

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA, *ex rel.*
MARK EUGENE DUXBURY and
DEAN McCLELLAN,

Relators,

v.

ORTHO BIOTECH PRODUCTS, L.P.,

Defendant.

Civil No. 03-12189 (RWZ)

**DEFENDANT'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
ITS MOTION TO DISMISS THE FIRST AMENDED COMPLAINT**

Susan L. Burke
BURKE PYLE LLC
4112 Station Street
Philadelphia, PA 19127
(Tel) (215) 487-6596
(Fax) (215) 482-0874

Ethan M. Posner (admitted *pro hac vice*)
Geoffrey E. Hobart (BBO# 547499)
Patrick S. Davies
Andrew W. Lamb
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(Tel) (202) 662-6000
(Fax) (202) 662-6291

Attorneys for Defendant Ortho Biotech Products, L.P.

Dated: January 17, 2007

TABLE OF CONTENTS

TABLE OF AUTHORITES ii

STATEMENT OF THE ISSUE AND PROCEDURAL BACKGROUND2

ARGUMENT4

I. THE COURT LACKS JURISDICTION OVER ALL CLAIMS IN THE AMENDED COMPLAINT UNDER THE FCA’S PUBLIC DISCLOSURE BAR4

 A. The FCA Public Disclosure Bar Prohibits *Qui Tam* Complaints Based Upon Previously Disclosed Information.....5

 B. The Essential Facts Supporting Counts I and II of the Amended Complaint Have Long Been Publicly Disclosed in Prior Litigation and Various Government and Media Reports8

 C. The Essential Facts Supporting Count III of the Amended Complaint Were Previously Publicly Disclosed by Another Relator13

 D. Relators’ Claims Are Clearly “Based Upon” the Prior Public Disclosures.....14

 E. Neither Duxbury Nor McClellan Qualifies as an Original Source15

II. ALL OF RELATOR McCLELLAN’S CLAIMS AND ALL OF RELATOR DUXBURY’S COUNT III CLAIMS ARE BARRED BY THE FIRST-TO-FILE RULE18

III. THE COURT SHOULD DISMISS THE “OFF-LABEL” ALLEGATIONS IN COUNT III FOR FAILURE TO STATE A VIOLATION OF THE FALSE CLAIMS ACT20

IV. THE COURT SHOULD DISMISS THE ENTIRE COMPLAINT UNDER RULE 9(b) FOR FAILING TO PLEAD ITS FRAUD CLAIMS WITH PARTICULARITY27

 A. The Amended Complaint Identifies No Actual False Claim With Specificity.....28

 B. Relators’ Vague and Conclusory Allegations of Each of OBP’s Three Alleged Fraudulent Schemes Similarly Fail to Satisfy Rule 9(b)32

V. ANY REMAINING CLAIMS IN THE AMENDED COMPLAINT SHOULD BE DISMISSED TO THE EXTENT THAT THEY ARE BASED ON CONDUCT OR EVENTS OCCURRING BEFORE THE TIME PERIOD PRESCRIBED BY THE APPLICABLE SIX-YEAR STATUE OF LIMITATIONS 34

TABLE OF AUTHORITIES

FEDERAL CASES

| | <u>Pages</u> |
|---|--------------|
| <i>Brown & Williamson Tobacco Corp. v. FDA</i> , 153 F.3d 155 (4th Cir. 1998)..... | 24 |
| <i>Buckman Co. v. Plaintiff's Legal Committee</i> , 531 U.S. 341 (2001) | 23 |
| <i>Campbell v. Redding Medical Ctr.</i> , 421 F.3d 817 (9th Cir. 2005)..... | 18, 19 |
| <i>Chongris v. Bd. of Appeals of the Town of Andover</i> , 811 F.2d 36 (1st Cir. 1987)..... | 20 |
| <i>Colonial Mortgage Bankers Corp. v. Lopez-Stubbe</i> , 324 F.3d 12 (1st Cir. 2003)..... | 20 |
| <i>Cooper v. Blue Cross & Blue Shield of Fla. Inc.</i> , 19 F.3d 562 (11th Cir. 1994)..... | 14 |
| <i>Cooperman v. Individual, Inc.</i> , 171 F.3d 43 (1st Cir. 1999) | 20 |
| <i>Corsello v. Lincare, Inc.</i> , 428 F.3d 1008 (11th Cir. 2005)..... | 27 |
| <i>Gredell v. Wyeth Labs., Inc.</i> , Civ. No. 05-2332, 2006 WL 2434932 | 23 |
| <i>Grynborg v. Koch Gateway Pipeline Co.</i> , 390 F.3d 1276 (10th Cir. 2004) | 18 |
| <i>Hindo v. University of Health Sciences/Chicago Med. Sch.</i> , 65 F.3d 608 (7th Cir. 1995) | 21 |
| <i>In re Pharm. Indus. Avg. Wholesale Price Litig.</i> , MDL No. 1456, Civ. No. 01-12257- PBS, 2006 WL 3102998 (D. Mass. Nov. 2, 2006) | 3, 5, 8, 10 |
| <i>McNutt v. General Motors Acceptance Corp.</i> , 298 U.S. 178 (1936) | 7 |
| <i>Murphy v. United States</i> , 45 F.3d 520 (1st Cir. 1995)..... | 7, 17 |
| <i>Palladino ex rel. United States v. VNA of S. N.J.</i> , 68 F. Supp. 2d 455 (D.N.J. 1999)..... | 19 |
| <i>Plubell v. Merck & Co.</i> , 434 F.3d 1070 (8th Cir. 2006)..... | 35 |
| <i>Sanderson v. HCA-The Healthcare Co.</i> , 447 F.3d 873 (6th Cir. 2006) | 27 |
| <i>United States ex rel. Atkins v. McInteer</i> , No. 04-16167, 2006 WL 3461441 (11th Cir. Dec. 1, 2006) | 29 |
| <i>United States ex rel. Blair v. Ortho Biotech, Inc.</i> , Civ. No. 03-02585 (D. Colo. Dec. 22, 2003)..... | 3 |

| | |
|---|---------------|
| <i>United States ex rel. Dick v. Long Island Lighting Co.</i> , 912 F.2d 13 (2d Cir. 1990)..... | 15, 16 |
| <i>United States ex rel. Doe v. John Doe Corp.</i> , 960 F.2d 318 (2d Cir. 1992)..... | 14 |
| <i>United States ex rel. Dox v. Iowa Health Sys.</i> , 29 F. Supp. 2d 1022 (S.D. Iowa 1998)..... | 23 |
| <i>United States ex rel. Feingold v. Adminastar Fed., Inc.</i> , 324 F.3d 492 (7th Cir. 2003)..... | 7 |
| <i>United States ex rel. Findley v. FPC-Boron Employees’ Club</i> , 105 F.3d 675 (D.C. Cir. 1997)..... | 7, 16 |
| <i>United States ex rel. Franklin v. Parke-Davis</i> , 147 F. Supp. 2d 39 (D. Mass. 2001)..... | 24, 26, 27 |
| <i>United States ex rel. Franklin v. Parke-Davis</i> , Civ. No. 96-11651PBS, 2003 WL. 22048255 (D. Mass. 2003)..... | 22, 26 |
| <i>United States ex rel. Fry v. Guidant Corp.</i> , Civ. No. 3:03-0842, 2006 WL. 1102397 (M.D. Tenn. Apr. 25, 2006)..... | 19 |
| <i>United States ex rel. Gathings v. Bruno's, Inc.</i> , 54 F. Supp. 2d 1252 (M.D. Ala. 1999)..... | 4 |
| <i>United States ex rel. Gilligan v. Medtronic, Inc.</i> , 403 F.3d 386 (6th Cir. 2005)..... | 6, 10 |
| <i>United States ex rel. Hampton v. Columbia/HCA Healthcare Corp.</i> , 318 F.3d 214 (D.C. Cir. 2003)..... | 18, 19 |
| <i>United States ex rel. Hess v. Sanofi-Synthelabo Inc.</i> , Civ. No. 05-570, 2006 WL. 1064127 (E.D. Mo. April 21, 2006)..... | 25, 26, 33 |
| <i>United States ex rel. Howard . Life Care Ctrs. of America, Inc.</i> , Civ. No. 1:03-CV-41, 2005 WL. 2674939 (E.D. Tenn. Oct. 20, 2005)..... | 4, 35 |
| <i>United States ex rel. Joshi v. St. Luke’s Hosp.</i> , 441 F.3d 552 (8th Cir. 2006)..... | 33 |
| <i>United States ex rel. Karvelas v. Melrose-Wakefield Hospital</i> , 360 F.3d 220 (1st Cir. 2004)..... | <i>passim</i> |
| <i>United States ex rel. LaCorte v. SmithKline Beecham Clinical Laboratories, Inc.</i> , 149 F.3d 227 (3d Cir. 1998)..... | 18 |
| <i>United States ex rel. LaCorte v. Wagner</i> , 185 F.3d 188 (4th Cir. 1999)..... | 19 |
| <i>United States ex rel. Lamers v. City of Green Bay</i> , 168 F.3d 1013 (7th Cir. 1999)..... | 21, 24 |

| | |
|---|-------------------|
| <i>United States ex rel. Lujan v. Hughes Aircraft Co.</i> , 243 F.3d 1181 (9th Cir. 2001) | 18, 19 |
| <i>United States ex rel. McKenzie v. BellSouth Telecomms., Inc.</i> , 123 F.3d 935 (6th Cir. 1997) | 14, 15, 16-17 |
| <i>United States ex rel. Mistick PBT v. Housing Authority</i> , 186 F.3d 376 (3d Cir. 1999) | 14 |
| <i>United States ex rel. O’Keeffe v. Sverdup Corp.</i> , 131 F. Supp. 2d 87 (D. Mass. 2001) | 6, 7, 8, 14, 17 |
| <i>United States ex rel. Ortega v. Columbia Healthcare, Inc.</i> , 240 F. Supp. 2d 8 (D.D.C. 2003) | 19 |
| <i>United States ex rel. Precision Co. v. Koch Industrial, Inc.</i> , 971 F.2d 548 (10th Cir. 1992) | 7, 14 |
| <i>United States ex rel. Rost v. Pfizer Inc.</i> , 446 F. Supp. 2d 6 (D. Mass. 2006), | 14, 28, 31, 33 |
| <i>United States ex rel. S. Prawer & Co. v. Fleet Bank of Me.</i> , 24 F.3d 320 (1st Cir. 1994)..... | 6-7 |
| <i>United States ex rel. Settlemire v. District of Columbia</i> , 198 F.3d 913 (D.C. Cir. 1999) | 6, 10 |
| <i>United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah</i> , Civ. No. 05- 4088, 2006 WL 3491784 (10th Cir. Dec. 5, 2006)..... | 29, 34 |
| <i>United States ex rel. Smith v. Yale Univ.</i> , 415 F.Supp.2d 58 (D. Conn. 2006) | 17 |
| <i>United States ex rel. Springfield Terminal Railway Co. v. Quinn</i> , 14 F.3d 645 (D.C. Cir. 1994) | 6-7, 8, 14 |
| <i>United States ex rel. Stevens v. State of Vt. Agency of Natural Resources</i> , 162 F.3d 195 (2d Cir. 1998) | 19 |
| <i>United States ex rel. Walsh v. Eastman Kodak Co.</i> , 98 F. Supp. 2d 141 (D. Mass. 2000) | 27, 30-31, 32, 33 |
| <i>United States v. AVX Corp.</i> , 962 F.2d 108 (1st Cir. 1992)..... | 20 |
| <i>United States v. Kitsap Physician Serv.</i> , 314 F.3d 995 (9th Cir. 2002)..... | 24 |
| <i>United States v. Rivera</i> , 55 F.3d 703 (1st Cir. 1995)..... | 34 |
| <i>United States v. Shaw</i> , 106 F. Supp. 2d 103 (D. Mass. 2000)..... | 32 |

| | |
|--|--------|
| <i>United States v. Southland Management Corp.</i> , 326 F.3d 669 (5th Cir. 2003)..... | 21 |
| <i>Vt. Agency of Natural Res. v. United States ex rel. Stevens</i> , 529 U.S. 765 (2000) | 19 |
| <i>Wang v. FMC Corp.</i> , 975 F.2d 1412 (9th Cir. 1992) | 15, 16 |

