Legal and Enforcement Risks and Trends for 2024

Lone Star HFMA Winter Conference
January 25, 2024

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Driving progress
through partnership

Legal Landscape

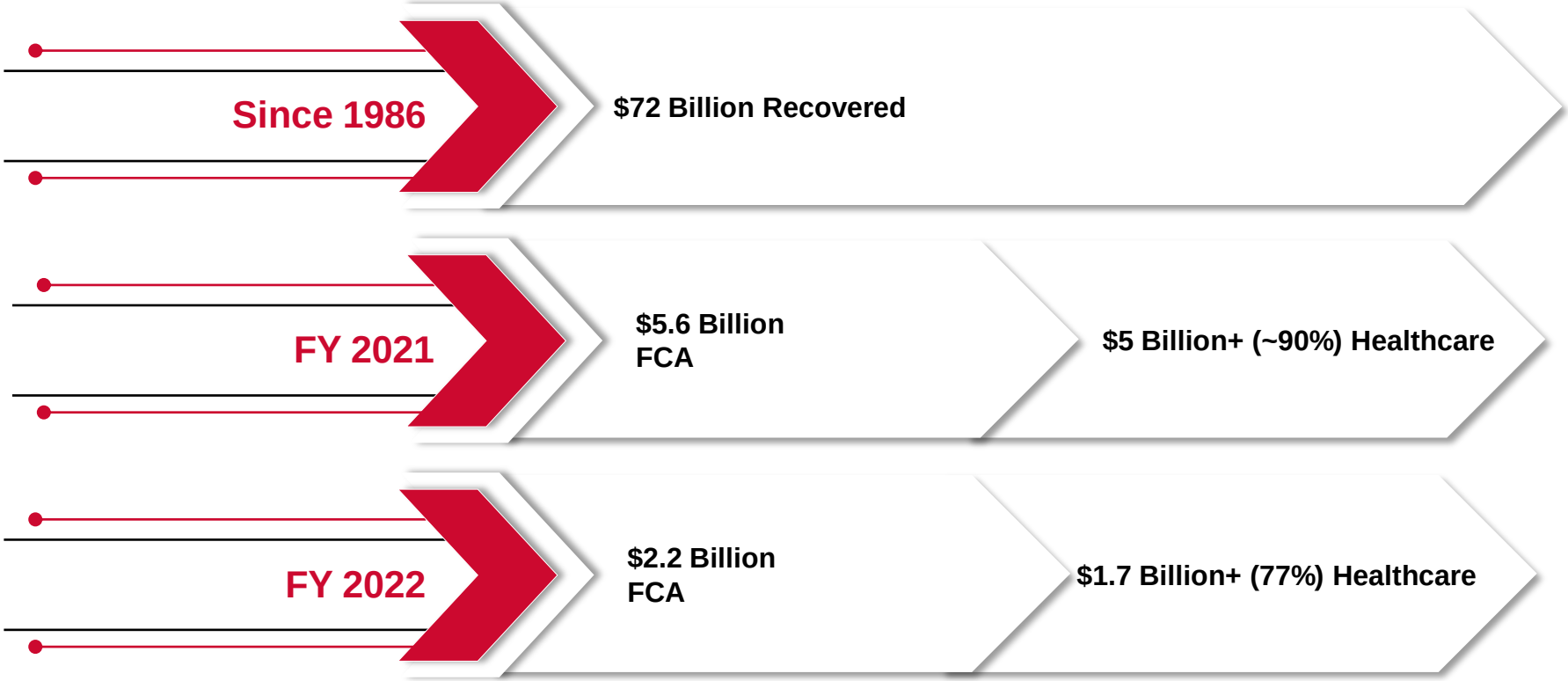
The False Claims Act

Relevant Laws

False Claims Act

- Prohibits knowingly and intentionally submitting, or causing another to submit, a materially false claim to a federal health care program
- A civil penalty for each false claim of $12,537 – $25,076
- Plus, up to three times the amount of damages
- May lead to exclusion from participation in government programs (e.g., Medicare)
- Government recovered $5.6 billion under the FCA in FY 2021

