UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 07-12153-RWZ

UNITED STATES OF AMERICA *ex rel.*
JAMES BANIGNAN AND RICHARD TEMPLIN *et al.*

v.

ORGANON USA INC.*, et al.*

Memorandum of Decision

June 1, 2012

ZOBEL, D.J.

Relators, James Banigan and Richard Templin, brought this qui tam action on behalf of the United States of America, twenty-seven states,[1] the District of Columbia, and the City of Chicago under the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and various state and local false claims statutes, against defendants Akzo Nobel N.V.,[2] Organon Biosciences N.V., Organon USA, Inc., Organon Pharmaceuticals USA, Inc., Organon International, Inc., Schering Plough Corp., Merck & Co., Inc. (collectively, "Organon" or "the Organon defendants"),[3] Omnicare, Inc., and

[1] California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin.

[2] Akzo Nobel has been dismissed for lack of personal jurisdiction (Docket ## 167-68).

[3] The Organon defendants were, at all relevant times, wholly-owned subsidiaries of Akzo Nobel N.V. Akzo Nobel sold Organon to Schering Plough in November 2007. Merck and Schering Plough merged in November 2009, with Merck continuing as the surviving public corporation. Merck and Schering Plough are sued in their capacity as successors in interest to Organon.

PharMerica, Inc.

Organon, Omnicare, and PharMerica[4] each move to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(6), 9(b), and 12(b)(1) (Docket ## 123, 125, 128). They also raise various other challenges to the state and local claims.

I. Background

A. Procedural History

Under the FCA's qui tam provisions a private individual, called a relator, may bring a civil action for violation of the Act on behalf of the United States. 31 U.S.C. § 3730(b). The United States can intervene and assume primary responsibility for the action, but the relator may proceed if the government declines to do so. Id. §§ 3730(c)(1), (b)(4)(B). Either way, the relator may share in any award – 15%-25% if the government intervenes; 25%-30% if it does not – and may be compensated for reasonable expenses, fees, and costs. Id. §§ 3730(d)(1)-(2).

Relators filed their Original Complaint under seal in the Southern District of Texas on September 13, 2007; the case was transferred to this court and the Original Complaint filed in camera and under seal on November 19, 2007 (Docket # 8). Relators filed an Amended Complaint (Docket # 23) and a Second Amended Complaint (Docket # 33) in camera and under seal on November 10, 2008, and March 23, 2010, respectively. The United States notified the court on April 23, 2010, of its decision not

[4] Although PharMerica, Inc., is the nominal defendant, its legal successor, PharMerica Long-Term Care, LLC, files the instant motion to dismiss. Docket # 123.

to intervene as to certain claims (Docket # 36), and on September 7, 2010, as to all remaining claims (Docket # 39). Fifteen plaintiff states[5] and the Commonwealth of Virginia notified the court of their decisions not to intervene on October 5, 2010 (Docket # 41) and October 28, 2010 (Docket # 49), respectively.[6] The court unsealed the case on October 29, 2010. Relators filed the operative Third Amended Complaint ("TAC") (Docket # 105) under seal on April 11, 2011. Defendants' motions to dismiss followed.

B. Statutory Background

Counts I-V of the TAC are under the FCA.[7] Counts I, II, and III are against Organon, PharMerica, and Omnicare and respectively allege violations of 31 U.S.C. §§ 3729(a)(1), (a)(2), and (a)(3)[8] as the statute appeared before it was amended in 2009.[9] Count IV alleges a violation of 31 U.S.C. § 3729(a)(7) against Organon only. In Count V, Relators – who are former employees of Organon and Schering Plough – allege that both companies retaliated against them in response to their investigation and initiation of their claims, in violation of 31 U.S.C. § 3730(h). Organon does not raise this count in its motion; thus, the court will not address it further.

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[5] California, Colorado, Connecticut, Florida, Georgia, Illinois, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Tennessee, Texas, and Wisconsin.

[6] On February 16, 2011, Maryland notified the court of its decision not to intervene. Docket # 98.

[7] Counts VI-XXXIV allege violations of state and local false claims statutes against all defendants and Count XXXV seeks common fund relief. See infra Part III.

[8] I refer to subsections of 31 U.S.C. § 3729 as "FCA subsection" followed by the relevant number. For example, § 3279(a)(1) is referred to as "FCA subsection (a)(1)."

[9] The FCA was significantly amended by the Fraud Enforcement and Recovery Act of 2009 ("FERA"). Pub. L. No. 111-21, 123 Stat. 1617 (2009). The revised statute took effect on May 20, 2009, over a year and a half after Relators filed their Original Complaint.

FCA subsections (a)(1)-(3) and (7) provide civil penalties for:

> (a) Any person who:
>
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
>
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> . . .
>
> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government[.]

31 U.S.C. §§ 3729(a)(1)-(3), (7). Relators' allegations in support of Counts I-IV fall into three categories: kickback claims against all defendants, and pricing and off-label marketing claims against the Organon defendants. The kickback claims allege violations of the Anti-Kickback Statute, 42 U.S.C. §§ 1320a-7b(b)(1)(B), (b)(2)(B), which makes it a crime to knowingly and willfully solicit, receive, offer, or pay "any remuneration" to induce business that is reimbursed under a federal health care program.[10] Compliance with the Anti-Kickback Statute is a condition of payment for any

[10] In relevant part, 42 U.S.C. § 1320a-7b(b)(1)(B) penalizes "whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good facility, service, or item for which payment may be made in whole or in part under a Federal health care program. . . ."

Section 1320a-7b(b)(2)(B) applies to "whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program. . . ."

claim submitted to a federal health care program, including Medicaid,[11] so that liability under the FCA can be predicated on a violation of the Anti-Kickback Statute. U.S. ex rel. Westmoreland v. Amgen, 812 F.Supp.2d 39, 54-55 (D. Mass. 2011) (collecting cases).

Defendants Omnicare and PharMerica are long-term care pharmacy providers ("LTCPs"). LTCPs provide pharmacy services to nursing homes and other long-term care facilities, whose resident population consists, in large part, of Medicaid patients.[12] According to the TAC, LTCPs enter into provider agreements with each state's Medicaid program to which they have submitted prescription drug reimbursement claims. These provider agreements require the LTCPs to comply with all state and federal laws, including the Anti-Kickback Statute.

C. Kickback Claims Against Organon, Omnicare, and PharMerica

According to the TAC, from 1999-2006 Organon, a pharmaceutical company, violated the federal Anti-Kickback Statute by engaging in a scheme to offer unlawful remuneration to LTCPs – Omnicare and PharMerica, among others[13] – in exchange for

[11] Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. A provider of health care services to a Medicaid recipient may submit claims for reimbursement to a state's Medicaid program, which in turn is reimbursed in part by the federal government. The precise percentage of each state's Medicaid obligation paid by the federal government varies by state. See 42 U.S.C. § 1396(d)(b)(discussing formula for calculating federal medical assistance percentage).

[12] LTCPs buy the drugs these facilities disburse to patients by contracting either with a long-term care buying group or group purchasing organization, or directly with the pharmaceutical company itself. According to the TAC, LTCPs have significant influence over the choice of drugs used in long-term care facilities.

[13] The TAC alleges that Organon engaged in a similar kickback scheme with LCTPs NeighborCare, NCS Healthcare, American Pharmaceutical Services, and Sunscript.

the pharmacies prescribing its antidepressants, Remeron Tablet and Remeron SolTab (collectively "Remeron"), to patients. This scheme allegedly resulted in the LTCPs filing hundreds of millions of dollars in fraudulent claims for Medicaid prescription drug reimbursements.

