Doing Business in the World of Whistleblowers

A Discussion of Enforcement Trends, Emerging Prosecution Tactics and Practical Compliance Strategies

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November 11, 2019

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Bradley

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Presentation Overview

1. Background Regarding Whistleblower-Driven Litigation in the Healthcare Industry
2. Current Trends
3. Practical Advice for Proactive Compliance & Best Practices After Whistleblower Allegations to the Government
4. Questions

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Background/Introduction

- As many healthcare and life sciences companies have learned, the regulatory landscape is complicated, evolving, and perilous.
- Even technical violations of healthcare regulations can bring stiff consequences.
- Whistleblowers are the leading origins of many government investigations and prosecutions.
- We discuss the background of these investigations and some notable prosecutions in recent years.

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Civil *Qui Tam*/False Claims Act Litigation

- The history of whistleblower (or *qui tam)* litigation in America finds its roots in the Civil War. Congress passed legislation to help the government combat fraud by federal contractors.
- The law remained on the books for over a century until it was significantly revamped in the mid-1980s. At that point, Congress sweetened the pot by granting whistleblowers 15 to 30 percent of the government's recoveries.
- The law has been strengthened and enhanced over the years, most recently in connection with enactment of the Affordable Care Act in 2009.

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Whistleblower Litigation under the False Claims Act

- According to the most recent statistics, the Department of Justice (DOJ) is maintaining a fast clip with respect to False Claims Act prosecutions.
- In fiscal year 2017, the federal government collected more than $3.7 billion in fraud recoveries from federal contractors.
- The vast majority of those recoveries came in the healthcare arena.

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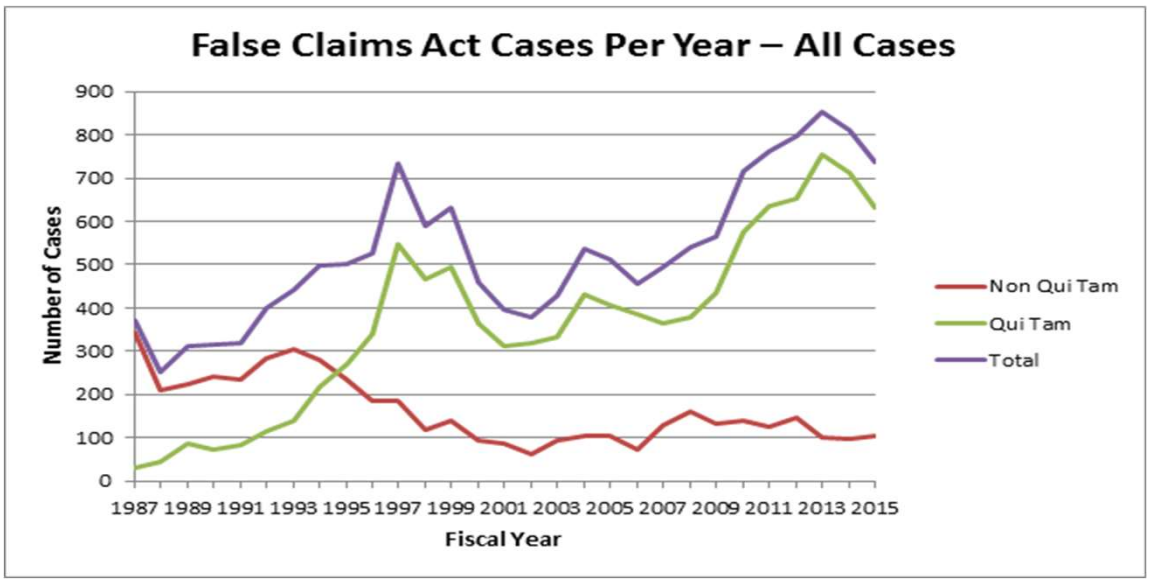

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Role of Whistleblowers in Government Litigation

- Of particular note is that more than 90% of the recoveries reached by DOJ—$3.4 billion out of $3.7 billion—were the result of *qui tam* lawsuits.

- *Qui tam* lawsuits, otherwise known as whistleblower lawsuits, are one of the fastest-growing segments of litigation in federal courts, a cottage industry of lawyers devoted to these cases.

