UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 11-10316-RGS

UNITED STATES OF AMERICA,
ex rel. SCOTT BARTZ

v.

ORTHO-MCNEIL PHARMACEUTICAL, INC.; JOHNSON & JOHNSON, INC.; JANSSEN PHARMACEUTICA, INC.; JANSSEN PHARMACEUTICA PRODUCTS, LP; MCKESSON CORPORATION; MCKESSON SPECIALTY PHAMACEUTICAL, LLC; OMNICARE, INC.; JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL NEUROLOGICS, INC.; JOM PHARMACEUTICAL SERVICES, INC.; and CENTOCOR ORTHO BIOTECH, INC.

MEMORANDUM AND ORDER ON
JOHNSON & JOHNSON DEFENDANTS' and
MCKESSON SPECIALTY PHAMACEUTICAL, LLC'S
MOTIONS TO DISMISS THIRD AMENDED COMPLAINT

March 2, 2012

STEARNS, D.J.

In this qui tam action, plaintiff Scott Bartz, a former employee of defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. (Ortho), alleges that the defendants collectively violated the False Claims Act (FCA), 31 U.S.C. § 3729(a). He also alleges that Johnson & Johnson, Inc. (J&J), and Ortho-McNeil Pharmaceutical, Inc., two of the

J&J defendants,[1] demoted and ultimately terminated him after he confronted corporate executives with accusations of wrongdoing. Bartz's allegations against the defendants have evolved over time, as reflected in the succession of Amended Complaints. They fall into three broad categories of alleged fraudulent conduct – the manipulation of rebate amounts owed to the federal government under Medicaid; the false reporting of the Average Manufacturer Price (AMP) and the Best Price of certain drugs;[2] and the payment of kickbacks to nursing home drug purchasers. At the heart of Bartz's allegations is the claim that pharmaceutical distributor McKesson Specialty Phamaceutical, LLC, took kickbacks from J&J as an inducement to purchase the anti-psychotic medication Risperdal Consta.

Defendants' began, appropriately, with a challenge to the court's subject matter jurisdiction, which they contend is ousted by operation of the "public disclosure" and "first-to-file" bars of the FCA. Defendants characterize Bartz's Third Amended

[1] Bartz refers to defendants Johnson & Johnson; Johnson & Johnson Health Care Systems, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc.; Ortho-McNeil Pharmaceutical, Inc.; Ortho-McNeil Neurologics, Inc.; Janssen Pharmaceutica, Inc.; Janssen Pharmaceutica Products, L.P.; JOM Pharmaceutical Services, Inc.; and Centocor Ortho Biotech, Inc., as the "J&J defendants."

[2] To obtain Medicare coverage, J&J must report its AMP and Best Price each quarter, and pay Medicaid a rebate – the greater of 15.1% of AMP or the difference between AMP and Best Price. Bartz alleges that J&J falsified its quarterly Medicare reports of both AMP and Best Price. Third Am. Compl. ¶¶ 51-61, 78c.

Complaint as a hotchpotch of stale allegations "that were previously presented in dozens of complaints and other public disclosures." Mot. to Dismiss at 2. They also assert that Bartz has not demonstrated that he has "'direct and independent' knowledge of these claims or that he voluntarily disclosed to the government all the information he had regarding these claims prior to filing his qui tam action as required under 31 U.S.C. § 3730(e)(4)(B)." *Id*. Bartz parries with his self-portrayal as an "original source" whose information "came from direct and independent knowledge" as a Sales Compensation Manager for Ortho, and who as a dutiful citizen "provided his information to the United States prior to filing [his Complaint]." Opp'n Mem. at 2.

PROCEDURAL BACKGROUND

On September 20, 2005, Bartz emailed the Securities & Exchange Commission (SEC), alleging that the J&J defendants had committed Medicare and Medicaid fraud. A month later, on November 16, 2005, Bartz's counsel presented the United States Attorney's Office in Philadelphia with an eighteen-page narrative of Bartz's claims, accompanied by 435 pages of documentary "evidence."[3] Orlow Decl. ¶ 4 (Opp'n Mem. - Ex. 3). Simultaneously, Bartz filed the first iteration of this Complaint in the United States District Court for the Eastern District of Pennsylvania.

[3] Bartz's original counsel, Marc Orlow and Ross Begelman withdrew from the case on May 31, 2011, but have since provided Bartz with a supporting affidavit.

The 2005 version of the Complaint asserted two claims under the FCA, 31 U.S.C. § 3729(a). Count I alleged that by "hiding discounts and distorting 'best price' through purchases of unneeded data, [and] shipments of free drugs, the J&J defendants were able to avoid paying larger Medicaid rebates which constitutes the making of false claims." Compl. ¶ 100. Count II alleged a conspiracy among the J&J defendants, McKesson, and Omnicare to "hid[e] the discounted/best price through purchases of (1) unneeded data, (2) shipments of free Drugs, (3) improperly assessing or charging service fees and/or administrative fees, and (4) receipt of 'service fees and/or administrative fees' not passed onto the Government payors." *Id.* ¶ 103. Bartz alleged that J&J was "inflating [its] earnings" by overstating sales of the drug Risperdal Consta by "stuffing the distribution channels with large quantities of product ahead of demand." *Id.* ¶ 29. Bartz specifically named McKesson and non-parties Cardinal Health, Inc., and AmerisourceBergen Corp. as the direct beneficiaries of the scheme because the "channel stuffing" gave them an "unfair advantage in the Medicare Part B bidding guidelines." *Id.* ¶ 47. Bartz contended that J&J "hid [the] channel stuffing . . . by reporting [pharmacy sales] once as an 'Institutional sale,' and a second time as a 'retail sale.'" *Id.* ¶ 38. The Complaint also stated that Janssen "appears to purchase sales data from key customers [McKesson] as a way of providing them a discount while fraudulently hiding the best price." *Id.* ¶ 43. Bartz claimed that in 2004,

McKesson, Cardinal, and AmerisourceBergen began billing J&J for a "service fee" for providing previously complimentary services, including overnight shipping, direct physician or customer billing, and the expedited processing of emergency orders. Bartz contends that these "fees" were in reality kickbacks.[4]

Bartz filed supplemental materials with the United States Attorney's Office on April 3, 2006, and amended his Complaint on July 7, 2007. Bartz embellished the Medicaid rebate fraud claim by adding the following details.

> The J&J Defendants recklessly and willfully corrupt "Best Price" calculations and reporting on the J&J Products through a variety of fraudulent schemes, which upper management executives were and are aware of by, inter alia, (i) providing discounts in the form of cash payments or reductions in price that constitute remuneration which they do not submit, report or certify to CMS [Center For Medicare and Medicaid Services], (ii) providing free goods that are conditional on the purchase of other products that constitute remuneration which they do not submit, report to certify to CMS, (iii) make payment of fees to distributors and customers such as McKesson and Omnicare requiring no services that act as discounts, (iv) fraudulently manipulate J&J finance databases, (v) fraudulent manipulation of data used to calculate prices, [vi] willfully, recklessly and fraudulently conspires with business partners via contracts, off the book agreements, payments, and joint ventures which fall outside Anti-kickback Safe Harbor provisions, all of which are designed to hide true prices & discounts, and to report false prices to the Government.

