APPROACHING HEALTHCARE FALSE CLAIMS ACT CASES FROM BOTH A DEFENSE AND A PLAINTIFF VANTAGE POINT.

Dallas Bar Association – Health Law Section (April 2019)

Rachel V. Rose, Jeff Ansley & Sean McKenna

DISCLAIMER

THE INFORMATION PRESENTED IS NOT MEANT TO CONSTITUTE LEGAL ADVICE. CONSULT YOUR ATTORNEY FOR ADVICE ON A SPECIFIC SITUATION.

OVERVIEW

- How Bringing a False Claims Act Case Differs From Other Cases
- The Granston Memo and the EDPA's Decision in *EMD Serono*
- Recent Trends in FCA Healthcare Litigation and Notable Cases
- EKRA
- HIPAA and Trade Secrets
- Handling a Civil-Criminal Case from the Defense Side and Counterclaims
- Take-Aways & Questions

FCA HISTORY

- 1863 Statute
- Statute Amended Twice
  - 1943
  - 1986
- Additional Changes/Enhancements
  - Fraud Enforcement and Recovery Act of 2009 (FERA) – expressly indicates that procedural amendments apply to cases pending when the amendments were enacted, while the 3729(a)(1)(B) amendments apply to pending claims as of June 7, 2008.
  - The Affordable Care Act (ACA) (note – silent as to the issue of retroactivity)

FCA AND DODD-FRANK HIGHLIGHTS

- **In December 2017, the U.S. Department of Justice (DOJ) announced that in FY2017, False Claims Act (FCA) settlements totaled $3.7 billion. The healthcare industry continued to dominate this landscape with nearly two-thirds of the total recoveries by the DOJ.**
- **Over the past several months, there have been court opinions applying the Supreme Court's 2016 *Escobar* decision, positive outcomes for the whistleblowers, as well as *Digital Realty Trust, Inc. v. Somers*, 583 U.S. ___ (2018), which relates to retaliation protections in Dodd-Frank cases.**
- **The Yates Memo**
- **The Granston Memo**
- **The Brand Memo**
- **The Rosenstein Memo**

WHAT DOES A "FALSE CLAIM" LOOK LIKE?

"A false claim may take many forms, the most common being a claim for goods or services not provided or provided in violation *of contract terms, specification, statute or regulation*."

(S. Rep. No. 99-345 at 9, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274 (emphasis added).

CATEGORIZING A FALSE CLAIM

- Escobar and Materiality
  - Factually False/Worthless Services Theory
  - Legally False (Express)
  - Legally False By Implied Certification
  - Reverse False Claim

ESCOBAR'S CRUCIAL DISTINCTION

- **The Court narrowed the Government and the First Circuit's perception of materiality – "that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation."**

BRINGING A FCA CASE

- Begin with § 3729(a)(1), where the plaintiff MUST prove:
  - (1) defendant presented or caused to be presented to an agent of the United States a claim for payment;
  - (2) the claim was MATERIALLY false or fraudulent; and
  - (3) the defendant knew the claim was false or fraudulent.
- Clearing FRCP 9(b) and 12(b)(6)
- The Seal and extensions
- Intervention versus non-intervention versus dismissal

THE GRANSTON MEMO & *EMD SERONO MEMORANDUM OPINION*

GRANSTON MEMO

- Purpose
  - To encourage prosecutors to seek the dismissal of qui tam law suits pursuant to its authority under 31 U.S.C. § 3730(C)(2)(A) when it is in the government's best interest to do something, something it has heretofore rarely done.
  - Although the Government may dismiss a qui tam action despite the Relator's objection, it's dismissal cannot be arbitrary and must be read in conjunction with other provisions of the FCA.

POLICY REASONS BEHIND THE GRANSTON MEMO'S ADVISING PROSECUTORS TO CONSIDER FILING A 12(B) MOTION

- Curb "meritless" qui tams;
- Prevent "parasitic or opportunistic qui tams";
- Prevent "interference with agency policies and programs";
- Control "litigation brought on behalf of the United States";
- Safeguard "classified information and national security interests";
- Address "egregious procedural errors".

SECTION 3730(C)(2)(A)

- This section mandates a hearing before a court may dismiss a *qui tam* action over a relator's objection.
- "If the government's right to dismiss is 'unfettered,' as the District of Columbia Circuit has held, a hearing would be superfluous, rendering the requirement of a hearing a nullity. *See Nat'l Ass'n of Mfrs. V. Dep't of Def.*, 138 S. Ct. 617, 632 (2018).
- In essence, this provision assures that the decision to dismiss is not arbitrary and without a valid government interest. "The Legislative Branch has delegated to the Executive Branch the authority to pursue these actions with the relator. Requiring some justification, no matter how insubstantial, for a decision not to pursue a false claim, acts as a check against the Executive from absolving a fraudster on a whim or for some illegitimate reason. It prevents the Executive from abusing power."

