UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ET AL. EX REL. JESSE POLANSKY,	:	
Plaintiff,	:	**MEMORANDUM & ORDER**
- against -	:	No. 04-cv-0704 (ERK)
PFIZER, INC.,	:	
Defendants.	:	

KORMAN, *J.*:

Beginning in April 2001, Dr. Jesse Polansky was employed by Pfizer as Director of Outcomes Management Strategies. He also served as the Medical Director for the Local Marketing Team Review Committee, which evaluates and approves the regulatory, legal, and scientific integrity of marketing programs for Pfizer's major metropolitan markets. One of Pfizer's drugs evaluated by the Committee on which Polansky served was Lipitor. Lipitor is a statin, a class of drugs that lowers cholesterol levels by blocking enzymes that are essential to cholesterol production.

Dr. Polansky's employment was terminated by Pfizer in 2003. Subsequently, in early 2004, Dr. Polansky filed a complaint in this case, which has been amended three times. The complaint alleges that Pfizer violated the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.* and various false claims provisions of state law, because of the manner in which it marketed Lipitor. The complaint also alleges that Pfizer violated Title VII, 42 U.S.C. § 2000e *et seq.* and New York law, because of the manner in which Polansky was terminated. I address the latter causes of action in a separate memorandum and order.

Specifically, with respect to the FCA claim, Polansky alleges that Pfizer pursued an off-label marketing scheme that caused federal and state health programs to pay false or fraudulent claims for reimbursement for prescriptions of Lipitor other than those indicated on its label. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be introduced into interstate commerce unless the Food and Drug Administration ("FDA") finds that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). In the course of the approval process, the manufacturer must submit a "specimen[] of the labeling proposed to be used for such drug," to include all material facts and adequate warnings. *Id.* at § 355(b)(1)(F). The scientists at the FDA who review the proposed labels evaluate the information contained in them and reject a manufacturer's application where the drug label does not sufficiently comply with the requirements of the FDCA or is otherwise false or misleading. 21 C.F.R. §§ 312.125(b)(6) and (b)(8). All of the language found in a drug label is subject to FDA approval, and cannot be changed without further approval. *Id.* at § 601.12. While the FDA has approved Lipitor as an adjunct to diet to lower raised cholesterol, Lipitor's label contains the following caveat, upon which the FCA claim is predicated:

> Therapy with lipid-altering agents should be a component of multiple-risk-factor intervention in individuals at increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol only when the response to diet and other non-pharmacological measures has been inadequate (see *National Cholesterol Education Program (NCEP) Guidelines*, summarized in Table 6).

(Compl. ¶ 50; Declaration of Adam B. Siegel, Ex. A, p. 8-9 ("Siegel Dec.")).

The NCEP Guidelines, to which the label makes reference, were promulgated under the auspices of the National Institutes of Health, National Heart, Lung and Blood Institute (Compl. ¶ 53, n.8) by an Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. (Compl. ¶ 53). Table 6 summarizes the NCEP Guidelines (the

"Guidelines"), which provide the basis for FDA-approved indications for the treatment of persons with elevated levels of LDL cholesterol. They appear directly below the above-quoted paragraph on Lipitor's label, as part of the "Indications and Usage" section.

The Guidelines apply not only to Lipitor, but to all statins. The most recent NCEP Guidelines, known as ATP III, were issued in May 2001, and updated in July 2004. (*Id.*). The governing principle of the Guidelines is that the intensity of cholesterol-lowering drug treatment should be adjusted to the patient's absolute risk for coronary heart disease. (Compl. ¶ 54). Thus, the Guidelines categorize patients into one of four risk categories – high, moderately high, moderate, and low to moderate – depending on their number of cardiac risk factors and the calculation of the patient's risk of having a heart attack within ten years. (*Id.*). The Guidelines also set forth three LDL cholesterol *goal levels* and four LDL cholesterol *cutpoint levels*. (Compl. ¶¶ 58, 62). LDL cholesterol *goals* are the levels to which the Guidelines recommend patients aspire in a particular risk category, while LDL cholesterol *cutpoints* are the levels at which the Guidelines recommend statin therapy. (Compl. ¶ 59). So, for example, the Guidelines recommend that moderate risk patients aspire to achieve a goal LDL cholesterol level of under 130 mg/dL, and that patients initiate therapeutic lifestyle changes when their cholesterol exceeds 130 mg/dL. The cutpoint at which the Guidelines recommend initiating statin therapy is 160 mg/dL or over. (Compl. ¶¶ 62, 64).

