



FALSE CLAIMS ACT ENFORCEMENT: EMERGING LEGAL AND COMPLIANCE ISSUES

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PRESENTED BY:

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Speaker Bio



MELISSA GOMEZ NELSON

Melissa Gomez Nelson is the Director of Litigation for Booz Allen Hamilton, where she leads a team of five and is responsible for managing the Company's litigation portfolio. Additionally, Melissa also serves as a legal integrator to the Civil Sector Business and serves as the head of the Diversity, Equity and Inclusion office for Legal, Ethics, Compliance and Corporate Affairs.

Melissa joined Booz Allen in May of 2020 after being a Partner at the global law firm of Dentons where her practice included litigation and investigations (both domestic and international). She has extensive experience leading every stage of litigation and has been a white collar defense attorney with a focus on defending clients against allegations of corruption and fraud. Melissa has proven adept in providing compliance advice and counseling that incorporates a strategic approach to navigating international and domestic anti-bribery, corruption, fraud and securities related issues for organizations of all sizes including government contractors. Additionally, she has represented multiple multinational corporations in connection with domestic and international criminal investigations related to these areas as well as the FCPA and False Claims Act. She also brings significant transformational experience in corporate records management.

Speaker Bio

Full Bio Available at <http://www.perkinscoie.com/ACanizares/>



ALEXANDER CANIZARES | PARTNER

Alexander Canizares represents government contractors and other companies in litigation, investigations, and regulatory matters involving federal departments and agencies. As a former trial attorney with the U.S. Department of Justice's (DOJ) Civil Division, Alex draws on his experience serving as lead counsel in complex cases involving the federal government to advise companies in the aerospace and defense, technology, healthcare, professional services, and other industries in a range of areas, including contract claims and disputes, False Claims Act (FCA) matters, bid protests, cybersecurity, and strategic counseling related to all phases of federal procurement.

Alex writes and speaks frequently regarding government contracts matters. He serves in multiple roles in the American Bar Association's Public Contract Law Section (PCLS), including as co-chair of the Procurement Fraud and False Claims Committee.

Speaker Bio

Full Bio Available at <https://www.perkinscoie.com/en/professionals/barak-cohen.html>



BARAK COHEN | PARTNER

Barak Cohen represents companies and individuals facing government enforcement and investigations in highly regulated industries, particularly the healthcare and government contracting industries. A former prosecutor in the U.S. Department of Justice, Barak led numerous white-collar investigations throughout the United States. Barak has particular experience representing companies that do business with the government, such as technology companies, medical labs, medical device companies, and pharmaceutical companies, and in investigations regarding the False Claims Act (FCA), the Anti-Kickback Statute (AKS), and the Eliminating Kickbacks in Recovery Act (EKRA), as well as in investigations led by agency inspectors general. He has also represented multinational companies in sensitive international investigations involving international corruptions laws, such as the Foreign Corrupt Bribery Act (FCPA) and the U.K. Bribery Act. Notably, Barak's work has included representing high-profile public officials, including multiple sitting members of Congress, in investigations regarding alleged campaign offenses and election crimes, as well as in state and federal ethics investigations.

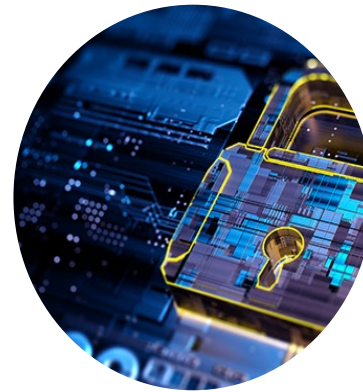
Agenda



**FCA
ENFORCEMENT
LANDSCAPE**



**EFFECTIVE
RESPONSES TO
FCA RISKS**



**KEY FCA RISK
AREAS**



QUESTIONS?



FCA ENFORCEMENT LANDSCAPE



Current FCA Enforcement Climate

- FCA enforcement climate continues to be robust, with focus on health care industry and vigorous relator's bar.
- \$5.6B total settlements and judgments in FY 2021.
 - Largest since 2014, second largest ever, but driven by a single opioid settlement.
 - Mostly (\$5B) in health care and life sciences industries.
- Congressional efforts to amend FCA uncertain.

