOJ) recently reported approximately $2.7 billion in False Claims Act (FCA) recoveries in fiscal year 2023. (1) The DOJ report on FCA settlements and recoveries wasn't issued until the end of February—the latest release date in history and one of the few superlatives among otherwise lackluster annual statistics.

The $2.7 billion recovered is less than half the approximately $5.6 billion obtained in fiscal year 2021, (2) and only slightly higher than the $2.2 billion in recoveries in fiscal year 2022. (3) Not surprisingly, in its report, DOJ focuses not on the amount recovered, but rather on the number of recoveries, which, at 543, is technically superlative as the highest number in the history of the FCA.

Of the total $2.7 billion recoveries, over $1.8 billion, or about 67%, came from settlements and judgments relating to the healthcare industry. While fiscal year 2023 marks the ninth consecutive year in which healthcare led among targeted industries, at 67% of total FCA recoveries, it falls below the more typical 80% in fiscal year 2022, or the 90% high-water mark in fiscal year 2021.

Statistics aside, perhaps the most significant developments involving FCA enforcement in fiscal year 2023 came from the courts. The Supreme Court decided two significant FCA cases, described below, and the lower courts continued to navigate myriad FCA issues, including materiality and causation elements that permeate FCA enforcement targeting the healthcare industry.

Curated from that body of cases are those below, which are, we believe, to be of significance, along with one noteworthy settlement.

1. In Unanimous Decision, Supreme Court Reverses Seventh Circuit, Holds Defendant's Subjective Belief Governs Scienter, Not Objectively Reasonable Standard

In a unanimous decision, dated June 1, 2023, the Supreme Court, in *United States ex rel. Schutte v. SuperValu Inc.*, [4] held that a defendant's subjective belief of its compliance with the law at the time of the submission of a claim is relevant to liability under the FCA.

The Seventh Circuit had extended the standard articulated in the Supreme Court's decision in *Safeco Insurance Co. of America v. Burr*, [5] a Fair Credit Reporting Act (FCRA) case, to the FCA, holding that a defendant's interpretation about usual and customary pricing was "objectively reasonable" even if it was not correct, and that the Centers for Medicare and Medicaid Services (CMS) guidance "was not sufficiently specific to warn SuperValu that its program likely would fall within the definition of [usual and customary] price." [6] There, in fact, the Seventh Circuit stated, "nothing in the language of the FCA suggests that a defendant's subjective intent is relevant." [7]

In April 2022, relators filed a petition for a writ of certiorari with the Supreme Court to clarify "[w]hether and when a defendant's contemporaneous subjective understanding or beliefs about the lawfulness of its conduct are relevant to whether it 'knowingly' violated the False Claims Act." [8] On June 1, 2023, the Supreme Court decided the case, holding that the FCA's scienter element is actually about a defendant's "knowledge and subjective beliefs—not

to what an objectively reasonable person may have known or believed." [9] In an opinion by Justice Clarence Thomas, the court stated that "[o]n their face and at common law, the FCA's standards focus primarily on what respondents thought and believed," and that both the text and common law focus on what defendants' subjective belief was when submitting their claims, "not what the defendant may have thought *after* submitting it." [10] And while SuperValu argued that it could not have known what "usual and customary" meant due to its "inherent ambiguity," the court reasoned that "[a]lthough the terms, in isolation, may have been somewhat ambiguous, that ambiguity does not preclude respondents from having learned their correct meaning—or, at least, becoming aware of a substantial likelihood of the terms' correct meaning." [11]

2. Supreme Court Afirms Third Circuit Ruling, Clarifies Requirements for Government Dismissal of Qui Tam Actions

Before the Supreme Court (finally) weighed in last year, it had initially refused to resolve a circuit split relating to the government's authority to dismiss qui tam actions after *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.* [12] In 2021, the Third Circuit, in *Polansky v. Executive Health Resources Inc.*, addressed the two questions that had permeated the various circuits—1) whether the government was required to intervene in a qui tam action before moving to dismiss the action and 2) what standard the government had to follow for a court to grant its motion to dismiss. [13]

The Third Circuit weighed in on that split in *Polansky*. It held that 1) "the government must intervene before it can move to dismiss, but it can seek leave to intervene at any point in the litigation upon a showing of good cause" and 2) Rule 41(a) is the appropriate standard for a court to consider when determining whether to grant or deny the government's motion to dismiss. [14] On January 26, 2022, the relator filed a petition for a writ of certiorari with the Supreme Court, [15] and on June 16, 2023, the Supreme Court decided the case in an 8-1 opinion. [16]