The complaint alleges that Pfizer sought to unlawfully broaden the patient population for which Lipitor is recommended for moderate risk patients described above. (Compl. ¶ ¶ 63, 69). Pfizer allegedly did so by "the reiteration and combination of several false and misleading themes: (1) 'if you are not at your LDL goal, you should consider drug therapy;' (2) 'Get to Goal' with the use of Lipitor; (3) diet and exercise will not suffice to reduce your risk of heart

disease; and (4) 'Lower [cholesterol] is better' (infinitely, and irrespective of risk category." (Compl. ¶ 72). These statements allegedly served to blur the distinction between goals and cutpoints and encouraged the onset of drug therapy among moderate risk patients at thirty LDL cholesterol points below the level recommended by the Guidelines. (Compl. ¶ 64).

Because the Guidelines are incorporated into Lipitor's label, Polansky alleges that promoting Lipitor therapy for patients outside these risk categories and cutpoints constitutes unlawful off-label promotion and, as such, off-label uses did not qualify for reimbursement under any federally-funded health care program. (Compl. ¶ 51-52). Consequently, Polansky alleges that "[e]ach prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment." (Compl. ¶ 226).

The complaint does not identify a single false claim or any doctor who received or viewed the Lipitor marketing materials, let alone any doctor who received or viewed these materials and then prescribed Lipitor to a patient for whom the Guidelines did not recommend statin therapy, on the mistaken belief that they did. Nor does the complaint identify any pharmacist who filled a prescription by such a physician, or any person who sought reimbursement for the cost of that prescription. The absence of such facts underlies Pfizer's motion to dismiss pursuant to Federal Rule of Civil Procedure 9(b).

DISCUSSION

I. The False Claims Act

Polansky filed the FCA action on behalf of the United States, sixteen states, and the District of Columbia. The FCA permits private persons (known as "relators"), to file a form of civil

action (known as *qui tam*) against, and recover damages on behalf of the United States from, any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.

31 U.S.C. § 3729(a)(1)-(2). "Claim" means "any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(c).

An FCA *qui tam* action may not be based on publicly disclosed information unless the relator is the original source of that information. 31 U.S.C. § 3730. The relator must first serve his or her complaint upon the government, where it remains under seal while the government investigates and decides whether to intervene. *Id.* § 3730(b)(2). If the government elects to intervene, it takes over the suit and adopts any or all of the allegations contained in the *qui tam* complaint, in which case the relator is entitled to fifteen to twenty-five percent of any proceeds recovered. *Id*. § 3730(c)(1), (d)(1). If, as in this case, the government does not exercise its right to intervene in the suit, the relator may serve the complaint upon the defendant and proceed with the action. *Id*. § 3730(b)(2), (b)(4)(B), (c)(3). If the relator succeeds in recovering funds for the government, he or she is entitled to twenty-five to thirty percent of the recovery. *Id*. § 3730(d)(2). Statutory penalties include a civil penalty of between $5,000 and $10,000 per claim and treble damages.

II. Rule 12(b)(6) Motion for Failure to Allege a Violation of the False Claims Act

Pfizer moves to dismiss Polansky's claims under the Federal False Claims Act and various false claims provisions of state law (Counts I, III through XIX), for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). I assume for present purposes that the complaint is sufficient to state a claim, though I dismiss it for failure to comply with Federal Rule of Civil Procedure 9(b).

