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FCA Enforcement And Litigation Trends To Watch

By **George Breen, Erica Bahnsen and Daniel Fundakowski** (March 2, 2023, 7:24 PM EST)

This article addresses select False Claims Act enforcement efforts and notable court activity from 2022, and trends and cases to watch in 2023.

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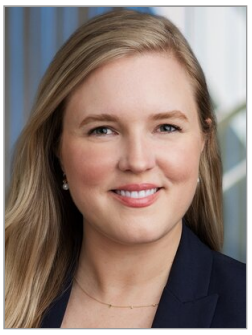

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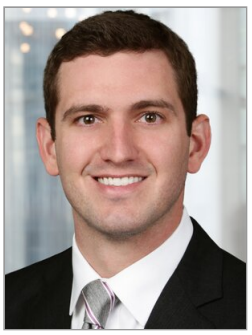

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DOJ 2022 FCA Recoveries

In fiscal year 2022, the U.S. Department of Justice filed 296 new FCA matters — the highest number of new cases brought by the government in reported history — but overall recoveries were the lowest in 14 years.[1] Of the 296 new FCA matters, 93 related to the health care and life sciences industries, which was consistent with filings in fiscal year 2021.

Total FCA recoveries exceeded $2.2 billion, a drop of more than 50% from the $5.7 billion recovered in fiscal year 2021.[2]

However, even in a down year likely due largely to the lack of major settlements with prescription opioid manufacturers, including a $2.8 billion resolution with Purdue Pharma LP in fiscal year 2021, health care and life sciences entities continue to be the primary focus of the enforcement effort by DOJ and relators.

More than $1.7 billion — over 80% of all recoveries — related to matters involving the health care and life sciences industries. Of the $1.7 billion recovered, $1.2 billion came from qui tam cases in which the government declined to intervene.

By contrast, $777 million was recovered in cases where the government intervened or otherwise pursued. This marks the first time since the statistics have been maintained that more monies were recovered from cases in which the U.S. declined than in cases in which the U.S. intervened.

Although total recoveries declined, it is notable that over 80% of recoveries were still from the health care and life sciences industries.

Health care and life sciences entities should expect continued focus from DOJ and relators, particularly following the pandemic, a time when investigations and litigations stalled. However, given the aggressive posture DOJ has taken with respect to enforcement and the increasing number of cases pursued by relators post-declination, we do not expect fiscal year 2023 to show a similar decline.

Leveraging the FCA to Enforce Cybersecurity Compliance

On Oct. 6, 2021, the DOJ launched its Civil Cyber-Fraud Initiative, intended to leverage the FCA to pursue cybersecurity-related fraud by government contractors and grant recipients.[3]

The initiative targets individuals and entities that are knowingly providing deficient cybersecurity products or services, knowingly misrepresenting their cybersecurity practices or protocols or knowingly violating obligations to monitor and report cybersecurity incidents and breaches.

On March 8, 2022, the DOJ announced its first settlement under the Civil Cyber-Fraud Initiative.[4]

Comprehensive Health Services LLC, a Florida-based medical services provider, agreed to pay $930,000 to resolve allegations that it violated the FCA by falsely representing to the State Department and the Air Force that it complied with contract requirements relating to the provision of medical services at State Department and Air Force facilities in Iraq and Afghanistan.

CHS allegedly failed to disclose that it had not consistently stored patients' medical records in a secure electronic medical record system and that it did not properly obtain certain controlled substances that were manufactured in accordance with federal quality standards.

Health care entities will likely be subject to further government enforcement under this initiative. Rigorous and ongoing monitoring and auditing of cybersecurity policies and practices for compliance in these areas — and ensuring understanding of contractual obligations — will be key in mitigating this enforcement risk.

Greater Attention on Telehealth Schemes

On April 12, 2022, the DOJ announced a settlement with Physician Partners of America LLC for $24.5 million.[5]

PPOA allegedly violated the FCA by billing for unnecessary medical testing and services, including evaluation and management of telemedicine services. PPOA was accused of using telemedicine during the COVID-19 pandemic to try to compensate for lost revenue from elective services. In addition, PPOA allegedly instructed medical providers to see patients by telemedicine twice a month, regardless of patient need.

On July 20, 2022, the U.S. Department of Health & Human Services Office of Inspector General issued a special fraud alert noting an increase in telehealth fraud schemes.[6]

The DOJ and OIG will likely continue targeting alleged telehealth fraud due to increased telehealth utilization during the pandemic. Because of the marked upsurge in telehealth use during the pandemic, the number of reimbursement claims would have increased exponentially, making telehealth ripe for enforcement action.

COVID-19 Fraud Enforcement Remains a DOJ Priority

The DOJ has consistently emphasized that COVID-19 fraud enforcement is a top priority, and enforcement actions show no signs of slowing.

