Mid-2024 FCA Enforcement And Litigation Trends To Watch

By **George Breen, Daniel Fundakowski and Richard Westling** (May 7, 2024)

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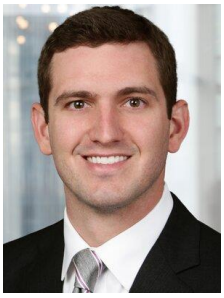

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This article addresses False Claims Act trends and notable enforcement efforts from 2023 through midyear 2024 and highlights key developments to watch during the remainder of this year.

DOJ Fiscal Year 2023 FCA Recoveries

According to U.S. Department of Justice statistics released on Feb. 22, the number of settlements, judgments and civil investigative demands under the FCA was the highest in history for the fiscal year ending Sept. 30, 2023.[1]

The same day, DOJ Principal Deputy Assistant Attorney General Brian M. Boynton reported at the Federal Bar Association's qui tam conference that the U.S. was a party to 543 FCA settlements and judgments in fiscal year 2023 — the most ever in a single year and a 54% increase from fiscal year 2022.[2]

Boynton also announced that the DOJ set a new record for issuing civil investigative demands; the Fraud Section issued 1,504 civil investigative demands for documents, interrogatory responses and testimony in fiscal year 2023.

While the $2.68 billion in total recoveries continues an upward trend from the $2.24 billion reported in fiscal year 2022, a primary takeaway is the focus on DOJ-driven investigations.

In fiscal year 2023, more money was recovered from qui tam cases in which the U.S. intervened or prosecuted (nearly $1.9 billion) than in cases where the government declined to intervene ($442 million) — a near inverse from fiscal year 2022.

As for new cases, whistleblowers filed 712 qui tam suits in fiscal year 2023 and received over $349 million — a considerable decrease from the $496 million in fiscal year 2022. DOJ-initiated cases also increased substantially, with 500 new matters in fiscal year 2023, up from 305 in fiscal year 2022.

With fiscal year 2023 in the books, recoveries under the FCA since the 1986 amendments now exceed $75 billion and have exceeded $2 billion annually for 15 consecutive years.

Healthcare Remains a Key Enforcement Priority in 2024

Since the early 2000s, the healthcare sector has consistently been the largest area of enforcement and recovery. More than $1.8 billion of the $2.68 billion recovered in fiscal year 2023 came from the healthcare industry, including drug and medical device manufacturers, durable medical equipment suppliers, home health and managed care providers, hospitals and more.

The DOJ continues to prioritize the pursuit of pandemic-related fraud schemes, resolving

approximately 270 FCA matters in connection with improper Paycheck Protection Program loans in fiscal year 2023 and recovering more than $48.3 million.

Within the healthcare sector, particular areas of enforcement activity in fiscal year 2023 included allegations of Medicare Advantage inaccurate diagnosis codes and upcoding, unnecessary services and substandard care in nursing homes and other providers, fraud related to the opioid epidemic, and violations of the FCA predicated on noncompliance with the Anti-Kickback Statute and the Stark Law.

In his February remarks, Boynton also named cybersecurity as a first priority, adding that the DOJ "is currently investigating many more cases involving alleged violations of cybersecurity requirements," which may or may not involve healthcare.[3]

Circuit Split on Causation for FCA Violations Predicated on AKS Noncompliance

The year 2023 presented a variety of novel FCA issues, a trend that is continuing into 2024.

First Circuit: U.S. v. Teva Pharmaceuticals USA

At issue in U.S. v. Teva Pharmaceuticals,[4] in the U.S. Court of Appeals for the First Circuit, is a 2010 amendment to the Anti-Kickback Statute, Title 42 of the U.S. Code, Section1320a-7b(g), which provides that any claim for Medicare reimbursement "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]."

The interpretation of those two words, "resulting from," will have significant implications for FCA litigants in establishing FCA causation. Two primary interpretations have emerged.

On the one hand, the U.S. Courts of Appeals for the Eighth and the Sixth Circuits have interpreted "resulting from" to require that but-for causation be established. On the other hand, the U.S. Court of Appeals for the Third Circuit's interpretation is that a plaintiff need only prove "a link between the alleged kickbacks and the medical care received."

