United States District Court
District of Massachusetts

UNITED STATES OF AMERICA *EX REL.* PAUL WORSFOLD,	)	
Plaintiff,	)	
v.	)	**Civil Action No. 09-11522-NMG**
PFIZER INC.,	)	
Defendant.	)	

MEMORANDUM & ORDER

GORTON, J.

Paul Worsfold ("Relator") brings this qui tam action on behalf of the United States, 26 individual states and two municipalities against defendant Pfizer, Inc. ("defendant" or "Pfizer"). Relator alleges that defendant's promotion of two proprietary anti-fungal medications, Vfend and Eraxis, violated the federal False Claims Act ("FCA") as well as several state law analogs. Pending before the Court is defendant's motion to dismiss.

I. Factual Background

The following allegations are drawn from the Fourth Amended Complaint and accepted as true for the purpose of resolving the pending motion to dismiss:

A. Parties

Relator Paul Worsfold, is a resident of Florida and worked as a District Manager of Western Florida in Pfizer's Anti-Infectives Division. In that capacity, Relator was responsible for the sale of Vfend and Eraxis and managed several salespersons.

Defendant is a Delaware corporation with its principal place of business in New York. Pfizer is principally engaged in the manufacture and sale of pharmaceuticals which it sells throughout the United States, including in the Commonwealth of Massachusetts.

B. The Drugs

Vfend, the branded name of the drug voriconazole, was originally developed by defendant during the 1990s in order to treat fungal infections arising in patients suffering from other serious conditions. The Food and Drug Administration ("FDA") first approved Vfend in 2002 and has since approved it for intravenous or oral treatment of a variety of infections, including invasive aspergillosis, esophageal candidiasis and Candida infections in the abdomen, kidney, bladder wall and wounds. Because such infections may be fatal if not treated promptly, physicians may prescribe Vfend before they obtain the results of a laboratory culture or other procedure aimed at diagnosing the patient's infection (a process known as "empiric

treatment"). The FDA approved Vfend for use in children ages 12 and older but denied a proposed indication for empiric treatment of febrile neutropenic patients, who, the Court discerns, are patients who develop a fever while suffering from an abnormally low number of white blood cells.[1] Vfend is also not indicated for prophylactic treatment, i.e. preventative treatment prior to any signs of a fungal infection, or for use in children ages 12 and younger.

Eraxis, the branded name of the drug anidulafungin, is another antifungal drug developed by Pfizer. In 2006, the FDA approved Eraxis for intravenous treatment of fungal infections including Candida infections. Eraxis is not indicated for use in neutropenic patients, as prophylactic treatment, as an empiric therapy or for use in pediatric patients.

C. Pfizer's Promotion of Vfend and Eraxis

Defendant began marketing both drugs shortly after they received FDA approval. Relator alleges that defendant specifically promoted Vfend and Eraxis for use in hospitals and other medical facilities offering chemotherapy services (collectively "cancer centers"), despite the fact that chemotherapy causes patients to become neutropenic and that

[1] "Neutropenia is defined as the presence of abnormally small numbers of neutrophils in the circulating blood. Neutrophils are a type of mature white blood cell." Juraska v. Astrue, No. 10-CV-596-PB, 2011 WL 5403225, at *1 n.3 (D.N.H. Nov. 8, 2011) (internal citations and quotations omitted).

neither drug was approved for use in febrile neutropenic patients. Relator also alleges that defendant specifically promoted Vfend and Eraxis for use at children's hospitals, despite the fact that neither drug was indicated for use in children under 12 years old.

Defendant developed and distributed a variety of marketing materials promoting Vfend for use in patients suffering from cancer and who were, therefore, likely to be neutropenic. Some materials proclaimed Vfend to be more effective against a wider array of fungal infections than other drugs available in the market, despite the fact that one such competing drug, Sporonox, was FDA-approved for use in febrile neutropenic patients. Other brochures depicted patients with leukemia and others who had recently received bone marrow and organ transplants which, relator asserts, promoted the prescription of Vfend to neutropenic patients.

Defendant also funded "seeding studies" at cancer centers around the country to promote Vfend, including one such study at the Moffitt Cancer Center, a facility within relator's sales region. The study at Moffitt concerned transitioning patients from an antifungal drug sold by a competitor (Spronox) to Vfend. Relator alleges that the effect of the study was to increase the prescription of Vfend as a prophylaxis. In March, 2008, in an

email to his supervisor, he estimated that as much as 80% of defendant's sales of Vfend at Moffitt were for prophylactic use.