FCA Recoveries in FY 2022



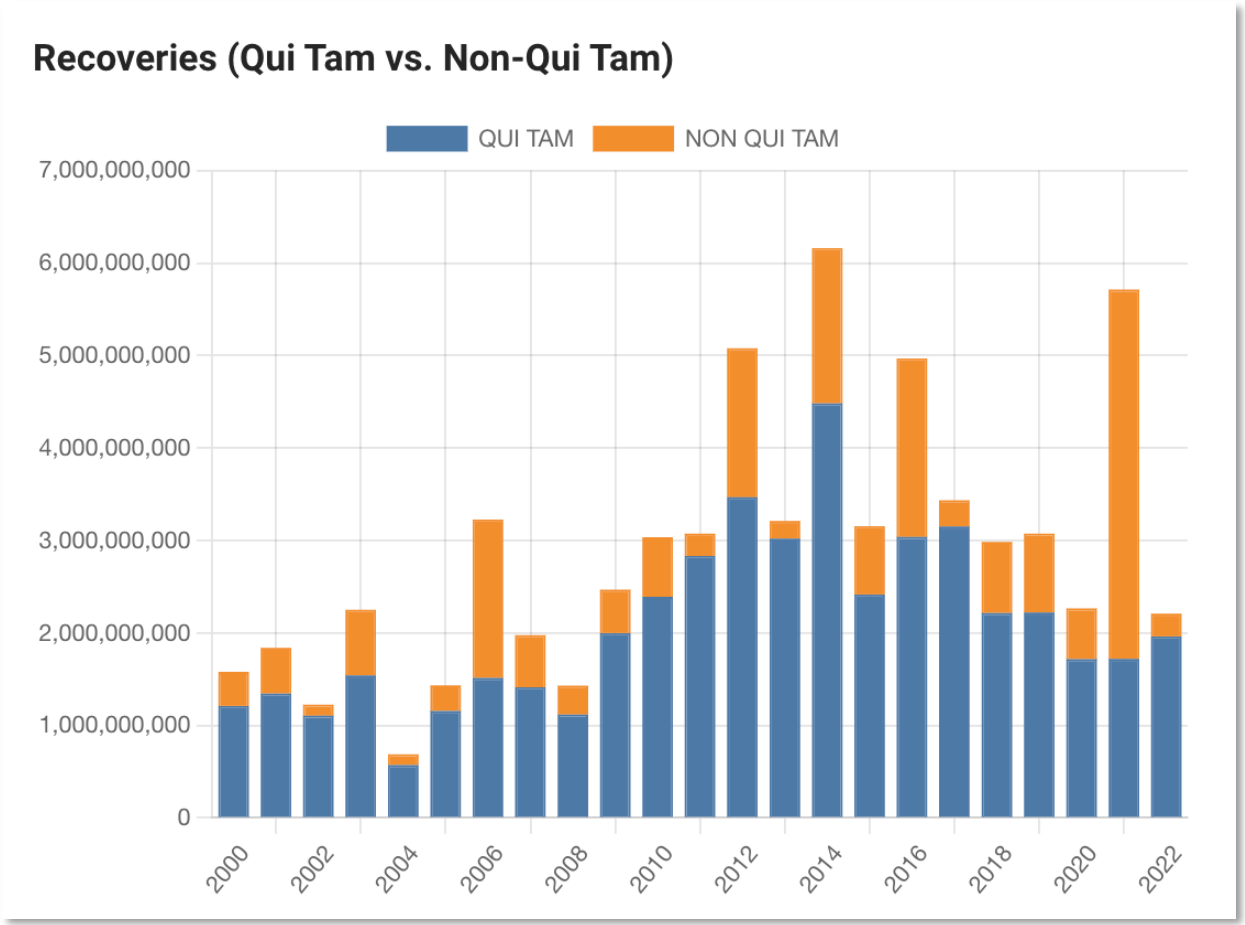
FCA Recoveries in FY 2022

FY 2021 ($5.6B)