In Teva, the U.S. government alleged that payments of over $350 million to two charities to cover the Medicare copay obligations of patients taking a multiple sclerosis drug violated the FCA and the AKS. Patients, including Medicare patients, were allegedly incentivized to purchase the drug as Teva was subsidizing the cost.

On July 14, 2023, the U.S. District Court for the District of Massachusetts issued an order denying Teva's motion for summary judgment and granting the U.S.' motion for partial summary judgment on materiality, causation and damages under the FCA.

The district court, following the First and Third Circuits, held that the government need not prove but-for causation at trial. Teva, asserting that but-for causation is the appropriate standard, moved to certify the case for interlocutory appeal to the First Circuit, arguing that the causation standard to prove falsity based on the 2010 AKS amendment is "a controlling question of law as to which there is substantial ground for difference of opinion."

U.S. District Judge Nathaniel M. Gorton allowed the motion to certify on Aug. 14, 2023. The First Circuit granted the request, and the case will be heard later this year.

First Circuit: U.S. v. Regeneron Pharmaceuticals Inc.

Meanwhile, another federal judge in the U.S. District Court for the District of Massachusetts followed the U.S. Courts of Appeals for the Sixth and Eighth Circuits' but-for standard.

In U.S. v. Regeneron Pharmaceuticals Inc.,[5] U.S. District Judge Dennis Saylor IV noted that any claim for Medicare reimbursement "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]."

Yet he noted that courts' interpretations of the meaning of "resulting from" have differed — the minimum being "a causal relationship of some kind between the AKS violation and the medical decision that resulted in the false claim."

Accordingly, Judge Saylor, finding the Sixth and Eighth Circuit decisions persuasive, agreed with Regeneron that the stricter but-for standard should apply. The upcoming First Circuit appeal in Teva should resolve the First Circuit divide.

In another recent FCA case alleging violations of the AKS, U.S. ex rel. Fesenmaier v. Cameron-Ehlen Group Inc. in the U.S. District Court for the District of Minnesota last year, U.S. District Judge Wilhelmina Wright cut a $487 million FCA jury verdict down to $216 million finding the award violated the excessive fines clause of the U.S. Constitution and was "grossly disproportional to the gravity of a defendant's offense."[6]

Of note, Judge Wright — in interpreting the Eighth Circuit's 2022 decision in Cairns v. D.S. Medical LLC — ruled that the but-for causation standard applies only when the FCA plaintiff is using the 2010 AKS amendment as the vehicle for establishing the FCA violation, and that a plaintiff can circumvent the but-for causation requirement by establishing materiality and falsity independently from the 2010 AKS amendment.

Under this theory, Judge Wright held the Third Circuit's more lenient causation standard from U.S. ex rel. Greenfield v. Medco Health Solutions Inc. in 2018 was appropriate, and the government met that standard at trial.

On Feb. 9, the case was transferred to U.S. District Judge Eric Tostrud — who had issued an opinion in United States ex rel. Louderback v. Sunovion Pharmaceuticals in November 2023, disagreeing with Judge Wright's decision in Fesenmaier, stating that the reasoning "rests on a flawed interpretation of the [2010 AKS amendment]," and "there is no such thing as a[n FCA] case premised on an Anti-Kickback violation that need not go through 42 U.S.C. § 1320a-7b(g)."

The defendants in Fesenmaier filed a notice of appeal to the Eighth Circuit in March.

Other Noteworthy FCA Developments From 2023

U.S. Supreme Court Weighs in on FCA's Scienter Component

The healthcare industry is now grappling with the FCA's scienter component following the consolidated June 1, 2023, U.S. Supreme Court decisions of U.S. et al. ex rel. Schutte et al. v. Supervalu Inc. and U.S. et al. ex rel. Proctor v. Safeway Inc.[7]

In Schutte, private parties sued retail pharmacies, claiming violations of the FCA through alleged fraud on the Medicare and Medicaid programs. Those government programs provide prescription drug coverage to their beneficiaries and usually limit the reimbursement to a pharmacy to the pharmacy's usual and customary charge to the public.

The respondent pharmacies, however, allegedly reported to Medicare and Medicaid their higher retail prices — as opposed to the lower discounted prices they offered customers through discount programs.

