Qui Tam Defense

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Mintz Levin Health Care *Qui Tam* Update

Recent Developments & Unsealed False Claims Act (FCA) Cases

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Trends & Analysis

- We have identified 58 health care–related *qui tam* cases that have been unsealed since our last *Qui Tam Update*. Of those, 33 cases were initiated after the start of 2012, with the remaining 25 cases filed in 2011 and before; the earliest of these cases began as far back as 2006.
- These cases were filed in 25 states. Several cases were filed in historically active jurisdictions for FCA cases, including the Eastern District of Pennsylvania, the Eastern District of New York, the District of New Jersey, and the District of Massachusetts.
- The government declined to intervene in 32 cases (55%), and at least six of the declined cases were voluntarily dismissed by the relator. The government intervened in 17 cases (some for the purpose of settlement, and three were dismissed with prejudice when the government intervened in connection with the settlement). In the remaining cases, the government's intervention decision was not clear from the case docket.
- Subject matter of claims:
    - 25 of the recently unsealed cases involved both state and federal claims.
    - 8 of the unsealed cases were filed against pharmaceutical companies.
    - 2 cases were filed against laboratory companies.
    - 3 of the cases alleged claims against diagnostic imaging companies.
    - 26 cases asserted claims against various providers, including physical therapists, hospitals, dermatologists, and hospice providers.
    - 5 of the recently unsealed cases were filed against pharmacies.
- Identity of relators:
    - Almost 75% of the relators in these 58 cases were employees or former employees of the defendants.
    - Several other relators were either employed by or affiliated with a competitor of the defendant.

Featured Case

***United States ex rel. John Rector v. Bon Secours Richmond Health Corp.*, No. 3:11cv00038JRS (E.D. Va.)**

Complaint Filed: January 18, 2011

Complaint Unsealed: April 19, 2013

Current Status: The court granted the defendants' motion to dismiss the relator's Second Amended Complaint under Fed. R. Civ. P. 9(b) and granted leave to amend the complaint.

Intervention Status: The United States and the Commonwealth of Virginia declined to intervene.

Name of Relator: John Rector

Defendant's Business: Bon Secours Health System, Inc. ("Bon Secours") is a nonprofit health system, which owns, manages, or has established joint ventures with acute care hospitals, a psychiatric hospital, nursing care facilities, assisted living facilities, and home care and hospice services. In the Second Amended Complaint, the relator named seven entities that are affiliated with, or are subsidiaries of, Bon Secours.

Relator's Relationship to Defendant: Temporary employee. Defendant Bon Secours Richmond Health System hired the relator through a temporary employment agency to work as a part-time patient-physician practice liaison (called a "concierge").

Relator's Counsel: Durrette Bradshaw, PLC and Stone & Magnanini, LLP

Claims: Relator alleged seven causes of action arising out of the defendants' "concierge" program: (1) presentation of a false claim (31 U.S.C. § 3729(a)(1)(A)); (2) making or using a false record or statement to cause a claim to be paid (31 U.S.C. § 3729(a)(1)(B)); (3) making or using a false record or statement material to an obligation to pay or transmit money to the government, commonly referred to as a "reverse false claim" (31 U.S.C. § 3729(a)(1)(G)); (4) conspiracy (31 U.S.C. § 3729(a)(1)(C)); (5) retaliation (31 U.S.C. § 3730(h)); (6) violations of the Anti-Kickback Statute (42 U.S.C. § 1320a-7b) and Physician Self-Referral Law, called the "Stark Law" (42 U.S.C. § 1395nn); and (7) violations of the Virginia Fraud Against Taxpayers Act.

Through the concierge program, Bon Secours, and its subsidiaries and related entities, allegedly performed work generally done by physicians' offices by scheduling patients, obtaining insurance pre-authorizations, communicating with the patients, and collecting patient co-payments and deductibles. The relator also alleged that concierges coded procedures for patients referred to Bon Secours facilities by using "cheat sheets," and they steered patients toward tests or procedures that would be reimbursed by payors and away from those that may not.

Reasons to Watch: While not a new case, this recent decision is a significant development concerning the application of Fed. R. Civ. P. 9(b) in FCA cases. The court dismissed the relator's claims because Fourth Circuit precedent holds that Rule 9(b), which states that allegations of fraud must be pleaded with particularity, requires the relator to identify specific false claims to plead an actionable violation of the False Claims Act. The court's analysis and dismissal of the relator's complaint demonstrate Rule 9(b)'s important gatekeeping function for FCA claims.

