

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel.
DR. PETER ROST,

Plaintiff,

v.

PFIZER INC and PHARMACIA
CORPORATION,

Defendants.

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Civil Action No. 03-11084-JLT

MEMORANDUM

August 30, 2006

TAURO, J.

Plaintiff-Relator, Dr. Peter Rost, (“Plaintiff”) brings this *qui tam* action against Defendants Pfizer, Inc. and Pharmacia Corporation (collectively “Defendants”), alleging violations of the Federal False Claims Act¹ (“FCA”) and similar state statutes.² Plaintiff asserts that Defendants, through illegal, off-label marketing of the drug Genotropin, knowingly caused the submission of false claims to federal and state health insurance programs. Defendants now move to dismiss

¹ See 31 U.S.C. § 3729 et seq. (2006).

² See California False Claims Act, Cal. Gov’t Code §§ 12650 et seq.; Delaware False Claims and False Reporting Act, Del. Code Ann. tit. 6, §§ 1201 et seq.; District of Columbia Procurement Reform Amendment Act, D.C. Code §§ 2-308-13 et seq.; Florida False Claims Act, Fla. Stat. §§ 68.081 et seq.; Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 et seq.; Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175 et seq.; Massachusetts False Claims Law, Mass. Gen. Laws ch. 12, §§ 5 et seq.; Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 et seq.; Tennessee Medicaid Fraud Prevention Law, Tenn. Code Ann. §§ 71-5-181 et seq.; Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 et seq.; Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 et seq.

Plaintiff's complaint, arguing that this court lacks subject matter jurisdiction and that Plaintiff's complaint fails to allege fraud with sufficient particularity. Plaintiff has moved for leave to take jurisdictional discovery and to stay any ruling on Defendants' Motion to Dismiss pending the completion of that discovery. For the reasons discussed below, Defendants' Motion to Dismiss is ALLOWED and Plaintiff's Motion for Leave to Take Jurisdictional Discovery and To Stay a Ruling on Defendants' Motion to Dismiss Pending Completion of Discovery is DENIED.

Background

Defendant Pfizer is a corporation principally engaged in the manufacture and sale of pharmaceuticals.³ Defendant Pharmacia Corporation, until early 2003, was also engaged in the manufacture and sale of pharmaceuticals. In April 2003, Pfizer acquired Pharmacia and, in doing so, assumed all of Pharmacia's rights and liabilities. Plaintiff, Dr. Peter Rost, is a physician who has worked in the pharmaceutical industry for approximately 15 years. In June 2001, Pharmacia hired Plaintiff as its vice president in charge of its Endocrine Care Unit. In his capacity as vice president, Plaintiff oversaw the worldwide marketing of the drug Genotropin, which is at the heart of this controversy. Plaintiff, however, had no role in the day-to-day marketing or sales of Genotropin.

³ The following background facts are drawn from the Pl.'s Compl., Defs.' Mem. in Supp. of Defs.' Mot. to Dismiss Compl., Pl.'s Mem. in Opp. to Defs.' Mot. to Dismiss Compl., Pl.'s Mem. in Supp. of Pl.'s Mot. for Leave to Take Jurisdictional Disc. and to Stay Ruling on Defs.' Mot. to Dismiss Pending Completion of Disc., and Defs.' Reply in Supp. of Defs.' Mot. to Dismiss and in Opp. to Pl.'s Mot. for Leave to Take Jurisdictional Disc. and to Stay Ruling on Defs.' Mot. to Dismiss Pending Completion of Disc., and Pl.'s Reply to Defs.' Resp. to Pl.'s Mot. for Leave to Take Jurisdictional Disc. and to Stay Ruling on Defs.' Mot. to Dismiss Pending Completion of Disc.

Under the Food, Drug, and Cosmetics Act (“FDCA”), pharmaceutical drug companies cannot distribute a drug in interstate commerce unless the Food and Drug Administration (“FDA”) has approved its use.⁴ After extensive testing, the FDA will approve a pharmaceutical drug for one or more specific uses and will establish a recommended dosage for those uses. Use of an approved drug for any purposes other than those specifically approved by the FDA is referred to as an “off-label” use. The FDCA does not prohibit physicians from prescribing an FDA approved drug for unapproved off-label uses. The FDCA does, however, prohibit drug manufacturers from marketing or promoting a drug for off-label uses.⁵ As a general rule, federal and state health care programs, such as Medicaid, do not reimburse the cost of drugs prescribed for off-label uses.

The present controversy arises from Defendants’ off-label marketing and distribution of the drug Genotropin, which occurred between 1997 and 2003. Genotropin is a recombinant, or man made, human growth hormone. The FDA has approved Genotropin as a prescription drug to treat a limited range of hormonal deficiencies in children and adults. The FDA has not approved Genotropin as a treatment for short children without hormonal deficiencies or as an anti-aging treatment for adults.

In 1997, Defendant Pharmacia began promoting and marketing Genotropin for off-label uses, such as to increase growth in short children and to delay the aging process in adults. Pharmacia’s promotional activities included giving bribes, kickbacks, and other incentives to

⁴ See 21 U.S.C. §§ 355(a) & (d).

⁵ See 21 U.S.C. §§ 331 & 352. The FDCA does allow off-label marketing of a drug when strict statutory requirements are met. These provisions of the FDCA, however, are not relevant in this case.

doctors to prescribe Genotropin for off-label uses, and providing similar payments to wholesale drug distributors to recommend Genotropin for off-label uses. Pharmacia also compensated its sales representatives for every new Genotropin patient, regardless of whether the drug was prescribed for an FDA approved or an off-label use. As a result of Pharmacia's promotional campaign, Defendants received significant revenues from sales of Genotropin. Between 1997 and 2003, Defendants generated more than \$550 million from the sale of Genotropin in the United States alone. During this time period, approximately sixty percent of all adult sales and twenty-five percent of all pediatric sales of Genotropin were for off-label uses.

Plaintiff first learned of Pharmacia's off-label marketing of Genotropin through his day-to-day employment. Plaintiff immediately raised his concerns with his superiors. Pharmacia, as a result, initiated an internal investigation, which ultimately reduced Pharmacia's off-label promotional activities. Plaintiff, however, continued to monitor the marketing and distribution of Genotropin and, despite internal information to the contrary, Plaintiff discovered that Pharmacia continued to promote Genotropin for off-label uses and persisted in sending kickbacks to physicians and distributors.

In July 2002, Pfizer announced plans to merge with Pharmacia, under which Pharmacia would become a subsidiary of Pfizer. In late 2002, Plaintiff raised his concerns about the marketing of Genotropin with Pfizer executives. Plaintiff even provided Pfizer representatives with evidence of Pharmacia's extensive off-label marketing campaign.

On April 16, 2003, Pfizer completed its acquisition of Pharmacia. Pfizer, in response to Plaintiff's information, immediately began its own investigation into the off-label marketing of Genotropin. On May 16, 2003, Pfizer voluntarily contacted senior officials at the FDA and the

Office of Inspector General (“OIG”) of the Department of Health and Human Services to disclose the issues surrounding their off-label marketing of Genotropin. On May 19, 2003, Pfizer sent a detailed letter to the FDA addressing the same issues. In this letter, Pfizer disclosed Pharmacia’s off-label marketing campaign and explained the corrective action that Pharmacia, and later Pfizer, took to remedy the misconduct. Pfizer also sent the FDA a spreadsheet listing various sales to doctors who prescribed Genotropin for off-label uses.

On May 21, 2003, Pfizer representatives met with senior OIG officials. At this meeting, Pfizer disclosed more information regarding the off-label promotion and distribution of Genotropin, including more evidence of unlawful payments to physicians. The OIG assigned an investigative agent to the case and took the matter under advisement. On June 3, 2003, Pfizer sent another letter to OIG, which provided further detail regarding Genotropin. Pfizer also sent a copy of this letter to the Department of Justice (“DOJ”).

On June 3, 2003, Plaintiff informed the United States Attorney for the District of Massachusetts that he was preparing to file a *qui tam* action alleging fraud relating to Defendants’ off-label marketing of Genotropin. On June 4, 2003, Plaintiff delivered a copy of his complaint to the U.S. Attorney’s office and, on June 5, 2003, he filed his complaint. Plaintiff’s complaint remained under seal while the government investigated Plaintiff’s allegations and evaluated whether to intervene in the action. On November 8, 2005 the United States Government, after almost three years of investigation, declined to intervene in the case.