The U.S. District Court for the Central District of Illinois held that the pharmacies' "usual and customary" prices were its discounted prices, not the higher retail prices, and concluded that the pharmacies submitted false claims. Yet the district court held pharmacies could not have acted knowingly under the FCA.

The Seventh Circuit affirmed, concluding that the Supreme Court's interpretation of the scienter provision in a 2007 Fair Credit Reporting Act case applied with equal force in the FCA context. According to the Seventh Circuit, the district court's failure to apply the FCRA standard — i.e., whether the pharmacies' incorrect understanding of "usual and customary" was objectively reasonable at the time — precluded liability under the FCA.

The Supreme Court, however, held that the FCA's scienter element refers to the defendant's knowledge and subjective beliefs — not to what an objectively reasonable person may have known or believed.

Also, in June 2023, the Supreme Court held in U.S. ex rel. Polansky v. Executive Health Resources that the government may move to dismiss an FCA action whenever it has intervened in the case, whether at the outset, during the seal period or later. The court rejected the government's contention that the government may move to dismiss an FCA case without intervening.[8]

Sixth Circuit Issues Decision Clarifying Remuneration Element of the AKS

In March 2023, the Sixth Circuit in U.S. ex rel. Martin v. Hathaway examined the interplay between the FCA and the AKS, prohibiting medical providers from making referrals in exchange for remuneration.

The court affirmed the dismissal of the qui tam complaint, holding that the behavior at issue — a hospital's decision not to hire an ophthalmologist in exchange for a commitment of continued surgery referrals from another ophthalmologist — was not a cognizable kickback scheme.

According to the Sixth Circuit, the FCA lawsuit that followed contained two legal flaws under the FCA and the AKS: the suit did not turn on a cognizable theory of remuneration and failed to establish causation.

While the AKS does not define "remuneration," the court concluded that it covers payments and other transfers of value — not simply any act that may be valuable to another. And while the FCA contains the word "payment," the court declined to find that "remuneration" means something broader.

On the causation issue, the Sixth Circuit — following the stricter standard discussed earlier — declined to find that the ophthalmologist plausibly alleged but-for causation.

The Road Ahead for the FCA in 2024

Causation Standard in AKS Cases

FCA causation in cases predicated on AKS noncompliance will continue to be closely

monitored this year as the First Circuit and other courts weigh in on the appropriate causation standard for claims under Title 42 of the U.S. Code, Section 1320a-7b(g).

Clarification on the AKS Willfulness Standard

The U.S. Court of Appeals for the Second Circuit issued a recent FCA opinion in U.S. ex rel. Hart v. McKesson Corporation examining the willfulness standard under the AKS.[9]

In March, the Second Circuit affirmed the U.S. District Court for the Southern District of New York's ruling that to act willfully in violation of the AKS, a defendant must act with the knowledge that the conduct is in some way unlawful.

In this case, the district court held that the relator failed to plead sufficient facts to allege that a pharmaceutical wholesaler's offer of free access to business management tools to customers constituted an unlawful kickback.

The Second Circuit vacated the dismissal of the relator's state law FCA claims and remanded for further proceedings, noting that "even though [the relator's] complaint is insufficient to state a federal FCA claim based on the federal AKS, it may be sufficient to state a state-law claim under one or more of the state anti-kickback laws cited in [the] complaint."

Increased Scrutiny for Private Equity

We also expect private equity firms investing in healthcare companies to be under increased government scrutiny this year.

During his Feb. 22 remarks at the Federal Bar Association's qui tam conference, Boynton specifically highlighted private equity firms and noted how the DOJ is committed to holding accountable "third parties that cause the submission of false claims" — to include "private equity firms among others."

A noted example of how investors can influence patient care is by "providing express direction for how a provider should conduct their business, or more indirectly by providing revenue targets or other indirect benchmarks intended to prioritize reimbursement."[10]

The U.S. Department of Health and Human Services Office of Inspector General, for example, will likely be examining where the money is flowing in such transactions, the incentives driving conduct that the agency views as questionable, how private equity firms are using and leveraging government funds, and how nursing homes use government healthcare program dollars following a private equity transaction.

Focus on Cybersecurity Compliance

The DOJ has also signaled an intense focus on cybersecurity. In his Feb. 22 conference remarks, Boynton pledged that the DOJ will "continue to dedicate resources to investigating companies that fail to comply with their cybersecurity obligations" and that these cases are expected to be a "significant area of enforcement in the coming years."

