

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 07-10288-RGS
CIVIL ACTION NO. 05-11518-RGS

UNITED STATES OF AMERICA,
ex rel. BERNARD LISITZA and DAVID
KAMMERER,

v.

JOHNSON & JOHNSON, ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC., and
JOHNSON & JOHNSON HEALTH CARE

MEMORANDUM AND ORDER ON
DEFENDANT JOHNSON & JOHNSON'S MOTION TO DISMISS

February 25, 2011

STEARNS, D.J.

In these qui tam actions, various plaintiffs¹ claim that defendants Johnson & Johnson (J&J),² Ortho-McNeil-Janssen Pharmaceuticals, Inc. (Ortho), and Johnson & Johnson Health Care Systems, Inc., unlawfully induced Omnicare, the nation's largest supplier of pharmaceutical drugs to nursing homes, to promote J&J's branded drugs over

¹Relators Bernard Lisitza and David Kammerer initiated the prosecution of these cases on behalf of the United States and several States. The United States and some of the named States have since moved to intervene and have filed their own Complaints.

²J&J reserves the right to argue at the "appropriate juncture" that it is not a proper defendant, citing In re Pharm. Indus. Average Wholesale Price Litig., 538 F. Supp. 2d 367, 391 (D. Mass. 2008) (dismissing the J&J parent where the complaint's allegations were directed solely to Ortho).

less costly alternatives, in violation of the False Claims Act, 31 U.S.C. § 3729 (FCA),³ the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (AKS), and various state consumer protection laws. Plaintiffs contend that Omnicare exploited its quasi-fiduciary status as an “independent” reviewer of patient medications to recommend J&J drugs in exchange for kickbacks disguised as payments for “physician data” and as purported grants and sponsorship fees. According to plaintiffs, these improper incentives “caused” Omnicare to falsely certify that it had complied with federal and state anti-kickback statutes and to file false claims for Medicaid and other government reimbursements.

J&J argues that the rebates were not unlawful because the “discount[s] or other reduction[s] in price” were “properly disclosed and appropriately reflected in the costs claimed or charges made,” and therefore fell within the safe harbor provision of the discount exception to the AKS. See 42 U.S.C. § 1320a-7b(b)(3)(A). J&J maintains that because plaintiffs have been unable to identify a single false claim, they have been forced to rely on a discredited “certification” theory of liability. J&J additionally argues that: (1) dismissal is compelled by the heightened pleading standard of Fed. R. Civ. P. 9(b); (2) the relators were neither the “first-to-file” nor the “original source” of the public information on which their Complaints are based; (3) the government’s unjust enrichment theory is precluded by the FCA; and (4) the individual States on whose behalf the relators have

³In May of 2009, Congress passed the Fraud Enforcement and Recovery Act (FERA) (Pub. L. No. 111-21, 123 Stat. 1617 (May 20, 2009)), which amended and enlarged certain basic provisions of the FCA. See Steven L. Briggerman, False Claims Act Amendments: A Major Expansion in the Scope of the Act, 23 No. 11 Nash & Cibinic Rep. ¶ 58 (November 2009) (“Whether taken individually or collectively, the amendments to the FCA constitute a major expansion in the coverage of the Act.”).

asserted claims either have no present interest in the lawsuit or no viable claims.

PROCEDURAL BACKGROUND

On October 28, 2003, plaintiff/relator Bernard Lisitza, a former Omnicare pharmacist, filed a sealed Complaint in the United States District Court for the Eastern District of Pennsylvania against Ortho. Lisitza amended the Complaint on November 24, 2006, to add J&J, Ortho's parent company, and a third defendant, Janssen, LP.⁴ The case was transferred to the District of Massachusetts on February 16, 2007.⁵ Lisitza thereafter filed a Second Amended Complaint on November 29, 2007, adding Pfizer, Inc., and Bristol Myers Squibb, Co., as defendants. On September 24, 2008, the United States declined to intervene in the lawsuit as then constituted. Pfizer and Bristol were voluntarily dismissed from the case on September 28, 2009.

On December 15, 2009, the United States moved to intervene against the remaining defendants. On May 4, 2010, the court also permitted the Commonwealth of Kentucky to intervene, followed on May 17, 2010, by the Commonwealths of Massachusetts and Virginia, and the States of Indiana and California. That same day, Lisitza filed a Third Amended Complaint in forty-one counts against the J&J defendants. The United States

⁴The Complaint sets out four distinct claims against the J&J defendants under the FCA – Count I (knowing presentment of a false claim, under 31 U.S.C. § 3729(a)(1)); Count II (knowingly making a false record or statement material to a false claim, under § 3729(a)(2)); Count III (knowingly making a false claim to avoid or conceal obligations, under § 3729(a)(7)); and Count IV (conspiracy to submit false claims, under § 3729(a)(3)).

⁵On July 26, 2007, this case was consolidated for administrative purposes with five related qui tam cases.

filed a Complaint of its own on January 15, 2010.⁶

In 2005, Kammerer filed a separate suit in the United States District Court for the Southern District of Illinois as relator for the United States, the District of Columbia, the States of California, Delaware, Florida, Hawaii, Illinois, Indiana, Louisiana, Nevada, New Hampshire, New Mexico, Tennessee, and the Commonwealths of Massachusetts and Virginia. He filed an Amended Complaint shortly thereafter, followed by a Second Amended Complaint on December 5, 2008, and a Third Amended Complaint on April 21, 2010.⁷

On June 7, 2010, the J&J defendants moved to dismiss all Complaints.

FACTUAL BACKGROUND

Omnicare is the largest provider of pharmacy services to the nation's nursing homes. It supplies prescription drugs to 1.4 million long-term care patients in forty-seven states. See Gov't Compl. ¶ 8.2. Omnicare also employs pharmacists who provide

⁶The Government's Complaint in the Lisitza filing is in four counts: Count I - kickbacks causing Omnicare to present false claims in violation of § 3729(a)(1) of the FCA; Count II - knowingly causing Omnicare to make or use false records or statements certifying that it was in full compliance with federal and state laws in violation of FCA § 3729(a)(1)(B); Count III - conspiracy to defraud the United States in violation of FCA § 3729(a)(3); and Count IV - unjust enrichment. The United States filed an identically worded Complaint in the Kammerer case.

⁷In the latest iteration of his Complaint, Kammerer makes four claims under the FCA: knowing presentment of a false claim in violation of 31 U.S.C. § 3729(a)(1); knowingly making a false record or statement material to a false claim in violation of § 3729(a)(2); knowingly making a false claim to avoid or conceal obligations in violation of § 3729(a)(7); and conspiracy to submit false claims in violation of § 3729(a)(3) (collectively Count I). Kammerer sets out claims under eighteen different state false claims statutes in Counts II through XIX.

“consulting” services to nursing homes.⁸ Id. ¶¶ 8, 20. As detailed in a 2003 J&J internal memorandum,

Omnicare has over 900 consultant pharmacists who review patient charts monthly and make recommendations based on the formulary and Omnicare programs for physicians. Pharmacists’ recommendations are accepted more than 80% of the time. Consultant pharmacists actively meet with physicians or correspond with them through the mail to obtain approval to make appropriate medication switches for all their applicable nursing home patients. . . . Omnicare consultant pharmacists receive monthly “report cards” showing them their success in obtaining goals for therapeutic programs.

