

FALSE CLAIMS ACT HALF YEAR IN REVIEW

A DAY ON HEALTH CARE LAW
PENNSYLVANIA BAR INSTITUTE
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1. Public Disclosure

United States ex rel. Rost v. Pfizer, 2006 WL 250145 (D. Mass. August 30, 2006).

Under the public disclosure bar of the FCA, no court shall have jurisdiction over an action that is based upon the public disclosure of the allegations in certain enumerated proceedings unless the relator is an original source of the information. 31 U.S.C. § 3730(e)(4)(A). In denying defendant's motion to dismiss on grounds of public disclosure, the district court in Rost addressed the important and still controversial issue of whether a voluntary disclosure to the government constitutes a public disclosure.

This matter involved allegations of off-label marketing by Pharmacia of the human growth hormone Genotropin. Relator, a Pharmacia vice president, claimed to have raised concerns about these marketing practices. When Pfizer acquired Pharmacia, it began its own investigation of the off-label marketing in response to relator's continued expressed concerns. Thereafter, Pfizer voluntarily disclosed the results of its investigation to the Food and Drug Administration, Department of Health and Human Services Office of Inspector General, and the U.S. Department of Justice. Thereafter, relator filed his qui tam action. Id. at *2-3.

Pfizer then moved to dismiss on the grounds that its voluntary disclosures constituted a "public disclosure" under the FCA. The court rejected this claim, reasoning that a disclosure to the government is not to the "public." Id. at *6. the court explained that "[t]he plain meaning and ordinary usage of the term "public" means the general public. The general public is an entity that is distinct, separate from, and independent of the government." Id. at *7. In so holding, the court parted ways with the opinion of the 7th Circuit in United States ex rel. Matthews v. Bank of Farmington, 166 F.3d 853 (7th Cir. 1999), but agreed with Judge Newcomer's opinion in United States ex rel. Brennan v. The Devereux Foundation, 2003 WL 151384 at *2 (E.D. Pa. 2003).

The court also addressed several other unsettled issues under the public disclosure bar. First, it ruled that "based upon" means "derived from" the public disclosure, rather than simply making allegations that are similar to those publicly disclosed. Id. at *8. As such the court adopted the minority view on this subject, a view rejected by the Third Circuit in United States ex rel. Mistick PBT v. Housing Authority of Pittsburg, 186 F.3d 376, 386-88 (3d Cir. 1999). Second, the court held that to qualify as an original source, the relator need not have been the source of the public disclosure nor have provided the government with his allegations prior to those allegations becoming public. Instead, the court found that the FCA requires only "that the Plaintiff disclose that information to the government before filing his action." Id. at * 11. This ruling of the Rost court is consistent with the Third Circuit. See United States ex rel. Stinson v. Prudential Ins. Co., 944 F.3d 1149, 1160 (3d Cir. 1990).

2. Relator's Objection to Settlement

- A. United States ex rel. Grober v. Summit Medical Group, Inc., 2006 WL 2037391 (W.D. Ky. July 18, 2006).

The court previously denied the relator's objection to the government's settlement of his false claims act claim and sent his claim for retaliation to arbitration, pursuant to the arbitration clause in the relator's employment contract. The terms of the agreement required the parties to split the cost of arbitration. As the arbitration drew near, the AAA sent the relator a bill for \$42,175, one half of the cost of arbitration incurred to date. The relator sought relief from the court, seeking to remove the action from arbitration or to excuse him from the obligation to pay one half of the cost. The court denied the requested relief, noting that the relator had done nothing to mitigate the cost of the arbitration (for example, agreeing to one arbitrator as opposed to three) and had not sought a fee reduction or waiver from the AAA.

- B. United States ex rel. Jiminez v. Dermatology Assocs. of San Antonio, No. SA 99-CA252-FB (W.D. Tx. Aug. 17, 2006).

The government proposed to settle the case for \$90,000. The relators objected and sought discovery in support of their objections. The court ordered the government and defendants to provide, "in camera, any and all information presently being withheld fro relators' counsel along with a summary of the government counsel's and defense counsel's analysis and reasoning as to why the information supports the proposed settlement and why the \$90,000 settlement is appropriate as compared with the relators' preliminary assessment of damages and penalties of \$5,000,000."

