UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel. WILLIAM VERRINDER, Plaintiff, v. WAL-MART CORPORATION, et al. Defendants.	Civil Action No. 13-11147-PBS

MEMORANDUM AND ORDER

June 21, 2016

Saris, C.J.

INTRODUCTION

Relator William Verrinder, a pharmacist, alleges that pharmacies operated by Wal-Mart Stores Incorporated (Wal-Mart), Kmart Corporation (Kmart),[1] and Rite Aid Corporation (Rite Aid) violated the False Claims Act, 31 U.S.C. § 3729 et seq. (FCA) by selling prescription drugs labeled with incorrect expiration dates and then billing the government for expired drugs. Relator, who worked at all three pharmacies,[2] contends that the

[1] Kmart is a wholly-owned subsidiary of Sears Holding Company.
[2] Relator worked as a pharmacist at Wal-Mart from November 2008 to January 2012 and at Kmart from March 2012 to January 2013.

defendants submitted various false claims to Medicare or Medicaid: (1) claims for prescriptions that will expire before the dates printed on the prescription vial label and before the patient can consume the medication as directed by his doctor, (2) claims for dispensing fees that inflated the number of unexpired doses dispensed, and (3) claims (by Kmart only) for the reimbursement of generic drugs using a false national drug code number for more expensive drugs.

The relator filed his first complaint on April 8, 2013, and an amended complaint on August 6, 2013, in the District of Maine. The case was then transferred to this district on May 9, 2013. On March 7, 2014, the Government declined to intervene. On October 12, 2015, the defendants moved to dismiss for failure to satisfy Federal Rules of Civil Procedure 9(b) and 12(b)(6). After hearing, the Court **ALLOWS** the motions by Rite Aid and Wal-Mart (Docket Nos. 61 and 63), and the motion by Kmart (Docket No. 59) with respect to the allegations of false claims for expired drugs. The Court will dismiss the claim against Kmart with respect to the alleged false billing of generic drugs in North Carolina unless the relator's complaint is amended to comply with Rule 9(b) within 30 days of this order.

Relator does not indicate that he ever worked at Rite Aid, but Rite Aid alleges the relator worked for the company from October 2004 to March 2006. See Docket No. 62 at 7. At hearing, the relator did not dispute this.

FACTUAL BACKGROUND

With all reasonable inferences drawn in the relator's favor, the amended complaint alleges the following facts with respect to each defendant.

I. Wal-Mart

Wal-Mart fills approximately 500 million prescriptions annually, 150 million of which are submitted to Medicare Part D and Medicaid. On average "about 15%" of the manufacturers' stock bottles of prescription medications expire in less than one year. Docket No. 20, Compl. ¶ 12. Wal-Mart's claim submission software, Connexus, automatically affixes a one-year expiration date to each prescription's label. Connexus also automatically submits claims for reimbursement to Medicare and Medicaid for refills while automatically assigning a one-year expiration date from the date prescriptions are refilled. The software automatically assigns a one-year expiration date even for "compounds that typically expire in a few days to weeks." Id. ¶ 14. Pharmacists sometimes change these dates "when necessary," but Wal-Mart may also submit claims for refills "without any human being checking the validity of the expiration date." Id.

Automatically generating a one-year expiration date expedites the prescription-filling process; pharmacists do not need to review the date listed on the stock bottles first. And time is of the essence at Wal-Mart: the company times each step

of the filling process and "reprimand[s] pharmacy technicians or pharmacists who take too long to complete any of the steps." Id. Pharmacists are allocated just over 60 seconds to complete all tasks related to a single prescription.

Wal-Mart removes stock bottles that are set to expire within three months, minimizing the risk that expired medications are dispensed. Wal-Mart pharmacies also return unused drugs, even before they are on the verge of expiration, based on data gathered from non-usage reports.

Relator identifies seven individuals involved in this allegedly fraudulent scheme: three executives who approved the process and four pharmacists who have filled prescriptions with incorrect expiration dates and then submitted claims to Medicare and Medicaid with these false dates.

II. Rite Aid

When Rite Aid fills a prescription, it uses proprietary software to automatically enter a one-year expiration date on all prescriptions. Rite Aid pharmacists then submit claims to Medicare and Medicaid with this one-year expiration date. Rite-Aid pharmacies have drugs on their shelves that expire in as little as 30 days. Relator estimates that "about 15%" of stock bottles on Rite Aid's shelves at any given moment expire in less than one year. Id. ¶ 32. Rite Aid does not require pharmacists to remove "sufficiently beforehand" medications that will soon

expire from its pharmacies' shelves, though Rite Aid does at some point send drugs back to its reverse distributor. Id. ¶ 33.

