Something Old, Something New: Department of Justice Issues New Guidance on Qui Tam Lawsuits.

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I. Introduction

"Qui tam" lawsuits brought by whistleblowers to report and expose fraud against the government have ballooned in recent years, spurred by publicity about settlements in the billions and rewards in the millions. Trump Administration appointees at the Department of Justice, while assuring Congress of their continuing devotion to investigating and prosecuting meritorious whistleblower actions, have recently issued memoranda that could affect the growing volume of cases. The new guidance suggests that the DOJ will assume a more active role in discouraging and even dismissing lawsuits that prosecutors view as lacking factual support and/or solid legal grounding. This shift would have a significant impact both on whistleblowers (and lawyers who bring such cases) and on the large corporations which often are their targets.

II. A Brief History of the False Claims Act

The False Claims Act ("FCA") (31 U.S.C. §§ 3729-33) is a federal law which empowers private citizen whistleblowers (or corporate entities) to file civil lawsuits alleging that fraud has been committed, or is being committed, against the U.S. Government, or against a private entity (such as a government contractor) that causes the Government to lose taxpayer money. The statute, sometimes known as the "Lincoln Law," was originally enacted during the Civil War (and signed by President Lincoln) in the wake of widespread wrongdoing by vendors to the Union Army, most infamously, a maker of uniforms using cheap cloth which had the unfortunate characteristic of disintegrating in the rain. In 1986, again in response to allegations of fraud by military contractors (the fabled "$600 toilet seat") the FCA was amended to increase the monetary incentives for whistleblowers, who since then can reap up to 30% of any amount recovered or won by or for the Government in their lawsuits. During the past three decades, nearly half the States have also enacted analogous False Claims Act, which parallel the federal statute but apply to state and local funds.

Driven by these incentives, and by increasing judgment and settlement amounts, FCA suits, as well as recoveries, are on the rise. In fiscal year 2015, the Department of Justice ("DOJ") obtained $3.5 billion in settlements and judgments from civil cases involving fraud and false claims against the Government; the amount recovered in 2016 increased to $4.7 billion. FCA suits may arise from several types of conduct. In the health care industry, FCA

liability may arise from business practices involving marketing medical devices and drugs for uses not approved by the FDA, improperly inducing or rewarding providers for their prescriptions or orders for diagnostic tests or medical procedures, overbilling for healthcare products and services, and breaching regulations governing pharmaceutical companies' labeling, design, and drug manufacturing processes.

Essentially any healthcare activity that the government pays for – directly or indirectly -- can implicate the False Claims Act. Health care providers bill Medicare, Medicaid, and TRICARE (the military healthcare insurance program) under various Current Procedural Terminology ("CPT") codes for treatments rendered to patients. Thus, fraudulent billing practices such as "upcoding" (for example, seeing every patient for five minutes and then charging Medicare for "complex" office visits) or "unbundling" (separately charging a single medical procedure as different items and services), billing for services not rendered, or billing for services that are not considered medically necessary under Medicare or Medicaid, can all be prosecuted by whistleblowers and/or the Government as FCA violations.

In the context of government contracting, contractors (and their subcontractors) who submit fraudulent requests for payment based on costs that are inflated or otherwise ineligible for reimbursement are also subject to FCA claims. Fraudulent activity can include falsifying documentation to show that all materials, or the finished product, meet contract specifications when in fact such materials or products are nonconforming. Even in an era of deregulation, federal agencies continue to view the FCA as an important enforcement tool. For example, the Pentagon recently enacted regulations requiring government contractors to comply with cybersecurity protocols.[1] Non-compliance with the government's cyber-protocols can also expose government contractors to FCA claims.

In *Universal Health v. United States ex rel. Escobar*[2], the Supreme Court endorsed the "implied certification" theory of liability, *i.e.*, that whenever a claim for payment is submitted to the government, the claimant impliedly represents that it is in compliance with relevant laws and regulations. This opened the door to liability for violations of a myriad of regulations under the theory that the defendant implicitly certified its compliance with regulations in connection to all claims submitted. Thus, a claimant is liable under the FCA where two conditions are met: (i) the claim for payment makes specific representations about the goods or services provided, and (ii) the party failed to

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[1] See Defense Federal Acquisition Regulation Supplement ("DFARS") Rule on Network Penetration and Contracting for Cloud Services.