The Supreme Court reasoned that the government's interest in FCA cases is the "predominant one"—being the "real party in interest" in a qui tam action. [17] That interest, the court held, "does not diminish in importance because the Government waited to intervene." [18] However, the court disagreed with the government's contention that it has "essentially unfettered discretion to dismiss," but still held that the "Government's views are entitled to substantial deference." [19] The court also stated that "[i]f the Government offers a reasonable argument for why the burdens of continued litigation outweigh its benefits, the court should grant the motion... even if the relator presents a credible assessment to the contrary." [20]

Ultimately, the court held that the Third Circuit reached the right conclusions: 1) "[t]he Government may move to dismiss an FCA action... whenever it has intervened—whether during the seal period or later on," and 2) "[t]he applicable standards for deciding such a motion are those set out in Federal Rule 41." [21]

Notably, the dissent in this case, written by Justice Thomas, not only disagreed with the majority, stating that the FCA does *not* "afford the Government [the] power to unilaterally dismiss a pending *qui tam* action after it has 'decline[d] to take over the action' from the relator at its outset," but went so far as to say he would vacate the judgment and remand so the Third Circuit could "consider the serious constitutional questions that may affect the disposition of the Government's motion to dismiss petitioner's *qui tam* suit." [22] Reviewing the structure, text, and history of the FCA, Justice Thomas concluded that there is "no statutory right to unilaterally dismiss a *qui tam* action" after the government declines to intervene. [23]

However, the noteworthy (and newsworthy) part of the dissent highlighted what Justice Thomas believes to be "serious constitutional questions" surrounding the qui tam provisions of the FCA. [24] Justice Thomas wrote that "[t]here are substantial arguments that the *qui tam* device is inconsistent with Article II and that private relators may not represent the interests of the United States in litigation." [25] In essence, Justice Thomas has now provided

FCA defendants an avenue to raise this argument—that relators cannot stand in the shoes of the United States government— in motions to dismiss or motions for summary judgment in the coming years.

While Justices Brett Kavanaugh and Amy Coney Barrett did not join the dissent, they issued a concurring opinion in which they opined that "the Court should consider the competing arguments on the Article II issue in an appropriate case." [26]

3. Sixth Circuit Joins Eighth Circuit, Holds But-For Causation Required in Anti-Kickback-Predicated FCA Cases

In *United States ex rel. Martin v. Hathaway*, [27] the Sixth Circuit further exacerbated the circuit split relating to the causation standard for FCA cases predicated on the Anti-Kickback Statute (AKS). In that case, the Sixth Circuit addressed two primary questions: whether the complaint 1) "turn[ed] on a cognizable theory of renumeration" and 2) "fail[ed] to establish causation." [28]

The case involved patients at Oaklawn Hospital (a hospital located in a small city in Michigan) needing ophthalmology services, who were limited to one local option. [29] That local option, South Michigan Ophthalmology, P.C., had two ophthalmologists—Dr. Darren Hathaway and Dr. Shannon Martin. [30] Dr. Hathaway and Dr. Martin would send patients who needed surgery to "the most convenient local option"—Oaklawn. [31] The referrals between Oaklawn and South Michigan took place "for many years." [32] Dr. Martin, whose husband worked at Oaklawn, received a tentative offer to be a physician at the hospital. [33] Dr. Hathaway found out about the offer and spoke to board members, essentially arguing that it would "force" him to take his cases elsewhere, even though "he had no desire" to do so. [34] The board ultimately voted not to hire Dr. Martin, "express[ing] concern about losing business if they hired" her. [35] Dr. Martin and her husband sued Dr. Hathaway, South Michigan, and Oaklawn Hospital, under the FCA, alleging that

"Oaklawn Hospital's rejection of Dr. Martin's employment in return for Dr. Hathaway's commitment to continue sending local surgery referrals violated the Anti-Kickback Statute." [36]

The significance of this case centered around the court's analysis of causation and whether the claims for reimbursement from Medicare or Medicaid were for "items or services resulting from a violation of the Anti-Kickback Statute." [37] The Sixth Circuit held that "[w]hen it comes to violations of the Anti-Kickback Statute, only submitted claims 'resulting from' the violation are covered by the False Claims Act" and that the "ordinary meaning of 'resulting from' is but-for causation." [38] The complaint, the Sixth Circuit held, failed to plausibly allege but-for causation as there was "not one claim for reimbursement identified with particularity in this case that would not have occurred anyway, no matter whether the underlying business dispute occurred or not." [39] The court also held that any decisions made by Dr. Martin that were independent would "break any plausible chain of causation" and any "[t]emporal proximity by itself does not show causation." [40] Thus, the Sixth Circuit took the same, heightened approach to causation as the Eighth Circuit in *United States ex rel. Cairns v. D.S. Medical LLC.* [41]