- C. United States ex rel. Nudelman v. International Rehabilitation Assocs., Inc., 2006 WL 925035 (E.D. Pa. April 4, 2006).

In this long and drawn out proceeding, the relator objected strenuously to the government's proposed settlement. The Court allowed a fairness hearing and received "voluminous submissions of the parties." In the end, the Court held that the settlement (enhanced by an amount allocated to future compliance obligations) was "fair, reasonable and adequate" and approved it over the relator's objections.

3. Alternate Remedies

- A. United States v. Lustman, 2006 WL 1207145 (S.D. Ill. May 4, 2006).

The defendant, the owner of a day care center, pleaded guilty to defrauding the Department of Agriculture out of \$25,000. Two relators sought to intervene in the criminal case to seek a portion of the \$25,000 restitution. The court denied the intervention, holding that the criminal prosecution was not an “alternate remedy” because the defendant had already paid restitution: “Simply put, there is nothing in which relators can participate.”

- B. United States ex rel. Hefner v. Hackensack Univ. Med. Ctr., 2006 WL 776795 (D.N.J. March 23, 2006)

In this non-intervened case, the court granted summary judgment in favor of Hackensack University Medical Center. Thereafter, the relator sought an order awarding him 25 to 30% of certain overcharges that Hackensack refunded to the government after the qui tam suit had been filed. Since plaintiff’s false claims act claims failed, there were no “proceeds” for the relator to share.

4. Totten Revisited

United States ex rel. DRC, Inc. v. Custer Battles, L.L.C., 2006 WL 2388790 (E.D. Va. Aug. 16, 2006)

The relators alleged that the defendants engaged in fraud with regard to several contracts for work in Iraq. After the Government declined to intervene, the district court dismissed some of the claims but allowed others to proceed. A trial was held concerning a \$3 million advance on the “ICE” contract and the jury returned a verdict for the plaintiffs, finding FCA single damages of \$3 million. The defendants then filed a Rule 50 motion for judgment as a matter of law. This decision grants the defendants’ motion, finding that the relators had not proven that any false claims were presented to the United States. The court begins its analysis by adopting the *Totten* holding that both 3729(a)(1) and (2) require presentment to the Government. The court says, “just as § 3729(a)(1) requires proof that false *claims* have been presented, or caused to be presented, to a United States government officer or employee working in his or her official capacity, § 3729(a)(2) also requires proof that any false *records* or *statements* were presented, or caused to be presented, to a United States government employee or officer working in their official capacity.” The court then notes that the contractor’s \$3 million request was submitted to the Coalition Provisional Authority (CPA). Although most CPA workers were employees of the U.S. government and the CPA was using Government funds (from various sources), the court holds

that the CPA was not an agency or instrumentality of the United States and U.S. employees of the CPA were not working in their official capacity as employees or officers of the United States government. Thus, claims submitted to the CPA did not satisfy the FCA's presentment requirement. The court then says that the relators did not prove that false statements to get the \$3 million advance were submitted to the United States by the CPA and so the FCA's presentment requirement never was met.

5. Corporate Versus Individual Privilege

United States ex rel. Magid v. Wilderman, 2006 WL 2346426 (E.D. Pa. Aug. 10, 2006)

In this, non-intervened case against an anesthesiology group, the relator sought production of documents that the group's former office manager claimed were privileged. The group agreed to waive any privilege and to produce the documents, but would not do so if the former office manager objected. The court rejects the office manager's claim that the communications were privileged as to her. Instead, the privilege belongs to the group and its waiver of the privilege compelled the production of the requested documents.

