Published on *The National Law Review* https://natlawreview.com

Qui Tam Update: Recent Developments & Unsealed Cases November 2013

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Trends and Analysis

- We have identified 32 health care-related *qui tam* cases unsealed since last month's *Qui Tam Update*. Of those, only four were filed in 2013. The majority (23 cases) were filed in 2012, with the remainder dating back as far as March 2009.
- These 32 cases were filed in 18 states and the District of Columbia. Several cases were filed in historically active jurisdictions for False Claims Act cases, including the Eastern District of Pennsylvania, the District of Massachusetts, and the Southern and Eastern Districts of New York.
- The government declined to intervene in about 60% of the cases in which the unsealed filings included the government's decision on intervention. The four cases profiled in this month's *Qui Tam Update* are all cases in which the government has not intervened.
- Subject matter of claims:
  - Half of the recently unsealed cases involved both state and federal claims.
  - Fourteen of the 32 recently unsealed cases included claims for relief under state or federal anti-whistleblower retaliation provisions.
  - Seven of the 32 reviewed cases (approximately 22%) alleged claims against skilled nursing facilities ("SNFs"), rehabilitation facilities, or entities delivering physical and occupational therapy services.
- Identity of relators:
  - More than 70% of the relators were employees or former employees of the defendants in these 32 cases.

    - One nonemployee relator worked for a third-party pharmacy benefit auditing company. The relator alleged that she discovered during her audit of the defendant pharmacy that a number of prescriptions were billed to Medicare but were never provided to patients and never left the pharmacy. *See United States ex rel. Hayes v. Family Choice Pharmacy, Inc. et al.*, No. 1:13-cv-05441 (S.D.N.Y.).

Featured Case

Qui tam cases occasionally make it to the Supreme Court, but one now under consideration for certiorari could have momentous impacts on which cases can move beyond the pleading stage.

Petition for Writ of Certiorari, *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc. et al.,* Docket No. 12-1349 (U.S. 2013)

Opinions below: *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.,* 2011 U.S. Dist. LEXIS 62755,*aff'd*, 707 F.3d 451 (4th Cir. 2013)

Complaint filed: September 14, 2009

Complaint unsealed: December 17, 2010

Current status: Petition for Writ of Certiorari filed May 10, 2013 from the decision of the Fourth Circuit concluding that 1) the relator did not plausibly allege in his complaint before the District Court that false claims had been presented to the government for payment or that Takeda had caused the presentment of any such false claims, and 2) the District Court did not abuse its discretion in denying the relator's request for leave to file a fourth amended complaint

Intervention status: The 22 individual states, the District of Columbia, and the United States filed notices of nonintervention or declination between April 6, 2009 and December 13, 2013. The United States also elected not to file a brief when the case was appealed to the Fourth Circuit.

Name of relator: Noah Nathan

Defendant's business: Pharmaceutical manufacturer

Relator's relationship to defendant: Employee. When the relator filed the complaint, he was a senior specialty sales representative; he had also been a sales representative at TAP Pharmaceuticals before it was succeeded by Takeda.

Relator's counsel: Originally DiMuro Ginsburg, PC and Bell & Bell LLP; currently MoloLamken LLP

Reasons to watch: The petition for certiorari requests that the high court resolve a circuit split regarding the degree of particularity with which a relator must plead a violation of the Civil False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*, posing the issue as follows:

> Whether Rule 9(b) of the Federal Rules of Civil Procedure requires that a complaint under the False Claims Act "allege with particularity that specific false claims actually were presented to the government for payment," as required by the Fourth, Sixth, Eighth, and Eleventh Circuits, or whether it is instead sufficient to allege the "particular details of" the "scheme to submit

> false claims” together with sufficient indicia that false claims were submitted, as held by the First, Fifth, Seventh, and Ninth Circuits.

This single sentence summarizes the circuit conflict concerning the standards employed by federal courts to allow FCA cases to proceed to discovery. The cost, burden and expense of the review and production of large volumes of documents as well as associated discovery disputes, even where such discovery ultimately reveals no actual fraud, can be substantial to potential defendants. Thus, Rule 9(b) serves an important “gatekeeping” function intended to ensure that only viable claims are permitted to reach discovery. The more flexible standard used in the First, Fifth, Seventh, and Ninth Circuits benefits relators who may lack claims-specific information about a defendant’s purportedly illegal conduct, whereas the stricter 9(b) standard used in the other circuits provides more protection to defendants.

