



Compliance & Enforcement in the Biden Administration

Washington Executive Course, Health Ethics Trust
Thursday, May 6, 2021, 9:00 a.m.

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Agenda

- Current COVID-19 Fraud Schemes
- September 30, 2020 Announcement
- Recent Cases
 - Telemedicine Cases
 - Sober Home Case, Eliminating Kickbacks in Recovery Act (EKRA) 18 § USC 220(a) 2018
 - Opioid Cases
- Government's Investigative Tools/Practices
- What to Expect in 2021 and Beyond
- Best Practices

Current Impact on Enforcement

- COVID-19 shelter in place orders lifting
- Courts and businesses reopening
- Focus of providers on vaccinations & combating disease
- Grand jury operations and delays
- Statutes of limitations
- Speedy trial waivers

Current Impact on Enforcement

- COVID-19 presents an opportunity for criminals to take advantage of beneficiaries, providers, and governmental assistance programs
 - Calls offering Covid19 testing in exchange for ID
 - PPP misuse
- US DOJ has experience with opportunistic fraud (e.g., TARP, Katrina)
- Price Gouging Task Force

September 30, 2020 -- Announcement

- “National Health Care Fraud and Opioid Takedown Results in Charges Against **345 Defendants** Responsible for More than **\$6 Billion** in Alleged Fraud Losses”
 - DOJ characterized the arrests as the largest health care fraud and opioid enforcement action in Department of Justice History
- Charged more than 100 doctors, nurses and other licensed medical professionals.
- DOJ CRM Fraud Section; Appalachian Regional Prescription Opioid (ARPO) Strike Force; and 43 U.S. Attorneys’ Offices & Agents from HHS-OIG, FBI, DEA
- “This nationwide enforcement operation is historic in both its size and scope, alleging billions of dollars in healthcare fraud across the country,” said AAG

New National Rapid Response Strike Force

- On Sept. 30, 2020, DOJ announced the creation of the National Rapid Response Strike Force of the Health Care Fraud Unit of the Criminal Division's Fraud Section.
- NRRSF's mission is to investigate and prosecute fraud cases involving "major health care providers" that operate in multiple jurisdictions, including major regional health care providers.
- NRRSF led the telemedicine initiative and sober homes cases.

Telemedicine Cases

- “[B]ad actors attempt to abuse telemedicine services and leverage aggressive marketing techniques to mislead beneficiaries about their health care needs and bill the government for illegitimate services,” said HHS Deputy Inspector General Gary Cantrell.
 - \$4.5 billion (86 criminal defendants in 19 districts) – related to the use of telecommunications technology to provide health care services remotely. Defendants allegedly paid doctors and NPs to order unnecessary durable medical equipment, genetic and other diagnostic testing, and pain medications, with only a brief telephonic conversation with patients they had never met or seen.
 - Telemedicine cases built on the efforts and impact of the 2019 “Operation Brace Yourself” Telemedicine and Durable Medical Equipment Takedown, which resulted in an estimated cost avoidance of more than \$1.5 billion in the amount paid by Medicare for orthotic braces in the 17 months following that takedown.

Opioid Cases

- “When doctors, pharmacists, and individuals exploit the weakness of a fellow human being in order to line their own pockets, DEA will use every tool at its disposal to stop and bring them to justice,” said DEA Assistant Administrator Tim McDermott.
- “Sober Homes” cases used *Eliminating Kickbacks in Recovery Act* (EKRA) 18 USC § 220(a) (2018).
 - SDFL case against physicians, owners and operators of substance abuse treatment facilities, as well as patient recruiters (“body brokers”).
 - Case alleging \$845 million of fraudulent claims for tests and treatments for vulnerable patients seeking treatment for drug and/or alcohol addiction.
 - Allegations involve the payment of kickbacks for the referral of patients to substance abuse treatment facilities and those patients were subjected to medically unnecessary drug testing and therapy sessions.
- Illegal prescription and/or distribution of opioids.

