

**UNITED STATES DISTRICT COURT
DISTRICT OF MAINE**

UNITED STATES OF AMERICA *ex rel.*)
PAUL P. McDERMOTT,)
)
Plaintiff)
)
v.)
)
GENENTECH, INC., et al.,)
)
Defendants)

Docket No. 05-147-P-C

RECOMMENDED DECISION ON MOTIONS TO DISMISS

The defendants, Genentech, Inc. and Biogen Idec, Inc. (“Biogen”), move separately to dismiss all claims asserted against them in this *qui tam* action. I recommend that Biogen’s motion be granted and Genentech’s motion be granted in part.¹

I. Applicable Legal Standards

The motions to dismiss invoke Fed. R. Civ. P. 9, 12(b)(1) and 12(b)(6). Genentech, Inc.’s Motion to Dismiss First Amended Complaint, etc. (“Genentech Motion”) (Docket No. 60) at 1; Biogen Idec, Inc.’s Motion to Dismiss the First Amended Complaint, etc. (“Biogen Motion”) (Docket No. 63) at 1.

Rule 9 imposes a heightened pleading standard with regard to certain types of factual allegations, including allegations of fraud. Where fraud is a necessary element of a claim, “the circumstances constituting fraud . . . shall be stated with particularity.” Fed. R. Civ. P. 9(b). Thus, unless a legal right exists for a claimant to conduct discovery and amend his or her allegations prior to dismissal, a fraud

¹ McDermott has requested oral argument on the motions. Relator’s Memorandum of Law in Opposition to Genentech, Inc.’s and Biogen-Idec, Inc.’s Motions to Dismiss, etc. (“Opposition”) (Docket No. 68) at cover. The parties’ papers provide a sufficient basis on which to decide the pending motions. The request for oral argument is accordingly denied.

claimant must be prepared at the very commencement of his or her case to present allegations of fraud that are specific with respect to time, place and content.

Freeport Transit, Inc. v. McNulty, 239 F. Supp.2d 102, 108-09 (D. Me. 2002).

When a defendant moves to dismiss pursuant to Rule 12(b)(1), the plaintiff has the burden of demonstrating that the court has jurisdiction over the subject matter. *Lundquist v. Precision Valley Aviation, Inc.*, 946 F.2d 8, 10 (1st Cir. 1991); *Lord v. Casco Bay Weekly, Inc.*, 789 F. Supp. 32, 33 (D. Me. 1992). The court does not draw inferences favorable to the pleader. *Hogdon v. United States*, 919 F. Supp. 37, 38 (D. Me. 1996). For the purposes of a motion to dismiss under Rule 12(b)(1) only, the moving party may use affidavits and other matter to support the motion. The plaintiff may establish the actual existence of subject-matter jurisdiction through extra-pleading material. 5A C. Wright & A. Miller, *Federal Practice and Procedure* § 1350 at 213 (2d ed. 1990); see *Hawes v. Club Ecuestre el Comandante*, 598 F.2d 698, 699 (1st Cir. 1979) (question of jurisdiction decided on basis of answers to interrogatories, deposition statements and an affidavit).

“[I]n ruling on a motion to dismiss [under Rule 12(b)(6)], a court must accept as true all the factual allegations in the complaint and construe all reasonable inferences in favor of the plaintiff[.]” *Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co.*, 267 F.3d 30, 33 (1st Cir. 2001). The defendants are entitled to dismissal for failure to state a claim only if “it appears to a certainty that the plaintiff would be unable to recover under any set of facts.” *State St. Bank & Trust Co. v. Denman Tire Corp.*, 240 F.3d 83, 87 (1st Cir. 2001); see also *Wall v. Dion*, 257 F. Supp.2d 316, 318 (D. Me. 2003).

II. Factual Background

The operative complaint includes the following relevant factual allegations.

Paul M. McDermott, a former employee of defendant Genentech, is a resident of Maine. First Amended Complaint (“Complaint”) (Docket No. 52) ¶ 1. Genentech is a Delaware corporation with its principal place of business in South San Francisco, California, and an office in Falmouth, Maine. *Id.* ¶¶ 1-2. Defendant Biogen is a Delaware corporation with its principal place of business in Massachusetts. *Id.* ¶ 3. Both defendants engaged in the development, manufacturing and marketing of Rituxan, a chemotherapeutic agent. *Id.* ¶¶ 2-3. Genentech licenses Rituxan from Biogen. *Id.* ¶ 6. The defendants market and sell Rituxan in the United States in collaboration with each other. *Id.* ¶ 9.

Rituxan is a biological product or biologic originally developed to treat relapsed or refractory, low-grade or follicular, CD20-positive non-Hodgkin’s lymphoma, a cancer of the immune system. *Id.* ¶ 11. In 1997 the United States Food and Drug Administration (“FDA”) approved Rituxan for the treatment of patients with non-Hodgkin’s lymphoma. *Id.* ¶ 12. It did not approve the use of Rituxan for any other purpose at that time. *Id.* ¶ 13.

Expensive pharmaceutical products are only widely prescribed when governmental medical expense reimbursement systems, such as Medicare or Medicaid, pay for such products. *Id.* ¶ 14. Pharmaceutical manufacturers like the defendants depend on governmental medical expense reimbursement systems to pay for expensive pharmaceutical products such as Rituxan. *Id.* ¶ 15. Federally funded medical reimbursement systems rely on the informed and impartial judgment of medical professionals to allocate increasingly scarce financial resources to provide necessary and appropriate care to the elderly and poor residents of the United States. *Id.* ¶ 17. To obtain payments from governmental medical reimbursement systems, a provider of health care must certify that the services is rendered to a patient were “medically indicated and necessary.” *Id.* ¶ 19. To be eligible for reimbursement under such systems, a drug or biologic must be used for a “medically accepted indication.” *Id.* ¶ 22.