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[4] Bartz also alleged a retaliation claim under New Jersey's Conscientious Employee Protection Act, N.J.S.A. 34:19-3, based on the alleged repercussions of his internal complaint to J&J that it had committed "Sarbanes Oxley violations." *Id.* ¶¶ 292-299.

First Am. Compl. ¶ 30 (Dkt # 14). *See also id*. ¶¶ 68-107, 157.

Bartz filed a Second Amended Complaint on October 30, 2007, adding five government entities as plaintiffs and alleging that the J&J defendants had failed to report accurate AMP, Average Sales Price (ASP), and Best Price for various drugs by failing to properly account for free goods, discounts, bundled sales, and service fees in the price listings.[5] *Id*. ¶¶ 68-104. On October 15, 2008, the United States declined to intervene in Bartz's lawsuit. *See* Dkt # 25.

On February 10, 2011, Bartz amended his Complaint again, making substantial additions (as well as deletions) to his claims in a 141-page, 358-paragraph Third Amended Complaint. *See* Dkt #74. Many of the allegations echoed past iterations of the Complaint, such as the non-reporting of data purchases and the gifting of goods, and data manipulation resulting in fraudulent reporting of AMP and Best Price. Bartz expanded the list of drugs said to figure in the illegal price reporting and kickback scheme to include Razadyne IR and Razadyne ER, and Risperdal. Bartz contends that J&J reported false and fraudulent (inflated) Average Wholesale Price (AWP), Wholesale Acquisition Cost (WAC), AMP, ASP, Best Price, and non-Federal Average

[5] Bartz's allegations had previously centered on the J&J drug Risperdal Consta. In the Second Amended Complaint, Bartz added allegations regarding the Alzheimer drug Razadyne (manufactured by Ortho-McNeil Neurologics, Inc.), while abandoning the "channel stuffing" claims against all defendants.

Manufacturers Price (non-FAMP) for these drugs causing retailers to receive inflated payments and reimbursements, making J&J products more attractive to retailers, and wrongfully reducing the rebate payments J&J owed to Medicaid.[6] Bartz alleges that the false price reports resulted from hidden discounts (primarily in the form of free goods), the underreporting of sales, the inflating of AMPs, the use of dummy accounts, and the misclassification of purchasers. *Id*. ¶¶ 152-199. Bartz maintains that various free goods, "performance rebates," "administrative fees," discounts, and service fee payments to Omnicare and drug wholesalers were illegal "kickbacks." *Id*. ¶¶ 232-258.

With regard to McKesson Specialty, Bartz asserts that it accepted kickbacks from J&J in connection with its purchase of J&J products. Bartz alleges that J&J's payment arrangements with McKesson Specialty ("and other distributors"), included illegal "kickbacks" in the form of "prompt pay cash discounts," fees paid to distributors

[6] Bartz claims that in 2004, J&J began excluding its sales to Omnicare pharmacies from its calculation of AMP. Bartz also contends that J&J excepted any drugs gifted to Omnicare (and others) from Best Price reporting, even when the bestowed drug was contingent on Omnicare's future purchases of the same drug. Third Am. Compl. ¶ 167. Bartz includes spreadsheets for sales of Risperdal from January of 2004 through June of 2005, recorded at $0.00 WAC. *Id*. ¶ 169. He also provides spreadsheets that allegedly indicate that invoiced sales of J&J products to "long term care pharmacies were significantly lower than the sell-out from those pharmacies." *Id*. ¶ 170. As an example, Bartz notes that in 2004, invoiced sales of Risperdal to long term care pharmacies were $376,069,057, while the sell-out was $485,287,183. *Id*.

for previously free services, "price protection payments," "discounts" to Group Purchasing Organizations, and payments for training materials and services. *Id.* ¶¶ 232-258. Bartz alleges that the "kickbacks" caused "Omnicare and others to file false reports for reimbursement to various healthcare programs" making the scheme actionable as a per se violations of the FCA (§§ 3729(a)(1), (2), (3), and (7)), and the false claims acts of twenty-two states, the District of Columbia, and the City of New York. *See* Opp'n Mem. at 5. To date, no State has moved to intervene in this lawsuit.

The Third Amended Complaint includes counts under 31 U.S.C. § 3729(a)(1) of the FCA for the presentation of false claims (Count I); a newly-minted FCA count for payment of kickbacks in violation of the federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b (Count II); retaliation in violation of 31 U.S.C. § 3730(h) of the FCA (Count III); violations of the New Jersey CEPA, N.J.S.A. 34:19-1 (Count IV); intentional infliction of emotional distress (Count V); and violations of various state FCAs (Counts VI - XXX).[7] Defendants Omnicare, Inc., and McKesson Corporation

[7] Like the federal FCA, these state statutes impose liability on any person who: (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval to a state; (2) knowingly makes, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state; or (3) conspires to defraud the state by getting a false claim allowed or paid. *See, e.g.*, Cal. Gov't Code § 12651(a)(1)-(3); Ga. Code Ann. § 49-4-18.1(a)(1)-(3); Haw. Rev. Stat. § 661-1(a)(1)-(3); 740 Ill. Comp. Stat. § 175/3(a)(1)(A)-(C); Ind. Code § 5-11-5.5-2(b); N.J. Stat. Ann. § 2A:32C-1; N.H. Rev. Stat. § 167:61-b(VII)(b); N.M.

moved to dismiss the FCA counts of the Third Amended Complaint. On February 23, 2011, Judge Paul Diamond granted J&J's unopposed motion to transfer venue of the case from the Eastern District of Pennsylvania to this court. On June 10, 2011, Bartz dismissed his claims against Omnicare and McKesson pending consent from the United States, the named States, and this court's approval. *See* 31 U.S.C. § 3730(b)(1); Mass. Gen. Laws ch. 12, § 5C(2).

The J&J defendants and McKesson Specialty now move to dismiss the Third Amended Complaint based on the FCA's public disclosure and first-to-file bars. Defendants list a series of lawsuits filed prior to Bartz's November 16, 2005 Complaint that contain allegations that J&J reported false AWP, WAC, AMP, and Best Price. In his Opposition to J&J's Motion to Dismiss, Bartz withdrew the AWP and WAC pricing fraud claims against all defendants. Opp'n Mem. at 11 n.11.