In his complaint, Plaintiff alleges that Defendants illegally marketed and distributed Genotropin for off-label uses. Defendants’ conduct, Plaintiff further argues, caused the

submission of false claims,⁶ seeking reimbursement for the cost of off-label prescriptions of Genotropin, to federal and state health care programs. Plaintiff contends that the submission of such claims violated the federal False Claims Act and similar state statutes.

Discussion

A. Subject Matter Jurisdiction Under the False Claims Act

1. Motion to Dismiss Standard

Defendants first move to dismiss Plaintiff's complaint for lack of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure.⁷ In considering a Rule 12(b)(1) motion to dismiss, this court must "construe the [c]omplaint liberally and treat all well-pleaded facts as true, according the plaintiff the benefit of all reasonable inferences."⁸ The court may also consider extrinsic materials, which include exhibits attached to the pleadings and any evidentiary materials submitted by the parties.⁹ In doing so, this court does not convert Defendants' motion to dismiss into a motion for summary judgment.¹⁰ "[T]he party invoking the jurisdiction of a federal court carries the burden of proving its existence."¹¹

⁶ A "claim" is defined as "any request or demand . . . for money or property" to which the government provides or will reimburse any part of the money or property requested. 31 U.S.C. § 3729(c).

⁷ See Fed. R. Civ. P. 12(b)(1).

⁸ Murphy v. United States, 45 F.3d 520, 522 (1st Cir. 1995).

⁹ See Patterson v. United States, 372 F. Supp. 2d 195, 199 (D. Mass. 2005) (citing Dynamic Image Techs., Inc. v. United States, 221 F.3d 34, 37-38 (1st Cir. 2000)).

¹⁰ See id. (citing Rakas v. United States, 352 F. Supp. 2d 47, 70 (D. Mass. 2005)).

¹¹ Murphy, 45 F.3d at 522 (quoting Taber Partners, I v. Merit Builders, Inc., 987 F.2d 57, 60 (1st Cir. 1993)).

2. The False Claims Act

The False Claims Act prohibits the submission of false or fraudulent claims for payment to the federal government.¹² The FCA, in relevant part, imposes liability on any person who “knowingly presents, or causes to be presented, to . . . the United States Government . . . a false or fraudulent claim for payment or approval,” or who “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.”¹³ Liability under the FCA, therefore, attaches only to the submission of a fraudulent claim for payment.¹⁴ Liability does not attach as a result of the underlying fraudulent conduct or to the government’s actual payment of particular false claims.¹⁵ The fundamental element of a FCA violation, therefore, is the existence of an actual false claim that has been presented to the government.¹⁶

The FCA authorizes private individuals to bring civil actions on behalf of the United States

¹² See 31 U.S.C. § 3729 et seq.

¹³ 31 U.S.C. §§ 3729(a)(1) & (2). The various state statutes under which Plaintiff brings his complaint prohibit the submission of false claims to their respective state governments and extend liability in situations virtually identical to those contained in the federal FCA. See Cal. Gov’t Code §§ 12651(a)(1) & (2); Del. Code Ann. tit. 6, §§ 1201(a)(1) & (2); D.C. Code §§ 2-308-14(a)(1) & (2); Fla. Stat. §§ 68.082(2)(a) & (b); Haw. Rev. Stat. §§ 661-21(a)(1) & (2); 740 Ill. Comp. Stat. 175/3(a)(1) & (2); Mass. Gen. Laws ch. 12, §§ 5B(1) & (2); Nev. Rev. Stat. §§ 357.040(1)(a) & (b); Tenn. Code Ann. §§ 71-5-182(a)(1)(A) & (B); Tex. Hum. Res. Code Ann. § 36.002; Va. Code Ann. §§ 8.01-216.3(A)(1) & (2).

¹⁴ See United States v. Karvelas, 360 F.3d 220, 225 (1st Cir. 2004) (citing United States v. Rivera, 55 F.3d 703, 709 (1st Cir. 1995)).

¹⁵ See id.

¹⁶ See id. (“Evidence of an actual false claim is ‘the *sine qua non* of a False Claims Act violation.’” (citing United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1311 (11th Cir. 2002))).

Government and on behalf of the private plaintiff himself.¹⁷ FCA actions brought by private individuals on behalf of the government are referred to as *qui tam* actions.¹⁸ In order to maintain a *qui tam* action, the plaintiff, or relator, must comply with the strict procedural requirements of the FCA.¹⁹ The private plaintiff must, for example, serve a copy of the complaint and disclose substantially all material evidence in the plaintiff's possession to the federal government.²⁰ Upon receipt of the complaint, the government may investigate the claims and may elect to intervene and take over prosecution of the action.²¹ The plaintiff's complaint remains under seal during the government's period of investigation.²² If the government chooses to intervene, the government itself conducts the civil action.²³ If the government chooses not to intervene in the matter, the private plaintiff has the right to continue to prosecute the case on behalf of the government.²⁴ If the *qui tam* action is successful, whether conducted by the government or the private plaintiff, the

¹⁷ See 31 U.S.C. § 3730(b). The various state statutes under which Plaintiff prosecutes this action similarly authorize private individuals to bring suit on behalf of the state government to whom a false claim was submitted. See Cal. Gov't Code § 12652(c); Del. Code Ann. tit. 6, § 1203(b); D.C. Code § 2-308-15(b); Fla. Stat. § 68.083(2); Haw. Rev. Stat. § 661-25; 740 Ill. Comp. Stat. 175/4(b); Mass. Gen. Laws ch. 12, § 5C(2); Nev. Rev. Stat. § 357.080; Tenn. Code Ann. § 71-5-183(b); Tex. Hum. Res. Code Ann. § 36.101; Va. Code Ann. § 8.01-216.5.

¹⁸ “‘*Qui tam*’ is an abbreviation for *quo tam pro domino rege quam pro seipso*, which literally means ‘he who as much for the king as for himself.’” Karvelas, 360 F.3d at 224 n.5 (internal quotation marks and citation omitted).

¹⁹ See 31 U.S.C. § 3730(b).

²⁰ Id. § (b)(2).

²¹ Id.

²² Id.

²³ Id. § (b)(4)(A).

²⁴ Id. § (b)(4)(B).

private plaintiff is entitled to a percentage of any financial award and, in some case, to reimbursement for reasonable expenses and attorneys' fees.²⁵

The basic policy underlying the *qui tam* provisions of the FCA is based on Congress' perceived necessity of enlisting private individuals to assist in discovering and prosecuting frauds committed against the government.²⁶ The *qui tam* provisions, accordingly, seek to encourage private individuals with knowledge of fraud committed against the government to come forward with their knowledge.²⁷ The authorization of private individuals to bring suit on behalf of the government, however, raises the threat of so-called "parasitic litigation."²⁸ Parasitic *qui tam* actions are those in which a plaintiff merely takes advantage of information already in the public domain and brings an opportunistic lawsuit based on the public information in the hopes of financial gain.²⁹ A parasitic lawsuit, in other words, feeds off already public information and has no independent basis of knowledge for its allegations. The history of the FCA's *qui tam* provisions exhibits the congressional struggle to balance the dual objectives of encouraging private individuals to disclose knowledge of fraud against the government and of prohibiting

²⁵ Id. § (d).

²⁶ See Karvelas, 360 F.3d at 224 (explaining that the FCA's *qui tam* provisions "were intended to aid the government in discovering fraud and abuse 'by unleashing a posse of *ad hoc* deputies to uncover and prosecute frauds against the government.'" (citing Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 784 (4th Cir. 1999))).

²⁷ See id.

²⁸ See, e.g., id. at 224-25; United States ex rel. S. Praver and Co. v. Fleet Bank of Maine, 24 F.3d 320, 326 (1st Cir. 1994).