When a pharmaceutical manufacturer promotes a drug or biologic to treat a particular medical condition, some doctors begin using the drug or biologic to treat that medical condition. *Id.* ¶ 27. Physicians may prescribe a drug or biologic for purposes or in dosages other than those approved by the FDA. *Id.* ¶ 28. When a pharmaceutical manufacturer extensively promotes an off-label use (a use for any condition that is not a medically accepted indication) of a drug or biologic, the natural and probable consequence of such promotion is that some health care providers will submit claims for payment to a governmental medical reimbursement system for the off-label use. *Id.* ¶¶ 23, 31. During all times relevant to the complaint, the defendants knew and/or intended that the off-label promotion of Rituxan for the treatment of rheumatoid arthritis would result in the increased submission of claims for payment to governmental medical reimbursement systems for the off-label use of Rituxan for this purpose. *Id.* ¶ 37.

In the 1990s the defendants began investigating the use of Rituxan for treatment of rheumatoid arthritis (“RA”). *Id.* ¶ 38. The FDA did not approve the use of Rituxan for treatment of RA until February 28, 2006. *Id.* ¶ 39. After the FDA approved Rituxan for treatment of non-Hodgkin’s lymphoma in 1997, the defendants began an extensive illegal promotional campaign for the off-label use of Rituxan to treat RA. *Id.* ¶¶ 40-41. The campaign included the illegal solicitation of physicians, illegal kickback schemes with physicians promoting Rituxan for off-label treatment of RA and training employees in methods of avoiding the detection of their off-label promotion activities. *Id.* ¶ 41. Genentech BioOncology sales representatives visited Rheumatology Associates in Providence, Rhode Island some time before January 25, 2005 and discussed dosing schedules and techniques for administering Rituxan to RA patients through intravenous infusion techniques. *Id.* ¶ 42. The sales representatives promised the office manager for Rheumatology Associates that they would supplement their in-office promotion by forwarding written instructions and materials demonstrating the ease with which they could administer Rituxan to RA patients. *Id.*

The defendants created a nationwide network of employees whose assigned duties involved the promotion of off-label sales and marketing activities regarding the use of Rituxan in treating RA. *Id.* ¶ 44. The defendants provided illegal kickbacks of money and other consideration to physicians through the use of sham consulting agreements to market Rituxan for off-label uses. *Id.* ¶ 45. These consulting agreements were intended to subvert the independent decision making process of physicians upon which patients and medical reimbursement systems rely. *Id.* Employees of the defendants identified certain rheumatologists as “key opinion leaders” who were then persuaded to enter into a “synergy consulting agreement” with one of the defendants. *Id.* ¶ 46. Such rheumatologists then received payment for sham services. *Id.* ¶ 48. Once the defendants transformed a rheumatologist into a consultant, they used the physician’s credibility in his or her professional community to expand their promotion of off-label use of Rituxan to treat RA. *Id.* ¶ 49.

Once a physician signed a “synergy consulting agreement,” he or she was paid \$2,000 to \$2,500 to moderate an “RA Roundtable Dinner.” *Id.* ¶ 51. The purpose of such dinners was to use the rheumatologist to promote the sales of Rituxan for off-label treatment of RA. *Id.* Using the consulting rheumatologist’s letterhead, an employee of one of the defendants would forward invitations to such a dinner signed by the rheumatologist to at least fifteen area rheumatologists. *Id.* ¶ 52. A pharmaceutical sales promotion firm, Health Answers Education, was used as a sham and a front for the dinners, in order to present them as an educational event produced by an independent continuing medical education organization. *Id.* ¶¶ 52-53. At these dinners the consulting rheumatologist presented as his or her own information and materials prepared and packaged by the defendants’ marketing personnel and consultants. *Id.* ¶ 57. The defendants did not allow the consulting rheumatologists to make any additions, deletions or changes to the materials to be presented. *Id.*

The defendants also promoted off-label uses of Rituxan through regional advisory board meetings, two-day events held regionally in major cities. *Id.* ¶ 60. Consulting rheumatologists acted as chairs for such meetings with agendas created by the defendants. *Id.* ¶ 61.

The defendants also persuaded rheumatologists to participate in the publication of articles promoting the use of Rituxan in the treatment of RA. *Id.* ¶ 63. Genentech marketing staff would select the subject of any such articles. *Id.* Genentech staff wrote the articles but would list the consulting rheumatologists as the authors. *Id.* ¶ 64.

Genentech management warned McDermott to avoid creating any record of discussions involving promotion and marketing of Rituxan for off-label treatment of RA. *Id.* ¶ 65. In November 2004 a member of Genentech's legal department advised McDermott and others to make sure that their business communications in promoting Rituxan for off-label treatment of RA did not adversely affect Genentech's position in any investigation or litigation. *Id.* ¶ 67.

During all relevant times, the defendants charged thousands of dollars, at times over \$15,000, for one treatment of Rituxan for an RA patient. *Id.* ¶ 75. Genentech told McDermott that he should tell rheumatologists how they should discuss the financial ramifications of Rituxan treatment with their Medicare patients afflicted with RA. *Id.* ¶ 77.

Over the five year period between 2000 and 2005, the defendants' annual sales of Rituxan increased from \$424 million to \$1.8 billion. *Id.* ¶ 81. Annual sales exceeding the latter figure for an expensive drug or biologic can only occur if a governmental medical reimbursement system reimburses claims for widespread use of that drug or biologic. *Id.* ¶ 80. A significant amount of Rituxan sales was a direct result of the off-label use of Rituxan to treat RA. *Id.* ¶ 82. The defendants' promotion of the off-label use of Rituxan for RA caused a substantial number of rheumatologists who otherwise would not have

done so to prescribe Rituxan for the off-label treatment of RA. *Id.* ¶ 86. During the eight-year period that the defendants promoted the off-label use of Rituxan, there were approximately 3,200 practicing rheumatologists in the United States. *Id.* ¶ 92. During that period Genentech employed approximately 50 representatives to promote the use of Rituxan to treat RA, the cost and expense of some of whom were shared by the defendants. *Id.* ¶ 93. No one, including the defendants, the government and McDermott, knows which specific Rituxan reimbursement claims submitted to the government were false or fraudulent. *Id.* ¶ 94.

