March 27, 2023

Top 10 False Claims Act Developments in 2022

By Robert T. Rhoad, Andy Liu and Haaleh Katouzian

Share:

Introduction

Recoveries under the False Claims Act (FCA) in FY2022 amounted to "only" $2.2 billion, well short of last year's (FY2021's) record high of $5.7 billion. (1) It is worth recalling that one half of FY2021's haul came from a single settlement in connection with Purdue Pharma FCA litigation. Similarly, a large portion of FY2022's also came from a single settlement—the $900 million obtained in the *Biogen* case (discussed below). But, unlike Purdue, DOJ elected not to intervene in *Biogen*, which itself will roughly double the record recoveries obtained in non-intervened *qui tam* cases under the FCA. Lastly, the over $250 million to the relator in Biogen sets the record for the highest single award ever paid to a *qui tam* relator in FCA history—so, there's that. And, once again, healthcare fraud was the predominant source of FCA recoveries, accounting for over 80% of all recoveries in FY2022. (2)

Statistics and records aside, 2022 brought about significant FCA case law developments at the Supreme Court and among the Circuits. Below is a summary of the most significant FCA developments of the past year, including cases before the Supreme Court and the Courts of Appeals, as well as emerging DOJ policy impacting FCA enforcement.

Supreme Court

This past year, the Supreme Court's involvement (or lack thereof) in FCA cases has been unprecedented. With petitions for writs of *certiorari* filed before the Supreme Court for significant FCA issues throughout 2022, the Supreme Court's decisions to grant or deny *certiorari* will have a lasting impact on the FCA's jurisprudence for 2023 and beyond. Thus, four of the six key case law developments address FCA cases that have garnered action (or conspicuous inaction) by the Supreme Court.

1. Rule 9(b) Particularity: Certiorari Denied

In 2022, Courts of Appeals addressed Federal Rule of Civil Procedure 9(b)'s particularity requirements—reaching very different interpretations of the pleading standard under that Rule. Even so, after petitions for certiorari were filed in *Johnson v. Bethany Hospice and Palliative Care LLC* (11th Circuit), *United States ex rel. Owsley v. Fazzi Associates, Inc.* (6th Circuit), and *Molina Healthcare of Illinois v. Prose* (7th Circuit), the Supreme Court invited the United States to express its views. For example, the Eleventh Circuit in *Bethany Hospice* required relators "to plead with particularity *the submission of an actual false claim* to the government[,]" [3] the Sixth Circuit in *Owsley* held that the relator's "complaint provided few details that would allow the defendants to identify any specific claims—of the hundreds or likely thousands they presumably submitted—that she thinks were fraudulent[,]" [4] and the Seventh Circuit in *Prose* held that while "Rule 9(b) requires specificity, ... it does not insist that a plaintiff literally prove his case in the complaint." [5]

Notwithstanding what these Courts of Appeals have held, the Solicitor General filed a brief in *Owsley* and denied the existence of a circuit split. In pertinent part, the brief stated that "[i]n recent years, ... the courts have largely converged on an approach that allows relators *either* to identify specific false claims *or* to plead other sufficiently reliable indicia supporting a strong inference that false claims were submitted to the government." [6] Rather than address the issue, the Supreme Court ultimately denied *certiorari* for all three cases on October 17, 2022. [7] Consequently, there remains a difference in interpretations among the Circuits, which will continue to result in contrasting applications of the Rule in FCA cases and, in some observers' views, "forum shopping."

2. The Government's Dismissal Authority: Certiorari Granted

Last year's article, "Top 10 False Claims Act Developments of 2021," [8] discussed the Third Circuit's opinion in *Polansky v. Executive Health Resources Inc.*, which analyzed the government's dismissal authority. [9] The Third Circuit held that the government must intervene before moving to dismiss, but that it may "seek leave to intervene at any point in the litigation upon a showing of good cause[,]" and upheld the dismissal of the case over the relator's objection. [10] The Third Circuit also held that Federal Rule of Civil Procedure 41(a) concerning voluntary dismissal applies to government motions to dismiss a *qui tam* action. [11]