²⁹ See, e.g., Karvelas, 360 F.3d at 224-25.

strictly parasitic lawsuits.³⁰

Since its initial passage in 1863, Congress has amended the FCA on several occasions.³¹ In 1943, Congress imposed a jurisdictional limitation on *qui tam* actions brought under the FCA.³² That limitation “precluded all *qui tam* actions ‘based on evidence or information the Government had when the action was brought.’”³³ The implicit rationale underlying this limitation was the assumption that if the government has knowledge of fraud before the plaintiff files his action, the government does not need the assistance of private individuals to discover such claims.³⁴ If the government does not bring its action based on these false claims, then “the government probably thought the suit meritless, and any private action was apt to be spurious, driven only by the lure of the [FCA]’s sizable damages.”³⁵

The ultimate result of the pre-1986 jurisdictional bar was a significant decrease in the use of the FCA’s *qui tam* provisions.³⁶ The pre-1986 limitation, furthermore, barred many

³⁰ See S. Prawer and Co., 24 F.3d at 326 (quoting United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 651 (D.C. Cir. 1994))

³¹ For a more detailed history of the FCA, see, for example, S. Prawer and Co., 24 F.3d at 324-26, and United States ex rel. LaValley v. First Nat’l Bank of Boston, 707 F. Supp. 1351, 1354-56 (D. Mass. 1988).

³² See S. Prawer and Co., 24 F.3d at 325.

³³ Id. (quoting 31 U.S.C. § 3730(b)(4) (amended by 31 U.S.C. § 3730(e)(4))).

³⁴ See United States ex rel. Cantekin v. Univ. of Pittsburgh, 192 F.3d 402, 408 (3d Cir. 1999).

³⁵ Id.

³⁶ S. Prawer and Co., 24 F.3d at 325.

meritorious and non-parasitic actions.³⁷ In 1986, Congress, fearing the growth of widespread and unchecked fraud against the government, set out to strike a new balance between encouraging private discovery and prosecution of fraud and preventing only those truly parasitic lawsuits.³⁸

Through the 1986 amendments, Congress sought to encourage more private enforcement actions.³⁹ Congress accomplished this goal by increasing financial awards to private plaintiffs, lowering a plaintiff's burden of proof, and allowing a private plaintiff to participate in actions in which the government elects to intervene.⁴⁰ In doing so, Congress also sought to maintain the prohibition against parasitic lawsuits.⁴¹ Congress, therefore, repealed the pre-1986 jurisdictional limitation, which barred all suits based on information already in the government's possession, and added a new jurisdictional provision to the FCA.⁴² This bar is called the "public disclosure bar."⁴³ By rejecting the pre-1986 jurisdictional bar and, in its place, enacting the current public

³⁷ See id. at 325-26; see also United States ex rel. State of Wisconsin v. Dean, 729 F.2d 1100 (7th Cir. 1984) (holding that, under the pre-1986 jurisdictional limitation, a claim by the state which discovered the fraud, investigated the fraud, disclosed the fraud to the federal government, and which was the original source of the information was jurisdictionally barred).

³⁸ See S. Praver and Co., 24 F.3d at 326 ("The history of the FCA *qui tam* provisions demonstrates repeated congressional efforts to walk a fine line between encouraging whistleblowing and discouraging opportunistic behavior. The 1986 amendments inevitably reflect the long process of trial and error that engendered them." (quoting Quinn, 14 F.3d at 651)).

³⁹ See id.

⁴⁰ See id.

⁴¹ See id.

⁴² See id.

⁴³ See id.

disclosure bar, Congress affirmatively “broadened the universe of potential plaintiffs.”⁴⁴

In rejecting the pre-1986 jurisdictional prohibition, Congress recognized that simply because the government possess information regarding fraud does not necessarily mean that the government is in a position to prosecute those claims.⁴⁵ As the Third Circuit Court of Appeals has explained:

(1) the government lacks the resources to investigate and prosecute all false claims even when the government has information revealing fraud; (2) a government official who is deemed to “have” the information may not recognize the connection between the information and a particular false claim; [and] (3) the official may have an interest in not bringing the fraud to light for a number of reasons, such as an interest in protecting the officials’s or the agency’s reputation⁴⁶

By enacting the 1986 amendments to the FCA, Congress affirmatively determined “[i]nformation that the government ‘has,’ but that was never publically disclosed does not bar a *qui tam* suit.”⁴⁷

3. The Public Disclosure Bar of the FCA

The FCA’s public disclosure jurisdictional bar states that:

No court shall have jurisdiction over an action under [the FCA] based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless . . . the person bringing the action is an original source of the information.⁴⁸

⁴⁴ See United States ex rel. LeBlanc v. Raytheon Co., 913 F.2d 17, 19 (1st Cir. 1990) (“LeBlanc I”).

⁴⁵ See Cantekin, 192 F.3d at 408.

⁴⁶ See id.

⁴⁷ See id.

⁴⁸ 31 U.S.C. 3730(e)(4)(A). The state statutes under which Plaintiff brings his complaint all contain virtually identical jurisdictional limitations. See Cal. Gov’t Code § 12652(d)(3)(A); Del. Code Ann. tit. 6, § 1206(c); D.C. Code § 2-308-15(c)(2)(A); Fla. Stat. § 68.087(3); Haw.

In assessing jurisdiction under the public disclosure bar, courts must examine three different issues. First, the court must determine whether the allegations of fraud in Plaintiff's complaint were "publically disclosed" before Plaintiff filed his action. Second, the court must examine whether Plaintiff's allegations are "based upon" that public disclosure. If the answer to either of these questions is "no," then the inquiry ends and this court has jurisdiction over Plaintiff's claims. If the answers to the first two questions are "yes," then the court must consider whether Plaintiff is an "original source" of the information in his complaint. If Plaintiff is an "original source," he may prosecute his *qui tam* action before this court.

a. Public Disclosure

The first issue for this court to consider is whether Defendants' voluntary disclosure of information to various government officials constitutes a "public disclosure" for purposes of the FCA's jurisdictional bar. Plaintiff argues that Defendants' disclosure does not rise to the level of a "public disclosure" because the information was not sufficiently public and because it was not disclosed in any one of the statutorily required manners.

Defendants made several voluntary disclosures to the government regarding the off-label marketing of Genotropin. First, on May 16, 2003, Defendants contacted senior officials at the FDA and the OIG to voluntarily disclose information related to the promotion of Genotropin. Defendants next wrote a letter to the FDA further detailing the Genotropin issues. On May 21, 2003, Defendants met with senior OIG officials to discuss Defendants' conduct related to

Rev. Stat. § 661-28; 740 Ill. Comp. Stat. 175/4(e)(4)(A); Mass. Gen. Laws ch. 12, § 5G(3); Nev. Rev. Stat. § 357.100(1); Tenn. Code Ann. § 71-5-183(e)(2)(A); Tex. Hum. Res. Code Ann. § 36.113(b); Va. Code Ann. § 8.01-216.8. This court, accordingly, will construe and analyze the state statutes' jurisdictional limitations consistent with the federal jurisdictional bar.

Genotropin. At this meeting, OIG agents informed Defendants that they had assigned an investigative agent to the matter. On June 3, 2003, Defendants sent a second letter to the OIG, a copy of which they sent to the DOJ, with additional details regarding their off-label Genotropin activities. Defendants here argue that these disclosures are sufficient to satisfy the “public disclosure” prong of the FCA’s jurisdictional bar.

In support of their argument, Defendants rely on United States ex rel. Mathews v. Bank of Farmington,⁴⁹ in which the Seventh Circuit Court of Appeals held that “[d]isclosure of information to a competent public official about an allege false claim against the government . . . [is a] public disclosure within the meaning of § 3730(e)(4)(A) when the disclosure is made to one who has managerial responsibility for the very claims being made.”⁵⁰ In so holding, the Mathews court first construed the term “public” as meaning ““authorized by, acting for, or representing the community.””⁵¹ Pursuant to that definition, the court reasoned that “[d]isclosure to an official authorized to act for or to represent the community on behalf of the government can be understood as public disclosure.”⁵² The Mathews court then examined the public policy underlying the *qui tam* provisions of the FCA.⁵³ The court noted that Congress, in passing the FCA, intended to encourage private citizens to come forward with information about false claims

⁴⁹ 166 F.3d 853 (7th Cir. 1999).

⁵⁰ Id. at 861.