[2] 136 S. Ct. 1989 (2016)

disclose noncompliance with material regulatory or contractual requirements. The Court further explained that "materiality" in this context means a misrepresentation or omission that would have actually affected the government's payment decision, not just whether it could have done so. This more stringent definition of materiality has enabled defendants to escape liability if they can show that the government agency receiving the claim (and approving the payment) had actual knowledge that the claimant was aware of the misrepresentation or omission, and paid anyway.

Businesses under government investigation or involved in litigation for FCA violations face not only major defense expenses, but potentially severe financial liabilities: the statute imposes treble damages (three times what the violation cost the government) plus a per-claim fine up to almost $22,000. Particularly in healthcare, which may involve the submission of thousands or even millions of individual claims (as may be the case with pharmaceuticals, medical devices, major health networks, and other regional or nationwide businesses), the potential liability would essentially be a corporate death sentence. Therefore, it is crucial for executives, in-house counsel, and outside law firms to identify issues of potential liability before they give rise to an FCA action, and if they do, to fully comprehend the scope and substance of particular cases so to try to manage and defend them effectively.

III. FCA/Qui-tam Basics

The FCA authorizes both the Attorney General and private persons, known as "relators" rather than plaintiffs, to bring civil suits on behalf of the federal government.[3] When a relator files suit and thus notifies the government of fraudulent conduct, and provides all material evidence as the FCA requires, the government must investigate, after which it may either intervene and essentially take over the action or decline intervention. If the government declines to intervene, the relator may pursue the government's claims independently, though the government monitors the litigation and receives any recovery. The government must also approve any settlement. To incentivize relators to bring *qui tam* actions on behalf of the government, the FCA rewards relators with a percentage of the government's recoveries. The relator will earn 15% - 25% of recovered damages where the government intervenes and 25% - 30% of recovered damages where the government does not intervene. Besides that reward, a successful relator (which includes one who obtains a favorable settlement) can also recover reasonable attorney's fees, costs and expenses from the defendant.

[3] 31 U.S.C. § 3730(a), (b).

By statute, the *qui tam* lawsuit is filed under seal, which seal lasts for a minimum 60-day period during which the government is supposed to investigate and decide whether to intervene.[4] The seal provision is intended to give the government the opportunity to investigate without the defendant even knowing about the lawsuit (something that corporate defense lawyers have long objected to on fairness grounds). The court's sealing order keeps the lawsuit secret from anyone except the court itself, the government, the relator and relator's counsel, and effectively makes it unlawful for anyone to reveal the existence of the case. In reality, nearly every investigation and intervention decision takes longer than 60 days, and in some cases, the process can last years. During the investigation, the government must ask the court for additional seal extensions, and is expected to update the court with the progress and anticipated length of the investigation.

After the investigation ends, the government makes a decision whether to intervene and essentially take over the case. If the government elects to intervene, the matter is unsealed and the litigation commences, with the government prosecuting the matter as plaintiff. If the government declines to intervene, the relator has the option to pursue the case independently (as long as he is represented by counsel; the statute does not permit relators to proceed *pro se*).

Here too, the reality of FCA cases is more complex than the statute's binary intervention and unsealing provisions would suggest. In cases where the government agrees with the relator's theory of liability, and its investigation corroborates the theory of liability, prosecutors will often obtain a "partial unsealing order" from the presiding judge permitting them to inform the defendant and its counsel of the lawsuit's existence. In most cases, corporate defendants will already have a good idea that they are targets of a *qui tam* action once they are subject to investigative methods such as the issuance of subpoenas or civil investigative demands, interviews of former and sometimes current employees, or if prosecutors fear the disappearance or destruction of evidence, execution of a search warrant.