The case against Takeda on its face involves allegations common in FCA suits against pharmaceutical companies: impermissible off-label sales and marketing practices in violation of the Food, Drug, and Cosmetic Act (FDCA), purportedly resulting in improper prescriptions of a drug billed to federal health care programs. Regardless, the issue presented in the relator’s petition may potentially spark a battle royal that will have far-reaching impact on the relator’s bar. Perhaps in acknowledgement of these potential impacts, the Supreme Court has invited the Solicitor General to submit its own brief to express the views of the United States on this issue.

One can only speculate which side of the debate the Solicitor General will take, if any. However, given that (i) since fiscal year 2007 it has taken the United States on average approximately 13 months to issue intervention decisions,[1] (ii) approximately 53% more *qui tam* cases were filed in FY 2012 than in FY 2007,[2] and (iii) the intervention rate has remained relatively constant over that period,[3] it is possible that the United States may seize this opportunity to support the use of Rule 9(b) to reduce the number of cases in the pipeline. On the other hand, the government reported earlier this year that its return on investment (“ROI”) “for every dollar spent on health care-related fraud and abuse investigations in the last three years was $7.90.”[4] Thus, the government may fear that narrowing Rule 9(b) will cut into their ROI for fraud-fighting efforts because it will have to meet those stricter pleading standards. Additionally, the relators’ bar has now been putting more of its resources toward pursuing declined cases without the government’s help, and winning. If the Supreme Court imposes even stricter pleading requirements, Rule 9(b) may prevent more of those declined cases from moving forward.

Recently Unsealed Cases

***United States ex rel. Fox Rx, Inc. v. Walgreen Company*, No. 1:12-cv-07382 (S.D.N.Y.)**

Complaint filed: Not shown on docket

Complaint unsealed: Oct 1, 2013

Intervention status: Declined on an undisclosed date

Claims: False certification of compliance with state laws governing the dispensing of generic drugs and prohibiting the dispensing of expired drugs, which resulted in the defendant overcharging the

Medicare Part D program and Medicaid programs in violation of the FCA, as well as the analogous laws of 26 states and the District of Columbia

Name of relator: Fox Rx, Inc., the parent corporation of Fox Insurance, Inc. Fox Insurance, Inc. was a Medicare Part D plan sponsor between 2006 and 2010.

Defendant's business: National retail pharmacy chain that provides prescription drugs to patients that are reimbursable under state and federal health care programs, including Medicaid and Medicare Part D

Relator's relationship to defendant: Fox Insurance, Inc. processed and paid prescription drug claims submitted to the Medicare Part D program by the Walgreen Company.

Relator's counsel: Millberg LLP (New York)

Summary of case: The relator alleges that the defendant overcharged its subsidiary insurance company, other Medicare Part D plan sponsors, and state Medicaid programs for prescription drug claims dispensed to beneficiaries because it failed to substitute generic drugs for brand-name drugs in states that require such substitution and submitted claims for drugs that were expired in violation of state and federal laws.

Current Status: Pending

Reasons to watch: The basis of many FCA allegations is that a defendant falsely certified (either expressly or impliedly) to compliance with a law when such compliance was a precondition of a valid claim for submission to the government. Cases involving false certifications of compliance with the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and the Stark Law, 42 U.S.C. § 1395nn, are common in the health care arena.[5]However, this *qui tam* not only relies on compliance with federal law as a basis for the certifications at issue, but also uses *state* laws as the basis for the false claims allegations at the federal and state levels. Of note, the relator did not allege that the pharmacy dispensed generic drugs and charged the Medicare Part D program for brand-name drugs.

***United States ex rel. Dolan v. Arlington Rehabilitation & Living Center et al.*, No. 1:10-cv-00368 (N.D. Ill.)**

Complaint filed: January 19, 2010

Complaint unsealed: September 12, 2013

Intervention status: Both the United States and the State of North Carolina declined to intervene. The State of Illinois apparently has not yet made a decision as to intervention.