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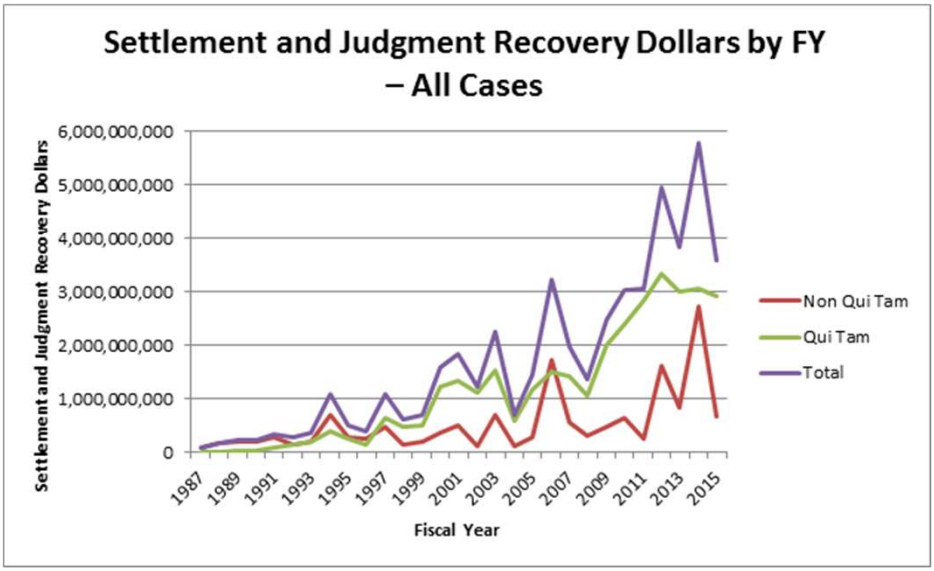

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False Claims Act Suits in Healthcare Space: Fla. Home Health Co. Pays $1.75 Million

- The former owner of a Florida-based home healthcare company paid $1.75 million to resolve a False Claims Act dispute in 2016.
- Among other allegations, the government claimed the company paid physicians illegal kickbacks to drum up business.
- The lawsuit was originally filed by a whistleblower.


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Wednesday, March 2, 2016
Former Owner Of Florida Home Health Care Companies Agrees To Pay $1.75 Million To Resolve Kickback And False Claims Act Allegations
Tampa, FL – Mark T. Conklin, the former owner, operator and sole shareholder of Recovery Home Care Inc. and Recovery Home Care Services Inc. (collectively RHC) has agreed to pay $1.75 million to resolve a lawsuit alleging that he violated the False Claims Act by causing RHC to pay illegal kickbacks to doctors who agreed to refer Medicare patients to RHC for home health care services, the Department of Justice announced today. Conklin sold the RHC companies to National Home Care Holdings LLC, on Oct. 9, 2012.
"Inducements of the type at issue in this case are designed to improperly influence a physician's independent medical judgment," said U.S. Attorney A. Lee Bentley, III for the Middle District of Florida. "This lawsuit and today's settlement evidence our office's ongoing efforts to safeguard federal health care program beneficiaries from the effects of such illegal conduct."
From 2009 through 2012, Conklin spearheaded a scheme whereby RHC, headquartered in West Palm Beach, allegedly paid dozens of physicians thousands of dollars per month to serve as sham medical directors who supposedly conducted quality reviews of RHC patient charts. According to the government's lawsuit, the physicians in many instances performed little or no work, but nevertheless received thousands of dollars from RHC. The government's complaint contended that these payments were, in fact, kickbacks intended to induce the physicians to refer their patients to RHC, in violation of the Anti-Kickback Statute and the Stark Law.
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Owner of Miami Home Health Agency Sentenced to 9 Years

- In 2017, the owner of a now-defunct home health agency was sentenced to nine years in prison and ordered to pay $15 million in restitution.
- Among other things, his alleged wrongdoing was paying bribes and kickbacks to recruit patients.
- Additionally, he treated patients with home-health services despite knowing the patients were not homebound.

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FOR IMMEDIATE RELEASE — Monday, December 11, 2017

Owner of Miami Home Health Agency Sentenced to More Than Nine Years in Prison for Role in $15 Million Medicare Fraud Conspiracy

The owner and operator of a defunct Miami, Florida home health agency was sentenced to 115 months in prison today for his role in a $15 million conspiracy to defraud the Medicare program.