Relator further alleges that defendant provided an incentive for its employees to promote Vfend and Eraxis for off-label uses, particularly through promotion at cancer centers, by setting sales quotas at unreasonably high levels. Relator and Phil Wegner, another district business manager based in Houston, both communicated concerns to defendant to that effect in late 2008. According to Wegner, Pfizer established a sales quota for Eraxis at a Texas cancer center of 372 "therapy days" per month for the first-half of 2007(equivalent to approximately $420,000 in alleged off-label sales for that time period). Mr. Wegner further remarked that simply lowering the quotas at cancer centers would be insufficient, in his opinion, to "remove the implied company direction to promote in 'off-label' settings."

D. Procedural History

Relator filed the Complaint ex parte and under seal in September, 2009. Following several amendments and extensions of the seal, plaintiff filed the Fourth Amended Complaint, the current iteration of the complaint, in November, 2010. The Fourth Amended Complaint proceeds in 29 counts and alleges that defendant violated the False Claims Act ("the FCA"), 31 U.S.C. §§ 3729 et. seq., and a plethora of state law analogs. More specifically, Relator alleges that defendant promoted Vfend and

Eraxis for the following off-label uses: (1) empiric treatment, (2) treatment of patients with neutropenia, (3) treatment of children under 12 years old, and (4) as a prophylaxis. As a result of such promotion, relator alleges that defendant knowingly caused doctors to present false claims for reimbursement from Medicare and Medicaid in violation of 31 U.S.C. § 3729(a)(1) and (2).[2]

Relator purports to sue on behalf of the United States, 26 states, the City of Chicago and the District of Columbia. In May, 2011, the United States and nearly all the remaining government entities declined to intervene in Relator's suit. Relator subsequently served the Fourth Amended Complaint upon defendant in September, 2011.

Plaintiff moved to unseal the case and compel responsive pleadings from defendant in February, 2012. Before the Court addressed that motion, in March, 2012, defendant simultaneously moved to dismiss Relator's claims in their entirety and to stay discovery pending resolution of the motion to dismiss. The Court allowed the motion to unseal and the motion to stay discovery in June, 2012, but took the motion to dismiss under advisement.

[2] Relator also alleged that defendant engaged in a conspiracy to defraud the government and a "reverse fraud" but withdrew those claims, along with claims based upon state laws of Maryland, New Mexico and Michigan, in his opposition to dismiss.

II. Legal Analysis

Defendant moves to dismiss Relator's Complaint on the grounds that: (1) the Court lacks jurisdiction to consider relator's allegations based upon the promotion of Vfend and Eraxis for empiric use and for treatment of neutropenic patients under Fed. R. Civ. P. 12(b)(1) because such allegations are barred under the "first-to-file" doctrine as a result of an earlier-filed suit in the Eastern District of Pennsylvania; (2) relator's allegations are insufficient to state a claim under the FCA and must be dismissed pursuant to Fed. R. Civ. P. 12(b)(6) because they do not allege promotion for "off-label" uses nor the submission of any "false" claims; and (3) relator's allegations fail to satisfy the heightened pleading standard imposed by Fed. R. Civ. P. 9(b).

Because the Court finds that the remaining claims fail the heightened pleading standard required by Fed. R. Civ. P. 9(b), it will not reach defendant's other arguments.

A. Relevant Statutory Background

A brief explanation of federal regulations governing the promotion of pharmaceuticals and reimbursement for their prescription is necessary in order to understand how liability under the FCA may arise for off-label promotion.

1. The Promotion of Pharmaceuticals for Off-Label Uses

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., regulates the approval and marketing of drugs. No drug may be marketed in the United States without prior approval by the Food and Drug Administration ("FDA") for its intended use. 21 U.S.C. § 360. A drug's intended uses are indicated on its FDA-approved label. 21 U.S.C. §§ 331, 352. Accordingly, pharmaceutical companies are prohibited from marketing a drug for an "off-label" use. See 21 U.S.C. §§ 355(a),(d) (prohibiting marketing unless drug demonstrated to be safe and effective). Although pharmaceutical companies may not market drugs for off-label uses, doctors may prescribe the drug for uses that are different than those approved by the FDA. See United States ex rel. Carpenter v. Abbott Labs., Inc., 735 F. Supp. 2d 395, 397 n.2 (D. Mass. 2010).