6. Counterclaims Against Relators

United States ex rel. McLean v. County of Santa Clara, 2006 WL 2067061 (N.D. Ca. July 25, 2006)

In this non-intervened case, the relator claimed that the Department of Children and Family Services of Santa Clara County, and several individuals related to the department, "invented fictional children for the purpose of over billing the state and federal governments." The relator had previously sued Santa Clara County three times in connection with the removal of the relator's children from her home. In 2004, the relator signed a Settlement Agreement with the County, including a broad release of "any and all claims," an agreement not to sue and an acknowledgement that the Settlement Agreement would act as a complete defense to any subsequent action arising from the subject matter of the Settlement Agreement. The County counterclaimed against the relator, alleging breach of the Settlement Agreement and fraudulent inducement to enter into the Settlement Agreement. The relator sought dismissal of the counterclaims under California's anti-SLAPP statute. The Court denied the motion and allowed the counterclaims to proceed, holding that while the relator was able to show that the counterclaims "arose from protected activity," the County was able to meet its burden of demonstrating a "probability of prevailing" on the counterclaims. In so doing, the court holds that the record was insufficient to determine whether, under prevailing Ninth Circuit precedent, an agreement to release qui tam claims is enforceable. Under existing precedent, a release

does not bar subsequent qui tam claims where the release was entered into without government knowledge or consent (United States ex rel. Green v. Northup Corp., 59 F.3d 953 (9th Cir. 1995)). Conversely, a release will bar a subsequent qui tam action where the government “had full knowledge of the plaintiff’s charges and had investigated them before [the parties] settled.” (United States ex el. Hall v. Teledyne Wah Chang Albany, 104 F.3d 230 (9th Cir. 1997)).

7. Touhy Discovery Issues

United States ex rel. Pogue v. Diabetes Treatment Centers of America, 2006 WL 1515914 (D.D.C. June 2, 2006)

Ruling on discovery disputes, the court holds that the Government is not a real party in interest in a declined qui tam action and that it is not a “person” so it is not subject to a Rule 45 subpoena. To obtain discovery, a defendant must comply with the agency’s Touhy regulations and seek review through the Administrative Procedure Act if not satisfied with the Government’s response. The court also refuses to compel the relator to respond to the defendant’s interrogatories because they are compound.

8. Best Price Theory of Liability

State of Nevada ex rel. Steinke v. Merck & Co., Inc., 2006 WL 1506901 (D. Nev. May 31, 2006)

Merck moved to dismiss this action filed under Nevada’s False Claims Act alleging that Merck failed to include certain discounted and free Zocor and Vioxx products in the “Best Price” reports Merck submitted to the federal government pursuant to the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8. Relying on the Medicaid Rebate Statute and Rebate Agreement Merck argued that it did not have to list any prices that were less than ten percent of the Average Manufacturer’s Price as these are “nominal prices” excluded from the reporting requirements. In this decision the Court recognizes that the Rebate Statute defines best price as excluding “prices that are merely nominal” but concludes that the phrase “merely nominal” means “without other qualifications”. Therefore, since Merck sold products at nominal prices in contracts that also required additional valuable considerations and conditions precedent these prices were not without qualification. The court rejects Merck’s argument and denies the motion to dismiss.

9. False Certification

- A. United States ex rel. Hendow v. University of Phoenix, 2006 WL 2571136 (9th Cir. Sept. 5, 2006).

In *Hendow*, the 9th Circuit also addressed the false certification theory of liability under the FCA. The University of Phoenix allegedly paid incentive compensation to student recruiters in violation of federal regulations governing financial aid grant money. The University successfully moved to dismiss in the district court, claiming that a failure to follow regulations did not make an FCA case. The 9th Circuit reversed, ruling that the defendant had expressly certified to compliance with regulations that prohibited incentive compensation. *Id.* at * 9. In addressing the element of materiality, the court finds that regulations that are a condition of “participation” in a federal program are the equivalent of those that are a condition of “payment.” This is because if one cannot participate then one cannot get paid. *Id.* In so doing, however, the court distinguishes the condition of participation versus payment distinction drawn by the 2nd Circuit in *Mikes v. Straus*, 274 F.3d 687, 701 (2d Cir. 2001) on the grounds that Mikes reasoning was confined to Medicare. *Id.* at * 11.