Enforcement Agencies

- Federal & State Governmental Investigations:
 - Criminal & Civil
 - DOJ/USAO (incl. DEA, FBI)
 - OIG
 - FDA, Postal Inspectors, Labor, IRS, DOD, VA, OPM
 - MFCU/State AGs
- Administrative
 - OIG (OI, OCIG)
 - MAC/ZPIC/UPIC/MEDIC
 - Insurers
 - SIUs

Origins of Healthcare Fraud Investigations

- Qui Tam Complaints
- Agency Investigations
 - HHS-OIG
 - FBI, FDA, VA, IRS, etc.
 - Consumer/Public Complaints
- Data Analytics
- Public Events
 - e.g., COVID-19 Outbreak, Opioid Epidemic
- Actions against industry competitors
- News/Press

How Do You Learn You're * Being Investigated?

- Voluntary/informal contact
 - A. Request for information
 - B. Call or knock on the door from AUSA or agent
 - C. Letter, including target letter
 - D. Grapevine (employee interviews, investigations of business contacts)
- Site visit or request for records from CMS, state, or OIG
- Subpoena
 - A. Federal Grand Jury
 - B. HIPAA/AID subpoena
 - C. IG subpoena
 - D. Civil Investigative Demand (CID)
 - E. OIG administrative subpoena (42 USC 1320a-7a(j))
 - F. State AG/MFCU criminal or civil
- Search warrant

Frequently Investigated Conduct

- Fraud/False Claims
- Kickbacks/Financial Relationships with Health Care Providers
- Insurance Reimbursement
- HIPAA/Patient Privacy Violations
- Opioid Distribution/Diversion
- Misbranding/Off-label Promotion
- Conspiracy/Racketeering Conspiracy
- False Statements
- Obstruction of Criminal Health Care Investigation
- Witness Tampering

Factors That Impact Criminal Enforcement

- Nature and Circumstances of Conduct
 - Rogue or systemic within company?
 - Does target have history of similar conduct?
 - One-off event or scheme to defraud?
 - Government focus is on actual fraud, kickbacks
- Patient Harm
- Economic Harm
- Whether Defendant Occupies Position of Trust
 - e.g., Health Care Provider, etc.
- Timing/Resources
 - Government has limited resources and wants to make an impact

Handling an Investigation

- Who to tell?
 - General counsel/other in-house lawyers
 - Corporate officers/managers
 - Depending on circumstances, outside lawyers
- What to do?
 - Have counsel issue litigation hold/document preservation notice
 - Identify persons likely to have relevant documents and knowledge
 - Collect relevant documents and data sources (e.g., emails, laptops, cell phones)
- Communicate with investigators
 - Identify subject matter of investigation
 - Narrow scope of document requests
- Initiate parallel internal investigation
 - Learn the facts to respond to government inquiries & demonstrate cooperation and commitment to compliance

U.S. FCA Overview

- 31 U.S.C. §§ 3729-3733
- Targets fraud in federal contracts & programs
- Prohibits “knowingly” submitting or causing the submission of “material” “false”hoods to get federal \$
- Implied false certification theory is increasingly common:
 - Liability based on alleged non-compliance with a “material” regulatory or contractual term despite any express statement of compliance