Id. ¶ 21. In the same memorandum, the authors note that Omnicare’s “consultant pharmacists are active in having physicians sign therapeutic interchange forms that allow pharmacists to review charts and make switches without having to consult with the physician.” Id. The memorandum reminded J&J’s sales force that consultant pharmacists have a “[h]igh degree of impact on product selection” in nursing homes and that their prescription recommendations are “highly motivated based on economics,” the focus of which was “less on net costs [to payors], and more on quality of product and ‘spread’ (their margin).” Id.

Lisitza was a pharmacy supervisor at an Omnicare facility in Illinois from 1995 until his termination in 2001. In addition to his managerial work, Lisitza filled prescriptions for nursing home patients. Prior to joining Omnicare, Lisitza owned and operated an

⁸The Department of Health and Human Services (HHS) requires nursing homes to arrange for outside pharmacists to review “at least once a month” each nursing home patient’s drug regimen. 42 C.F.R. § 483.60(c). Congress intended this review as an “independent” check on the use of psychopharmacologic drugs as “chemical restraints imposed for purposes of discipline or convenience and not required to treat the [nursing home] resident’s medical symptoms.” 42 U.S.C. § 1396r(c)(1)(A)(ii).

independent pharmacy. Kammerer worked for Omnicare as a financial analyst from September of 1997 until he resigned in April of 2002. Kammerer and Lisitza (joined by the government intervenors) allege that J&J funneled kickbacks through Omnicare to the consultant pharmacists to induce them to recommend J&J drugs over those of its competitors.⁹ Id. ¶¶ 25-48. Of particular interest to J&J was the encouragement of Omnicare pharmacists to develop “intervention” programs targeted at treating physicians. Id. ¶¶ 21-22. “J&J viewed consultant pharmacists engaged in such intervention programs as an ‘Extension of [the J&J] Sales Force.’” Id. ¶ 22.

J&J and Omnicare signed agreements in 1997 and 2000 under which Omnicare received rebates on the purchase price of a J&J drug if it satisfied two criteria: first, Omnicare’s purchases of the drug had to meet a threshold share of the market based on a comparison to its purchases of similar drugs from J&J’s competitors; and second, Omnicare had to successfully implement the “Active Intervention” and “Appropriate Use” Programs. Compl. ¶¶ 25-26, 28; Gov’t Opp’n - Exs. 10, 11, 15. The Rebate Agreements explained the Programs as follows:

Active Intervention Program shall mean a program, applied by [Omnicare] and accepted by [J&J] in writing, which is designed to appropriately shift market share to [J&J]’s Product. Active interventions can include, but are not limited to, disease management initiatives, written correspondence to Participating Providers prescribing or dispensing pharmaceutical products, educating nursing home staff regarding [J&J]’s Products, [and] conducting clinical intervention programs through which consultant pharmacists recommend Supplier’s Products when appropriate.

Appropriate Utilization Program or “AUP” shall mean a program applied

⁹The Complaints filed by the State intervenors copy the factual allegations made by the United States in its Complaint.

by [Omnicare], and accepted in writing by Supplier, designed to cause the appropriate use of [J&J]'s Products.

Gov't Opp'n - Exs. 10, 15.

In November of 1998, J&J and Omnicare amended the 1997 Agreement with respect to the drug Levaquin. The amendment specified that:

[a]ll Rebates are contingent upon the existence of and adherence to the following interventions:

- Levaquin[®] will have a Selected formulary position and will be first line therapy for quinolones, when clinically appropriate and indicated. For the purpose of this Amendment, "Selected" shall mean . . . Levaquin[®] is favored, when clinically appropriate and indicated, over all other branded Drugs also available.

* * *

- [Omnicare's] appropriate personnel will actively participate in educational and promotional programs discussing Levaquin[®]'s clinical advantages.

Gov't Compl. ¶ 26.

The 2000 Agreement also included a "Schedule of Qualifying Intervention Programs" for specific drugs. Id. ¶ 28. The Schedule read as follows:

Duragesic and Ultram approved AUP

- National Pain Management Initiative was jointly developed by [Omnicare] and [J&J] to enhance compliance to this Agreement and completed by June 30, 1999. The training initiative was designed to and accomplished the following:

* * *

- Train consultant pharmacists to identify residents receiving inappropriate or inadequate pain management therapy and where Duragesic and Ultram may be appropriate alternative medications.

- Equip consultant pharmacists to effectively communicate recommendations regarding pain management to prescribing physicians and other health care

professionals.

Levaquin

- Levaquin® will have a Selected formulary position and will be first line therapy for quinolones, when clinically appropriate and indicated. . . . “Selected” shall mean . . . Levaquin® is favored, when clinically appropriate and indicated, over all other branded Drugs also available.

* * *

- [Omnicare’s] appropriate personnel will actively participate in educational and promotional programs discussing Levaquin®’s clinical advantages.

- [Omnicare] will facilitate access of [J&J] representatives to its Participating Sites.

Risperdal

- Risperdal® will have a Selected formulary position and will be the first line anti-psychotic, when clinically appropriate and indicated. . . . “Selected” shall mean . . . Risperdal® is favored, when clinically appropriate and indicated, over all other branded Drugs also available. All other competitive atypical antipsychotic products in the Defined Market are Prior Authorized for Risperdal® failure.

- During the first two quarters following the effective date of this Agreement, [Omnicare] shall work with [J&J] to implement communication effort to inform attending physicians of Risperdal®’s formulary position and to enhance compliance of this Agreement.

- [Omnicare]’s appropriate personnel will actively participate in educational and promotional programs discussing Risperdal®’s clinical advantages. [J&J] will organize such programs. [Omnicare] will facilitate access of [J&J] representatives to its Participating Sites.

Id. From 1999 through 2004, plaintiffs allege that J&J paid Omnicare rebates in the millions of dollars, much of it in the form of interest-free loans. See Gov’t Compl. ¶ 29.

According to plaintiffs, in 1999, J&J became concerned that the mounting tide of kickbacks to Omnicare would “entitle” it to the so-called “best price” on Risperdal. In an August 25, 1999 email circulated within J&J’s Health Care Systems, Contract Marketing

and Analysis Division, a J&J financial analyst concluded that the total rebates on J&J's sales of Risperdal to Omnicare in the final quarter of 1998 and the first quarter of 1999 "needed to be reduced because the combined front end price and performance rebate exceeded 15%." This "achievement" threatened to trigger additional payment obligations on the part of J&J under the Medicaid Drug Rebate Statute.¹⁰

According to the government,

[r]ather than risk paying Omnicare higher rebates that might result in a new "best price" for Risperdal, J&J decided to find another way of paying Omnicare to use J&J's products without having to report to the Secretary of HHS the effect of those payments on Omnicare's net price for Risperdal. In late 1999, J&J began discussing with Omnicare the concept of J&J paying Omnicare for data identifying physician prescribers of antipsychotics, in lieu of paying Omnicare reportable rebates. These discussions culminated in J&J and Omnicare signing a "Consulting and Services Agreement" [C&S Agreement] in October 2000.

Gov't Opp'n at 6. Pursuant to the C&S Agreement, J&J paid Omnicare \$4.65 million for "physician data" that Omnicare had previously supplied to J&J free of charge.¹¹ See Gov't Compl. ¶¶ 33, 38.

According to plaintiffs, additional kickbacks were masked as "grants," "educational

¹⁰Under the Medicaid Drug Rebate Statute, a drug manufacturer must report on a quarterly basis to the Secretary of HHS each drug's "average manufacturer price" and "best price." See 42 U.S.C. § 1396r-8(b)(3)(A). The manufacturer must pay each state Medicaid program a quarterly rebate equal to the total number of drug units (e.g., pills) purchased by the state Medicaid agency multiplied by the greater of (1) 15.1 percent of the drug's average manufacturer price, or (2) the difference between the average manufacturer price and the best price. See 42 U.S.C. § 1396r-8(c)(1)(A).