2. Reimbursement of Prescriptions under Medicare and Medicaid

Whether a claim for payment is "false" for purposes of liability under the FCA, in the off-label promotion context, turns on whether the claim is reimburseable under the relevant federal program, i.e. Medicaid or Medicare.

Reimbursement under Medicaid is, in most circumstances, allowed only for "covered outpatient drugs." Id. at 409 (quoting 42 U.S.C. § 1396b(i)(10)). Covered outpatient drugs do not

include drugs that are "used for a medical indication which is not a medically accepted indication," which, in turn, depends upon whether the particular use of that drug is FDA-approved or included in one of the identified drug compendia. Id. (citations omitted). Most state Medicaid programs reimburse for prescriptions of drugs for off-label uses. See United States ex rel. Banigan v. Organon USA, Inc., 883 F. Supp. 2d 277, 294-95 (D. Mass. 2012); see also United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co., No. 96-cv-11651-PBS, 2003 WL 22048255, at *2-3 (D. Mass. Aug. 23, 2003).

Reimbursement of off-label prescriptions under Medicare Part A or B, for inpatient and outpatient treatments, turns on whether an item or service is "reasonable and necessary for the diagnosis or treatment" of an illness. See 42 U.S.C. § 1395y (a)(1)(A). An off-label use may be covered under Part A or B if the Medicare carrier determines that it is

> medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

Ctrs. For Medicare & Medicaid Servs., Medicare Benefits Policy Manual, Chapter 15 § 50.4.2. Courts have recognized that "off-label use of a drug or medical device is not the same as a medically unnecessary use of that drug or device." U.S. ex rel. Nowak v. Medtronic, Inc., 806 F. Supp. 2d. 310, 317 (D. Mass. 2011) (internal quotations citations omitted).

3. The False Claims Act

FCA liability arises when a "provider knowingly asks the Government to pay amounts it does not owe." United States ex rel. Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1311 (11th Cir. 2002). The qui tam provisions of the FCA supplement federal law enforcement resources by allowing whistleblowers (known as relators) to bring certain fraud claims on behalf of the government. United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 16 (1st Cir. 2009). In return, a relator is entitled to a portion of the proceeds from the suit, whether or not the government elects to intervene as an active participant in the action. Id.

In relevant part, the FCA imposes liability on persons or entities who (1) knowingly submit or otherwise cause the submission of false claims to the government or (2) knowingly make, use or cause false records to be submitted to the government in order to get a false claim paid by them. See 31 U.S.C. § 3729(a)(1), (2).[3]

In order to establish liability under subsection (a)(1) (a "presentment" claim), a relator must prove that the defendant

[3] The FCA was amended in May, 2009 by the Fraud Enforcement and Recovery Act, Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621, which, among other changes, re-numbered the relevant statutory provisions. Because Relator does not allege conduct occurring on or after May, 2009, the Court applies the old statutory scheme.

> (1) present[ed] or cause[d] to be presented to the United States government, a claim for approval or payment, where (2) that claim is false or fraudulent, and (3) the action was undertaken 'knowingly,' in other words, with actual knowledge of the falsity of the information contained in the claim, or in deliberate ignorance or reckless disregard of the truth or falsity of that information.

Nowak, 806 F. Supp. 2d. at 342 (citations and quotations omitted).

By contrast, in order to establish liability under (a)(2), which has no "presentment" requirement, a relator must prove the recording of a false statement with the intent that it be relied upon for payment by the government when presented (i.e. with the specific intent to defraud the government). See id. at 343 (citations omitted). That scienter requirement has since been relaxed by Congress with the result that for (a)(2) claims submitted to the government after June 7, 2008, a relator must demonstrate only that the false statement was uttered "knowingly," similar to the state of mind required under (a)(1). Id.

B. Failure to Plead Fraud with Particularity under 31 U.S.C. § 3729(a)(1) and (2)

Federal Rule of Civil Procedure 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir.

2009). Because a relator's FCA claims sound in fraud, they must be pled with the specificity required by that rule. In the context of FCA claims based upon off-label promotion, the heightened pleading standard serves to give notice to defendants of the alleged false claims submitted by others and to discourage plaintiffs from alleging fraud in the hopes of conducting embarrassing discovery and forcing settlement. See U.S. ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 733 (1st Cir. 2007) ("Rost II").