On January 26, 2022, the relator in *Polansky* filed a petition for a writ of *certiorari* with the Supreme Court. The question presented was "[w]hether the government has authority to dismiss an FCA suit after initially declining to proceed with the action, and what standard applies if the government has that authority." [12] Notwithstanding that the Supreme Court had previously declined to address this very issue in denying *certiorari* in *United States ex rel. CIMZNHCA, LLC v. UCB, Inc*, [13] the Supreme Court granted *certiorari* in *Polansky*. [14] At issue is the standard for government dismissal, for example, whether the government has unfettered discretion to dismiss *qui tam* suits, whether it must show a valid government purpose for dismissal, or—as the relator in *Polansky* argued—whether the government has no ability to dismiss a *qui tam* suit once it has declined to intervene. [15]

Oral argument was heard late last year but the Supreme Court has yet to issue an opinion. [16] It is likely that the Court will ultimately side with the government that the government should be liberally allowed to intervene and voluntarily dismiss *qui tam* actions even when it initially declined intervention.

3. Knowledge/Scienter: Certiorari Granted

In 2021, in *United States ex rel. Schutte v. SuperValu, Inc.*, the Seventh Circuit held that the *Safeco* standard applies to the FCA. [17] *Safeco Insurance Co. of America v. Burr* created the standard: Companies who mistakenly interpret a statute are not acting in reckless disregard if the interpretation of the statute is "not objectively unreasonable," even if the defendant did not actually hold the mistaken belief. [18] In *Safeco*, the Supreme Court addressed an alleged violation of the Fair Credit Reporting Act (FCRA) and reasoned that the phrase "willfully fails to comply" in the statute "reach[es] reckless FCRA violations." [19] The standard has caused a stir in the FCA universe, and in *SuperValu*, the Seventh Circuit held that the *Safeco* standard applied to the FCA and the 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." [20]

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." [21] Unlike the Solicitor General's brief filed in *Owsley* regarding 9(b) particularity, after receiving an invitation from the Supreme Court, the United States filed a brief urging the granting of the writ, stating that "[w]hen a defendant has submitted false claims with one of th[e] culpable states of mind, it cannot escape liability merely by showing that its claims were consistent with an objectively reasonable (but wrong) understanding of the law" and stated that the question presented warrants review because it "has generated disagreement in the courts of appeals and is important to efforts to fight fraud involving the public fisc." [22] Two additional cases with virtually the same questions presented—another from the Seventh Circuit, *United States ex rel. Proctor v. Safeway, Inc.*, [23] and one from the Fourth Circuit, *United States ex rel. Sheldon v. Allergan Sales, LLC* [24] —had petitions for *certiorari* filed before the Supreme Court. On January 13, 2023, the Supreme Court granted *certiorari* for *SuperValu and Safeway*, consolidating the cases. [25]

As stated last year, the vagaries in statutory and regulatory requirements are vast. The application of *Safeco* allows for some protection for entities navigating complex healthcare requirements, and the Supreme Court's review of the standard could clarify the metes and bounds protecting those faced with ambiguous statutes, regulations, and rules.

4. The Anti-Kickback Statute's Intent Standard: Certiorari Denied

In 2022, the Second Circuit addressed the Anti-Kickback Statute's (AKS) intent element in *Pfizer, Inc. v. United States Department of Health and Human Services*. [26] In *Pfizer*, the Second Circuit held, *inter alia*, that "a person must 'knowingly and willfully' provide prohibited remuneration to be liable, which means [that the person] must have offered the payment with the intent to violate a known legal duty" and "to violate the AKS, one must intend to induce the purchase of a *federally reimbursable* healthcare product." [27] The Second Circuit disagreed with Pfizer's characterization of the lower court's opinion and reasoned that the lower court instead "concluded based on the plain meaning of the text that the AKS 'prohibits knowingly and willfully

providing remuneration which is intended to induce a purchase of [certain] medical treatments or services.'" [28]

Ultimately, the Second Circuit affirmed the Southern District of New York's decision, [29] and Pfizer filed a petition seeking a writ of *certiorari* on October 7, 2022. [30] The petition sought the Supreme Court's opinion on the question presented of "[w]hether the AKS is violated only if the person offering the 'remuneration ... to induce' the purchase of federally reimbursed healthcare intends to corrupt the recipient's medical decision making." [31] The petition argued that courts "have strayed from congressional intent by reading out of the AKS any element of corruption or inherently bad conduct." [32] The Supreme Court denied the petition, leaving the Courts of Appeals to address a key element for FCA cases premised on an alleged AKS violation. [33]