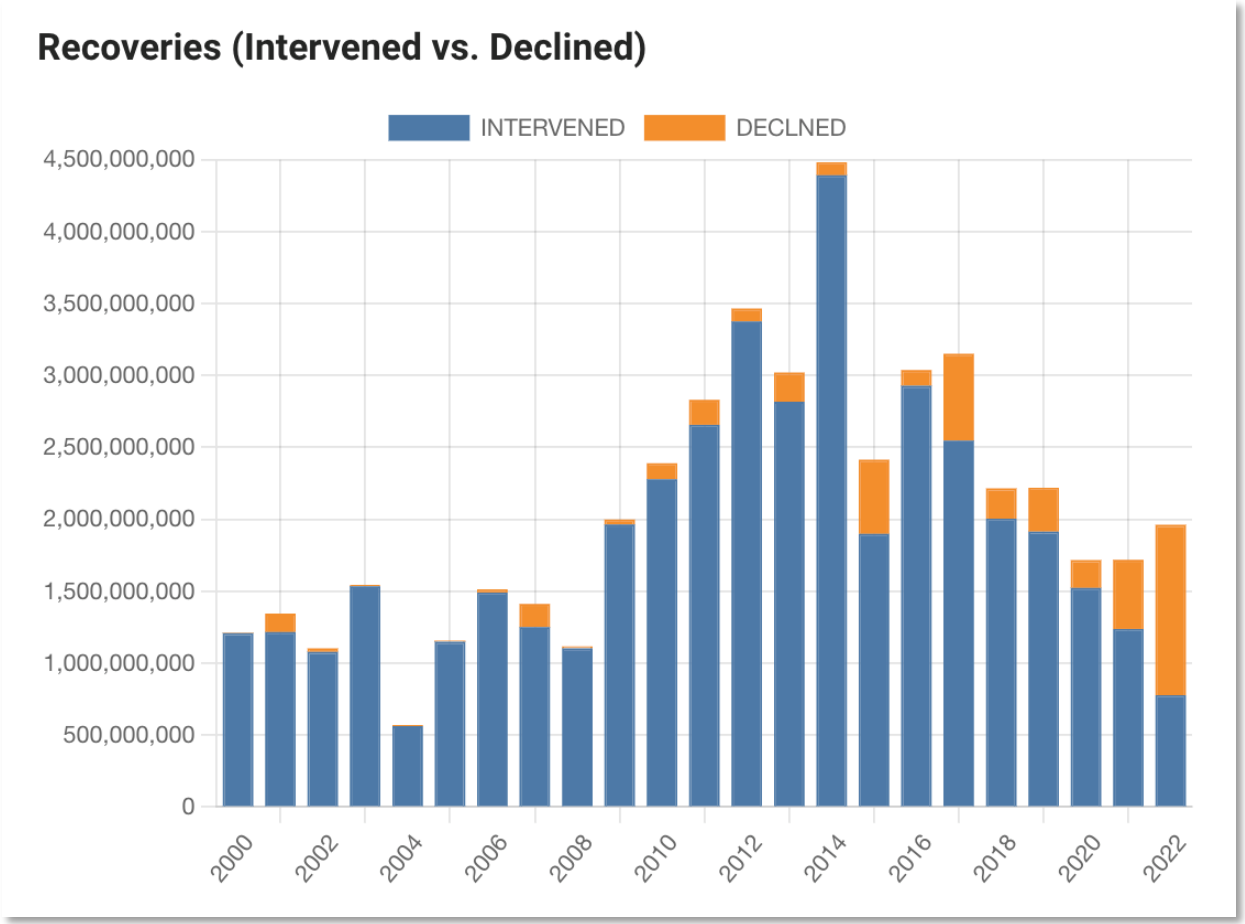
- Several blockbuster opioid-related FCA settlements drove 2021 recoveries
- $2.8B (Purdue Pharma)
- $225M (Sackler Family)
- $600M (Invidior)

FY 2022 ($2.2B)