⁵¹ Id. (quoting 12 Oxford English Dictionary 779 (2d ed. 1989)).

⁵² Id.

⁵³ See id.

submitted to the government.⁵⁴ The court then reasoned that Congress created these incentives to private individuals precisely to bring knowledge of fraud against the government to the attention of governmental authorities.⁵⁵ Once the government has the information, the court explained, the government can then take the necessary steps to investigate the allegations and remedy the situation through criminal prosecution, civil enforcement, settlement agreement, or other appropriate means.⁵⁶ The Seventh Circuit, therefore, held that:

Since a public official in his official capacity is authorized to act for and to represent the community, and since disclosure to the public official responsible for the claim effectuates the purpose of disclosure to the public at large, disclosure to a public official with direct responsibility for the claim in question of allegations or transaction upon which a qui tam claim is based constitutes [a] public disclosure within the meaning of [the statute].⁵⁷

The First Circuit Court of Appeals has not determined whether disclosure to a competent government official is enough, by itself, to constitute a public disclosure under the FCA. Few courts, in fact, have directly faced the issue. Those courts that have considered this question, however, have reached different conclusions.⁵⁸

This court rejects Defendants' argument and, in doing so, rejects the holding and rationale

⁵⁴ Id.

⁵⁵ Id.

⁵⁶ Id.

⁵⁷ Id.

⁵⁸ See id. at 859-62; United States ex rel. Brennan v. The Devereux Found., 2003 WL 151384, at *2 (E.D. Penn. 2003) (rejecting the holding of the Mathews case and finding that Defendants' notification of public officials did not constitute a public disclosure); United States ex rel. Cosens v. Yale-New Haven Hosp., 233 F. Supp. 2d 319, 327 (D. Conn. 2002) (adopting the Mathews approach without discussion).

of the Seventh Circuit in Mathews. This court, therefore, holds that disclosure to a competent government official, alone, does not, and in fact cannot, constitute a public disclosure under the FCA's public disclosure bar.⁵⁹ This holding is supported by the plain and ordinary definitions of the terms "public" and "disclosure," and the history and public policy underlying the post-1986 FCA.

The term "public" is ordinarily defined as something that is "exposed to general view . . . of, relating to, or affecting all the people or the whole area of a nation or state . . . [or] accessible to . . . all members of the community."⁶⁰ The term "disclosure" is ordinarily defined as something that is exposed to view or made known.⁶¹ A "public disclosure," therefore, is information that someone has exposed, made known, or at least made accessible, to all members of the community or, in other words, the general public.

The plain meaning and ordinary usage of the term "public" means the general public. The general public is an entity that is distinct, separate from, and independent of the government. Although the government does represent the general public, it does not become the public itself. The phrase "government official" is simply not interchangeable with the common conception of the general public. To construe the term "public" as a synonym for the government or for government officials is a linguistic stretch this court is unwilling to make.

The Mathews court's holding, and Defendants' argument, moreover, conflict with the

⁵⁹ See Brennan, 2003 WL 151384, at *2.

⁶⁰ Merriam-Webster's Collegiate Dictionary 941 (10th ed. 2000); see also Black's Law Dictionary, 1242 (7th ed. 1999) (defining "public" as "[r]elating or belonging to an entire community, state or nation [and] [o]pen or available for all to use, share, or enjoy").

⁶¹ Merriam-Webster's Collegiate Dictionary 330.

history of the FCA and the public policy underlying the 1986 amendments to the statute.⁶² In 1986, Congress rejected the FCA's pre-1986 jurisdictional limitation, which barred *qui tam* actions that were based on information that the government already had in its possession.⁶³ The Mathews court's rule, taken to its logical extreme, represents a reversion to and restatement of the previously rejected jurisdictional limitation. Under the Mathews holding, if the government has knowledge of a particular fraud that neither the government nor anyone else has disclosed to the general public, the government's possession alone may bar the plaintiff's action. Congress intended to avoid such a result when it rejected the "government possession" bar and substituted a jurisdictional bar of only those actions based on public disclosures of information. Information that the government possess, but that it does not disclose to the general public is not a public disclosure under the FCA.

The Mathews court's holding, and Defendants' arguments, also fail as a matter of policy. In the 1986 amendments to the FCA, Congress recognized that the government's possession of knowledge of fraud does not necessarily mean that the government will or is in a position to prosecute the fraud.⁶⁴ The government, most importantly, does not have the resources to investigate and prosecute all allegations of fraud brought to its attention and may have reasons to forego taking any action on the matter.⁶⁵ Congress had these precise concerns in mind in 1986

⁶² See S. Praver and Co., 24 F.3d at 326.

⁶³ See id. at 325-26.

⁶⁴ See Cantekin, 192 F.3d at 408.

⁶⁵ See id.

when it strengthened incentives for private individuals to bring *qui tam* actions.⁶⁶ Congress believed that *qui tam* actions were necessary to protect the government from widespread and sophisticated fraud and, therefore, enlarged the class of potential *qui tam* plaintiffs and relaxed the previous jurisdictional limitations.⁶⁷

Congress intended the public disclosure bar as a means to prohibit only those truly parasitic lawsuits.⁶⁸ Actions in which the disclosed information lies only in the hands of the government and the party who disclosed it to the government are not parasitic. When the private plaintiff does not, and cannot, know the information in the government's possession, there is no public host for the plaintiff to feed off. A plaintiff cannot take advantage of information in the public domain, when no such information exists. In other words, a parasite cannot exist without a host. The present case is the paradigm example of this principle.

Defendants' disclosures to the government also fail to satisfy the specific statutory criteria necessary for a public disclosure to invoke the FCA's jurisdictional bar. The public disclosure bar prohibits *qui tam* actions only when a plaintiff's allegations are "based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media"⁶⁹ The FCA's list of circumstances in which a qualified public disclosure

⁶⁶ See S. Praver and Co., 24 F.3d at 326.

⁶⁷ See id.

⁶⁸ See id.

⁶⁹ 31 U.S.C. § 3730(e)(4)(A).

can occur is exhaustive.⁷⁰ The public disclosure bar, therefore, only prohibits *qui tam* actions “based on information made available to the public during the course of a government hearing, investigation or audit or from the news media.”⁷¹

Defendants argue that their disclosures to OIG, FDA, and DOJ officials occurred during the course of an administrative investigation and, therefore, satisfy the statutory requirements. Defendants argument is mistaken. Defendants offer no evidence that an investigation took place before Plaintiff filed his complaint. Defendants state only that the OIG assigned an agent to the case. The assignment of an investigative agent to the case does not, in and of itself, show that a government investigation was ongoing. Defendants, furthermore, did not disclose any information during the course of any government investigation. Defendants disclosures to the government, at best, initiated the government’s investigation. The fatal flaw of Defendants’ argument, in any case, is that none of the information disclosed by Defendants to the government was ever exposed, by either Defendants or the government, to the general public.

This court holds that Defendants’ voluntary disclosure of information to various government officials does not constitute a public disclosure for the purposes of the FCA’s jurisdictional bar. The FCA, therefore, does not prohibit this court from exercising jurisdiction over Plaintiff’s *qui tam* action.

b. Based Upon

⁷⁰ See LeBlanc I, 913 F.2d at 20 (interpreting the plain language of the public disclosure bar to hold that “[i]t does not deny jurisdiction over actions based on disclosures other than those specified”); United States ex rel. O’Keeffe v. Sverdup Corp., 131 F. Supp. 2d 87, 91 (D. Mass. 2001).

⁷¹ LeBlanc I, 313 F.2d at 20.

Defendants next contend that Plaintiff's *qui tam* action is "based upon" its disclosures to the government. Plaintiff, of course, disagrees. For the purposes of this argument, this court will assume Defendants' disclosures were "public disclosures" and will proceed to consider whether Plaintiff's complaint is "based upon" those disclosures.

