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Annual Review 2022

January 24 – 27, 2022

DAY 4

12:00 p.m. FCA/FCPA: Fraud & Enforcement

2:00 p.m. Statutes, Regulations, Executive Orders & Policies

THURSDAY, JANUARY 27, 2022

12:00 PM to 4:00 PM



Alan Chvotkin
President, Pub K
Partner, Nichols Liu LLP

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SESSION 11

FCA/FPCA: FRAUD AND ENFORCEMENT

THURSDAY, JANUARY 27, 2022
12:00 PM to 1:50 PM



Andy Liu, Partner

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Overview

- 2021 – FCA by the Numbers
- Key FCA Developments – Cases, Regulatory, and Policy
- “New” DOJ Guidance
- Key Criminal Procurement Fraud Developments
- Key FCPA Developments
- Trends and the Forecast for 2022

2021 – FCA by the Numbers

- General Observations
- Industry
- Qui Tam v. Non-Qui Tam
- Recovery Trends
- What the Stats DON'T Tell Us

Key FCA Developments – Cases, Regulatory, and Policy

■ Use of Agency Guidance Documents

- Before 2017 – DOJ routinely relied on non-binding agency guidance documents in FCA cases to help establish that defendant submitted false claims and that it acted knowingly.
- Nov. 16, 2017 – Sessions Memo prohibited “improper guidance documents” that sought to bind private parties without notice-and-comment rulemaking.
- Jan. 25, 2018 – Brand Memo stated that DOJ “should not treat a party’s noncompliance with an agency guidance document as presumptively or conclusively establishing that the party violated the applicable statute or regulation.”

Key FCA Developments – Cases, Regulatory, and Policy

■ Use of Agency Guidance Documents

- Oct. 9, 2019 – President Trump issued E.O. 13891 “to require that agencies treat guidance documents as non-binding both in law and in practice.”
- Jan. 20, 2021 – President Biden revokes E.O. 13891.
- July 1, 2021 – Garland Memo rescinds the Brand Memo.
- July 16, 2021 – DOJ issues interim final rule implementing E.O. 13992, “Revocation of Certain Executive Orders Concerning Federal Regulation.”

Key FCA Developments – Cases, Regulatory, and Policy

■ Use of Agency Guidance Documents

➤ Takeaways

- DOJ will likely be emboldened to try to demonstrate violations by seeking to admit guidance to prove knowledge where a subject has received notice of a rule, even if informal.
- Heightened importance of cases like *U.S. ex rel. Schutte v. SuperValu, Inc.*, F.4th 455 (7th Cir. 2021) (summary judgment properly granted to defendant on scienter b/c “no authoritative guidance warned [defendant] away from its permissible interpretation” of its “usual and customary” drug prices when it sought reimbursements under Medicare and Medicaid).

Key FCA Developments – Cases, Regulatory, and Policy

■ DOJ's New Cyber Fraud Initiative (Oct 2021)

- Led by Civil Division's Commercial Litigation Branch, Fraud Section
- Utilizes the "False Claims Act" and includes a "Whistleblower" provision
- Enforcing against Entities or Individuals who are:
 - (1) knowingly providing deficient cybersecurity products or services,
 - (2) knowingly misrepresenting their cybersecurity practices or protocols, or
 - (3) knowingly violating obligations to monitor and report cybersecurity incidents and breaches.

Key FCA Developments – Cases, Regulatory, and Policy

■ Procurement Collusion Strike Force

- ▶ Launched November 2019
- ▶ DOJ Criminal Enforcement
 - ▶ Market Manipulation/Trade Restraints in Aerospace Industry (e.g., *U.S. v. Patel et al.*, [Criminal Complaint](#))
 - ▶ Bid Rigging in DoD Security Services (e.g., G4S Secure Solutions NV, [Press Release](#); Individual Employees, [Press Release](#))

Key FCA Developments – Cases, Regulatory, and Policy

■ Procurement Collusion Strike Force

- ▶ Antitrust Concerns Infusing Civil and FCA Enforcement?
 - ▶ Stated Antitrust Priorities (ABA PCL Conference [Keynote Remarks](#))
 - Set-Aside Fraud
 - Infrastructure
 - ▶ Praise for Whistleblowers in Antitrust Matters

Key FCA Developments – Cases, Regulatory, and Policy

■ Circuit Split on “Objective Falsity”

- ▶ Supreme Court declines to resolve Circuit Split
 - *U.S. v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019) (requiring objective falsity)
 - vs.
 - *U. S. ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 100 (3d Cir. 2020) (medical opinions can give rise to FCA liability)
 - *U.S. ex rel. Winter v. Gardens Regional Hospital and Medical Center*, 953 F.3d 1108, 1117 (9th Cir. 2020) (same)

Key FCA Developments – Cases, Regulatory, and Policy

■ Knowledge & Materiality Requirements for “Highly Sophisticated” Defendants

- ▶ *United States ex. Rel Prose v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732 (7th Cir. 2021)
 - Reversed the district court’s grant of defendant’s F.R.C.P 12(b)(6) motion to dismiss a *qui tam* complaint where the district court based the dismissal on plaintiff’s failure to allege fraud with particularity under F.R.C.P 9(b).
 - Determined that the relator adequately alleged the “knowledge” element because the defendant was a “highly sophisticated member of the medical-services industry” who was “familiar” with the contract.
 - Noted that “[r]equiring more concrete proof of knowledge would run afoul of Rule 9(b).”

