IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

UNITED STATES OF AMERICA *ex rel.* NOAH NATHAN, *et al.*,	)	
Plaintiffs/Relator,	)	Case No. 1:09-cv-1086 (AJT)
v.	)	
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

In this False Claims Act case, the plaintiff, relator Noah Nathan ("Relator" or plaintiff) alleges that defendants Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. (collectively "Takeda") engaged in a fraudulent marketing scheme that caused false claims to be filed with the United States, namely, requests for payment or reimbursement under the federal Medicare, Medicaid, TRICARE, CHAMPVA and Federal Employee Health Benefit programs, for "off-label" prescriptions of Takeda's drug Kapidex. By Order dated May 4, 2011, the Court dismissed Relator's Second Amended Complaint, with leave to amend, primarily on the grounds that Relator failed to plead facts with sufficient specificity to state a claim. On May 18, 2011, Relator filed a Third Amended Complaint; and on June 9, 2011, Takeda filed a Motion to Dismiss Relator's Third Amended Complaint [Doc. No. 76] (the "Motion") pursuant Fed. R. Civ. P. 12(b)(6) and Fed. R. Civ. P. 9(b).

Relator's Third Amended Complaint, like his Second Amended Complaint, fails to identify any specific false claims or any specific prescriptions, physicians, pharmacies, payments or reimbursements that caused such a false claim to be filed. *See* Relator's Opp., at 18 (acknowledging failure to plead that specific off-label prescriptions were submitted for

reimbursement by the government). Nevertheless, Relator opposes the Motion essentially on the grounds that he may satisfy the specificity requirements for fraud-based claims, such as those under the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "FCA"), by pleading statistics concerning the make-up of Kapidex sales, together with other allegations concerning Takeda's marketing campaign, the misrepresentations to prescribing physicians by Takeda sales representatives that were an integral part of that marketing strategy, the patient populations served by medical specialists to whom Takeda distributed sample 60 milligram dosages of Kapidex, and the medical conditions for which, and dosages at which, Kapidex is approved by the Food and Drug Administration (the "FDA"). Upon consideration of the Motion, the memoranda and exhibits in support thereof and in opposition thereto, and the arguments of counsel at a hearing on July 8, 2011, and for the reasons contained in this Memorandum Opinion, the Court finds that the Third Amended Complaint fails to state a claim on which relief may be granted and the Court will grant the Motion.

I. BACKGROUND

Although considerably more detailed, Relator's 126 page, 660 paragraph Third Amended Complaint, viewed in the light most favorable to Relator, is substantially the same in substance as Relator's Second Amended Complaint, which this Court dismissed by Order dated May 4, 2011. In sum, Relator contends that Takeda is illegally promoting Kapidex, a drug which is considered to be in the medical category of drugs known as proton pump inhibitors. Specifically, Relator alleges that Takeda has caused the filing of false claims, and made and used false statements that were material to false claims, by: (1) promoting Kapidex to rheumatologists, whose patients suffer from conditions for which Kapidex has not been approved for treatment; (2) misrepresenting, through its sales representatives, the nature and efficacy of Kapidex and how it compares with Takeda's Prevacid, a predecessor drug which had been approved for certain medical conditions for which Kapidex is not approved; and (3) exclusively

providing 60 milligram sample doses to gastroenterologists, rheumatologists, otolaryngologists and primary care physicians, despite the fact that the great majority of these doctors' patients have conditions for which there is no approved dosage of Kapidex or for which the only approved dosage of Kapidex is 30 milligrams. *See e.g.* 3d Am. Compl., ¶¶ 6, 129-222. As in the Second Amended Complaint, the Relator's Third Amended Complaint asserts claims pursuant to the FCA (Counts I & II), and various state statutes (Counts III through XXVIII). Relator seeks injunctive relief, treble damages, civil penalties, and attorney fees, costs and expenses.

II. ANALYSIS

A. Relevant Pleading Standard

Relator's Third Amended Complaint must satisfy both Fed. R. Civ. P. 12(b)(6) and 9(b). To satisfy Fed. R. Civ. P. 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do." *Iqbal*, 129 S. Ct. at 1949 (internal quotation marks omitted). Relator's FCA claim must also be pleaded with particularity pursuant to Rule 9(b). Rule 9(b) requires Relator to plead, with specificity, the "who, what, when, where, and how of the alleged fraud." *United States ex. rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) ("an FCA plaintiff must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby") (internal quotation marks omitted).