To satisfy Fed. R. Civ. P. 9(b), a relator must do more than merely "suggest fraud was possible," id., and, at a minimum, the complaint must specify the "time, place, and content of an alleged false representation." Gagne, 565 F.3d at 45 (internal quotation omitted). In other words, it must set forth "the who, what, where, when, and how of the alleged fraud." United States ex rel. Walsh v. Eastman Kodak Co., 98 F. Supp. 2d 141, 147 (D. Mass. 2000) (internal quotation omitted). Conclusory accusations related to "plans and schemes" are insufficient. Rost II, 507 F.3d at 731. Rule 9(b) may, however, be satisfied where "some questions remain unanswered" as long as "the complaint as a whole is sufficiently particular to pass muster under the FCA." Gagne, 565 F.3d at 45.

Proof of unlawful, off-label promotion alone cannot sustain a successful FCA action. See U.S. ex rel. Karvelas v. Melrose-

Wakefield Hosp., 360 F.3d 220, 234 (1st Cir. 2004) ("[A]lleged violations of federal regulations are insufficient to support a claim under the FCA."); see also Nowak, 806 F. Supp. 2d. at 346 ("The FCA does not impose liability for all fraudulent acts, only for fraudulent claims."). Evidence of an actual false claim is, accordingly, "the sine qua non" of an FCA violation. Karvelas, 360 F.3d at 225 (internal quotations and citation omitted).

With respect to claims under § 3729(a)(1), a relator's burden under Rule 9(b) varies according to whether the defendant is alleged to have submitted false claims itself ("direct claims") or is instead alleged to have induced a third party to do so (e.g., through the payment of kickbacks, a kind of "indirect claim"). Duxbury, 579 F.3d at 29 (citing Rost II, 507 F.3d at 733). When alleging "direct claims," a relator must identify the "particular false claims submitted," including

> who filed the claims, the content of the claims, when such claims were submitted, where such claims were submitted, and how much it sought in payment.

Nowak, 806 F. Supp. 2d at 352 (citation omitted).

In the context of "indirect claims," a relator can satisfy Fed. R. Civ. P. 9(b) by providing

> factual or statistical evidence to strengthen the inference of fraud beyond possibility, without necessarily providing details as to each false claim.

Duxbury, 579 F.3d at 29 (quotations and citation omitted). Put differently, absent evidence of each of the particular false claims for reimbursement that were submitted, a relator may satisfy Rule 9(b) by alleging particular details of a scheme to submit false claims paired with "reliable indicia" that lead to a strong inference that false claims were actually submitted. Id. (citing United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009)).

With respect to claims under § 3729(a)(2), it is not enough to allege that records or statements at issue were made in violation of federal law; a relator must allege that the statements were actually false. Rost II, 507 F.3d at 733. For example, in a prior case in this Court, the relator specifically alleged that sales representatives exaggerated the efficacy and safety of Neurontin, a pharmaceutical, when meeting with doctors in order to induce them to prescribe that drug. United States ex rel. Franklin v. Parke-Davis, Div. of Warner Lambert Co., 147 F. Supp. 2d 39, 45 (D. Mass. 2001). The district court, while concluding that the relator's complaint alleged fraudulent conduct, noted that allegations involving "unlawful [but] truthful promotion" would present a "much closer question." Id. at 52.

Finally, because the heightened pleading standard of Rule 9(b) "generally applies to state law fraud claims brought in

federal court", the Court will apply the rule to all of Relator's claims. Rost II, 507 F.3d at 731 n.8.

C. Application

Relator alleges that Pfizer violated § 3729(a)(1) both by submitting false claims for reimbursement to the government, directly, and by causing physicians to submit false claims. Relator also alleges that Pfizer made false statements or created false records in violation of § 3729(a)(2). For the reasons that follow, all of Relator's allegations are insufficiently particular and will be dismissed.

1. Direct Claims under § 3729(a)(1)

Relator's allegations that Pfizer submitted false claims directly to the government are exceedingly vague. The bulk of the Fourth Amended Complaint is devoted to Pfizer's purported off-label promotion of Vfend and Eraxis to physicians. Nowhere does Relator allege details evidencing how Pfizer itself, rather than intermediary physicians, submitted a false claim to the government. Considering that the First Circuit Court of Appeals subjects allegations of directly submitted false claims to even greater scrutiny than those that are indirectly submitted, Relator's allegations of direct false claims are plainly insufficient and will be dismissed. Cf. Nowak, 806 F. Supp. 2d at 352 (dismissing direct claims where relator described two sales of biliary stents to government hospitals because

allegations failed to describe, inter alia, any false statements uttered, who made them, and to which government employees).