¹¹In giving its endorsement in an internal memorandum to the concept of a "data" payment program, the J&J Omnicare sales team effused that "[it] believes [Omnicare] to be the gold standard of Pharmacy Providers" and that Omnicare had "been able to switch propoxyphene prescriptions to Ultram and ha[d] done an outstanding job in generating Risperdal market share." Gov't Compl. - Ex. 20.

funding,” or “meeting sponsorship fees.” These included: (1) a \$300,000 “Program Fee” that J&J paid Omnicare in late 1999 to extol the benefits of Risperdal to nursing home physicians; (2) “grants” totaling \$251,000 in 2000 and 2001 for an Omnicare program promoting the prescribing of J&J drugs, including Risperdal (*id.* ¶¶ 46-47); and (3) “sponsorship fees” ranging from \$27,000 to \$50,000 that J&J paid from 1999 through 2004 to underwrite the costs of junkets taken by Omnicare managers to the Amelia Island Resort in Florida (*id.* ¶ 48).¹²

DISCUSSION

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (internal quotation omitted). “When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.” *Id.* at 1950. In *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), the Supreme Court explained that, “[w]hile a complaint attacked by a Rule 12(b)(6) motion does not need detailed factual allegations, a plaintiff’s obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Id.* at 555 (internal citations and quotations omitted).

Motion to Dismiss Relators

¹²The characterization of the payments as “fees” relieved J&J of the obligation of reporting them to the Secretary of HHS as a rebate affecting Risperdal’s “best price.” See Gov’t Compl. ¶¶ 43-45.

The court's review begins where it must – with J&J's jurisdictional challenge.¹³ J&J maintains that the relators were neither the “first-to-file” nor the “original source” of the allegations on which their Complaints are based. See 31 U.S.C. §§ 3730(b)(5), 3730(e)(4)(A). With regard to the Kammerer Complaint and certain of Lisitza's claims, the court agrees.

The FCA divests the district court of jurisdiction over qui tam actions that are based on publicly disclosed information, unless the relator is an original source of the information. Where a relator fails to qualify as an “original source,” government intervention does not cure the jurisdictional defect. See Rockwell Int'l Corp. v. United States, 549 U.S. 457, 468 (2007) (“An action originally brought by a private person under the False Claims Act does not become one brought by the government just because the government intervenes and elects to ‘proceed with the action’; rather, such an action becomes an action brought by the government only after the private person has been determined to lack the jurisdictional prerequisites for suit under 31 U.S.C.A. §§ 3730(a)-(b) and (e)(4)(A).”).

Public Disclosure Provisions of the FCA

Congress has mandated that a relator is barred from filing a qui tam complaint under the FCA based

upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

¹³The burden of proving subject matter jurisdiction rests with the party asserting it. See In re New Motor Vehicles Canadian Exp. Antitrust Litig., 522 F.3d 6, 14 (1st Cir. 2008).

31 U.S.C. § 3730(e)(4)(A). Courts analyze the public disclosure bar in a four-step process that asks:

(a) whether there has been public disclosure of the allegations or transactions in the relator's Complaint; (b) if so, whether the public disclosure occurred in the manner specified in the statute; (c) if so, whether the relator's suit is "based upon" those publicly disclosed allegations or transactions; and (d) if the answers to these questions are in the affirmative, whether the relator falls within the "original source" exception as defined in § 3730(e)(4)(B).

United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 728 (1st Cir. 2007), abrogated on other grounds by Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662 (2008).

Allegations of fraud are publicly disclosed when they are "placed in the public domain." Rost, 507 F.3d at 730-731. See also United States ex rel. Doe v. John Doe Corp., 960 F.2d 318, 322 (2d Cir. 1992). While the allegations need not be accessible to all members of the public, they must be disseminated beyond the inner precincts of government itself. See Rost, 507 F.3d at 728. This requirement is not onerous. Allegations in a civil or criminal complaint that are on file in a court clerk's office, or are reported in the news media are "publicly disclosed" for purposes of section 3730(e)(4)(A). United States ex rel. Poteet v. Bahler Med., Inc., 619 F.3d 104, 111 (1st Cir. 2010) ("A civil complaint filed in court qualifies as a public disclosure. The cases are in agreement."), citing Kennard v. Comstock Res., Inc., 363 F.3d 1039, 1043 (10th Cir. 2004) ("Once a complaint is filed, a civil action has commenced and public disclosure has occurred. . . . It is not necessary that the filing clerk or any member of the public [actually] read the complaint."). See also Graham Cnty. Soil & Water Conserv. Dist. v. United States ex rel. Wilson, 130 S.Ct. 1396, 1411 (2010) (the term "administrative" as defined in §

3730(e)(4)(A) is not limited to federal sources); United States v. Johnson Controls, Inc., 457 F.3d 1009, 1013 (9th Cir. 2006) (civil complaint filed in state court satisfies the disclosure rule).

If the court finds a prior disclosure, it then determines whether the disclosure comes from one of the three statutorily specified categories – (1) “criminal, civil, or administrative hearing[s],” (2) “congressional, administrative, or Government Accounting Office report[s], hearing[s], audit[s], or investigation[s],” or (3) “from the news media.” Poteet, 619 F.3d at 113. The Poteet Court found a civil complaint to be the equivalent of a disclosure in a “civil hearing.” Id. at 113 & n.10 (“We agree with the D.C. Circuit’s reasoning and hold that, as used in the statute, ‘hearing’ is synonymous with ‘proceeding.’ Because a disclosure in a civil complaint is a disclosure in a civil proceeding, we conclude that the disclosures in [prior-filed complaints] emanate from a statutorily listed source.”). At the next step in the analysis, the court determines whether the pending qui tam case is “substantially similar” in its subject matter to the prior public disclosure. Id. at 114. See also United States ex rel. Ondis v. City of Woonsocket, 587 F.3d 49, 58 (1st Cir. 2009). Finally, the court determines whether the relator is nonetheless an “original source” of the information and thus falls within the exception to the public disclosure rule.¹⁴ Id. at 58-59.

¹⁴The statute defines an “original source” as a person “who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action.” 31 U.S.C. § 3730(e)(4)(B). Knowledge is “direct” when “‘marked by the absence of an intervening agency, instrumentality, or influence: immediate.’” Ondis, 587 F.3d at 59, quoting Webster’s Third New Int’l Dictionary 640 (3d ed. 2002). The relator’s knowledge must, of course, be independent of the public disclosure. Ondis, 587 F.3d at 59; Glaser v. Wound Care Consultants, Inc., 570 F.3d 907, 921 (7th Cir. 2009); Minn. Ass’n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1048 (8th Cir. 2002).

J&J claims that the Lisitza and Kammerer Complaints are both barred by an FCA action filed on July 16, 2002, by Deborah Maguire, another former Omnicare employee. See United States ex rel. Maguire v. Omnicare, Inc., No. 02-11436 (D. Mass. July 16, 2002). As the filings in the Maguire case are “publicly disclosed” the task is to compare her pleadings to those of Lisitza and Kammerer. In her qui tam Complaint, Maguire alleged that Omnicare violated the FCA by engaging in “kickbacks-for-switching” schemes that for all practical purposes are identical to those alleged by Lisitza and Kammerer. Maguire maintained that Omnicare violated the anti-kickback laws by soliciting price discounts from drug manufacturers in exchange for promises that Omnicare’s consulting pharmacists would recommend their drugs as preferred “lower cost alternatives.” Id. ¶¶ 18, 26.

Relators respond that the Maguire Complaint does “not qualify as a ‘pending action’ under the first-to-file rule” as Maguire did not name any of the drug manufacturers as defendants or as culpable parties.¹⁵ See In re Natural Gas Royalties Qui Tam Litig., 566 F.3d 956, 962 (10th Cir. 2009) (“[T]he identity of a defendant constitutes a material element of a fraud claim.”). 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

¹⁵At oral argument, J&J’s counsel stressed that “the Maguire Complaint, filed a year before either of the relators here, even specifically refers to Risperdal as one of the drugs which this kickback scheme was operating.” Tr. at 69. 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. However, there is no mention of any drug in Maguire’s original Complaint – it was not until she amended her Complaint on June 25, 2005, that she listed Risperdal by name. See First Am. Compl. ¶ 24, United States ex rel. Maguire v. Omnicare, Inc., No. 02-11436 (D. Mass. July 16, 2002).

government on notice of a fraudulent scheme involving a specific defendant. See United States ex rel. Duxbury v. Ortho Biotech Prods., 579 F.3d 13, 32 (1st Cir. 2009); United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1188-1189 (9th Cir. 2001).¹⁶

J&J next points to an action that Lisitza filed on October 27, 2003, in the United States District Court for the Northern District of Illinois, alleging that Omnicare entered into illicit “market share” or “switching” arrangements with “TAP [Pharmaceuticals, which] would pay ongoing kickbacks to Omnicare including payments for every . . . prescription switched from other manufacturers’ [products].” See Compl. ¶ 5, United States ex rel. Lisitza v. TAP Pharm. Prods., Inc., No. 03-7578 (N.D. Ill. Oct. 27, 2003). Lisitza also alleged that Omnicare designated rebated drugs as “preferred,” and then solicited “Physician Authorization Letters” approving the switching of drugs by “falsely informing physicians that the switch . . . would save the patient, the client nursing home, and Medicaid money.” Id. ¶¶ 6-11, 28-30. Lisitza specifically accused J&J’s subsidiary (and current defendant) Ortho of engaging in the same fraudulent conduct with respect to the drug Levaquin. Id. ¶¶ 60-61.

Relators argue in response that there is no bar because the Illinois suit “effectively IS this suit.” Lisitza Mem. at 9-10 (emphasis intended in original). Contemporaneously with the Illinois lawsuit against Ortho, Lisitza filed parallel actions in the Eastern District

¹⁶See also United States ex rel. Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123, 131 (D. Mass. 2010) (“Where almost identical facts have been alleged against the corporate affiliates[,] . . . the government likely had adequate notice of the scheme and thus [subsequent similar] claims should be barred.”); In re Natural Gas Royalties, 566 F.3d at 962 (“[W]e have applied the first-to-file bar when two actions did not name the same defendant, but instead named different members of the same corporate family.”).

of Pennsylvania and the Northern District of Illinois against Omnicare and others alleging the identical “kickbacks-for-switches” scheme. Eventually, this run of cases was consolidated before this court. The court does not believe that Lisitza should be penalized for sounding the alarm about what he perceived as a fraud of galloping dimensions in as many fora as would accept his filing fee.

That is not the case, however, with regard to Kammerer. Lisitza’s Complaint plainly anticipated Kammerer’s in every substantive respect. While acknowledging that Kammerer did not file suit until nearly two years after Lisitza, relators insist that Kammerer’s claims are “unique” in “establishing separate channels for recovery for the Government” Lisitza Mem. at 10. This is not borne out by a reading of the two Complaints. Lisitza’s Complaint details the alleged fraud – Kammerer’s later-filed Complaint simply adds a sprinkle of factual garnish.¹⁷ See Poteet, 619 F.3d at 115 (“Although these details [identifying a particular medical device and describing how the defendant influenced third-parties] undoubtedly add some color to the allegation, the allegation ultimately targets the same fraudulent scheme. That is enough to trigger the public disclosure bar.”); Ondis, 587 F.3d at 58 (same). While Kammerer was the first to name J&J specifically, Lisitza had earlier named Ortho in connection with “market share” or “switching” schemes relating to the drug Levaquin.¹⁸ In addition, Lisitza had referenced

¹⁷According to J&J, Kammerer reviewed Lisitza’s October of 2003 Complaint pursuant to a partial unsealing Order before filing his own Complaint in April of 2005.

¹⁸As previously discussed, the first-to-file rule bars an action against a corporate affiliate where an earlier action pled the same fraudulent conduct. See In re Natural Gas, 566 F.3d at 962-963; Grynberg v. Koch Gateway Pipeline Co., 390 F.3d 1276, 1279 (10th Cir. 2004); United States ex rel. Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d

the “Risperdal kickbacks” in a January of 2003 amendment to his Complaint and in his 2003 Relator’s Disclosure Statement. See United States ex rel. Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 516-518 (6th Cir. 2007) (an FCA complaint should be read in conjunction with its statutorily required disclosure statement); United States ex rel. Franklin v. Parke Davis, 147 F. Supp. 2d 39, 47-48 (D. Mass. 2001) (same). The Kammerer Complaint will be dismissed as barred by the public disclosure rule.

J&J next contends that the public disclosure rule defeats this court’s jurisdiction over Lisitza’s “best price” allegations. See Lisitza Compl. ¶¶ 282-291. J&J cites four separate complaints filed in 2003 (before Lisitza filed his) in which relators made “best price” allegations against J&J.¹⁹ In County of Suffolk (New York) v. Abbott Labs., Inc., No. 03-C-10643, MDL No. 1456 (D. Mass. Aug. 1, 2003), the plaintiff County alleged that J&J and others had reported false best prices and did not as a matter of routine “report the actual ‘best price’” to Medicaid, and while “utiliz[ing] an array of other inducements to stimulate sales of their drugs. . . . including educational grants, volume discounts, and rebates.” Suffolk Compl. ¶¶ 84, 87. Suffolk specifically named Aciphex, Duragesic, Risperdal, Ultram, Topamax, and Levaquin, id. ¶¶ 250-251, many of the same drugs identified in the relators’ best price allegations. Similarly, the Westchester and Rockland

214, 217 (D.C. Cir. 2003).

¹⁹The previously filed cases which J&J allege bars Lisitza’s best price claim are Cnty. of Suffolk (New York) v. Abbott Labs., Inc., No. 03-10643, MDL No. 1456 (D. Mass. Aug. 1, 2003); Cnty. of Westchester v. Abbott Labs., Inc., No. 03-6178 (S.D.N.Y. Aug. 18, 2003); Cnty. of Rockland v. Abbott Labs., Inc., No. 03-7055 (S.D.N.Y. Sept. 10, 2003); and State of Nevada v. Am. Home Prods. Corp., No. 01-12257, MDL No. 1456 (D. Mass. Sept. 30, 2003).

Complaints accused J&J, among others, of “routinely” failing to report best prices by omitting “discounts, free samples and other inducements.” Westchester Compl. ¶¶ 79, 236; Rockland Compl. ¶¶ 78, 236. Finally, the Nevada Complaint accused J&J of “routinely requir[ing] customers [to] keep secret the prices they were being charged for J&J drugs” and omitting from its “best price” calculations numerous “inducements” such as “volume discounts, rebates, [and] educational grants.” Nevada Compl. ¶¶ 302, 316, 392. These complaints, singly and collectively, brought to light all of the “essential elements” of Lisitza’s best price allegations. See Ondis, 587 F.3d at 54. Consequently, the best price allegations are barred unless Lisitza can show that he is their “original source.” 31 U.S.C. § 3730(e)(4)(B). See United States ex rel. Poteet v. Medtronic, 552 F.3d 503, 514 (6th Cir. 2009), quoting United States ex rel. McKenzie v. BellSouth Telecomm., Inc., 123 F.3d 935, 940 (6th Cir. 1997) (“Any ‘action based even partly upon public disclosures’ will be jurisdictionally barred.”).