This Circuit adheres to a strict application of Rule 9(b) to FCA claims and both trial and appellate courts have repeatedly emphasized that Rule 9(b)'s particularity requirement must be satisfied in FCA cases. *See e.g. Wilson, supra*; *United States ex rel. Elms v. Accenture LLP*, 341 Fed. Appx. 869, 873 (4th Cir. 2009) (affirming dismissal of FCA case in which the plaintiff "submitted only one invoice ... and failed to allege with particularity any alleged rebate or

credit" that was not reported to the government, and rejecting argument that plaintiff should be excused from pleading with specificity because requisite information is in possession of defendants); *United States ex rel. Radcliffe v. Purdue Pharma L.P.*, 582 F. Supp. 2d 766, 784 (W.D. Va. 2008) (dismissing complaint because it did "not describe even a single instance in which a physician was influenced to prescribe [the drug] based on [the defendant's] misrepresentations, and where a claim was made by the pharmacist to the government"); *United States ex rel. Martinez v. Virginia Urology Ctr., P.C.*, Case No. 3:09-cv-442, 2010 U.S. Dist. LEXIS 77078, at * 12-15 (E.D. Va. Jul. 29, 2010) (granting motion to dismiss, and explaining "a plaintiff's conclusion that fraudulent claims were submitted must be supported by particularized allegations regarding not only time, place and content, but also the identity of the person making the misstatement and what was obtained thereby"). There have been cases in this Circuit, relied on by the Relator, that have not required at the pleadings stage the identification of specific false claims, but only where there has been an adequate description of a fraudulent scheme that makes the submission of all claims for reimbursement submitted by the defendant fraudulent. *See e.g. United States ex rel. Decesare v. Americare in Home Nursing*, 757 F. Supp. 2d 573, 583 (E.D. Va. 2010).

In advancing his claims, Relator relies on a less demanding standard, adopted by some courts outside this Circuit, that would permit Relator to proceed without alleging the "who, what, when, where, and how" as to specific claims submitted to the government in violation of the FCA as long as his complaint contains "factual or statistical evidence to strengthen the inference of fraud beyond possibility." *See e.g. In re Pharmaceutical Industry Average Wholesale Price Litigation*, 538 F. Supp. 2d 367, 390 (D. Mass. 2008) (quoting *United States ex rel. Rost v. Pfizer*, 507 F.3d 720, 733 (1st Cir. 2007)). However, courts in this Circuit have clearly explained that a relator's allegation that "fraud must be occurring" is not sufficient to satisfy Rule 9(b), *see Decesare*, 757 F. Supp. 2d at 583 (applying *Elms*, 341 Fed. Appx. at 873); and for the reasons

discussed below, Relator's statistics-based version of this theory does not satisfy his obligation to plead his claims under the FCA with specificity.

B. Relator's Claim Pursuant to 31 U.S.C. § 3729(a)(1)(A) (Count I)

The FCA creates a cause of action against 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). Relator's Third Amended Complaint, like his Second Amended Complaint, fails to plead facts sufficient to establish that any specific false claims were presented to the United States for payment or approval, or that Takeda's promotional activities caused such presentment.

1. Presentment of a False or Fraudulent Claim for Payment or Approval

Relator has failed to identify any specific instances in which Takeda caused a pharmacist or other healthcare provider to submit a claim for reimbursement to the government based on a non-reimbursable prescription. Nevertheless, Relator seeks to satisfy its pleading obligations through a combination of statistics and general allegations concerning the patient populations served by medical specialists to whom Kapidex was marketed, and to whom samples of Kapidex were distributed.

Relator first alleges that rheumatologists do not treat any conditions for which Kapidex has been approved, and therefore all prescriptions written by rheumatologists for Kapidex are off-label. *See e.g.*, 3d Am. Compl., ¶ 6. Then, relying on an attached affidavit, rather than allegations actually made in the Third Amended Complaint (which only contends that Takeda engaged in a campaign to promote Kapidex to rheumatologists, 3d Am. Compl., ¶¶ 149-169), Relator contends that rheumatologists in Relator's territory wrote two prescriptions during a sample month, July 2009, and that Relator's territory is one of over 500 territories in the United States. Based on these allegations, Relators contends that the two prescriptions must have been non-reimbursable under any government program and that there are "likely tens of thousands of

prescriptions written by rheumatologists when all of the territories are accounted for during the 28 month period during which Kapidex has been promoted." Relator's Opp., at 13. Completing the journey he must travel, the Relator then contends that "there should be no question that some of these prescriptions were reimbursed by government programs, given the other data presented by Relator indicating that a significant percentage of prescriptions from his territory and his district were submitted for reimbursement to government programs." Id.