2. Indirect Claims under § 3729(a)(1)

Relator's allegations regarding indirectly submitted false claims deal exclusively with Pfizer's off-label promotion of Vfend and Eraxis. He alleges that over the course of seven years Pfizer, through the development of marketing materials and setting of high sales quotas at cancer centers and pediatric hospitals, encouraged sales representatives to persuade physicians to prescribe Vfend and Eraxis for off-label uses. Based upon greater specifics concerning the dissemination of those marketing materials at two cancer centers, one in Florida and another in Texas, Relator asserts that Pfizer caused false claims to be submitted to Medicare and Medicaid throughout the United States.

Relator does not, however, identify a single false claim for reimbursement actually presented to a federal or state government based upon an identified, purportedly off-label use of Vfend or Eraxis. That defect, coupled with further deficiencies in Relator's complaint discussed infra, requires dismissal. Evidence of an actual false claim remains the sine qua non of an FCA claim, Karvelas, 360 F.3d at 225, and the fact that Pfizer may have violated federal regulations governing off-

label promotion is "insufficient to support a claim under the FCA." Id. at 234.

Relator argues that, nevertheless, he has satisfied Rule 9(b) by identifying "factual or statistical evidence" to strengthen the inference beyond mere possibility that Pfizer caused a physician to submit a false claim for reimbursement. See Duxbury, 579 F.3d at 29. The First Circuit implied in United States ex. rel. Rost v. Pfizer that, in FCA cases involving the submission of indirect false claims, the failure to identify an actual false claim is not necessarily fatal. See 507 F.3d at 726, 732-33 (analyzing Rost's allegations for "factual or statistical evidence"). In practice, Relator asks this Court to be the first to refrain from dismissal when no specific false claims have been alleged because, where courts have found Rule 9(b) satisfied under the "extrapolation" approach, the relators have alleged "at least some specific false claims." Nowak, 806 F. Supp. 2d at 355-56 (collecting cases). Even in Duxbury, a case upon which Relator relies, the relator 1) identified eight medical providers who allegedly submitted false claims, 2) provided information with respect to the dates and amounts of those claims and 3) identified the government healthcare program to which the claims were submitted. See 579 F.3d at 29-30. In spite of those details,

however, the First Circuit noted that the relator's claim presented a "close call." Id. at 30.

Regardless of whether Relator's failure to identify any false claims actually submitted is fatal, in and of itself, the remaining allegations are insufficient to strengthen the inference that a false claim was actually submitted "beyond possibility." First, Relator has not alleged such factual evidence permitting the Court to infer that actual false claims were submitted. Although he avers generally that Pfizer promoted Vfend and Eraxis off-label at cancer centers and pediatric hospitals, Relator does not identify 1) any providers at those facilities who received marketing communications promoting the off-label uses of those drugs; 2) any providers so contacted who prescribed the drugs for those off-label purposes; 3) any pharmacies or hospitals filling such prescriptions; or 4) the approximate date, location, content or amount of any false claim submitted to any government health care program.

Second, the purported statistical evidence advanced by Relator in lieu of such specifics also fails to create the requisite inference of fraud. Relator estimates, in conclusory fashion, that half of all sales of Vfend and Eraxis at cancer centers, nationwide, were for off-label purposes. Even if this Court credited such an allegation, the First Circuit has already found insufficient allegations that a drug was purportedly used

off-label in more than half of all adult sales of a drug and that more than a quarter of pediatric sales were for off-label purposes. See Rost II, 507 F.3d at 732 (concluding that such statistics created a "possible but not a necessary inference or even a strong inference that doctors" prescribed the drugs for off-label purposes).

Finally, Relator's attempt to resuscitate his vague allegations by pointing specifically to defendant's alleged activities at the Moffitt Cancer Center is also unavailing. Relator alleges that, as a result of Pfizer's off-label promotion of the drug, Vfend served as the "workhorse" antifungal medication at Moffitt. He further alleges that, according to an email he sent, in March, 2008, 80% of Vfend sales were for off-label, prophylactic purposes. He further argues that because Medicaid and Medicare are two of the largest payors of drugs in the United States, the Court may reasonably infer that Pfizer's off-label marketing caused false claims to be presented.