FACTUAL BACKGROUND

Bartz, a New Jersey resident, was employed by various J&J defendants from August 23, 1999, to April 20, 2007. Bartz initially worked as a sales representative for Janssen Pharmaceutica, Inc., where he was promoted to "Senior Analyst, Sales Incentive Compensation" on February 17, 2003. Third Am. Compl. ¶ 11. On January

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Stat. Ann. § 27-14-4(A)-(D); N.Y. State Fin. Law § 189(1)(a)-(c); 63 Okla. St. Ann. § 5053.6; R.I. Gen. Laws Ann. 1956, § 9-1.1-5.

5, 2004, Bartz was transferred to Ortho, and on January 5, 2004, was promoted to "Sales Incentive Compensation Manager." *Id*. ¶¶ 11, 107-109, 126. On June 7, 2005, Bartz was demoted, ostensibly because his "internal customers were not happy, including [the] National Sales Director . . . [and] Field Sales Director." *Id*. ¶ 105. On June 27, 2005, Bartz received a notice of "Reassignment" with a concomitant salary reduction and change in the structure of his bonus earnings. *Id*. ¶ 108. In July of 2005, he received a "very critical evaluation from his supervisor." *Id*. Bartz was terminated by J&J on April 20, 2007, allegedly in retaliation for his whistleblowing.

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 on its face." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (internal quotation omitted). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss 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." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations and quotations omitted). "A suit will be dismissed if the complaint does not set forth 'factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal

theory.'" *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 384 (1st Cir. 2011), quoting *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008).

Bartz's federal FCA claims are based on 31 U.S.C. § 3729(a)(1) and (a)(2). Subsection (a)(1) prohibits the knowing presentment of a false claim for payment to the government, or (as alleged here) causing such a presentment to be made. Subsection (a)(2) prohibits the creation or use of false records and statements as part of a scheme to persuade the government to pay a false claim. While subsection (a)(1) requires an actual presentment of a false claim, subsection (a)(2) prohibits making or the causing to be made a false record or statement in support of a false claim.[8]

The review begins, where it must, with the J&J defendants and McKesson Specialty's jurisdictional challenges under the "public disclosure," "first-to-file," and "original source" bars. "Nothing can justify adjudication of a suit in which . . . there is some [ ] obstacle to justiciability." *Sherman v. Cmty. Consol. Sch. Dist. 21*, 980 F.2d

[8] These and other provisions of the FCA were significantly amended by the Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. No. 111-21, 123 Stat. 1617 (2009). Most FERA amendments took effect on May 20, 2009. The amendment to Section 3729(a)(2) applies retroactively to claims pending on or after June 7, 2008. *See United States ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395, 401-403 (D. Mass. 2010) (analyzing FERA's effective date and retroactivity provisions). While Bartz makes reference in his Third Amended Complaint to FERA's amendments (*see* n.1), all of his allegations involve events occurring between 1999 and 2007, before FERA's effective date and prior to the retroactive application of Section 3729(a)(2). Accordingly, the pre-FERA version of the FCA applies in this case.

437, 440 (7th Cir. 1992). Whether a relator is qualified to bring a qui tam action under the FCA is a question of subject matter jurisdiction. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 468 (2007). "The basis for jurisdiction must be apparent from the facts existing at the time the complaint is brought." *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 510 (6th Cir. 2009), citing *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95 (1998).

Public Disclosure Bar of the FCA

By act of Congress, 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.

31 U.S.C. § 3730(e)(4)(A). A sequential four-step analysis is followed in determining whether a lawsuit is precluded by the public disclosure bar:

> (1) whether there has been public disclosure of the allegations or transactions in the relator's complaint; (2) if so, whether the public disclosure occurred in the manner specified in the statute; (3) if so, whether the relator's suit is "based upon" those publicly disclosed allegations or transactions; and (4) 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 common fodder, they must be disseminated beyond the government's inner precincts. *See Rost*, 507 F.3d at 728. If the court finds a prior disclosure of an alleged fraud, it then determines whether the disclosure comes from one of the three statutorily specified sources – (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." *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 113 (1st Cir. 2010), quoting *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1401-1402 (2010). Allegations contained 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 § 3730(e)(4)(A). *Poteet*, 619 F.3d at 111 ("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 United States v. Johnson Controls, Inc.*, 457 F.3d 1009, 1013 (9th Cir. 2006) (civil complaint filed in state court satisfies the disclosure rule).[9]

The J&J defendants and McKesson Specialty assert that Bartz's FCA claims are barred by a parade of previously filed cases. J&J lists the following "public disclosures" of Bartz's allegations: various AWP cases (J&J's Mem. - Exs. 1 - 8); several news media reports (*Id*. - Exs. 14, 15, 18 and 19); and several Massachusetts FCA cases - *Maguire*, *Kammerer*, and *Lisitza* (*Id*. - Exs. 9 - 11). To determine whether these various sources trigger the public disclosure bar, the court must compare their content with Bartz's Amended Complaint and extract any "substantial similarit[ies]" in their factual assertions. *Poteet*, 619 F.3d at 114. The test is one of similarity, and not originality of sources. "[A]s long as the relator's allegations are substantially similar to information disclosed publicly, the relator's claim is 'based upon' the public disclosure even if he actually obtained his information from a different source." *United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 57 (1st Cir. 2009).

[9] The United States Supreme Court also reads the phrase "administrative . . . report, hearing, audit, or investigation" to encompass not only federal, but also state and local, government sources. *See Graham Cnty.*, 130 S. Ct. at 1411.

In August of 2003, the State of Montana filed suit against J&J (and others) alleging the reporting of false AWP, AMP, and Best Price "by failing to accurately account for [defendants'] practices of offering free goods, volume discounts, credits, [and] rebates" and by failing to properly account for "chargebacks, credits, rebates, hidden price discounts and/or other unlawful financial inducements, including free samples." *Montana v. Abbott Labs., Inc.*, No. CV-02-09-H-DWM (D. Mont. Aug. 1, 2003) Compl. ¶¶ 9, 12; *compare* Bartz Compl. ¶¶ 612, 651. The City of New York made almost identical allegations against J&J in a 2004 lawsuit – that J&J reported false AWP, AMP, and Best Price for its pharmaceutical products by failing to properly account for "chargebacks, two percent prompt pay discounts, free samples distributed by sales representatives, and other credits, rebates and hidden discounts and financial incentives." *City of N.Y. v. Abbott Labs., Inc.*, No. 04-CV-06054 (S.D.N.Y. Aug. 4, 2004) Compl. ¶¶ 117-121. The New York Complaint also alleged that J&J paid "an array" of illegal "inducements to stimulate sales of [its] drugs . . . including . . . volume discounts, and rebates or free goods . . . designed to result in a lower net cost to the purchaser while concealing the actual cost price beneath a high invoice price." *Id.* ¶ 120.