As described in Mintz Levin's November 2013 *Qui Tam Update*, federal circuit courts of appeal are split over Rule 9(b)'s requirements to plead FCA claims. Some courts have held that a complaint under the False Claims Act must allege with particularity that specific false claims *actually* were presented to the government for payment; others have applied a more relaxed standard and relators can allege the particular details of a scheme to submit false claims, supporting an inference that false claims were submitted. The applicable pleading standard is important because it dictates the specificity required for pleadings to survive a motion to dismiss and proceed to discovery. Despite the circuit split, however, the United States Supreme Court recently denied a petition for a *writ of certiorari* to review Rule 9(b)'s pleading requirement in the context of the FCA and resolve the circuit split.

In the Fourth Circuit, relators must allege with "some indicia of reliability . . . that an actual false claim was submitted to the government." United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 457 (4th Cir. 2013) ("*Nathan*"). As the Fourth Circuit held in *Nathan*, when a defendant's actions "*could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment." *Id*.

Applying the *Nathan* standard, the district court in the *Bon Secours* case granted the defendants' motion to dismiss the relator's claims because "[n]othing in the record indicates that any of the Named Defendants necessarily submitted false claims to the Government." Memorandum Opinion, at p.14. Instead of identifying any specific claims, the relator based his allegations of false claims on a patient log that he created while he worked as a concierge. The log, according to the relator, showed that the defendants submitted or caused others to submit false claims because some of the patients on the log were covered by Medicare, Medicaid, or TriCare. The court found that the relator's log did not satisfy Rule 9(b)'s pleading standard, concluding that the relator "cannot plausibly claim that the [defendants] themselves *actually* submitted false claims." *Id*. (emphasis in original).

Recently Unsealed Cases

***United States ex rel. Beth Gorawksi v. Berchtold Corp.,* No. 2:11-cv-2601-RMG (D.S.C.)**

Complaint Filed: September 27, 2011 (First Amended Complaint filed May 22, 2012; Second Amended Complaint

filed March 24, 2014)

Complaint Unsealed: February 11, 2014

Intervention Status: The United States intervened on December 24, 2013 for the purpose of settlement.

Claims: Relator brought claims against Berchtold Corporation ("Berchtold"), and eight of its principals, executives, and employees, alleging the defendants violated five sections of the FCA: 31 U.S.C. § 3729(a)(1)(A) (false claims); 31 U.S.C. § 3729(a)(1)(B) (false statements); 31 U.S.C. § 3729(a)(1)(G) ("reverse" false claim through failure to return an overpayment); and 31 U.S.C. § 3729(a)(1)(C) (conspiracy); 31 U.S.C. § 3730(h) (retaliation). Relator also asserted related common law and employment claims.

Name of Relator: Beth Gorawksi

Defendants' Business: Berchtold manufactures, markets, and services surgical equipment, including operating tables, lights and cameras, and operating room booms.

Relator's Relationship to Defendants: Relator is a former employee of Berchtold.

Relator's Counsel: John Whitney Sowards; Joseph P. Griffith, Jr.

Summary of Case: The relator alleged ongoing fraudulent conduct by the defendants relating to sales of surgical tables and related equipment to military hospitals, despite her repeated inquiries and warnings regarding the impropriety of certain actions. Relator, a government contracts agent for Berchtold, claimed that defendant Michael Ward — a Berchtold salesman who ultimately pled guilty to criminal charges relating to the case — and other Berchtold employees overcharged the government possibly more than $1 million for surgical equipment. She alleged the defendants lied about whether certain supplies were included on the Federal Supply Schedule and overstated the "Best Pricing" available, even submitting fraudulent invoices to avoid true price detection. Relator also alleged the defendants falsified product numbers to avoid detection, and padded their bills by charging for phantom equipment.

Current Status: The United States settled the FCA claims (aside from the retaliation claim) with Berchtold for $3.6 Million, and all claims against the individual defendants were dismissed. Relator received over $867,000 from the settlement, and the trial for her FCA retaliation claim and common law employment claims against Berchtold is scheduled for September 2014.

Reason to Note: The case is yet another example of civil and criminal resolution of conduct brought to the government's attention through a *qui tam* complaint, which the government verified through an investigation. The relator provided multiple emails about the overcharges to the government, including emails between Ward and contracting agents about concealing the government pricing lists and falsifying product lists and invoices. In one email to executives, Ward allegedly boasted that he gained Berchtold "$1.2 Million in pure profit" selling surgical tables to Brooke Army Medical Center in Texas at "$12,000 per unit above GSA [government contracted] pricing," and he highlighted a $17,000 line item he added to the invoice for a standard component on those tables, purportedly telling the executives to "enjoy the $522,000 in gravy." Ward no longer works for Berchtold (which was recently purchased by Stryker Corporation, a medical technology company), and he ultimately pled guilty to a federal criminal charge of Making and Using a False Document for allegedly providing a false invoice for a sale of equipment to Kaiser Hospital showing inflated prices.