- *Qui tam* actions continue to drive cases and settlements.
 - FY 2021: 598 qui tam actions (avg. 11 actions per week) and resulting in \$1.6B.
- Sept. 2022 - Largest-ever whistleblower reward (\$266M) (*Biogen*) in declined case with \$900M settlement.



DOJ Policies Relevant to FCA and White-Collar Enforcement

FCA AND COOPERATION CREDIT

- Justice Manual 4-4.112: DOJ to award credit in FCA cases for ***voluntary disclosures, cooperation, and remedial action.***
- Settlement strategies should consider highlighting existing compliance program, cooperation.
- Max. credit may not exceed USG's "full compensation" for losses.
- FAR mandatory disclosure rule imposes separate obligation.

DOJ CRIMINAL FOCUS

- Renewed DOJ focus on individuals.
- Focus on speed.
- Absent aggravating factors, DOJ won't seek guilty plea when company has voluntarily self-disclosed, cooperated, remediated misconduct.
- New compliance metrics.
- Won't require independent compliance monitor if company cooperated, self-disclosed, and implemented/tested an effective compliance program.

FCA - Key Case Law Developments

- **SCOTUS to decide DOJ dismissal authority**
 - *United States ex rel. Polansky v. Executive Health Resources, Inc.* (S.Ct. 21-1052).
 - Oral argument Dec. 6th – SCOTUS reviewing (1) whether USG may dismiss *qui tam* action after initially declining to intervene and (2) what standard of judicial review applies if USG has authority.
 - **Takeaway:** will clarify their scope and timing, but DOJ discretion to dismiss will likely remain broad.
- **Knowledge (“reckless disregard”)**
 - *United States ex rel. Schutte v. SuperValu, Inc.* (S. Ct. 22-111)
 - 7th, 3rd, 8th, 9th, D.C. Circuits – held that “objective reasonableness” standard for determinations of scienter under Supreme Court’s *Safeco* (2007) applies to FCA cases.
 - Split over whether scienter may be defeated if (1) defendant has an **objectively reasonable** interpretation and (2) no authoritative guidance warned it away.
 - **Takeaway:** consequential case raising key strategic considerations for parties and their counsel.
- **Rule 9(b) pleading standard**
 - SCOTUS interest in Circuit split over heightened standard for pleading fraud but denied certiorari.
 - **Takeaways:** whether specific false claims must be pled and with how much specificity remains open.



EFFECTIVE RESPONSES TO FCA RISKS



DOJ and Internal Investigations

- Defining scope of investigation and who should investigate (outside/in-house).
- Preparing for and conducting witness interviews.
- Anticipating whistleblower risks and current/former employees.
 - ***United States ex rel. Felten v. William Beaumont Hosp.*** (6th Cir. 2021) – Held: FCA gives cause of action to former employees alleging post-termination retaliation.
- DOJ Civil Investigative Demands (31 USC 3733).
 - CIDs can seek documents and testimony.
 - Not governed by FRCP.
 - ***General Medicine P.C.*** No. 3:20-mc-00053 – held third party had standing to challenge CID—but denied the challenge.

Protecting Attorney-Client Privilege

- **SCOTUS to Review Legal Advice v. Business Advice**
 - *In Re Grand Jury (No. 21-1397)* – SCOTUS to consider whether attorney-client privilege protects attorney-client communications involving legal and non-legal advice, i.e., dual-purpose communications. Oral arg. Jan. 9, 2023.
 - Circuit split over “**primary purpose**” test—communications are privileged where significant purpose is to obtain or give legal advice.
 - **Takeaway:** case will have significant ramifications for investigations and litigation. Highlights need for best practices to reduce risks of waiver.
- **Marking and labeling communications as privileged**
 - Mark privileged communications as such. But indiscriminate labeling of privilege gives rise to risks too.
- **Personal devices and third-party messaging**
 - DOJ scrutiny and focus on company policies, training. Third-party messaging apps present challenges.
- **Disclosures to the government and privilege (FAR 52.203-13)**
 - *In re Fluor Intercontinental, Inc.* (4th Circuit 2020) – No waiver arises from mandatory disclosure just because it covers “same topic” as legal advice.