The AWP class action litigation (a collection of non-qui tam cases) consolidated before Judge Saris also predated Bartz's claims. In the AWP cases, plaintiffs alleged

that J&J's false reporting of AWPs was part of a conspiracy with others in the pharmaceutical distribution chain to conceal "volume discounts, rebates, off-invoice pricing, [and] free goods," by "ke[eping them] 'off the book[s],' so as to not be reflected in the AWP." *In re Pharm. Indus. Average Wholesale Price Litig.*, MDL 1456, Civ. No. 01-12257, Third Am. Compl. ¶ 183 (D. Mass. Oct. 17, 2005); *see also id.* (alleging "non-public financial inducements to stimulate [drug] sales"); *id.* ¶ 447 (listing each of the J&J drugs also identified in Bartz's Third Amended Complaint).

On April 11, 2005, relator Dr. William St. John LaCorte, in a Second Amended Complaint filed in Louisiana, alleged that J&J subsidiary Janssen paid "financial inducements in the form of discounts, remuneration, rebates, or kickbacks" to AmerisourceBergen subsidiary PharMerica in order to promote the sales of its drugs. *United States ex rel. LaCorte v. AmerisourceBergen Corp.*, 02-3168 (D. La. 2005), Second Am. Compl. ¶ 118. LaCorte also alleged that "[t]he financial inducements the Defendants receive from pharmaceutical manufacturers [identified to include Janssen] in exchange for achieving and maintaining the targeted market share result in these manufacturers charging the Defendants substantially less for the substituted drugs than the 'best prices' for these drugs these pharmaceutical companies are reporting and certifying to the DHHS [Department of Health & Human Services] each quarter." *Id.* ¶ 127. LaCorte contended that as a result, "[t]he United States government is not . .

. receiving the actual 'best price' for these drugs required by law and the manufacturer's Rebate Agreement with the Secretary of the DHHS" because the pharmaceutical manufacturers submit "inaccurate utilization, cost and pricing data . . . to the DHHS, CMS, and other government agencies." *Id*. ¶¶ 127-128. LaCorte also specified that "Janssen gave [AmerisourceBergen subsidiary] PharMerica price discounts or rebates or other financial incentives on the purchase of Risperdal." *Id*. ¶ 163. In exchange, PharMerica obtained "unauthorized financial inducements from Janssen to promote the use of Risperdal and increase its market share," resulting in Risperdal being favored over cheaper alternatives. *Id*. ¶ 168. *See also id.* ¶¶ 158-175.

In March of 2005, a lawsuit filed by the Commonwealth of Pennsylvania alleged that J&J "used free goods . . . as a method of providing hidden price concessions or reductions in the acquisition costs for their drugs," including the provision of "free product bundled with other products, such as 'buy ten get one free' deals." *Commonwealth of Pennsylvania v. Abbott Labs.*, No. 212 M.D. 2004, Am. Compl. ¶¶ 97-98 (J&J - Ex. 1). Pennsylvania also alleged that J&J falsely reported AWP, AMP, and Best Price by omitting the accounting of "free goods" and by failing to properly account for "routine discounts, rebates, off-invoice transactions, . . . and other inducements offered to participants in the drug distribution chain." *Id*. ¶¶ 103, 505, 710-711.

Defendants also point to several FCA actions filed in this session. On July 16, 2002, Deborah Maguire, a former Omnicare employee, filed suit alleging that Omnicare accepted kickbacks in exchange for ordering J&J's Risperdal. *See United States ex rel. Maguire v. Omnicare, Inc.*, No. 02-11436-RGS (D. Mass. July 16, 2002). Specifically, the *Maguire* Complaint alleged that Omnicare "solicit[ed] price discounts from drug manufacturers in exchange for promises that Omnicare's consulting pharmacists would recommend particular drugs." *Maguire* Am. Compl. ¶ 26; *see also id*. ¶ 18 (alleging that "Omnicare's promises to recommend particular drugs through its pharmacy consultants" were not sheltered by the AKS's "safe harbor" provisions).

Thereafter, on October 28, 2003, and October 27, 2005, plaintiffs David Kammerer and Bernard Lisitza, respectively, filed related cases naming J&J, among others, as a defendant. Kammerer alleged that Omnicare had received kickbacks from J&J to give purchasing preference to its products, allegedly in violation of both the AKS and FCA. *See United States ex rel. Kammerer v. Omnicare*, (D. Mass. 05-11518-RGS), First Am. Compl. ¶¶ 2-4, 48, 53-59. The kickbacks to Omnicare were allegedly in the form of "'post-purchase discounts' and rebates, as well as free goods, price-freezes, grants and other cash payments." *Id*. ¶ 2. Kammerer also alleged that J&J "concealed cash and in-kind remuneration intended to secure Omnicare's business, including free product and various cash payments," and that such inducements were

wrongly excluded from J&J's best price reports "on various products." *Id.* ¶ 58.

In *United States ex rel. Lisitza v. Pfizer*, No. 03-C-5958 (E.D. Pa. 2003), Lisitza alleged that Omnicare received kickbacks from J&J's subsidiary Ortho-McNeil to favor its products over others, again violating both the AKS and FCA. Compl. ¶¶ 2-6, 53-62 (J&J - Ex. 11). The *Lisitza* Amended Complaint (filed in November of 2006) alleged that "the result" of the kickback scheme was that Omnicare was given "a far better net price on its 'preferred' medication than it gave any other entity – after the kickbacks were subtracted. This net price was Defendant Manufacturers' true 'best price.' [J&J] did not disclose this actual best price to the government. As a result, [J&J's] Medicaid rebates were grossly understated." *Lisitza* Am. Compl. ¶ 13.

The Complaint in *United States ex rel. Pauly v. Johnson & Johnson*, No. CV06-2461 (C.D. Cal. 2006) (J&J - Ex. 13), was filed on April 26, 2006, prior to the filing of Bartz's Second and Third Amended Complaints. The *Pauly* Complaint contained allegations that the J&J defendants "concocted a new illegal scheme to disguise discounts to wholesalers so that defendants could then falsely report an inflated ASP in their quarterly ASP reports to CMS." *Id.* ¶ 14. Pauly also contended that the J&J defendants had "funnel[ed] undisclosed discounts to a select group of Remicade® wholesale distributors, while giving discount prices to end purchasers," while "knowingly [not reporting] these discounts as adjustments in their quarterly ASP

calculations to CMS." *Id.* ¶ 15. Also echoed in Bartz's Third Amended Complaint is the allegation by Pauly that the J&J defendants engaged in an "Inventory Fee" scheme that was, "in reality, a disguised volume discount . . . to encourage medical providers purchasing their drugs to receive an inflated reimbursement rate from CMS." *Id.* ¶ 18.

