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DOJ's Use of the False Claims Act: A Critique

Gregory M. Luce

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Sheraton Raleigh Hotel
421 South Salisbury Street
Raleigh, NC 27601

Gregory M. Luce, Esq.
Skadden Arps Slate Meagher & Flom LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005 2111
202-371-7310
gregory.luce@skadden.com
THE FALSE CLAIMS ACT: REINING IN EXPANSIVE THEORIES OF LIABILITY
by Greg Luce

Topic: Recent court decisions demonstrate the judiciary's increasing unwillingness to accept novel and expansive theories of illegality as predicates to imposing False Claims Act ("FCA") liability; however, even as some of the more expansive theories of liability are summarily dispensed, congressional leaders seek to open a floodgate of qui tam suits through the introduction of the False Claims Correction Act.

• Narrowing the Field of Relators: The Supreme Court's Ban on "Claim Smuggling"
The FCA eliminates federal jurisdiction over an action predicated on publicly disclosed information "unless the action is brought by the Attorney General or the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A) (emphasis added). Qui tam relators seeking to expand the universe of claims eligible for federal court review often bundle allegations in a multi-claim complaint; however, in light of recent action by the Supreme Court relators must prepare for vigorous examination of the jurisdictional basis for each claim.

○ In Rockwell International Corp. v. United States, 549 U.S. 457 (2007), the Supreme Court examined whether the qui tam relator was an original source of the FCA claims asserted. The Court found § 3730(e)(4) requires relators to establish 'original source' status for each and every claim based, in whole or in part, on a public disclosure and that relators cannot bootstrap jurisdiction for one claim by establishing original source status for another, or as characterized by Justice Scalia "claim smuggle". Essentially, a relator's decision to join all claims in a single complaint will not rescue claims jurisdictionally barred under section (e)(4).

• Line of Sight Liability: Falsity without Intent "To Get" Government Funds
Individuals and entities that receive government funds in exchange for goods or services often employ a network of subcontractors and consultants as part of their normal business practices. Historically, false statements by third-parties could predicate a FCA action, provided the false statement was materially relied upon by a primary contractor in obtaining government funds, and despite the fact that the third-party might be unaware of the government's involvement. However, in a recent landmark decision the Supreme Court clarified the circumstances under which a subcontractor's false statements may give rise to potential FCA liability.

○ In Allison Engine v. United States, 128 S.Ct. 2123 (2008), the Court held that, even though FCA sections (a)(2) and (a)(3) do not facially require "pre-sentment" of a false claim to the government, it is insufficient to merely show that a government prime contractor used "government money" to pay the third-party subcontractor. Instead, plaintiff's must show the subcontractor's false statement was made in order "to get" a false claim "paid or approved by the Government."
Allison Engine raises significant questions surrounding FCA liability for health care providers reimbursed under state administered health programs, such as the Sole Community Provider program ("SCP"). Under the SCP, health care providers servicing rural and isolated communities receive supplemental payments from state administrators. The federal government helps shoulder costs associated with SCP programs by providing a portion of a state's SCP funding. Arguably, in the wake of Allison Engine, claims for SCP payments that would otherwise give rise to FCA liability would only do so if the claim was submitted with the intent "to get" federal funds, an evidentiary burden not easily overcome.

In United States v. McInteer, 345 F. Supp 2d 1302 (N.D. Al. 2004), the qui tam relator alleged that defendants failed to provide adequate patient care as required by federal law and that the submission of claims to the state Medicaid administrator amounted to a violation of the FCA. The court determined that the only directly defrauded entity was a grantee of federal funds, the Alabama Medicaid Agency, and that absent an allegation or suggestion of direct presentation of a false claim to a federal officer the complaint failed to establish subject matter jurisdiction.

Pleading with Particularity: The Who, What, When, Where and How of an Alleged Fraud: Qui tam relators are often disgruntled former employees with limited knowledge of health care's intricate reimbursement mechanisms. As a result, relators frequently file qui tam complaints lacking the specificity required to inform defendants of the facts surrounding an alleged FCA violation, instead making bare assertions of global fraudulent schemes allegedly assignable to all involved parties, no matter how attenuated their relationship to the falsity may be. Increasingly, courts are inclined to summarily dismiss these sweeping and inadequate complaints.