FCA – KEY RISK AREAS



FCA Cases and Private Equity

- DOJ continues to focus on private equity investors that knowingly cause the submission of false or fraudulent claims, particularly healthcare companies.
- In 2020, Ethan Davis, then-PDAG for USDOJ Civil Division, stated USDOJ's interest in cases against private equity that invested in companies that misused CARES Act funds.
- Examples of health care FCA cases against PE investors:
 - U.S. ex rel. Medrano and Lopez v. Diabetic Care Rx LLC, No. 15-CV-62617 (S.D. Fla.)
 - U.S. ex rel. Martino-Fleming v. South Bay Mental Health Centers (AG for Massachusetts)
 - U.S. ex rel. Johnson et al. v. Therakos, Inc. et al., No. 12-cv-1454 (E.D. Pa.)
- Takeaways:
 - Pre-acquisition due diligence and remediation are critical.
 - Private equity may be found culpable for “spillover” post-acquisition conduct.
 - Post-acquisition remediation is important.
 - Post-acquisition expansion must be thoughtful.

The FCA Cybersecurity Enforcement Landscape

- Cybersecurity non-compliance is a growing area of FCA enforcement focus and attention.
- DOJ Civil Cyber-Fraud Initiative (Oct. 2021).
 - Deficient cyber products
 - Misrepresentations regarding cybersecurity policies and practices
 - Knowing violations of cyber incident reporting requirements
- **Markus** (E.D. Cal.) (July 2022) – \$9M settlement of alleged false claims based on cybersecurity non-compliance. Precedent on key issues such as materiality and falsity.
- **Comprehensive Health Services LLC** (March 2022): first DOJ settlement of FCA cyber case under initiative. Resolved allegations of false representations re: compliance with contract requirements relating to storage of medical records.
- Key issues: interpretation of ambiguity (knowledge), damages.



FCA and Cybersecurity

- Increased DoD scrutiny of cybersecurity
 - June 16, 2022 Memo re: remedies
 - DIBCAC Medium Assessments
- New FAR Rules are on the way.
 - Incident Reporting
 - Uniformity in contract clauses
 - Software Security (Sept. OMB memo)
- Cyber Incident Reporting for Critical Infrastructure Act of 2022 (Pub L 117-103)
- CMMC
 - Rulemaking process (May 2023).
 - FCA risks and third-party/self assessments.
- FCA cybersecurity risks are heightened and different.
 - Large universe of personnel.
 - Fast-moving regulatory changes.
- FCA risks should be part of cybersecurity compliance.
 - Document decision-making including NIST 800-171 scoring.
- Policies and training for identifying and safeguarding CUI.
- CMMC creates potential strains in prime-sub relations re: verifying subs certified at appropriate level.

Other FCA Enforcement Areas

- **Small Business Fraud**
 - ***TriMark USA*** Feb. 2022 (N.D.N.Y.) - \$48.5M settlement.
 - Largest-ever FCA recovery based on alleged small business contracting fraud.
 - Contractor allegedly fraudulently induced service-disabled veteran contracts.
 - Relator was competitor. Highlights risks for resellers, suppliers, indirect sellers.
 - ***Numet Machining Techniques, LLC*** June 2022 (D. Conn.) - \$5.2M settlement. Gov't alleged that post-acquisition company falsely certified that it was small biz.
 - Company self-disclosed under MDR as part of diligence during sale of company.
 - **Takeaway:** diligence in M&A is key to identify and remedy small biz status changes.
- **Defective Pricing and TINA disclosures**
 - ***PowerSecure, Inc.*** Nov. 2022 (D.P.R.) - \$8.4M settlement. Contractor allegedly failed to provide certified cost or pricing data to Army Corps of Engineers in sole source contract.
- **PPP Loans/Pandemic Relief**
 - ***Prosperity Bank*** Sept. 2022 (S.D. Texas) - First FCA settlement against PPP lender.



QUESTIONS?

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