GRANSTON MEMO SPLITS

- Split in the courts:
  - *Swift v. United States (D.C. Circuit)* – court found that the government had "unfettered discretion" to dismiss complaints under §3730(C)(2)(A).
  - *U.S. ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.* (9th Circuit) – the government MUST do two things: (1) identify a valid government purpose for dismissal; and (2) show a rational relation between the dismissal and accomplishment of the valid government purpose. The 10th Circuit also follows this "rational relationship" test which requires the government to justify its decision. The EDPA also follows this interpretation.

EMD SERONO, INC. (EDPA)

- SMSFP, LLC is a limited liability shell company established by Verani Partners, LLC, doing business as National Health Care Analysis Group, a LLC comprised of other similar entities.
- The aforementioned companies are relators in multiple *qui tam* actions making substantially the same allegations in eight judicial districts.
- SMSFP filed this case in EDPA on Oct. 21, 2016. It amended its complaint to add a natural person, a former Pfizer employee, as a co-relator on April 26, 2017.
- June 28, 2017, after investigating the case for over 18 months, the government declined to intervene and the seal was lifted on August 30, 2018.

EMD SERONO PART II

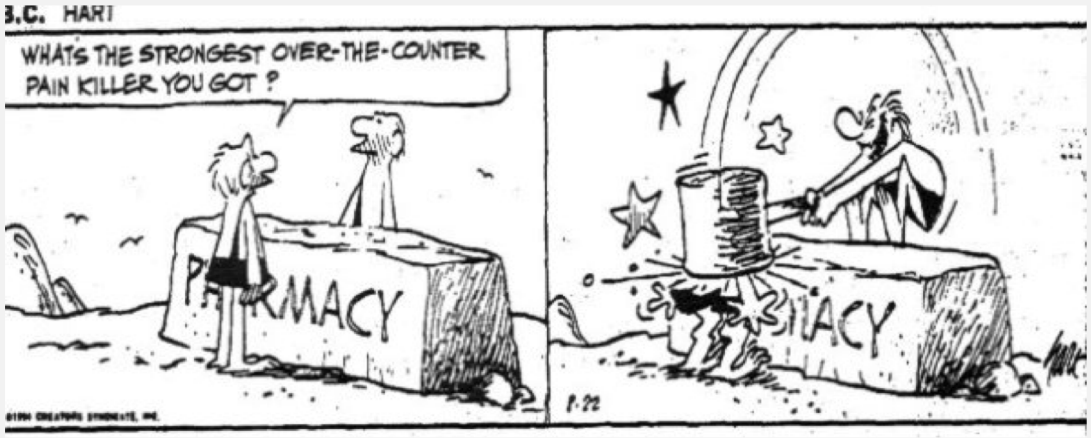
- Government moved to dismiss contending that "the allegations lack merit, and continuing to monitor, investigate, and **prosecute the case will be too costly and contrary to the public interest.**

CASE TRENDS

HOT AND EMERGING AREAS

- Subsidizing the copays of a company's own drugs (Recent settlement of $122.6 million against Jazz Pharmaceutical, Alexion and Lundbeck)
- Meaningful Use (*eClinical Works and Greenway*)
- Upcoding (*CareWell Urgent Care*)
- EKRA and the Travel Act

INTRODUCTION TO THE OPIOID EPIDEMIC.



WHAT ARE OPIOIDS?

- The National Institute on Drug Abuse defined opioids as, "medications that relieve pain. They reduce the intensity of pain signals reaching the brain and affect those brain areas controlling emotion, which diminishes the effects of a painful stimulus."

THE SUPPORT ACT

- The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act"), Pub. L. 115-271 (Oct. 24, 2018) addresses various aspects related to the opioid crisis through a series of over 120 separate bills.
- Legislative History
- On June 22, 2018, the House of Representatives passed, with rare bipartisan support, its version of the SUPPORT Act. Immediately thereafter, the House version of the SUPPORT Act was sent to the Senate for the Senate's consideration and approval.
- On September 17, 2018, the Senate passed its version of the SUPPORT Act. The Senate version of the SUPPORT Act went back to the House for consideration.
- On September 25, 2018, House and Senate negotiators agreed on a final legislative package to address the opioid crisis.
- On September 28, 2018, the House voted 393-8 to pass the negotiated SUPPORT Act.
- On October 3, 2018, the Senate voted 98-1 to pass the negotiated SUPPORT Act as passed by the House on September 28, 2018.

EKRA

- The SUPPORT Act's Section 8122 - Eliminating Kickbacks in Recovery Act of 2018 ("EKRA").
- The prior version of the bill, the Opioid Crisis Response Act, which passed in the Senate on September 17, 2018, did not include the EKRA provisions.
- One consideration that comes out of EKRA is that it must be read *in pari materia* with other statutes that concern the same subject or matter. In this instance, it is prudent to read the federal Anti-kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, the Physician Self-Referral Law ("Stark Law"), 42 U.S.C. § 1395nn and the International Travel Act of 1961 ("Travel Act"), 18 U.S.C. § 1952 in conjunction with EKRA.

