



View from a Federal Prosecutor: Legal Pitfalls to Avoid

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RESPONDING TO AN INVESTIGATIVE REQUEST FROM THE FEDERAL GOVERNMENT—AVOIDING PITFALLS



Overview

- Hot Topics
- Genesis of Investigation
- Government Investigative Techniques
- How to Respond to the Government



Hot Topics: Granston Guidance

- January 10, 2018—eight-page memo leaked from DOJ.
 - Authored by Director of Commercial Litigation Branch of the Fraud Section, Michael Granston.
 - Suggests 7 factors government attorneys should consider in deciding whether or not to seek dismissal of meritless *qui tam* actions.
 - 31 U.S.C. § 3730(c)(2)(A).
- May indicate shift in DOJ's enforcement strategy with respect to FCA.



Granston Guidance

- Advises prosecutors to argue 1 of 7 bases for dismissal:
 - Claims Lacking in Merit;
 - Parasitic *qui tam* Actions;
 - Actions that Threaten Agency Policy or Programs;
 - Actions that Interfere with Other FCA Cases;
 - Cases that Risk National Security Harm;
 - Cases Where Costs Will Exceed Gain;
 - Where Claim May Frustrate an Investigation.



Granston Guidance

- Granston gives 3 reasons he encourages dismissal of weak FCA cases:
 - to advance the government's interests;
 - to preserve its limited resources;
 - and to avoid potentially adverse precedent.



Hot Topics: Kickback “Taint”

- A relator must link alleged kickbacks to specific claims for payment submitted to gov’t.
- It is not enough to merely allege “taint” of a kickback scheme to render false every claim submitted while scheme is ongoing.
- “Temporal proximity” is insufficient to survive summary judgment under the FCA.
 - *See U.S. ex rel. McBride v. Halliburton*, No. 15-7144 (D.C. Cir. 2017); *U.S. ex rel. Greenfield v. Medco Health Systems, Inc. et al*, No. 1:2012cv00522 (D.N.J. 2016).



Hot Topics: Recent FCA Cases

- DME provider billed D.C. Medicaid for supplies that were not provided—Sept. 2017.
 - Pleaded guilty to charge of health care fraud.
 - Billed maximum allowable amount of incontinence supplies, while only providing amount patient actually needed.
 - Obtained ≈\$580,000 not entitled to from state Medicaid program.
 - Restitution and 2 years in prison with 3 years of supervised release.

Press Release, Dept. of Justice, U.S. Attorney's Office, District of Columbia, Owner of Durable Medical Equipment Company Pleads Guilty to Health Care Fraud (Sept. 19, 2017) (available online)



Recent FCA Cases

- DME provider operated DME companies that did not in fact provide any equipment to beneficiaries.
 - Nov. 2017—DME provider plead guilty to a charge of conspiracy to commit health care fraud.
 - Submitted almost \$1 million in false claims.
 - Personally received more than \$300,000 from false claims.

Press Release, Dept. of Justice, Office of Public Affairs, Operator of Purported Durable Medical Equipment Providers Pleads Guilty to Health Care Fraud Charges for Role in Durable Medical Equipment Fraud Scheme (Nov. 20, 2017) (available online).



Recent FCA Cases

- Innovative Therapies/Cardinal Health agreed to pay \$2.715 million to settle False Claims Act allegations—June 2017.
 - Allegedly companies caused submission of false claims through marketing of negative pressure wound treatment devices as DME.
 - Marketed certain models of devices as DME, despite knowing devices did not have expected life of durable device.
 - Relator in this case will receive \$488,700.

Press Release, Dept. of Justice, U.S. Attorney's Office, Middle District of Tennessee, Durable Medical Equipment Manufacturer Agrees To Pay \$2.715 Million To Resolve False Claims Allegations (June 29, 2017) (available online).