J&J next points to contemporary news stories and industry journal publications that anticipated the basic outline of Bartz's claims. In 2004, the Wall Street Journal reported that AmerisourceBergen, Cardinal Health, and McKesson "aim to charge brand-drug companies fees for services the wholesalers have long performed, such as packing, shipping, and billing for drugs, as well as for some extras, such as providing data." Heather Won Tesoriero, *Drug Wholesalers Change Methods – Distributors Set Service Fees For Manufacturers In Shift From 'Arbitrage' Approach*, Wall St. J., Nov. 12, 2004, at C3. Similar reports appeared in the trade journals. *See* R. David Yost, *New Economics of the Pharmaceutical Supply Chain*, 62 Am. J. Health-Syst. Pham. 525-526 (Mar. 2005) (reporting that "[t]he big three distributors (AmerisourceBergen, Cardinal Health, and McKesson) . . . are driving additional efficiencies in the supply chain as the distributor-manufacturer relationship evolves to a fee-for-service model. In this model, pharmaceutical manufacturers pay wholesalers for the services they provide in moving products from the manufacturers to customers."); *Cardinal to Restate Earnings; Urgency Behind Fee-For-Service?*, The Pink Sheet, Sept. 20, 2004,

Vol. 66, No. 38, Article # 660380023 ("The Cardinal [Health earnings] restatement is likely to encourage wholesalers to continue to be aggressive in seeking to move past those contracts to a fee-for-service arrangement. . . . That reality may be one factor in the decision by Cardinal and McKesson to set deadlines for manufacturers to accept new contracting models that involve payment directly for distribution services."); Jim Miller, *New Supply-Chain Dynamics Create a Distribution Services Sector*, Pharm. Tech., at 86 (Jan. 2004) (identifying AmerisourceBergen, Cardinal Health, and McKesson as distributors using a "new distribution business model [which] will emphasize a fee-for-service relationship between the pharmaceutical company and the distributor. Distributors will receive a negotiated fee for storing the product, handling and fulfilling orders from pharmacies, and shipping the drug to the pharmacies. They expect to receive premium fees for higher-value services such as handling drugs that require maintenance of a cold chain or controlled substances requiring extra security.").[10] McKesson Specialty points the court to two additional articles regarding the practice of pharmaceutical wholesalers charging administrative fees for services previously provided for free. *See* Dinah Wisenberg, UPDATE: *Drug Wholesaler*

[10] The U.S. Government subsequently endorsed this transition to a fee-for-service model by permitting fees to be paid for these services and excluding these fees from price reporting. *See, e.g.*, 2010 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 42 U.S.C. § 1396r-8(k)(1)(B)(I).

Warnings Reflect Ongoing Pressure, Dow Jones News Service, Oct. 6, 2004; Dinah Wisenberg, UPDATE: *AmerisourceBergen Slashes FY05 Forecast,* Dow Jones News Service, Mar. 28, 2005. It also points to a government report regarding "prompt payment discounts" to demonstrate that these were no secret prior to Bartz's first filing of his Complaint. *See* U.S. Gov't Accountability Office, GAO-05-102, Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns About Rebates Paid to States, Feb. 2005 at p. 17, available at http://www.gao.gov/new.items/d05102.pdf. ("In examining manufacturers' practices, we found that they generally provided a prompt payment discount of 2 percent of the purchase price to wholesalers and others that purchased drugs from them directly, when they paid within a specified period. In most cases, when the manufacturers we reviewed sold a drug directly to a purchaser, they reduced the purchaser's price by any applicable prompt payment discount when determining best price and AMP.").

As a matter of law, the information in these previously filed complaints and news reports are "public disclosures" for purposes of the barring rule of the FCA. *See Poteet*, 619 F.3d at 113. A comparison of these disclosures with the allegations made by Bartz demonstrates that all of the "essential elements" of Bartz's claims – the allegedly false AMP and Best Price arising from free goods and hidden discounts, and the "kickbacks" in the form of discounts and payment of administrative fees to promote

particular pharmaceutical products – were in the public domain prior to Bartz's various Complaints through the AWP Litigation, the Massachusetts Litigation, the *LaCorte*, *Pauly*, *Montana*, *City of New York*, and *Commonwealth of Pennsylvania* lawsuits, and general news reporting. Although these materials did not specifically reference the ASP and non-FAMP reporting, their allegations regarding AWPs, WACs, AMPs, and Best Prices were more than sufficient to place the government on notice of J&J's alleged reporting fraud.[11] *See, e.g.*, *Ondis*, 587 F.3d at 58 ("When the material elements of a fraud are already in the public domain, the government has no need for a relator to bring the matter to its attention."); *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F. 3d 371, 380 (5th Cir. 2009) ("[O]nce the government knows the essential facts of the fraudulent scheme, it has enough information to discover related fraud."); *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 391 (6th Cir. 2005) (applying public disclosure bar where prior allegations, although reflecting "a slightly different type of fraud than the fraud alleged . . . were sufficiently general that they could encompass the fraud alleged in the qui tam action."). As J&J persuasively argues, "the data included and excluded in ASP is, by statute, the same as Best Price." 42 U.S.C. § 1395w-3a. Similarly, there are significant similarities

[11] While Bartz states in his Opposition Memorandum that he is withdrawing the AWP and WAC pricing fraud claims, some of the related allegations remain relevant to the court's consideration of other of Bartz's claims.

between the data rules for AMPs, Best Price, and non-FAMP.[12] *See* 42 U.S.C. § 1396r-8(k)(1) (AMP); 42 U.S.C. § 1396r-8(c)(1)(c) (Best Price); 38 U.S.C. § 8126(h)(5) (non-FAMP).

Bartz claims that he slips under the public disclosure bar because he has gathered for government consumption additional tidbits, including financial accounting records and explanations of internal accounting policies. Regardless of the value to the government of these elaborations on what was already known, the public disclosure bar's focus is on notice and not detail.

> Allowing such a suit would allow potential qui tam plaintiffs to avoid the public disclosure bar by pleading their complaints with more and more detailed factual allegations slightly different from more general allegations already publicly disclosed. Given that the purpose of the qui tam action is to prosecute fraud of which the government is unaware, such a result would not advance Congress' purpose, and would only multiply the number of parasitic qui tam actions pursued by plaintiffs.

Dingle v. Bioport Corp., 388 F.3d 209, 215 (6th Cir. 2004).

Bartz argues that the Best Price allegations brought to light prior to his Complaint were too vague to qualify as true (and therefore disqualifying) disclosures. This court rejected this same argument in *Lisitza:*

> [i]n *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

[12] As J&J notes, "[n]on-FAMP is, after all, Non-Federal Average Manufacturer Price and AMP is Average Manufacturer Price." J&J Mem. at 11 n.5.

> 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 . . . Risperdal, . . . and Levaquin, *id*. ¶¶ 250-251, many of the same drugs identified in the relators' best price allegations. Similarly, the *Westchester* and *Rockland* 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.