COMPARING EKRA SAFE HARBORS TO AKS SAFE HARBORS

- EKRA, 18 U.S.C. §220 makes it a federal crime to receive or offer "[i]llegal remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories" (the "Recovery Kickback Prohibition"). This wording is broad and extends beyond clinical laboratory arrangements with treatment facilities and includes other payers in addition to federal and state government programs, such as Medicare and Medicaid. Penalties under this new law carry a $200,000 fine "per occurrence" and up to 10 years in prison.
- Although similar to the federal Anti-kickback Statute (including some of the AKS safe harbors), EKRA created an entirely new offense.

KEY DIFFERENCES

- EKRA applies to all improper referrals to recovery homes, clinical treatment facilities, or laboratories – regardless of whether the referred service relates to substance use disorder treatment. Laboratories also include physician-owned labs.
- EKRA applies to all payors, hence it is more expansive than the federal AKS and more analogous to the Travel Act.
- EKRA applies to specific entities – recovery homes, clinical treatment facilities and clinical laboratories.
- EKRA contains eight "safe harbors" – some of which track existing AKS safe harbors and some new ones.

HIPAA & TRADE SECRETS

DOES PROVIDING PHI TO AN ATTORNEY AND THE GOVERNMENT VIOLATE HIPAA?

- **NO.**

HIPAA – CFR § 164.502(J)(1)

- (i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services or conditions provided by the covered entity potentially endangers one or more patients, workers or the public; **AND**
- (ii) The disclosure is to (B) an attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct described in paragraph (j)(1)(i) of this section.
- **APPLICATION in PRACTICE:**
  - DEFENSE MAY RAISE AN OBJECTION THAT THIS IS A HIPAA VIOLATION and may even file a separate law suit.
  - PLAINTIFF's COUNSEL **MUST** BE ABLE TO MEET BOTH PRONGS AND HAVE A GOOD FAITH BELIEF THAT UNLAWFUL CONDUCT IS IN PLAY AND THAT THE PERSON IS NOT USING THE PHI FOR ANY OTHER REASON (i.e., selling the PHI or taking it to a competitor).

DOJ'S SCOPE OF SUBPOENA AUTHORITY

- Section 248 of HIPAA authorizes the Attorney General to issue subpoenas requesting production of certain documents and testimony in investigations relating to "any act or activity involving a federal health care offense." *See* 18 U.S.C. §3486(a)(1)(A)(i)(I).
- The legislative history of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) suggests that Congress granted subpoena authority to the Attorney General in investigations of healthcare fraud and abuse in order to facilitate enforcement of federal statutes and thereby to improve the "availability and affordability of health insurance in the United States." *See* H.R.Rep. No. 104-496, at 1, 66-67.

TRADE SECRETS – BALANCING TEST

- "The law has a long history of recognizing the general rule that certain contracts, though properly entered into in all other respects, will not be enforced, or at least will not be enforced fully, if found to be contrary to public policy." *Kashani v. Tsann Kuen China Enter. Co.*, 118 Cal. App. 4th 531, 540, 13 Cal. Rptr. 3d 174 (2004) (alteration omitted) (quoting 15-79 Corbin on Contracts § 79.1 (2003))
- : "A promise or other term of an agreement is unenforceable on grounds of public policy if legislation provides that it is unenforceable or the interest in its enforcement is clearly outweighed in the circumstances by a public policy against the enforcement of such terms." Restatement (Second) of Contracts § 178 (1981). The Restatement lists a series of factors to be considered when making this determination, including "any special public interest in the enforcement of the particular term" and the strength of the public policy against enforcement [*19] of the term "as manifested by legislation or judicial decisions." *Id.*

COUNTER CLAIMS AGAINST WHISTLEBLOWERS

COUNTERCLAIMS AGAINST WHISTLEBLOWERS

- Generally disfavored and dismissed by courts when:
  - Seeking contribution for bringing case or causing business losses rejected against public policy.
- Breaches of independent contractual obligations allowed.
  - Trade secrets/proprietary theft.
  - Violation of employment-related covenants
  - Breaches of *confidentiality*

CIVIL V. CRIMINAL AND DEFENSE TIPS

TAKE-AWAYS

COMPLIANCE LEADING PRACTICES: PREVENTING FCA CASES

- Tracking all reports/assessments
- Documenting investigation plan
- Preservation of information
- Protections to ensure confidentiality
- Conducting investigation
- Determining scope of disclosure
- Reporting of conclusions/findings to appropriate parties
- Corrective actions for responsible persons/departments
- Discipline of bad actors
- Non-retaliation reinforcement
- Taking remedial measures (repayment or disclosure)

THANK YOU & QUESTIONS

Rachel V. Rose, JD, MBA, Principal

Rachel V. Rose – Attorney at Law, PLLC (Houston)
rvrose@rvrose.com|713.907.7442

Jeffrey J. Ansley, Partner

BellNunnally – Attorneys & Counselors (Dallas)

jansley@bellnunnally.com| 214.740.1408

Sean McKenna, Principal

Law Office of Sean McKenna, PLLC (Dallas)

sean@seanmckennalaw.com| 786.973.3762