Recent FCA Cases

- Diabetic medical equipment companies pay more than \$12 million to resolve False Claims Act allegations—Sept. 2016.
 - U.S. Healthcare Supply LLC an Oxford Diabetic Supply Inc. allegedly used fictitious entities to make unsolicited phone calls to Medicare beneficiaries.
 - The companies submitted claims to Medicare for equipment sold based on calls.
 - Violates the Medicare Anti-Solicitation Statute.

Press Release, Dept. of Justice, Office of Public Affairs, Diabetic Medical Equipment Companies to Pay More Than \$12 Million to Resolve False Claims Act Allegations (Sept. 7, 2016) (available online).



Recent FCA Cases

- Linde AG's Lincare unit agreed to pay \$20 million to resolve whistleblower lawsuit.
 - Lawsuit brought by former employees—DOJ did not intervene.
 - Allegedly:
 - billed for oxygen equipment and tanks even when customers did not use or require them;
 - fabricated customer oxygen orders ; and
 - improperly waived customer co-payments and deductibles.



Hot Topics: Current DME Trends with Heightened Risk

- Telehealth
- Remote Patient Monitoring
- Orthotics
- Ventilators
- Diabetic Test Strips
- Management Service Organizations



Hot Topics: Taken Together

- There are indicators that the gov't will be less likely to intervene in the future
 - Granston Memo
 - Courts have been requiring a showing a materiality in cases of implied certification under *Escobar*.
- However, the Civil Division remains active, collecting an estimated \$2.6B from companies in the health care industry in 2017.



Genesis of an Investigation

- How Does It Start?
 - Whistleblower
 - Disgruntled Employee
 - Competitor's Complaint
 - Government Audit
 - HIPAA Breach Notification
 - Self-Disclosures



Genesis of an Investigation

- Why Does It Start?
 - Rumor, Innuendo, Suspicion, Speculation – All It Takes
 - Whistleblower
 - Agents Convince AUSA of Wrong Doing
 - AUSAs Are the Gate Keepers
 - OIG Work Plan Investigations
 - Claims Data Analysis



Genesis of an Investigation

- How Long Will It Last
 - The Government's Moves at the Government's Pace
 - “I'm From the Government and I'm Here to Help”
 - How Long is the Statute of Limitations?
 - Cooperation and Transparency vs. Catch Me If You Can
 - Text Messages and Emails—The Slippery Slope of No Context
 - Credibility with the AUSA—Key to Cooperation and Control



Genesis of an Investigation

- Mind Set of an Assistant U.S. Attorney
 - Criminal vs. Civil
 - Bad Actors vs. Reckless Conduct
 - Obstruction is the New Darling Charge
 - Cooperation: What Does it Mean? What Do You Get?
 - Self-Reporting: Is It Worth It?



Investigative Techniques

- What is in the Tool Boxes?
 - Criminal
 - Wiretaps
 - Pen Registers
 - Search Warrants
 - Arrest Warrants
 - Immunity
 - Grand Jury Subpoena
 - 5K Motions
 - Guns and Badges (Deception – Can They Lie to You?)



Investigative Techniques

- What is in the Tool Boxes?
 - Civil
 - Subpoenas Under 18 U.S.C. § 3486
 - Documents
 - Civil Investigative Demands
 - Documents and Depositions
 - Guns and Badges
 - Suspension and Debarment (Can't Use But a Real Concern)
 - Requests for Interviews and Cooperation



Different Contact Methods

- Civil Investigative Demands
 - Compulsory pre-complaint procedure used to obtain:
 - Documentary evidence;
 - Answers to interrogatories; and
 - Oral testimony
 - Used by DOJ in False Claims Act cases



Different Contact Methods

- Grand Jury Subpoena
 - *Subpoena Duces Tecum*—appear and produce documents
 - Consider scope – is the request overly broad?
 - Develop schedule with gov't
 - Investigation/litigation hold
 - *Subpoena Ad Testificandum*—appear and give testimony
 - Fifth Amendment Privilege
 - Attorney-Client Privilege