III. Kmart

Kmart automatically assigns a one-year expiration date to prescriptions. However, it does not automatically submit claims to Medicare and Medicaid with this default date. Kmart pharmacists submit Medicare and Medicaid claims knowing "that Kmart pharmacies have drugs that expire in as little as 30 days" and that "about 15%" of stock bottles expire in less than one year. Id. ¶ 26.

Kmart removes and sends to a reverse distributor drugs that expire at the end of any given month. For example, during January, the pharmacy returns drugs that will expire on January 31. As to all three defendants, the relator asserts that one could use the records of the individual drugs sent back by each company and the date the drugs expired to "determine the date the prescription was filled, compare expiration dates and whether Medicare or Medicaid paid for that prescription" to ascertain if each defendant submitted false claims. Id. ¶ 31.

DISCUSSION

I. False Claims Act

The FCA, 31 U.S.C. § 3729 et seq., establishes a scheme that permits either the Attorney General or a private party to initiate a civil action alleging fraud on the government. See 31

U.S.C. § 3730(a), (b). A private enforcement action under the FCA is a qui tam action and the private party is referred to as the relator. See United States ex rel. Eisenstein v. City of New York, 556 U.S. 928, 932 (2009). Even if the relator has not been personally injured by the defendant's action, the relator possesses standing because he sues as a partial assignee of the United States' claims against the defendant. See Vt. Agency of Nat. Res. v. United States ex rel. Stevens, 529 U.S. 765, 773 (2000). Even if the United States declines to intervene (as here), the relator retains "the right to conduct the action." 31 U.S.C. § 3730(c)(3). However, the government remains the "real party in interest" in a qui tam prosecution. Eisenstein, 556 U.S. at 934; see also United States ex rel. Karvelas v. Melrose–Wakefield Hosp., 360 F.3d 220, 231 (1st Cir. 2004).[3]

The FCA imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). A "claim" "includes direct requests to the Government for payment as well

[3] The First Circuit has recognized that Karvelas has been abrogated on other grounds by United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 46 n.7 (1st Cir. 2009). See Claudio-De Leon v. Sistema Universitario Ana G. Mendez, 775 F.3d 41, 49 (1st Cir. 2014). Karvelas remains good law for the propositions for which it is cited here, including the level of particularity required by Rule 9(b) in FCA cases. See, e.g., United States ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 123 (1st Cir. 2013).

as reimbursement requests made to the recipients of federal funds under federal benefits programs." Universal Health Servs., Inc. v. United States ex rel. Escobar, No. 15-7, slip op. at 3 (U.S. June 16, 2016) (citing 31 U.S.C. § 3729(b)(2)(A)). A person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" is also liable under the FCA. 31 U.S.C. § 3729(a)(1)(B). A person who "conspires to commit a violation of" the preceding subsections is similarly liable. Id. § 3729(a)(1)(C).

Knowledge under the FCA is defined as "actual knowledge of the information" contained in the claim, or in "deliberate ignorance" or "reckless disregard" of the truth or falsity of that information. Id. § 3729(b). The statute does not require proof of "specific intent to defraud," that is, intent to present false or fraudulent claims to the government. Karvelas, 360 F.3d at 225. "Individuals who violate the FCA are liable for civil penalties and double or treble damages plus the costs incurred in bringing the FCA lawsuit." Id.

II. Rule 9(b)

"False Claims Act plaintiffs must . . . plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b)." Escobar, No. 15-7, slip op. at 16 n.6. "[S]uch pleadings invariably are inadequate unless they are linked to allegations, stated with particularity, of the actual

false claims submitted to the government that constitute the essential element of an FCA qui tam action." Karvelas, 360 F.3d at 232. The heightened pleading standard of Rule 9(b) "means that a relator must provide details that identify particular false claims for payment that were submitted to the government." Id. The plaintiff must, at a minimum, "specify the who, what, where, and when of the allegedly false or fraudulent representation." Alt. Sys. Concepts, Inc. v. Synopsys, Inc., 374 F.3d 23, 29 (1st Cir. 2004). Conclusory allegations are not sufficient to satisfy Rule 9(b). United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 731 (1st Cir. 2007), overruling in part recognized by United States ex rel. Wilson v. Bristol-Myers Squibb, Inc., 750 F.3d 111, 113-14 (1st Cir. 2014). A "qui tam relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery." Karvelas, 360 F.3d at 231. Rule 9(b) prevents relators "from filing allegations of fraud merely in the hopes of conducting embarrassing discovery and forcing settlement." Rost, 507 F.3d at 733.

The First Circuit has explained Rule 9(b)'s heightened pleading standard:

> [D]etails concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals

> involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in a complaint. However, we believe that some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).