III. Discussion

The first amended complaint asserts three claims: causing false or fraudulent claims for payment to be presented to the government in violation of 31 U.S.C. § 3729(a)(1), a *qui tam* claim against both defendants (Count One); conspiracy to defraud the government in violation of 31 U.S.C. § 3729(a)(3), also a *qui tam* claim against both defendants (Count Two); and retaliatory discharge under 31 U.S.C. § 3730(h) against Genentech (Count Three). Complaint ¶¶ 95-119.

A. Counts One and Two

The defendants contend that this court lacks subject-matter jurisdiction over McDermott's *qui tam* claims. Genentech Motion at 8-12; Biogen Motion at 6-9. The statutes governing these claims are referred to as the False Claims Act and provide, in relevant part:

(a) Liability for certain acts. — Any person who —

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval; [or]

* * *

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

* * *

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person

(b) Knowing and knowingly defined. — For purposes of this section, the terms “knowing” and “knowingly” mean that a person, with respect to information

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- (1) has actual knowledge of the information;
 - (2) acts in deliberate ignorance of the truth or falsity of the information; or
 - (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(a) & (b).

(b) Actions by private persons. — **(1)** A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

* * *

(d) Award to qui tam plaintiff. . . .

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys’ fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

* * *

(e) Certain actions barred. . . .

(3) In no event may a person bring an action under subsection (b) which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.

(4)(A) No court shall have jurisdiction over an action under this section 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 new media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, “original source” means 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.

* * *

(h) Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole. Such relief shall include reinstatement with the same seniority status such employee would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys’ fees. . . .

31 U.S.C. § 3730. Both defendants also contend that the first amended complaint fails to state a claim on which relief may be granted and that it fails to comply with Fed. R. Civ. P. 9(b). Genentech Motion at 12-18; Biogen Motion at 16-25.

1. 31 U.S.C. § 3730(e)(3). The First Circuit has not addressed the proper construction of the public-disclosure bar to such claims established by 31 U.S.C. § 3730(e)(4). It addressed the bar established by 31 U.S.C. § 3730(e)(3) in *United States ex rel. S. Praver & Co. v. Fleet Bank of Maine*, 24 F.3d 320 (1st Cir. 1994), holding that this subsection of the statute was ambiguous and construing it as seeking to avoid “circumstances involving ‘parasitic’ *qui tam* actions which are not otherwise barred by § 3730(e),” *id.* at 327. If “the *qui tam* case is receiving ‘support, advantage, or the like’ from the ‘host’ case (in which the government is a party) ‘without giving any useful or proper return’ to the government (or at least having the potential to do so),” the court “may properly conclude that there is an identity between ‘the basis’ of the *qui tam* action and ‘the subject of’ the other suit or proceeding” and find the *qui tam* action to be barred. *Id.* at 327-28. The First Circuit directed trial courts to “proceed with caution before applying the statutory

bar of § 3730(e)(3) in ambiguous circumstances.” *Id.* at 328. It noted that the mere potential for “adding funds to the government’s coffers, *without more*, should not be regarded as constituting useful or proper return to the government.” *Id.* (emphasis in original). In that case, the First Circuit found that the *qui tam* action had the potential to provide a useful or proper return to the government because the government was not proceeding against the defendants for fraud or otherwise in the “host” case and that the government could not have sued at least one of the defendants in the “host” case as it was constituted. *Id.* Here, there is no suggestion that the government cannot pursue the defendants as a result of the subpoena issued to Genentech on October 4, 2004 under section 248 of the Health Insurance Portability and Accounting Act of 1996, Declaration of Edward Wiitala in Support of Genentech’s Motion to Dismiss First Amended Complaint, etc. (“Wiitala Decl.”) (Docket No. 61) ¶ 2.² The parties differ on the question whether the government is proceeding against Genentech in a “host” case for fraud based on the same allegations or transactions.

Genentech asserts that the claims in this action “are plainly based upon the allegations or transactions that are the subject of the ongoing Government investigation.” Genentech Motion at 11. This is so, it contends, because the government investigation “likewise focuses on whether Genentech improperly promoted Rituxan for any off-label uses, specifically including [rheumatoid arthritis].” *Id.* In support of this assertion, Genentech quotes the following language from the subpoena served on Genentech by the U. S. Department of Justice, requiring Genentech to produce, among many other documents, “virtually all

² Biogen merely asserts in a footnote that it is entitled to protection under § 3730(e)(3) because “the allegations here are also the subject of a ‘proceeding in which the Government is already a party . . .’” citing authority to the effect that “‘industry-wide’ investigations bar FCA actions as to all industry participants.” Biogen Motion at 9 n.7. There is no suggestion in the materials submitted by Genentech in support of its motion on this point that the investigation at issue is “industry wide” or directed at any entity other than Genentech. *See* Wiitala Decl. and attached exhibits. Biogen has not established that it is entitled to dismissal on the basis of § 3730(e)(3).

documents relating to ‘marketing or sales efforts for Rituxan for . . . Rheumatoid arthritis,’ along with many more documents, including any that relate to ‘the marketing or promotion of Rituxan for approved, or unapproved indications.’” *Id.* at 11.³ It is impossible to tell from the subpoena, which is written in extremely broad terms, whether the promotion of off-label use of Rituxan is a “focus” of the investigation in furtherance of which the subpoena was apparently served. In any event, the initial problem with Genentech’s argument, and a point made in response by McDermott, Opposition at 25-27, is that the subpoena establishes at most that a government investigation is ongoing, while section 3730(e)(3) speaks only of “a civil suit” or “an administrative civil money penalty proceeding,” 31 U.S.C. § 3730(e)(3).