Courts that have considered the issue of how to determine whether an FCA action is "based upon" publically disclosed information have split into two different camps.⁷² The majority of courts have held that an action is "based upon" a public disclosure "when the supporting allegations are similar to or 'the *same as* those that have been publically disclosed . . . *regardless of where the relator obtained his information.*'"⁷³ The minority approach, on the other hand, interprets "based upon" as meaning "derived from."⁷⁴ These courts hold that an "action is 'based upon' a public disclosure of allegations only where the relator has actually derived from that

⁷² See Mathews, 166 F.3d at 863-64; United States ex rel. Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1348-49 (4th Cir. 1994); O'Keeffe, 131 F. Supp. 2d at 92; United States ex rel. LeBlanc v. Raytheon Co., 874 F. Supp. 35, 40 (D. Mass. 1995) ("LeBlanc II").

⁷³ O'Keeffe, 131 F. Supp. 2d at 92 (quoting United States ex rel. Doe v. John Doe Corp., 960 F.2d 318, 324 (2d Cir. 1992)) (emphasis in original); see also United States ex rel. Mistick PBT v. Housing Auth. of Pittsburgh, 186 F.3d 376, 386-88 (3d Cir. 1999) (holding that "a *qui tam* action is 'based upon' a qualifying disclosure if the disclosure sets out either the allegations advanced in the *qui tam* action or all of the essential elements of the *qui tam* action's claims"); United States ex rel. Biddle v. Bd. of Trustees of Leland Stanford Jr. Univ., 161 F.3d 533, 536-40 (9th Cir. 1998); United States ex rel. McKenzie v. Bellsouth Telecomms., Inc., 123 F.3d 935, 940-41 (6th Cir. 1997) (holding that "based upon" means similar to or supported by); Fed. Recovery Servs. v. United States, 72 F.3d 447, 451 (5th Cir. 1995); Cooper v. Blue Cross and Blue Shield of Florida, Inc., 19 F.3d 562, 566-67 (11th Cir. 1994); Quinn, 14 F.3d at 652-55 (D.C. Cir.); United States ex rel. Precision Co. v. Koch Indus. Inc., 971 F.2d 548, 552-53 (10th Cir. 1992).

⁷⁴ See Mathews, 166 F.3d at 863 (7th Cir.); Siller, 21 F.3d at 1348 (4th Cir.); LeBlanc II, 874 F. Supp. at 40-41 (D. Mass); LaValley, 707 F. Supp. at 1366-67 (D. Mass).

disclosure the allegations upon which his *qui tam* action is based.”⁷⁵ The First Circuit has not yet entered this debate.⁷⁶ Three courts in this district have faced the issue and have split two to one in favor of the minority rule.⁷⁷

This court adopts the minority rule and holds that a *qui tam* action is “based upon” a public disclosure only when the allegations supporting the action are “derived from” the public disclosure. This interpretation of “based upon” is amply supported by the plain language of the statute and the ordinary meaning of the phrase “based upon.”⁷⁸ “To ‘base upon’ means to ‘use as a basis for.’”⁷⁹ The common and ordinary definition of the phrase “based upon” is synonymous with “derived from,” which means “to take, receive, or obtain . . . from a specific source.”⁸⁰ The phrase “based upon,” however, does not correspond with, nor is it synonymous with, the phrases “similar to” or “same as.”⁸¹ Such a linguistic leap is not supported by the ordinary definition or usage of the phrase “based upon.” Using the plain meanings of these phrases, information that is identical to a public disclosure is not necessarily based upon or derived from that disclosure. The

⁷⁵ Siller, 21 F.3d at 1348.

⁷⁶ See O’Keeffe, 131 F. Supp. 2d at 92.

⁷⁷ See id. at 92-93 (adopting the majority view that “based upon” means “similar to” or the “same as”); LeBlanc II, 874 F. Supp. at 41 (suggesting the court’s agreement with the minority position); LaValley, 707 F. Supp. at 1366-67 (holding that plaintiff’s knowledge was not based upon the public disclosures because plaintiff’s knowledge was independent of those disclosures).

⁷⁸ See Mathews, 166 F.3d at 863; Siller, 21 F.3d at 1348; see also Mistick, 186 F.3d at 395-97 (Becker, C.J., dissenting).

⁷⁹ Siller, 21 F.3d at 1348 (quoting Webster’s Third New International Dictionary 180 (1986)).

⁸⁰ Merriam-Webster’s Collegiate Dictionary 311.

⁸¹ See Mathews, 166 F.3d at 863.

minority view's interpretation, therefore, is more consistent with the plain language of the statute and the plain and ordinary meaning of the words therein.⁸²

In addition to giving effect to the plain and unambiguous language contained in the public disclosure bar, the minority position better serves the policies behind the FCA.⁸³ With the 1986 amendments to the FCA, Congress attempted to strike a balance between encouraging private individuals with knowledge of fraud to disclose that information and prohibiting parasitic actions where an opportunistic plaintiff takes advantage of information already in the public domain.⁸⁴ *Qui tam* actions that contain allegations similar, or even identical, to publically disclosed information are not necessarily parasitic.⁸⁵ Such actions are parasitic only when the plaintiff's allegations are actually derived from, or leached off, the public disclosures.⁸⁶ The majority view's interpretation strikes too broadly and effectively prohibits actions that have not "fed off" public disclosures and are thus not parasitic.⁸⁷ The "derived from" interpretation, on the other hand, serves to filter out only those *qui tam* actions which are truly parasitic.

The primary objection to the "derived from" interpretation of the "based upon" prong is

⁸² See id.; Siller, 21 F.3d at 1348; LeBlanc II, 874 F. Supp. at 41.

⁸³ See Mathews, 166 F.3d at 863; Siller, 21 F.3d at 1348; see also Mistick, 186 F.3d at 398-402 (Becker, C.J., dissenting).

⁸⁴ See Mistick, 186 F.3d at 400 (Becker, C.J., dissenting) (citing S. Rep. No. 99-345, at 1-8, 23-24 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5266-73, 5288-89); S. Praver and Co., 24 F.3d at 326.

⁸⁵ See Mathews, 166 F.3d at 863; Siller, 21 F.3d at 1348.

⁸⁶ See Mathews, 166 F.3d at 863; Siller, 21 F.3d at 1348.

⁸⁷ See Mathews, 166 F.3d at 863; Siller, 21 F.3d at 1348.

that this interpretation renders the “original source” exception superfluous and redundant.⁸⁸ The “original source” exception allows a plaintiff to prosecute a *qui tam* action that is based upon a public disclosure when that plaintiff has direct and independent knowledge of the fraud.⁸⁹ Courts in the majority camp contend that the “derived from” standard and the “independent knowledge” standard conflate into the same analytical determination.⁹⁰ That argument posits that any allegations not derived from public disclosures are necessarily the product of the plaintiff’s independent knowledge.⁹¹ These plaintiffs, therefore, will always succeed on the “based upon” prong of the public disclosure bar, and the original source exception becomes meaningless as the analysis will never reach that stage.⁹²

The confluence of the “based upon” and the “original source” prong may flow from Congress’ drafting or from the complex and overlapping nature of the 1986 amendments to the FCA.⁹³ This possibility, however, does not provide a basis for discarding the plain meaning of the phrase “based upon” for a judicially engrafted substitute which has no linguistic or grammatical connection with the actual and unambiguous congressional language used in the public disclosure

⁸⁸ See, e.g., Mistick, 186 F.3d at 385-86; Biddle, 161 F.3d at 538; O’Keeffe, 131 F. Supp. 2d at 93.

⁸⁹ See 31 U.S.C. §§ 3730(e)(4)(A) & (B).

⁹⁰ See, e.g., Mistick, 186 F.3d at 385-86; Biddle, 161 F.3d at 538.

⁹¹ See, e.g., Mistick, 186 F.3d at 385-86; Biddle, 161 F.3d at 538.

⁹² See, e.g., Mistick, 186 F.3d at 385-86; Biddle, 161 F.3d at 538.

⁹³ See Mistick, 186 F.3d at 399 (Becker, C.J., dissenting).

bar.⁹⁴ The burden falls on Congress, not the judiciary, to correct perceived errors in statutory texts.

This court, furthermore, is not convinced that the “derived from” interpretation renders the “original source” exception completely superfluous. The exact boundaries of the “derived from” standard are not fully delineated. For instance, must a plaintiff’s complaint derive entirely from the public disclosure? Or does the plaintiff’s complaint need only derive a portion of its information from the public disclosure? If so, how much is sufficient to constitute a complaint “based upon” that public disclosure? Is it enough that plaintiff’s basic framework of knowledge is derived from the public disclosure, even when all of his specific factual allegations are derived through his own individual investigations? There also exists the corresponding question of how much independent knowledge is sufficient for a plaintiff to qualify as an original source? These questions are not easy questions to answer,⁹⁵ and this court need not answer them here.