Importantly, the standard employed by the Sixth and Eighth Circuits differs from the one used by the United States District Court for the District of Massachusetts in *United States v. Teva Pharmaceuticals USA, Inc.* [42] In the *Teva* case, the court was faced with a similar situation—whether the government (or relator) needed to prove but-for causation in an AKS-predicated FCA claim. [43] The district court cited a First Circuit case, *Guilfoile v. Shields*, [44] which, in turn, relied on a Third Circuit decision, *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, [45] stating that "if there is a *sufficient causal connection* between an AKS violation and a claim submitted to the federal government, that claim is false within the meaning of the FCA." [46] Teva, the defendant in the case, argued that the district court should follow the but-for standard, which is followed in the Sixth and Eighth Circuits. [47] The district court found "the First Circuit's analysis

persuasive, if not binding" and held that "the government need not prove 'but for' causation." [48]

And while the district court in *Teva* did not apply but-for causation, another judge in the same district *did* adopt a but-for causation test. In *United States v. Regeneron Pharmaceuticals, Inc.*, [49] Chief Judge F. Dennis Saylor IV described the standard in *Greenfield* as "fraught with problems," and highlighted the persuasiveness of the *Cairns* and *Martin* statutory analysis. [50] In that case, and contrary to decision in *Teva*, Judge Saylor applied a but-for causation standard. [51]

Teva has since filed an interlocutory appeal to the First Circuit, arguing that but-for should apply to the analysis. [52] On November 17, 2023, the First Circuit certified the appeal and ordered briefing. [53] Similarly, the government also filed an appeal in *Regeneron*, which the First Circuit certified for appeal and docketed in December 2023. [54]

And while the Supreme Court denied a petition for a writ of certiorari in the *Hathaway* case in 2023, [55] it is possible that the First Circuit's decision on this controversial issue could present another opportunity for the Supreme Court to soon weigh in and resolve the conflict.

4. Cigna Group Pays $172 Million to Resolve Allegations Surrounding Unsupported Coding in Medicare Advantage (Part C) Claims

On September 30, 2023, DOJ announced a $172 million settlement, which resolved allegations that the Cigna Group violated the FCA "by submitting and failing to withdraw inaccurate and untruthful diagnosis codes for its Medicare Advantage Plan enrollees in order to increase its payments from Medicare." [56] The settlement amount is the highest healthcare settlement reported by DOJ in 2023. [57] The press release states that Cigna owns and operates Medicare Advantage (MA) Organizations (i.e., Medicare Part C) that offer MA plans to beneficiaries. These plans allow beneficiaries to "obtain[] their

Medicare-covered benefits" through private insurance MA plans. [58] CMS pays the MA plan a fixed amount for each beneficiary, but that amount is adjusted based on "risk" factors "to ensure that MA plans are paid more for those beneficiaries expected to incur higher healthcare costs and less for healthier beneficiaries expected to incur lower costs." [59] MA plans send to CMS the risk adjustment data so that CMS can make the adjustments. [60]

The government stated in its press release that Cigna operated a "chart review" program where Cigna "retrieved medical records... from healthcare providers documenting services" rendered under Cigna plans. Through that program, Cigna "retained diagnosis coders to review those charts to identify all medical conditions that the charts supported and to assign the beneficiaries diagnosis codes for those conditions." Then "Cigna relied on the results of those chart reviews to submit additional diagnosis codes to CMS that the healthcare providers had not reported for the beneficiaries to obtain additional payments from CMS." [61]

The government alleged that "Cigna's chart reviews also did not substantiate some diagnosis codes that were reported by providers and previously submitted by Cigna to CMS," and "Cigna did not delete or withdraw these inaccurate and untruthful diagnosis codes, however, which would have required Cigna to reimburse CMS." [62] Therefore, the allegation centered around whether "Cigna used the results of its chart reviews to identify instances where Cigna could seek additional payments from CMS, while improperly failing to use those same results when they provided information about instances where Cigna was overpaid." [63]

The company, in addition to the payment of the $172 million settlement, entered into a five-year corporate integrity agreement with the U.S. Department of Health and Human Services Office of Inspector General, which will require, *inter alia*, certifications from the company's board, annual risk assessments, and audits on risk-adjustment data.