Courts of Appeals

5. The Pro Tanto Rule Applies to Damages Under the FCA: United States v. Honeywell International Inc.

In *United States v. Honeywell International Inc.*, the government alleged that Honeywell purchased material for bulletproof vests that were sold to the government despite knowing that the material was defective. [34] The government, while litigating the matter against Honeywell, settled with other defendants "for their role in manufacturing and supplying the vests." [35] Even so, the government, notably, was "claim[ing] damages for the full amount paid for the vests," trebled damages to about $35 million. [36] Honeywell filed an interlocutory appeal after, during the course of the litigation, the government settled with other defendants for $36 million. [37] The district court held that, regardless of the settlements, Honeywell needed to pay its "proportionate share" of the total $35 million, even after the government reached the other settlements. [38]

In its appeal, Honeywell argued that a *pro tanto* approach should be used to calculate damages —"dollar for dollar, credit against its common damages liability equal to those settlements." [39] The D.C. Circuit reasoned that the "threshold question" was "whether the FCA provides a settlement offset rule." [40] Because the statutory text, the common law in 1863, and case law did not address the settlement offset rule, the D.C. Circuit held that a federal common law rule was necessary—that rule would be the *pro tanto* rule. [41] The *pro tanto* rule is both "compatible with the FCA" but also "a better fit with the statute and the liability rules that have been partnered

with it." [42] On October 26, 2022, DOJ announced that Honeywell would pay $3.35 million to resolve the FCA allegations. [43]

6. *But-For Causation Applies to FCA Violations Based on AKS Violations:* United States ex rel. Cairns v. D.S. Medical LLC

In *United States ex rel. Cairns v. D.S. Medical LLC*, the Eighth Circuit addressed the causation requirement in the AKS. [44] To prove a "false or fraudulent" claim under the FCA, one can show that the claim "'includes items or services *resulting from* a violation' of the anti-kickback statute." [45] In *Cairns*, a neurosurgeon treated degenerative-disc diseases and spinal disorders. [46] To treat those conditions, the doctor would use spinal implants. [47] The Court noted that the purchase of these implants would generate commissions for distributors. [48] In this case, the neurosurgeon purchased the implants from his fiancée's wholly owned company, and his fiancée "made $1.3 million in commissions from one manufacturer alone." Physicians "grew suspicious of [the neurosurgeon's] high implant use" and "his cozy financial relationship with" his fiancée, so they filed FCA complaints outlining violations of the FCA. [49] The government then intervened and filed its own complaint. [50] Three of the FCA claims "alleged that the couple and their businesses submitted false or fraudulent Medicare and Medicaid claims after violating the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), (g)." [51] The district court instructed the jury in the case "that the government could establish falsity or fraud once it proved, by a preponderance of the evidence, 'that the Medicare or Medicaid claim failed to disclose the anti-kickback statute violation.'" [52] The jury returned a verdict against the defendants on two of the claims. [53]

The defendants, including the neurosurgeon's practice, his fiancée, and D.S. Medical, [54] appealed, and the Eighth Circuit was faced with, *inter alia*, a question about the lack of a but-for causation instruction to the jury. [55] The Eighth Circuit, looking to the plain meaning of the statute and interpreting the 2010 amendment to the AKS, held that "results from" requires but-for causation. [56] Disagreeing with the district court, the Eighth Circuit held that "just because a claim fails to disclose an anti-kickback violation does not mean that there is a connection between the violation and the included 'items or services.'" [57] "Causation is an 'essential element' that must be proven, not presumed." [58] Ultimately, the Eighth Circuit held that it "do[es] not suggest that every case arising under the [FCA] requires a showing of but-for causation," but "when a plaintiff seeks to establish falsity or fraud through the 2010 amendment [to the AKS], it

must prove that a defendant would not have included particular 'items or services' but for the illegal kickbacks." [59]

This decision is contrary to the Third Circuit's decision in *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, [60] a result the Eighth Circuit acknowledged. [61] The Eighth Circuit disagreed with the Third Circuit's approach and stated that "[a]lthough we understand its point of view, it adopted an approach that we have already rejected: relying on legislative history and 'the drafters' intentions' to interpret the statute." [62] This issue of the AKS's causation element, and the fundamental differences in interpretation between the Circuits, may be one ripe for Supreme Court review in the coming year.