Acting Assistant Attorney General John P. Cronan of the Justice Department's Criminal Division, Acting U.S. Attorney Benjamin G. Greenberg of the Southern District of Florida, Special Agent in Charge George L. Piro of the FBI's Miami Field Office, Special Agent in Charge Shimon R. Richmond of the U.S. Department of Health and Human Services Office of Inspector General's (HHS-OIG) Miami Field Office and Special Agent in Charge Brian Swain of the U.S. Secret Service's (USSS) Miami Field Office made the announcement.

Yunesky Fornaris, 38, of Miami, was sentenced by U.S. District Judge Joan A. Lenard of the Southern District of Florida, who also ordered Fornaris to pay $15.1 million in restitution and forfeit the gross proceeds traced to the offense. Fornaris pleaded guilty on Oct. 3 to one count of conspiracy to commit wire fraud.

As part of his guilty plea, Fornaris admitted that between April 2010 and July 2016, he owned, controlled, and managed the business at Elite Home Care LLC (Elite), and that he and his co-conspirators submitted false and fraudulent home health care claims from Elite to the Medicare program via interstate wire. Fornaris further admitted to concealing his true ownership interest in Elite by not listing his ownership interest on the Medicare enrollment application and to enlisting patient recruiters to recruit patients to Elite in exchange for illegal bribes and kickbacks.

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$21 Million Settlement: Upcoding and Medically Unnecessary Health Services

- A Kentucky-based home-health company resolved civil False Claims Act allegations in 2016 that cost it $21 million.
- The alleged wrongdoing here involved "upcoding," which is the submission of inaccurate billing codes to gain higher government payouts.
- The company also provided home-health services that were not medically necessary.

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FOR IMMEDIATE RELEASE — Thursday, July 7, 2016

Louisville Based MD2U, a Regional Provider of Home-Based Care, and Its Principal Owners Admit to Violating the Federal False Claims Act and Being Liable for Millions

Knowingly Presented False Claims and Altered Records to Get False Claims Paid Will Pay Millions to Settle Allegations

MD2U Holding Company, including its related companies and individually named owners, have agreed to pay millions to resolve a government lawsuit alleging that they violated the federal False Claims Act by knowingly submitting false medical claims to Medicare and other government health care programs, altering records to support false claims and providing services that were medically unnecessary, announced U.S. Attorney John E. Kuhn Jr. for the Western District of Kentucky

"Unfortunately, our healthcare system is under assault from a small minority of providers who engage in fraudulent billing, overbilling and providing unnecessary services," said U.S. Attorney Kuhn. "In an effort to control these losses and force accountability, my office and the Department of Justice pursues and recovers false and fraudulent billings as one of its highest priorities. This significant case against MD2U is but one example of the vigorous work against healthcare fraud taking place in the Western District and across the nation."

"This provider billed for medically unnecessary home visits and often grossly exaggerated the level of service provided," said Special Agent in Charge Derrick L. Jackson for the U.S. Department of Health and Human Services' Office of Inspector General (HHS-OIG) in Atlanta. "The OIG is committed to protecting the integrity of federal health care programs by aggressively pursuing entities that increase their revenue through deceitful schemes and trickery."

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Fla. Home Health Agency Settles Dual FCA Cases

- Just last month, a Florida-based home health agency settled two False Claims Act cases—both of which originated through whistleblower lawsuits.
- The company allegedly paid a physician for work he never completed in exchange for patient referrals.
- Additionally, a physician allegedly approved care plans for patients he never saw.


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Friday, June 7, 2019
United States Settles False Claims Act Cases Against Home Health Agency
Tampa, FL – The United States has settled two cases against Nurse on Call, a home health agency with locations in Sarasota and Orlando, that allege False Claims Act violations arising from having a medical director approve care for patients without having seen the patients, the alleged payment of kickbacks in the form of a sham medical director agreement, and payments to the spouses of referring physicians.
Nurse on Call allegedly paid kickbacks in the form of a sham medical directorship to a physician to refer patients to Nurse on Call. The physician allegedly did little, if any, of the work for which Nurse on Call paid him as medical director. Sham medical director agreements to induce patient referrals violate the Anti-Kickback Statute and the Stark Law. Nurse on Call also allegedly paid some employees in a manner that accounted for the volume of referrals by their physician spouses, in violation of the Stark Law. Finally, Nurse on Call allegedly requested another medical director to approve plans of care for patients whom the director never saw, in violation of Medicare regulations.
"The Anti-Kickback Statute and the Stark Law help to ensure that financial interests do not compromise the medical decision-making process," said U.S. Attorney Maria Chapa Lopez. "Additionally, Medicare regulations requiring physicians to have face-to-face contact with patients helps to ensure that any care provided is necessary and reasonable. Our office will continue to use every tool at our disposal to combat fraud and abuse in our health care programs."
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Current Trends: High-Level

- While some predicted that the Trump administration might curb the enforcement priorities or otherwise lessen the risks for healthcare companies, this administration is continuing to investigate and prosecute cases.
- Much of this continued growth in cases is the result of a years-long whistleblower bar that has invested significant resources and continues to develop a pipeline of cases.
- Further, many whistleblowers are continuing to pursue their cases on their own, even if the government chooses not to intervene.