United States ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 123 (1st Cir. 2013) (quoting Karvelas, 360 F.3d at 233) (alterations and internal quotation marks omitted). Actual documentation is not required at the motion to dismiss stage, but a relator is "required to describe with particularity some of the documents containing false claims for payment that the defendants allegedly submitted to the United States." Karvelas, 360 F.3d at 230 n.11. Rule 9(b) applies to all three of the FCA's core provisions. Karvelas, 360 F.3d at 227-28 (subsection (a)(1)(A)); Rost, 507 F.3d at 731 (subsection (a)(1)(B)); Gagne, 565 F.3d at 45 (subsection (a)(1)(C)).

Where "it is alleged that the defendant caused a third party to submit a claim to the government, then the First Circuit applies a somewhat more flexible standard." United States ex rel. Garcia v. Novartis Pharm. Corp., No. 15-1470, 2016 WL 3361591, at *6 (1st Cir. June 17, 2016) (emphasis in original) (internal quotation marks omitted). Archetypes of the category of inducement cases justifying a relaxed standard—where

the information regarding specific false claims may be peculiarly within the perpetrator's knowledge—include allegations based on kickbacks and off-label promotion. See United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 29-30 (1st Cir. 2009) (illegal kickbacks); Rost, 507 F.3d at 732 (off-label promotion).

In such cases, a plaintiff may be able to satisfy Rule 9(b) by alleging "factual or statistical evidence to strengthen the inference of fraud beyond possibility" as to the existence of false claims. Duxbury, 579 F.3d at 29-30 (quoting Rost, 507 F.3d at 733); see also United States ex rel. Nargol v. Depuy Orthopaedics, Inc., No. CV 12-10896-FDS, 2016 WL 407064, at *19 (D. Mass. Feb. 2, 2016) ("[A] qui tam complaint alleging that a defendant induced a third party to submit false claims to the government for reimbursement must allege two things to satisfy Rule 9(b): (1) particular details of a scheme to cause the submission of false claims to the government; and (2) factual or statistical evidence that strengthens the inference of fraud on the government beyond a mere possibility.").

Under the relaxed standard, a relator may not have to identify specific claims, but he must "allege 'the time, place, and content of an alleged false representation.'" Duxbury, 579 F.3d at 30 (quoting Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996)). "Merely alleging that a scheme was wide-

ranging—and, therefore, that a fraudulent claim was presumably submitted—will not suffice." Garcia, 2016 WL 3361591, at *6. The methodology by which a fraud claim may have been made is also insufficient. See Walsh v. Eastman Kodak, 98 F. Supp. 2d 141, 147 (D. Mass. 2000).

III. Allegations Regarding False Expiration Dates

Relator alleges that each defendant submitted false claims and made false statements in violation of § 3729(a)(1)(A) and § 3729(a)(1)(B). Relator also alleges that Wal-Mart and Kmart conspired with their employees to submit false claims in violation of § 3729(a)(1)(C). Specifically, the relator alleges that the defendants were required to submit prescription expiration dates to Medicare and Medicaid, and submitted claims with false expiration dates. In his amended complaint, the relator alleged that "Medicare and Medicaid require pharmacies to submit expiration dates for claims to be paid: no expiration date equals no paid claim." Docket No. 20, Compl. ¶ 11. After the defendants asserted in their motions to dismiss that the pharmacies do not submit expiration dates to Medicare and Medicaid, see, e.g., Docket No. 62 at 16 n.5, the relator backtracked and alleged that pharmacies are "required to submit data regarding the number of days supply they have provided to the patient." Docket No. 93 at 2. According to the relator, a "drug dispensed with a false expiration date causes a false

certification of ‘days supply’ because the drug will not be safe and effective for the full number of days it is dispensed for.” Id. at 4.

Whether the allegation is that the false information in the claim is the false expiration date or the days supply, this allegation is insufficient under Rule 9(b). “In the context of a defendant that submits claims directly to government programs . . . relators must provide details that identify particular false claims for payment that were actually submitted to the government.” Rost, 507 F.3d at 732. The relator does not identify a single false claim submitted by any of the three defendants. While the relator does allege that the prescription vials were mislabeled or misbranded because they contained a false expiration date, he does not plead one claim submitted to the government which billed for expired drugs or contained a false date in the claim itself. Because he was a pharmacist at each of these pharmacies, this knowledge was not peculiarly within the alleged perpetrators’ knowledge.