This case highlights the need for a robust corporate compliance program to respond to complaints about conduct when they arise and the potential costs associated with failing to follow applicable rules and regulations when doing business with government agencies.

***United States ex rel. Ryan v. Endo Pharms Inc.,* No. 05-cv-3450 (E.D. Pa.); *United States ex rel. Weathersby v. Endo Pharms. Inc.,* No. 10-cv-2039 (E.D. Pa.); *United States ex rel. Dhillon v. Endo Pharms.,* No. 11-cv-7767 (E.D. Pa.)**

Complaints Filed: *Ryan* (July 5, 2005); *Weathersby* (May 4, 2010); *Dhillon* (December 21, 2011)

Complaint Unsealed: Unknown

Intervention Status: Intervened

Claims: Among other things, the U.S. government alleged that Endo Pharmaceuticals Inc. violated 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1) (criminal misbranding of a drug label for not bearing "adequate directions for use"). In addition, the U.S. government and three relators brought civil claims against Endo Pharmaceuticals Inc. and its subsidiary Endo Health Solutions Inc. (and relator Weathersby also included an individual, James Hailey, as a defendant), alleging that the defendants violated the False Claims Act, 31 U.S.C. §§3729-3733 — including,

specifically, 31 U.S.C. §§ 3729(a)(1)-(3) (false claims, false statements, and conspiracy), 31 U.S.C. § 3729(a)(7) ("reverse" false claims through failure to return an overpayment), and 31 U.S.C. § 3730(h) (retaliation). In addition, the relators and the government alleged violations of the false claims act statutes of 26 states and the District of Columbia.

Names of Relators: Peggy Ryan; Max Weathersby; Dr. Gursheel Dhillon

Defendant's Business: Pharmaceutical manufacturer

Relators' Relationships to Defendants: Ryan and Weathersby are former Endo sales representatives; Dhillon is a physician (who was unaffiliated with Endo).

Relator's Counsel: Counsel for Ryan – James Hoyer Law Firm; Counsel for Weathersby – Blank Rome LLP; Counsel for Dhillon – None (Pro Se)

Summary of Case: Relators, the U.S. government, and state governments alleged that, between 2002 and 2006, Endo Pharmaceuticals Inc. marketed its drug Lidoderm for off-label uses. During those years, the FDA only approved Lidoderm for the relief of pain associated with post-herpetic neuralgia ("PHN"), a complication of shingles. The government alleged that Endo misbranded Lidoderm because its labeling lacked adequate directions for use in the treatment of non-PHN related pain. In addition, the government alleged that Endo sales managers both instructed certain sales representatives to expand sales conversations with doctors beyond PHN and encouraged the promotion of Lidoderm in workers' compensation clinics.

Whistleblowers and the government also alleged that, from 1999 through 2007, Endo caused false claims to be submitted to federal health care programs, including Medicaid, by promoting Lidoderm for unapproved uses.

Current Status: Endo Health Solutions Inc. and its subsidiary Endo Pharmaceuticals Inc. agreed to pay $192.7 million to resolve criminal and civil liability arising from Endo's marketing of the prescription drug Lidoderm for uses not approved by the FDA. The resolution included a deferred prosecution agreement ("DPA"), forfeiture totaling $20.8 million, and civil false claims settlements with the federal government, the states, and the District of Columbia totaling $171.9 million. Endo Pharmaceuticals further agreed to implement and maintain a number of enhanced compliance measures, including making publicly available the results of certain clinical trials and requiring an annual review and certification of its compliance efforts by the CEO of its parent company, Endo Health Solutions. In addition, as part of the settlement, Endo agreed to enter into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General that requires Endo to implement measures designed to avoid or promptly detect conduct similar to that which gave rise to this resolution (similar to the enhanced compliance measures required under the DPA).