Key FCA Developments – Cases, Regulatory, and Policy

■ Anti-Kickback Violations and the FCA

- ▶ *U.S. ex rel. Lutz v. Mallory et al.*, 998 F. 3d 730 (4th Cir. 2021), *cert. denied sub nom. Dent v. U.S.*, No. 21-445, 2021 WL 5284633 (Nov. 15, 2021)
- ▶ AKS Theories:
 - “P&H Fees” paid by laboratories to physicians based on referrals of reimbursable lab testing services were kickbacks
 - Commission payments by laboratories to third-party sales company that “arranged for” the P&H Fees also constituted unlawful kickbacks
 - Commission payments by third-party sales company to independent contractor sales representatives also constituted unlawful kickbacks
- ▶ The 4th Circuit rejected Defense arguments based on the plain language of the Medicare Anti-Kickback Statute (regardless of pre-existing HHS OIG Advisory Opinion guidance)

Key FCA Developments – Cases, Regulatory, and Policy

■ Fraudulent Inducement and But-For Causation

- ▶ *United States ex rel. Cimino v. Int'l Bus. Machines Corp.*, 3 F.4th 412 (D.C. Cir. 2021)
- ▶ The Facts
 - Relator alleged IBM and IRS entered into a software license agreement, but that upon learning that IRS was uninterested in renewing, IBM fraudulently induced IRS to extend the contract.
 - IBM allegedly collaborated with Deloitte, resulting in an audit finding that IRS owed IBM \$292M for noncompliance with the contract terms.

Key FCA Developments – Cases, Regulatory, and Policy

■ Fraudulent Inducement and But-For Causation

▶ *United States ex rel. Cimino v. Int'l Bus. Machines Corp.*, 3 F.4th 412 (D.C. Cir. 2021)

▶ The Facts

- IBM then allegedly offered to waive that fee in exchange for the IRS renewing the agreement.
- Relator alleged that once the new agreement was in place, IBM nonetheless collected \$87M of the noncompliance penalty by disguising that amount as fees for products/services that were never provided.
- Court granted IBM's motion to dismiss, and relator appealed.

Key FCA Developments – Cases, Regulatory, and Policy

■ Fraudulent Inducement and But-For Causation

- ▶ *United States ex rel. Cimino v. Int'l Bus. Machines Corp.*, 3 F.4th 412 (D.C. Cir. 2021)
- ▶ The Holding
 - D.C. Circuit held that relator “was required to plead actual causation under a but-for standard.”
 - D.C. Circuit rejected relator’s “argument that he needed to plead *only* proximate cause under the substantial factor test.” (emphasis in original).

Key FCA Developments – Cases, Regulatory, and Policy

■ Data Analytics, Rules 8(a) and 9(b)

- ▶ *Estate of Helmly v. Bethany Hospice and Palliative Care of Coastal Georgia, LLC*, 853 F. App'x 496 (11th Cir. 2021)
 - Relator failed to satisfy Rule 9(b) specificity
 - Mathematical probability is not sufficiently reliable – need to connect the dots specifically to show that defendant submitted a false claim
- ▶ *Integra Med Analytics LLC v. Providence Health & Services*, 854 F. App'x 840 (9th Cir. 2021)
 - Relator's statistical analysis and self-defined "fraud" insufficient to satisfy Rule 8 on element of falsity
 - On facts alleged, Relator could not exclude an alternative explanation of lawful conduct (Defendant was simply ahead of national billing trends)

Key FCA Developments – Cases, Regulatory, and Policy

■ Safeco and Determinations of Scienter under the FCA

- ▶ *Safeco Ins. Co. of America v. Burr*, 551 U.S. 47 (2007)
 - The Supreme Court held that a defendant does not act with “reckless disregard” if “(1) the interpretation was objectively reasonable and (2) no authoritative guidance cautioned defendants against it.
- ▶ *United States ex rel. Schutte v. SuperValu, Inc.*, 9 F.4th 455 (7th Cir. 2021)
 - The Seventh Circuit applied the Safeco’s scienter standard in the False Claims Act setting.
 - Held that a defendant does not “knowingly” act under the False Claims Act “if (a) it has an objectively reasonable reading of the statute or regulation and (b) there was no authoritative guidance warning against its erroneous view.”