A relator’s “original” knowledge must be independent of any public disclosure. Poteet, 552 F.3d at 515; Glaser, 570 F.3d at 921; Minn. Ass’n of Nurse Anesthetists, 276 F.3d at 1048. Lisitza contends that his is a unique perspective as he “was ordered to participate in the fraudulent ‘kickbacks-for-switches’ schemes” and thus “did much ‘more’ than merely understand the significance of the publicly disclosed information.” Lisitza Opp’n at 14 n.23. Lisitza insists that because of his superior knowledge, the “perfunctory best price allegations made in the complaints that J&J cites lack the detail set forth in [his] Complaint, especially when amplified by the facts set forth in the Government Complaints.” Lisitza Opp’n at 10-11. This embellishment aside, Lisitza fails to provide any evidence that

he is a person “who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action.”²⁰ 31 U.S.C. § 3730(e)(4)(B). See also Ondis, 587 F.3d at 59. Consequently, Lisitza’s best price fraud allegations will be dismissed.

Motion to Dismiss FCA Claims

“The [federal] FCA imposes liability upon persons who (1) present or cause to be presented to the United States government, a claim for approval or payment, where (2) that claim is false or fraudulent, and (3) the action was undertaken ‘knowingly,’ in other words, with actual knowledge of the falsity of the information contained in the claim, or in deliberate ignorance or reckless disregard of the truth or falsity of that information.” United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004), quoting 31 U.S.C. § 3729(a)(1)(b). Under Allison Engine, 553 U.S. at 672-673, the elements of an FCA claim include proof that J&J knew, as a “natural, ordinary and reasonable consequence of its acts,” that Omnicare would submit one or more false claims for payment.²¹ Id. at 672; Karvelas, 360 F.3d at 225. While under the conspiracy prong of the FCA, liability does not require proof of the actual presentment of a claim, it does require proof that a defendant “intended to defraud the government [by getting false claims

²⁰In footnote 23 of his Opposition Memorandum, Lisitza refers the court to the “disclosure statement” that accompanies his Complaint. The court cannot locate any such document in the record.

²¹This court has recently concluded that Congress did not intend § 3729(a)(1)(B), which was adopted in 2009, to apply retroactively to FCA cases pending on the date of the amendment. See United States ex rel. Carpenter v. Abbott Labs., Inc., 723 F. Supp. 2d 395, 402-403 (D. Mass. 2010).

paid]” and “that the false record or statement would have a material effect on the Government’s decision to pay the false or fraudulent claim.” United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 46 (1st Cir. 2009).

Plaintiffs contend that J&J “caused” the making of false payments by the paying of kickbacks to Omnicare. J&J does not deny that the payments to Omnicare were made, but disputes that they were unlawful. J&J argues that its data acquisition fees, grant awards, sponsorship fees, and other payments all fell within the safe harbor provision of the statutory discount exception of the AKS. Moreover, J&J maintains that all of its payments to Omnicare were “properly disclosed and appropriately reflected in the costs claimed or charges made.” J&J Mem. at 8.

The court disagrees. While the raw amounts of the rebates may have been disclosed, the terms and conditions of their payment were not. Under the Rebate Agreements, Omnicare qualified for a rebate on a specified drug only if its purchases of the drug from J&J met market share thresholds at the expense of J&J’s competitors, and only if it succeeded in implementing the “Active Intervention ” and “Appropriate Use” Programs with its pharmacists. Moreover, as the United States alleges, rather than running the risk that Omnicare’s earning of higher rebates might lead to a new “best price” for Risperdal, J&J resorted to a subterfuge, paying Omnicare \$4.65 million for physician data that had no comparable value. Gov’t Compl. ¶ 33. The United States also notes that “[a]fter the signing of the agreement, Omnicare continued to provide some of this data ‘randomly,’ but did not provide J&J with much of the data required by the agreement.” Gov’t Opp’n at 6.

Under both the actual presentment and conspiracy theories of liability, “a false claim” must be alleged. “[T]he statute attaches liability, not to the underlying fraudulent activity or to the government’s wrongful payment, but to the ‘claim for payment.’” United States v. Rivera, 55 F.3d 703, 709 (1st Cir. 1995). J&J asserts that the counts predicated on reimbursement claims submitted by Omnicare to Medicaid are flawed because plaintiffs have failed to adequately allege that any of the submitted claims were “false.” There are three bases on which a claim may be “false or fraudulent” for purposes of the FCA: (1) factual falsity; (2) legal falsity under an “express” certification theory; and (3) legal falsity under an “implied” certification theory. United States ex rel. Hutcheson v. Blackstone Med., Inc., 694 F. Supp. 2d 48, 61 (D. Mass. 2010). “A ‘factually false’ claim is one in which the goods or services provided are either incorrectly described or which makes a claim for a good or service never provided.” Westmoreland, 707 F. Supp. 2d at 133.²² “A claim is legally false under an express certification theory when the party making the claim for payment expressly represents compliance with a statute or regulation, and such compliance is a precondition to payment.” Id. No particular form of “certification” is required, so long as the statement of compliance was knowingly false when made. Id., citing United States ex rel. Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1172 (9th Cir. 2006). A claim is legally false under the implied certification theory when a claimant makes no express statement regarding compliance with a statute or regulation, but by

²²At oral argument, government counsel stated that factual falsity *is* at issue because the government “didn’t get the benefit of its bargain.” Tr. at 37-38 (emphasis supplied). This argument, however, appears to be directed towards the government’s unjust enrichment claim.

submitting a claim, the claimant implies that it has complied with all of the stated conditions for payment. See Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 531-533 (10th Cir. 2000) (collecting cases); Scolnick v. United States, 331 F.2d 598 (1st Cir. 1964) (per curiam) (imposing False Claims Act liability based upon the mere cashing of check to which the payee was not entitled); Murray & Sorenson, Inc. v. United States, 207 F.2d 119, 123-124 (1st Cir. 1953) (finding that when a government subcontractor submitted bids, “there was an implied false representation that the bids were at a figure which the corporate defendant would have submitted in competition instead of at a somewhat higher figure suggested by the contractors’ purchasing agent [who was taking kickbacks from a subcontractor].”).

According to the United States, Omnicare submitted false claims to state Medicaid programs from 1999 to 2004. The government contends that by not disclosing the “kickback arrangements with J&J,” Omnicare “violated multiple certifications that [it] made when it submitted reimbursement claims for J&J drugs.” Gov’t Opp’n at 15. In this regard, the United States points to state Medicaid provider agreements that require compliance with the AKS.²³ In response, J&J contends that, as a matter of law, “broad language requiring compliance with ‘all applicable state and federal laws’ is insufficient to constitute an express certification of compliance” with the AKS.²⁴ J&J also argues that the provider

²³Massachusetts, for example, requires its Medicaid providers to comply “with all state and federal statutes, rules, and regulations applicable to the Provider’s participation in MassHealth.” Mass. Compl. ¶ 23.