- Record amount of FCA activity
- 948 new FCA matters initiated, more than ever before
- 351 FCA settlements & judgments, second-highest recorded in a single year
- 14th straight year exceeding $2B



Source: Reed Smith LLP (based on DOJ FCA FY2022 Statistics)



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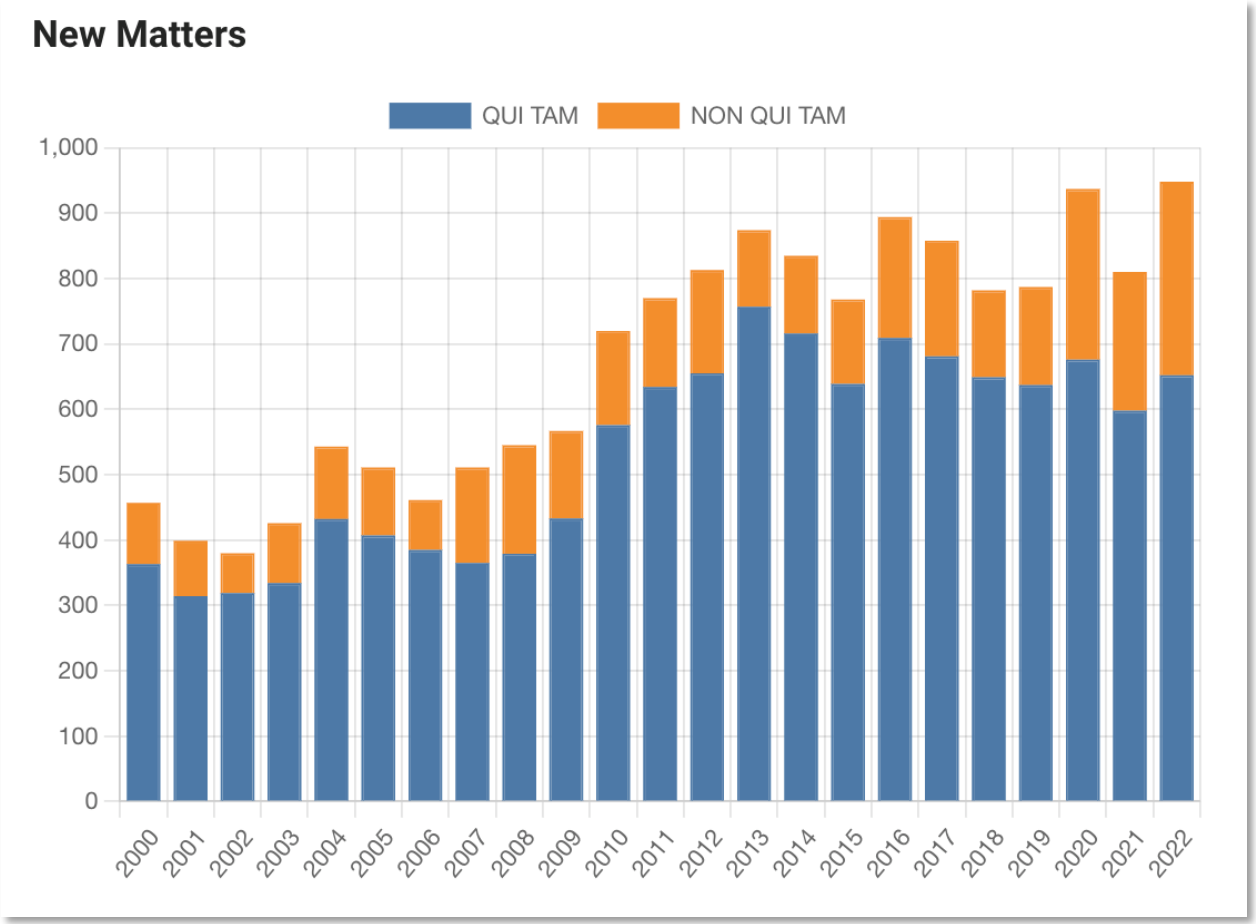

Source: Reed Smith LLP (based on DOJ FCA FY2022 Statistics)