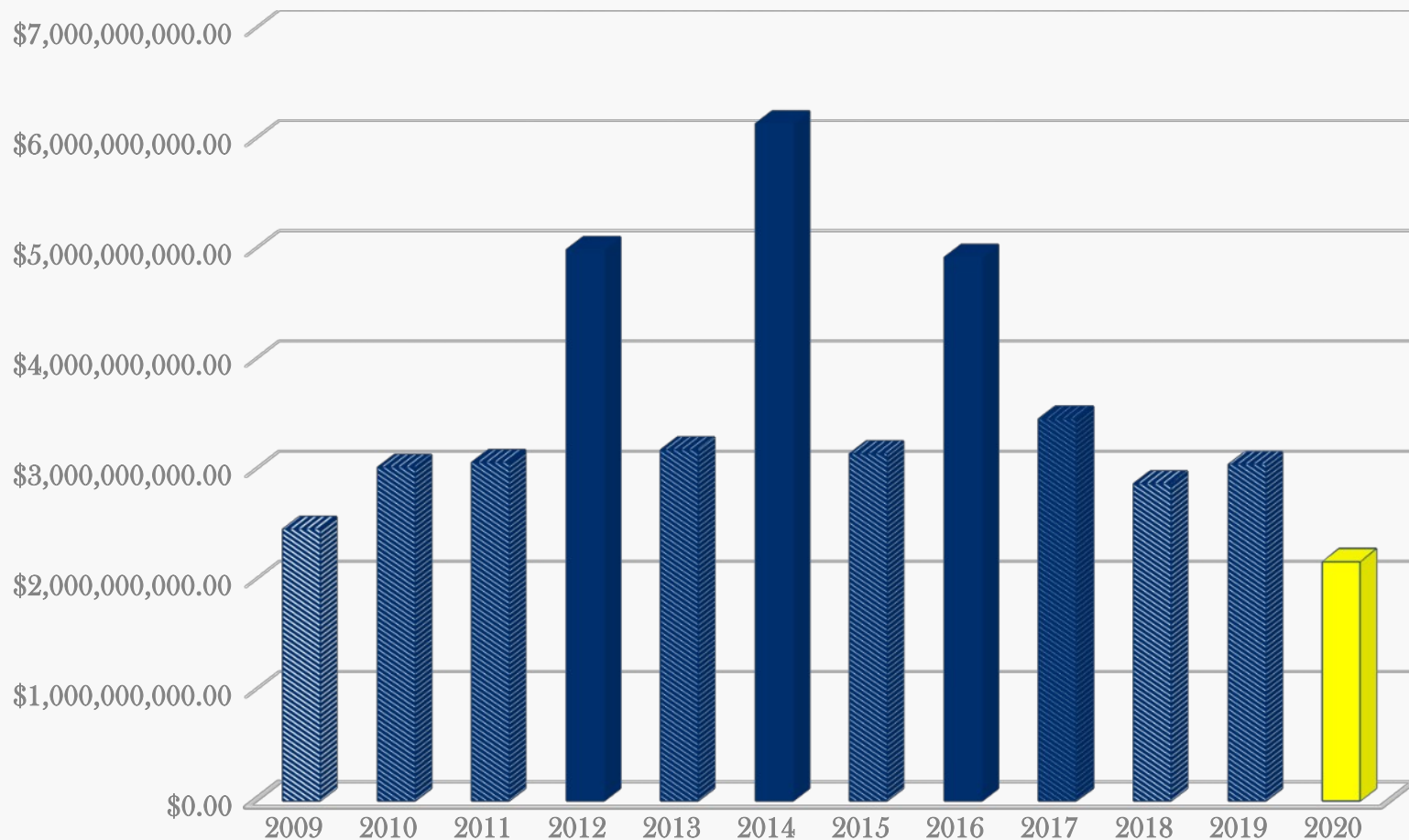
U.S. FCA Overview

- Allows suits by private “*qui tam* relators”
 - Increasing trend of “corporate” relators, including for-profit ventures
- Significant financial incentives for relators and DOJ – and significant settlement incentives for defendants
 - DOJ recoveries (judgments + settlements) average ~ \$3 billion annually since FY2009
 - DOJ can seek 3x damages *and/or* up to ~ \$24k penalty for EACH false claim
 - Relators can get 15% to 30% of DOJ’s recovery, plus attorney’s fees
- Many state analogues – often joined in federal suits, but also filed in state court and pursued as State AG investigations