Depending on the answers to these questions, there may be cases in which enough of the plaintiff’s complaint is derived from public disclosures to justify finding the complaint to be “based upon” those disclosures, but where the plaintiff has sufficient independent knowledge of other essential elements of his claim to qualify as an original source.⁹⁶ There may also exist cases in which the public disclosures are so widespread as to make it extremely difficult, or impossible, for

⁹⁴ See id. (“While it is entirely possible that Congress, in enacting the complex and overlapping amendments to the FCA in 1986, failed to foresee that its new ‘based upon’ language could render the ‘original source’ exception superfluous, this provides scant basis for our failure to give effect to plain congressional language.”).

⁹⁵ See id. at 399 (asking similar questions about the boundaries of the “based upon” and “original source” prongs of the public disclosure bar).

⁹⁶ See id.

the plaintiff to successfully disprove a causal link between those disclosures and his action.⁹⁷ If the plaintiff had prior direct knowledge of the publically disclosed fraud, but failed to file suit until after the disclosure, the plaintiff may have less difficulty pointing to his direct and independent source of information and thus establishing himself as an original source.⁹⁸

In any case, this court holds that a *qui tam* action is “based upon” a public disclosure when the action is “derived from” information contained in that disclosure. In this case, Plaintiff’s complaint is not derived from Defendants’ disclosures to the government. Plaintiff’s complaint derives from his own independent investigation of Defendants’ off-label marketing scheme, and from his personal knowledge of Defendants’ activities. Plaintiff, furthermore, had no knowledge of Defendants’ disclosures to the various government officials. Defendants’ disclosures were made during the course of three confidential letters and one private meeting with government officials. The only people who knew the content of Defendants’ disclosures were the representatives of Defendants who made the disclosures and the government who received them. Neither party ever disclosed that information to the general public or to Plaintiff. Even assuming that Defendants’ conduct constituted a public disclosure, Plaintiff’s *qui tam* complaint is not “based upon” that disclosure. Plaintiff claims, therefore, are not jurisdictionally barred by the FCA’s public disclosure bar.

c. Original Source

Defendants next argue that Plaintiff is not an “original source” of the information in his complaint. Defendants argue that Plaintiff has failed to sufficiently allege that he is an original

⁹⁷ Id. at 400.

⁹⁸ Id.

source and that, nevertheless, Plaintiff has failed to establish that he disclosed his information to the government before Defendants made their disclosure. Plaintiff disagrees and argues that the original source provision does not require an original source to disclose its information to the government before the public disclosure occurs. For completeness, this court now assumes that Defendants' disclosure to the government was a public disclosure and that Plaintiff's complaint is based on that disclosure, and will consider whether Plaintiff is an "original source" of the information supporting his complaint.

Under the public disclosure bar, a plaintiff may bring a *qui tam* action that is based upon a public disclosure if the plaintiff is "an original source of the information."⁹⁹ An "original source" is defined as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information."¹⁰⁰ This statutory definition requires that an original source draft his or her complaint from both "direct" and "independent" knowledge of the fraudulent conduct.¹⁰¹ A *qui tam* plaintiff's knowledge is considered direct when the plaintiff acquires it "through her own efforts without an intervening agency."¹⁰² A plaintiff's knowledge is "independent" if it is not dependant upon information contained in any public disclosures.¹⁰³ The traditional "original source" is an insider

⁹⁹ 31 U.S.C. § 3730(e)(4)(A).

¹⁰⁰ Id. § 3730(e)(4)(B).

¹⁰¹ See id.

¹⁰² O'Keefe, 131 F. Supp. 2d at 93 (citing Quinn, 14 F.3d at 656).

¹⁰³ See id.

whistleblower, whose knowledge derives from his or her own individual investigatory efforts conducted prior to any public disclosure of the information.¹⁰⁴

Defendants argue that for a *qui tam* plaintiff to qualify as an original source, the plaintiff must also disclose his or her information to the government *before* any public disclosure occurs. Defendants additional temporal factor has support in courts of appeal outside of this circuit.¹⁰⁵ There are, in fact, three different approaches that courts have taken in defining the necessary elements of the original source exception.¹⁰⁶ The First Circuit Court of Appeals has not had an occasion to evaluate the different approaches.

The first approach to the original source provision holds that the statute requires only that a *qui tam* plaintiff have direct and independent knowledge of the facts alleged in his or her complaint and that the Plaintiff disclose that information to the government before filing his action.¹⁰⁷ This approach relies primarily on the plain language of the FCA.¹⁰⁸ Courts that have adopted a second approach have added the requirement that an original source “must have directly or indirectly been a source to the entity that publically disclosed the allegations on which a

¹⁰⁴ See id.

¹⁰⁵ See, e.g., McKenzie, 123 F.3d at 942-43; United States ex rel. Findley v. FPC-Boron Employees’ Club, 105 F.3d 675, 690-91 (D.C. Cir. 1997).

¹⁰⁶ See McKenzie, 123 F.3d at 941-43.

¹⁰⁷ See United States ex rel. Fine v. Advanced Sciences, Inc., 99 F.3d 1000, 1006-07 (10th Cir. 1996); Siller, 21 F.3d at 1355 (6th Cir.); Cooper, 19 F.3d at 568 & n.13 (11th Cir.); United States ex rel. Stinson v. Prudential Ins. Co., 944 F.2d 1149, 1160 (3d Cir. 1990); United States ex rel. Houck v. Folding Carton Admin. Comm., 881 F.2d 494, 504-05 (7th Cir. 1989); O’Keeffe, 131 F. Supp. 2d at 93 (D. Mass.).

¹⁰⁸ See Cooper, 19 F.3d at 568 n.13.

suit is based.”¹⁰⁹ Finally, the third approach, which Defendants argue in this case, requires that an original source inform the government of his or her allegations before those allegations are otherwise publically disclosed.¹¹⁰ Courts that have adopted this approach have reasoned that only a true whistleblower needs incentive to bring a *qui tam* action.¹¹¹ A true whistleblower, these courts argue, is the person who initially alerts the government to the alleged fraud.¹¹² Once the fraud is in the public domain – where it is presumably available to the government – whistleblowers are unnecessary, and to allow *qui tam* actions to go forward in these cases does not serve the purpose of the FCA.¹¹³

After consideration of the above approaches to the original source provision, this court adopts the first approach, and holds that, in order to qualify as an original source, a *qui tam* plaintiff need only have direct and independent knowledge of the alleged fraud and have disclosed that information to the government prior to bringing his or her *qui tam* action. The unambiguous language of the FCA dictates this court’s interpretation.¹¹⁴ Nothing in the plain language of the public disclosure bar or in the statutory definition of “original source” supports the additional

¹⁰⁹ United States ex rel. Dick v. Long Island Lighting Co., 912 F.2d 13, 16 (2d Cir. 1990); see also Wang v. FMC Corp., 975 F.2d 1412, 1418 (9th Cir. 1992).

¹¹⁰ See McKenzie, 123 F.3d at 942; Findley, 105 F.3d at 690.

¹¹¹ See McKenzie, 123 F.3d at 942; Findley, 105 F.3d at 691.

¹¹² See McKenzie, 123 F.3d at 942; Findley, 105 F.3d at 691.

¹¹³ See McKenzie, 123 F.3d at 942-43; Findley, 105 F.3d at 691.

¹¹⁴ See Siller, 21 F.3d at 1355 (“In addition to having direct and independent knowledge of the information on which the allegations in the public disclosure is based, he need only provide his information to the government before instituting his *qui tam* action, as the provision unambiguously states.”).

requirement that an original source must also be a source of information to the entity which publically discloses that information.¹¹⁵ Similarly, the statutory language does not even suggest that an original source must disclose his or her knowledge to the government prior to public disclosure of similar information.¹¹⁶ Although the courts that adopt these approaches may think these additional requirements better serve the purpose of the FCA, the text of the statute simply does not support either additional requirement.

In the face of unambiguous statutory language, it is inappropriate to look beyond the text of the FCA's original source provision.¹¹⁷ That text requires that an original source: (1) have independent knowledge of the fraud alleged in his complaint; (2) have direct knowledge of that fraud; and (3) have disclosed his information to the government before filing suit.¹¹⁸ No other requirements are even suggested by the statutory text.

In this case, Plaintiff qualifies as an original source. In his position as vice president of Pharmacia's Endocrine Care Unit, Plaintiff personally uncovered evidence of Pharmacia's unlawful conduct. In response to his discoveries, Plaintiff diligently monitored the marketing, distribution, and sales of Genotropin, and repeatedly brought the issues to the attention of his superiors both at Pharmacia and at Pfizer. Defendants, in fact, began their internal investigations,

¹¹⁵ See id.

¹¹⁶ See, e.g., Cooper 19 F.3d at 568 n.13.

¹¹⁷ See Lamie v. United States, 540 U.S. 526, 534 (2004) ("It is well established that 'when the statute's language is plain, the sole function of the courts-at least where the disposition required by the text is not absurd-is to enforce it according to its terms.'" (quoting Hartford Underwriters Ins. Co. v. Union Planters Bank, N. A., 530 U.S. 1, 6 (2000))); Siller, 21 F.3d at 1355.

¹¹⁸ See 31 U.S.C. § 3730(e)(4)(B).

ultimately producing the voluntary disclosure to the government, only after Plaintiff came forward with the results of his personal investigation. Plaintiff's knowledge regarding Defendants' off-label marketing of Genotropin resulted from his direct discovery of information through his personal efforts and investigation. Plaintiff, furthermore, was not a party to Defendants' private meetings with government officials and he never read Defendants' letters to the government. Plaintiff did not have knowledge of the content of Defendants' disclosures and, therefore, his information cannot be dependant on those disclosures. Plaintiff's knowledge is, accordingly, both direct and independent. Finally, Plaintiff did voluntarily disclose his information to the government before he filed his action. Plaintiff informed the United States Attorney of his allegations and later sent the United States Attorney a copy of his complaint, all before he filed his *qui tam* action. Plaintiff, accordingly, is an original source of the information alleged in his complaint.¹¹⁹

4. Conclusion: This Court has Subject Matter Jurisdiction over Plaintiff's Claims

This court finds that Plaintiff's complaint is not jurisdictionally barred by the FCA's public disclosure bar. Defendants' disclosure of information to government officials is not a "public disclosure" under the FCA's public disclosure bar. Even assuming that Defendants' disclosures to the government does constitute a public disclosure, Plaintiff's complaint is not "based upon" that disclosure. In any case, Plaintiff qualifies as an original source as it is unambiguously defined in

¹¹⁹ Even if this court adopted the second approach to the original source provision, which requires the original source to have directly or indirectly provided the entity that publically discloses the information with that information, Plaintiff would still qualify as an original source. Through his employment with Defendants, Plaintiff discovered the Genotropin fraud and disclosed his findings to his superiors within Pharmacia and Pfizer. Plaintiff's actions, in fact, initiated Defendants' internal investigation and ultimately led to Defendants' voluntary disclosure to government officials.

the FCA. This court, therefore, has jurisdiction over Plaintiff's FCA claim and his accompanying state claims.¹²⁰

B. Fraud: The Heightened Pleading Requirement of Rule 9(b)

Defendants next challenge Plaintiff's claims as being deficiently plead under Rule 9(b) of the Federal Rules of Civil Procedure. Defendants argue that Plaintiff has failed to plead fraud with sufficient particularity. Plaintiff opposes Defendants' motion, arguing that the court should relax the heightened pleading requirements of Rule 9(b) and that, notwithstanding relaxation of the standard, his complaint satisfies the heightened pleading rules. Having found that this court has jurisdiction to hear Plaintiff's case, this court will now evaluate the sufficiency of Plaintiff's pleadings.

Rule 9(b) of the Federal Rules of Civil Procedure requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity."¹²¹ This heightened pleading standard require a plaintiff to set forth with particularity in his or her complaint, the "'who, what, when, where and how of the alleged fraud."¹²² Under Rule 9(b), a

¹²⁰ Having found jurisdiction to hear Plaintiff's federal FCA claim, this court finds that it has similar jurisdiction to hear Plaintiff's state claims, all of which are based on statutes with jurisdictional bars virtually identical to the FCA's public disclosure bar. See Cal. Gov't Code § 12652(d)(3)(A); Del. Code Ann. tit. 6, § 1206(c); D.C. Code § 2-308-15(c)(2)(A); Fla. Stat. § 68.087(3); Haw. Rev. Stat. § 661-28; 740 Ill. Comp. Stat.175/4(e)(4)(A); Mass. Gen. Laws ch. 12, § 5G(3); Nev. Rev. Stat. § 357.100(1); Tenn. Code Ann. § 71-5-183(e)(2)(A); Tex. Hum. Res. Code Ann. § 36.113(b); Va. Code Ann. § 8.01-216.8.

¹²¹ Fed. R. Civ. P. 9(b).

¹²² United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (quoting United States ex rel. Walsh v. Eastman Kodak Co., 98 F. Supp. 2d 141, 147 (D. Mass. 2000) (internal quotations omitted)); see also Arruda v. Sears, Roebuck & Co., 310 F.3d 13, 18-19 (1st Cir. 2002).

plaintiff must allege with specificity the circumstances of the fraud, but need not plead all of the evidence or facts that support those allegations.¹²³

The heightened pleading requirements of Rule 9(b) apply to fraud claims brought under the FCA.¹²⁴ As all of Plaintiff's state claims allege fraud under statutes similar to the FCA,¹²⁵ the requirements of Rule 9(b) apply equally to Plaintiff's state claims.¹²⁶ In any claim brought under the FCA, the plaintiff must specify the "time, place, and content of the alleged false or fraudulent representations."¹²⁷ The fundamental element of a FCA allegation is a false or fraudulent claim that is submitted to the government for payment.¹²⁸ At a minimum, therefore, the heightened pleading standard requires a plaintiff to "provide details that identify particular false claims for payment that were submitted to the government."¹²⁹ An FCA allegation must state with particularity the circumstances of the underlying schemes, misconduct, and wrongful activities,

¹²³ See id. at 46-47 (citing Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1298, at 625-26 (2d ed. 1990)).

¹²⁴ Karvelas, 360 F.3d at 228.

¹²⁵ See Cal. Gov't Code §§ 12651(a)(1) & (2); Del. Code Ann. tit. 6, §§ 1201(a)(1) & (2); D.C. Code §§ 2-308-14(a)(1) & (2); Fla. Stat. §§ 68.082(2)(a) & (b); Haw. Rev. Stat. §§ 661-21(a)(1) & (2); 740 Ill. Comp. Stat. 175/3(a)(1) & (2); Mass. Gen. Laws ch. 12, §§ 5B(1) & (2); Nev. Rev. Stat. §§ 357.040(1)(a) & (b); Tenn. Code Ann. §§ 71-5-182(a)(1)(A) & (B); Tex. Hum. Res. Code Ann. § 36.002; Va. Code Ann. §§ 8.01-216.3(A)(1) & (2).

¹²⁶ Cf. Karvelas, 360 F.3d at 227-28 (holding that the federal False Claims Act is an anti-fraud statute to which Rule 9(b)'s heightened pleading requirements apply).

¹²⁷ Id. at 232.

¹²⁸ See id. at 225 ("Evidence of an actual false claim is 'the *sin qua non* of a False Claims Act violation.'" (quoting Clausen, 290 F.3d at 1311)).

¹²⁹ Id. at 232.

which allegedly resulted in the submission of fraudulent claims.¹³⁰ Pleadings that merely state the procedural framework of the alleged fraud, however, “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.”¹³¹ A plaintiff, in other words, must identify with particularity “actual false claims that the defendants submitted to the government.”¹³²

Courts may relax the strict heightened pleading requirements in certain circumstances.¹³³ In the context of Rule 9(b), relaxation of the pleading standard means that a court will give the plaintiff the opportunity “to plead generally at the outset and then later amend the complaint, filling in the blanks through discovery.”¹³⁴ Relaxation of the standard is appropriate in limited circumstances, such as where “the opposing party is the only practical source for discovering the specific facts supporting a pleader’s conclusion.”¹³⁵ The First Circuit Court of Appeals, however, has rejected the application of a relaxed pleading standard to fraud claims brought under

¹³⁰ See id.