²⁴In Hutcheson and Westmoreland, Judge Young adopted the reasoning of the Second Circuit in finding that implied certification applies only where explicit preconditions of payment are expressly stated in the relevant statute or regulations. See Westmoreland,

agreement is a condition of participating in the program, not a precondition of payment, and that a provider's continued participation in a given program is "enforced through administrative mechanisms," and not the FCA. See Conner, 543 F.3d at 1220. J&J also points out that only very recently, as part of the comprehensive health care reform plan, did Congress provide that a claim submitted to Medicare or Medicaid in violation of the AKS also violates the FCA. See Patient Care and Affordable Care Act, Pub. L. No. 111-148, § 6402(f)(1) (2010) (PCAC Act).

The United States, however, points out that Omnicare made two different certifications to the Medicaid program.

MR. SHAPIRO: I want to address the argument that the certifications in this case were insufficient, because here there were two different certifications that Omnicare made. It made certifications in its provider enrollment forms. In other words, in order to become eligible for Medicaid, it had to certify with every state that it was going to comply with the law, all state and federal regulations and statutes that apply to Medicaid. And it did so over and over. This was not just a one-time thing. So even if we were to accept the argument that if you promise once, that promise doesn't carry forward. In this case, if that's an issue, we can present . . . the Court with dozens if not hundreds of enrollment forms that Omnicare submitted to the states because it kept requiring new pharmacies and kept certifying over and over again that it was complying with the law.

THE COURT: I'm not going to give you too much assistance with your argument, but haven't most courts rejected that distinction between conditions of participation?

707 F. Supp. 2d at 133, citing Mikes v. Straus, 274 F.3d 687, 700 (2d Cir. 2001). But see United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1219 (10th Cir. 2008) (rejecting the contention that "*any* failure by [a provider] to comply with *any* underlying Medicare statute or regulation during the provision of *any* Medicare-reimbursable service renders . . . the resulting payments false."); Mikes, 274 F.3d at 697 (holding that FCA "does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions.").

MR. SHAPIRO: In the kickback context they have. I think that — I don't — I agree that that distinction has some validity in some contexts. Courts have not accepted that distinction in the kickback context. The Third Circuit explicitly rejected it, the Seventh Circuit and the Eleventh Circuit either explicitly or implicitly rejected it. Numerous courts have assumed that a kickback is a condition of payment.

And I just — on the certifications it's also important — so there's two certifications going on here. They only talked about the enrollment forms. But there's also a claim form that gets submitted with every claim. If it gets submitted in electronic form, then it gets submitted pursuant to an electronic claim submission agreement. In that case, too, the providers are certifying that they are complying with the law and there has not been a material omission. So, again, that word "material" appears. One of the criticisms that J&J has made of the Medicaid form is that it does not explicitly refer to the Anti-Kickback Statute. And Mr. Sarraille suggests that somehow J&J was not on notice about the Anti-Kickback Statute. If J&J didn't know about the Anti-Kickback Statute, that will be a fact that comes out in discovery. We have alleged that J&J was well aware of the Anti-Kickback Statute. It's frankly impossible — firstly, it's incredible to believe that J&J did not understand that compliance with the Anti-Kickback Statute was important and that a violation of the Anti-Kickback Statute was a felony. You can see that in J&J's internal e-mails attached to our papers where J&J employees are concerned about going to jail because they might be violating the Anti-Kickback Statute. They were on notice here. This was not a secret to them.

Tr. at 34-36.

The court agrees that in the case of the AKS, compliance is not merely a condition of participation in federal health care programs, but is also material to the government's decision to pay any claim resulting from a kickback. See U.S. v. Rogan, 517 F.3d 449, 452 (7th Cir. 2008) (rejecting the argument that a kickback was immaterial to the validity of Medicare and Medicaid claims); McNutt ex rel. United States v. Haleyville Med. Supplies, Inc., 423 F.3d 1256, 1259 (11th Cir. 2005) ("[C]ompliance with federal health care laws, including the [Anti-Kickback] Statute, is a condition of payment by the Medicare program."); United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 243 (3d Cir. 2004)

(same); United States ex rel. Fry v. The Health Alliance of Greater Cincinnati, 2008 WL 5282139, at *12 (S.D. Ohio Dec. 18, 2008) (holding that “violations of the [AKS] . . . are material as a matter of law”); United States ex rel. Bidani v. Lewis, 264 F. Supp. 2d 612, 616 (N.D. Ill. 2003) (finding a violation of the AKS “material to the government’s treatment of claims for reimbursement” and that to find otherwise, “would put the government in the position of funding illegal kickbacks after the fact.”).²⁵ As the Tenth Circuit observed in Conner, “some regulations or statutes may be so integral to the government’s payment decision as to make any divide between conditions of participation and conditions of

²⁵The majority of trial courts, including two in this district, have also held that violations of the AKS cause any resulting claims to be false. See United States ex rel. Kosenske v. Carlisle HMA, Inc., 2010 WL 1390661, at *9 (M.D. Pa. Mar. 31, 2010) (“Claims submitted in violation of the [Anti-Kickback] Act qualify as ‘false claims’ under the FCA”); Mason v. Medline Indus., Inc., 2010 WL 653542, at *7 (N.D. Ill. Feb. 18, 2010) (holding that a “cost report tainted by unlawful kickbacks or bribes is false or fraudulent for purposes of the FCA.”); United States ex rel. Jamison v. McKesson Corp., 2009 WL 3176168, at *12 (N.D. Miss. Sept. 29, 2009) (“[F]ailure to comply with the kickback laws is, in and of itself, a false statement to the government.”); United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc., 565 F. Supp. 2d 153, 159 (D.D.C. 2008) (“[I]n other cases that have held violations of AKS . . . can be pursued under the FCA, since they would influence the Government’s decision of whether to reimburse Medicare claims.”); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 12, 18 (D. Mass. 2007) (holding that “the FCA is violated when a Medicaid claim is presented to the state government in violation of the Anti-Kickback statute.”); United States ex rel. Kneepkins v. Gambro Healthcare, Inc., 115 F. Supp. 2d 35, 43 (D. Mass 2000) (holding that “alleged violations of the Anti- Kickback Law . . . state a claim under the False Claims Act” because the illegal kickback agreement was an “omitted material fact” to the reimbursement claim); United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017, 1047-1048 (S.D. Tex. 1998), quoting Peterson v. Weinberger, 508 F.2d 45, 52 (5th Cir. 1975) (finding that “the FCA reaches ‘all fraudulent attempts to cause the Government to pay out sums of money’ in light of the legislative history and the purpose of the FCA that submission of such claims for services that were statutorily ineligible for payment under the Medicare Act constitutes a false claim within the ambit of the FCA.”).

payment a ‘distinction without a difference.’” 543 F.3d at 1222, quoting Hendow, 461 F.3d at 1177. See also United States ex rel. Quinn v. Omnicare, 382 F.3d 432, 443 (3d Cir. 2004) (“If a provider does not comply with the Medicaid regulations, . . . not only will the provider be ineligible to participate in the Medicaid programs, but Medicaid may seek to recover the money it paid to the provider for services covered by the claims.”); S. Rep. No. 99-345, at 9 (1986), as reprinted in 1986 U.S.C.C.A.N. 5266, 5274 (explaining that “a false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation,” and noting that “claims may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program.”).

Rule 9(b)

J&J maintains that each of the Complaints should be dismissed for failure to comply with Fed. R. Civ. P. 9(b), which imposes on an FCA plaintiff the duty to allege “with particularity” “the actual false claims submitted to the government” and the “[u]nderlying schemes and other wrongful activities that result[ed] in the submission of fraudulent claims.” Karvelas, 360 F.3d at 232. It is true, as relators argue, that where a defendant is alleged to have “cause[d]” a third party to file a false claim, the complaint need not “provid[e] details as to each false claim.” Duxbury, 579 F.3d at 29. However, there must be a predicate showing of a “connecting causal link.” Rost, 507 F.3d at 732 & n.9.