5. Third Circuit Holds that Government Action "Not Dispositive" of Materiality Under *Escobar*

In United States ex rel. Druding v. Care Alternatives, former employees of Care Alternatives brought suit against the company, alleging that the hospice provider "submitted claims for Medicare reimbursement despite inadequate documentation in patients' medical records supporting hospice eligibility." (64) Patients must be certified as terminally ill to qualify as eligible for Medicare hospice benefits. (65) The certification must "(1) be signed by at least one physician, and (2) be accompanied by '[c]linical information and other documentation that support the medical prognosis' of terminal illness in the medical record." (66)

In 2008, relators filed their complaint against Care Alternatives. (67) In that case, the district court granted Care Alternatives' motion for summary judgment, which was based on the relators' failure to show falsity. (68) The Third Circuit reversed the judgment, holding that "summary judgment on falsity [was] improper" because "there was substantial evidence of Care Alternatives' noncompliance with [42 C.F.R. § 418.22]" and remanded the case back to the district court to resolve the other issues raised in Care Alternatives' summary judgment motion, including materiality. (69) On remand, the district court found "'no evidence' that Care Alternatives' 'insufficiently documented certifications... were material to the Government's decision to pay.'" (70) The government could see what documentation was (or was not) submitted to it, but still continued to pay—"despite the inadequacy of missing supporting documentation where compliance with 42 C.F.R. 418.22 was otherwise lacking." (71) The relators appealed. (72)

The Third Circuit held that "it was erroneous" to treat one *Escobar* (73) factor —the government's decision to pay (i.e., government action")—as dispositive "while overlooking the factors that could have weighed in favor of materiality." (74) The court, in its opinion, considered three of the *Escobar* factors—1) whether 42 C.F.R. § 418.22(b)(2) was an "express condition of payment," 2) whether the noncompliance with 42 C.F.R. § 418.22(b)(2) was "minor or

insubstantial" or "went to the very essence of the bargain," and 3) whether the government's actions—to "continually reimburse... despite knowledge of the inadequacies in the documentation" *and* relators "produc[ing] 'no evidence' explaining away 'the Government's apparent disregard of the inadequacies'"—disproves materiality. (75)

As to the first factor, the court held that "§ 418.22(b)(2) is identified as a condition of payment," but that "designation does not necessarily preclude summary judgment." (76) The court also said that "[r]elators have adduced evidence that bears on the importance of § 418.22(b)(2)'s documentation requirement and the substantiality of Care Alternatives' alleged violations," so "a jury should have been permitted to weigh § 418.22(b)(2)'s condition of payment status alongside *Escobar's* other factors." (77)

Analyzing the second factor, the Third Circuit reviewed "the importance of § 418.22(b)(2) and the magnitude of Care Alternatives' alleged violations." (78) It held that "§ 418.22(b)(2)'s requirement that physicians' signed certifications be supported by the patients' medical records is an essential form of oversight," and that "Care Alternatives' violations were not just isolated incidents but were part of a pattern of significant noncompliance." (79)

Finally, as to the third factor, which the district court used to decide the alleged violations were not material, the Third Circuit held that it would "not equate the government's awareness of allegations of fraud with 'actual knowledge' that fraud occurred." (80) The Third Circuit reasoned that "a reasonable jury... could conclude that the government's inaction is not conclusive." (81) The court ultimately reversed the district court's grant of summary judgment, holding that "[a] jury must be permitted to weigh the government's inaction alongside *Escobar's* other factors." (82)

6. Relators Fail to Meet 9(b) Particularity Requirement in Case Relating to Auto-Approvals and AI Systems

The decision in *Doe 1 v. EviCore Healthcare MSI, LLC* [83] amplifies the current circuit split surrounding the Rule 9(b) requirement—an issue outlined in our *eSource* article last year. [84] That article discusses the Supreme Court's 2022 decision to deny all petitions for certiorari relating to the differing interpretations of the Rule 9(b) pleading standard among the circuits. The three-way circuit split centered around whether a court would: 1) require specific details of false claims to be pleaded (11th Circuit), 2) generally require the specific details of false claims to be pleaded, but with certain exceptions (1st, 4th, 6th, 8th Circuits), and 3) not require specific details of false claims to be pleaded and allow submission of false claims to be inferred from circumstances (reliable indicia of fraud) (2nd, 3rd, 5th, 7th, 9th, 10th, and DC Circuits).