Lisitza, 765 F. Supp. 2d at 123-124.[13] Finally, compounding the bar to Bartz's claims are the lawsuits brought by the Pennsylvania Attorney General and the State of Illinois naming J&J and alleging false price reporting based upon "free goods, hidden price concessions . . . rebates, discounts and other incentives." *Commonwealth of Pennsylvania v. TAP Pharm. Prod., Inc.*, No. 212 M.D. 2004, Compl. ¶¶ 97-98 (filed March 14, 2005); *State v. Abbott Labs, Inc.*, No. 05-CH-02474, Compl. ¶¶ 56, 60, 63 (Ill. Cir. Ct. 2005) (filed Feb. 7, 2005). This assemblage of publicly disclosed material

[13] Bartz argues that several of the prior cases discussed by the court in its *Lisitza* decision were not qui tam cases. Opp'n Mem. at 10. There is nothing in the FCA's public disclosure exception or precedential case law declaring non-qui tam cases incapable of alerting the government to fraud any more so than newspaper and trade publications.

had set the government squarely on any trail of fraud long before Bartz arrived on the scene with his claims and allegations.

Original Source

Despite the apparent prior public disclosures of the essential elements of Bartz's claims, a possible "escape hatch" nonetheless remains open if Bartz can show that he is their "original source." *See Ondis*, 587 F.3d at 58-59. A relator claiming to be an "original source" must (1) "ha[ve] 'direct and independent knowledge' of the information supporting [his] claims and (2) [must have] 'provided the information to the Government before filing an action.'" *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 16 (1st Cir. 2009). The word "before" is important: section 3730(b)(4) "does not permit us to consider the Information which was provided [to the government] after the filing of the [second-filed] Complaint." *Id*. at 33. *See also United States ex rel. Nowak v. Medtronic, Inc.*, 2011 WL 3208007, at *18 (D. Mass. July 27, 2011). On the issue of whether he in fact is an "original source," Bartz bears the burden of proof. *See* 31 U.S.C. § 3731(c); *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 913 (7th Cir. 2009).

Bartz's claim to be an original source makes its first appearance in the Third Amended Complaint, where it is said in passing that "the allegations set forth in the Complaint are based upon the direct and independent knowledge of the relator, a

former insider of the J&J Defendants . . . . This lawsuit is based solely on information and knowledge obtained by Relator in his position as a J&J insider." Third Am. Compl. ¶ 13. No supporting details are offered. Nor do the three prior iterations of the Complaint contain any mention of disclosures to the government or statements that would corroborate Bartz's status as an original source.[14] *See Duxbury*, 579 F.3d at 28 ("[W]e are under no obligation to credit McClellan's conclusory [original source] allegations, which simply parrot the elements of the statute."). Viewed as a single piece, the Complaints present a kaleidoscope of ever-shifting parties and fraud claims. While the initial Complaint had focused on so-called "channel stuffing," by the time the Third Amended Complaint had evolved, these claims had disappeared to be replaced by generic allegations of kickbacks in violation of the AKS, and the claims of fraudulent price reporting have shrunk to allegations involving only the AMP and Best Price.

In his Opposition, Bartz makes the claim that he was "well positioned to observe

[14] J&J asserts in its Reply Brief that Bartz's counsel admit that much of the information contained in the Third Amended Complaint was gleaned from the Texas Attorney General's investigative files – materials obtained after Bartz's initial Complaint was filed. *See* Reply at 8 & n.9; Opp'n Mem. - Exs. C & F. Bartz counters with the affidavit of Susan Miller, an Assistant Attorney General for the State of Texas, who avers that her office files contain date-stamped materials from Bartz from December 5, 2006, with additional materials dated May 30, 2007. The Third Amended Complaint was filed in this court on February 10, 2011.

first-hand the sales data used to calculate sales bonuses." Opp'n Mem. at 13. Bartz cites as his sources for sales information J&J's "Information Management Department" (including Xponent®, Plan Trak™, and DDD™), and data derived from records obtained from Omnicare, McKesson and VA CARES. Third Am. Compl. ¶¶ 92-96. However, on the operative elements of his claims (fraudulent price reporting and kickbacks), Bartz makes no showing even suggesting any first-hand knowledge. He simply states in an affidavit that he "copied numerous documents and data from the computer systems I had access to as part of my employment. I provided the documents and data to my counsel to forward to the United States and the various states." Bartz Decl. ¶ 3.

J&J points out that AMP and Best Price, under current program requirements, are reported in the Drug Data Reporting System, which is a Centers for Medicare and Medicaid Services (CMS) system, not a J&J system, and that only certain enumerated employees can access the CMS system using their Social Security numbers. *Cf.* 42 C.F.R. 447.510(g). Similarly, ASP is reported to CMS through a proprietary system. Bartz does not claim that he had access to either of these systems either directly or surreptitiously.

With regard to the timing of Bartz's government disclosures, his former counsel states that on September 20, 2005, Bartz emailed the SEC a summary of his allegations, and then on November 16, 2005, counsel delivered to the Philadelphia U.S. Attorney's

Office an eighteen-page narrative, with 435 pages of attachments, outlining J&J's "Medicare/Medicaid fraud, violation of federal securities laws and concealing the 'best prices' of J&J drugs." Orlow Decl. ¶ 4. Noticeably missing from this recital is any evidence that Bartz was in fact an original source of the claims made in his initial Complaint, much less the revisionist claims set out in the Third Amended Complaint.

First-to-File Rule

Even if one were to assume that Bartz qualified as an original source regarding the allegations in the Third Amended Complaint, his FCA counts would still be barred by the first-to-file rule. Once a relator files a qui tam action 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). The First Circuit has held that § 3730(b)(5) "bar[s] a later allegation [if it] states all 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 *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 232-233 (3d Cir. 1998) (under the "essential facts" standard, § 3730(b)(5) can still bar a later claim "even if that claim incorporates somewhat different details," so long as it states "the same elements of a fraud described in [the] earlier suit."). This jurisdictional bar serves the dual purpose of preventing parasitic claims based on allegations already known to the government

and of avoiding duplicative suits.

A sealed Complaint is considered for purposes of the first-to-file bar, which the First Circuit has held to be "'exception-free.'" *Duxbury*, 579 F.3d at 33, quoting *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187 (9th Cir. 2001). The goal of the first-to-file bar is "to provide incentives to relators to 'promptly alert [] the government to the essential facts of a fraudulent scheme.'" *Duxbury*, 579 F.3d at 24, quoting *Lujan*, 243 F.3d at 1188. Its purpose is to "stop repetitive claims." *Id*. at 1187. The only caveat that this court has applied, consistent with *Poteet*, 552 F.3d at 516, is that "if the first complaint is either jurisdictionally precluded or legally incapable of serving as a complaint . . . then it does not properly qualify as a 'pending action' brought under the FCA, 31 U.S.C. § 3730(b)(5)."[15] *Lenke*, 604 F. Supp. 2d at

[15] In a recent D.C. Circuit opinion, Chief Judge Sentelle held that "first-filed complaints need not meet the heightened standard of Rule 9(b) to bar later complaints; they must provide only sufficient notice for the government to initiate an investigation into the allegedly fraudulent practices, should it choose to do so." *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011). Judge Sentelle reasoned that

> [n]othing in the language of Section 3730(b)(5) incorporates the particularity requirement of Rule 9(b), which militates against reading such a requirement into the statute. The statutory text imposes a bar on complaints related to earlier-filed, "pending" actions. The command is simple: as long as a first-filed complaint remains pending, no related complaint may be filed. Further, Rule 9(b) is designed to protect defendants in fraud cases from frivolous accusations and allow them to prepare an appropriate response. Section 3730(b) is designed to allow

323 (internal citations omitted).