Given the heightened scrutiny on cybersecurity compliance, companies would be well served to update cybersecurity and information security policies to align with best practices and regulatory requirements, regularly evaluate contractual terms, monitor enforcement actions to stay on top of ongoing trends, and ensure incident response plans are up-to-date.

The DOJ Continues Focus on Self-Disclosure and Cooperation Factors

The DOJ has historically demonstrated a willingness to consider cooperation factors when companies or individuals disclose misconduct that could serve as the basis for FCA liability.

The concept of FCA cooperation credit is not new — the Civil Division released formal guidance in 2019 explaining how the DOJ awards credit to defendants who cooperate during FCA investigations.

In June 2023, the DOJ began explicitly referencing cooperation[11] in its settlement agreements when crediting entities with voluntary disclosure, cooperation and remediation in FCA matters. The DOJ will consider all appropriate factors, including an entity's voluntary self-disclosure of misconduct and taking steps to cooperate with an ongoing government investigation.

The focus on self-disclosure and cooperation shows no signs of slowing in 2024. On April 15, the DOJ's Criminal Division announced a pilot program on voluntary self-disclosures for individuals — whereby "prosecutors will offer [non-prosecution agreements] to individuals who voluntarily disclose original information about certain types of criminal conduct involving corporations, fully cooperate with authorities, and pay any applicable victim compensation, restitution, forfeiture, or disgorgement, including returning any ill-gotten gains."

The pilot program applies to disclosures made after April 15.

Companies would be well advised to evaluate existing compliance programs and ensure adequate processes are in place to prevent and detect misconduct. Compliance programs should also include internal reporting mechanisms that are accessible and facilitate an appropriate investigation of complaints.

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[1] Department of Justice, False Claims Act Settlements and Judgments Exceed $2.68 Billion in Fiscal Year 2023, February 22, 2024, available at https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023.

[2] Department of Justice, Principal Assistant Attorney General Brian M. Boynton Delivers Remarks at the 2024 Federal Bar Association's Qui Tam Conference, February 22, 2024, available at https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-brian-m-boynton-delivers-remarks-2024.

[3] In 2021, the DOJ launched its Civil Cyber-Fraud Initiative, which uses the FCA to hold accountable entities and individuals that put U.S. information and systems at risk by violating federal cybersecurity requirements.

[4] United States v. Teva Pharmaceuticals USA, Inc., 2023 WL 4565105 (D. Mass. Jul. 14, 2023).

[5] United States v. Regeneron Pharmaceuticals, Inc., 2023 WL 7016900 (D. Mass. Sept. 27, 2023).

[6] United States ex rel. Fesenmaier v. Cameron-Ehlen Grp, Inc., No. 13-cv-3003 (D. Minn., Feb. 8, 2024).

[7] United States ex rel. Schutte v. Supervalu Inc., 598 U.S. 739 (2023).

[8] United States ex rel. Polansky v. Executive Health Resources, 599 U.S. 419 (2023).

[9] United States ex rel. Hart v. McKesson Corp., No. 23-726-cv (2d. Cir. Mar. 12, 2024).

[10] Department of Justice, Justice Department, Federal Trade Commission and Department of Health and Human Services Issue Request for Public Input as Part of Inquiry into Impacts of Corporate Ownership Trend in Health Care, March 5, 2024, available at https://www.justice.gov/opa/pr/justice-department-federal-trade-commission-and-department-health-and-human-services-issue. Also, on March 5, the DOJ, Federal Trade Commission (FTC), and Department of Health and Human Services issued a request for public input as part of an inquiry into the impacts of corporate ownership—including by private equity firms—on patient health/outcomes, worker safety, quality of care, and health care affordability. In an FTC workshop the same day exploring the role of private equity investment in health care markets, fraud and abuse enforcement (both federal and state laws) was suggested as one strategy—along with antitrust laws—of going after alleged bad actors in the private equity space. See Federal Trade Commission, FTC to Host Virtual Workshop on Private Equity in Health Care, February 14, 2024, available at https://www.ftc.gov/news-events/news/press-releases/2024/02/ftc-host-virtual-workshop-private-equity-health-care.

[11] See Section 4-4.112 of the Justice Manual.