STATE CASE

| | |
|---|---|
| <i>Duxbury v. Ortho Biotech, Inc.</i> , Civ. No. 52348-1-I, 2004 WL. 938588 (Wash. Ct. App. May 3, 2004) | 1 |
|---|---|

FEDERAL STATUTES AND RULES

False Claims Act

| | |
|----------------------------------|----------------|
| 31 U.S.C. § 3729(a)(1)-(2) | 21 |
| 31 U.S.C. § 3729(b) | 21 |
| 31 U.S.C. § 3730(b)(5) | 18, 19 |
| 31 U.S.C. § 3730(e)(4) | 7 |
| 31 U.S.C. § 3730(e)(4)(A)..... | 5-6, 8, 14, 15 |
| 31 U.S.C. § 3730(e)(4)(B)..... | 16, 17 |
| 31 U.S.C. § 3731 | 34 |
| 31 U.S.C. § 3731(b)(1) | 34 |

Other

| | |
|-----------------------------------|--------|
| 42 U.S.C. § 1320a-7b(b3)..... | 32 |
| 42 U.S.C. § 1395x(t)(2)(B)..... | 23, 25 |
| 42 U.S.C. § 1396a(a)(10)9A) | 23 |
| 42 U.S.C. § 1396d(a)(12) | 23 |
| 42 U.S.C. § 1396r-8(k)(6) | 23 |
| D. Mass. R. 4.1(b)..... | 4 |

| | |
|--------------------------------|---------------|
| Fed. R. Civ. P. 4(m)..... | 4, 33, 35 |
| Fed. R. Civ. P. 9(b)..... | <i>passim</i> |
| Fed. R. Civ. P. 12(b)(1) | 4, 5 |
| Fed. R. Civ. P. 12(b)(5) | 4 |
| Fed. R. Civ. P. 12(b)(6) | 4, 20 |
| Fed. R. Civ. P. 15(c) | 34, 38, 39 |
| Fed. R. Civ. P. 15(c1) | 34 |
| Fed. R. Civ. P. 15(c2) | 34 |
| Fed. R. Civ. P. 15(c3) | 34 |

FEDERAL REGULATIONS AND PROPOSED RULE

| | |
|---|----|
| 42 C.F.R. § 440.120(a)..... | 23 |
| 42 C.F.R. § 1001.952(d) | 32 |
| 42 C.F.R. § 1001.952(h) | 32 |
| Medicare Program, Payment Reform for Part B Drugs, 68 Fed. Reg. 50428-01 (proposed Aug. 20, 2003) (to be codified at 42 C.F.R. pt. 405)..... | 12 |

Procrit® (“Procrit”) is the brand name for epoetin alfa, a widely-prescribed drug marketed by Ortho Biotech Products, L.P. (“OBP”) that has provided enormous health and life-sustaining benefits to millions of Americans suffering from anemia caused by chemotherapy, chronic kidney disease, HIV infection, and blood loss from certain types of surgery. Plaintiff Mark E. Duxbury (“Relator Duxbury”) was an OBP sales representative fired in 1998 for making racially and sexually harassing remarks and for failing to complete his expense reports timely and accurately. The Amended Complaint is the latest in a long series of spurious litigation that Relator Duxbury has initiated against OBP in a misguided campaign to exact revenge for a firing caused by his own wrongdoing.

Relator Duxbury first sued OBP for wrongful discharge in 2001. He got nowhere with the trial court, losing on summary judgment, and lost on appeal.¹ He then filed the Original Complaint in this case, holding himself out as a “whistleblower” exposing OBP “fraud” in reporting the average wholesale price (or “AWP”) that the Medicare program sometimes used to reimburse Providers for Procrit prescriptions. That lawsuit – based entirely on information that had already been widely and publicly disclosed not only by the government and by the media, but also by his own lawyers – also went nowhere, with the Justice Department declining to intervene after a multi-year investigation. Then his prior counsel, Hagens Berman LLP, withdrew from the case.

Undaunted, Relator Duxbury has now hired new counsel, found himself a new Relator, Dean McClellan (another ex-OPB employee), and filed an Amended Complaint. This

¹ See *Duxbury v. Ortho Biotech, Inc.*, Civ. No. 52348-1-I, 2004 WL 938588, at *1-2, *6-7 (Wash. Ct. App. May 3, 2004) (referring to reports of “consistently poor performance of [Duxbury’s] administrative duties” and “repeated sexual and racial comments” that the court described as “gravely inappropriate behavior that offended a major [OBP] client”).

time, he not only repeats the previously disclosed allegations that OBP committed “AWP” fraud in violations of the False Claims Act – he alleges for the first time that OBP violated the FCA by illegally promoting Procrit “off-label” as well. OBP denies this allegations, and in fact Procrit was approved as safe and effective by the FDA for once weekly dosing at 40,000 units for chemotherapy patients, the alleged “off-label” use in this case. The Court need not wade into the merits, however, because the claims are legally deficient under Rule 12 and Rule 9(b).

More than *eight years* after Relator Duxbury was fired, and more than a year after the Justice Department declined to intervene in this case, Relators advance yet another complaint that fails to establish the Court’s subject matter jurisdiction, fails the False Claims Act’s “first to file” bar, fails to state a cognizable claim under the False Claims Act, and is so devoid of the requisite particularity that it fails Rule 9(b). While this action is brought under the False Claims Act, the federal “whistleblower” statute, Relators’ allegations demonstrate that they are not whistleblowers at all but rather copy cats. Their “kickback,” AWP, and “off-label” allegations are all based upon prior, public lawsuits alleging the same issues, thus triggering the False Claims Act’s “public disclosure” bar. And even if Relators could get past the public disclosure bar, their claims cannot survive because, among other things, they do not identify a single actual false claim submitted to the Government.

STATEMENT OF THE ISSUE AND PROCEDURAL BACKGROUND

The Amended Complaint alleges that OBP, a biopharmaceutical company, violated the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (2006) (“FCA”), in marketing Procrit® (“Procrit”) to health care providers (“Providers”) in three ways. Relators contend that OBP (1) provided unlawful “kickbacks” to Providers, (2) published inflated average wholesale price (“AWP”) figures allegedly relied on by Medicare for reimbursement, and (3) improperly

promoted Procrit “off-label” for a dosage of 40,000 units once a week to chemotherapy patients, even though FDA approved Procrit as safe and effective for 40,000 unit once-weekly dosing *before* the Amended Complaint was filed. Relators allege that OBP caused Providers to submit millions of Procrit prescriptions for millions of unidentified Medicare reimbursement claims that Medicare would not have paid had it known of OBP’s conduct. The Amended Complaint does not identify any actual prescription or specify any particular reimbursement claim, but still alleges that Providers must have made millions of “false claims” for Procrit prescriptions. *See* Am. Compl. ¶ 90.

These allegations against OBP, which OBP denies, are far from new. Prior complaints, as well as government and news media reports, have publicly alleged the same basic conduct. In fact, in 2002, the law firm that Duxbury was later to use for his initial 2003 filing here, Hagens Berman LLP, filed on behalf of other clients a massive and highly publicized class action in this district, *see* Master Consolidated Class Action Compl. (“MCC”), *In re Pharm. Indus. Average Wholesale Price Litig.*, Civ. No. 01-12257-PBS, MDL No. 1456, Docket Entry No. 148 (D. Mass. Sept. 6, 2002) (“AWP MDL”) that made the same “kickback” and AWP allegations later made in this case. And on December 22, 2003, three years before Relators first filed their off-label dose promotion count in the Amended Complaint, another relator, Kurt Blair, filed an FCA *qui tam* complaint in the District of Colorado raising the same allegations. *See* Compl., *United States ex rel. Blair v. Ortho Biotech, Inc.*, Civ. No. 03-02585 (D. Colo. Dec. 22, 2003) (Ex. A) (“Blair Complaint”).

Represented by Hagens Berman LLP, Duxbury alone again brought suit against OBP by filing the Original Complaint under seal on November 6, 2003. On July 12, 2005, after the United States declined to intervene, this Court ordered that the Original Complaint be

“unsealed and served” on OBP. Relator Duxbury did not do so until October 12, 2006, however, and shortly thereafter (acting through new counsel) sought leave to file the Amended Complaint, which this Court granted. Apparently copying the Blair Complaint, the Amended Complaint in this case added a new count for “off-label dose promotion” and a new relator, Dean McClellan, who had also worked in OBP sales until 2004 and whom Duxbury allegedly had “developed as an additional Relator.” *See* Am. Comp. ¶ 28. Relators served the Amended Complaint on OBP on October 27, 2006.²

ARGUMENT

OBP moves to dismiss the Amended Complaint in the first instance under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction. Should the Court conclude that it has subject matter jurisdiction over any of Relators’ claims, OBP moves in the alternative to dismiss Count III under Fed. R. Civ. P. 12(b)(6) for failure to state a claim and the Amended Complaint in its entirety under Fed. R. Civ. P. 9(b) for failure to plead fraud with sufficient particularity.