Bartz maintains that he has pled "different types of wrongdoing, based on different material facts" than prior relators and that the "fraud he alleges gives rise to a separate recovery of actual damages by the government." Opp'n Mem. at 16. Bartz contends that

> (1) [his] Medicaid Rebate Claims are not precluded because, although Kammerer and Lisitza pled a similar claim, their Medicaid Rebate Claims are not "pending" – they were dismissed by this Court for jurisdictional reasons, and neither Duxbury nor Pauly pled such a claim; (2) [his] Price Reporting Claim is not precluded because none of the four relators pled the widespread, detailed false ASP and non-FAMP pricing scheme Bartz pled; and (3) with respect to [his] Kickback Fraud Claims, the free goods and other specified kickbacks provided to Omnicare and others by J&J during the time Bartz worked at J&J were not pled by any of the four relators.

> recovery when a qui tam relator puts the government on notice of potential fraud being worked against the government, but to bar copycat actions that provide no additional material information. As the district court found, a complaint may provide the government sufficient information to launch an investigation of a fraudulent scheme even if the complaint does not meet the particularity standards of Rule 9(b).

Id. *But see Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 973 (6th Cir. 2005) ("A complaint that is insufficient under Rule 9(b) is dismissed precisely because it fails to provide adequate notice to the defendant of the fraud it alleges. . . . A complaint that fails to provide adequate notice to a defendant can hardly be said to have given the government notice of the essential facts of a fraudulent scheme, and therefore would not enable the government to uncover related frauds." (internal citations omitted)).

Id. at 17.

None of these assertions bears scrutiny. In the first instance, the *LaCorte* Second Amended Complaint (filed April 11, 2005) alleged that J&J reported false Best Prices for products including Risperdal, and made various payments to wholesalers and their subsidiaries, including AmerisourceBergen, that allegedly amounted to illegal kickbacks. *See, e.g., LaCorte* Compl. ¶ 72 (defendants – including wholesaler AmerisourceBergen and its subsidiaries – "solicit[ed] and receive[d] special deals, 'arrangements', and other incentives and inducements in exchange for their agreement to create, drive and maintain market share for these companies' [including Janssen] products," among them, Risperdal); *id.* ¶ 127 ("The financial inducements the Defendants receive from pharmaceutical manufacturers in exchange for achieving and maintaining the targeted market share result in these manufacturers charging the Defendants 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."); *id*. ("The United States government is not . . . receiving the actual 'best price' for these drugs required by law and the manufacturer's Rebate Agreement with the Secretary of the DHHS."); *id*. ¶ 128 (alleging that the pharmaceutical manufacturers submit "inaccurate utilization, cost and pricing data . . . to the DHHS, CMS, and other government agencies."); and *id*. ¶¶ 163, 168 ("Janssen gave [AmerisourceBergen

subsidiary] PharMerica price discounts or rebates or other financial incentives on the purchase of Risperdal," and PharMerica obtained "unauthorized financial inducements from Janssen to promote the use of Risperdal and increase its market share.").

Bartz argues, unpersuasively, that none of the cited first-filed cases were pending actions under § 3730(b)(5). Again, this is not the case. The *Kammerer, Lisitza*, *Maguire*, and *Duxbury* complaints were not dismissed in their entirety under Rule 9(b), and all were pending at the time Bartz filed this litigation in November of 2005. *See Lujan*, 243 F.3d at 1188 (a later-dismissed action was "pending" "for purposes of § 3730(b)(5) because [the first] action was pending when [the relator] brought her claim."); *United States ex rel. Chovanec v. Apria Healthcare Grp., Inc.*, 606 F.3d 361, 365 (7th Cir. 2010) (same). The *Pauly* Complaint, filed in April of 2006, alleged (as does Bartz) that J&J reported false ASPs, which did not include undisclosed discounts for inventory service fees. Pauly alleged that J&J and its wholly-owned subsidiary Centocor (a J&J defendant in this case) "[have] a history of allegedly falsely inflating the AWP of its drugs under Medicaid . . . to market[] the spread [which] amounts to an illegal kickback to providers." *Pauly* Compl. ¶ 13. Pauly averred that "with the advent of the new ASP pricing structure for Medicare Part B drugs, effective January 1, 2005, [J&J and Centocor] concocted a new illegal scheme to disguise discounts to wholesalers so that [they] could then falsely report an inflated ASP in their quarterly

reports to CMS." *Id*. at ¶ 14. Pauly further explained in excruciating detail how J&J and Centocor carried out the scheme with regard to J&J's drug Remicade (a drug named by Bartz in his Third Amended Complaint). This identicality of elements with the prior-filed complaints is fatal to Bartz's claims.

FCA Retaliation Claim

The FCA protects employees from being "discharged, demoted, . . . or in any other manner discriminated against in the terms and conditions of employment . . . because of lawful acts done by the employee . . . in furtherance of an [FCA] action . . . , including investigation for, initiation of, testimony for, or assistance in an [FCA] action. . . . " 31 U.S.C. § 3730(h). An FCA retaliation claim requires proof of three elements: "(1) the employee must have been engaging in conduct protected under the Act; (2) the employer must have known that the employee was engaging in such conduct; and (3) the employer must have discriminated against the employee because of her protected conduct." *Cafasso, United States ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1060 (9th Cir. 2011), quoting *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1269 (9th Cir. 1996). An employee terminated because he or she attempts to expose a violation of the False Claims Act is entitled to reinstatement, back pay, and other appropriate compensation. *See* 31 U.S.C. § 3730(h)(2).

Tracking the language of § 3730(h), Bartz asserts that J&J retaliated against him

by "demoting, harassing and terminating his employment." Third Am. Compl. ¶ 291. J&J counters that Bartz is not entitled to whistleblower protection because he did not make J&J specifically aware of his FCA claims.

> Relator does not allege that he complained to J&J of false claims to the government; instead he alleges that he complained about "inaccurate data" and "Sarbanes Oxley violations," referencing his "channel stuffing" claims. [Third Am. Compl.] ¶ 113; see also [Second Am. Compl.] ¶¶ 132-154 (same). These allegations do not support a § 3730(h) retaliation claim.

J&J Mem. at 29.