In United States ex rel. Isaacs v. Dr. Houshang Seradj, No. 00-CIV-317-W (W.D.Ok. January 30, 2008), relators alleged that numerous defendants individually and collectively engaged in a consistent pattern and practice of willfully submitting false and fraudulent claims for federal reimbursement. On defendants' motion to dismiss, the court analyzed whether the complaint stated with particularity the circumstances constituting the fraud, plainly setting forth the time, place and content of the false representation, the identity of the party making the false statements and the consequences emanating therefrom. The court concluded that "lumping" or grouping together business defendants (as both the relators and government had done) without regard to their corporate form, as well as generalized accusations of wrongdoing directed at defendants without distinguishing among and between them, would not suffice. The court found that a complaint failing to reasonably inform each defendant of the fraudulent activities in which it allegedly engaged can not stand. Consequently, the court granted defendant's Rule 9(b) motion to dismiss; ultimately, however, the court allowed modification of the complaint in order to permit identification of individuals alleged to have engaged in specific wrongful acts.
Continuing Viability of Expansive Predicate Theories of FCA Liability: Despite recent Supreme Court action, *qui tam* relators and the government continue to probe the fringes of the FCA, exploring the judiciary's inclination to entertain novel and innovative theories of liability.

The Anti-Kickback Statute and the FCA: The federal Anti-kickback statute (42 U.S.C. § 1320a-7b(b)) makes it a felony to knowingly and willfully solicit or receive remuneration "in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal healthcare program."

- In *United States ex rel. Rost v. Pfizer Inc.*, No. 03-11084-PBS (D. Mass., Boston Sept. 18, 2008), plaintiffs alleged Pfizer unlawfully engaged in marketing tactics (like the provision of financial incentives, direct payments, and travel boondoggles: otherwise known as "kickbacks") to promote the off-label use of Genotropin, thereby causing physicians to submit thousands of false claims for federal reimbursement. In denying defendant's motion to dismiss, the court acknowledged plaintiffs failed to identify with particularity the payment of any improper kickback, but instead determined that this evidentiary shortcoming was not case-dispositive and permitted discovery on the issue.

Outlier Payments – A recent trend in FCA prosecutions gaining traction in federal courts arises under the Outlier Payment provision of CMS's Prospective Payment System ("PPS"). Medicare's PPS does not reimburse hospitals for actual costs incurred, but rather pays a predetermined amount for each inpatient discharge based on the average cost of a patient's diagnosis, adjusted for various hospital specific factors such as geography. Outlier Payments are designed to compensate hospitals for patients whose inpatient stays are more costly than those of other patients with similar diagnoses, and that exceed a certain fixed threshold set by CMS. While no CMS regulation, nor any other federal law, appears to limit hospital charges, recent litigation indicates that, in practice, CMS believes hospitals must abide by an amorphous reasonableness standard and follow prevailing market charge levels. Violation of this standard has been pejoratively termed "turbo-charging." Where the government believes a hospital raised charges for the purpose of increasing its Outlier Payments, or "turbo-charged", it may attempt to hold the facility liable under the FCA.

- In *Boca Raton Comm. Hosp. Inc. v. Tenet Healthcare Corp.*, 502 F. Supp. 2d 1237 (S.D. Fla. 2007), plaintiffs alleged that by manipulating charges in order to increase its outlier payments, defendant caused CMS to reduce the outlier payments available to non-turbocharging hospitals. Ultimately granting defendant's motion for summary judgment due to plaintiff's lack of standing, the
court clearly expressed its distaste for such a practice, stating in dicta "The evidence in this case paints a clear picture of unmitigated corporate greed [and] shameless appetite for profit at the expense of a taxpayer supported medical system." Id at 1239.

Similarly, in Longmont United Hosp. v. St. Barnabas Corp., No. 07-cv-3236 (3d Cir. Jan. 5, 2009), following defendant's settlement with the DOJ of "turbo-charging" allegations, plaintiff asked the court to examine whether defendant's "turbo-charging" was the proximate cause of its decrease in Medicare reimbursements. Plaintiff theorized the "turbo-charging" scheme both increased the cost threshold necessary to qualify for Outlier Payments, and decreased the amount of any Outlier Payment actually remitted. The court found that, at best, plaintiff suffered harms indirectly related to defendant's alleged "turbo-charging" and that any impact on plaintiff hinged entirely upon CMS's administration of the Medicare reimbursement system.

The Physician Self-Referral ("Stark") Law and the FCA: The federal Physician Self-Referral Law (42 U.S.C. § 1395nn), commonly known as the Stark law, prohibits a physician from referring a Medicare patient for designated health services to any entity with which the physician or a member of his or her immediate family has a financial relationship.

In United States v. Carlisle, No. 07-4616 (3d Cir. Jan. 21, 2009) the court examined, inter alia, whether an exclusive service arrangement triggered the restrictions placed by the Stark law on the submission of claims for services rendered. Plaintiffs asserted that defendant's false certification of compliance with CMS's laws and regulations, including its certification of compliance with the Stark law, predicated multiple FCA violations. Reversing the lower court's dismissal of the action, the Third Circuit found defendant had in fact violated the Stark law and remanded the matter for a determination of whether defendant's actions arose to the 'knowing' submission of false claims for payment.