Last year, the Second Circuit addressed Rule 9(b) in an FCA case. In *eviCore*, two relators (former employees of eviCore) filed a complaint against eviCore, alleging that 1) "eviCore's systems, which required the clinical reviewers to input certain patient information into a database, would direct those reviewers to auto-approve all requests relating to certain providers, therapies, and populations and, in doing so, to ignore acceptable standards of clinical practice, evidence-based decision making, and reviewers' own clinical judgment," and 2) "eviCore deployed artificial intelligence systems to approve certain requests based on flawed criteria without manual review." [85] The crux of the allegations was that eviCore violated the FCA when it allegedly "provided worthless services to the insurance companies it contracted with, or at least failed to provide the medical necessity review services that insurance companies contracted it to perform, and caused those insurance companies to bill the government for unnecessary and fraudulently approved medical services." [86]

The district court dismissed the complaint for failure to allege falsity and failure to plead claims with sufficient particularity (under Rule 9(b)). [87] The Second Circuit reviewed the complaint's dismissal pursuant to 9(b) de novo and agreed with the district court, ultimately holding that relators did not plead fraud with the requisite particularity nor did they allege facts that would

"support a strong inference of fraud"—i.e., failing to satisfy the Rule 9(b) requirement. [88]

First, relators claimed that "the volume of eviCore's approvals made it inevitable that fraudulent claims were approved." [89] The Second Circuit said these "speculative allegations" were not enough. [90] Similarly, the complaint alleged that "eviCore breached its contracts with private insurance companies," but the Second Circuit held that the complaint "did not identify any specific contracts that governed those relationships during the period relevant to the allegations or any specific provisions that eviCore breached." [91] Even if it had, however, breach of contract alone "does not bespeak fraud." [92] Finally, the Second Circuit disagreed that relators' allegations "created a strong inference of fraud." Relators did not even allege that any *one* of the entire categories of requests that eviCore approved were fraudulent or resulted in the federal government paying for unnecessary services. [93]

7. Ninth Circuit Holds One Penalty Per Project Is Proper, Not One Penalty Per Line Item

In *Hendrix ex rel. United States v. J-M Manufacturing Co., Inc.*, [94] a relator and five public agency plaintiffs brought a qui tam action against J-M Manufacturing Co., alleging that it violated the FCA (and various state FCAs), by claiming its pipes were compliant with industry standards when they were not. [95] J-M Manufacturing was manufacturing and selling pipes, and between 1996 and 2006, the plaintiffs bought and installed those pipes. [96] The bid specifications for the projects required pipes to be compliant with various industry standards. [97] J-M Manufacturing's brochures said their pipes met the various standards and it placed a stamp on each pipe, saying it complied with the industry standard. [98] Twenty-six projects were at issue in the case. [99]

After one of the phases during the trial in the case, the jury returned a unanimous verdict against J-M manufacturing, answering "yes" to whether 1) J-M "presented or caused to be presented" a false or fraudulent claim for

payment or approval, 2) J-M "made or used a false record or statement in order to get a false or fraudulent claim paid or approved," 3) J-M acted knowingly, and 4) the "false or fraudulent aspect of the claim was material to the plaintiff's decision-making." (100) Thus, "[t]he jury answered 'yes' to the... questions for each project and described each claim as false because" the company "falsely represented uniform compliance" with the industry standards. (101)

Ultimately, the district court awarded one penalty per project. (102) The Ninth Circuit stated that the "jury's finding of falsity and materiality did not mean that *every* stick of pipe was non-compliant," but only that J-M Manufacturing "did not uniformly comply with industry standards and could have delivered *some* non-compliant pipe." (103) Importantly, the Ninth Circuit reasoned that plaintiffs could not establish during the trial how much non-compliant pipe they received during the projects and they were not able to identify the pieces of non-compliant pipes. (104) The Ninth Circuit upheld that decision, holding that only one penalty *per project* (not per pipe) was appropriate. (105)

While this case addresses penalties in a non-healthcare case, this ruling is of significance to healthcare industry FCA defendants, particularly in fending off arguments of the government and/or relators that each line item included in a submission under a federal health program constitutes a separate claim for purposes of potential FCA penalty calculations. In fact, this could even affect healthcare claims that rely on extrapolation and treating each claim as separate for purposes of calculating damages.

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Endnotes

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