Organon participated in this scheme primarily in two ways. First, it aimed to prevent Remeron Tablet's 1998 patent expiration from affecting the drug's total sales by converting long-term care patients' prescriptions from Remeron Tablet to the patent-protected Remeron SolTab. Second, it tried to increase Remeron's market share by switching as many long-term care patient prescriptions as possible from competitor antidepressants to Remeron. These two processes are respectively described in the TAC as "conversion" and "therapeutic interchange."

Relators allege that Organon provided LTCPs, including PharMerica and Omnicare, with unlawful kickbacks to induce the LTCPs to participate in the conversion and therapeutic interchange scheme. It offered direct kickbacks, allegedly disguised as market-share discounts and rebates, as well as a "conversion rebate" for switching prescriptions from Remeron Tablet to Remeron SolTab, and a "therapeutic interchange bonus" for making Remeron a "preferred" drug and instituting a therapeutic interchange program that encouraged prescription of Remeron over competitor antidepressants. TAC ¶ 77. Organon also gave LTCPs other kickbacks to entice them to purchase and recommend Remeron, including "data sharing agreements, research and educational grants, sponsorship of annual meetings and continuing education programs, payments for advertising initiatives, offers of nominally priced Remeron product, entertainment,

gifts and other inducements." TAC ¶ 81. Relators allege that Organon, through its "Remeron SolTab Therapeutic Interchange Toolkit," marketed the drug to LTCPs by touting the LTCPs' "opportunity to profit" at Medicaid's expense based on the "spread" (difference between the average wholesale price of the drug, and the discounted price paid by the LTCPs), rebates, and discounts offered. TAC ¶¶ 88-91.

PharMerica and Omnicare not only received but also allegedly solicited such kickbacks from Organon in exchange for prescribing Remeron. For example, the TAC alleges that Organon budgeted for, and PharMerica provided Organon with, data sharing agreements under which Organon would pay PharMerica for data on Remeron and its competitor drugs. PharMerica's National Director of Clinial Programs and Development pitched its "Vendor in Partnership" ("VIP") program to Organon, which the TAC alleges was "little more than a conduit to funnel money to PharMerica in exchange for prescriptions," TAC ¶ 109 and Ex. 46-47; after Organon agreed to participate, PharMerica made Remeron a "preferred" product. TAC ¶ 114. PharMerica also solicited, and Organon provided, sponsorship of PharMerica's annual meeting in 2001.

Likewise, Omnicare is alleged to have actively solicited discounted pricing for Organon pharmaceutical products. Omnicare placed Remeron on "unrestricted access," which meant it was available on Omnicare's formulary of drugs without restrictions such as prior physician authorization for use, and was not targeted for therapeutic interchange to competitors' products. TAC ¶126. Purchasing agreements for Remeron in 2002 tied the amount of rebate Omnicare received to the conversion

rates from Remeron Tablet to Remeron SolTab. In addition to market-share rebates, discounts, conversion rebates, and therapeutic interchange bonuses, Organon and Omnicare traded proposals to study the effects of Remeron in the long-term care population, and Organon ultimately funded an outpatient study on the efficacy of and tolerance for Remeron SolTab in patients in Omnicare's nursing homes. Organon also offered nominally-priced Remeron SolTab to Omnicare, with the understanding that the offer was contingent upon Omnicare's later purchase of a similar quantity of the drug at contracted pricing.

Relators allege that, as a result of the aforementioned kickback scheme, PharMerica and Omnicare facilities purchased Remeron and then submitted reimbursement claims to state Medicaid programs. See TAC ¶ 118 (representative sample of PharMerica Medicaid reimbursement claims for Remeron filed in North Dakota between 2002-2004); id. ¶ 119 (representative sample of PharMerica Medicaid reimbursement claims for Remeron filed in Arizona); id. ¶ 142 and Ex. 66 (representative sample of Omnicare Medicaid reimbursement claims for Remeron filed in Arizona).

D. Pricing Claims Against Organon

In order for a drug manufacturer to have its products compensated under Medicaid, the manufacturer must have entered into a rebate agreement with the Secretary of the Department of Health and Human Services. 42 U.S.C. § 1396r-8(a)(1). Under the rebate agreement, the manufacturer must report quarterly to the Centers for Medicare and Medicaid Services ("CMS") both the average manufacturer price ("AMP")

and the "best price" for each of its covered drugs, and pay a quarterly rebate to Medicaid equal to the greater of the difference between the AMP and "best price," or a stated "minimum rebate percentage." Id. § 1396r-8(c)(1)(A). The rebate payment is made to ensure that Medicaid is receiving the best price for any covered outpatient drug.[14] Id. § 1396r-8(b).

Count IV of the TAC alleges that Organon violated FCA subsection (a)(7) by improperly reducing its rebate liability to state Medicaid programs in the following ways. First, it concealed its true best price for Remeron Tablet and Remeron SolTab by failing to disclose to CMS the kickbacks it provided to LTCPs (e.g., data sharing agreements, research grants, educational grants, and sponsorships), mischaracterizing transactions for the sale of Remeron as "nominal," and/or entering into discount arrangements on other drugs in exchange for the purchase of Remeron. Second, it lowered its reported AMP for Remeron by including in its AMP calculation the discounts and rebates it gave to LTCPs. And, third, it sold Remeron at a discounted price to entities not qualified to receive the discounts,[15] which resulted in Organon improperly excluding these transactions from its best price calculations.

E. Off-Label Marketing Claims Against Organon

[14] A covered outpatient drug is defined in 42 U.S.C. § 1396r-8(k)(2) to include a prescription drug which is approved for "safety and effectiveness" under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 355, 357, 355(j). The definition does not include a drug "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3).

[15] 42 U.S.C. § 256b establishes "covered entities" which are entitled to received statutorily defined discounts on outpatient drugs. Pharmaceutical manufacturers are required to participate in this so-called "340B program" as a condition of having drug charges reimbursed by Medicaid. County of Santa Clara v. Astra USA, Inc., No. C 05-03740, 2006 U.S. Dist. LEXIS 57176 (N.D. Cal. July 28, 2006).

Relators further allege that Organon promoted "off-label" uses for Remeron Tablet and Remeron SolTab in order to maximize the success of the therapeutic interchange program. Relators allege that, to be eligible for reimbursement under a state Medicaid program, a drug must be included on a state's drug formulary. They further allege that under federal law, a state Medicaid program "may exclude or restrict coverage" in certain instances, inter alia, if "the prescribed use is not for a medically accepted indication." TAC ¶ 207 (citing 42 U.S.C. § 1396r-8(d)(1)). A "medically accepted indication" is any use which either is approved by the FDA or supported by a citation in any of the drug compendia identified by the Medicaid statute. 42 U.S.C. §§ 1396r-8(k)(6), 1396r-8(g)(1)(B)(i)(identifying compendia).