These allegations are insufficient to establish for the purposes of the FCA either that non-reimbursable prescriptions were written or, if they were non-reimbursable, that they were submitted for reimbursement.[1] There is nothing about these allegations that establishes beyond a possibility that "tens of thousands of prescriptions" of Kapidex were written by rheumatologists and that "some of these prescriptions were reimbursed by government programs." In fact, even as to the two postulated prescriptions, there is no allegation that either was in fact submitted for reimbursement by a federal agency. Even if they were, there is nothing that prevents a rheumatologist from prescribing Kapidex for an approved condition at an approved dosage and Relator makes no allegations, either in or outside of his Third Amended Complaint, as to what these two prescriptions were for or for what dosage they were written. In short, these allegations are insufficient to plead an FCA violation even as to the two alleged prescriptions; and they certainly are inadequate to establish any claim as to any other prescriptions. *See e.g. Birkbeck v. Marvel Lighting Corp.*, 30 F.3d 507, 511 (4th Cir. 1994) (endorsing view that sample sizes of between five and thirteen are "too small to have any predictive value").

Relator next points to 16 primary care physicians from his district who received 60 milligram samples from Takeda, and who wrote 98 prescriptions for Kapidex that were submitted to Medicare for reimbursement. Relator first alleges that primary care physicians do

[1] As an initial matter, as this Court clearly explained in its prior Order, Relator may not avoid dismissal by attempting to plug holes in his complaint with supplemental affidavits. The Court has considered the substance of these affidavits in order to assess whether Relator should be granted further leave to amend his complaint.

not treat conditions for which the 60 milligram dose is appropriate, thus presumably making all of the 60 milligram prescriptions by primary care physicians off-label. However, he does not allege that the prescriptions issued were in fact for 60 milligram doses. *See* 3d Am. Compl., ¶¶ 284-301. To cure this gap in proof, Relator argues that it is reasonable to infer that over 90% of these prescriptions were, in fact, issued at the 60 milligram dose because over 90% of Takeda's overall sales of Kapidex are at the 60 milligram dose. 3d Am. Compl., ¶¶ 310, 345-348. Relator does not, however, allege any basis on which to assume that the overall level of 60 milligram doses, as a percentage of overall Kapidex sales, corresponds to the prescriptions that were actually issued by these primary care physicians. There are also no factual allegations that would lead this Court to conclude that primary care physicians, generally, prescribed 60 milligram doses of Kapidex at levels that correspond to Takeda's overall rate of Kapidex sales.

Similarly, Relator contends that approximately 9,000 Kapidex prescriptions were submitted for federal reimbursement in two particular sales districts during periods in 2009 and 2010. 3d Am. Compl., ¶¶ 312-313. Relator does not allege, however, the dosages of these prescriptions: and these statistics suffer from the same inadequacies as those pertaining to the 16 primary care physicians discussed above in that Relator does not explain the basis for his assumption that the overall 90% rate of 60 milligram doses can be attributed to these prescriptions as well. *See* 3d Am. Compl., ¶¶ 314, 345-348. Moreover, these statistics do not identify the types of doctors issuing the prescriptions, the types of illnesses for which they issued the prescriptions at issue, or whether the doctors were subjected to Takeda's sample distribution practices.

Finally, Relator points to several physicians who attest in sworn declarations that they were not aware that Kapidex was available in a 30 milligram dosage, and whom Relator claims prescribed 60 milligram Kapidex doses to Medicare patients over the age of 65 for conditions for

which the 60 milligram dosage of Kapidex was not approved by the FDA 3d Am. Compl., ¶ 278, 281, Ex. 9, 10, 14. By supplemental affidavit, one of these physicians further avers that certain of these patients contacted his office for prescription refills. Yaffe Aff. [Doc. No. 81-3], at ¶ 3. However, there are no allegations or averments as to when the alleged prescriptions were issued, or that any claims for payment were actually submitted to Medicare in connection with these prescriptions. *See e.g. Rost*, 507 F.3d at 733 (explaining "[i]t may well be that doctors who prescribed [a drug] for off-label uses as a result of [the defendant's] illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed [the drug] for off label uses only where the patients paid for it themselves, or when the patients' private insurers paid for it"). As a result, Relator has failed to identify any false claims, or plead facts that would establish "beyond possibility" that false claims were in fact submitted, and Relator's Section 3729(a)(1)(A) claim will be dismissed for failure to state a claim.

2. Causation

The Third Amended Complaint, like the Second Amended Complaint, also fails to plead facts sufficient to make plausible Relator's claim that Takeda "caused" any off-label prescriptions to be issued.[2] Courts recognize that physicians are not unsophisticated lay persons and it is reasonable to assume that they are familiar with relevant medical literature. *See United States ex rel. Polansky v. Pfizer, Inc.*, Case No. 04-cv-0704, 2009 U.S. Dist. LEXIS 43438, at *19 (E.D.N.Y. May 22, 2009). This is not to say that off-label promotion cases cannot be