J&J strenuously objects to relators’ assertion that the alleged “kickbacks” to

Omnicare caused the submission of false claims to Medicaid.²⁶

Even if we accept, for purposes of argument, the “kickback” allegations, the complaint lacks any factual or legal basis to support an inference that each and every claim for reimbursement of a J&J drug resulted from a “kickback.” Nor could there be: to so allege, Plaintiffs would have to take the nonsensical position that no J&J product ever would have been provided to a nursing home patient by Omnicare but for the purported “kickbacks.” That claim is belied by the United States’ complaint itself, which acknowledges that, even before the period at issue, Omnicare purchased more than \$100 million in J&J product.

J&J Mem. at 20-21.

The argument – if borne out by discovery – strikes the court as one more appropriate for summary judgment. For present purposes, the Complaint of the United States is sufficiently pled. It specifies the relevant time period (1999-2004), the manner in which the kickbacks were paid (through “rebates,” payments for data, “grants,” sponsorship fees, and other similar payments, see id. ¶¶ 25-48), and the claims alleged to be false that flowed from the various kickback schemes. Gov’t Opp’n - Ex. 55. To illustrate the depth of the relationship between J&J and Omnicare, the United States has attached to its Complaint the specific contracts at issue (id. at Exs. 10, 11, 15, 28-29, 37), certain “key” communications between Omnicare and J&J (id. at Exs. 5-6, 33, 40, 43), and internal J&J memoranda and email messages containing unguarded and revealing discussions of the rebate programs (id. at Exs. 1-4, 7-9, 12-14, 16-27, 30-32, 34-36, 42, 46, 49-54).

²⁶J&J also contends that Rule 9(b) requires dismissal of the “best price” allegations made by the relators and the State of Indiana. As these claims have been found by the court to be barred by the public disclosure rule, the argument is moot.

The government's Complaint focuses with special emphasis on Omnicare's efforts to promote the J&J antipsychotic drug Risperdal.²⁷ The Complaint sets out details regarding the "Risperdal Initiative" and quotes from an internal J&J memorandum boasting that the effort "has generated an all time market share high of 55.5% throughout the 1st quarter of 2000. This market share represents Omnicare's ability to persuade physicians to write Risperdal in the areas of Behavioral Disturbances associated with Dementia." Compl. ¶ 52. The Complaint also points to a J&J memorandum citing a July 2001 internal report that two Omnicare pharmacies, "Jacobs Healthcare (16,000 beds) and Lawrence Weber (12,000 beds) [had] started a [Physician Authorization Letter] initiative with Risperdal in the month of May. The authorization letter requests a substitution to Risperdal from any new prescription of Zyprexa or Seroquel." *Id.* ¶ 54, Ex. 50. The J&J memorandum continues that "[i]n 2002, J&J's Long-Term Care Group reported that, in a recent meeting, Omnicare's Director of Clinical Operations had stressed that Risperdal is their primary intervention." *Id.* at Ex. 51.²⁸

These allegations are sufficiently particularized to satisfy Rule 9(b). See United States ex rel. Westmoreland v. Amgen, Inc., 2010 WL 3622033, at *6 (D. Mass. Sept. 20, 2010) ("Although Relator cannot identify each particular instance of a knowingly false certification, the Complaint as a whole is sufficiently particular to strengthen the inference of fraud beyond possibility."), citing Rost, 507 F.3d at 732 ("Rule 9(b) may be satisfied

²⁷Plaintiffs allege that between 1999 and 2004, Omnicare's annual purchases of J&J's antipsychotic drugs nearly tripled to almost \$300 million despite Congress's warning against the overuse of antipsychotic drugs by nursing home providers.

²⁸The Complaint also details Omnicare's similar efforts to promote Levaquin.

where, although some questions remain unanswered, the complaint as a whole is sufficiently particular to pass muster under the [False Claims Act].”).

Unjust Enrichment

J&J argues that the government’s unjust enrichment theory should be dismissed as Congress has “spoken to [the] particular issue” in enacting the FCA and “the scheme established by Congress addresses the [remedy] problem formerly governed by federal common law.” Milwaukee v. Illinois, 451 U.S. 304, 312 (1981). Unjust enrichment is an “equitable stopgap for occasional inadequacies in contractual remedies at law.” Mass. Eye & Ear Infirm. v. QLT Phototh., Inc., 412 F.3d 215, 234 (1st Cir. 2005). Because it is a theory of recovery and not an independent cause of action it is often pled (as it is here) in the alternative to a claim for damages at law. The viability of the theory is well established. Its applicability, however, is an issue for later consideration.

The State Law Claims²⁹

Nevada

In May of 2009, the State of Nevada settled a 2002 lawsuit in which J&J had been

²⁹J&J asserts that relators have alleged claims under various state False Claims Act that “were not enacted until after the period at issue” and “do not apply retroactively.” J&J Mem. at 33-34. J&J notes that as “a general rule . . . statutes do not apply retroactively,” but acknowledges that some of the statutes apply to part of the period in question. See Carpenter, 723 F. Supp. 2d at 402-403 & n.15 (holding that FERA’s retroactivity language applies to “claims” for reimbursement under the FCA, not pending legal “claims”). But see Matthew Titolo, Retroactivity and the Fraud Enforcement and Recovery Act of 2009, 86 Ind. L.J. 257, 300-301 (2011) (parsing the drafting history of FERA in concluding that Congress intended the FCA amendments to overrule the holding in Allison Engine and for FERA to apply retroactively to cases pending at the time of its enactment.) The court is not, however, inclined to embark on a ferreting expedition given the lack of any further specification by J&J as to which state statutes may or may not be affected.

named a defendant. See State of Nevada v. Am. Home Prods. Corp., No. 01-cv-12257, MDL No. 1456, In re Pharm. Indus. Average Wholesale Price Litig. (D. Mass. Sept. 30, 2003). As part of the settlement, Nevada released “the Johnson & Johnson Group, and each and every one of their subsidiaries” from liability for all claims

including but not limited to any claims regarding any drug price published by any commercial price reporting service, or provided by the Released Parties to any such commercial price reporting service (including, but not limited to, AWP, SWP, SLP, WAC, NWP, WNP, WPP and Direct Price) and / or any marketing activity relating to any such price, including, but not limited to, any reference to the difference between (1) a price paid and (2) any reported price or reimbursement rate based on such a reported price, *or any claims relating to the submission of claims to the State for payment or reimbursement, for any drug manufactured, marketed, sold, or distributed by any Released Party (collectively the Released Claims)*. The State of Nevada further covenants that it will not sue the Released Parties for any claim of any type based on or arising out of future conduct, events, transactions, or practices which are substantially the same as those described in the Amended Complaint.

J&J Mem. - Ex. 7 at 5-6 (emphasis added). As the agreement clearly encompasses the FCA claims in this case, the Nevada claims will be dismissed.

Texas

At the time relators filed suit, the State of Texas qui tam statute required dismissal of their claims if the State did not intervene within 60 days of being served with the Complaint. See Tex. Hum. Res. Code Ann. § 36.104(b) (1997). An amendment to the law, approved May 4, 2007, allowing qui tam suits to proceed without intervention by the State, specifies that it “applies only to conduct that occurs on or after the effective date of this Act. Conduct that occurs before the effective date of the Act is governed by the law in effect at the time the conduct occurred, and that law is continued in effect for that

purpose.” Id. As Texas has never moved to intervene, the Texas claims will also be dismissed.