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Recent DOJ Commitment to Continuing Enforcement

- Last summer, DOJ announced the arrest of more than 600 individuals.
- This was the largest healthcare fraud takedown to date, topping the record years of 2013-2017.

Over 600 Individuals Charged in 2018 Healthcare Fraud Takedown

In the largest healthcare fraud takedown to date, OIG and DoJ reported charging individuals involved in fraud schemes that cost Medicaid and Medicare $2 billion.

Source: Thinkstock

By Jacqueline LaPointe

June 28, 2018 - The HHS Office of the Inspector General (OIG) and Department of Justice (DoJ) recently announced the largest healthcare fraud takedown to date, with over 600 defendants charged with participating in fraud schemes amounting to about $2 billion in losses to Medicare and Medicaid.

Of the over 600 defendants charged, 165 were medical professionals, including 32 doctors who allegedly participated in healthcare fraud schemes involving prescribing and distributing opioids and other narcotics.

The charges jointly announced by the OIG and DoJ also involved claims submitted to Medicare, Medicaid, TRICARE, and private insurance companies for medically unnecessary prescription drugs that were oftentimes never purchased or given to patients.

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More Recent DOJ Efforts: Largest Hiring in Decades

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FOR IMMEDIATE RELEASE Monday, June 4, 2018

On the 500th Day of the Trump Administration, Attorney General Sessions Announces 311 New Assistant United States Attorney Positions

Largest Increase in AUSAs in Decades Allocates Prosecutors to Focus on Violent Crime, Civil Enforcement, and Immigration Crimes

Today, on the 500th day of the Trump Administration, Attorney General Jeff Sessions announced that the Department of Justice is taking a dramatic step to increase resources to combat violent crime, enforce our immigration laws, and help roll back the devastating opioid crisis. In the largest increase in decades, the Department of Justice is allocating 311 new Assistant United States Attorneys to assist in priority areas. Those allocations are as follows: 190 violent crime prosecutors, 86 civil enforcement prosecutors, and 35 additional immigration prosecutors. Many of the civil enforcement AUSA's will support the newly created Prescription Interdiction & Litigation Task Force which targets the opioid crisis at every level of the distribution system.

"Under President Trump's strong leadership, the Department of Justice is going on offense against violent crime, illegal immigration, and the opioid crisis—and today we are sending in reinforcements," said Attorney General Jeff Sessions. "We have a saying in my office that a new federal prosecutor is 'the coin of the realm.' When we can eliminate wasteful spending, one of my first questions to my staff is if we can deploy more prosecutors to where they are needed. I have personally worked to re-purpose existing funds to support this critical mission, and as a former federal prosecutor myself, my expectations could not be higher. These exceptional and talented prosecutors are key leaders in our crime fighting partnership. This addition of new Assistant U.S. Attorney positions represents the largest increase in decades."

To see more information on the locations of the 311 Assistant United States Attorney positions click here.

Attachment(s): Download Assistant United States Attorneys List

Press Release Number: 18 - 721

Component(s): Office of the Attorney General

Updated June 4, 2018

- Also last summer, DOJ announced the largest increase in Assistant US Attorneys in decades.
- Nearly 1/3rd of the new hires were hired to specifically focus on affirmative civil enforcement—or *qui tam*/whistleblower cases.

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There's Also Room for Cautious Optimism, However

- While some of these signs appear ominous, there is room for cautious optimism.
- First, early last year, DOJ announced two separate directives that might significantly help defendants facing *qui tam*/whistleblower suits.
  - **Granston Memo** – Addressing possible declination of meritless cases; and
  - **Brand Memo** – Eliminating DOJ's use of sub-regulatory guidance as a basis for bringing forth affirmative civil litigation

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Courts Have Provided Some Reason for Optimism

- Additionally, the federal courts—including the Supreme Court—have provided defendants with considerable legal arguments in recent years.
- Of most significance is a 2016 Supreme Court case—*Universal Health Services v. United States ex rel. Escobar* ("Escobar")
- Broadly speaking, this case has caused courts to place more emphasis on ***materiality***—or the showing that the alleged fraud really mattered.