Different Contact Methods

- Forthwith Subpoena
 - Used when high risk of destruction/alteration of documents/files/evidence
 - Require production “forthwith”
 - Need prior approval of a United States Attorney
 - DOJ guidance—should only be used when an immediate response is justified



Different Contact Methods

- Search Warrants
 - If agents appear with search warrant:
 - Notify designated person;
 - Notify counsel;
 - Obtain copy of search warrant;
 - Limit search to area authorized by warrant



Different Contact Methods

- Telephone Inquiry
 - Initial contact should:
 - Ascertain names and agency;
 - Request call-back number;
 - Explain company representative will call back;
 - Designated person should call back, after speaking with in-house and outside counsel
 - Preferably with counsel on the line



Different Contact Methods

- Government In-house visit
 - Gov't cannot compel interview
 - Company should not instruct employees to refuse interview; leave it to the employee and their counsel to decide
 - Advise employees they can speak with counsel before interview
 - Agent may approach at employee's home
 - Could be called before a grand jury



Different Contact Methods

- Contact with Management
 - What these individuals say can be binding on company
 - Counsel should insist on being present
 - Must be especially careful early in investigation
 - Gov't may try to interview individuals before internal investigation or retention of counsel



Different Contact Methods

- Administrative Subpoena
 - Certain agencies may issue administrative subpoenas or summons—similar to grand jury subpoena
 - Upheld so long as “reasonable”
 - Within the authority of agency;
 - Demand not too indefinite; and
 - Reasonably relevant to proper inquiry
 - HIPAA regulations:
 - Must disclose if request for “health oversight”
 - If for “violation of law,” only court authorization or CID



How to Respond

Goals of Initial Contact: Goals

- Appear professional and prepared (sets tone for the investigation; narrows the investigation)
- Facilitate all authorized searches procedures
- Gather information about investigation
- Protect privileges and privacy rights
- Get counsel involved
- Get them out



Initial Contact

- Businesses, including healthcare companies, should prepare for federal agents:
 - Appearing at reception, asking questions, requesting documents, and presenting warrants
- Proper training and response policies ensure:
 - Professional response, protection of privacy rights, and protection of waivers/privilege



Initial Contact: Steps

- Steps for individual approached by gov't agent:
 - Immediately contact designated person
 - If agents physically present—request they remain in reception area
 - Do not give any additional information (name or location of designated person)
- This approach gives designated person a few moments notice and prevents agents from wandering unescorted.



Initial Contact: Gather Intel.

- Steps for designated person:
 - Ascertain identity;
 - Request credentials;
 - Request business cards, or names and phone numbers;
 - Inquire as to nature of visit;



Initial Contact: Gather Intel.

- Steps for designated person (cont.):
 - Ascertain identity of prosecutor assigned;
 - Ask why investigation initiated;
 - Indicate full cooperation;
 - Explain not in position to answer substantive questions
 - Direct to legal counsel and provide contact info



Initial Contact: Gather Intel.

- “Target” vs. “Subject” of Investigation
 - Target—person as to whom the prosecutor or grand jury has substantial evidence linking him or her to the commission of a crime
 - Subject—a person whose conduct is within the scope of the grand jury’s investigation
- Provides some guidance on seriousness of investigation



Other Issues of Concern

- Privacy and Privileges
 - Provider
 - Attorney-Client Privilege
 - Work Product Protection
 - Doctor-Patient Privilege
 - Fifth Amendment Privilege
 - Employee/Client/Patient
 - Disclosure of patient files requires a court order
 - Improper disclosure could result in civil lawsuit



Other Issues of Concern

- Trade Secrets
 - Grand jury secrecy provides some protection
 - May also discuss with gov't—often willing to make appropriate arrangements
- Public Relations
 - Should speak with unified voice
 - Careful not to waive any privileges
- Potential Independent Investigation



Takeaways

- Preparing in advance:
 - Identify designated persons
 - Train employees on how to react to initial contact by gov't agents
 - Inform employees of policies and rights if approached (both on site and off site)
- Advanced preparation prevents inadvertent waiver of rights and privileges



Questions?