[2] The Court notes that there appears to be a division among the courts regarding whether, to establish causation in fact, the Court must apply a "substantial factor" test or a "but for" causation test to claims under the FCA. *See e.g., United States ex rel. Franklin Parke-Davis*, Case No. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754, at *12-13 (D. Mass. 2003); *United States ex rel. Hess v. Sanofi-Synthelabo Inc.*, Case No. 4:05CV570MLM, 2006 U.S. Dist. LEXIS 22449, at * 23 (E.D. Mo. Apr. 21, 2006). The Court concludes that there is no need to determine whether the "but for" test or the "substantial factor" test applies since the Court concludes that Relator's allegations are insufficient under either test.

prosecuted under the FCA. However, off-label FCA cases generally involve allegations that the judgment of a physician was altered or affected by the defendant's fraudulent activities, which also typically involve improper payments, benefits or inducements, or misrepresentations. *See e.g. United States ex rel. Carpenter v. Abbott Labs, Inc.*, 723 F. Supp. 2d 395, 398-400 (D. Mass. 2010) (involving kickbacks, misrepresenting studies, FDA approval and the efficacy of the drug, and presenting doctors with studies supporting off-label use); *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 45-46 (D. Mass. 2001) (involving kickbacks, providing false information to doctors regarding the safety and efficacy of the drug, and misrepresentations regarding credentials); *Strom ex rel. United States v. Scios, Inc.*, 676 F. Supp. 2d 884, 888-89 (N.D. Cal. 2009) (noting that the relator alleged that defendants hired ghostwriters to write and submit articles favorable to their drug in journals, but attributed the work to doctors and nurses); *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 538 F. Supp. 2d at 373-74 (explaining that the relator alleged the defendant paid "cash bribes" to hospitals). As this Court noted in its May 4, 2011 Order, physicians are not prohibited from prescribing drugs for off-label uses, and Relator has not made any allegations regarding kickbacks or other improper incentives or attempts to distort otherwise objective medical literature. Moreover, the Court finds, for the reasons discussed below, that Relator has failed to allege facts that would support an actionable misrepresentation claim. Accordingly, this Court finds that Relator has not pleaded facts that would articulate a plausible theory of causation, and Relator's Section 3729(a)(1)(A) claim will be dismissed on this basis as well.

C. Relator's Claim Pursuant to 31 U.S.C. § 3729(a)(1)(B) (Count II)

The FCA also imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). Relator's allegations regarding the existence of affirmative misrepresentations do not, however, meet Rule 9(b)'s requirements For example, Relator alleges that a certain identified Takeda sales manager stated during an October 2009 training session that she had only

been promoting Kapidex to rheumatologists for NSAID gastric protection, which is not a medically accepted indication, but does not allege what she said to the physicians, when the alleged statements to physicians were made or where the statements were made, or identify the physicians to whom she made the representations. 3d Am. Compl., ¶ 155. Likewise, Relator's allegations regarding "Sales Representative E" ("SRE") do not identify the practice or the physician with whom SRE communicated, or when in May 2011 the meeting took place. 3d Am. Compl., ¶ 251. Furthermore, Relator has not alleged what these physicians did as a result of these marketing efforts, or that the alleged false statements were material to a claim for payment, or even that the recipient physician(s) issued any off-label prescriptions, much less that any such prescriptions were submitted for federal reimbursement. [3] In the absence of any alleged misrepresentations that would satisfy the requirements of Rule 9(b), the Court will also dismiss Relator's Section 3729(a)(1)(B) claim.

D. Leave to Amend and Supplemental Jurisdiction

Given the previous opportunities which this Court has granted Relator to file an amended complaint and to address the deficiencies that this Court identified in its May 4, 2011 Order, the Court finds that granting Relator leave to file a further amended complaint would be futile. Accordingly, this Court will dismiss Relator's FCA claims without leave to file a further amended complaint. The Court declines to exercise supplemental jurisdiction over Relator's state law claims (Counts III through XXVIII), which are hereby dismissed without prejudice.

CONCLUSION

For the above reasons, the Court concludes that in the absence of specific instances of false claims presented because of Takeda's conduct, and in the absence of any actionable misrepresentations, Relator fails to state a claim under the FCA. Relator's statistical and general allegations concerning what ailments are treated by what physicians, and the general nature of

[3] Relator's other allegations are even less detailed. *See e.g.* 3d Am. Compl., ¶¶ 232-250.

Takeda's promotional activities, do not supply the needed specificity under Rule 9(b), do not satisfy *Iqbal* and *Twombly*, and do not raise an inference of fraud beyond mere possibility. The Court will therefore grant Takeda's Motion, dismiss Relator's FCA claims (Counts I and II) without leave to amend, and dismiss Relator's remaining state law claims (Counts III through XXVIII) without prejudice.

An appropriate Order will issue.

/s/
Anthony J. Trenga
United States District Judge

Alexandria, Virginia
September 6, 2011