III. Rule 9(b) Motion for Failure to Plead Fraud with Particularity

Generally, a complaint need only state "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). Each allegation should be "simple, concise, and direct," with no technical form of pleading required. Fed.R.Civ.P. 8(d)(1). However, in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Fed.R.Civ.P. 9(b). Rule 9(b) applies to FCA cases because the FCA is an anti-fraud statute. *See Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476 (2d Cir. 1995) (per curiam); it also applies to *qui tam* actions under state statutes similar to the FCA. *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 n.8 (1st Cir. 2007); *Universal Commc'n Sys., Inc. v. Lycos, Inc.*, 478 F.3d 413, 427 (1st Cir. 2007); *see also* 5A Wright & Miller, *Federal Practice and Procedure*, § 1297 (3d ed. 2004).

Generally speaking, Rule 9(b) requires a plaintiff alleging fraud to: "1) specify the statements that the plaintiff contends were fraudulent; 2) identify the speaker; 3) state where and when the statements were made; and 4) explain why the statements were fraudulent." *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004); *see also Shields v. Citytrust Bancorp.*, 25 F.3d 1124, 1128 (2d Cir. 1994). In other words, "Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud." *United States ex rel. Thompson v. Columbia/HCA*

Healthcare Corp., 125 F.3d 899, 903 (5th Cir. 1997) (internal quotation marks and citations omitted). This means that

> a relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details 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. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232-33 (1st Cir. 2004) (internal citations and quotations omitted).

A. Pleading a False Claim with Particularity

The FCA "was enacted in 1863 with the principal goal of stopping the massive frauds perpetrated by large [private] contractors during the Civil War." *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 781 (2000). "[T]he statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'" *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995). "Underlying schemes and other wrongful activities that result in the submission of fraudulent claims are included in the 'circumstances constituting fraud or mistake' that must be pled with particularity pursuant to Rule 9(b). However, such 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; *see also United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996).

Thus, a relator cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding, that as a result of the fraudulent scheme, false claims must have been submitted. *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 (1st Cir. 2007); *United States ex rel. Sikkenga v. Regence Bluecross of Utah*, 472 F.3d 702, 727 (10th Cir. 2006); *Karvelas*, 360 F.3d at 232; *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002), *cert. denied*, 537 U.S. 1105 (2003); *see also United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 441 (3d Cir. 2004); *United States ex rel. Schmidt v. Zimmer, Inc.*, 2005 WL 1806502, at *3 (E.D.Pa. 2005). Rather, actual false and fraudulent claims are "the *sine qua non* of a False Claims Act litigation." *Clausen*, 290 F.3d at 1311; *see also United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 551 F.Supp.2d 100, 114 (D. Mass. 2008). The distinction between a false and fraudulent claim is "simply the degree of scienter involved." *United States ex rel. Totten v. Bombardier Corp. and Envirovac, Inc.*, 286 F.3d 542, 552 (D.C. Cir. 2002); *see also United States v. TDC Mgmt. Corp.*, 24 F.3d 292, 297 (D.C. Cir. 1994) (distinction turns on "whether the defendant acted with an intent to deceive").

Polansky has alleged only one of the details "some of [which] . . . must be pleaded in order to satisfy Rule 9(b)." *Karvelas*, 360 F.3d at 233. Specifically, he alleges that that Lipitor was the "particular good[] . . . for which the government was billed." *Id.* Nevertheless, as observed above, he has not identified any false claims or physicians who were induced to write a prescription for an off-label use. Nor does he allege that Pfizer affirmatively misrepresented the indications for which Lipitor was approved by the FDA. The essence of his claim is that Pfizer advocated that Lipitor be prescribed in cases in which its use was not recommended by the Guidelines. This is insufficient to satisfy Rule 9(b).

B. Relaxation of Rule 9(b)

Polansky does not dispute that he has failed to identify particular false claims that were submitted to the government. Indeed, it is not even clear that any false or fraudulent claim was filed. Thus, during the oral argument of the motion, Polansky's lawyer could not articulate in what way the claims that were filed by patients or pharmacists on behalf of patients for reimbursement were false. There is no dispute that the patient received Lipitor for which Medicare and Medicaid were billed. There is likewise no dispute that Lipitor is a safe and effective drug for lowering cholesterol. Nor did the FDA conclude otherwise. Instead, for a subset of patients, it provided that therapeutic lifestyle changes should first be used.