Illinois

Lisitza’s Illinois claims are brought under a criminal statute, the Illinois Insurance Fraud Claims Fraud Prevention Act, 740 Ill. Comp. Stat. 92/1. The court agrees with J&J that Lisitza does not have standing to prosecute a criminal claim under the Act. The court can find no case in which Illinois has permitted a private litigant to usurp the function of the Illinois Attorney General under the Act. The California law cited by Lisitza interpreting California’s insurance fraud statute is irrelevant. Consequently, the Illinois claims will be dismissed.

Kentucky

J&J claims that Kentucky’s state claims are flawed – that J&J is not a medical “provider” as required by Counts 9, 11, and 13; that the state statutes cited in Counts 10 and 12 do not authorize private causes of action; and that the Kentucky Attorney General lacks standing to file a claim under the state Consumer Protection Act, Ky. Rev. Stat. § 367.170 (KCPA) (Count 14). The Kentucky Medicaid Fraud Statute (KMFA) defines “provider” to include “an individual, company, corporation, association, facility, or institution which is providing or has been approved to provide medical services, goods, or assistance to recipients under the Medical Assistance Program.” Ky. Rev. Stat. § 205.8451(7). According to the Commonwealth, it is a party to an agreement with J&J whereby J&J pays it quarterly rebates in return for which J&J “is providing or has been approved to provide”

prescription drugs to Medicaid recipients in Kentucky.³⁰ With regard to J&J's argument that Ky. Rev. Stat. § 446.070 does not authorize a private right of action, the Kentucky courts have held otherwise.

KRS 446.070 provides an avenue by which a damaged party may sue for a violation of a statutory standard of care if the statute in question provides no inclusive civil remedy and if the party is within the class of persons the statute is intended to protect. Hargis v. Baize, 168 S.W.3d 36, 40 (Ky. 2005). It provides that “[a] person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation.” KRS 446.070. . . . Kentucky courts have held that the “any statute” language in KRS 446.070 is limited to Kentucky statutes and does not extend to federal statutes and regulations or local ordinances.

Young v. Carran, 289 S.W.3d 586, 589 (Ky. App. 2008). Finally, as to J&J's cited cases challenging the Attorney General's right to bring an action under the KCPA, courts have determined that “those cases apply only to the section of the KCPA authorizing a private right of action, Ky. Rev. Stat. Ann. § 367.220, and not to actions brought by the Attorney General under § 367.190.” Fed. Trade Comm'n v. Mylan Lab., Inc., 99 F. Supp. 2d 1, 6 (D.D.C. 1999). Consequently, the motion to dismiss the Kentucky claims will be denied.

Indiana

J&J contends that Counts 5, 6, 7 and 8 of the State of Indiana Complaint in Intervention must be dismissed as inadequately plead. The court agrees that as to Count 8, Indiana has failed to plead the statutory requirement that proceeds from any alleged racketeering activity be used to “acquire an interest in property” or “establish or operate”

³⁰The Commonwealth also maintains that provider liability “flows through it” by virtue of J&J's agency relationship with Omnicare – a not implausible argument.

the racketeering enterprise (which Indiana rather dubiously identifies as the “Switching Scheme”). See Indiana Compl. ¶ 100. To constitute an “enterprise there must be an ascertainable structure distinct from that inherent in a pattern of racketeering.” Waldon v. Indiana, 829 N.E.2d 168, 176 (Ind. Ct. App. 2005). See also NOW v. Scheidler, 510 U.S. 249, 259 (1994) (“The [RICO] enterprise . . . is an entity that was acquired through illegal activity or the money generated from illegal activity.”). Here, Indiana has pled the same conduct as both the pattern and the enterprise. See Waldon, 829 N.E.2d at 176, quoting United States v. Rogers, 89 F.3d 1326, 1337 (7th Cir. 1996) (“If the enterprise is just a name for the crimes the defendants committed, or for their agreement to commit these crimes that was charged separately in the conspiracy count, then it would not be an enterprise within the meaning of the statute. Otherwise two statutory elements – enterprise and pattern – would be collapsed into one.”). The State of Indiana also fails to plead any “pattern” of racketeering activity from which funds were used to acquire an interest in property or to establish or operate the supposed enterprise. Count 8 will therefore be dismissed. However, the court does find that Count 5 (Medicaid fraud - Improper Payments Statute Ind. Code § 35-43-5-7.1) and Count 7 (Indiana AKS, Ind. Code § 12-15-24-2) are adequately pled. (Count 6 simply asks for treble damages under the Indiana Medicaid Fraud Statute if a violation of Count 5 is eventually found).

Virginia

J&J argues that the claims of the Commonwealth of Virginia – brought under Va. Code § 32.1-312, Virginia’s Fraud Against Taxpayer’s Act (FATA) – should be dismissed (1) as barred by the statute of limitations; and (2) because the FATA, as enacted, does not

encompass inducement claims. As the FATA is modeled on the federal FCA, the Attorney General invites the court to apply federal law in interpreting its provisions. See Andrews v. Browne, 662 S.E.2d 58, 62 (Va. 2008) (appropriate to look to federal law in interpreting a Virginia Securities Act provision that was adopted from federal securities law); Hechler Chevrolet, Inc. v. Gen. Motors Corp., 337 S.E.2d 744, 747-748 (Va. 1985) (utilizing federal case law discussing the Automobile Dealers' Day in Court Act, 15 U.S.C. §§ 1221-1225, in interpreting Virginia automobile franchise law); Brailey v. Commonwealth, 686 S.E.2d 546, 552 (Va. Ct. App. 2009) ("The relevant language of Code § 58.1-348.1 tracks the language of the federal statute, and, thus, we find the interpretation of the federal statute persuasive in our analysis."). The Virginia Complaint alleges that J&J provided illegal kickbacks to Omnicare to induce it to purchase and promote J&J's branded drugs. Using FCA law as a guide, the court finds the allegations of a fraudulent scheme sufficiently pled.

J&J also contends that the Virginia claims are time-barred because the State failed to file within the allotted three years. The Attorney General states that "there was no statute of limitations applicable to a Section 32.1-312 claim during the relevant time period (1999-2004). The statute of limitations upon which J&J relies did not come into existence until July 1, 2007." Intervening States Opp'n at 14, citing 2007 Va. Acts 569. Although the absence of a statute of limitations seems implausible, the court will rely on the Attorney General's representation for present purposes. Consequently, the motion to dismiss the Virginia claims will be denied.

ORDER

For the foregoing reasons, J&J's motions to dismiss are ALLOWED in part and

DENIED in part. The Kammerer claims are DISMISSED in their entirety. Lisitza's claims of "best price" fraud are DISMISSED. J&J's motion to dismiss the claims brought by or asserted in the name of the State of Nevada, the State of Texas, and the State of Illinois is ALLOWED. J&J's motion to dismiss the claims of the State of Indiana is ALLOWED as to Count 8 and otherwise DENIED. J&J's motion to dismiss the claims of the Commonwealth of Kentucky and the Commonwealth of Virginia is DENIED. The parties will file within fourteen (14) days of the date of this Order a joint proposed order regulating the future course of discovery in this matter.

SO ORDERED.

/s/ Richard G. Stearns

UNITED STATES DISTRICT JUDGE

Publisher Information

Note* This page is not part of the opinion as entered by the court. The docket information provided on this page is for the benefit of publishers of these opinions.

1:05-cv-11518-RGS United States of America v. Abbott Laboratories
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Date filed: 07/19/2005
Date of last filing: 02/23/2011

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