7. "Disagreement in Clinical Judgment" Not Enough for FCA Plausibility: Holzner v. DaVita Inc.

In *Holzner v. DaVita, Inc.*, a relator appealed the dismissal of his claims by a lower court, where he alleged "three interconnected frauds designed to optimize appellees' profits by providing medically unnecessary products and services and/or unreasonably expensive medications." [63] Additionally, the district court denied the relator leave to amend his complaint. [64] Relator alleged that defendants were fraudulently optimizing profits through unnecessary products, services, and expensive medications. [65] The Ninth Circuit cited a 2020 case, *United States ex rel. Winter v. Gardens Regional Hospital & Medical Center, Inc.*, [66] and stated that "[a] provider's opinion or certification that a certain treatment or service is medically necessary can be false or fraudulent 'if the opinion is not honestly held, or if it implies the existence of facts—namely, that [the service] is needed to diagnose or treat a medical condition, in accordance with accepted standards of medical practice—that do not exist.'" [67] The relator's fourth amended complaint did not do that—"[t]he medical literature on which [he] relies is not as definitive as he would have it: it does not establish new guidelines for practitioners or otherwise compel a change of practice among nephrologists." [68]

The Ninth Circuit held that the relator was "attempting to use the FCA to force dialysis facilities to reject the considered opinions of treating nephrologists regarding the need for dialysis treatments" or prescription drugs "based on *his* reading of the relevant literature." [69] Instead, all relator's complaint did was "show no more than a disagreement in clinical judgment" and "not … a plausible inference that the nephrologists' certifications that these interventions are medically necessary—or appellees' reliance on those certifications—were false or fraudulent." [70] The

Court also agreed that relator's leave to amend be denied because the clarification that one of his prescription drug claims were not as cost effective would be "futile" because the challenge was clear in the fourth amended complaint and that, ultimately, he "had the detailed analysis of the district court to guide him and had a full and fair opportunity to address the deficiencies identified" after multiple iterations of his complaint. [71]

The Ninth Circuit's reaffirmation of the notion that differing clinical judgments, untainted by fraud or dishonesty, can negate falsity, further bolsters a key defense in FCA case implicating healthcare providers.

Settlements

8. Biogen Inc.

On September 26, 2022, DOJ announced one of the largest FCA settlements in history. Biogen Inc. (Biogen) agreed to pay $900 million to resolve FCA allegations. [72] As mentioned above, almost half of FY2022's recovery came from this settlement. [73] The lawsuit was brought by a relator, Michael Bawduniak, a former Biogen employee, in the District of Massachusetts. [74] The heart of the allegations concerned the AKS—Biogen paid kickbacks to induce physicians to prescribe Biogen's drugs, which resulted in false claims to Medicare and Medicaid. [75] The press release indicates that relator alleged that from 2009 to 2014, "Biogen offered and paid remuneration, including in the form of speaker honoraria, speaker training fees, consulting fees and meals, to health care professionals who spoke at or attended Biogen's speaker programs, speaker training meetings or consultant programs to induce to prescribe" Biogen drugs. [76]

The relator's share of the settlement will exceed $265 million, [77] and it sets an all-time record for a relator in any *qui tam* case. Moreover, it is worth noting that the government declined to intervene in this case and the settlement's magnitude, itself, will double the amounts recovered in non-intervened *qui tam* cases from the prior year (which had surpassed all prior records).

9. Mallinckrodt

Another pharmaceutical company, Mallinckrodt ARD LLC (Mallinckrodt), agreed to pay $260 million to resolve FCA allegations. [78] The allegations involved Medicaid drug rebates and, like Biogen, illegal kickbacks relating to Mallinckrodt's drug H.P. Acthar Gel. [79] Though the cases were brought by relators, the government intervened in all of the cases. [80] The press release