IV. Recent DOJ Guidance and its Potential Effect on Qui Tam Litigation

Traditionally, defense counsel had limited means of obtaining an early dismissal of FCA actions being pursued by relators after government declination. FCA actions were disposed of at an early stage based on only the following grounds: (a) public disclosure bar[5]; (b) first-to-file bar[6]; (c) statute of

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[4] 31 U.S.C. § 3730(b)(2).
[5] 31 U.S.C. § 3730(e)(4)(A).
[6] 31 U.S.C. § 3730(b)(5).

limitations[7]; (d) failure to state a claim[8]; or (e) failure to plead fraud with particularity.[9] Recently, in *Universal Health v. United States ex rel. Escobar*[10], the Supreme Court endorsed the "implied certification" theory of liability, *i.e.*, that whenever a claim for payment is submitted to the government, the claimant impliedly represents that it is in compliance with all material laws and regulations. However, the Court explained that "materiality" means a misrepresentation or omission that would have actually affected the government's payment decision, not just whether it could have done so. This more stringent definition of materiality has enabled defendants to escape liability if they can show that the government agency receiving the claim (and approving the payment) had actual knowledge that the claimant was aware of the misrepresentation or omission, and paid anyway.

In January 2018, the DOJ issued two memoranda that provide FCA defendants with another avenue of limiting their liability or outright exculpating themselves in *qui tam* actions. The two memos focus on meritless *qui tam* actions being prosecuted by the relator after government declination, and the DOJ's reliance on a defendant's noncompliance with regulatory guidance issued by the agency responsible for promulgating the underlying regulation as conclusive evidence that the defendant violated the law.

The first memo, issued by Michael D. Granston, Director of the DOJ Civil Fraud Section, set out new policy concerning the government's authority to dismiss non-intervened FCA suits under 31 U.S.C 3730(c)(2)(A). This authority is very broad and undefined; the statute does not require the government to specify a reason for seeking dismissal, and implicitly places the burden on the relator to convince the judge that the case should not be dismissed. However, the DOJ has rarely exercised this authority, and, perhaps because the FCA authorizes the relator to pursue the suit on the government's behalf, and reserves the government's right to seek intervention at any time, it has tacitly supported such efforts, including filing *amicus*-type memoranda expressing the Government's position on certain legal theories.

The Granston Memo questions existing practice, stressing that the government expends significant resources in monitoring or participating in non-intervened cases.[11] The memo further notes that meritless or weak claims of liability often result in adverse court decisions (including at the appellate

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[7] 31 U.S.C. § 3731(b).
[8] FRCP 12(b)(6).
[9] FRCP 9(b).
[10] 136 S. Ct. 1989 (2016)
[11] Michael D. Granston, *Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A),* Jan. 10, 2018.

level) that hinder the government's ability to enforce the FCA. The revised policy requires line prosecutors to review declined cases and consider whether seeking dismissal would promote the following goals: (1) curbing meritless *qui tam* actions; (2) preventing parasitic or opportunistic *qui tam* actions; (3) preventing interference with agency policies and programs; (4) controlling litigation brought on behalf of the United States; (5) safeguarding classified information and national security interests; (6) preserving government resources; and (7) addressing egregious procedural errors.[12]

The second memo, issued by Associate Attorney General Rachel Brand, bars the government from introducing as evidence in its civil enforcement actions a company's failure to comply with an agency's guidance documents, including in FCA cases initiated by DOJ (*i.e.*, without a relator filing a *qui tam* lawsuit) or in *qui tams* where the government intervenes.[13] The Brand Memo reinforces the principle that executive-agency guidance documents are merely that – guidance -- and do not create additional legal obligations beyond the scope of enacted statutes or duly promulgated regulations. The Brand Memo abrogates the DOJ's longstanding practice of using evidence of noncompliance with agency guidance to prove civil claims against regulated businesses. One example which will doubtless have a significant impact on healthcare fraud cases is the frequently-cited advisory opinions of the Office of Inspector General of the Health and Human Services department on what free or discounted services or "things of value" given to prescribers constitute illegal kickbacks.

Although the new DOJ guidance has been welcomed by corporate counsel and the FCA defense bar, it remains to be seen how DOJ attorneys will interpret and implement Granston's recommendations and Brand's prohibitions. A probable practical outcome will be for defense counsel regularly to ask the government to request dismissal of *qui tam* lawsuits under the Granston criteria whenever DOJ declines intervention. Further, relators' counsel may be less eager to file *qui tams* when whistleblowers bring them evidence of corporate practices that are inconsistent with, or even contrary to, agency guidance such as OIG advisory opinions.

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[12] See *Id.*

[13] Memorandum for Heads of Civil Litigating Components, United States Attorneys: Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases," from Associate Attorney General Rachel Brand, January 25, 2018, https://www.justice.gov/file/1028756/download.