¹³¹ Id.; see also Walsh, 98 F. Supp. 2d at 147 (“Relator’s First Amended Complaint, in essence, sets out a methodology by which the vendors might have produced false invoices, which in turn could have led to false claims. Without citing a single false claim arising from an allegedly false invoice, Relator has not met even a bare-bones Rule 9(b) test.”).

¹³² Karvelas, 360 F.3d at 235.

¹³³ See, e.g., id. at 228-31; Franklin, 147 F. Supp. 2d at 47.

¹³⁴ Karvelas, 360 F.3d at 228-29.

¹³⁵ Id. at 229 (quoting Boston & Maine Corp. v. Hampton, 987 F.2d 855, 866 (1st Cir. 1993)).

the FCA.¹³⁶ In doing so, the court held that “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.”¹³⁷

In this case, Plaintiff argues that relaxation of the pleading standard is appropriate because of the exceedingly complex nature and extensive time-line of Defendants’ fraudulent activities. The First Circuit has not adopted, or for that matter rejected, an exception to the heightened pleading requirements for complex, numerous, and lengthy schemes.¹³⁸ The court has, however, suggested its hostility to such an exception.¹³⁹ In discussing the issue, the First Circuit noted that it could not “find any basis in the history or requirements of the FCA, or in most of the precedents, for relieving [plaintiff] of his burden of pleading fraud with particularity because he chose to allege sixteen complex schemes.”¹⁴⁰ The court also reasoned that “allowing a relator to plead generally at the outset and amend the complaint at the 12(b)(6) stage after discovery would be at odds with the FCA’s procedures for filing a *qui tam* action and its protections for the government (which is, of course, the real party in interest in a *qui tam* action).”¹⁴¹ Although the

¹³⁶ See id. at 231.

¹³⁷ Id.

¹³⁸ See id. at 231 n.14 (stating that the court has not yet adopted a “complex scheme” exception to the heightened pleading requirements of Rule 9(b)).

¹³⁹ See id.

¹⁴⁰ Id. (citing Yuhasz v. Brush Wellman, Inc., 341 F.3d 559, 564 (6th Cir. 2003) (“[A] plaintiff should not be able to avoid the specificity requirements of Rule 9(b) by relying upon the complexity of the edifice which he created.” (citation and quotation marks omitted))).

¹⁴¹ Id. at 231.

court did not specifically reject the application of a complexity exception to Rule 9(b), the First Circuit's reasoning indicates to this court that such an exception is inappropriate in this case.

To the extent that Plaintiff relies upon United States ex rel. Franklin v. Parke-Davis,¹⁴² his reliance is misplaced. In Franklin, the district court relaxed the heightened pleading requirements, finding that although the plaintiff failed to identify specific off-label prescriptions for Medicaid patients, the plaintiff did not have reasonable pre-discovery access to such patient specific information.¹⁴³ The Franklin case, however, was decided before the First Circuit rejected any relaxation of the requirements of Rule 9(b) in FCA claims and before the First Circuit indicated its hostility to the complexity exception to the pleading requirements. In light of the more recent First Circuit ruling, this court finds that both relaxation of the heightened pleading requirements and recognition of a complexity exception to Rule 9(b) are inappropriate in this case.¹⁴⁴ Plaintiff, therefore, must satisfy the strict heightened pleading requirements of Rule 9(b) with the allegations of his complaint as filed.

Plaintiff's complaint fails to satisfy the strict pleading requirements of Rule 9(b). Plaintiff's complaint alleges, in great detail, the framework of Defendants' illegal marketing, promotion, and distribution of Genotropin. Plaintiff's complaint discusses bribes, kickbacks, and other financial incentives given from Defendants to various drug distributors and physicians. Plaintiff's complaint, furthermore, alleges very serious violations of federal regulations regarding the

¹⁴² 147 F. Supp. 2d 39 (D. Mass. 2001).

¹⁴³ Id. at 49.

¹⁴⁴ See Karvelas, 360 F.3d at 232 & n.14 (holding that "a qui tam relator may not present general allegations in lieu of details of actual false claims in the hope that such details will emerge through subsequent discovery").

marketing, distribution, and sale of pharmaceuticals. Liability under the FCA, however, does not rest on violations of federal law or regulations.¹⁴⁵ Instead, FCA liability flows solely from the existence of a false claim for payment that has been submitted to the government.¹⁴⁶ To satisfy the pleading requirements of Rule 9(b), therefore, Plaintiff must identify actual false claims submitted to the government.¹⁴⁷

Plaintiff's complaint fails to identify one actual false claim that was submitted to the government for the reimbursement of an off-label prescription of Genotropin. Plaintiff instead speculates that Defendants' marketing activities must have caused physicians to prescribe Genotropin for off-label uses and that some of these prescriptions were inevitably reimbursed by federal and state government health care programs. The existence of conduct which may lead to false claims does not satisfy the heightened pleading requirements.¹⁴⁸ No matter how likely the existence of false claims, this court cannot speculate that such claims inevitably flowed from Defendants' activities.¹⁴⁹ Without specific details of even one actual false claim that was submitted to any federal or state government, Plaintiff fails to satisfy Rule 9(b)'s heightened

¹⁴⁵ See id. at 234.

¹⁴⁶ See id.

¹⁴⁷ See id.

¹⁴⁸ See id. at 235; Walsh, 98 F. Supp. 2d at 147 (holding that the plaintiff failed to satisfy Rule 9(b) when his complaint did not cite one single false claim arising out of the defendants alleged methodology that may have produced false claim invoices).

¹⁴⁹ See Karvelas, 360 F.3d at 235 (“Karvelas does describe the procedures allegedly used by the hospital to submit false claims to the United States, the alleged existence of such procedures does not permit us to speculate that false claims were in fact submitted.”); Walsh, 98 F. Supp. 2d at 147.

pleading requirements on all of his federal and state fraud claims. As Plaintiff has failed to plead fraud with sufficient particularity, Plaintiff's complaint is dismissed.

C. Plaintiff's Motion for Leave to Take Jurisdictional Discovery

In response to Defendants' Motion to Dismiss, Plaintiff has moved for leave to take jurisdictional discovery and to stay this court's ruling on Defendants' Motion to Dismiss pending completion of this discovery. Plaintiff argues, in short, that Defendants' Motion to Dismiss is based substantially on evidence outside the four corners of Plaintiff's complaint. Plaintiff, therefore, contends that he cannot adequately oppose Defendants' motion without discovery on the jurisdictional issues presented in Defendants' motion. As stated above, this court finds that the facts currently before the court establish that this court does in fact have subject matter jurisdiction over Plaintiff's *qui tam* action. It is therefore unnecessary for Plaintiff to conduct any additional discovery on the issue and Plaintiff's motion is moot. Plaintiff's Motion for Leave to Take Jurisdictional Discovery and to Stay Ruling on Defendants' Motion to Dismiss Pending Completion of Discovery is accordingly DENIED.

Conclusion

In conclusion, this court holds that the public disclosure bar of the False Claims Act does not bar this court's jurisdiction over the instant case. In asserting subject matter jurisdiction, this court, however, finds that Plaintiff has failed to plead his federal and state fraud claims with sufficient particularity to satisfy Rule 9(b) of the Federal Rules of Civil Procedure. For these reasons, Defendants' Motion to Dismiss is ALLOWED. Having found subject matter jurisdiction on the facts currently before the court, Plaintiff's Motion for Leave to Take Jurisdictional Discovery and to Stay Ruling on Defendants' Motion to Dismiss Pending Completion of

Discovery is DENIED. Plaintiff's complaint is hereby dismissed in its entirety.

AN ORDER WILL ISSUE.

/s/ Joseph L. Tauro
United States District Judge

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1:03-cv-11084-JLT United States of America v. Pfizer, Inc. et al
Joseph L. Tauro, presiding
Date filed: 06/05/2003 Date of last filing: 07/25/2006

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