The FDA approved Remeron for the treatment of depression in adults. Relators allege, however, that Organon marketed Remeron as an anti-anxiety substitute and played up the drug's side effects of somnolence (drowsiness) and increased appetite or weight gain, realizing that these side effects could be viewed as "positive" for the elderly population who experienced anxiety, sleep disturbances and had trouble maintaining weight. Organon marketed these side effects as though they were approved indications of the drug, and also promoted off-label use of Remeron in children and adolescents for the treatment of depression, attention deficit disorder ("ADD") and attention deficient hyperactivity disorder ("ADHD"). Furthermore, Relators allege that Organon marketed Remeron as effective for treating patients with anxiety, despite "a 1999 warning from the FDA that this claim was false and misleading." TAC ¶ 215. Organon also is alleged to have paid kickbacks to primary care physicians who prescribed a large amount of

Organon's drugs, in order to influence those physicians to promote off-label uses of Remeron. These kickbacks took the form of allegedly excessive speaker fees; special organized speaker programs; payments for participation in promotional teleconferences, preceptorships, tutorials, and advisory boards; consulting fees; and lavish relationship-building events such as dinners and receptions.

Relators allege that LTCPs submitted claims for reimbursement to state Medicaid programs for Remeron prescriptions that were tainted by off-label promotion, in violation of the FCA, 31 U.S.C. § 3729(a). In support, they proffer Medicaid reimbursement claims for Remeron where the drug was prescribed for off-label uses including insomnia, anxiety, loss of appetite and weight gain, TAC ¶¶ 242-44 and Ex. 92, and was prescribed for use by children, id. ¶¶ 249 and Ex. 94.

II. Analysis of Federal Claims

I first address the jurisdictional issues before turning to defendants' other grounds for dismissal. U.S. ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 727 (1st Cir. 2007) ("The threshold question in a False Claims Act case is whether the statute bars jurisdiction.").

A. First-to-File and Public Disclosure Bars

The FCA's qui tam provisions "attempt[ ] to reconcile two conflicting goals, specifically, preventing opportunistic suits, on the one hand, while encouraging citizens to act as whistleblowers, on the other." United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir. 1998) ["SmithKline"]. To strike the appropriate balance between these two goals, the FCA limits a district court's subject matter jurisdiction in qui tam actions through several jurisdictional bars, two of which

defendants invoke here.

1. First-to-File Bar

The "first-to-file" bar provides that once a relator has filed a qui tam suit under the FCA, "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).[16] "'[A] goal behind the first-to-file rule' is to provide incentives to the relators 'to promptly alert[ ] the government to the essential facts of a fraudulent scheme.'" United States ex rel. Duxbury v. Ortho Biotech Products, L.P., 579 F.3d 13, 32 (1st Cir. 2009) ["Duxbury"] (quoting United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1188 (9th Cir. 2001)). The first-to-file bar precludes "a later allegation [if it] states all of the essential facts of a previously filed claim" or "the same elements of a fraud described in an earlier suit." Duxbury, 579 F.3d at 32 (quoting SmithKline, 149 F.3d at 232-33) (emphasis added by First Circuit). "Under this 'essential facts' standard, § 3730(b)(5) can still bar a later claim 'even if that claim incorporates somewhat different details.'" Duxbury, 579 F.3d at 33 (quoting SmithKline, 149 F.3d at 232-33).[17]

[16] This provision was unaffected by amendments to the FCA enacted by FERA in 2009 and the 2010 Patient Protection and Affordable Care Act ("PPACA"), Pub. L. 111-148, 124 Stat. 119.

[17] Despite Relators' urging, I decline to additionally require that an allegedly first-filed qui tam action comply with Fed. R. Civ. P. 9(b) in order to bar a later qui tam suit. See Relators' Consol. Resp. to Defs.' Mots. to Dismiss at 30 (Docket # 141) (citing U.S. ex rel. Poteet v. Medtronic, Inc., 552 F.3d 503, 516 (6th Cir. 2009)(dicta)). Imposing this additional requirement would frustrate the purpose of the first-to-file bar by raising the threshold for it to apply. See U.S. ex rel. Batiste v. SLM Corp.,740 F.Supp.2d 98, 104 (D.D.C. 2010) (declining to require allegedly first-filed suit to comply with Rule 9(b), noting that "the point of Rule 9(b)'s heightened pleading standard is that it provides more than what is normally required to give adequate notice of the essential elements of a claim. . . . [I]t is entirely plausible that a complaint may provide sufficient information to cause the government to launch its own investigation of a fraudulent scheme without providing enough information under Rule 9(b) to protect the defendant's interests."). The First Circuit has not taken a position on this issue.

2. Public Disclosure Bar

The so-called "public disclosure" bar deprives a court of subject matter jurisdiction over a 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 Accountability Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A).[18] If there has been "a public disclosure of the allegations or transactions in the relator's complaint . . . in the manner specified in the statute," the court must then determine "whether the relator's suit is 'based upon' those publicly disclosed allegations or transactions." Duxbury, 579 F.3d at 21 (citing Rost, 507 F.3d at 728). An action is "based upon" a public disclosure "when the relator's allegations are substantially similar to allegations or transactions already in the public domain. . . . " U.S. ex rel. Ondis v. City of Woonsocket, 587 F.3d 49, 58 (1st Cir. 2009).

If the answer to the aforementioned inquiry is in the affirmative, then the court must determine whether the relator is an "original source." Duxbury, 579 F.3d at 21. A relator qualifies as an "original source" if he (1) is an individual with "direct and independent knowledge of the information on which the allegations are based;" and (2) has "voluntarily provided the information to the Government before filing" the qui tam action. 31 U.S.C. § 3730(e)(4)(B).

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[18] PPACA significantly amended the language in 31 U.S.C. § 3730(e). Since PPACA does not mention retroactivity, Graham County Soil and Water Conservation Dist. v. U.S. ex rel. Wilson, 130 S.Ct. 1396, 1400 n.1 (2010), I apply the version of section 3730(e) in effect at the time this case was filed. Id. (applying prior version of statute to interpret scope of public disclosure bar in case filed in 2001).

The FCA does not permit "jurisdiction in gross." U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P., 551 F.Supp.2d 100, 105 (D. Mass. 2008) (quoting Rockwell Int'l Corp. v. United States, 549 U.S. 457, 476 (2007)). Rather, the court must examine each claim to determine whether either jurisdictional bar applies. Id.

B. Jurisdictional Analysis of Kickback Claims Against PharMerica and Organon and Pricing Claims Against Organon

1. Kickback Claims Against PharMerica and Organon

PharMerica and Organon argue that United States ex rel. St. John La Corte v. Amerisource Bergen Corp. and PharMerica, Inc., No. 02-3168 (E.D. La.) ["Amerisource"], is a first-filed case that bars Relators' kickback claims against them. The Amerisource Original Complaint was filed on October 18, 2002. See Docket # 152 Ex. A. First and Second Amended Complaints were filed on December 12, 2003 (Docket # 152 Ex. B) and April 11, 2005 (Docket # 152 Ex. C), respectively.[19] To determine whether the first-to-file bar applies, I must compare the Relators' complaint with the Amerisource complaints.

The Amerisource relator, LaCorte, alleged that PharMerica contracted with several pharmaceutical manufacturers to receive "financial inducements in the form of discounts, remuneration, rebates, or kickbacks on some of [the manufacturer's] specific pharmaceutical products and supplies in exchange for PharMerica providing the

[19] All of the Amerisource complaints were unsealed well before Relators filed their Original Complaint. See March 1, 2004 Order unsealing Amerisource Original and First Amended Complaints (Docket # 123 Ex. C); June 7, 2005 Order unsealing Amerisource Second Amended Complaint (Docket # 123 Ex. E).

manufacturer with an agreed upon market share and volume for those specific products and supplies." Amerisource Orig. Compl. ¶ 58; Amerisource Sec. Am. Compl. ¶ 118 (same, and noting the drugs were included on PharMerica's "Select Formulary"). PharMerica allegedly achieved these market share targets through a process of "therapeutic interchange," whereby it substituted a "preferred drug" for the drug specifically prescribed. Amerisource Orig. Compl. ¶ 25.