While it is possible that some of the prescription vials included expired drugs, the allegations would not even pass muster under a relaxed standard to support an “inference of fraud beyond possibility.” See id. at 733. Relator himself admits the defendants removed stock bottles from their shelves as their expiration dates neared, shipping the unused medicine

back to reverse distributors. Wal-Mart "requires pharmacy technicians and pharmacists to examine each and every" stock bottle "and remove from drug shelves all medications that expire" within three months. Docket No. 20, Compl. ¶ 19. Kmart "requires their pharmacy managers to return drugs that expire at the end of the month to a reverse distributor." Id. ¶ 30. Rite Aid also sends drugs that are about to expire to a reverse distributor. Id. ¶¶ 33-34. Relator's complaint is accordingly "somewhat self-denying" which "certainly does not assist the inference" that the defendants submitted false claims to Medicare and Medicaid. See United States ex rel. Booker v. Pfizer, Inc., 9 F. Supp. 3d 34, 57 (D. Mass. 2014).

IV. Allegations Regarding Dispensing Fees

Relator's allegations that the three defendants submitted false dispensing fees for reimbursement are similarly inadequate under Rule 9(b). Relator states that the three defendants seek reimbursement not only for the cost of the medications provided, but also for the costs incurred in filling the prescriptions. Relator asserts that these dispensing fees are greater for a 90-day prescription than for a 30-day prescription. According to the relator, when a pharmacy bills for the 90-day dispensing fee, the claim is sometimes false because the corresponding prescription may contain fewer than 90 unexpired doses.

Again, the relator offers no specifics about a single false claim involving an inaccurate dispensing fee. Instead, the relator repeats the following conclusory statement with respect to each of the three defendants:

> [Each company's] pharmacy technicians and pharmacists billed for the service of dispensing a 90 days supply of medication but constructively dispensed a smaller days supply of medication because the medication either expired before the expiration date on the prescription label or expired before the patient could use the medication according to his or her doctor's instructions.

Docket No. 20, Compl. ¶¶ 38, 42, 44, 46, 49, 52-53, 55, 60, 68, 71, 74, 77, 80, 83, 86. Other than repeating this allegation—word-for-word—sixteen times, the relator offers no additional detail to support his allegation that the three defendants falsely submitted claims to Medicare or Medicaid for dispensing fees to which they were not entitled. All allegations relating to false dispensing fees fail to satisfy Rule 9(b).

V. Allegations Regarding Submission of Claims for More Expensive Generic Drugs

Only one set of allegations remains: that Kmart submitted claims for reimbursement of various generic drugs using a false national drug code (NDC) number. According to the amended complaint, when dispensing a drug that has two NDC numbers, Kmart submits a false claim for the more expensive one, even though "most of the prescription, if not all of it in some cases, is filled with the cheaper drug." Id. ¶ 27. Relator

alleges that this occurs in at least two states. “In North Carolina, Lea Lilie demands that pharmacists mix expensive and cheap generics together with the expensive generic usually the one that was billed” to the government payers. Id. Relator then lists seven specific pharmacists involved in this scheme.

Kmart makes two arguments in response. First, Kmart “disputes that Relator has properly pled this allegation . . . because it is mentioned only in the factual allegations of his complaint; he does not raise any claim for relief on this basis.” Docket No. 60 at 16 n.6. Second, Kmart argues that the relator has not offered sufficient detail to find that this allegation raises a plausible FCA claim.

While none of the counts explicitly raise the practice of swapping out more expensive generic drugs for cheaper ones, and then billing for the more expensive version, the relator did address these issues in three paragraphs of his complaint. See Docket No. 20, Compl. ¶¶ 27-29. Furthermore, Kmart was aware of these allegations, devoting two pages in its motion to dismiss to respond to them. See Docket No. 60 at 15-17.

Relator has provided some details about this allegation against Kmart, indicating where this practice occurred, how the fraud was perpetrated, and who participated. However, he does not identify one false claim submitted to Medicare or Medicaid as a result of this scheme. Because the relator alleges that

Kmart directly submitted false claims to government payers—rather than inducing or causing a third party to submit claims to the government—the Duxbury standard does not apply here. See Garcia, 2016 WL 3361591, at *6.

To satisfy Rule 9(b), the relator—who worked as a pharmacist at Kmart for nearly one year—must plead the allegations against Kmart with particularity, providing, for example, details concerning the dates of the claims, the content of the bills submitted, the relevant NDC numbers, the amount of money charged to the government, the particular drugs for which the government was billed, and the individuals involved in the billing. See Ge, 737 F.3d at 123. The Court will dismiss the claim against Kmart unless it is amended within thirty days to comply with Rule 9(b).

ORDER

Defendant Wal-Mart's Motion to Dismiss (Docket No. 63) is **ALLOWED**. Defendant Rite Aid's Motion to Dismiss (Docket No. 61) is **ALLOWED**. Defendant Kmart's Motion to Dismiss (Docket No. 59) is **ALLOWED** in part. With respect to the generic drug allegations only, the Court allows the relator thirty days to amend his complaint to comply with Rule 9(b).

/s/ PATTI B. SARIS
Patti B. Saris
Chief United States District Judge