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Court Precedent (con't)

- Since Escobar was decided two years ago, courts have struggled with concepts of "materiality."
- However, more and more run-away jury verdicts are being overturned and defendants have been emboldened.
- There is a significant up-tick in the number of defendants willing to take False Claims Act to litigation and, in some cases, trial.

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Assessment of Future Trends

- While its hard to predict with rigor what will happen in the next few years in the False Claims Act space, it seems almost certain that whistleblowers will continue to file suits.
- Whistleblower firms will continue to devote resources to these types of cases as the potential paydays are very likely.
- Therefore, for many companies in regulated spaces, the question of whether the next *qui tam* will come is more a question of "when", rather than "if."

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Practical Proactive Compliance Strategies

- We describe some high-level suggestions for companies to turn potential government informants into proactive internal watchdogs.
- We emphasize that "no one size fits all" and that no strategy will deter all potential *qui tam* relators or government informants.
- Further, we note that many companies will likely already have many of these suggestions in place.

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General Compliance Strategy: Establish and Advertise Whistleblower Hotline Programs

- A whistleblower hotline is often a key component of an effective corporate compliance and ethics program.
- According to some research studies, in companies with an internal hotline, tips account for over half of all fraud detection. A best practice is to consider making the hotline anonymous as anonymity often generates more calls.
- Hotlines become stale, however. Therefore, the best proactive strategy is to make the hotlines fresh and meaningful.
- Make sure employees know about the hotline – emphasize it at meetings, in newsletters, on intranet sites, and anywhere else.

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General Compliance Strategy: Promote a Sense of Agency Throughout the Organization

- Employees generally tend to report concerns only when they feel a sense of agency—or, otherwise feel that their reported concerns are being addressed.
- This, of course, starts with the tone at the top. Make sure all individuals—from the top down—feel like their concerns are being heard and addressed, as appropriate.
- Consider ways to show that complaints are taken seriously—perhaps by addressing complaints at staff meetings or otherwise publicizing the work done to ameliorate employees' concerns.
- Consider ways to "close the feedback loop."

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General Compliance Strategy: Benchmark Your Compliance Program

- A best practice is to benchmark, or otherwise measure, the effectiveness of internal compliance systems.
- Companies should benchmark their compliance programs to internal (e.g., location, business units and departments) and external (e.g., peers and industry) data sources.
- Data benchmarking provides companies with comparative information to determine reporting patterns that are higher than, lower than or in line with peers and their industry.

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General Compliance Strategy: Follow-up With the Whistleblower

- When suspected unethical or unlawful activity is reported, no matter whether corroborated or otherwise, follow-up with the whistleblower.
- Many government whistleblowers first report the concerns internally and then only turn to the government after they feel that their concerns were not addressed.
- So, develop a system to close the feedback loop and keep the whistleblowers informed about their concerns.

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Once a Whistleblower Reports Problems

- No matter how good your proactive compliance program, the possibility of a whistleblower suit will linger.
- Most importantly, do not panic when receiving word of a whistleblower lawsuit. The number of suits and the intensity of scrutiny is increasing, so this should be somewhat expected. But, nonetheless, take the investigation seriously.
- We offer several practical suggestions should you receive notice of a whistleblower lawsuit

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After Receiving DOJ Subpoena

- First, you will likely learn of a suit via a DOJ subpoena.
- Carefully read the subpoena – understand what is being investigated and what is requested.
- Second, notify the proper officials in the company – in-house counsel, senior management, possibly the Board of Directors.
- Consider employing outside counsel proficient in dealing with the Department of Justice.

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After Counsel is Engaged

- Make sure to preserve all records.
- Instruct employees to maintain and not delete any responsive records.
- Consider, as necessary, halting any automatic deleting protocols.
- Identify relevant custodians and locations of responsive records

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Dealing with Suspected Whistleblowers

- Be cautious as anyone may have reported suspected "fraud" to the government.
- But don't over-react. You might not know exactly who or when someone reported "fraud" to the government.
- Most importantly, if you receive notice that you're possibly in the midst of a whistleblower lawsuit, do not retaliate against any suspected whistleblowers.

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