LaCorte does not name Organon as one of the pharmaceutical companies providing kickbacks, but he does the equivalent by listing "Remeron" as one of PharMerica's "preferred drugs." Id. ¶ 31. See United States ex rel. Lisitza v. Johnson & Johnson, 765 F.Supp. 2d 112, 122 n.15 (D. Mass. 2011) ("The court agrees that, for purposes of prior disclosure, specifying a formulaic drug as part of a kickback scheme is synonymous with naming the company that produces it."). While the reference to Remeron was removed from the body of later complaints, in both the First and Second Amended Complaints, relator LaCorte alleged that PharMerica created a "Select Formulary" listing as "preferred drugs" those for which it was receiving kickbacks, and he attached to these complaints a "PharMerica Senior Select Drug Formulary" dated March 1, 2003, which included Remeron SolTab on the list of "Formulary Preferred Products." Amerisource First Am. Compl. ¶ 63 and Ex. E; Amerisource Sec. Am. Compl. ¶ 123 and Ex. 7. See also Amerisource First Am. Compl. Ex. X and Sec. Am.Compl. Ex. 28 (September 2002 letter from PharMerica National Director of Clinical Program Development to health care professionals explaining that Remeron SolTab is included within PharMerica's Select Formulary). Through this scheme, PharMerica allegedly

submitted falsely inflated claims for drug reimbursements to Medicaid, in violation of the False Claims Act. Amerisource Original Compl. ¶ 33.

Relators' kickback allegations against Organon and PharMerica state the same essential elements of fraud described in the Amerisource complaints: receipt and/or solicitation of kickbacks in exchange for switching patients to "preferred" drugs and filing false or fraudulent Medicaid reimbursement claims for those drugs. These elements are sufficient to put the government on the trail of the alleged fraud against PharMerica and Organon. That Relators' kickback claims involve additional details and types of kickbacks does not change the outcome. See Duxbury, 579 F.3d at 33; SmithKline, 149 F.3d at 234 (explaining that "once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds").

Likewise, under a public disclosure bar analysis, Relators' kickback allegations against PharMerica and Organon are substantially similar to the kickback allegations disclosed in the Amerisource complaints. It is of no matter that Organon itself was not named as a defendant in the Amerisource case; the Amerisource complaints publicly disclose the essential elements of a fraudulent kickback scheme involving Remeron, and thus Organon. United States ex rel. Poteet v. Bahler Medical, Inc., 619 F.3d 104, 111 (1st Cir. 2010) (civil complaint filed in court qualifies as public disclosure); U.S. ex rel. Feingold v. AdminaStar Federal, Inc., 324 F.3d 492, 495 (7th Cir. 2003) ("A 'public disclosure' exists under § 3730(e)(4)(A) when the critical elements exposing the transaction as fraudulent are placed in the public domain.").

2. Pricing Claims Against Organon

The Amerisource First and Second Amended Complaints also allege that with regard to "preferred drugs," PharMerica "directly caused, or . . . aided, abetted, or conspired with pharmaceutical manufacturers to cause, false quarterly cost reports, 'best price' reports, and rebate reports" to be filed with the Department of Health and Human Services and CMS, in order to "conceal, avoid, or decrease the amount of rebate obligation payable each quarter to State Medicaid agencies and credited to the United States government. . . ." First Am. Compl. ¶ 158; Second Am. Compl. ¶ 222. The Amerisource complaints allege that "these acts, omissions, and concealments have in fact caused the government a financial loss by receiving millions of dollars less than the rebates that were due to be paid to the government each quarter." Id. These claims and supporting allegations[20] disclose a fraudulent pricing scheme, the essential elements of which are alleged against Organon in this case.

The outcome is the same under a public disclosure analysis. Thus, under the FCA's first-to-file and public disclosure provisions, Amerisource bars all federal claims against PharMerica, as well as federal kickback and pricing claims against Organon.

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[20] Amerisource First Am. Compl. ¶¶ 27-32 and Sec. Am. Compl. ¶¶ 78-83 (describing manufacturers' price reporting and rebate obligations under Medicaid); First Am. Compl. ¶ 67 and Sec. Am. Compl. ¶ 127 (alleging that manufacturers charge PharMerica "substantially less for the substituted drugs than the 'best prices' for these drugs these pharmaceutical companies are reporting and certifying to the DHHS each quarter" and that the federal government "is not, in fact receiving the actual 'best price' for these drugs required by law and the manufacturer's Rebate Agreement with the Secretary of the DHHS."); First Am. Compl. ¶ 68 and Sec. Am. Compl. ¶ 128 (alleging that PharMerica submits "unauthorized or excessive bills" to Medicare and Medicaid and receive "unauthorized or inflated reimbursement . . . based on inaccurate utilization, cost and pricing data submitted by the Defendants and the pharmaceutical manufacturers to the DHHS, CMS, and other government agencies."); First Am. Compl. ¶ 71 and Sec. Am. Compl. ¶ 131 ("Because neither the true 'best price' nor the data from which it can be determined ever is accurately reported to the DHHS and CMS, the United States government is caused a financial loss, and both the pharmaceutical manufacturers and Defendants reap a financial windfall at the government's expense by receiving inflated reimbursements or unauthorized reimbursements.").

C. Jurisdictional Analysis of Off-Label Marketing Claims Against Organon

Organon argues that Relators' off-label marketing claims should be barred because they are based on public disclosures made in FDA warning letters about Remeron, which were sent to Organon in January and April of 1999 and made available on the FDA's web site. See TAC ¶¶ 220-226 and Ex. 84. The letters warn that Organon's promotional materials that "represent Remeron [Tablet] as particularly effective in treating anxiety" were "false and misleading." Ex. 84 (Apr. 1999 letter, discussing Jan. 1999 letter). The warning letters largely focus on Organon's promotional claims that Remeron was safer or more effective at treating anxiety than selective serotonin reuptake inhibitors (SSRIs), another type of antidepressant medication.

While an FDA warning letter can make a disclosure under 31 U.S.C. § 3730(e)(4)(A), United States ex rel. Gross v. AIDS Research Alliance-Chicago, 415 F.3d 601, 606 (6th Cir. 2005), the essential elements of the fraudulent off-label promotion scheme alleged in the TAC are not disclosed in the letters at issue here. "To be a disclosure 'of fraud' the disclosure must contain either (1) a direct allegation of fraud, or (2) both a misrepresented state of facts and a true state of facts, so that the listener or reader may infer fraud." Bahler Medical, 619 F.3d at 110 (internal citations omitted). The FDA warning letters do neither. Warnings that it is false, misleading, and unsubstantiated for Organon to market Remeron as appropriate for the treatment of anxiety or as superior to other types of anti-anxiety drugs (e.g., SSRIs) are not substantially similar to the scheme alleged here; namely, that Organon marketed Remeron as the ideal anti-depressant for geriatric patients by touting the side-effects as

approved indications, and that it marketed the drug for treatment of children with ADD and ADHD. Nor do they juxtapose a misrepresented and true state of facts, such that a reader of the warning letters could infer the fraudulent scheme alleged in the TAC.