Reasons to Watch: Although the size of Endo's settlement is significantly smaller than other recent settlements for off-label marketing (e.g., a 2012 settlement with GlaxoSmithKline for $3 billion and a 2013 settlement with Johnson & Johnson for $2.2 billion), Endo is a much smaller company than the other pharmaceutical company defendants and the allegations against Endo only involved one drug. Of greater significance is the fact that the Endo case involved multiple federal prosecutors' offices working together and dividing responsibilities — the U.S. Attorney's Office for the Eastern District of Pennsylvania handled the civil investigation and the U.S. Attorney's Office for the Northern District of New York handled the criminal investigation. This kind of cooperation is increasingly common among health care fraud enforcement agencies and indicates that the government continues to be willing to dedicate resources across offices and jurisdictions to investigate and prosecute off-label marketing. In addition, the government used its asset forfeiture authority to place a hold on, and ultimately seize, a $10 million wire transfer to Endo, which the government alleged constituted the proceeds of Endo's off-label marketing. The government has a powerful arsenal of weapons available to exert pressure on companies under investigation for criminal conduct, and the Endo case demonstrates the government's willingness to use every tool at its disposal.

***United States ex rel. Stephens v. Malik,* No. 2:12-cv-00306-WCL-PRC (N. Ind.)**

Complaint Filed: August 1, 2012

Complaint Unsealed: March 25, 2014

Intervention Status: The United States intervened in part on March 24, 2014.

Claims: Referring patients to an agency in which the referring physician, Dr. Arshad Malik ("Dr. Malik") had a direct financial interest, which allegedly violated the Stark Law and the AKS and, in turn, the FCA. In addition, the defendants allegedly submitted fraudulent Medicare claims that were falsely inflated (or "upcoded") for home health services that did not otherwise qualify as a covered service under the applicable Medicare rules. These practices constituted violations of 31 U.S.C. §§ 3729(a)(1)(A) (false claims) & 3729(a)(1)(G) ("reverse" false claims through

failure to return an overpayment).

Relator additionally alleged unjust enrichment and payment by mistake.

Name of Relator: Bradley Stephens

Defendant's Business: Prime Health Care Services, Inc. ("Prime Care") is a home health care agency. Dr. Malik refers patients to Prime Care.

Relator's Relationship to Defendant: Former employee of a competing provider.

Relator's Counsel: Holt, Fleck & Romine, LLP

Summary of Case: Relator, in connection with his employment at a home health care agency, met with Dr. Malik about a referral for speech therapy services that had been made to the relator's employer. During that meeting, Dr. Malik purportedly refused to sign a referral form, stating instead that the patient would be receiving services from Dr. Malik's own agency. Relator was later informed that Dr. Malik would in fact sign off on the referral, and when the relator went to retrieve the signed form, he contends that he "noticed an absurdly large number of referral documents to Prime Care and no other." When he commented on this, the relator was told that Dr. Malik sent all his patients to Prime Care because he and his brother owned it. Based on this interaction, the relator began his own research and investigation by asking health care professionals and patients about their knowledge of Dr. Malik and his agency. Relator alleged that Dr. Malik had either a direct or indirect ownership interest in Prime Care based on Dr. Malik's familial relationship with both Prime Care's principal and the principal's wife. Relator further alleged that Dr. Malik refers "all or nearly all of his patients to Prime Care for services."

In addition, the relator alleged the defendants documented or created a continued need for home health services, even if none actually existed.

Current Status: On March 24, 2014, the United States elected to intervene in part, and its Notice of Election to Intervene in Part and Decline in Part indicates its intent "to proceed with the Stark issues in this action." The case is currently pending.

Reasons to Watch: The case illustrates the risks companies face from potential relators who have had only the slightest interaction with the company. Quite apart from internal company practices that may attract the attention of would-be whistleblowing employees, companies should also be aware that their conduct is being examined by other professionals with whom they interact. Even if such interaction is brief and isolated, a single encounter may be enough to encourage a potential whistleblower outside the company to begin his or her own investigation. In addition, the evident interest of the United States specifically in the Stark issues in the case is noteworthy in that it appears the United States may be paying more attention to Stark liability in the FCA context.

For more information, including details relating to the above cases, please contact **Hope S. Foster** at **202.661.8758** or HSFoster@mintz.com.

About Our Health Care Enforcement Defense Practice

Mintz Levin's Health Care Enforcement Defense Practice is comprised of health law, employment, and white collar defense attorneys with experience in government investigations and health care regulatory compliance matters. We regularly help clients conduct internal investigations designed to detect and correct problems before the government becomes involved. We have represented clients in federal and state government investigations and litigation across the country in matters initiated by the Criminal and Civil Divisions at the Department of Justice, United States Attorneys, the Office of Inspector General for the Department of Health and Human Services, the Drug Enforcement Administration, State Attorneys General, Medicare and Medicaid contractors, and the 50 Medicaid Fraud Control Units. We have helped clients avoid potentially ruinous civil fines, incarceration, other criminal and administrative penalties, and exclusion by combining our regulatory knowledge with our investigative, employment-related and litigation capabilities.

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