I. THE COURT LACKS JURISDICTION OVER ALL CLAIMS IN THE AMENDED COMPLAINT UNDER THE FCA’S PUBLIC DISCLOSURE BAR.

Count I of the Amended Complaint alleges that OBP unlawfully “gave kickbacks” to Providers in violation of the Medicare laws and FCA “to induce them to prescribe

² In response to OBP’s September 29, 2006 Motion to Dismiss Complaint, the Court considered whether Local Rule 4.1(b) mandated “automatic dismissal” for Duxbury’s failure to serve the Original Complaint within 120 days. *See also* Fed. R. Civ. P. 4(m). As an FCA complaint, the 120-day period began when this Court unsealed the Original Complaint on July 12, 2005. *See, e.g., United States ex rel. Howard v. Life Care Ctrs. of Am., Inc.*, Civ. No. 1:03-CV-41, 2005 WL 2674939, at *2 (E.D. Tenn. Oct. 20, 2005); *United States ex rel. Gathings v. Bruno’s, Inc.*, 54 F. Supp. 2d 1252, 1260 (M.D. Ala. 1999) (dismissing FCA complaint as to one defendant just over four months after its unsealing under Rule 4(m)) The Court held that this action could proceed. OBP respectfully disagrees, asserts that it was not properly served, mandating dismissal under Rule 12(b)(5), and otherwise preserves its rights on this issue.

Procrit.” Am. Compl. ¶ 228. Count II claims that these same “kickbacks” and other OBP practices “increased the spread between the effective cost [to Providers] and the AWP for Procrit” and thus caused Providers to submit claims for Procrit prescriptions to the Medicare program at an “inflated amount.” Am. Compl. ¶¶ 258, 259. The essential allegations supporting both of these claims are *exactly* the same as those publicly disclosed in an earlier lawsuit that Relator Duxbury’s original counsel, Hagens Berman LLP, filed in 2002 as lead counsel for other plaintiffs in an enormous and widely publicized class action still pending in this district alleging essentially the same conduct by OBP and other pharmaceutical companies with respect to AWP.³ The same essential allegations also have been the subject of many previously-issued government and news media reports.

Likewise, Count III of the Amended Complaint, alleging “off-label promotion,” regurgitates facts and claims that already have been made public by another relator in an earlier FCA lawsuit – an FCA case that was also declined by the Justice Department. *See* Notice of the U.S., *Blair*, Docket Entry No. 19 (Nov. 15, 2005) (Ex. B). This Court thus lacks jurisdiction under the FCA’s “public disclosure” bar to hear any of the claims in the Amended Complaint, and the Amended Complaint therefore should be dismissed under Fed. R. Civ. P. 12(b)(1).

A. The FCA Public Disclosure Bar Prohibits *Qui Tam* Complaints Based Upon Previously Disclosed Information.

The FCA provides that:

No court shall have jurisdiction over an [FCA *qui tam*] action ... 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

³ Master Consolidated Class Action Compl. (“MCC”), *In re Pharm. Indus. Average Wholesale Price Litig.*, Civ. No. 01-12257, MDL No. 1456, Docket Entry No. 148 (D. Mass. Sept. 6, 2002) (“AWP MDL”).

media, unless ... the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). Under this provision, if “there has been a public disclosure within the meaning of the statute” and “the relator ‘based’ his suit on the public disclosure,” the Court lacks jurisdiction to hear the relator’s claim unless “the relator is ‘an original source of the information.’” *United States ex rel. O’Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 91 (D. Mass. 2001) (quotation omitted).

The “public disclosure” bar does not require that an FCA defendant, in order to defeat a court’s jurisdiction, show that every fact supporting a relator’s allegations of fraud was publicly disclosed before the relator filed his lawsuit. OBP must show merely that the prior public disclosure was “sufficient to put the government on notice of the likelihood of related fraudulent activity.” *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 389 (6th Cir. 2005); *see also United States ex rel. Settlemire v. District of Columbia*, 198 F.3d 913, 919 (D.C. Cir. 1999) (prior public disclosure need not set forth a relator’s specific claims but only the same “general practice” alleged in the relator’s complaint along with a relevant “inference of fraud”). This interpretation of the statute is consistent with the FCA’s intent to “walk a fine line between encouraging [true] whistle-blowing” by private citizens of false claims against the government that the government otherwise could not have discovered and “discouraging opportunistic behavior” by plaintiffs seeking to profit at the government’s expense by filing “parasitic” FCA lawsuits based on information that was already in the public domain and thus already known or available to the government. *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 651 (D.C. Cir. 1994); *see also United States ex rel. S. Prawer & Co. v. Fleet Bank of Me.*, 24 F.3d 320, 326 (1st Cir. 1994).

Put another way, the public disclosure bar distinguishes “suits which the government is capable of pursuing itself” from “those which the government is not equipped to bring on its own.” *Quinn*, 14 F.3d. at 651; *S. Praver & Co.*, 24 F.3d at 326. As stated by the Seventh Circuit, “the function of a public disclosure is to bring to the attention of the relevant authority that there has been a false claim against the government.” Once the government is aware of the fraud, it is “in a position to vindicate society’s interests, and a *qui tam* action would serve no purpose.” *United States ex rel. Feingold v. Adminastar Fed., Inc.*, 324 F.3d 492, 495 (7th Cir. 2003); *see also United States ex rel. Findley v. FPC-Boron Employees’ Club*, 105 F.3d 685, 690 (D.C. Cir. 1997) (noting that once an allegation is properly in the public domain, a further *qui tam* suit would have the effect of “either pressuring the government to prosecute cases when it has good reason not to or reducing the government’s ultimate recovery”).

Notably, the relator bears the burden with respect to the public disclosure issue. By its terms, the public disclosure bar is an issue of subject matter jurisdiction. *See* 31 U.S.C. § 3730(e)(4) (“No court shall have jurisdiction over an action ... based upon the public disclosure of ...”). Since federal courts are of limited jurisdiction, the presumption is that no jurisdiction exists, and “the party invoking the jurisdiction ... carries the burden of proving its existence.” *See Murphy v. United States*, 45 F.3d 520, 522 (1st Cir. 1995) (noting jurisdictional pleading “may not rest merely on unsupported conclusions ... or conclusory descriptions of a general scenario”) (quotations omitted). The party invoking federal jurisdiction must “allege in his pleading the facts essential to show jurisdiction,” and “must support [those facts] by competent proof.” *McNutt v. General Motors Acceptance Corp.*, 298 U.S. 178, 189 (1936). “[S]tatutes conferring jurisdiction on federal courts are to be strictly construed, and doubts resolved against federal jurisdiction.” *United States ex rel. Precision Co. v. Koch Indus., Inc.*,

971 F.2d 548, 553 (10th Cir. 1992) (*quoting F&S Constr. Co. v. Jensen*, 337 F.2d 160, 161 (10th Cir. 1964); *United States ex rel. O’Keeffe v. Sverdup Corp.* 131 F. Supp. 2d 87 (D. Mass. 2001) (citing *Precision Co.*). The Amended Complaint – like the Original Complaint that preceded it – fails to allege facts establishing jurisdiction. In fact, it is the very essence of a “parasitic” lawsuit.

B. The Essential Facts Supporting Counts I and II of the Amended Complaint Have Long Been Publicly Disclosed in Prior Litigation and Various Government and Media Reports.

Relator Duxbury filed the Original Complaint more than a year *after* his former counsel, Hagens Berman LLP, filed a Master Consolidated Class Action Complaint (“MCC”) on behalf of other clients that alleged all of the essential facts forming the basis both for the Original Complaint, as well as Counts I and II of the Amended Complaint. *See* MCC, AWP MDL, Docket Entry No. 148.⁴ No fewer than 18 paragraphs in the Amended Complaint feed directly off of the MCC. *Compare* Am. Compl. ¶¶ 32-34, 40-45, 64, 71-74, 91-92, 95, 129 *with* MCC, AWP MDL ¶¶ 141-49, 158-60, 162, 164-65.⁵ For example, both the MCC and the Amended Complaint allege that OBP:

⁴ The public disclosure bar applies both to civil “proceedings” as well as civil “hearings.” *See United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 652 (D.C. Cir. 1994) (“It is clear from statutory context that the term “hearing” was intended to apply in a broad context of legal proceedings under § 3730(e)(4)(A).... If court documents could be copied at will to provide a basis for *qui tam* suits, a half-century of precedent would be swiftly refuted”); *O’Keeffe*, 131 F. Supp. 2d at 92 (same standard).

⁵ *Compare* Orig. Compl. ¶¶ 12-20, 28-31, 33-34 (and MCC ¶¶ 157, 163 *with* Orig. Compl. ¶¶ 27, 32). Clearly, the AWP and related “kickback” allegations in the Amended Complaint were conceived in the MCC, incorporated into the Original Complaint in this case, and came to rest in the Amended Complaint. This is not surprising since the MCC and the Original Complaint were drafted by the same law firm. Essentially identical language also appears in an earlier complaint filed by the state of Montana – which was also represented by Hagens Berman LLP. *Compare* Orig. Compl. ¶¶ 12-23, 28-31, 33-34 *and* Am. Compl. ¶¶ 32-34, 40-48, 64, 72-73, 91, 95, 129 *with* State of Montana’s Sec. Am. Compl., redacted, AWP MDL, Docket Entry No. 597 (D. (continued...))

published ... AWP ... that did not reflect the actual pricing structure of the drugs, but was [sic] created solely to cause [overpayment] Defendant ... created and perpetuated this scheme so that ... [p]roviders who purchased these drugs at a low cost would bill ... at the inflated AWP and earn a substantial profit from the “spread” between the real cost and the ... AWP-related reimbursement rates.

Am. Compl. ¶¶ 71-72; MCC, AWP MDL ¶¶ 159 (ellipses for omissions from one or both).

Similarly, just as in this case, the MCC alleges that OBP implemented its “AWP scheme” in part by giving free samples to providers “to offset the total cost associated with the purchases of the drugs, thereby increasing the ‘spread,’” MCC ¶ 162; *compare with* Am. Compl. ¶¶ 91, and thus “effectively and improperly passed on the cost of the free [samples]” to Medicare, MCC ¶ 164; *compare with* Am. Compl. ¶ 95; *see also* MCC ¶ 4. Just as in this case, the MCC also asserts that OBP may have provided other inducements to stimulate its drug sales, including “volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and grants,” all of which were “designed to lower the [P]roviders’ net cost of purchasing [drugs from OBP].” MCC ¶ 165; *compare with* Am. Compl. ¶ 129.⁶ In addition, much like the Original Complaint and the Amended Complaint, the MCC further alleges that OBP “created promotional materials and worksheets to allow them to market the spread between the published AWP and the actual selling price [of drugs] to doctors.” MCC ¶ 297; *compare with, e.g.,* Am. Compl. ¶ 119 (training and promotional materials developed to market the

Mass. Aug. 1, 2003; notice of compl.’s filing on docket Sept. 17, 2003; docket shows redacted compl. avail. Nov. 6, 2003) ¶¶ 142-44, 146-52, 170-71, 176, 178-79, 181, 183-84 (“Montana Sec. Am. Compl.”) (*compare also* Orig. Compl. ¶¶ 27, 32 *with* Montana Sec. Am. Compl. ¶¶ 175, 182). *Compare also* State of Nevada’s Am. Compl., AWP MDL, Docket Entry No. 922 (D. Mass. Sept. 30, 2003; docket shows publicly avail. July 15, 2004) ¶¶ 107-17, 133-34, 139, 141-42, 144, 146-47 (also represented by Hagens Berman LLP).