Organon also argues that Relators' claims are based on publicly disclosed "claims data" which Relators obtained from state Medicaid agencies. On the record before me, it is neither clear exactly which "claims data" was obtained, nor that such data was a written response to a request for records under the Freedom of Information Act ("FOIA"), such that it may constitute an administrative report under the FCA. See Schindler Elevator Corp. v. United States ex rel. Kirk, 131 S.Ct. 1885, 1890 (2011) (holding that a federal agency's written response to a request for records under the FOIA constitutes a "report" within the meaning of the FCA's public disclosure bar); Ondis, 587 F.3d at 55 (holding that "a response to a FOIA request is an act of public disclosure because the response disseminates (and thus, discloses) information to the members of the public (and, thus, outside the government's bailiwick)."). .

D. Jurisdictional Analysis of Relators' Claims Against Omnicare

Omnicare contends that several "first-filed" cases bar Relators' kickback claims against it. Additionally, it argues that the kickback claims in the TAC were based on public disclosures made in these cases, in settlement agreements between Omnicare and the federal government, and in documents given to Relators by the Texas Attorney General's Office. For ease of discussion, I adopt Omnicare's nomenclature, and refer to

the allegedly "first-filed" cases as LaCorte,[21] the Illinois Actions,[22] and the Massachusetts Actions.[23]

1. First-to-File Bar

While the details of each complaint may differ, all of these purportedly first-filed cases at their core allege that Omnicare participated in a "kickback-for-switching" scheme, by accepting and/or soliciting kickbacks from pharmaceutical manufacturers in exchange for switching patient prescriptions to certain "preferred" drugs, and then submitting Medicaid reimbursement claims for those drugs in violation of the FCA. Unlike the Amerisource complaints, however, none of these cases mentions Organon, Remeron Tablet or Remeron SolTab. Omnicare admits as much, but agues that "[t]he fact that the prior qui tam complaints involved other drugs is of no merit. At most Relators merely add different details to the same essential facts disclosed in the earlier-filed qui tam actions." Omnicare Reply Memo. at 12 (Docket # 158).

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[21] United States ex rel. St. John LaCorte v. Omnicare, Inc., No. 00-03733 (E.D. La.) (Original Complaint filed on Dec. 20, 2000) (Docket # 133 Ex. 5).

[22] United States ex rel. Lisitza v. Omnicare, Inc., No. 01-07433 (N.D. Ill) ["Lisitza I"] (Original Complaint filed on Sept. 26, 2001) (Docket # 127 Ex. F.), and United States ex rel. Kammerer v. Omnicare, Inc., No. 04-2074 (N.D. Ill) ["Kammerer I"].

[23] United States ex rel. Maguire v. Omnicare, Inc., No. 02-11436 (D. Mass.) ["Maguire"] (Original Complaint filed July 26, 2002) (Docket # 127 Ex. A); (First Amended Complaint filed June 22, 2005) (Docket # 127 Ex. B).

United States ex rel. Lisitza v. TAP Pharmaceutical Products, Inc. et al., No. 07-10026-RGS, (D. Mass) ["Lisitza II"]. (Second Amended Complaint filed on November 1, 2007) (Docket # 133 Ex. 4). Lisitza II was originally filed on October 27, 2003 in the Northern District of Illinois as Case No. 03-7578. The action was subsequently transferred to this district.

United States ex rel. Kammerer v. Abbott Laboratories et al., No. 05-11518 (D. Mass.) ["Kammerer II"] (First Amended Complaint filed Oct. 27, 2005) (Docket # 127 Ex. C) On July 26, 2007, Kammerer II was administratively consolidated with Maguire and Lisitza II by order of the court. The Massachusetts actions – Maguire, Kammerer II, and Lisitza II – were unsealed on or about October 24, 2008.

Omnicare fails to appreciate that the drug itself is an essential element of the fraudulent scheme alleged against it. Its prior involvement in a scheme involving specific pharmaceutical manufacturers and drugs does not mean that it necessarily engaged in such fraudulent conduct with other manufacturers or drugs. See U.S. ex rel. Branch Consultants v. Allstate Ins. Co., 560 F.3d 371, 380 (5th Cir. 2009) (declining to apply the first-to-file bar broadly where the allegedly first-filed case does not allege a "true industry-wide fraud or concerted action among a narrow group of participants" but rather implicated only four specific insurers among the approximately 95 who participated in the government program at issue); id. (noting that the "potential for fraud exists in any government program" and that the allegedly first-filed complaint "tells the government nothing about which of the ninety-one other insurers . . ., if any, actually engaged in any fraud.").

While the FCA's first-to-file bar precludes a qui tam suit where a prior action gave the government sufficient notice of the essential elements of fraud, the policy underlying the provision counsels that the bar should not apply if the government would uncover such fraud (if at all) only by exhausting its investigative resources. Id. ("[F]orcing the government to expend its limited time and resources wading through the records of ninety-one [ ] insurers in an attempt to identify specific instances of fraud would completely undermine the enforcement component of the FCA's qui tam provisions."). Although Lisitza II alleges that Omnicare's "kickbacks-for-switching" scheme was

"nationwide,"[24] these generic allegations of widespread fraud are insufficient to provide the requisite notice to the government under the first-to-file bar. Johnson & Johnson, 765 F.Supp.2d at 122 ("Only when an earlier filed suit has named a member of the same corporate family are courts inclined to find generic allegations sufficient to put the government on notice of a fraudulent scheme involving a specific defendant."). The first-to-file rule does not bar Relators' kickback claims against Omnicare.

2. Public Disclosure Bar

Similarly, the public disclosure bar does not preclude the kickback claims against Omnicare. The allegations made in the LaCorte, Illinois, and Massachusetts actions are public disclosures. Bahler Medical, 619 F.3d at 111. But since the drug involved is an essential element of the scheme and, as explained above, prior actions do not discuss either Organon or Remeron, the prior complaints do not disclose the fraudulent scheme alleged in the TAC.[25] See id. at 110 ("prior public disclosure of fraud occurs when the essential elements exposing the particular transactions as fraudulent find their way into the public domain") (internal quotations omitted); In re Pham. Indus. Avg. Wholesale Price Litig., 538 F.Supp.2d 367, 287 (D. Mass. 2008) (public disclosure must be "adequate to set the government squarely on the trail of fraud") (internal quotation marks

[24] Lisitza II First Am. Compl. ¶ 27 (Docket # 127 Ex. K) (alleging that the "kickbacks-for-switching" scheme "was not limited to the named 'preferred' medications, but was undertaken by TAP [Pharmaceuticals], other 'preferred' drug manufacturers, and Omnicare nationwide, for other drugs wherever such wholesale switching was possible and profitable, costing the government and private insurance companies tens of millions of dollars.").

[25] Likewise, the 2009 Settlement Agreement between Omnicare and the United States, which covered Omnicare's acceptance of kickbacks in exchange for purchasing and promoting Johnson & Johnson's drug Risperdal, fails to disclose the essential elements of fraud alleged here. Docket # 127 Ex. D. The same goes for the 2006 Settlement Agreement in the Illinois actions. Docket # 127 Ex. I.

omitted). Generalized claims of industry-wide fraud also will not trigger the public disclosure bar. United States ex rel. Cooper v. Blue Cross and Blue Shield of Fla., Inc., 19 F.3d 562, 566 (11th Cir. 1994) (allegations of widespread Medicaid fraud made in sources in which a particular insurance company was not specifically named or otherwise directly identified were insufficient to trigger the public disclosure bar); U.S. ex rel. Baltazar v. Warden, 635 F.3d 866, 868 (7th Cir. 2011) ("As far as we can tell, no court of appeals supports the view that a report documenting widespread false claims, but not attributing them to anyone in particular, blocks qui tam litigation against every member of the entire industry.").