FCA Recoveries in FY 2022

Key takeaways

Health care remains largest target: More than $1.7B (77%) resulted from health care cases

Declined cases outpaced intervened cases: More than $1.1B (50%) resulted from declined *qui tam* cases; first time in history declined *qui tam* cases outpaced intervened *qui tam* cases

***Qui tams* remain largest driver:** More than $1.9B (89%) related to cases initiated by “whistleblowers”

Non-*qui tams* on the rise: 296 new government-initiated cases filed in 2022; second time since 1993 this number exceeded 200

FCA Recoveries: FY 2023 YTD

Key takeaways

Blockbuster Supreme Court decisions: *Polansky* (DOJ dismissal authority), *SuperValu* (scienter standard)

Somewhat mixed first half of 2023: Lower-than-usual recoveries through settlements

- First half of 2023: 36 resolutions totaling $485 million
- First half of 2022: 29 resolutions totaling $500 million

Rare federal jury trial: $487 million jury verdict

Pandemic fraud enforcement is ramping up: Increasing focus on civil recoveries (FCA); use of data analytics; serial relators; lenders in the crosshairs; and a very busy N.D. Miss.

FCA Federal Jury Trial

Key takeaways

Precision Lens case presents a rare example of a FCA case that was tried before a jury

Precision Lens (ophthalmology distributor) and its owner found guilty of providing kickbacks to surgeons between 2006-2015 after 7-week trial

- Kickbacks included: “high-end skiing, fishing, golfing, hunting, sporting and entertainment vacations, often at exclusive destinations,” and “trips to New York City to see a Broadway musical, the College Football National Championship Game in Miami, Florida, and the Masters golf tournament in Augusta, Georgia”

Jury found a total of 64,575 false claims

- Singles damages = $43M
- Treble damages = $131M; penalties at the minimum end of statutory range = $359M
- Total: $490M

Common Risk Areas

Case Examples

Physician Compensation and Recruiting

***U.S. ex rel. Fischer v. Community Health Network et al,* No. 1:14-cv-01215 (S.D. Ind. 2014)**

Allegations:

Generated referrals to facilities within its network by aggressively acquiring physician practices and paying salaries over market rate.

- Determined compensation based on based on the anticipated increase in reimbursement for ancillary services billed as hospital services rather than physician practices
- Misrepresented and obscured information to external valuation firms retained to evaluate physician salaries under Stark Law

Awarded physicians service line financial performance bonuses based on meeting referral targets

Result:

- **$345 Million** Settlement (Dec. 2023)

Overbilling

***U.S. ex rel. Griffin v. Mediscope Global Services et al,* No. 3:21-cv-00183 (S.D. Tex. 2021)**

Allegations:

- Hospital manipulated Medicare and Tricare paperwork to overcharge Federal and State health insurance programs and receive inflated "outlier" payments far above allowed reimbursement.
- Hospital double-billed the cost of COVID-19 tests by charging both HHS and Texas for the same tests, and seeking government reimbursements for tests without verifying whether patients had private insurance that would cover the cost
- Executives ignored concerns raised by former medical billing administrator, failed to detect inflated outlier payments, and withheld records from a consultant hired to review payment data.

Result:

- **$2 Million** Settlement (Dec. 2023)
- Terminated from Medicare & excluded from Federal health insurance program for **10 years**

Kickbacks

***USA et al. v. True Health Diagnostics LLC et al.,* No. 4:16-cv-00547 (E.D. Tex. 2022)**

Allegations:

- Three physicians accepted monetary bribes by management service organizations in exchange for ordering lab tests from a few select hospitals, specifically Little River.
- Little River was designed as a critical access center. This designation, reserved for small hospitals in rural areas, allowed Little River to receive higher Medicare reimbursements.
- The COO of Little River was also required to pay a settlement for faking Medicare, Medicaid and Tricare claims and turning a blind eye to the hospital's scheme to facilitate the kickbacks.