Key FCA Developments – Cases, Regulatory, and Policy

■ Dismissals under 31 U.S.C. § 3730(c)(2)(A)

- ▶ *Cimznhca, LLC v. United States*, 141 S. Ct. 2878 (2021) (S. Ct denial of cert.)
 - Leaves 7th Circuit “Third Option” analysis in place
 - Procedural issue (intervention) and Dismissal standard (Rule 41)
 - Detailed statutory analysis
- ▶ *U.S., ex rel. Health Choice Alliance, L.L.C. v. Eli Lilly & Co., Inc.*, 3 F.4th (5th Cir. 2021)
 - Focus on 3730(c)(2)(A) “hearing”
 - Applied *Sequoia Orange* standard –

Key FCA Developments – Cases, Regulatory, and Policy

■ Dismissals under 31 U.S.C. § 3730(c)(2)(A)

- ▶ *Polansky v. Exec. Health Res. Inc.*, 17 F.4th 376 (3d Cir. 2021)
 - Adopted 7th Circuit approach: U.S. must intervene and then Rule 41 standards apply
 - Notes difference in appellate review standard for motion to dismiss (*de novo*) vs. Rule 41 (arbitrary and capricious)
- ▶ *U.S. ex rel. Borzilleri v. Bayer Healthcare Pharmaceuticals, Inc.*, No. 20-1066 (1st Cir. January 21, 2022)
 - “We are unpersuaded by [CIMZNHCA’s] application of Rule 41 to the unique context of a *qui tam* action.”
 - The Government must give its reasons for dismissal, but the motion should be granted unless the Relator can show that the government is “transgressing constitutional limitations or perpetrating a fraud on the court.”

Key FCA Developments – Cases, Regulatory, and Policy

False Claims Act Amendments of 2021

- ▶ Materiality – Relator or the Gov't may establish materiality by preponderance of the evidence. Burden then shifts to defendant who can rebut materiality by clear and convincing evidence.
- ▶ Cost shifting – Contains a cost shifting provision under which the Gov't can move to require a party to reimburse the Gov't for discovery costs in a case where the Gov't declines to intervene. The requesting party will have to reimburse the Gov't for discovery costs, unless it can demonstrate that discovery is relevant, proportional, and not unduly burdensome to the Gov't.

Key FCA Developments – Cases, Regulatory, and Policy

False Claims Act Amendments of 2021

- ▶ Dismissal – Provides that the Gov't bears the burden of demonstrating the reasons for dismissal, and the relator must have the opportunity to show that the reasons for dismissal are fraudulent, arbitrary and capricious, or contrary to law.
- ▶ Anti-retaliation – Amends the FCA's anti-retaliation provision to apply to any employee – to address a Circuit split as to whether the provisions apply to only current, as opposed to current and former, employees.
- ▶ Applicability – The Act would apply to all litigation pending at the time of passage, as well as future litigation.

Key Criminal Procurement Fraud Developments

- Continued focus on individuals
 - ▶ Cooperation credit requires companies to provide information about *all* individuals involved
- Charging decisions will consider *all* prior misconduct
- Renewed consideration of use of monitors

Key FCPA Developments

- 18 enforcement actions (lowest number in years)
- \$360M (lowest number in years)
- Corporate enforcement actions totaling \$282M (down from 12 actions and \$6.4B in 2020)

Trends and the Forecast for 2022

- FAR 52.222-50 (Combatting Trafficking in Persons)
- Private Equity Firms
- COVID-related cases/COVID-19 Fraud Enforcement Task Force
- Telehealth
- Others

Trends and the Forecast for 2022

FAR 52.222-50 (Combatting Trafficking in Persons)

- ▶ “Justice Department Awards Nearly \$87 Million to Combat Human Trafficking and Help Victims” (Dec. 23, 2021)
 - Source: <https://www.justice.gov/opa/pr/justice-department-awards-nearly-87-million-combat-human-trafficking-and-help-victims>
- ▶ FAR 52.222-50 (b) Policy. The United States Government has adopted a policy prohibiting trafficking in persons including the trafficking-related activities of this clause. Contractors, contractor employees, and their agents shall not
 - (1) Engage in severe forms of trafficking in persons during the period of performance of the contract;
 - (5) (i) Use misleading or fraudulent practices during the recruitment of employees or offering of employment...;
 - (6) Charge employees or potential employees recruitment fees;
 - (8) Provide or arrange housing that fails to meet the host country housing and safety standards;

Trends and the Forecast for 2022

■ Private Equity Firms

- ▶ Dec. 1, 2020 – SBA reveals that 2,528 private equity-backed companies were approved for PPP loans of \$150,000 or more.
- ▶ July 21, 2021 – DOJ announces \$1.8M settlement with private equity firm Ancor Holdings LP, based on allegations it discovered alleged fraudulent activity of its portfolio company during diligence but took no actions to stop it.
- ▶ Oct. 14, 2021 – Announced that private equity firm H.I.G. Growth Partners, LLC, and H.I.G. Capital, LLC and two executives of a H.I.G. subsidiary that owned a mental health center, agreed to pay a total of \$25M to settle FCA suit alleging fraudulent billing to Medicaid.

Trends and the Forecast for 2022

- FAR 52.222-50 (Combatting Trafficking in Persons)
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- Telehealth
- Others

THANK YOU!

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