The State of Texas investigated Organon's marketing and sales practices with regard to Remeron while it was deciding whether to intervene in Relators' qui tam suit. As part of its investigation, the Texas Attorney General acquired certain documents from Organon in response to a Civil Investigative Demand served on the pharmaceutical company. Texas agreed to share these documents with Relators for their use in this case. See Nov. 13, 2008 Letter from Texas Attorney General's Office to Relators (Docket # 95 Ex. 1).

Omnicare argues that the Texas documents constitute public disclosures under section 3730(e)(4). Since these documents were produced in connection with Relators' qui tam suit, however, they are not "public disclosures" under the FCA. See U.S. ex rel. Fry v. Guidant Corp., No. 3:03-0842, 2006 WL 1102397, at *8 (M.D. Tenn. Apr. 25, 2006)(documents produced to Tennessee Attorney General by defendant in connection with qui tam suit, which were subsequently shared with relator in same suit, "would not

have made their way to the public absent the filing of the qui tam case" and "do not, therefore, qualify as 'public disclosures' for purposes of public disclosure bar") (citing U.S. ex rel. Wang v. FMC Corp., 975 F.2d 1412, 1416 (9th Cir. 1992) ("Evidence publicly disclosed for the first time during the discovery phase of a qui tam suit is not barred from use in that same suit by section 3730(e)(4)(A). If it were, qui tam plaintiffs would have little choice but to waive their right to discovery for fear of disclosing information that would bar the claims for which they might wish discovery in the first place.")). Cf. U.S. v. Northrop Corp., 5 F.3d 407, 411 (9th Cir. 1993) (extending Wang to situation where disclosure results from a criminal investigation by the government based on information provided by a qui tam plaintiff); id. ("[T]here is no reason to draw a distinction between disclosure resulting from civil discovery by the government or a qui tam plaintiff, and disclosure resulting from a criminal investigation by the government based on information provided by a qui tam plaintiff. Such a distinction would allow the government to limit the potential recovery of qui tam plaintiffs unfairly simply by initiating a criminal investigation, and would subvert Congress's desire to combat fraud by providing broad incentives for qui tam suits.").

Defendants' reliance on Seal 1 v. Seal A, 255 F.3d 1154, 1161-62 (9th Cir. 2001), is misplaced. There, relator filed a qui tam suit under the FCA against Packard-Bell NEC, Inc. ("PBNEC"), which prompted a government investigation into PBNEC's allegedly fraudulent practices. That investigation turned up documents disclosing probable fraud not only by PBNEC but also by Zenith, one of its competitors. After the U.S. Attorney allowed relator to review documents obtained during the PBNEC

investigation, relator brought a separate qui tam suit against Zenith. The district court held that it had jurisdiction over relator's FCA case against PBNEC, but dismissed the Zenith case for lack of jurisdiction under the public disclosure bar. The Ninth Circuit affirmed, noting that the PBNEC relator was an "an outsider to the Zenith investigation who now seeks to profit from it as an FCA relator." 255 F.3d at 1162. Unlike the Seal 1 relator, Relators here have sued the same defendants throughout; they are not pursuing a case against a new defendant based on the Texas documents.

E. Rules 9(b) and 12(b)(6)

Having ascertained that the court has jurisdiction over off-label marketing claims against Organon and kickback claims against Omnicare, I next evaluate whether these claims merit dismissal for failure to state a claim under Fed. R. Civ. P. 12(b)(6) or failure to plead fraud with particularity under Fed. R. Civ. P. 9(b).[26]

To survive a motion to dismiss under Rule 12(b)(6) "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (internal quotation marks omitted). The facts pleaded must allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. Id.

Fed. R. Civ. P. 9(b) also applies to Relators' claims under 31 U.S.C. § 3729(a)(1)-(3). U.S. ex rel. Gagne v. City of Worcester., 565 F.3d 40, 45 (1st Cir. 2009). To comply with the rule, a complaint must specify the "time, place, and content of an alleged false

[26] "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).

representation"; conclusory allegations are insufficient. Id. See also U.S. ex rel. Gagne v. City of Worcester, No. 06-40241, 2008 WL 2510143, at *4 (D. Mass. June 20, 2008) (Rule 9(b) requires pleader to set forth with particularity the "who, what, when, where, and how of the alleged fraud"). Still, "the rule may be satisfied . . . where, although some questions remain unanswered, the complaint as a whole is sufficiently particular to pass muster under the FCA." Gagne, 565 F.3d at 45 (internal quotation marks omitted).

1. Off-Label Marketing Claims Against Organon

To state a claim under FCA subsections (a)(1)-(3), Relators must sufficiently plead that the Medicaid reimbursement claims filed as a result of Organon's conduct (here, its off-label promotion of Remeron) were "false or fraudulent." Organon contends that if a state Medicaid program chooses to reimburse a claim for a drug prescribed for off-label use, then that claim is not "false or fraudulent," and liability cannot therefore attach for reimbursement. The court agrees. See United States ex rel. Rost v. Pfizer, Inc., 253 F.R.D. 11, 16 (D. Mass. 2008) (discussing approvingly defendant's argument that state approval undermines the assertion of a "false claim"); U.S. ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co., No. 96-11651, 2003 WL 22048255, at * 3 (D. Mass. Aug. 22, 2003) (noting that if the Medicaid statute gives states the discretion to cover off-label, non-compendium prescriptions, and a state exercised its discretion to cover such prescriptions, then an off-label prescription in that state would not be a false claim). Organon's argument assumes that state Medicaid programs have the discretion to cover reimbursement for off-label use of a drug that is not supported by a citation in a medical compendium listed in the Medicaid statute; whether the Medicaid statute authorizes such

discretion is up for debate.

The statute appears to give states the ability to choose whether they will cover off-label, non-compendium prescriptions. See 42 U.S.C. § 1396r-8(d)(1)(B)(i) ("A State may exclude or otherwise restrict coverage of a covered outpatient drug if – (i) the prescribed use is not for a medically accepted indication. . . .") (emphasis added). An off-label use that is not supported by a citation in a listed medical compendium is "not for a medically accepted indication." Id. § 1396r-8(k)(6) (defining "medically accepted indication" as any use approved by the FDA or supported by a citation in a medical compendium listed in the Medicaid statute). On the other hand, the statute appears to limit a state's discretion to restrict coverage only to "covered outpatient drug[s]," the definition of which does not include drugs "used for a medical indication which is not a medically accepted indication" (i.e., non-compendium drugs prescribed for off-label use). See 42 U.S.C. § 1396r-8(k)(3).[27]

Relators do not allege, and Organon does not concede, that any state denies Medicaid coverage for an off-label prescription not included in a medical compendium. Nor do they allege that states must deny coverage of such prescriptions under the Medicaid statute; they allege only that states "may" do so. TAC ¶¶ 207-208. This is insufficient to establish that Medicaid reimbursement claims for Remeron filed because of Organon's off-label marketing scheme were "false or fraudulent." Relators' off-label

[27] The Parke-Davis court noted this statutory ambiguity, and invited an amicus brief from the federal government on the issue. 2003 WL 22048255, at * 3. It ultimately left the debate unresolved, however, because the defendant conceded that at least eight states did not provide reimbursement for off-label drug prescriptions not included in a medical compendium; thus, the court found that defendant's argument did not provide a basis for summary judgment under the FCA and was relevant only to damages. Id.

marketing claims fail under Rule 12(b)(6). See U.S. ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc., No. 1:09-cv-1086, 2011 WL 2182422, at *3 (E.D. Va. May 4, 2011) (dismissing relator's FCA claims because "Relator failed to plead facts that would establish that off-label prescriptions for [drug at issue] were not reimbursable under each of the government programs that Relator identifies.").