In May 2021, the U.S. attorney general established the COVID-19 Fraud Enforcement Task Force, which forged a partnership between the DOJ and other agencies, with a shared goal of combating pandemic-related fraud.[7] In 2022, the DOJ announced three new COVID-19 fraud strike force teams and a litany of enforcement actions.

The task force recently investigated and settled with MorseLife Health System Inc. based on allegations that MorseLife facilitated COVID-19 vaccination of hundreds of individuals who were ineligible to participate in the Centers for Disease Control and Prevention's long-term care program, including board members, donors and potential donors.[8]

The program was designed to vaccinate long-term care facility residents and staff at the beginning of the pandemic, when the vaccine supply was limited. MorseLife agreed to pay the U.S. $1.75 million to resolve potential liability under the FCA.

The task force is also investigating fraudulent COVID-19 testing schemes.

A Florida laboratory owner, Christopher Licata, recently pled guilty to a $6.9 million conspiracy to defraud Medicare by paying kickbacks and bribes to patient brokers to obtain doctors' orders for lab tests that were then billed to Medicare.[9] When patients sought COVID-19 tests, Licata bundled the COVID-19 tests with more expensive, medically unnecessary tests, such as respiratory pathogen panel testing and various genetic tests.

Health care and life sciences entities can expect more enforcement actions, and a broader scope of enforcement, as the DOJ continues to investigate distributions and expenditures of COVID-19 funds.

Focusing on Individual Accountability and Voluntary Self-Disclosure in the Criminal Context

On Sept. 15, 2022, U.S. Deputy Attorney General Lisa Monaco announced revised DOJ policies on criminal enforcement for corporate misconduct.[10]

Expanding upon the 2015 Yates memo,[11] the Monaco memo makes clear that the DOJ's first priority in corporate criminal matters is individual accountability.

Prosecutors are encouraged to complete investigations and pursue any appropriate criminal charges against individuals prior to, or at the same time as, entering into a resolution with a company. The DOJ will consider a company's history of prior misconduct when entering into a resolution with a company, especially misconduct involving the same personnel.

Changes were also made to the DOJ's corporate enforcement policy, rewarding voluntary self-disclosure. Under the revised policies, the DOJ may decline to prosecute if:

- The voluntary self-disclosure was made immediately upon the company becoming aware of the allegation of misconduct;
- At the time of the misconduct and the disclosure, the company had an effective compliance program and system of internal accounting controls; and
- The company provided extraordinary cooperation with the DOJ's investigation and undertook extraordinary remediation.

If a company voluntarily self-discloses misconduct, fully cooperates, and timely and appropriately remediates, and the DOJ proceeds to seek penalties, the DOJ will recommend 50% to 75% off the low end of the penalty range.[12]

For the remainder of 2023, we expect a reinvigorated look at individual actors in matters brought under the FCA. Entities should prioritize compliance and auditing functions in preparation for potential enforcement action, and be poised for voluntary self-disclosure, if needed.

Rule 9(b) Pleading Standard for FCA Cases

Federal Rule of Civil Procedure 9(b) requires that, for allegations of fraud, a party must state with particularity the circumstances constituting fraud.

The U.S. Supreme Court, without a written order, recently denied three petitions for certiorari and declined the opportunity to clarify whether Rule 9(b) requires an FCA complaint to plead specific instances of submitted false invoices, sufficiently representative of the larger body of submitted false claims, where it otherwise pleads specific facts regarding a fraudulent scheme.[13]

The Supreme Court's reticence to take up these petitions follows the solicitor general's recommendation to deny certiorari. According to the solicitor general, perceptions of disarray among the circuits simply reflect courts' application of a fact-intensive standard to a range of different types of allegations.

For now, we expect the standard for pleading fraud with particularity will continue to be addressed by courts focusing upon the specific facts of a given case.

The Role of Clinical Judgment in the FCA Falsity Requirement

While the FCA requires that claims be false or fraudulent in order to give rise to liability, the statute does not define those terms, and this has become a contentious issue for FCA cases predicated on the propriety of clinical judgments.

In the landmark 2019 ruling of United States v. AseraCare, the U.S. Court of Appeals for the Eleventh Circuit held that FCA liability must be based on an objective falsehood, not a subjective difference of opinion.[14]

The U.S. Court of Appeals for the Ninth Circuit recently reapplied this standard in Holzner v. DaVita Inc., where the relator alleged that DaVita provided medically unnecessary products and services and/or unreasonably expensive medications in violation of the FCA.

The Ninth Circuit affirmed the district court's dismissal of the relator's claims on the grounds that he had not plausibly alleged a false statement in order to establish FCA liability.[15] The court explained that the allegations show no more than a disagreement in clinical judgment, as "[t]he medical literature on which Holzner relies ... does not establish new guidelines for practitioners or otherwise compel a change of practice among nephrologists."