Claims: Rendering nonvalue services, prescribing medically unnecessary services, upcoding, and submitting false cost reports in violation of the FCA as well as analogous false claims laws of Illinois and North Carolina

Name of relator: Raymond Dolan

Defendants' businesses: The corporate defendants include skilled nursing facilities, supportive living centers and a contract therapy provider.

Relator's relationship to defendants: The relator is a registered professional nurse whom Arlington Rehabilitation and Living Center formerly employed as a Corporate Nurse before his termination in July 2007.

Relator's counsel: Clifford Law Offices P.C. (Illinois)

Summary of case: The relator alleges that a family-owned health care business engaged in a scheme by which the skilled nursing facilities ("SNFs") and supportive living centers it owned and managed were required to use a family-owned contract therapy provider for therapy services. Together, the family-owned businesses allegedly colluded to provide medically unnecessary services (at times by unlicensed staff) and to fabricate clinical data, time spent with patients, and level of care provided. The contract therapy provider allegedly sent therapists into facilities without doctors' orders, as required, where the therapists formulated plans of care without consulting contemporaneously with a medical doctor. The relator also contends that the required doctors' signatures were obtained after the fact and the patients' records were then backdated. The relator further alleges that the facilities perpetuated a pattern of medically unnecessary physical therapy, occupational therapy, and speech-language pathology services by paying hundreds of thousands of dollars in kickbacks via medical director contracts, bonuses based on Medicare reimbursements, and flat monthly fees.

Current status: The case is currently pending, with a scheduling conference set for December 11.

Reasons to watch: Although the federal government has declined to intervene, this case illustrates that SNFs continue to be attractive targets for would-be whistleblowers. Because most patients in SNFs are beneficiaries of either Medicare or Medicaid, the majority of services rendered are potentially subject to a false claims action. The Department of Justice has shown continued interest in false claims cases involving SNFs and has recently reiterated its intent "to hold skilled nursing facilities accountable for the rehabilitation therapy services they deliver to some of the most vulnerable in our society," and for "the provision of excessive and medically unnecessary therapy services."[6] Perhaps in response to this enforcement posture, many plaintiffs' firms openly advertise that they are looking for employees of SNFs with any information concerning false claims submitted to federal health care programs. In light of this environment, SNFs should expect continued government scrutiny for the foreseeable future.

***United States ex rel. Beaujon v. Plaza Health Network*, No. 1:12-cv-20951 (S.D. Fla.)**

Complaint filed: March 7, 2012

Complaint unsealed: October 11, 2013

Intervention status: The United States filed its notice of nonintervention on October 16, 2013.

Claims: Retaliation under 31 U.S.C. § 3730(h), violations of the AKS and Stark Law, billing for medically unnecessary services and services not rendered, billing for upcoded services, improper billing for services performed by nonphysicians or for individual rather than group/concurrent therapy, and submission of false records in violation of the FCA

Name of relator: Stephen M. Beaujon

Defendants' businesses: The Plaza Health Network (also known as Hebrew Homes) is a nonprofit network of nursing homes and rehabilitation facilities. The relator also filed suit against the corporate entities that operate and manage the facilities and the president of the Plaza Health Network in his individual capacity.

Relator's relationship to defendants: The relator is a certified public accountant ("CPA") who has served as the defendant's Chief Financial Officer since 2002. As of the date of filing the complaint, the relator was still employed by the defendant.

Relator's counsel: Morgan Verkamp, LLP (Ohio) and O'Quinn Stumphauser, P.L. (Florida)

Summary of case: The relator alleges that the defendant engaged in multiple schemes that led to the submission of false claims to federal health care programs. For instance, the defendant allegedly caused its skilled nursing facilities ("SNFs") to enter into sham medical directorship agreements with physicians in violation of the AKS and the Stark Law in exchange for their referral of patients to the facilities. The compensation paid to these medical directors allegedly exceeded fair market value in violation of the statute. Additionally, the relator alleges that the defendants, in violation of Medicare payment rules applicable to skilled therapy services at SNFs, billed for services rendered by unskilled staff and misrepresented the severity of the SNF patients' conditions to allow billing at a higher Resource Utilization Group ("RUG") category for reimbursement. The defendant also allegedly falsified therapy logs, resulting in the provision of medically unnecessary services, billing for services not rendered, and billing for individual therapy when each patient actually participated in group or concurrent therapy. Last, the relator contends that the defendant levied adverse actions against him as a result of his repeated efforts to address these allegedly unlawful practices.