Genentech contends that the investigation is an administrative civil money proceeding because it “could result in monetary penalties should the Government seek them.” Genentech Motion at 12. It cites *Prawer* for the proposition that section 3730(e)(3) requires the rejection of any and all suits which the government is capable of pursuing itself. *Id.* If that were the proper construction of that statutory subsection, the requirement that a private action be filed in camera and remain under seal for at least 60 days while the government considers whether to intervene and proceed with the action itself, 31 U.S.C. § 3730(b)(2), would be rendered meaningless. The language from *Prawer* cited by Genentech is actually that of Judge Wald in *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645 (D.C.Cir. 1994), which the First Circuit characterized in *dictum* as “summariz[ing] rather well the objectives of the 1986 amendments” to the False Claims Act. 24 F.3d at 326. That remark cannot be stretched to encompass the application urged here by Genentech.

³ Genentech quotes in its unsealed motion from the subpoena, which is Exhibit A to the Wiitala Declaration, a document that Genentech itself designated as confidential under the confidentiality order entered in this case. Docket No. 61, Exh. A. I have quoted only that portion of the subpoena quoted by Genentech in its motion.

With respect to its first argument, Genentech relies on *United States ex rel. Found. for Fair Contracting, Ltd. v. G&M E. Contracting*, 259 F.Supp.2d 329 (D.N.J. 2003). Genentech Motion at 12. In that case, the United States Department of Labor conducted an investigation of alleged violations of the Davis-Bacon Act by the defendants which began before the plaintiff/relator filed its *qui tam* action. 259 F.Supp.2d at 331-34. Approximately one year after the court action was filed, the Department concluded its investigation and the defendants paid back wages found by the Department to be due. *Id.* at 334, 337. The court held that “to allow plaintiff’s *qui tam* suit to proceed, even though it is based on the same facts underlying the DOL investigation, would provide for a second recovery by another entity despite the resolution of the government’s investigation into the very same transactions, in contravention of the statutory purpose.” *Id.* at 337. Here, there is nothing but Genentech’s speculation to suggest that the government will obtain redress through its investigation for the wrongs alleged by McDermott. *Fair Contracting* is distinguishable.⁴ *See also* S. Rep. No. 345, 99th Cong., 2d Sess. 1986, 1986 U.S.C.C.A.N. 5266, 5290 (“While a pending criminal investigation of the allegations contained in the *qui tam* complaint will often establish ‘good cause’ for staying the civil action, the Committee does not intend that criminal investigations be considered an automatic bar to proceeding with a civil fraud suit.”). Genentech has not established that it is entitled to dismissal of Counts One and Two pursuant to 31 U.S.C. § 3730(e)(3).

2. 31 U.S.C. § 3730(e)(4). McDermott devotes a great deal of time and effort to the question whether this action should be dismissed under the public-disclosure bar established by 31 U.S.C. § 3730(e)(4).

Genentech asserts that McDermott’s *qui tam* claims “are plainly based upon the allegations that the news

⁴ More analogous is *United States ex rel. Johnson v. Shell Oil Co.*, 26 F. Supp. 2d 923 (E.D.Tex. 1998), in which the court held that letters from the federal Minerals Management Services to certain defendants ordering them based on state-government investigations to pay certain royalties and informing them that failure to do so “may be considered a violation subjecting you to penalties . . .” did not constitute civil penalty proceedings under section 3730(e)(3). *Id.* at 927- (continued on next page)

media publicly disclosed in October 2004—the alleged improper promotion of Rituxan for off-label uses, including for RA.” Genentech Motion at 9. It cites several news articles and its own press release in support of this argument. *Id.* It also contends that McDermott “has not even alleged that he is an original source” and that he cannot claim that status because “a relator who must seek discovery or request information from the government to plead his *qui tam* claim cannot be an original source.” *Id.* Biogen contends that an investigation by the Senate Finance Committee constitutes a public disclosure before this action was brought of “purported marketing for off-label uses and the impact on Medicare and Medicaid reimbursement programs.” Biogen Motion at 7. It also asserts that the complaint must be dismissed under section 3730(e)(4) as a result of its failure to allege how McDermott obtained the knowledge essential to being an original source and to describe the information he provided to the government on the dates alleged in paragraph 100 of the first amended complaint. *Id.* at 8.

McDermott responds that the congressional inquiry on which Biogen relies makes no mention of “improper Government reimbursement of Rituxan for treatment of RA as alleged here” and that he has alleged that he disclosed the allegations underlying the complaint to the government “a full month prior to the June 9, 2005 date on which Congress initiated its industry-wide inquiry.” Opposition at 7-8 (emphasis omitted). In response to Genentech’s arguments, McDermott asserts that the words “based upon” in section 3730(e)(4) must be construed to mean “actually derived from,” an interpretation which he admits represents the minority position among federal circuit courts of appeals that have addressed the question. *Id.* at 8-19. He contends that the First Circuit “will likely adopt” the minority position when faced with the question and that the defendants have not presented evidence that his allegations were in fact “derived from”

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any public disclosure, so that the only possible conclusion is that section 3730(e)(4) does not bar this action.

Id. at 19-22. He argues in the alternative that he is an “original source” because his allegations are based on direct and independent knowledge and that he provided “the information” to the government prior to filing this action, as alleged in paragraph 100 of the first amended complaint. *Id.* at 22-25.