This argument misstates the requirements of an FCA retaliation claim. The issue is not whether the employee in so many words informed the employer of the exact nature of his investigative activities, but whether the employer knew (or believed) of the employee's "disloyal" acts, and punished him accordingly. In the Third Amended Complaint, Bartz has pled that J&J knew that he "had engaged in 'whistleblowing activities' and that he'd made 'allegations about Medicaid'" as reflected in a memo signed by H.R. Director Stephany Jones.[16] Third Am. Compl. ¶ 124. Bartz also states

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[16] Bartz also alleges that

> [h]e also became aware that sales data used by the J&J Defendants to report financial results as well as AMP, ASP, AWP, non-FAMP, and Best Price, did not match sales data delivered by IM to the Incentive Compensation Department ("IC") where Relator worked. Specifically, data delivered by IM to IC excluded sales of J&J Products that were

that he made numerous complaints to J&J about (what he viewed as) the company's illegal practices. As the First Circuit instructs, a plaintiff

> need not have known that his actions could lead to a qui tam suit under the FCA, or even that a False Claims Act existed, in order to demonstrate that he engaged in protected conduct. *See United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 741 (D.C. Cir. 1998) (holding that "even an investigation conducted without contemplation-or knowledge of the legal possibility of-a False Claims Act suit can end up being 'in furtherance' of such an action"). However, conduct protected by the FCA is limited to activities that "reasonably could lead" to an FCA action; in other words, investigations, inquiries, testimonies or other activities that concern the employer's knowing submission of false or fraudulent claims for payment to the government. *See id.* at 740.

United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 237 (1st Cir. 2004), abrogated on other grounds by *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 42 (1st Cir. 2009). The allegations of Bartz's Third Amended Complaint

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> made to the VA, Omnicare and certain McKesson distribution centers and McKesson customers. Furthermore, Relator learned free goods invoiced to Omnicare with a WAC of $0.00 were excluded from databases used by the J&J Defendants to determine and report AMP, BP, ASP, and non-FAMP. Relator confirmed [the] discrepancies . . . but when Relator pointed out the errors, the J&J Defendants failed and refused to correct the errors, and began attempting to silence him. . . . By March 2005, Relator had a good faith, objective basis to believe, and did in fact believe that the data errors were the result of a cover-up by IM of fraudulent activity by the J&J Defendants, because his efforts to correct what he originally viewed as errors were met with stiff resistance by the J&J Defendants.

Third Am. Compl. ¶¶ 99-101.

are sufficient to meet this pleading standard for a retaliation claim.[17]

McKesson Specialty

Bartz's claim in his initial Complaint was that J&J paid kickbacks in the form of fees to McKesson Specialty for services it had originally provided free of charge, and for channel stuffing with regards to Risperdal Consta sales. The Third Amended Complaint refers to McKesson and McKesson Specialty collectively. Bartz has since dismissed McKesson from this litigation. In his Opposition Bartz states that his claim against McKesson Specialty (which is contained in Count II) is "one in which kickbacks are provided to McKesson Specialty and physicians for purchasing Risperdal Consta." Bartz argues that J&J made the "payments to McKesson . . . in connection with 'marketing the spread' for Risperdal Consta to physicians." Opp'n Mem. at 3, citing the Third Am. Compl. ¶¶ 225-231, 258.

> McKesson entered into several agreements with the J&J Defendants for the marketing and sale of Risperdal Consta during the time Bartz was employed by the J&J Defendants. As Bartz explained, "[i]n the case of Risperdal Consta, the retailer may be either the physician, since this is a physician-administered drug, or a specialty pharmacy from which the physician may direct the patient to purchase the Risperdal Consta and which will deliver it to the physician for administering." *Id.* at ¶ 255, n.5. In other words, McKesson operated as the specialty pharmacy for Risperdal Consta, selling this physician-administered drug to physicians and clinics, which then administered the drug to patients and submitted

[17] Relator notes in his Opposition Memorandum that he "has decided not to pursue his claim for intentional infliction of emotional distress." Opp'n Mem. at 29.

> claims for reimbursement for the drug-"buying and billing" the drug, and receiving the benefit of the spread – the kickback. For those physicians who chose not to "buy and bill" Consta, but did administer it, McKesson sold Consta to specialty pharmacies which themselves sold the drug directly to patients, delivering it to physicians for their administration to the purchasing patients. Those specialty pharmacies received the benefit of the spread – or kickback – and submitted claims for reimbursement to payors, including Medicare, Medicaid, Tricare and other government health care providers.
>
> When McKesson sold Consta to physicians and clinics, it was a direct purchaser, not a purchasing agent. *Id*. at ¶ 258. In this role, McKesson is not entitled to an "administrative fee" under the Safe Harbor Provisions of the AKS. *Id*. The J&J Defendants paid McKesson an "administrative fee" of 3% to 3.5% for this service, which "fee" was originally denominated as a discount, then later the word "discount" changed to "fee." *Id*. at ¶ 257. However denominated, the fee or discount was not subject to an AKS safe harbor, as it was a hidden discount and there was no fair market value determination of the value of the services McKesson was providing to the J&J Defendants, and, in fact, in its role as direct purchaser, McKesson was not legally entitled to receive "administrative fees." In addition, McKesson received a "prompt pay" discount of 2%, whether or not it met the required payment terms. When it did not meet such terms, this "prompt pay discount" was an illegal kickback and not within a safe harbor. *Id*. Thus, these reductions in cost of Risperdal Consta to McKesson were illegal kickbacks.[18]

Opp'n Mem. at 4-5.

In March of 2010, the AKS was amended to state that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the FCA]." Patient Protection and Affordable

[18] It is important to note that these FCA claims set out in Bartz's Opposition are not those pled against McKesson Specialty in the Third Amended Complaint.

Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 § 6402(g) (2010). This amendment expressly applies only to drugs dispensed after July 1, 2010. *Id.* Bartz's employment at J&J terminated on April 20, 2007, and Bartz fails to identify any illegal "kickback" allegedly paid to McKesson Specialty after 2006. *See* Third Am. Compl. ¶¶ 232-258. As a result, the PPACA amendment is inapplicable to Bartz's Relator's claim against McKesson Specialty. Moreover, as set out above, several of the previously-filed Complaints name J&J as defendant and specify Risperdal as part of the kickback scheme.[19] *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.").

ORDER

For the foregoing reasons, the J&J defendants' motion to dismiss Counts I and II is ALLOWED, but the motion is DENIED as to Counts III and IV (N.J. CEPA). Bartz has WAIVED Count V. McKesson Specialty's motion to dismiss is ALLOWED. Because the FCA retaliation claim is the only remaining federal claim, the court declines supplemental jurisdiction over the state false claims act counts –

[19] This court has previously held that for purposes of the first-to-file rule, "specifying a formulaic drug as part of a kickback scheme is synonymous with naming the company that produces it." *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 121-122, n.15 (D. Mass. 2011).

Counts VI through XXX. *See* 28 U.S.C. § 1367(c)(2) ("the [state health care fraud] claim(s) substantially predominate[] over the [retaliation] claim over which the district court has original jurisdiction."). The court will retain jurisdiction over the New Jersey state retaliation claim.

SO ORDERED.

/s/ Richard G. Stearns

UNITED STATES DISTRICT JUDGE