Qui Tam Process

1. Relator files a sealed “*qui tam*” complaint and gives DOJ a copy, plus other material evidence
2. Under seal at least 60 days – often longer
3. DOJ investigates, consults affected agency (*e.g.*, CMS, DOD-IG, etc.), can reach out to defendant and issue subpoenas for documents and depositions
4. DOJ then decides whether to:
 - intervene in the suit (whether to litigate or to settle) - § 3730(b)(4)(A)
 - let the relator handle it (for now) - § 3730(b)(4)(B)
 - move to dismiss the suit altogether - § 3730(c)(2)(A)

Expect More False Claims Act Enforcement & Recoveries



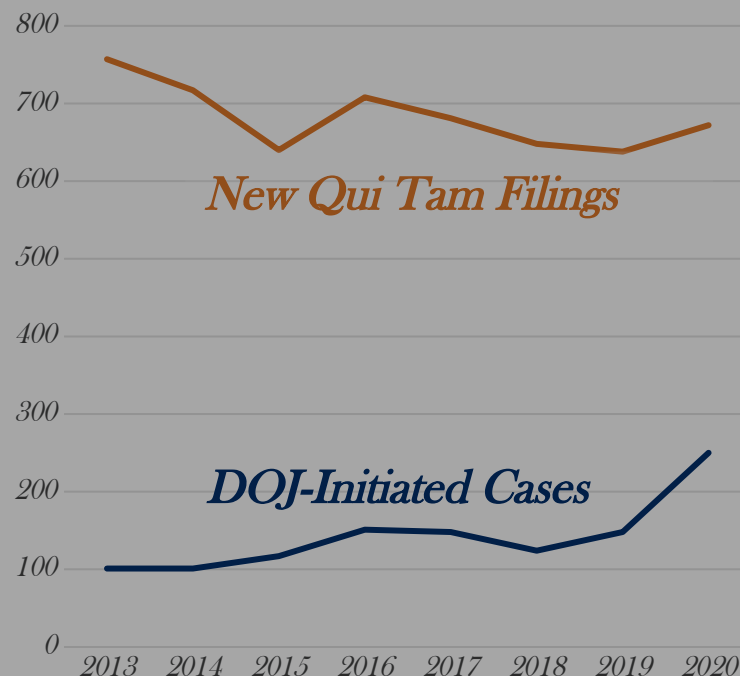
DOJ-Initiated Cases On The Rise

After 1986 amendments, *Qui Tams* skyrocketed & DOJ filings dropped:

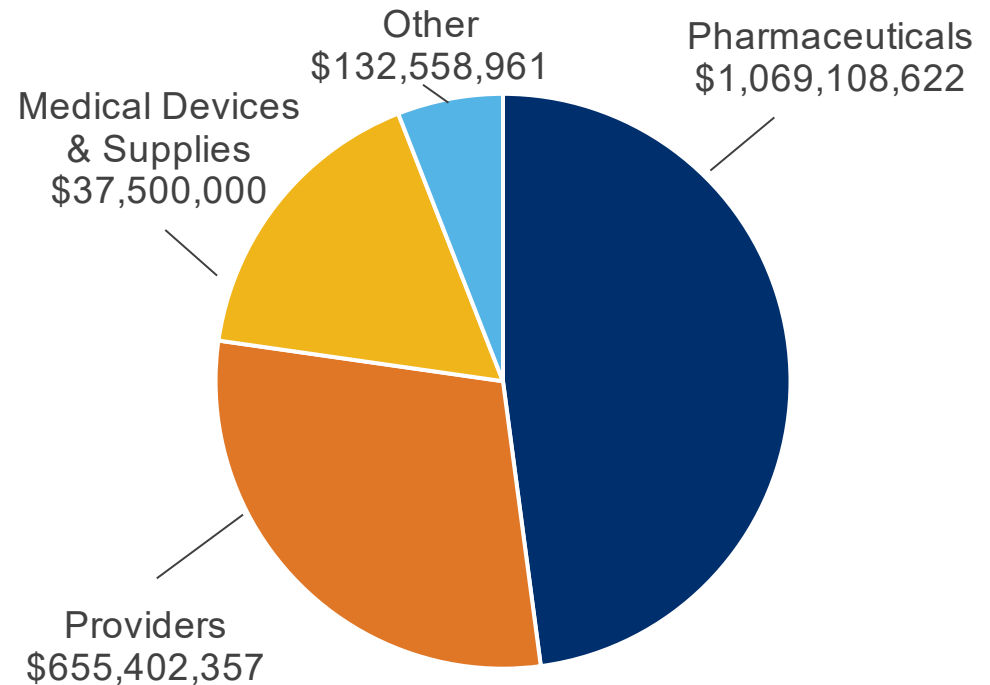
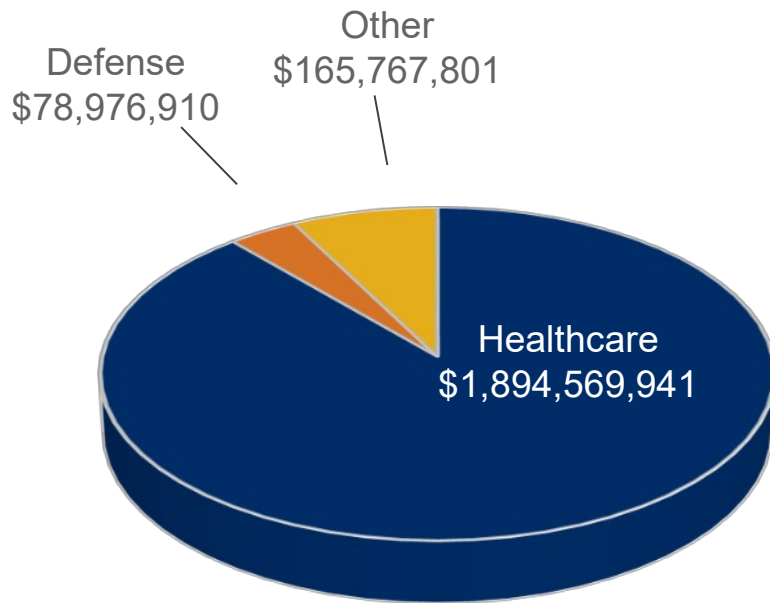
- 1986: 30 QTs vs. 341 US actions
- 2020: 672 QTs vs. 250 US actions

Since 2013, DOJ filings have regained steam:

- 2013: 757 QTs vs. 101 US actions
- 2020: 672 QTs vs. 250 US actions



Most FCA Defendants Are Healthcare Companies/Providers



Source: Arnold & Porter's Qui Notes Blog

FCA Reaches Every Type of Healthcare Provider

- Kickbacks
- Part D
- Services Not Rendered
- Stark Law / Self-Referrals
- Up-Coding
- Unbundling
- False Certification (e.g. lack of medical necessity, risk adjustment factors)

Recent Major Settlements Involved:

- Ambulance & Transportation Services (4)
- Clinics (12)
- Dental (4)
- Device Companies (5)
- Diagnostic Services (1)
- Drug Companies (7)
- Drug Distributor (1)
- DME (3)
- Electronic Health Records (1)
- Home Health Providers (7)
- Hospice Care (2)
- Hospitals & Health Systems (6)
- Identity Theft (2)
- Laboratories (4)
- Managed Care / Medicare Advantage (2)
- Medical Devices (1)
- Nursing Homes & Facilities (4)
- Pharmacies (9)
- Physical Therapy (2)
- Physician & Other Practitioners (6)
- Prescription Drugs & Opioids (8)
- Private Health Insurance Fraud (1)
- Psychiatric & Psychological Testing & Services (3)

HHS/DOJ Health Care Fraud and Abuse Control Program
June 2020 Report
<https://oig.hhs.gov/publications/docs/hcfac/FY2019-hcfac.pdf>

Example: Risk Adjustment Factors

- **MAOSs:** Under Medicare Part C, CMS buys insurance from private insurers (Medicare Advantage Organizations, or MAOs) for Medicare beneficiaries.
 - In 2019, 34% of Medicare beneficiaries received coverage through a MAO.
 - By 2029, an estimated 47% of Medicare beneficiaries will receive coverage through a MAO.
- **Base Capitation Rate:** MAOs submit annual bids to CMS based on an average beneficiary risk profile.
- **Risk Adjustment:** CMS adjusts the base capitation rate based on factors such as age, gender, disability status, institutional factors, and health status.
- **Risk of False Claims:** When submitting claims, MAOs certify the accuracy, completeness, and truthfulness of applicable payment data, including risk adjustment factors.

FCA Working Group - December 2020

- Cross-Agency Coordination (HHS, DOJ, and OIG)
- Comprised of former DOJ FCA and healthcare fraud prosecutors, former private counsel for healthcare and life sciences companies, and HHS attorneys
- Then-HHS Secretary Alex Azar:
“This working group strengthens our partnership with DOJ and OIG on using the False Claims Act to pursue bad actors and protect taxpayer funds. Ensuring that resources are focused on bad actors will *deter would-be fraudsters and avoid burdening those working in good faith to comply with the law.*”

DOJ Is Exploring Its Authority to Nix Qui Tam Cases

- (c)(2)(A) Dismissals
 - “Granston Memo” (January 2018)
 - DOJ Response to Senator Grassley Letter (December 2019)
 - DOJ moved to dismiss 45 *qui tam* actions out of 1,170 filed since Granston Memo issued (10 were filed by same professional relator group; 12 were *pro se*)
- Possible resolution of the (c)(2)(A) split on the horizon?
 - Supreme Court declined twice in 2020 to take up the split
 - In a July 2020 speech, Senator Grassley announced he was working on legislation to “clarify” DOJ’s authority, and then reiterated in February 2021 keynote remarks at Federal Bar Association Qui Tam Conference his “concerns about the department’s use of its dismissal authority”

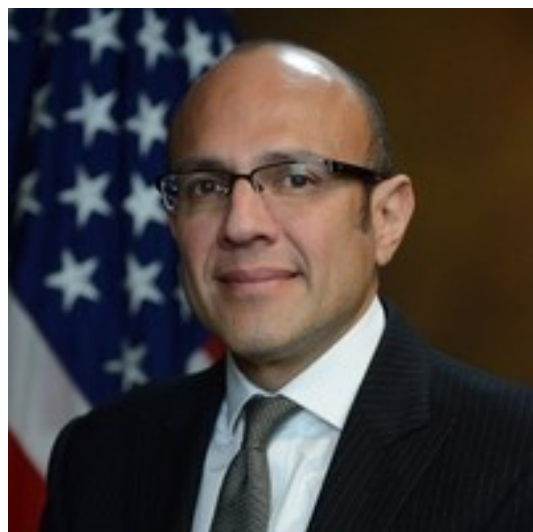
Expect Biden Administration to Expand Enforcement

- Trump Administration emphasized:
 - National security, cybercrime, and the technology sector
 - Healthcare, FCPA, and FCA
- Biden Administration has signaled its emphasis will be:
 - All of the above, plus financial services & environmental
 - More healthcare-related enforcement:
 - COVID-19 & stimulus: First FCA settlement re: CARES Act PPP
 - Healthcare tech (EHR/telehealth)
 - Private equity investors / M&A
 - Abuse and exploitation of senior citizens
 - Opioid crisis

Biden Administration Supports FCA Enforcement

- Attorney General Merrick Garland wrote or joined an opinion or dissent in approximately 14 cases involving the FCA while on the D.C. Circuit and seems to hold a high view of the FCA as an enforcement tool against fraud.
- Garland dissented in *U.S. ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004)
 - Garland wrote that the majority’s decision finding lack of presentment to government agency left “vast sums of federal monies without [FCA] protection.”
 - Congress amended FCA in 2009 to bring it in line with Garland’s dissent (superseding *Totten* and *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662 (2008))

Biden's AAG Nominees (April 2021)



Javier M. Guzman

Assistant Attorney General (Nominee)
Civil Division, Department of Justice



Kenneth Polite

Assistant Attorney General (Nominee)
Criminal Division, Department of Justice

Biden Administration Is Filling Enforcement Positions

- Biden has prioritized filling vacancies; only 45% of key DOJ positions were filled as of November 2020
- Potential replacement of DOJ's full-time compliance counsel, previously held by compliance expert Hui Chen who resigned shortly after Trump's election

Biden Administration Is Using Data Analytics



Brian Boynton
Acting Assistant Attorney General
Civil Division
U.S. Department of Justice

“The data can even allow us to demonstrate and quantify sophisticated relationships, such as a physician offering controlled substance prescriptions to a patient who is likely to divert them. Identifying these types of relationships can help us combat prescription drug abuse as well as many other types of health care fraud. **Indeed, the Civil Division has been actively using its data analysis for this very purpose.**”

Expect Biden Administration To Expand Corporate Enforcement

- New focus on corporate actors and financial institutions
 - Fines on corporations were down 76% during Trump Administration
- Strengthening of whistleblower laws, particularly to further protect employees of employers who receive federal grants or contract with federal agencies, subjecting those employers to increased claims involving whistleblower retaliation

Expect More Enforcement Activity

- Biden’s “Buy American” campaign promoting federal procurement of American-made goods and services could spur a cycle of *qui tams* for violations, depending on how EO is implemented
- **Bottom line**: More investigations and cases, including a continued increase in cases brought directly by DOJ

Our FCA & Enforcement Blogs

QuiNotes.com

- In-depth analysis of new FCA cases
- Real-time recoveries tracker

EnforcementEdge.com

- Cross-practice coverage of all other enforcement by DOJ, federal regulators, and the states

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QUI NOTES RECOVERIES MAP STATISTICS RECOVERIES LIST GLOSSARY FALSE CLAIMS ACT PRACTICES

QUI NOTES: UNLOCKING THE FALSE CLAIMS ACT

Welcome to Qui Notes, Arnold & Porter's forum for all things False Claims Act (FCA). Here, you will find insightful commentary and news on FCA recoveries as they happen. Our interactive "recovery map" and "statistics" pages show where the action is both geographically and by industry. Basic concepts are covered in our glossary, but use tags and the search tool to find points of particular interest. Whatever your issue, our FCA experts will keep a steady stream of posts coming so you are never out-of-date. The FCA is a potential trap for anyone doing business with the government—we hope Qui Notes will help you unlock it. Thanks for visiting.

BLOG POSTS

October 25, 2019
Taking Escobar Seriously
By Martin S. Meyel, Christian D. Sheehan

In its most Escobar decision, the Supreme Court declared that the FCA's materiality standard is "demanding" and "rigorous." In many instances since this pronouncement, however, courts have

FALSE CLAIMS ACT SNAPSHOT	
\$98.3 Million Recovered	Total Dollars
18	Total Number of Recoveries
\$5.46 Million Recoveries	Median Recoveries
Q3 FY 20	

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[Read our welcome post](#)

Blog Posts

March 26, 2021

On-Demand Webinar: What the Biden Administration Could Mean for Government Investigations

Questions



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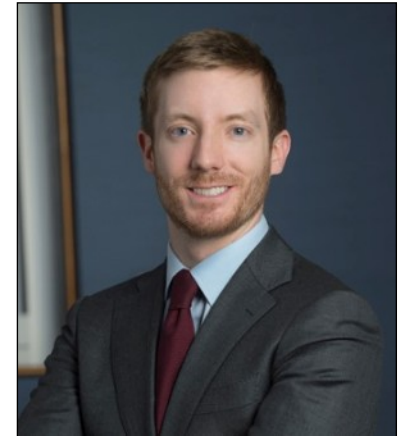
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