I have reviewed all of the documents submitted by Biogen in support of its argument that McDermott’s complaint is “based upon the public disclosure of allegations or transactions . . . in a congressional . . . investigation, or from the news media,” 31 U.S.C. § 3730(e)(4), which are included in Exhibits A through D to its motion, Biogen Motion at 5-6 & n.5. Nothing in those documents refers sufficiently specifically to Biogen or the marketing of Rituxan for off-label use to allow the conclusion that the allegations in the first amended complaint are “based upon” any public disclosure, whether that term is interpreted to mean “actually derived from” or “similar or identical to.” It is therefore unnecessary to consider whether McDermott has adequately alleged that he was the original source of such information for purposes of Biogen’s motion. On the showing made, Biogen is not entitled to dismissal under section 3730(e)(4).

McDermott responds to Genentech’s arguments on this point with the same assertions. Opposition at 3-7, 8-25. A much closer question is presented in this instance with respect to the alleged public disclosure because the subpoena on which Genentech relies is evidence of an “administrative . . . investigation,” which is one of the sources of public disclosure listed in section 3730(e)(4). When addressing subject matter jurisdiction in the context of section 3730(e)(4),

[t]he inquiry into whether a court may hear a qui tam relator’s claim has three parts: (1) Have the allegations made by the plaintiff been “publicly disclosed”? (2) If so, is the lawsuit “based upon” that publicly disclosed information? (3) If so, is the plaintiff an “original source” of the information?

United States v. Bank of Farmington, 166 F.3d 853, 859 (7th Cir. 1999). McDermott contends that the nature of the government's investigation has not been disclosed and that the disclosures identified by Genentech "do not even hint at any fraud by anyone against anyone, much less 'disclose' fraud by Genentech against the United States government." Opposition at 5, 7.

Genentech relies on Exhibits B, D and E to the Wiitala declaration as evidence of public disclosure. Genentech Motion at 9. Exhibit B provides nothing resembling the allegations in the first amended complaint. It is a press release that merely states that Genentech has been served with a subpoena requesting documents "related to the promotion of Rituxan (rituximab), a prescription treatment for relapsed or refractory, low-grade or follicular, CD20 positive, B-cell non-Hodgkin's lymphoma." Press Release, Exh. B to Wiitala Decl. Exhibit D is an article from the *San Francisco Chronicle* dated October 6, 2004 in which unidentified "[a]nalysts" are quoted as saying "it's possible that investigators are looking into whether Genentech improperly touted Rituxan for so-called off label uses that haven't been approved by the Food and Drug Administration" and which states that "Genentech has also sponsored studies showing the drug has potential to treat rheumatoid arthritis." "Drug Firm Served Subpoena," *San Francisco Chronicle* (Oct. 6, 2004) (Exh. D to Wiitala Decl.) at 1, 2. Exhibit E is an article from *The Globe and Mail* stating that "Deutsche Bank Securities Inc. speculated in an analyst's report that the documents requested could relate to an investigation to determine whether Genentech inappropriately targeted Rituxan for other off-label uses," and "[a]nalysts expect Rituxan could also be used as a treatment for rheumatoid arthritis." "Report on Business: Money & Markets, At The Bell," *The Globe and Mail* (Oct. 6, 2004) (Exh. E to Wiitala Decl.) at 1, 2.

The defendants have cited no helpful authority on the means of determining when sufficient information has been disclosed to qualify as "publicly disclosed" under section 3730(e)(4). In *United*

States ex rel. Rabushka v. Crane Co., 40 F.3d 1509 (8th Cir. 1994), cited in this regard by McDermott, Opposition at 6, the court held that “mere disclosure of the subject matter transaction” was insufficient, and that “the essential elements exposing the transaction as fraudulent must be publicly disclosed as well,” 40 F.3d at 1512. Similarly, in *Wang v. FMC Corp.*, 975 F.2d 1412, 1418 (9th Cir. 1992), the court distinguished between allegations, which is the word used in section 3730(e)(4), and information on which allegations are based. Application of this case law⁵ leads me to conclude that the fraud on the government as a result of the promotion of Rituxan for treatment of rheumatoid arthritis alleged in the first amended complaint is not readily discerned from the disclosures cited by Genentech and therefore the transactions and allegations were not publicly disclosed. My conclusion makes it unnecessary to consider the remaining two elements of the section 3730(e)(4) jurisdictional test.

3. *Rules 12(b)(6) and 9(b)*. The matter does not end with a determination that this court has subject matter jurisdiction over the *qui tam* allegations as pleaded, however. “Evidence of an actual false claim is the *sine qua non* of a False Claims Act violation.” *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004) (citation and internal quotation marks omitted). Addressing an argument that a *qui tam* claim was not pleaded with sufficient particularity under Rule 9(b), the First Circuit noted: “We have said that Rule 9(b) requires that a plaintiff’s averments of fraud specify the time, place, and content of the alleged false or fraudulent representations.” *Id.* at 226. When such averments are made on the basis of information and belief, the complaint must also set forth the facts on which the belief is founded. *Id.* “FCA claims involve ‘averments of fraud’ that must be pled with particularity under Rule 9(b).” *Id.* at

⁵ Consideration of the opinion in *United States ex rel. Longstaffe v. Litton Indus., Inc.*, 296 F.Supp.2d 1187 (C.D.Cal. 2003), cited by Genentech in its reply memorandum on this point, Genentech, Inc.’s Reply In Support of its Motion to Dismiss First Amended Complaint, etc. (“Genentech Reply”) (Docket No. 73) at 2, an opinion specifically invoking existing Ninth Circuit precedent, 296 F.Supp.2d at 1192, does not affect this analysis. The public disclosure involved in that case was far (continued on next page)

227. “[T]he details of the actual presentation of false or fraudulent claims to the government can and must be pled with particularity in order to meet the requirements of Rule 9(b).” *Id.* at 228.