Current status: The case is currently pending.

Reasons to watch: The Southern District of Florida has long been recognized as a hotbed of health care enforcement activity, particularly with regard to SNFs. Despite the government's decision to not intervene in the action at this time, the progress and locale of the case reveals some interesting procedural aspects unique to the FCA. Specifically, a close examination of the docket reveals that the judge repeatedly denied extensions of time for the government to make a decision regarding intervention. An order dated October 2, 2013, states "this is the United States' fourth request for extension over a period of nineteen months." This case illustrates increasing concern[7] by some judges about repeated routine requests by the government for extensions of time to enable it to continue investigating the defendant under seal without informing the defendant of the pending adverse claims. Additionally, the relator's occupation (he is a CPA) may signal an emerging trend of whistleblowers who are auditors and other professionals with financial accounting expertise, a development that we have noted in past *Qui Tam Update*s.[8]

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[1] Letter from Jim Esqua, Assistant Secretary of the U.S. Department of Health and Human Services and Ronald Weich, Assistant Attorney General at the U.S. Department of Justice to Senator Charles E. Grassley, (Jan. 24, 2011), at 14, available

at http://www.taf.org/DOJ-HHS-joint-letter-to-Grassley.pdf.

[2] Civil Division, U.S. Department of Justice, "Fraud Statistics – Overview" (Oct. 24, 2012) at 8, available athttp://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf.

[3] See fn. 1 at 14-15. The Department of Justice reported that it had intervened in an average of 22.2% of *qui tams* filed, but this statistic does not describe how many cases filed within a particular year result in the government deciding to intervene in the matter.

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[4] Press Release, Departments of Justice and Health and Human Services Announce Record-breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud, (Feb. 11, 2013) available athttp://www.hhs.gov/news/press/2013pres/02/20130211a.html. Some organizations estimate the ROI to be even higher. *See e.g.,* Taxpayers Against Fraud, "Fighting Healthcare Fraud Using Whistleblower Statute Returns $20 For Every $1 Invested," (Oct. 2013) available at http://www.taf.org/publications/reports/fighting-healthcare-fraud-using-whistleblower-statute-returns-20-every-1.

[5] For a past advisory that explains certification theories underlying FCA cases, see Thomas S. Crane and Brian P. Dunphy, "Will the Supreme Court Weigh In? Implied Certification Theory Under the False Claims Act," (Oct. 7, 2011) available athttp://www.mintz.com/newsletter/2011/Advisories/1428-1011-NAT-HCED/web.htm.

[6] Department of Justice, "Northern Virginia Therapy Provider to Pay $700,000 to Resolve False Claims Act Allegations, (Feb. 13, 2013) available at http://www.justice.gov/opa/pr/2013/February/13-civ-193.html.

[7] Sheri Qualters, "Cases deluge Boston court," National Law Journal (Aug. 1, 2011) available athttp://www.law.com/jsp/nlj/PubArticleNLJ.jsp?id=1202509061967&slreturn=20131027223158 (subscription required); Ellyn Sternfield and Stephanie Willis, "Qui Tam 'Seal' Windows Shrinking?" (Aug. 22, 2011) available athttp://www.healthlawpolicymatters.com/2011/08/22/breaking-the-%E2%80%9Cseal%E2%80%9D-and-making-the-government-decide-to-intervene-in-false-claims-act-cases/.

[8] Kevin McGinty, Samantha Kingsbury, and Stephanie Willis, "Mintz Levin Health Care *Qui Tam Update*: Recent Developments & Unsealed Cases," (Aug. 2013) available at http://www.mintz.com/newsletter/2013/Newsletters/3157-0613-NAT-LIT/index.html; Kevin McGinty, Brian P, Dunphy, and Samantha Kingsbury, "Mintz Levin Health Care *Qui Tam Update*: Recent Developments & Unsealed Cases," (Oct. 2013) available at http://www.mintz.com/newsletter/2013/Newsletters/3502-1013-NAT-LIT/index.html.

National Law Review, Volume III, Number 339

Source URL:https://natlawreview.com/article/qui-tam-update-recent-developments-unsealed-cases-

november-2013