Result:

- **$880K** Settlement (Dec. 2023)

Kickbacks

***U.S. et al. ex rel. Joseph Nocie v. Steward Health Care System et al.*, No. 1:18-cv-11160 (D. Mass. 2023)**

Allegations:

- Steward Health paid its chief of cardiac surgery approximately $4,868,500 in incentive compensation that was calculated in part based on the number of cases he referred to the medical center.
- Steward recruited the doctor in 2012 to increase the number of cardiovascular surgeries at St. Elizabeth's Medical Center to boost profits from reimbursements from Medicare and other insurers
- The doctor received approximately $4,868,500 in incentive compensation that was calculated in part based on the number of cases he referred to the medical center. The doctor submitted more than 1,000 claims to Medicare knowing that the claims for those referred services were not eligible for payment.

Result:

- **$4.7 Million** Settlement (Dec. 2023)

Pandemic Relief Fraud

No significant hospital pandemic relief fraud cases in 2024 as of yet

However, DOJ signals intent for continued, robust enforcement in 2024 and beyond

"Pay and chase" environment

Early "chase" was focused on most egregious fraud (e.g., PPP loans used to purchase sports cars)

Second wave will be focused on the FCA

Affirmative cases brought against borrowers and lenders

Nature of FCA investigations (sealed complaints) means we will not learn about the investigations happening today for possibly several years

Cybersecurity & Healthcare

***United States ex rel. Lawler v. Comprehensive Health Servs., Inc. et al.*, Case No. 20-cv-698 (E.D.N.Y.)**

Allegations:

- CHS is a provider of global medical services that contracted to provide medical support services at government-run facilities in Iraq and Afghanistan. Under one of the contracts, CHS submitted claims to the State Department for the cost of a secure electronic medical record (EMR) system to store all patients' medical records.
- Between 2012 and 2019, CHS failed to disclose to the State Department that it had not consistently stored patients' medical records on a secure EMR system.
- The State Department and Air Force contracts also required CHS to provide medical supplies, including controlled substances, that were approved by the U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA)
- Between 2012 and 2019, CHS falsely represented to the State Department and Air Force that certain substances provided under those contracts were approved by the FDA or EMA.

Result:

- **$930K** Settlement (Mar. 2022)

Cybersecurity & Healthcare

***United States ex rel. Awad et al. v. Coffey Health System,* No. 2:16-CV-03034 (D. Kan.)**

Allegations:

- The hospital submitted false claims to the Medicare and Medicaid Programs pursuant the Electronic Health Records (EHR) Incentive Program.
- Under the program, the HHS offers incentive payments to healthcare providers that adopt certified EHR technology and meet certain requirements relating to their use of the technology.
- To obtain the payments, providers must attest that they satisfy applicable HHS-adopted criteria, including measures for analyzing and addressing security risks to electronic health records.
- The hospital failed to satisfy the requirements and falsely attested that it conducted or reviewed security risk analyses.

Result:

- **$250K** Settlement (2019)

Cybersecurity & Healthcare

***Doe v. eviCore Healthcare MSI, LLC,* 2023 WL 2249577 (2d Cir. Feb. 28, 2023** (Only case to date involving AI and FCA)

Allegations:

- EviCore deployed artificial intelligence systems to approve certain requests based on flawed criteria and without manual review, and as a result furnished “worthless services” to its insurance company clients.
- EviCore also allegedly caused those insurers to bill federal healthcare programs for medically unnecessary services.

Result:

- The case was dismissed because the Relator's failed to identify a fraudulent or unnecessary procedure, but the alleged novel legal theory that use of flawed AI can constitute a “worthless service” for purposes of FCA liability was not addressed and left open.

Additional Considerations

Collaboration between finance, legal, compliance, etc.

How to respond to complaints or concerns

When to contact internal counsel

When to hire outside counsel

Additional Considerations

Insurance

- Self-insurance
- Potential for coverage of defense costs
- Strategies for maximizing insurance protection
- Who are your partners?

Management of potential whistleblowers

- Taking complaints seriously
- Transparency of corrective action taken as a result of issue raised, and/or sharing results of investigation that concluded no issue
- Importance of involving legal team early

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