In this regard, Genentech points to paragraph 93 of the first amended complaint, Genentech Motion at 1, 12, although it apparently means to cite paragraph 94, which states:

As a result of the lengthy period during which Genentech and Biogen illegally promoted *Rituxan* for the treatment of RA and during which healthcare providers submitted the false or fraudulent claims; as a result of the massive number of such claims submitted throughout the entire United States during that span of years; and as a result of the secret and confidential nature of the reimbursement claims the disclosure of which is prohibited by law, no one (including Defendants, the Government and Relator) knows which specific *Rituxan* reimbursement claims among the thousands submitted to the Government were false or fraudulent as alleged above, and it would be impossible for anyone to identify them without formal discovery and court assistance. The existence, submission and Government payment of numerous such false claims are a fact beyond doubt, however.

First Amended Complaint ¶ 94 (italicization in original). Genentech argues that McDermott does not “allege who submitted any false claims, when those claims were submitted, what those claims said about the indication for which Rituxan was being prescribed, how much money was claimed, or how — if at all — those particular claims were linked to the specific activities that McDermott believes constituted improper promotion.” Genentech Motion at 14. Without such allegations, Genentech asserts, McDermott has failed to comply with the pleading requirements of *Karvelas*.

In *Karvelas*, the First Circuit 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.” 360 F.3d at 231.

more extensive than that demonstrated by Genentech here.

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.

As applied to the FCA, Rule 9(b)’s requirement that averments of fraud be stated with particularity — specifying the “time, place, and content” of the alleged false or fraudulent representations, 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, like the Eleventh Circuit, 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. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301 (11th Cir. 2002)] at 1312 n.21.

Id. at 232-33. As is the case here, the complaint in *Karvelas*

never specific[ed] the dates or content of any particular false or fraudulent claim allegedly submitted for reimbursement by Medicare or Medicaid. It provides no identification numbers or amounts charged in individual claims It does not identify or describe the individuals involved in the improper billing or allege with particularity any certification of compliance with federal regulations in order to obtain payments. . . . Nor does the complaint provide the source of information and factual basis for [the relator’s] conclusory allegations that [any individual] submitted actual false or fraudulent claims to the government.

Id. at 233. The First Circuit also quoted with approval the following language from *Clausen*, 290 F.3d at 1311: “[I]f Rule 9(b) is to be adhered to, some indicia of reliability must be given in the complaint to support the allegation of *an actual false claim* for payment being made to the Government.” (Emphasis in original.) *Karvelas*, 360 F.3d at 234. The First Circuit concluded, “*Karvelas*’s failure to identify with

particularity any actual false claims that [were] submitted to the government is, ultimately, fatal to his complaint.” 360 F.3d at 235. This holding appears to require that the complaint in the case at hand be dismissed as well.⁶

McDermott, however, invokes language from *Karvelas* to the effect that a “relaxed rule of pleading” may be allowed as an exception in future cases where “the alleged conduct took place over a long period of time or involved numerous occurrences,” *id.* at 231 n.14, and asserts that a relaxed standard of pleading is necessary in this case because “otherwise, the *qui tam* provisions of the FCA will be rendered a dead-letter with respect to drug manufacturers’ illegal, off-label drug promotion schemes,” Opposition at 28. He contends that it would be “impossible” for any relator to allege schemes like the one set out in his complaint with sufficient particularity under *Karvelas* “because the only facts McDermott has omitted are facts which are not even known to Defendants themselves and cannot be known by them or by any relator.”

Id.

First, the First Circuit specifically found in the cited *Karvelas* footnote that three years did not “present[] an exceptionally long period of time” sufficient to entitle a plaintiff to the relaxed rule of pleading recognized by some other circuits in FCA *qui tam* cases. 360 F.2d at 231 n.14. McDermott carefully does not mention the time span of the conduct he alleges as the basis of his complaint. A review of the first amended complaint reveals that the only specific dates alleged run from August 4, 2004 to November 17, 2004, First Amended Complaint ¶¶ 55-56, 58, or some date prior to January 25, 2005, *id.* ¶ 42. This period does not begin to approach the three years which the First Circuit indicated was insufficient to

⁶ On December 11, 2006, without seeking leave to do so, McDermott filed a pleading entitled “Notice of Subsequently Decided Case Authority in Support of Relator’s Opposition to Defendants’ Motions to Dismiss the First Amended Complaint.” Docket No. 79. Attached to this pleading was a slip copy of *United States ex rel. Salmeron v. Enterprise Recovery Sys., Inc.*, ___ F.Supp.2d ___, 2006 WL 3445579 (N.D.Ill. Nov. 30, 2006). This late-filed opinion is inconsistent with (*continued on next page*)

generate the relaxed pleading standard. If McDermott sought to invoke this possible exception to the requirements of *Karvelas*, he needed to do more than state in conclusory fashion that he is entitled to it; he needed to proffer factual allegations that could possibly establish his entitlement to do so.

Next, McDermott has not provided any factual support for his allegation that it would be “impossible” for him, or any plaintiff/relator in his position, to learn about specific claims submitted to Medicare or Medicaid for reimbursement for the use of Rituxan to treat rheumatoid arthritis.⁷ He asserts, without citation to authority, that “the who, what[,] when and where of specific claims for medical reimbursement . . . are confidential under HIPPA, and the disclosure of such confidential patient information by any physician who submitted the false claims for reimbursement is punishable by civil and criminal penalties.” Opposition at 28-29. Under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA,” sometimes written as “HIPPA”), a person who knowingly discloses individually identifiable health information to another person is subject to fine or imprisonment. 42 U.S.C. § 1320d-6(a)(3) & (b). “Individually identifiable health information” is defined as information that is created or received by a health care provider and relates to the physical or mental health or condition of an individual or payment for the provision of health care to an individual and identifies the individual or as to which there is a reasonable basis to believe that the information can be used to identify the individual. 42 U.S.C. § 1320d(6). Contrary to McDermott’s representation, HIPAA does not preclude a health care provider from disclosing the “what, when and where of specific claims for medical reimbursement,” so long as the patient is not identified or

First Circuit precedent on the requirements of Rule 9(b) in the context of an FCA claim as set forth in *Karvelas*.