Significantly, the FDA did not preclude physicians from prescribing Lipitor even without first resorting to therapeutic lifestyle changes. On the contrary, as a general matter, the FDA has acknowledged that "accepted medical practice often includes drug use that is not reflected in approved drug labeling" and that "the package insert [which is the label] is informational only." *See* Food & Drug Admin., *Use of Approved Drugs for Unlabeled Indications,* 12 FDA Drug Bulletin 4, 5 (1982). Thus, "a physician may prescribe [a drug] for . . . patient populations that are not included in approved labeling. Such . . . 'unlabeled' uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature." *Id*.; *see also Foreword to the 62nd Edition,* Physicians' Desk Reference (62nd ed. 2008). ("The FDA has . . . recognized that the F[ood] D[rug] & C[osmetics] Act does not . . . limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may choose to prescribe it for uses or in treatment regimens or patient populations that are not included in

approved labeling. The FDA also observes that accepted medical practice includes drug use that is not reflected in approved drug labeling.").

Notwithstanding the freedom that a physician enjoys to write prescriptions for off-label use, Polansky would pin FCA liability on Pfizer because the physicians who wrote the prescriptions were led to do so by Pfizer "saying over and over again, if you don't get to goal in three months, consider Lipitor." (Tr. of Oral Arg. at 13). Such advocacy for the off-label use of Lipitor may have violated the FDCA, and subjected Pfizer to its enforcement provisions, which include "injunctions, seizures, civil penalties, and even criminal liability." Ralph F. Hall & Robert J. Berlin, *When You Have a Hammer Everything Looks Like a Nail: Misapplication of the False Claims Act to Off-Label Promotion*, 61 Food & Drug L.J. 653, 665 (2006). Indeed, Polansky cites a letter from the FDA to the CEO of Bristol-Myers Squibb, warning that their promotional materials for the statin Pravachol "broaden[ed] the conditions and patient populations for which Pravachol [was] indicated." (Decl. of Shayne Stevenson, Ex. T).

Nevertheless, the mere fact that Pfizer may have been violating FDA regulations does not translate into liability for causing a false claim to be filed. "Violations of laws, rules, or regulations alone do not create a cause of action under the FCA. It is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit." *Hopper*, 91 F.3d at 1266.

> Thus, some request for payment containing falsities made with scienter (i.e., with knowledge of the falsity and with intent to deceive) must exist. This does not mean that other types of violations of regulations, or contracts, or conditions set for the receipt of moneys, or of other federal laws and regulations are not remediable; it merely means that such are not remediable under the FCA or the citizen's suit provisions contained therein.

Id. at 1265.

Nor is this a case that would appear to come under the "legally false" certification theory the Second Circuit adopted in *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001). Under that theory, a "claim . . . is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment." *Id.* at 697. There are two kinds of certifications that can fall within this category. One is a claim that expressly "certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." *Id.* at 698. No such certification is alleged to have been made here. The second category involves an implied certification. "An implied false certification claim is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *Id.* at 699. Specifically, "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Id.* at 700. Thus, "[l]iability under the Act may properly be found . . . when a defendant submits a claim for reimbursement while knowing – as that term is defined by the Act, *see* 31 U.S.C. § 3729(b) – that payment expressly is precluded because of some noncompliance by the defendant." *Id.*

Pfizer did not file any claims for reimbursement and made no implied certifications to obtain payment. Nor does Polansky allege that Pfizer made any representation to any physician that such use was permitted by the Guidelines or that its use was consistent with the label. On the contrary, the physicians who wrote prescriptions were not unsophisticated lay persons. Consequently, it is reasonable to assume that they were familiar with the Guidelines, the Physicians' Desk Reference, the American Heart Association Guidelines, and Lipitor's labeling, all of which reflect the Guidelines' cutpoints. Physicians' Desk Reference 2460 (62nd ed. 2008); American Heart Association, Cholesterol Levels Recommendation, *available at*