Off-Label Pharmaceutical Marketing – Part of the FDA's mission is to ensure that pharmaceuticals brought to market are safe and effective. While the FDA does not itself conduct clinical research, the New Drug Application ("NDA") and Investigational New Drug Application ("IND") processes are designed to ensure that a drug's indicated uses (that is, the uses approved by the FDA) are fit for medical utilization. Not infrequently, the active component in an FDA approved drug results in unintended or unforeseen medical effects. Where a physician prescribes a drug for a non-indicated use, in order to take advantage of a drug's unintended yet potentially beneficial effects, it is referred to as off-label prescribing. FDA regulations prohibit pharmaceutical companies from actively marketing a drug's off-label effects, and instead encourage drug companies to seek approval for new uses under its IND review process. Drug companies that intentionally disregard the FDA's ban on off-label marketing risk FCA liability by "causing" a provider's presentation of claims to CMS for the payment of pharmaceuticals prescribed for off-label uses.
In *United States v. Aventis Pharms., Inc.*, 512 F. Supp. 2d 1158 (N.D. Ill. 2007), plaintiffs alleged that defendant violated the FCA by promoting and marketing off-label uses of Lovenox, which in turn caused healthcare providers to present false claims to the government. Accepting relators theory of liability, the court found that they had drawn a reasonable inference that claims for reimbursement regarding off-label uses were submitted to the federal government and denied defendant’s motion to dismiss.

**Technical and Inadvertent Administrative Violations:** To succeed on an FCA claim, a *qui tam* relator or the government must demonstrate that an alleged claim or statement is false or fraudulent. In making this determination most courts requiring a showing of "materiality:" that is, evidence that (1) the alleged false statement or claim was essential to the government's funding decision; (2) the government specifically relied on the falsity; and (3) the falsity caused the government to pay out sums it otherwise would not have paid. Despite this strict and unambiguous requirement, the Department of Justice has sought FCA liability for technical and immaterial noncompliance with administrative regulations.

In *United States ex rel. Conner v. Salina Regional Health Center, Inc.*, 543 F.3d 1211 (10th Cir. 2008), the Tenth Circuit recently rejected an FCA claim in which a relator alleged that a health center failed to comply with a variety of Medicare regulations, including quality of care standards, but nevertheless certified compliance with the laws and regulations regarding the provision of health care services in its annual cost reports. The court noted that the certification at issue "contains only general sweeping language and does not contain language stating that payment is conditioned on perfect compliance with any particular law or regulation." The Tenth Circuit also distinguished between conditions of program participation and conditions of payment in rejecting the "broader theory that a cost report certification could expressly condition all Medicare payments on compliance with a full host of technical Medicare requirements, including quality of care standards."

- **The False Claims Correction Act of 2007** (s. 2041): Senator Charles Grassley (R-IA) recently introduced a bill that, if adopted, would increase the viability of numerous whistleblower claims:
  - Proposed revisions in many cases would permit federal employees to bring *qui tam* actions and largely eliminate the FCA’s "original source" requirements:
  - "Retention of overpayments" – the retention of a known overpayment could serve as the basis for an FCA suit:
  - The FCA would no longer require a false claim to be presented to an officer or employee of the government, provided the money or property are spent on the government's behalf.
• **Magnitude of Recent Settlements:** Though not binding upon nonparties, settlement agreements are increasingly relied upon by the Department of Justice as a source of leverage in out-of-court negotiations, in effect creating a shadow-body of common law. The United States secured $1.34 billion in settlements and judgments in the fiscal year ending Sept. 30, 2008, pursuing allegations of fraud against the federal government. This brings total recoveries since 1986, when Congress substantially strengthened the FCA, to more than $21 billion. Although just underway, 2009 recoveries already exceed those of 2008.

  o **On January 26, 2009,** Pfizer, Inc. disclosed that it agreed to pay approximately $2.3 billion to settle a federal investigation into its alleged off-label marketing of Bextra, a prescription pain killer. If approved by the court, the settlement would mark largest entered into by a health care company, dwarfing Eli Lilly’s recent settlement for similar allegations.

  o **On January 15, 2009,** Eli Lilly and Company agreed to plead guilty and pay $1.415 billion for promoting its drug Zyprexa for uses not approved by the FDA. This resolution included a criminal fine of $515 million, the largest criminal fine to date levied against an individual corporation in a United States. Eli Lilly will also pay up to $800 million in a civil settlement with the federal government and the states.

  o **On November 25, 2008,** Bayer HealthCare LLC (Bayer) agreed to pay the United States $97.5 million plus interest to settle allegations that it paid kickbacks to a number of diabetic suppliers and caused those suppliers to submit false claims to Medicare. The settlement resolves allegations that Bayer engaged in a cash-for-patient scheme through which the company paid 11 diabetic suppliers to convert their patients to Bayer’s products from supplies manufactured by its competitors.