⁶ *See also* MCC ¶ 4 (“In some cases, the Defendant Drug Manufacturers [including OBP] also provide chargebacks, rebates, hidden price discounts and/or other unlawful financial inducements, including free samples, to further increase the provider’s spread and, therefore, their incentive to prescribe [the manufacturer’s drug].”).

“spread”). Finally, the MCC also specifically claims that OBP’s alleged AWP scheme involved Procrit. *See* MCC, AWP MDL ¶¶ 108-09, 134, 294 (alleging “deliberate scheme to inflate AWP’s [published in “compendia” such as “Red Book,” “Blue Book,” and “Medi-Span’s *Master Drug Database*”] and to market the spread to increase the sales of its products”). The MCC then goes on to allege, as does both the Original Complaint and the Amended Complaint here, that OBP’s “AWP scheme” allegedly caused “massive federal expenditures” for Procrit, *id.* ¶ 295, and led to Medicare overpayments “based on the inflated AWP,” *id.* ¶ 4. Similar complaints filed by Hagens Berman LLP and others, some on behalf of individual states and some made public prior to Duxbury’s Original Complaint, allege the same “general practice” by OBP and others of “inflating AWP” at Medicare’s expense that Relators are now alleging here.⁷ Judge Saris, who has been presiding over the AWP MDL since 2002, referred in her opinions to these AWP and “kickback” allegations well before Relators filed any complaint in this case. *See, e.g., In re Pharm. Indus. Avg. Wholesale Price Litig.*, 263 F. Supp. 2d 172, 178-79 (D. Mass. May 13, 2003). OBP has consistently denied these allegations, and the Justice Department has declined to intervene in the present FCA case making the same allegations.

⁷ *See supra* note 5; *Settemire*, 198 F.3d at 919 (only alleging same “general practice” required); *see also Gilligan*, 403 F.3d at 389. The first Amended MCC, which Hagens Berman LLP also filed before filing the Original Complaint in this case, also contains the same essential allegations of a “scheme” by OBP “to inflate AWP’s” and claims that the scheme involved the “fraudulent” maintenance of Procrit’s price at 20.8% less than AWP. Am. MCC, AWP MDL, Docket Entry No. 597 (D. Mass. June 18 & Nov. 5, 2003) ¶¶ 4, 104-05, 142-54, 159-67, 436-45. *See also, e.g., County of Suffolk Am. Compl.*, AWP MDL, Docket Entry No. 450 (D. Mass. Aug. 1, 2003; entered on public docket Aug. 4, 2003) ¶¶ 1, 8-11, 13-18, 41, 251, 256-57 (accusing OBP of “routinely and systematically inflating the reported AWP’s” for Procrit, while concealing that inflation, resulting in overcharges to Suffolk and to Medicaid and Medicare).

Even before the AWP MDL, the essential facts forming the basis for Relators' AWP and related "kickback" claims were the subject of numerous government reports.⁸ In December 1997, for example, the HHS Inspector General ("OIG") issued a report referring to Medicare reimbursement for epoetin alfa (marketed by OBP as Procrit).⁹ This report noted that, while Medicare allowed reimbursements based on "estimated acquisition cost" ("based on surveys of actual invoice prices") as well as AWP, Medicare carriers "utilized AWP." *See* 1997 OIG Rept. at 1. But, the report stated, "physicians and suppliers are often able to purchase drugs for prices that are much lower than the official AWP's provided by manufacturers." *Id.* at 7. The report also contrasted AWP with "actual acquisition cost," which, the report asserted, would include "all discounts, rebates, and any other benefit in cash or in kind." *Id.* at 2. According to the report, relying on actual acquisition cost for epoetin alfa (marketed by OBP as Procrit) rather than AWP would have resulted in a 17% savings for 1995 and 13% for 1996 – the AWP "spreads" for those years. *See id.* at C-2, C-3.

Similarly, a September 2001 Government Accountability Office ("GAO") report publicly disclosed that for 2001 the "average widely available discount from AWP" for Procrit

⁸ In deciding a motion to dismiss under Rule 12(b)(1), the Court is free to consider not only the allegations of the complaint, but also extrinsic evidence, including affidavits, without converting the motion into one for summary judgment under Rule 56. *See, e.g., Skwira v. United States.*, 344 F.3d 64, 71-72 (1st Cir. 2003) (district court has broad authority to "consider extrinsic evidence, and hold evidentiary hearings in order to determine its own jurisdiction"). A motion to dismiss for lack of jurisdiction pursuant to the public disclosure bar of the FCA is properly raised under Federal Rule of Civil Procedure 12(b)(1). *United States ex rel. LeBlanc v. Raytheon Co.*, 874 F. Supp. 35, 37 (D. Mass. 1995), *aff'd*, 62 F.3d 1411, 1995 WL 471105 (1st Cir. 1995).

⁹ *See* OIG, *Excessive Medicare Payments for Prescription Drugs* (December 1997), available at <http://www.oig.hhs.gov/oei/reports/oei-03-97-00290.pdf> (last visited Jan. 16, 2007) ("1997 OIG Report").

was 15.2 percent.¹⁰ While noting that Medicare carriers “use published AWP to determine the Medicare-allowed amount, or payment level,” the report stated that AWP were akin to “a ‘list price,’ ‘sticker price,’ or ‘suggested retail price,’ reflecting the fact that AWP is not necessarily the price paid by a purchaser or a consistently low or ‘wholesale’ price.” *Id.* at 9; *see also id.* at 1. The report further noted that the transaction price to Providers at the time of sale often did not reflect the “final net cost to the purchaser,” since purchasers often obtain various forms of discounts and rebates (including “chargeback” arrangements and “payments for services related to providing drugs”). *Id.* at 10, 13, 21, 25.

These reports thus publicly disclosed – and in considerable detail – the same alleged “general practice” by OBP that formed the basis for both the Original Complaint and Counts I and II of the Amended Complaint – namely, that the AWP calculated for epoetin alfa, marketed by OBP as Procrit, often exceeded the price that Providers paid for the drug because of discounts not taken into account in calculating AWP. *See, e.g.,* Am. Compl. ¶¶ 5, 70, 228, 250. Indeed, in all likelihood it was these and other government and media reports¹¹ that led Relator

¹⁰ GAO, *Payments for Covered Outpatient Drugs Exceed Providers’ Costs*, GAO-01-1118 (Sept. 2001) (“2001 GAO Report”) at 12, 14, *available at* <http://www.gao.gov/new.items/d011118.pdf> (last visited Jan. 16, 2007) (“2001 GAO Report”). *See also* Subcomm. on Health and Subcomm. on Oversight & Investigations for Comm. on Energy & Commerce, House of Reps., Joint Hearing, *Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers*, Serial No. 107-65 (Sept. 21, 2001) at 87-88, 250-52, 365-68, 380-81 (testimony mentioning erythropoietin – epoetin alfa – alleging AWP improperly exceeds actual prices with discounts; tables alleging percentages by which Medicare exceeded Dept. of Veterans Affairs, wholesale catalog, physician/supplier, and acquisition cost figures for epoetin alfa).

¹¹ *See also, e.g.,* Medicare Program, Payment Reform for Part B Drugs, 68 Fed. Reg. 50428-01, 50429-30, 50444 (proposed Aug. 20, 2003) (to be codified at 42 C.F.R. pt. 405) (asserting “[n]umerous” GAO, OIG, and DOJ reports note AWP spreads, and alleging a 15.2% “widely available discount” from AWP for epoetin alfa in 2001). Prior news media disclosures also suggested AWP spreads for Procrit resulting in Medicare overpayment. *See, e.g.,* Fair Disclosure Wire, “Q4 2002 Johnson & Johnson Earnings Conference Call – Final” (Jan. 21, (continued...))

Duxbury's former counsel and other prominent plaintiffs firms to initiate what ultimately became the AWP MDL, in which Relators' essential facts were once again publicly disclosed.

C. The Essential Facts Supporting Count III of the Amended Complaint Were Previously Publicly Disclosed by Another Relator.

Relators' "off-label promotion" claims in Count III are equally parasitic. Three years *before* Relators filed the Amended Complaint, which effectively first set forth their off-label dose promotion claim, Kurt Blair filed a 95-paragraph FCA *qui tam* complaint in the District of Colorado raising against OBP this claim as to Procrit in detail. *See* Compl., *United States ex rel. Blair v. Ortho Biotech, Inc.*, Civ. No. 03-02585 (D. Colo. Dec. 22, 2003) (Ex. A) ("Blair Complaint"). The Justice Department also declined to intervene in this case.

The Original Complaint in this case was filed (under seal) on November 6, 2003, six weeks before the Blair Complaint. *Unlike* the Blair Complaint, however, the allegations in the Original Complaint in this case focused exclusively on OBP's allegedly fraudulent scheme to inflate the AWP for Procrit and the various alleged "kickbacks" and other wrongful payments that OBP made to Providers as part of this purported scheme. The Original Complaint contained *none* of the allegations of "off-label promotion" that appeared in the Blair Complaint.

Moreover, although the Blair Complaint was filed six weeks after Duxbury's Original Complaint, it was unsealed and made public nearly a year *before* Relators filed the Amended Complaint. *See* Order Denying Mot. to Extend Seal Period, *Blair*, Civ. No. 03-02585, Docket Entry No. 21 (Nov. 18, 2005) (Ex. C). The Amended Complaint in the present case re-

2003) (discussion of Johnson & Johnson drugs including Procrit and addressing Merrill Lynch participant question on "discrepancy between AWP and list price" and "the threatening litigation out there because of the ongoing controversy between what Medicare pays and your list price"); Washington Bus. Info., Inc., "New CMS Pricing Proposals Could Cut Billions in Payments" (Aug. 25, 2003) (discussing proposals to address the "spread" between the 95% of AWP "Medicare pays and the actual market price" and thus alter epoetin alfa payments).

alleges – largely through the new relator and at times words for word – the same essential facts purporting to support the off-label promotion scheme that were previously publicly disclosed in the unsealed Blair Complaint. *Compare, e.g.,* Blair Compl. ¶ 90 with Am. Compl. ¶ 273 (alleging in nearly identical language improper off-label “claims were made across the United States” beginning around 1998); *compare more generally* Blair Compl. ¶¶ 8, 10, 14-16, 19-24, 26-27, 36, 38-43, 74, 81-86, 88-90 with Am. Compl. ¶¶ 6-7, 49-50, 132, 148-69, 198, 271-87 (with Blair Compl. ¶¶ 10, 14-15, 90 containing language nearly identical to Am. Compl. ¶¶ 49-51, 273). The public disclosure of the off-label allegations in the Blair Complaint defeats this Court’s jurisdiction to hear Count III of the Amended Complaint just as surely as the previously filed AWP litigation defeats the Court’s jurisdiction over Counts I and II.

D. Relators’ Claims are Clearly “Based Upon” the Prior Public Disclosures.

Relators’ claims are clearly “based upon” these prior public disclosures within the meaning of section 3730(e)(4)(A) as well. The general rule is that an FCA claim is “based upon” a public disclosure if the “allegations or transactions” noted in the disclosure are substantially or essentially the same as those alleged in the later claim.¹² Here, that test is easily satisfied.¹³

¹² *See, e.g., United States ex rel. Mistick PBT v. Hous. Auth.*, 186 F.3d 376, (3d Cir. 1999) (“based upon” means that the prior “disclosure sets out either the allegations advanced ... or all of the essential elements of the ... claims”); *United States ex rel. McKenzie v. BellSouth Telecomms., Inc.*, 123 F.3d 935, 940 (6th Cir. 1997) (“supported by ... substantial identity”); *Springfield Terminal Ry.*, 14 F.3d at 654 (allegation or “critical elements” of the fraud “in the public domain”); *Cooper v. Blue Cross & Blue Shield of Fla. Inc.*, 19 F.3d 562, 567 (11th Cir. 1994) (same); *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 553-54 (10th Cir. 1992) (“supported by ... in any part”); *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2d Cir. 1992) (similar to those disclosed “regardless of where the relator obtained his information”); *O’Keefe*, 131 F. Supp. 2d at 92-93 (adopting majority position).

¹³ Other courts have held that “based upon” requires a finding that the relator specifically “derived” its information from the prior disclosure, *see, e.g., Rost*, 446 F. Supp. 2d at 19 (adopting the “minority rule”), but Relators’ claims would be barred even under this rule. Given that Relators’ essential allegations mirror allegations in so many prior complaints and reports, in (continued...)

Relators' claims *mirror* allegations in many prior complaints and reports, in words often repetitive of prior complaints filed by the very same law firm originally representing Duxbury. As shown above, both Relators have borrowed much language specifically as to AWP and related kickback claims from a prior complaint (MCC) in the AWP MDL pending before Judge Saris, *see supra* Part I.B, and have relied as well on the Blair Complaint for the new "off-label promotion" claim, *see supra* Part. I.C. And Relator McClellan's claims expressly rely upon Duxbury's Original Complaint, as well. *See* Am. Compl. ¶¶ 28-29, 31. Relators' claims are thus unquestionably "based upon" prior disclosures. Consequently, these claims must be dismissed unless Relators can qualify themselves as "original sources" – which, as shown below, they cannot do.

E. Neither Duxbury Nor McClellan Qualifies as an Original Source.

Relators fail as sources, much less original sources, of the relevant information for three reasons. First, they were not the original sources of the publicly disclosed information. For each Relator, the public disclosure bar defeats this Court's jurisdiction to hear his claims unless he can demonstrate that he is an "original source of *the information*" – meaning the information that was publicly disclosed by one of the statute's specified means. § 3730(e)(4)(A) (emphasis added). "An FCA qui tam action may not be based on publicly disclosed information unless the relator is the original source of *that information*." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225, 230 (1st Cir. 2004) (emphasis added); *McKenzie*, 123 F.3d at 941-42 (requiring original sources to be indirect or direct sources of the publicly

words often repetitive of prior complaints filed by the very law firm originally representing Duxbury here (for Counts I and II) and repetitive of the prior Blair Complaint (as to Count III), it is clear that all their allegations are essentially derived from prior disclosures specified by the public disclosure bar.

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

Relators do not even allege that they were the source of information disclosed in the prior government and media reports and prior AWP MDL.¹⁴

Second, even if Relators were sources of the prior publicly disclosed information, they still would not qualify as “original sources” under the FCA. An “original source” under the FCA is one who “has voluntarily provided the information to the Government *before* filing an action under this section which is based on th[e] information.” 31 U.S.C. § 3730(e)(4)(B) (emphasis added). Courts have interpreted this requirement to mean that the “original source” relator must provide the government with the essential information supporting his claims *before* the relator or anyone else publicly discloses it reasoning that to allow otherwise would strip the relator of his status as a “true whistleblower.” As noted by *Karvelas*: “An FCA qui tam action may not be based on publicly disclosed information unless the relator is the *original source of that [publicly disclosed] information*” (emphasis added). 360 F.3d at 225; *see also id.* at 230; *McKenzie*, 123 F.3d at 941-42; *Dick*, 912 F.2d at 16; *Wang*, 975 F.2d at 1418. But to be that “original source,” a relator must also have “voluntarily provided the information to the Government.” 31 U.S.C. § 3730(e)(4)(B). *Karvelas* and the FCA thus together require informing the government of the relevant information *prior* to a specified public disclosure.

¹⁴ In fact, Relator McClellan freely admits that he is not the “original source” of any essential information in the Amended Complaint. *See* Am. Compl. ¶ 28 (“Relator Duxbury is the original source of the claims and allegations contained in the original Complaint and the Amended Complaint. Through the course of his investigation Relator Duxbury developed Relator McClellan as an additional Relator.... who provides [only] additional supporting facts and information.”).

The relator thus bears the burden of alleging not just that he provided information to the government before filing his *qui tam* suit, but that he provided the information before the relevant disclosures. *See, e.g., United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 691 (D.C. Cir. 1997) (“[T]he only reading of the statute that accounts for the requirement that an ‘original source’ voluntarily provide information to the government before filing suit . . . is one that requires an original source to provide the information to the government prior to any public disclosure.”); *United States ex rel. McKenzie v. Bellsouth Telecomm., Inc.*, 123 F.3d 935, 943 (6th Cir. 1997) (“[T]he relator must provide the government with the information prior to any public disclosure.”). Relators nowhere allege having done so.

Third, even if Relators did in fact inform the government of the essential facts supporting their claims in the Amended Complaint before others had publicly disclosed them (which they did not), Relators still cannot qualify as “original sources” because they did not have “direct and independent knowledge” of any of the purported false claims. *See* 31 U.S.C. § 3730(e)(4)(B). The requisite “direct and independent” knowledge of an actual FCA violation must include knowledge of “the actual submission of false claims.” *See United States ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 77 (D. Conn. 2006) (citing *Karvelas*) (evidence of an actual false claim is “the sine qua non of a False Claims Act violation”). Relators have no such knowledge. First, having left OBP in 1998, Relator Duxbury was in no position to have “direct and independent knowledge” of any OBP activities after 1998. Second, more broadly, Relators never identify a *single* false claim, claiming ignorance because “[t]he false claims were submitted by Providers with most of whom Relator has had no dealings, and the records of the false claims are not within Relator’s control.” *See* Am. Compl. ¶¶ 232, 251, 273; *see also infra* Part IV.A. Obviously, a relator cannot have “direct and independent” knowledge of the false

claims when he cannot identify a single false claim. *See Murphy*, 45 F.3d at 522 (conclusory descriptions are insufficient to establish subject matter jurisdiction); *O’Keeffe*, 131 F. Supp. 2d at 93, 96 (secondhand information not “direct”). Neither Duxbury nor McClellan are the “true whistleblowers” that the FCA has in mind, and this Court has no jurisdiction to hear their claims.

II. ALL OF RELATOR McCLELLAN’S CLAIMS AND ALL OF RELATOR DUXBURY’S COUNT III CLAIMS ARE BARRED BY THE FIRST-TO-FILE RULE.

Independently of the public disclosure bar, the FCA also divests this Court of jurisdiction over most of the claims alleged in the Amended Complaint under the “first-to-file” rule. Under this rule, once one relator files a *qui tam* complaint, all subsequent would-be relators are barred from bringing any claims arising from or related to the same essential set of facts. *See Campbell v. Redding Med. Ctr.*, 421 F.3d 817, 821 (9th Cir. 2005); *LaCorte*, 149 F.3d at 234 (citation omitted). “When a person brings an [FCA *qui tam*] action ... no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” 31 U.S.C. § 3730(b)(5). This “first-to-file bar” applies to *all* claims based on any set of facts alleged in the first relator’s complaint:

[T]he phrase “related action based on the facts underlying the pending action[.]” clearly bars claims arising from events that are already the subject of existing suits.... A later case need not rest on precisely the same facts as a previous claim Rather, if a later allegation states all the essential facts of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim, even if that claim incorporates somewhat different details.

United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 232-33 (3d Cir. 1998); *see also Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279 (10th Cir. 2004) (§ 3730(b)(5) bars any “related claim based in significant measure on the core fact[s] or general conduct relied upon in the first *qui tam* action”); *cf. also United States ex rel. Hampton v. Columbia/HCA Healthcare Corp.*, 318 F.3d 214, 217 (D.C. Cir. 2003) (“same material elements

of fraud”); *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1188-89 (9th Cir. 2001) (same material facts). A claim relies upon the “same essential facts” if it alleges facts similar or closely connected to those supporting a prior claim, “even if the allegations cover a different time period or location within a company.” *See Lujan*, 243 F.3d at 1188 (quotation omitted). “[S]uch duplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds.” *LaCorte*, 149 F.3d at 234; *see also Lujan*, 243 F.3d at 1189 (same); *Grynberg*, 390 F.3d at 1279 (government notice of potential fraud claim satisfies the purpose of qui tam suits); *Hampton*, 318 F.3d at 217 (the FCA aims to “reject[] suits which the government is capable of pursuing itself”).

The first-to-file bar is “exception-free,” *Lujan*, 243 F.3d at 1183, and cannot be avoided simply by amending a complaint to add a new relator – as is attempted here – when the new relator’s claims unquestionably would have been barred had they been brought on their own. *See United States ex rel. Fry v. Guidant Corp.*, Civ. No. 3:03-0842, 2006 WL 1102397, at *6 (M.D. Tenn. Apr. 25, 2006) (denying leave to amend to add a relator with claims related to those in first relator’s complaint); *United States ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp. 2d 8, 11, 14 (D.D.C. 2003) (“Amendment does not provide a back door to avoid this exception-free bar [‘of jurisdiction’].”); *Palladino ex rel. United States v. VNA of S. N.J.*, 68 F. Supp. 2d 455, 477-79 (D.N.J. 1999) (dismissing under § 3730(b)(5) claims of a relator added by amendment as related to those of the first relator).¹⁵ For the same reasons, addition-by-

¹⁵ *See also United States ex rel. LaCorte v. Wagner*, 185 F.3d 188, 191 (4th Cir. 1999) (“By drafting the statute in such unequivocal language, Congress made the strongest possible statement against private party intervention in qui tam suits.”); *United States ex rel. Stevens v. State of Vt. Agency of Natural Res.*, 162 F.3d 195, 205 (2d Cir. 1998) (FCA’s first-to-file bar (continued...))

amendment cannot cause Relator McClellan's claims to "relate back" to the date of the Original Complaint. *See Ortega*, 240 F. Supp. 2d at 14 ("[I]t is clearly outside the intent and purpose of § 3730(b)(5) to permit relation back.").