http://www.americanheart.org/presenter.jhtml?identifier=4500. More significantly, the prescriptions for Lipitor, which Polansky alleges represented a false or fraudulent record or statement (Compl. ¶ 226), were not claims that were submitted for payment. Indeed, because the FDA has expressly advised physicians that, "'unlabeled' uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature," Food & Drug Admin., *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bulletin 4, 5 (1982), and because physicians "commonly exercise professional medical judgment and prescribe drugs for uses not within the indications articulated by the FDA," *Weaver v. Reagen*, 886 F.2d 194, 199 (8th Cir. 1989) (quoting agreement among experts), the entities to which reimbursement claims are made could hardly be understood to have operated on the assumption that the physician writing the prescription was certifying implicitly that he was prescribing Lipitor in a manner consistent with the Guidelines.

In sum, the facts in this case are the opposite of the "archetypal *qui tam* FCA action," which is "filed by an insider at a private company who discovers his employer has overcharged under a government contract." *Hopper*, 91 F.3d at 1266. They also bear no resemblance to other FCA actions that have been sustained "under theories of supplying substandard products or services; false negotiation, including bid rigging and defective pricing; and false certification." *Id.* (internal citations omitted). While I do not decide the case on this ground, because a motion for summary judgment would be a more appropriate vehicle, the tenuous nature of the cause of action provides all the more justification for a strict application of Rule 9(b), as opposed to a relaxed pleading standard of Rule 9(b).

None of the exceptions upon which Polansky relies justifies such a relaxation here. Some courts relax Rule 9(b) in fraud cases where much of the factual information needed to fill out a plaintiff's complaint lies peculiarly within the opposing party's knowledge. *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990); *In re Ann Taylor Stores Securities Litigation*, 807 F.Supp. 990, 1004 (S.D.N.Y. 1992); *United States ex rel. Howard v. Lockheed Martin Corp.*, 499 F.Supp.2d 972, 975 (S.D.Ohio 2007); *United States ex rel. Absher v. Momence Meadows Nursing Center, Inc.*, 2007 WL 685693, at *3 (C.D.Ill. Mar. 2007). Thus, pleadings may be based upon information and belief as to these facts, "in which event the allegations must be accompanied by a statement of the facts upon which the belief is based." *DiVittorio v. Equidyne Extractive Industries, Inc.*, 822 F.2d 1242, 1247 (2d Cir. 1987). The rationale for reducing the pleading burden when information is in the defendant's possession appears to spring from the fact that an adverse party would not willingly divulge incriminating information. *Lawrence v. Richman Group of Conn., LLC,* 2004 WL 2377140, at *4-5 (D.Conn. Sept. 30, 2004). Where the information needed to fill out the complaint is in the hands of third parties, rather than defendants, this rationale for reducing the pleading burden does not apply.

Polansky argues for a second exception to Rule 9(b) where a relator sues a defendant that did not itself submit the false claims for a government reimbursement. While the Second Circuit has not addressed the issue whether relaxation of Rule 9(b) in these circumstances is appropriate, the Sixth Circuit has explicitly refused to relax Rule 9(b)'s pleading requirements where the facts are within the control of a third party. *See Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003) (refusing to relax Rule 9(b) where third parties are alleged to have relevant information because Rule 9(b) may be relaxed "where information is *only* within the opposing party's knowledge.").

There is, however, dictum in *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007), which Polansky cites to support his position that Rule 9(b) should be relaxed because the claims at issue are in the hands of third parties. The *Rost* Court quoted *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004), for the proposition that "Rule 9(b) may be satisfied where, although some questions remain unanswered, the complaint as a whole is sufficiently particular to pass muster under the FCA." *Rost*, 507 F.3d at 732. In *Rost*, the First Circuit gave a relator the "benefit of such flexibility" because the alleged submission of false claims was not done by defendants themselves but by doctors who were allegedly induced by defendants into prescribing the drug Genotropin off-label. *Id*. Nevertheless, *Rost* held that the complaint – which alleged an off-label marketing scheme involving, *inter alia*, incentive payments to sales representatives, a "study program" which funneled improper payments to doctors, and a financial incentive to distributors – did not pass muster under Rule 9(b). "Rost's complaint amply describes illegal practices in which Pfizer allegedly engaged. But those practices, while illegal, are not a sufficient basis for an FCA action because they do not [directly] involve claims for government reimbursement" submitted by Pfizer. *Id*. at 732.