⁷ Even if it were “impossible” to bring a *qui tam* FCA claim based on claims for reimbursement for the use of Rituxan to treat rheumatoid arthritis, that outcome could well be due to the language used by Congress in drafting the applicable statutes or to the uniform interpretation of that language by the federal courts. Neither reason for such an outcome necessarily means that the statutory language or the case law should be disregarded as a matter of public policy, as McDermott seems to suggest.

identifiable as a result of the disclosure. McDermott could certainly comply with the pleading requirements of *Karvelas* without running afoul of HIPAA. The difficulty McDermott might encounter in obtaining such information is not reason enough to ignore *Karvelas*, where the plaintiff, a respiratory therapist formerly employed by the defendant hospital, alleged that the hospital knowingly submitted false claims to obtain Medicare and Medicaid payments in violation of the False Claims Act. 360 F.3d at 223. He alleged that of 21,000 arterial blood gas tests performed in the hospital over a three-year period, “a large percentage” of bills submitted to the government for an unspecified number of these tests falsely certified compliance with federal standards. *Id.* at 234. The First Circuit found this pleading insufficient. *Id.* at 234-35. At no time did the First Circuit suggest that pleading in the necessary degree of specificity should include information that identified or could be used to identify individual patients.

This omission alone is sufficient to require the granting of the motions to dismiss. *See generally United States ex rel. Hess v. Sanofi-Synthelabo Inc.*, 2006 WL 1064127 (E.D.Mo. Apr. 21, 2006), at *1-*2, *4-*11. Even if that were not the case, the defendants have also argued that McDermott has not alleged the submission of any false or fraudulent claims to the government because each of the claims he alleges must have been submitted would have identified Rituxan as the medication prescribed and rheumatoid arthritis as the medical condition for which it was prescribed, a true representation. Genentech Motion at 15-18; Biogen Motion at 10-11. “It cannot be an actionable violation of the FCA for an individual to provide truthful information to the government, in order to allow the government to determine whether or not that information establishes eligibility for a certain program.” *United States ex rel. Burlbaw v. Orenduff*, 400 F.Supp.2d 1276, 1289 (D.N.M. 2005).

McDermott responds that “prescription drugs are legally reimbursable under Medicaid and Medicare if they are used for a medical indication approved by the FDA or listed in certain medical

compendia,” citing 42 U.S.C. §1396r-8(k)(3) and (6). Opposition at 34. Since the requests for reimbursement that must have been submitted did not fit this definition, he asserts, they were not reimbursable when they were submitted and such claims “routinely” have been held to give rise to liability under the False Claims Act. *Id.* at 36. In reply, Genentech points out, Genentech Reply at 6, that the use of Rituxan for treatment of rheumatoid arthritis has been recognized in one of the medical compendia admitted by McDermott to be included in the cited statutory definition, Opposition at 34 n.4, specifically the DRUGDEX Information System, *see also* 42 U.S.C. § 1396r-8(g)(1)(B)(i)(III), since at least December 2003,⁸ making it reimbursable under the relevant government programs during the entire period of time specifically mentioned in the first amended complaint.

This argument does not save McDermott from dismissal of Counts One and Two. It is not necessary to reach the defendants’ remaining arguments on these claims, with one exception. Count Two pleads a conspiracy. First Amended Complaint ¶¶ 102-03. To the extent that a conspiracy claim could survive the dismissal under Rule 12(b)(6) of the substantive allegations underlying the conspiracy, Biogen has moved separately to dismiss the conspiracy claim for failure to state a claim on which relief may be granted. Biogen Motion at 23-25. McDermott did not respond to this portion of the motion to dismiss, which may be granted for that reason alone. *See ITI Holdings, Inc. v. Professional Scuba Ass’n, Inc.*, 2006 WL 240618 (D. Me. Jan. 31, 2006), at *1 n.1. While Genentech does not make such a separate request, should it be necessary to grant the motion to dismiss as to Count Two for this reason, the court should dismiss Count Two as against Genentech *sua sponte*.

⁸ Genentech has requested that the court take judicial notice of this fact. Genentech, Inc.’s Supplemental Request for Judicial Notice of Certain Facts and Documents (Docket No. 74) at 2. McDermott filed no response to this request, which is hereby granted. *See* Docket No. 70 (granting without objection earlier request for judicial notice filed by Genentech (Docket No. 62)).

4. *Count Three.* Count Three asserts a claim only against Genentech for retaliatory discharge in violation of 31 U.S.C. § 3730(h). First Amended Complaint ¶¶ 105-19. Genentech seeks dismissal of this count under Rule 12(b)(6) as well. Genentech Motion at 19-20. It relies on *Karvelas* to support its contention that McDermott’s allegations of protected conduct do not concern the alleged submission of fraudulent claims to the government and so do not state a claim under section 3730(h). *Id.* at 20. The statute provides, in relevant part:

Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole.

31 U.S.C. § 3730(h). In *Karvelas*, the First Circuit stated:

To prevail on a False Claims Act retaliation claim, a plaintiff must show that 1) the employee’s conduct was protected under the FCA; 2) the employer knew that the employee was engaged in such conduct; and 3) the employer discharged or discriminated against the employee because of his or her protected conduct.