What all of this means, in sum, is that while Relator Duxbury may not have won the "race to the courthouse" against *all* potential relators (including Relator Blair as to "off-label promotion"), *Campbell*, 421 F.3d at 821, by filing his Original Complaint he clearly won the race against Relator McClellan. Under the "exception-free" first-to-file rule, Relator McClellan cannot assert any claims in the Amended Complaint that are based on essentially the same facts that Relator Duxbury already asserted in the Original Complaint. At a minimum, this would include both Counts I and II of the Amended Complaint. As far as Count III is concerned, Kurt Blair won the "race to the courthouse" against both Relators here. *See supra* Part I.C. The Blair Complaint was the first to allege an improper off-label Procrit-promotion scheme.

For these reasons, even if the "public disclosure" bar is found not to apply (which it should), the "first-to-file" rule independently deprives this Court of jurisdiction to hear *any* of Relator McClellan's claims in the Amended Complaint and all claims alleged by either Relator in Count III as well.

III. THE COURT SHOULD DISMISS THE "OFF-LABEL" ALLEGATIONS IN COUNT III FOR FAILURE TO STATE A VIOLATION OF THE FALSE CLAIMS ACT.

Should the Court conclude that it has subject matter jurisdiction over Count III despite the public disclosure and first-to-file bars, Count III must still be dismissed under Fed. R. Civ. P. 12(b)(6) for failing to allege cognizable FCA claims.

allows states to be parties to FCA suits only as original qui tam plaintiffs), *rev'd on other grounds*, *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765 (2000).

Dismissal of a complaint under Rule 12(b)(6) is appropriate if, accepting as true all “well-pleaded allegations” and “reasonable inferences,” the complaint “presents no set of facts justifying recovery.” *Cooperman v. Individual, Inc.*, 171 F.3d 43, 46 (1st Cir. 1999). “[E]mpirically unverifiable conclusions, not logically compelled, or at least supported, by the stated facts, deserve no deference.” *See United States v. AVX Corp.*, 962 F.2d 108, 115 (1st Cir. 1992). Courts also “exempt [from deference] ... those ‘facts’ which have since been conclusively contradicted by plaintiff’s concessions or otherwise.” *See Chongris v. Bd. of Appeals of the Town of Andover*, 811 F.2d 36, 37 (1st Cir. 1987). Finally, Rule 12(b)(6) permits courts to consider matters “susceptible to judicial notice,” as well as “matters of public record.” *Colonial Mortgage Bankers Corp. v. Lopez-Stubbe*, 324 F.3d 12, 15-16 (1st Cir. 2003).

The FCA is a highly punitive statute, and as such it is meant to be directed only against those who are clearly “out to cheat the federal government,” *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999), by using an outright “lie.” *Hindo v. Univ. of Health Scis./Chicago Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995). “Innocent mistakes or negligence are not actionable.” *Lamers*, 168 F.3d at 1018. *See also United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 681 (5th Cir. 2003) (special, five-judge concurrence). Nor are “errors based simply on faulty calculations or flawed reasoning,” *Lamers*, 168 F.3d at 1018 (citing *Wang*, 975 F.2d at 1420-21), or “statements [that] resulted from confusion,” *Lamers*, 168 F.3d at 1019. “[T]he FCA is not an appropriate vehicle for policing technical compliance with administrative regulations,” *id.* at 1020, and “imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA.” *Id.* at 1018. *See also Southland Mgmt. Corp.*, 326 F.3d at 682 (special concurrence).

In Count III, Relators allege that OBP is liable under the FCA for promoting “off-label” a 40,000 unit once-a-week dose of Procrit (which is now FDA approved) in such a way as to cause Providers to submit false claims to the Medicare program. But there are no allegations that OBP “knowingly” filed or caused a false claim within the meaning of the FCA – or, for that matter, that any claim that any Provider may have submitted to Medicare was necessarily “false” as a result. Liability under FCA § 3729(a)(1)-(2) can only attach when a defendant either (1) “knowingly presents or causes to be presented ... a false or fraudulent claim” or (2) “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.” “Knowingly” entails either “actual knowledge of the information” or “deliberate ignorance [or] ... reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b). Section 3729(a)(2), in fact, requires a “double-falsehood,” that is, the making or causing to be made a false record to get a false or fraudulent claim paid by the government. *See Franklin*, 2003 WL 22048255, at *1. Count III must be dismissed for failing to allege such falsity in anything other than a conclusory and legally unsupportable fashion.

To begin, unlike virtually all other “off-label” promotion cases pending in this district and elsewhere (including the *Parke-Davis* Neurontin litigation) the Relators do not allege that Procrit was promoted for a use for which it was not indicated – the allegation is that OBP promoted Procrit at a once-weekly *dose* of 40,000 units for chemotherapy patients. Relators concede that this dose was approved in the mid-1990s for treating blood loss in surgery patients. *See Am. Compl.* ¶ 62. But Relators also concede that Procrit was approved at *all times* at 10,000 units three times a week for chemotherapy patients; and Relators concede as well that Procrit was approved by the FDA in 2004 (before Relators added their off-label promotion claim) for

use with chemotherapy patients at the 40,000 unit once-a-week dose, *see* Am. Compl. ¶ 272, which has provided enormous health and life-sustaining benefits to millions of Americans.

Nor do Relators contest that there is anything wrong with physicians prescribing Procrit or other medicines for uses or doses for which they may not be indicated. In fact, both the courts and the FDA have long acknowledged the legality and patient benefits of such off-label utilization. *See, e.g., Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350-51 (2001) (prescribing off-label “is an accepted and necessary corollary of the FDA’s mission to regulate without directly interfering with the practice of medicine”).¹⁶ Nor do Relators appear to contest that a statement promoting a drug for a use or dose for which it has not been approved by the FDA (as “promotion” is defined under the FDCA and FDA regulations) is inherently false. *See Gredell v. Wyeth Labs., Inc.*, Civ. No. 05-2332, 2006 WL 2434932, at *3 (Ill. App. Ct. Aug. 23, 2006). Were it otherwise, Medicare and Medicaid would not expressly provide coverage for off-label indications for prescription drugs – as they do.¹⁷ In fact, Relators appear to concede

¹⁶ Just last month, a senior FDA official confirmed that off-label information is a *positive* force in medicine: “Physicians will not be able to always wait for FDA to approve a new label for every one of their patients, and drug companies will not be able to conduct a trial to explore every possible contingency. In the future, personalization of care could mean that we will have much more off-label use of new medicines, guided by the latest literature, at least until our regulatory approaches are able to fully adapt to a different paradigm where treatment is highly specific to individual patients. Yet policy forces are tugging in exactly the opposite direction by placing restrictions on the exchange of some of the most pertinent information.” Scott Gottlieb, FDA Deputy Commissioner for Medical and Scientific Affairs, *Remarks at FDA/CMS Summit*, Washington, D.C. (Dec. 5, 2006), *available at* <http://www.fda.gov/oc/speeches/2006/windhover1205.html> (last visited Jan. 16, 2007).

¹⁷ Medicaid reimbursement is *not* conditioned on whether a drug is prescribed for an approved (“on-label”) indication. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(12); 42 C.F.R. § 440.120(a). In fact, federal law *requires* Medicaid plans to reimburse for a prescription for any “medically accepted indication” – a category that includes not only FDA-approved indications, but also *off-label* uses that are “included or approved for inclusion” in certain drug compendia. 42 U.S.C. § 1396r-8(k)(6). *See also Hess*, 2006 WL 1064127, at *2.

that where Medicare reimbursed for Procrit at 40,000 units once-a-week, the Medicare carriers knowingly covered and reimbursed that dose, as they are authorized to do under federal Medicare law.¹⁸ Finally, Relators appear not to contest that a violation of the FDA promotional regulations (even if they had alleged one) does not, standing alone, constitute a violation of the FCA. *See Lamers*, 168 F.3d at 1020 (“[T]he FCA is not an appropriate vehicle for policing technical compliance with administrative regulations.”).¹⁹ More broadly, the Amended Complaint fails to allege a cognizable FCA claim for several reasons.

First, Relators never even allege that OBP caused the submission of any *particular* false claim. Relators make lots of general allegations about “off-label promotion,” but they never allege that a particular doctor submitted a particular claim to Medicare for a particular patient, much less that such a claim was false. A relator’s inability to identify or sufficiently describe a false claim is fatal to a *qui tam* action under the FCA. *See United States v. Kitsap Physician Serv.*, 314 F.3d 995, 997 (9th Cir. 2002).

¹⁸ Relators explicitly concede that Medicare carriers often knowingly reimburse for an off-label use of an approved drug. *See* Am. Compl. ¶ 39 (quoting 42 U.S.C. § 1395x(t)(2)(B)). For most of the operative period covered by the Amended Complaint, federal law permitted Medicare carriers to reimburse “FDA approved drugs used for indications other than what is indicated on the official label ... if the carrier determine[d] the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.” HHS Ctr. for Medicare & Medicaid Servs., Carriers Manual § 2049.4, *available at* 2003 WL 24033868. *See also* 42 U.S.C. § 1395x(t) (amending the term “drugs” to include any drugs or biologics used in an anti-cancer chemotherapeutic regime for a “medically accepted indication,” defined in turn to include (1) any use approved by the FDA, and (2) any off-label use of an FDA approved drug if (a) supported by, or approved for inclusion in, the major drug compendia, or (b) determined by the local carrier to be medically accepted based on clinical evidence in peer reviewed medical literature).

¹⁹ In fact, the vast majority of Relators’ examples of “off-label promotion” are internal company statements that were never communicated to Providers. Such internal statements not communicated expressly to Providers are not “promotion,” as defined by the FDCA and FDA regulations. *See Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 163 (4th Cir. 1998).

Second, Relators never allege that OBP made any false statements to doctors to cause them to file any particular claim, whether false or not. Unlike the allegations in *Franklin*, for example, Relators do *not* allege that OBP personnel made false statements to Providers or Medicare about Procrit's safety or efficacy at the 40,000 unit dose (and any such allegation could not be credited, as the FDA has approved Procrit as safe and effective at the 40,000 unit once-a-week dose, as Relators concede). Nor is there any allegation that OBP or any Provider made a false statement or false claim to Medicare to obtain reimbursement for the off-label "dose" for any particular patient. Nor is there any allegation that OBP or any particular Provider made a material false statement to Medicare to obtain reimbursement for the off-label dose. *See Franklin*, 147 F. Supp. 2d at 50 (fraudulent statement must be "material"). In fact, as Relators concede, the relevant Medicare payment form, HCFA 1500, required Providers to list the precise indication for which Procrit was being prescribed as well as the dose. Thus, there is no allegation that any Provider (and certainly not OBP) made a false or even misleading statement on the Medicare HCFA 1500 form. Relators never explain how OBP could cause the submission of a false claim (even if Relators had provided the necessary details about such a false claim) given that the Medicare carriers would have had to make an explicit and knowing determination to cover that alleged "off-label dose" of Procrit. *See, e.g.*, 42 U.S.C. § 1395x(t)(2)(B).

These types of pleading failures doomed a very similar "off-label promotion" claim in *United States ex rel. Hess v. Sanofi-Synthelabo Inc.*, Civ. No. 05-570, 2006 WL 1064127 (E.D. Mo. Apr. 21, 2006). There, the court observed the same deficiencies that plague this Amended Complaint – "Plaintiff does not allege that Defendant made any misrepresentations to doctors, to the Government or to anyone else regarding [the drug in question]; ... Plaintiff does not allege a single doctor prescribed [the drug] improperly; that

...any doctors who may have prescribed [the drug] and sought reimbursement from Medicare made any misrepresentations to Medicare[.]” *Id.* at *4. The court further observed that claims for reimbursement that were paid by the relevant Medicare carrier in that case could not constitute FCA violations, as the Medicare carrier in question had knowingly covered the claims. *Id.* at *8 (noting defendant’s openness with the government). Given those particular circumstances and pleading deficiencies, the court in *Hess* dismissed the FCA claims under Rule 12 because relator had never alleged that “Defendant deliberately lied nor that the data provided by Defendant either to its sales representatives or to doctors was incorrect or false.” *Id.* at *9. The court found that without an allegation of such deliberate falsehoods (“lies”) to doctors or Medicare, the Relator’s allegations could not state a cognizable False Claims Act claim. *Id.*

In dismissing the FCA claims in the *Hess* off-label promotion case, the court distinguished Judge Saris’ opinion in *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001), in ways that are equally applicable here. Unlike the complaint in *Hess* and the Amended Complaint in this case, Judge Saris in *Franklin* relied heavily on allegations that defendant’s “medical liaisons” made affirmative false statements and false claims to doctors about the drug’s “safety and efficacy” and lied about their scientific credentials and posed as researchers. *See id.* at 45; *Hess*, 2006 WL 1064127, at *10. Such allegations about falsity are absent here, and the FDA settled any question as to safety and efficacy long ago. Next, the *Hess* court noted that unlike the Relator in *Hess*, the Relator in *Franklin* identified particular physicians who were provided with false statements about the safety and efficacy of the drug, and particular physicians who submitted claims to the federal government for reimbursement. *Hess*, 2006 WL 1064127, at *10. The Amended Complaint here is equally devoid of allegations

about lies or false statements to Providers about the safety and efficacy of Procrit.²⁰ And there is one more reason why this case is distinguishable from *Franklin* that was not even present in *Hess* – unlike *Franklin*, which involved a claim to *Medicaid* that did “not require [Providers] ... to list the indication for which the drug is being prescribed,” in this case the relevant *Medicare* coverage rules for Procrit *did* require Providers to identify precisely the alleged off-label dose in question. See *United States ex rel. Franklin v. Parke-Davis*, Civ. No. 96-11651PBS, 2003 WL 2048255, at *4 (D. Mass. Aug. 22, 2003). Judge Saris in *Franklin* relied heavily on the fact that *Medicaid* was *unknowingly* covering claims for off-label uses, see *Franklin*, 147 F. Supp. 2d at 53, but here the relevant *Medicare* carriers knowingly reimbursed Procrit at 40,000 units once-a-week, for which it is now approved as safe and effective in any event.

Reduced to its essence, the Amended Complaint alleges lots of internal marketing statements regarding utilization of Procrit at 40,000 units once-a-week, but it never alleges particular false statements, lies, or false claims to doctors or *Medicare*. That is the “*sine qua non*” of an FCA case, *Karvelas*, 360 F.3d at 225, and that is absent here.

IV. THE COURT SHOULD DISMISS THE ENTIRE COMPLAINT UNDER RULE 9(b) FOR FAILING TO PLEAD ITS FRAUD CLAIMS WITH PARTICULARITY.

Even if the Court decides that it has subject matter jurisdiction, it should still dismiss the Amended Complaint in its entirety for failing to plead its allegations of fraud with anything approaching the particularity required by Fed. R. Civ. P. 9(b). Rule 9(b) seeks to prevent “strike suits” and “suits that simply hope to uncover relevant information during discovery.” See *Karvelas*, 360 F.3d at 226; see also *Franklin*, 147 F. Supp. 2d at 46 (Rule 9(b)

²⁰ As Judge Saris indicated in *Franklin*, her ruling might very well have been different if the plaintiff had alleged only “a technical violation of FDA’s prohibition on off-label marketing.” 147 F. Supp. 2d at 52.

aims to preclude “strike suits and fishing expeditions”). There is no question that “Rule 9(b) applies to claims [brought] under the FCA.” *Karvelas*, 360 F.3d at 228.

In an FCA case, Rule 9(b) requires a relator to set forth with particularity “the ‘who, what, when, where, and how’ of the alleged fraud.” *See United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000). Moreover, since FCA liability attaches “not to ... underlying fraudulent activity ... but to the ‘claim [to the Government] for payment,’” “a relator must [also] provide details that identify *particular false claims* for payment that were submitted” *See Karvelas*, 360 F.3d at 225, 232 (emphases added); *see also Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005) (FCA liability attaches to a false claim to the Government, “not the disregard of government regulations” or improper “internal policies”); *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006) (same). “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),” but “such pleadings invariably are inadequate unless they are linked to allegations, stated with particularity, of the *actual false claims* submitted to the government.” *Karvelas*, 360 F.3d at 232 (emphasis added). In short, “[n]o matter how likely the existence of false claims,” courts simply “cannot speculate that such claims inevitably flowed” from the other allegedly fraudulent activities outlined in an FCA complaint. *Rost*, 446 F. Supp. 2d at 28; *see also Karvelas*, 360 F.3d at 235. As demonstrated below, the Amended Complaint falls far below these standards.

A. The Amended Complaint Identifies No Actual False Claim With Specificity.

The 69-page Amended Complaint purports to describe a massive fraudulent scheme involving OBP and thousands of Providers occurring continuously and nationwide for at least fourteen years and costing Medicare untold millions of dollars. *See, e.g.*, Am. Compl.

¶¶ 90, 232, 247. Yet despite the apparent scope of Relators’ allegations, Relators cannot identify with particularity a *single actual false claim* that *any* Procrit Provider (even those identified in the Amended Complaint) has *ever* submitted to Medicare. Rather, Relators assert that they are constrained from pleading false claims with sufficient particularity because the actual “false claims” were “submitted by [P]roviders with most of whom Relator has had no dealings, and the records of the false claims are not within Relator’s control.” Am. Compl. ¶¶ 232, 251, 273. Relators also suggest that further “[s]pecification of the vast number of false claims would be burdensome to the Court and to the parties.” *Id.*

If accepted, Relators’ argument would lead to precisely the kind of lawsuit that Rule 9(b) is designed to avoid: a “suit[] that simply hope[s] to uncover relevant information during discovery.” *See Karvelas*, 360 F.3d at 226; *see also Rost*, 446 F. Supp. 2d at 26 (“The First Circuit ... has rejected the application of a relaxed pleading standard to fraud claims brought under the FCA,” which would allow a plaintiff the opportunity to “plead generally at the outset and then later amend the complaint, filling in the blanks through discovery.”). Moreover, the law is clear that – even for allegedly large or complex schemes – a relator must directly describe the “*sine qua non*” of an FCA claim by identifying “individual [reimbursement] claims for specific tests, supplies, or services.” *See Karvelas*, 360 F.3d at 225, 233. This requires that at least “some” of the following appear in the relator’s complaint: “the dates ... [‘on which any such claims were filed’], the content of the forms or bills submitted [including their ‘particular[] certification of compliance with federal regulations,’ if at issue], their identification numbers, the amount of money charged to the government [‘in individual claims for specific tests, supplies, or services’], 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 upon those practices.” *Id.* at 233, 234; *see also Sikkenga*, 2006 WL 3491784, at *18 (interpreting *Karvelas* as setting forth the First Circuit “requirements” under Rule 9(b)).²¹

In this case, *no* paragraph in the Amended Complaint specifies a particular date on which *any* allegedly fraudulent claim was submitted; *none* identifies the specific content of any particular form or bill submitted for fraudulent payment (including any allegedly improper certifications); *none* provides identification numbers for any form or bill; *none* sets forth the actual amount of money charged to the Government in any particular reimbursement claim; *none* identifies the specific goods or services for which the Government was billed (except for, one infers, unidentified quantities of unidentified doses for unidentified uses of Procrit, which is demonstrably insufficient); and *none* sets forth the length of time between the alleged fraudulent practices and the submission of claims based upon those practices. Thus, the Amended Complaint provides none of the specifics required by law to enable OBP to single out “any one single cost report, or bill, or piece of paper that was sent to the Government to obtain funding.” *See Karvelas*, 360 F.3d at 233 (quotation omitted). Just as in *Karvelas*, although Relators’ Amended Complaint is lengthy, its length does nothing to compensate for its lack of specificity. *See id.* (violation of Rule 9(b) despite “describing at considerable length ... sixteen schemes”).

Nor can the relator escape Rule 9(b)’s requirements by alleging that subsequent discovery might unearth the alleged false claims. In the Amended Complaint, Relators suggest that they are unable to identify any false claim because the claims were submitted by other

²¹ Moreover, each allegedly fraudulent scheme asserted against an FCA defendant must provide such “specifics” for “at least some” of the reimbursement claims. *See Karvelas*, 360 F.3d at 233-34 (analyzing each scheme separately); *see also Sikkenga*, 2006 WL 3491784, at *18 (same standard); *United States ex rel. Atkins v. McInteer*, No. 04-16167, 2006 WL 3461441, at *4 (11th Cir. Dec. 1, 2006) (“some” similar specifics required “for at least some of the claims”).

parties (*i.e.*, Providers) and thus the actual claims were in the hands of the government or these parties. *See* Am. Comp. ¶¶ 232, 251, 273 (“The false claims were submitted by [P]roviders with most of whom Relator [*sic*] has had no dealings, and the records of the false claims are not within Relator’s [*sic*] control.”) Addressing this precise issue, the First Circuit stated in *Karvelas* that “as [the relator] correctly notes, every FCA *qui tam* action involves allegations of false or fraudulent claims submitted to the government. In many of these cases, the information needed to fill the gaps of an inadequately pleaded complaint will be in the government’s hands.” 360 F.3d at 230. Nevertheless, the court dismissed the complaint, 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.” *Id.* at 231. Similarly, in *Walsh*, Judge Saris rejected the relator’s argument that he could not comply with Rule 9(b) because documents related to the alleged fraudulent claims were “with in the exclusive control of the vendors” and dismissed the complaint for failing to cite a “single false claim arising from an allegedly false invoice.” 98 F. Supp. 2d at 147.