Rost also rejected the argument that the complaint satisfied the primary purpose of pleading fraud with particularity, which he argued was to give notice to Pfizer of the false claims. *Id.* at 733. This argument failed first because "the complaint does not give notice to Pfizer of false claims submitted by others for federal reimbursement of off-label uses, only of illegal practices in promotion of the drug," and, second, because "notice is not the only reason for the requirement of Rule 9(b)." *Id.* On the contrary, "[i]t is a serious matter to accuse a person or company of committing fraud, and the mere accusation often causes harm." *Id.* Moreover, "the

rule discourages plaintiffs from filing allegations of fraud merely in the hopes of conducting embarrassing discovery and forcing settlement." *Id.* *Rost*'s complaint failed because, at most, it "raise[d] facts that suggest fraud was possible; but the complaint contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility." *Id.*

Because this language suggests by implication that a complaint could pass muster under Rule 9(b) if "factual or statistical evidence strengthen[ed] the inference of fraud beyond possibility," Polansky alleges that, from 2001 through 2005, annual sales of Lipitor increased 126%, from $5.4 billion to $12.2 billion. (*See* Compl. ¶ 6). During this period, Medicaid (approximately 50% of which is funded by the United States, with the remainder from state governments) paid $2.5 billion for Lipitor. (Compl. ¶ 11). Nevertheless, the increase in Lipitor's sales is actually less than the 156% increase between 2000 and 2005 in the sales of all statin medications. *See* Maggie Fox, Reuters (Jun. 25, 2008), *available at* http://www.reuters.com/article/healthNews/idUSN2548466020080625. Indeed, none of the statistical evidence on which Polansky relies directly addresses the category of moderate risk patients, at which Pfizer's Lipitor advocacy allegedly was directed. Moreover, the Medicaid scheme does not contain a flat prohibition against reimbursement for off-label prescriptions. Instead, it leaves the issue to the discretion of the states. 42 U.S.C. § 1396r-8(d)(1)(B).

Much more significantly, during the period for which these statistics are provided, heart disease experts have been advising patients to lower LDL cholesterol levels below targets set in the NCEP Guidelines. Consumer Reports Best Buy Drugs, The Statin Drugs: Prescription and Price Trends, at 4 (Consumer's Union Feb. 2007). Indeed, one study has found that "[l]owering cholesterol far beyond the levels recommended by most doctors [and the Guidelines] can substantially reduce heart patients' risk of suffering or dying of a heart attack." Gina Kolata,

New Conclusions on Cholesterol, N.Y. Times, at A22 (Mar. 9, 2004). Dr. Eugene Braunwald, chairman of the Harvard Medical School group that conducted this study, said that "people with LDL levels over 100, whether or not they have symptoms of heart disease, were 'accidents waiting to happen' and should get those levels down." *Id.* Moreover, research has shown that "a high dose of Lipitor lowers heart attacks and strokes more than a lower dose." Alex Berenson, *Mixed Reviews for 2 of Pfizer's Top Drugs*, N.Y. Times, at C16 (Mar. 9, 2005). Another study found that Lipitor halted plaque growth in coronary arteries in a manner that another statin did not. *See* Gina Kolata, *Study of Two Cholesterol Drugs Finds One Halts Heart Disease*, N.Y. Times, at A1 (Nov. 13, 2003). In 2004, the NCEP Guidelines themselves were modified in a way that would result in the increased use of statins. *See generally* Scott M. Grundy, et. al., *Implications of Recent Clinical Trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines* (July 13, 2004). Moreover, while it did not affect the statistics for the years at issue here, another study, the JUPITER Trial (Justification for the Use of Statins in Primary Prevention: an Intervention Trial Evaluating Rosuvastatin), found that using statins to treat people with normal cholesterol lowered the risk of heart attacks and strokes. *Changing the Cardiovascular Prevention Game*, Harvard Health Letter (Jan. 1, 2009), *available at* 2009 WLNR 7797265 ("The JUPITER results come on the heels of others that have demonstrated benefits from lowering LDL to previously unheard of levels. We don't propose throwing in the towel on lifestyle changes, but as a practical matter, that may mean millions more of us will be advised to take statins."). Indeed, an update of the NCEP Guidelines is due out later this year. *Id.*

These published studies, the existence of which I may take judicial notice on a motion to dismiss, *see Automated Salvage v. Wheelabrator Envtl. Sys.*, 155 F.3d 59, 67 (2d Cir. 1998), are

significant because of the likelihood that physicians would rely on them in choosing to prescribe statins. Significantly, as I have already observed, the FDA does not prohibit physicians, who are free to do so, from prescribing Lipitor for patients with normal cholesterol. Consequently, against the backdrop of the clinical trials and studies discussed above, as well as the tenuous theory underlying his FCA cause of action, the statistical evidence offered by Dr. Polansky does not "strengthen the inference of fraud beyond possibility." *Rost*, 507 F.3d at 733. This consideration aside, the implied dicta in *Rost* seems to me to conflate the issue of whether the complaint alleged "enough facts to state a claim to relief that is plausible on its face," *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007), with the pleading standard prescribed in Rule 9(b).

IV. Leave to Amend and Request for Court-Ordered Discovery

Pursuant to Federal Rule of Civil Procedure 15(a), leave to amend a complaint should freely be given "when justice so requires." Grounds for denial generally involve undue delay, bad faith, dilatory motive of the requesting party, repeated failure to cure deficiencies, and futility of amendment. *Foman v. Davis*, 371 U.S. 178, 182 (1962). "[I]n the preliminary stages of the lawsuit, the trial court should permit discovery and freely grant leave to amend the complaint under Rule 15." *Gary Plastic Packaging Corp. v. Merrill Lynch, Pierce, Fenner & Smith*, 756 F.2d 230, 236 (2d Cir.1985). While Polanksy has amended his complaint on three prior occasions, it was not in response to a motion by Pfizer. Instead, it occurred during the period when the complaint was sealed while the United States Attorney was making a judgment as to whether to intervene.

Polansky has also requested that he be permitted to take the discovery necessary to obtain claims processing information and to then file an amended complaint. Most courts do not permit

parties to conduct discovery in order to satisfy the requirements of Rule 9(b). *See United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 559-61 (8th Cir. 2006); *Karvelas*, 360 F.3d at 231; *Clausen*, 290 F.3d at 1313 n.24. "The reluctance of courts to permit qui tam relators to use discovery to meet the requirements of Rule 9(b) reflects, in part, a concern that a qui tam plaintiff, who has suffered no injury in fact, may be particularly likely to file suit as a pretext to uncover unknown wrongs." *Karvelas*, 360 F.3d at 231. Moreover, "[w]hen a plaintiff does not specifically plead the minimum elements of [his] allegation, it enables [the plaintiff] to learn the complaint's bare essentials through discovery and may needlessly harm a defendant['s] goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and, at worst, are [sic] baseless allegations used to extract settlements." *Clausen*, 290 F.3d at 1313 n. 24. Moreover, allowing a *qui tam* relator to amend his or her complaint after conducting discovery would mean that "the government will have been compelled to decide whether or not to intervene absent complete information about the relator's cause of action." *Karvelas*, 360 F.3d at 231. Such an approach is inconsistent with the relator's procedural obligations under the FCA and with the FCA's protections for the government, the real party in interest in a *qui tam* action. *Id*.

CONCLUSION

Pfizer's motion to dismiss the False Claims Act and related state law causes of action, (Counts I, and III through XIX) is granted with leave to replead. Pfizer's motion to dismiss Polansky's claims pursuant to the FCA Retaliation provision (Count II), and the New York Whistleblower Statute (Count XXIII) is denied for the reasons stated in a separate Memorandum and Order filed today.

SO ORDERED.

Brooklyn, New York
May 22, 2009

Edward R. Korman

Edward R. Korman
Senior United States District Judge