The shortcomings already identified undermine Relator's underlying assumption that any prescription of Vfend for an off-label use by a physician at Moffitt was necessarily caused by Pfizer's actions and was not simply the result of that physician's exercise of his or her independent judgment. Moreover, the 80% figure itself does not identify 1) what

percentage of individuals at Moffitt were covered under Medicare or Medicaid and, thus, could have resulted in the submission of claims for reimbursement to the government, or 2) what percentage of claims for Vfend were not reimbursable and were, therefore, "false." In any event, Relator's claims are less detailed than the claims previously identified as a "close call" by the First Circuit in Duxbury, 579 F.3d at 30, and the 80% figure is not enough to salvage Relator's claim.

3. § 3729(a)(2) Claims

Relator's allegations that defendant knowingly made a false record or statement material to a false claim, in violation of § 3729(a)(2), also fail. First, Relator has not alleged that Pfizer made any false statements with the specific intent of defrauding the government and mere allegations that a company intended to promote off-label uses and profit from such sales fails to demonstrate that Pfizer intended to do so at the government's expense. See Nowak, 806 F. Supp. 2d at 357 (finding intent requirement not satisfied because allegations did not show defendant intended the government to pay). Accordingly, the Fourth Amended Complaint is insufficiently particular to survive dismissal as to any false statements made by Pfizer prior to June, 2008 (when revisions to (a)(2) became effective).

Second, and more critically, Relator's allegations of off-label promotion do not include any materially false statements

or records. As discussed supra, Relator's allegations are devoid of any statements made by specific employees of Pfizer to any physicians in order to promote the off-label uses of Vfend or Eraxis, much less any false statements. Moreover, none of the marketing materials purportedly aimed at neutropenic patients involve any explicitly false statements, such as a representation that Vfend was indicated for use in neutropenic patients or that the drug is safer for neutropenic patients than competing drugs. New York v. Amgen, 652 F.3d 103, 110 (1st Cir. 2011) (stating claim is false for purposes of the FCA when it "misrepresent[s] compliance with a material precondition of Medicaid payment"). Having failed to describe any qualifying false statements by Pfizer, much less the speakers or the time, Relator has failed to satisfy heightened pleading standards even for any claims that may have been submitted after June, 2008.

In sum, Relator's Fourth Amended Complaint is much closer to the complaint held insufficient in Rost II than to the complaint found satisfactory in Duxbury because it fails to provide any information concerning 1) any false claim that was submitted or 2) the identity of providers who actually submitted such a claim. Without such details, Relator fails to satisfy Rule 9(b)'s heightened pleading requirements on all of his federal and state fraud claims. Defendant's motion to dismiss

will be allowed and the Fourth Amended Complaint will be dismissed.

III. Leave to Amend

In his opposition to dismissal Relator seeks leave to amend his Fourth Amended Complaint on the basis that he has obtained additional data from Medicaid regarding the program's payment for Vfend and Eraxis which he claims will remedy any defects in his allegations concerning a fraudulent incentive plan. Such vague allegations do not merit granting leave to amend. As an initial matter, Relator fails to specify how he obtained said claims data from Medicaid and information obtained pursuant to a Freedom of Information Act request, the most likely route, constitutes a "public disclosure" upon which a relator may not base his FCA claims. See United States ex. rel. Ondis v. City of Woonsocket, 587 F.3d 49, 55 (1st Cir. 2009). Moreover, for the reasons stated above, sales data regarding the government's payment of off-label use of the drugs does not automatically lead to the inference that false claims were submitted and does not establish the inference of fraud beyond possibility.

In conclusion, Relator has already amended his allegations four times and failed to satisfy the heightened pleading standard imposed under Fed. R. Civ. P. 9(b). His vague assertion of newly obtained information might not satisfy the public disclosure bar and is, in any event, insufficient to

remedy the many defects in his allegations. Accordingly, Relator's request to re-plead his allegations will be denied.

ORDER

In accordance with the foregoing, defendant's motion to dismiss (Docket No. 45) is **ALLOWED** and the case is **DISMISSED** and, treating Relator's opposition to defendant's motion (Docket No. 48) as a motion for leave to amend, that motion is **DENIED.**

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated November 22, 2013