- B. United States ex rel. Fry v. Guidant Corp., 2006 WL 2633740 (M.D. Tenn. Sept. 13, 2006)

The defendant allegedly concealed from its hospital customers the existence of warranty rebates and upgrade credits for the medical devices it supplied to them. Nevertheless, it used such cost savings to persuade the treating physicians to order those devices. As a result, the hospitals purchased the devices but failed to take advantage of the rebates and credits, which ultimately resulted in the government paying more for those devices. *Id.* at *1-5. In denying the defendant’s motion to dismiss, the court holds that the concealment essentially caused the hospital to fail to follow the Medicare Intermediary Manual requiring that rebates and credits be reflected on the hospitals’ cost reports. This, in turn, resulted in the hospitals falsely certifying, albeit unwittingly, to compliance with applicable regulations. The court holds that this “could demonstrate that the claims at issue were false or fraudulent.” *Id.* at * 11. Guidant then could be found liable for the hospitals unknowing false certifications “if it can be shown that [Guidant] caused the hospitals’ failure to comply with those regulations by concealing the existence of warranty credits.” *Id.* at *12. In addressing this question of causation, the court relies in part on the reasoning of the 3d Circuit in *United States ex rel. Schmidt v. Zimmer*, 386 F.3d 235, 243-45 (3d Cir. 2004).

- C. United States v. Chapman University, 2006 WL 1562231 (C.D.Cal. May 23, 3006)

Relators alleged that the defendant falsely certified that applicants for therapist licenses had fulfilled the state law requirements for minimum hours of class room instruction and supervised clinical work. Id. at 1. Relator's false certification theory was based on five categories of allegedly false representations to government authorities about defendant's compliance with state law. Id. at * 4. The court grants defendant's motion to dismiss in part and denied it in part. Essentially the allegations survived for those representations that were sufficiently alleged to have been tied to a claim to the government for payment, but dismissed for those that were not. Id. at * 4-10.

10. Fraud In Inducement

United States ex rel. Hendow v. University of Phoenix, 2006 WL 2571136 (8th Cir. Sept. 5, 2006).

In Hendow, the 9th Circuit adopts the "promissory fraud" or "fraud-in-the -inducement" theory of United States ex rel. Main v. Oakland City Univ., 426 F.2d 914 (7th Cir. 2005), cert. denied, 126 S.Ct. 1786 (2006). Under that theory, any claim caused to be submitted to the government based a promise that one intends not to keep when made is a false claim for purposes of the FCA. Mere breaches after the fact, however, are insufficient to establish scienter. Rather, the promise must be false when made. Id. at *7. As such, the court rules, the elements of promissory fraud are the same as for the false claims act generally: (1) a claim that is false; (2) scienter through falsity that is knowingly perpetrated; (3) the underlying fraud is material to the government's decision to pay; and (4) there must be a claim. Id.

11. Notable Settlements

1. Schering Plough

On August 29, 2006, Schering Plough Corporation together with its subsidiary Schering Sales Corporation settled both criminal charges and civil liabilities in connection with illegal sales and marketing programs for its cancer drugs Temodar and Intron A. the settlement also addressed fraud against the Medicaid program involving Schering's drugs Claritin Reditabs and K-Dur. The settlement includes a plea of guilty to one count of conspiracy to commit fraud with the payment of \$180,000,000 criminal fine and \$255,000,000 payment to resolve the civil liabilities.

2. Serono

In October 2005, Swiss biotech company Serono agreed to pay \$704 million to settle criminal and civil claims that it improperly marketed Serostim, a human growth hormone used by AIDS patients to combat wasting. According to the charges, Serono provided computer software to physicians that led them to falsely diagnose AIDS wasting, paid kickbacks to physicians and pharmacies to prescribe Serostim, and marketed the product for off-label uses. The four relators were awarded \$51 million.

3. St. Barnabas Health Care System and Tenet Healthcare Corporation

In June 2006, the government announced that St. Barnabas Corporation and Tenet Healthcare Corporation has agreed to pay \$265 million and \$900 million respectively to settle allegations that hospitals in each chain improperly inflated the costs that they reported to Medicare, so as to receive additional money called “outlier payments.” A New York Times article reports that these settlements are “part of a wave of Medicare fraud investigations that, according to a federal report, have reached more than 450 hospitals nationwide.”