360 F.3d at 235. The First Circuit considers “conduct . . . protected under the FCA” to be “conduct that reasonably could lead to a viable FCA action.” *Id.* at 236. The conduct alleged must be “investigation or reporting of false or fraudulent claims knowingly submitted to the government.” *Id.* at 237. Internal reporting is protected activity under the FCA only when it alleges fraud on the government. *Id.*

McDermott points to paragraphs 32, 33, 34, 106, 108, 110, 117 and 118 in support of his contention that he has “alleged sufficient facts to satisfy the requirement that he engaged in protected conduct.” Opposition at 45. The critical paragraphs are 32 and 33, because the other cited paragraphs merely recite that McDermott informed two of his superiors on three separate occasions that Genentech

sales representatives were improperly promoting Rituxan for the treatment of rheumatoid arthritis. First Amended Complaint ¶¶ 106, 108, 110. This is insufficient under *Karvelas*. Paragraphs 32 and 33 allege that “it is common knowledge in the pharmaceutical industry” that promotion of off-label use of a drug by its manufacturer has “the natural and probable consequence . . . that some healthcare providers will inevitably submit ineligible claims for payment to a governmental medical reimbursement system . . . for the off-label use,” and paragraph 33 also alleges that such promotion “is a species of fraud against the U.S. Government” as a result. *Id.* ¶¶ 32-33. Given the indulgent standard to be applied to construction of the allegations in a complaint when a motion to dismiss is under consideration, this combination of allegations appears adequate, although barely, to state a claim under section 3730(h) as it is interpreted in *Karvelas*.

Genentech is not entitled to dismissal of Count Three on the showing made.

IV. Conclusion

For the foregoing reasons, I recommend that (i) Genentech’s motion to dismiss (Docket No. 60) be **GRANTED** as to Counts One and Two of the First Amended Complaint and otherwise **DENIED** and (ii) Biogen’s motion to dismiss (Docket No. 63) be **GRANTED**.

NOTICE

A party may file objections to those specified portions of a magistrate judge’s report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which de novo review by the district court is sought, together with a supporting memorandum, within ten (10) days after being served with a copy thereof. A responsive memorandum shall be filed within ten (10) days after the filing of the objection.

Failure to file a timely objection shall constitute a waiver of the right to de novo review by the district court and to appeal the district court’s order.

Dated this 14th day of December, 2006.

/s/ David M. Cohen
David M. Cohen
United States Magistrate Judge

Plaintiff

PAUL P MCDERMOTT
ex rel
UNITED STATES OF AMERICA

represented by **JOSEPH H. GROFF, III**
JENSEN, BAIRD, GARDNER &
HENRY
TEN FREE STREET
P.O. BOX 4510
PORTLAND, ME 04112
775-7271
Email: jgroff@jbgh.com

GEORGE A. ZELCS
KOREIN TILLERY
205 NORTH MICHIGAN AVENUE
SUITE 1950
CHICAGO, IL 60601
312-641-9750
Email: gzelcs@koreintillery.com

MYRON M. CHERRY
MYRON M. CHERRY &
ASSOCIATES, LLC
30 NORTH LASALLE STREET
SUITE 2300
CHICAGO, IL 60602
(312) 372-2100
Email: mcherry@cherry-law.com

STEPHEN M. TILLERY
KOREIN TILLERY LLC
701 MARKET STREET
SUITE 300
ST. LOUIS, MO 63101
314-241-4844

Email: stillery@koreintillery.com

V.

Defendant

GENENTECH INC

represented by **JOHN W. KEKER**
KEKER & VAN NEST LLP
710 SANSOME STREET
SAN FRANCISCO, CA 94111-1704
US
(415) 391-5400
Email: jkeker@kvn.com

JOHN H. RICH, III
PERKINS, THOMPSON,
HINCKLEY & KEDDY
ONE CANAL PLAZA
P. O. BOX 426 DTS
PORTLAND, ME 04112
774-2635
Email: jrich@perkinsthompson.com

DAVID J. SILBERT
KEKER & VAN NEST
710 SANSOME STREET
SAN FRANCISCO, CA 94111
415-391-5400
Email: dsilbert@kvn.com

JAN NIELSEN LITTLE
KEKER & VAN NEST
710 SANSOME STREET
SAN FRANCISCO, CA 94111
415-391-5400
Email: jlittle@kvn.com

JENNIFER H. PINCUS
PERKINS, THOMPSON,
HINCKLEY & KEDDY
ONE CANAL PLAZA

P. O. BOX 426 DTS
PORTLAND, ME 04112
207-774-2635
Email: jpincus@perkinsthompson.com

PAUL E. KALB
SIDLEY AUSTIN LLP
1501 K STREET, NW
WASHINGTON, DC 20005
202-736-8050
Email: pkalb@sidley.com

RYAN M. KENT
KEKER & VAN NEST
710 SANSOME STREET
SAN FRANCISCO, CA 94111
415-391-5400
Email: rkent@kvn.com

STEPHEN C. PAYNE
SIDLEY AUSTIN LLP
1501 K STREET, NW
WASHINGTON, DC 20005
202-736-8050
Email: spayne@sidley.com

Defendant

BIOGEN-IDEC INC

represented by **WILLIAM J. KAYATTA, JR.**
PIERCE, ATWOOD LLP
ONE MONUMENT SQUARE
PORTLAND, ME 04101-1110
791-1100
Email: wkayatta@pierceatwood.com

ANTON VALUKAS
JENNER & BLOCK
ONE IBM PLAZA
CHICAGO, IL 60611
(312) 222-9350
Email: AValukas@jenner.com

CHRIS GAIR

JENNER & BLOCK
ONE IBM PLAZA
CHICAGO, IL 60611
(312)222-9350
Email: CGair@jenner.com

MARK E. PORADA

PIERCE, ATWOOD LLP
ONE MONUMENT SQUARE
PORTLAND, ME 04101-1110
791-1100
Email: mporada@pierceatwood.com

STEPHANIE A. SCHARF

JENNER & BLOCK
ONE IBM PLAZA
CHICAGO, IL 60611
(312)222-9350
Email: SScharf@jenner.com