There is a circuit split on this issue that remains to be resolved. The U.S. Courts of Appeals for the Third and Sixth Circuits have rejected the Eleventh and Ninth Circuits' stance that the FCA requires proof of objective falsity, and held instead that a difference of medical opinion can be sufficient to show that a statement is false.[16]

Eighth Circuit's Stance on Alleged Anti-Kickback Statute Violations

In United States ex rel. Cairns v. DS Medical LLC, the U.S. Court of Appeals for the Eighth Circuit recently held that, to prove that a false claim includes items or services resulting from a violation of the Anti-Kickback Statute, plaintiffs must show an actual or but-for causal link between alleged kickbacks and claims for government money.[17]

In other words, a defendant would not have included particular items or services but for the illegal kickbacks. With this ruling, the Eighth Circuit departed from the Third Circuit's 2018 decision in U.S. ex rel. Greenfield v. Medco Health Solutions, which held that to prove a false claim "resulted from" a kickback, plaintiffs need not show a but-for causal link, but rather "that at least one ... claim[] sought reimbursement for medical care that was provided in violation of the [AKS]."[18]

The Eighth Circuit's reading of the FCA's causation requirement significantly affects the defense of FCA cases premised on AKS violations. We expect this position will be advanced by defendants in resisting such claims on a going-forward basis.

Government Authority to Dismiss a Declined Case Over a Relator's Objection

Circuits are currently divided on what standard to apply when the government exercises its statutory dismissal authority, but the Supreme Court is set to resolve that divide. In United States ex rel. Polansky v. Executive Health Resources Inc., the Supreme Court heard oral argument on the government's right to seek dismissal, over a relator's objection, of an FCA action in which the government declined to intervene at the outset.[19]

Though the Supreme Court did not clearly signal the exact mechanics of the government's right to dismiss, all the justices appeared to support the government's authority to dismiss a declined case over a relator's objection and appeared to contemplate that the government's burden to articulate a basis for its dismissal would be a minimal one.

Supreme Court to Assess Reckless Disregard Scienter for FCA Cases

In 2007's Safeco Insurance Co. v. Burr decision, the Supreme Court held that a defendant who acts under an incorrect interpretation of a relevant statute or regulation does not act with the requisite reckless disregard scienter if the interpretation was objectively reasonable and no authoritative guidance cautioned the defendant against it.[20]

In U.S. ex rel. Schutte v. SuperValu in 2021, the U.S. Court of Appeals for the Seventh Circuit joined the Third, Eighth, and Ninth Circuits in applying the Supreme Court's reasoning in Safeco, a case involving the Fair Credit Reporting Act, to interpret "reckless disregard" in the FCA context.[21]

The relator alleged that the defendants, a group of retail pharmacies, charged Medicare Part D and Medicaid programs their retail cash prices as their usual and customary prices for drugs rather than prices offered through competitor price-match discount programs.

The Seventh Circuit affirmed the dismissal of the complaint, holding that the defendants' interpretation of the law at issue was objectively reasonable, without any contrary authoritative guidance, so the defendants could not be shown to have acted knowingly as required under the FCA.

The relator in the pending Supreme Court case — SuperValu and a companion case from the Seventh Circuit, U.S. ex rel. Proctor v. Safeway Inc. — asks the court to answer "whether and when a defendant's contemporaneous subjective understanding or beliefs about the lawfulness of its conduct are relevant to whether it 'knowingly' violated the [FCA]."[22] Argument is currently scheduled for April 18.

The Supreme Court's ruling is highly anticipated, as it is expected to provide clarity on the scope of this defense for defendants accused of certifying compliance with complex regulatory schemes.

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[14] United States v. AseraCare, Inc., 938 F.3d 1278 (11th Cir. 2019).

[15] Holzner v. DaVita Inc., No. 21-55261, 2022 WL 726929 (9th Cir. Mar. 10, 2022).

[16] United States ex rel. Druding v. Care Alternatives, 952 F.3d 89 (3d Cir. 2020); United States v. Paulus, 894 F.3d 267 (6th Cir. 2018).

[17] United States ex rel. Cairns v. DS Med. LLC, No. 20-2445, 2022 WL 2930946 (8th Cir. July 26, 2022).

[18] United States ex rel. Greenfield v. Medco Health Solutions, Inc., 880 F.3d 89, 98 (3d Cir. 2018).

[19] United States ex rel. Polansky v. Executive Health, No. 21-1052 (U.S. Dec. 6, 2022).

[20] Safeco Insurance Company of America v. Burr, 551 U.S. 47 (2007).

[21] U.S. ex rel. Schutte v. SuperValu Inc., No. 21-1326, cert. granted (Jan. 13, 2023).

[22] U.S. ex rel. Proctor v. Safeway Inc., No. 22-111, cert. granted (Jan. 13, 2023).