Relators’ failures to allege any false claim specifically clearly compels dismissal. In *Karvelas*, the relator “did not set forth the specifics ... of any one single cost report, or bill, or piece of paper that was sent to the Government to obtain funding.” 360 F.3d at 233. The First Circuit held that this “failure to identify with particularity any actual false claims ... [was] fatal to his complaint.” *Id.* at 235 (noting specific problems in failing to “specif[y] the dates or content of any particular false or fraudulent claim,” provide “identification numbers or amounts charged in individual claims for specific tests, supplies, or services,” or “allege with particularity any certification of compliance with federal regulations in order to obtain payments”). More recently, in *Rost*, Judge Tauro dismissed an FCA case with prejudice because the relator failed to

meet this “minimum” of providing “details that identify particular false claims for payment that were submitted to the government.” 446 F. Supp. 2d at 26 (citation omitted). “No matter how likely the existence of false claims,” Judge Tauro held it was improper to “speculate that such claims inevitably flowed from Defendants’ activities.” *Id.* at 28 (citing *Karvelas*, 360 F.3d at 235). Relators’ failures as to claim submissions are “fatal.”

Similarly, in *Walsh*, 98 F. Supp. 2d at 147, Judge Saris dismissed a *qui tam* complaint against several hospitals and vendors alleging that the hospitals submitted cost reports to federal health care programs that did not reveal certain discounts. The defendants contended that the complaint failed to meet the requirements of Rule 9(b) because the complaint did “not identify or describe any specific hospital cost reports or transactions that allegedly gave rise to violations of the FCA.” *Id.* at 147. The court agreed, stating, *id.*:

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.

B. Relators’ Vague and Conclusory Allegations of Each of OBP’s Three Alleged Fraudulent Schemes Similarly Fail to Satisfy Rule 9(b).

Relators’ failure to comply with Rule 9(b) extends well beyond their inability to identify actual false claims. Relators also fail to plead the “who, what, when, where, and how” of all three of the alleged fraudulent schemes. *See Walsh*, 98 F. Supp. 2d at 147. For example, the numerous allegations of OBP’s violations of anti-kickback laws are not supported by the identification with particularity of a *single* false certification of compliance or claim submitted to Medicare. *See, e.g., id.* ¶¶ 233-38, 253-58, 276-81. Similarly, Relators’ description of OBP’s alleged AWP scheme relies almost exclusively on conclusory allegations that unspecified grants, rebates, and other payments to Providers fraudulently aimed to inflate Procrit’s AWP. *See, e.g., id.* ¶ 27. No particular claim is identified. Likewise, the allegations that OBP and Providers

“misused free samples” lack specificity,²² as do numerous allegations of misconduct where there are possible statutory safe harbors under federal law, including many of the allegations of fraudulent discounts or rebates²³ and educational grants.²⁴ The allegations in the Amended Complaint concerning Advisory Board memberships and “phony” drug studies (as connected to AWP) are also sorely lacking in specificity, *see, e.g.*, Am. Compl. ¶¶ 109, 124-27, as well as Relators’ mere listing of some “improper inducements.” Relators never allege *any* single false claim that was filed (or by when) for any of these issues.

As to the off-label dosing allegations, Judge Tauro’s holding in *Rost*, 446 F. Supp. 2d at 27-28, reveals a situation directly analogous to the case here:

Plaintiff’s complaint fails to identify one actual false claim that was submitted to the government for the reimbursement of an off-label prescription Plaintiff instead speculates that Defendants’ marketing activities must have caused physicians to prescribe ... for off-label uses and that some of these prescriptions were inevitably reimbursed The existence of conduct which may lead to false claims does not satisfy the heightened pleading requirements. No matter how likely the existence of false claims, this court cannot speculate that such claims inevitably flowed from Defendants’ activities.

More than *three years* have passed since the Original Complaint and was filed in this case, and more than a year has passed since that complaint was unsealed. Moreover, the Court allowed Relators a year *beyond* that permitted by Fed. R. Civ. P. 4(m) to serve the Original

²² *See* Am. Compl., ¶¶ 91-103, 130, 211(b)-(d), 211(g), 212(a)-(f).

²³ *See* Am. Compl., ¶¶ 104-19, 130, 211(a), 211(c), 211(e)-(g), 212(a), 212(c)-(e); 42 U.S.C. § 1320a-7b(b)(3) (2006) (no violation “if the reduction in price is properly disclosed and appropriately reflected in the costs claimed”); 42 C.F.R. § 1001.952(h) (2006) (discounts and rebates “safe harbor”); *see also United States v. Shaw*, 106 F. Supp. 2d 103, 110-22 (D. Mass. 2000) (discussion of “safe harbors”); *Walsh*, 98 F. Supp. 2d at 149 (Rule 9(b) failure with respect to “safe harbors”).

²⁴ *See* Am. Compl. ¶¶ 120-23, 130, 211(a), 211(h), 212(a)-(c), 212(e); 42 C.F.R. § 1001.952(d) (“safe harbor” for “personal services contracts,” which could cover educational services); *Walsh*, 98 F. Supp. 2d at 149.

Complaint on OBP and to file the Amended Complaint. Yet, despite being given all of this time and latitude, Relators have still failed to present any particularized facts supporting their claims. Indeed, not only have Relators fallen fall short, on all fronts, of meeting clearly established Rule 9(b) requirements, “[w]ithout citing a *single* false claim ... [they have] not met even a bare-bones Rule 9(b) test.” *See United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147-48 (D. Mass. 2000) (emphasis added and citation omitted) (dismissing with prejudice for such Rule 9(b) failure); *see also Hess*, 2006 WL 1064127, at *12 (quoting *United States ex rel. Joshi v. St. Luke’s Hosp.*, 441 F.3d 552, 559-60 (8th Cir. 2006)) (“a *qui tam* complaint must be sufficient at the onset [to satisfy] ... the procedural obligation under th[e] FCA to ‘disclose all material evidence and information known to the relator in order to allow the government to decide whether or not to intervene,’” and dismissing with prejudice under Rule 9(b)).

V. ANY REMAINING CLAIMS IN THE AMENDED COMPLAINT SHOULD BE DISMISSED TO THE EXTENT THAT THEY ARE BASED ON CONDUCT OR EVENTS OCCURRING BEFORE THE TIME PERIOD PRESCRIBED BY THE APPLICABLE SIX-YEAR STATUTE OF LIMITATION.

Relator Duxbury filed the Original Complaint as the sole plaintiff on November 6, 2003. Both Relators filed the Amended Complaint on October 27, 2006. Counts I and II of the Amended Complaint include allegations of misconduct extending “from December 1992 to the present.” *See* Am. Compl. ¶¶ 232, 251. The FCA has a six year statute of limitations. *See* 31 U.S.C. § 3731(b)(1).²⁵ At a minimum, therefore, the Court should dismiss any claims in the

²⁵ As the Tenth Circuit recently noted: “§ 3731(b)(2) was not intended to apply to private *qui tam* relators at all.” *Sikkenga*, 2006 WL 3491784, at *16. It is thus only the six-year provision of § 3731(b)(1) that applies to Relators here. *See also United States v. Rivera*, 55 F.3d 703, 706 n.2 (1st Cir. 1995) (current statute has similar six-year statute of limitations for *qui tam* relators).

Amended Complaint that Relators allege arose before November 6, 1997, which is six years before Relator Duxbury filed the Original Complaint.

Moreover, if the Court concludes that any claims in the Amended Complaint are based on facts materially different from those alleged in the Original Complaint, the statute of limitations must necessarily limit those claims to six years prior to the date of the *Amended* Complaint, or October 27, 2000. *See* Fed. R. Civ. P. 15(c). This is so for several reasons. First, the FCA does not expressly permit new and distinct claims to relate back. *See* 31 U.S.C. § 3731; Fed. R. Civ. P. 15(c)(1). Second, it is axiomatic that new and distinct claims cannot arise from the same “conduct, transaction, or occurrence . . . attempted to be set forth in [an] original pleading.” Fed. R. Civ. P. 15(c)(2).

Finally, Relator McClellan’s claims in particular are *all* governed by a statute of limitations calculated from the date of the Amended Complaint because, under the first-to-file rule, he unquestionably can only be a Relator if he is found to have beaten both Blair and Duxbury to the courthouse – and, for him to do that, all of his claims would have to be new and distinct from those alleged in the Original Complaint. Moreover, OBP neither knew nor should have known that Relator Duxbury intended to add Relator McClellan during the 120-day period for serving the Original Complaint under Fed. R. Civ. Pro. 4(m), which began when this Court unsealed the Original Complaint on July 12, 2005. *See United States ex rel. Howard v. Life Care Ctrs. of Am., Inc.*, No. 1:03-CV-41, 2005 WL 2674939, at *2 (E.D. Tenn. Oct. 20, 2005). Such lack of notice, for well over a year, clearly prejudiced OBP’s ability to address McClellan’s claims. *See* Fed. R. Civ. P. 15(c)(3); *Plubell v. Merck & Co.*, 434 F.3d 1070, 1072 (8th Cir. 2006) (“[T]he attitude taken in revised Rule 15(c) toward change of defendants extends by analogy to amendments changing plaintiffs” (quotation omitted).)

Accordingly, the Court should dismiss (1) any (otherwise viable) claims in the Amended Complaint by Relator Duxbury that are not based on facts materially different from those first asserted in the Original Complaint to the extent that they arose before November 6, 1997; (2) any (otherwise viable) new and distinct claims by Relator Duxbury in the Amended Complaint to the extent they arose before October 27, 2000; and (3) dismiss all (otherwise viable) claims by Relator McClellan to the extent that they arose before October 27, 2000.

CONCLUSION

For the reasons set forth above, OBP requests that Relators' Amended Complaint be dismissed in its entirety and with prejudice.

Respectfully submitted,

Dated: January 17, 2007

Susan L. Burke
BURKE PYLE LLC
4112 Station Street
Philadelphia, PA 19127
(Tel) (215) 487-6596
(Fax) (215) 482-0874

/s/ Ethan M. Posner
Ethan M. Posner (admitted *pro hac vice*)
Geoffrey E. Hobart (BBO# 547499)
Patrick S. Davies
Andrew W. Lamb
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(Tel) (202) 662-6000
(Fax) (202) 662-6291

Attorneys for Defendant Ortho Biotech Products, L.P.