2. Kickback Claims against Omnicare

Relators' claims against Omnicare are based on allegations that Organon paid Omnicare two types of illegal kickbacks: (1) market share rebates and discounts pursuant to written purchasing agreements ("discount kickbacks"); and (2) other incentives such as research grants, sponsorship of annual meetings, data purchasing agreements, nominal-price transactions, and participation in corporate partnership programs ("collateral kickbacks"). See TAC ¶¶ 121-32, 133-41. Omnicare argues that the claims based on discount kickback allegations fail because all discounts and rebates were disclosed in accordance with the safe harbor provisions of the Anti-Kickback Statute.[28] 42 U.S.C. § 1320a-7b(b)(3)(E); 42 C.F.R. § 1001.952(h). Further, it argues that all kickback claims against it fail because Relators do not articulate with particularity Omnicare's involvement in the fraudulent kickback scheme.

(a) Anti-KickBack Statute's Safe Harbor Provisions

[28] Omnicare does not argue that the statutory discount exception applies. Under the discount exception, criminal penalties shall not apply to "a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program[.]" 42 U.S.C. § 1320a-7b(b)(3)(A). See also United States v. Shaw, 106 F.Supp.2d 103, 113 (D. Mass. 2000) (describing the discount exception and the safe harbor provisions as independent bases for a defendant to claim an exemption from liability under the statute).

The Anti-Kickback Statute's criminal penalties do not apply to "any payment practice specified by the Secretary [of Health and Human Services]" in applicable regulations. 42 U.S.C. § 1320a-7b(b)(3)(E). These so-called "safe harbors" carve out certain payments, including "discounts," from the statute's definition of illegal remuneration.

A drug buyer, like Omnicare, must comply with certain standards in order to invoke the discount safe harbor's protection. 42 C.F.R. § 1001.952(h). First, "[t]he discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service[.]" 42 C.F.R. § 1001.952(h)(1)(iii)(A). Second, the buyer must provide, "upon request by the Secretary or a State agency" an "invoice, coupon or statement" from the seller that "fully and accurately" reports such discount. 42 C.F.R. § 1001.952(h)(1)(iii)(B), (h)(2)(iii)(B).

Omnicare argues that the market-share discounts and rebates included in its Remeron purchasing agreements with Organon meet these standards because the agreements fixed and disclosed the terms of the discounts and rebates, and because Relators have not alleged that Omnicare failed to provide the contracts reflecting the discounts and rebates upon request by the government. Relators respond that the rebate amounts and discounts were not properly disclosed because the contracts did not disclose the complete terms and conditions of the discount or rebate (i.e., that the payments were made to induce or in exchange for drug conversion and therapeutic interchange) and that the full terms and amounts of the discount were allegedly

concealed in various sham collateral contracts.

Given the statutory details, Relators have the better of the argument. The safe harbor provision defines "discount" as a "reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction." 42 C.F.R. § 1001.952(h)(5). This definition is exhaustive. 42 C.F.R. § 1001.952(h)(5)(vii) (the term "discount" does not include "other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section"). And the term does not embrace collateral kickbacks or reductions in price which are not passed on to Medicaid, as alleged in the TAC. See 42 C.F.R. § 1001.952(h)(5)(i)-(iii) (excluding from the definition of discount "cash payment or cash equivalents"; "supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service"; "a reduction in price applicable to one payer but not to Medicare, Medicaid, or other Federal health care programs"). Therefore, the kickback allegations against Omnicare are not protected by the discount safe harbor. See also Johnson & Johnson, 765 F.Supp. 2d at 125 (rejecting defendant's invocation of safe harbor provisions because "[w]hile the raw amounts of the rebates may have been disclosed, the terms and conditions of their payment were not"); cf. United States v. Shaw, 106 F.Supp.2d 103, 115-16 (D. Mass. 2000) ("Nor is it the case, as defense argues, that [under the statutory discount exception] any discount, 'properly disclosed and appropriately reflected', is exempt from criminal liability. What makes the activity illegal is not the label that someone attaches to the form of the transaction, even if the form may give rise to the rebuttable inference of illegality. The reason behind the transaction and the requisite state of mind underlying the criminal act are more significant than form and

label.").

(b) Claims Under § 3729(a)(1)

FCA subsection (a)(1) requires that the defendant knowingly present a false claim for payment to the government. To meet this "presentment requirement" under Rule 9(b), the complaint must identify with particularity the false claims for payment submitted to the government, by pleading at least some details such as

> 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, and individuals involved in the bills, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices.

U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232-33 (1st Cir. 2004), abrogated in non-relevant part by Gagne, 565 F.3d at 46 n.7. Relators have done so, identifying claims for reimbursement that Omnicare submitted to Medicaid for Remeron during the years when Omnicare was allegedly receiving illegal kickbacks. See TAC ¶¶ 142-43, and Ex. 66.

Relators have sufficiently pled the "who, what, and when" of Omnicare's participation in the kickback scheme, but Omnicare argues that Relators fail to allege with particularity how the discounts and rebates induced Omnicare to participate in the therapeutic interchange program or convert prescriptions from Remeron Tablet to Remeron SolTab. The TAC contains allegations supporting the claim that rebate payments drove Omnicare's conversion of prescriptions. For example, on May 20, 2002, when Organon amended its contract with Omnicare to increase the conversion rebate if Omnicare met certain targets, "Omnicare promptly converted 94% of Remeron

prescriptions [that month], the highest rate of conversion for any long-term care pharmacy provider." TAC ¶ 130. Further, the TAC references a meeting between Dan Maloney, Omnicare's Vice President of Pharmaceutical Purchasing, and an Organon representative on or about January 25, 2002. Notes from that meeting indicate that Omnicare explicitly instructed American Pharmaceutical Supply ("APS") – an LTCP that it acquired in late 2001 or early 2002 – to convert from Remeron to Remeron SolTab without asking questions because it was a financial decision. TAC ¶ 168, Ex. 60.[29] The complaint further alleges that, in "November 2001, Omnicare's corporate officers met with [John] Maddox [of Organon] and told him that they wanted to develop a 'partnership' with Organon and that Omnicare 'could really drive [market] share for Remeron SolTab.'" TAC ¶ 127. Maddox and Omnicare's Maloney are also alleged to have discussed Omnicare's desire to have different purchasing contracts prepared for its members in different states; the contracts would differ based on the state's method of calculating its Medicaid reimbursements, and "Omnicare would put pressure on their members to buy via the correct contract." TAC ¶ 127 and Ex. 59. These allegations describe the "how" of the kickback scheme with sufficient particularity. Gagne, 565 F.3d at 45.