indicated that "[p]ursuant to the Medicaid Drug Rebate Program, drug manufacturers are required to pay quarterly rebates to state Medicaid programs in exchange for Medicaid's coverage of the manufacturers' drugs," but that Mallinckrodt "knowingly underpaid rebates due for Acthar from 2013 until 2020." [81] The rebates, used "to insulate the Medicaid program from drug price increases outpacing inflation[,]" are calculated by a comparison of a "Base Date Average Manufacturer Price (AMP), which is the drug's price on the date that the 'dosage form and strength' of the drug was first marketed or 1990, whichever is later, to its current price." [82] DOJ alleged that Mallinckrodt paid rebates for Acthar in 2013 "as if Acthar was a 'new drug' first marketed in 2013" when Acthar was approved in 1952, and that Acthar's price per vial was over $28,000 in 2013, so Mallinckrodt was "ignoring all pre-2013 price increases for Medicaid rebate purposes significantly lowered Medicaid rebate payments for Acthar." [83] In its settlement agreement, Mallinckrodt admitted that Acthar was approved by the U.S. Food and Drug Administration and marketed before 1990. [84] Additionally, DOJ alleged that Mallinckrodt "used a foundation as a conduit to pay illegal kickbacks in the form of copay subsidies for Acthar so it could market the drug as 'free' to doctors and patients while increasing its price." The ultimate settlement resulted in about $234.7 million to settle the rebate allegations and close to another $26.3 million to settle the AKS allegations. [85] The relators will receive about $29.6 million of the recovery. [86]

Among other significant aspects of this case is its representation of the emergence in FCA enforcement involving the use of foundations and other conduits for the payments of alleged kickbacks.

DOJ Developments

10. DOJ Announces Chief Compliance Officer Certifications

In 2022, DOJ, through Assistant Attorney General Kenneth A. Polite, Jr., announced a new "tool" it would use in corporate resolutions going forward. First, on March 25, 2022, Assistant Attorney General Polite spoke at New York University's Law Program on Corporate Compliance and Enforcement. [87] There, focusing on the role of chief compliance officers (CCOs), he described CCOs' functions as having "true independence, authority, and stature within the company." [88] In a move to "further empower" them, he stated that he "asked [his] team to consider requiring both the Chief Executive Officer and the Chief Compliance Officer to certify at the end of the term of the agreement that the company's compliance program is reasonably designed and

implemented to detect and prevent violations of the law..., and is functioning effectively." (89) Additionally, he left open the possibility that other resolutions "will require additional certification language." (90) In the speech, Assistant Attorney General Polite stated he has been a CCO and "know[s] the challenges." The certifications, he claimed, were "not punitive in nature" but "a new tool in [their] arsenal to combat those challenges." (91) In September, Assistant Attorney General Polite gave another speech at The University of Texas Law School. (92) He again mentioned the CCO certifications, stating they "underscore [DOJ's] message to corporations: investing in and supporting effective compliance programs and internal controls systems is smart business and the department will take notice." While acknowledging the concern about the certifications, he stated that "[f]or too long, [compliance personnel] have complained that compliance doesn't have the same voice in corporate decision-making" and the "certifications and other resources are empowering [them] to demand that voice." (93)

DOJ's insistence on these certifications amplifies the risks for CCOs. Vagaries exist as to what constitutes a "reasonably designed" compliance program, and DOJ's insistence on imposing these certifications on CCOs does the opposite of what they claim to be the intention. The certifications put CCOs at personal risk for potential company violations even if the certifications include caveats. The unintended consequence of these requirements could diminish the desire of the most highly qualified individuals to serve in compliance roles in light of the enormous exposure they might face.

Endnotes

Authors

Robert T. Rhoad, Esq.
Nichols Liu LLP, Washington, DC

Robert "Bob" T. Rhoad is a partner at Nichols Liu LLP in Washington, DC. Mr. Rhoad's practice focuses on the defense of healthcare and government contractor clients in cases under the federal False Claims Act (and its state and local analogues) and all other types of fraud and abuse matters from investigation, through litigation/trial, and on appeal. He can be reached at rrhoad@nicholsliu.com.

Andy Liu, Esq.
Nichols Liu LLP, Washington, DC

Andy Liu is a partner at Nichols Liu LLP in Washington, DC. Mr. Liu's practice focuses on the representation of healthcare and government contractor clients in all phases of administrative, civil, and criminal disputes, including False Claims Act litigation. He can be reached at aliu@nicholsliu.com.

Haaleh Katouzian, Esq.
Nichols Liu LLP, Washington, DC

Haaleh Katouzian is an associate at Nichols Liu LLP in Washington, DC. Ms. Katouzian's practice focuses on the representation of clients in litigation matters and internal investigations, including False Claims Act matters. She can be reached at hkatouzian@nicholsliu.com.

ENTITY:

HEALTH LAW SECTION

TOPIC:

HEALTH