On the other hand, Relators' collateral kickback allegations fail to satisfy Rule 9(b). Relators allege that Organon's 2001 Business Plan budgeted for sponsorship of Omnicare annual meetings, data purchases, and other initiatives, TAC ¶ 134, and that

[29] The notes read "Discussed APS moving into the Omnicare 'family[.]' They just finished meetings, where they were given instructions to USE Remeron SolTab. CONVERT from Remeron to RST [Remeron SolTab]. DON'T ASK QUESTIONS, THIS IS A FINANCIAL DECISION WITH CLINICAL ADVANTAGES." TAC Ex. 60 (capitalization in original).

Organon's 2003 budget estimated $50,000 for "Omnicare Partnership Initiatives" in the form of educational grants. TAC ¶ 141. That Organon budgeted for payments to Omnicare does not confirm that such payments were actually made, that Omnicare solicited them, or that the payments were inducements to participate in the conversion or therapeutic interchange scheme alleged. Relators' conclusory allegation that "Omnicare actively pursued Organon to participate in corporate partnership programs, which were mainly ways to funnel money to Omnicare in exchange for Remeron prescriptions," TAC ¶ 141, does not satisfy Rule 9(b).

Relators also allege that Organon and Omnicare "traded proposals to study Remeron in the long-term care patient population." TAC ¶ 135. Yet they concede that Organon rejected as too expensive Omnicare's proposed study, TAC ¶ 137, and, in February 2001, it canceled the other study, telling "Omnicare to cease work . . . and [paying] it for its work up to that point." TAC ¶ 139. They do not allege that such payments did not reflect the value of the work performed. Finally, Relators allege that in November 2001, Organon sold Omnicare a quantity of Remeron SolTab at a nominal price, upon the verbal understanding that the "offer was contingent upon Omnicare's later purchase of a similar quantity of Remeron SolTab at contracted pricing." TAC ¶ 140. But they do not identify the employees involved in the deal, nor allege that Omnicare made the subsequent purchase under the terms of the purported verbal agreement.

In sum, Relators' direct kickback claims against Omnicare survive under subsection (a)(1), but their collateral kickback claims fail for lack of particularity under Rule 9(b).

(c) Claims Under § 3729(a)(2) and (a)(3).

In Allison Engine Co., Inc. v. U.S. ex rel. Sanders, 553 U.S. 662, 672-73 (2008), the Supreme Court imposed a specific intent requirement upon all suits brought under subsections (a)(2) and (a)(3).[30] Subsection (a)(2) requires proof that "the defendant made a false record or statement for the purpose of getting a false or fraudulent claim paid or approved by the government." Allison Engine, 553 U.S. at 671 (internal quotation marks omitted). The defendant must have "intend[ed] the Government to rely on that false statement as a condition of payment." Id. at 672. Under subsection (a)(3)'s conspiracy provisions, it is insufficient to plead "that the alleged conspirators agreed upon a fraud scheme that had the effect of causing a private entity to make payments using money obtained from the Government[]"; rather, the complaint must show that the defendants "intended 'to defraud the Government.'" Id. Furthermore, if defendants are alleged to have made a false record or statement to induce government payment of a false or fraudulent claim, the complaint must show that they "agreed that the false record or statement would have a material effect on the Government's decision to pay the false or fraudulent claim." Id. at 672-73.

Relators allege that Omnicare is "the nation's largest provider of pharmacy services to long-term care facilities," TAC ¶ 26; Medicaid patients make up the majority of residents in long-term care facilities, id. ¶ 42; Omnicare representatives wanted to partner

[30] The 2009 FERA amendments eliminated subsection (a)(2)'s specific intent requirement. FERA made these amendments retroactive to any claims for reimbursement pending on June 7, 2008. See U.S. ex rel. Carpenter v. Abbott Laboratories, Inc., 723 F.Supp.2d 395, 402-03 (D. Mass. 2010). Since Relators concede that no claims for reimbursement were pending on June 7, 2008, the 2009 amendments do not apply to this case, and I therefore apply the version of the FCA that was in force prior to the 2009 amendments, including the specific intent requirement.

with Organon and "drive [market] share for Remeron SolTab," id. ¶ 127; Omnicare negotiated the form of its purchasing agreements with Organon based on the state's method of calculating its Medicaid prescription drug reimbursement, id. ¶ 127 and Ex. 59; Omnicare submitted false claims for reimbursement for Remeron to state Medicaid programs, id. ¶ 142; and the "ultimate submission [by LTCPs] . . . of false claims to the state Medicaid programs was a foreseeable factor in the Government's loss, and a consequence of the Defendants' fraudulent schemes." TAC ¶ 327. Construed in the light most favorable to Relators, these allegations sufficiently plead that Omnicare knew that Medicaid would be the primary payor for long-term care prescriptions, that it agreed to participate in the kickback scheme, and that it was amply familiar with the Medicaid system to know that any false record or statement it submitted would be material to the government's decision to pay or approve a claim. These allegations are sufficient to plead specific intent under subsections (a)(2) and (a)(3). See U.S. v. Hawley, 619 F.3d 886, 895-96 (8th Cir. 2010) (government made sufficient showing of intent under subsection (a)(2) to survive summary judgment, where defendant had extensive experience selling federally reinsured crop insurance to know that false insurance applications and acreage reports would be material to the government's decision to pay or approve the false claim); U.S. v. Ven-A-Care v. Actavis Mid. Atl. LLC, 659 F.Supp.2d 262, 270 (D. Mass. 2009) ("Given the structure of the Medicaid system, the natural and foreseeable consequence of submitting a false claim to Medicaid is that the United States will provide funds to pay the false claim.").

III. State and Local Claims

Relators concede that Count XXXI, alleging fraud against the City of Chicago, should be dismissed. The parties agree that the following state and local false claims statutes mirror the FCA: California, Delaware, District of Columbia, Florida, Hawaii, Illinois, Indiana, Massachusetts, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, and Virginia. Dismissal of all federal claims (save for the retaliation claim (Count V)) against Organon and PharMerica, likewise calls for dismissal of all claims against them under these aforementioned statutes.[31] Pending further briefing by the parties, I decline to dismiss the state and local claims against Omnicare, or to dismiss the remaining state claims against Organon and PharMerica.

IV. Conclusion

PharMerica's Motion to Dismiss (Docket # 123) is ALLOWED as to all federal claims (Counts I-III), and all state and local claims as enumerated in Part III of this Memorandum of Decision. The Organon Defendants' Motion to Dismiss (Docket # 128) is ALLOWED as to Counts I-IV, and all state and local claims as enumerated in Part III of this Memorandum of Decision. Omnicare's Motion to Dismiss (Docket # 125) is ALLOWED as to Relators' collateral kickback claims, and otherwise DENIED. Count XXXI is dismissed against all defendants.

The following claims remain against PharMerica and the Organon Defendants: Counts X (Georgia), XIV (Louisiana), XVI (Michigan), XIX (New Hampshire), XXVI (Texas), XXVIII (Wisconsin), XXIX (Connecticut), XXXII (Colorado), XXXIII (Maryland),

[31] Counts VI-IX, XI-XIII, XV, XVII-XVIII, XX-XXV, XXVII, XXX, XXXIV.

and XXXV (Common Fund Relief). Count V also survives against the Organon Defendants only. All federal, state and local claims (except for Count XXXI) survive against Omnicare to the extent they are not based on collateral kickback allegations.

June 1, 2012
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE