UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 07-10237-RGS

UNITED STATES OF AMERICA ex. rel.
JACQUELINE KAY POTEET and JOHN DOE

v.

LAWRENCE G. LENKE, M.D., et al.

MEMORANDUM AND ORDER ON
DEFENDANTS' MOTIONS TO DISMISS

March 20, 2009

STEARNS, D.J.

On February 7, 2007, plaintiff/relator Jacqueline Kay Poteet commenced this action under the False Claims Act (FCA), 31 U.S.C. §§ 3729 et seq., by filing a sealed Complaint against 120 spine surgeons (the "doctor defendants") and eighteen medical device distributors (the "distributor defendants"). Poteet alleges that defendants defrauded the federal government by accepting kickbacks from medical device manufacturer Medtronic, Inc., and Medtronic Sofamor Danek U.S.A., Inc. (MSD), in exchange for promoting MSD's medical products.[1,2] Poteet is a former Memphis-based Senior Manager of Travel Services for MSD.

The government formally declined to intervene in Poteet's action on June 7, 2007.

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[1]As required under the FCA, Poteet filed the Complaint *in camera* to give the government at least sixty days to investigate and determine whether or not to intervene in the case. See 31 U.S.C. § 3730(b)(2).

[2]MSD is a subsidiary of Medtronic. MSD manufactures and sells spinal implants and other surgical devices.

Poteet filed her Amended Complaint on September 20, 2007. The doctor defendants moved to dismiss the action based on the FCA's first-to-file and public disclosure rules. The distributor defendants also moved to dismiss contending, *inter alia*, that the Amended Complaint fails to meet the particularity requirements of Rule 9(b). In opposing the motions, Poteet asserts that "the pre-eminent issue in this case" is MSD's promotion of "off-label"[3] uses of INFUSE™.[4]

On December 7, 2008, Poteet moved to voluntarily dismiss eighty of the doctor defendants. The court rejected the dismissal notice for failure to comply with 31 U.S.C. § 3730. On December 10, 2008, Poteet filed an Amended Notice of Voluntary Dismissal as to the same defendants (with the exception of Dr. Rolando Puno). The United States filed a Statement of Consent. The court granted the motion on December 16, 2008.

On December 15, 2008, the court heard argument on the remaining defendants'

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[3]Off-label use of a drug or device occurs when a physician prescribes a use that is not specifically approved by the FDA. However, the FDA has never as a general matter prohibited the off-label prescription of drugs. See Steven R. Salbu, Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy, 51 Fla. L. Rev. 181, 189-192 (1999). The FDA also does not prohibit physicians from conducting off-label studies to probe the effectiveness of off-label uses of a drug or medical device so long as the studies are not paid for by the manufacturer. However as Ausness points out, the federal government discourages off-label prescription use by imposing FDA restrictions on the dissemination of information by drug companies about potential off-label therapies and by restricting Medicaid from reimbursing health care providers for off-label uses. See Richard C. Ausness, "There's Danger Here, Cherie!": Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-Label Uses, 73 Brook. L. Rev. 1253, 1253 (2008).

[4]INFUSE™ Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device is approved by the FDA for single-level lumbar spinal fusion operations. INFUSE™ is a protein that promotes bone growth and eliminates the need for harvesting an autogenous bone graft from a patient's hip.

motions to dismiss.[5] After the hearing, the Court of Appeals for the Sixth Circuit issued an anticipated decision, United States ex rel. Poteet v. Medtronic, Inc., 552 F.3d 503 (6th Cir. 2009). The appeal involved the dismissal of the qui tam case that Poteet had filed in 2003 in the Western District of Tennessee (Poteet I). In that action (brought against Medtronic and MSD, twelve physicians, and five healthcare providers), Poteet claimed that MSD had paid doctors kickbacks in the form of meals, entertainment, and holiday trips to encourage them to use MSD products.[6] The Sixth Circuit upheld the dismissal of Poteet's claims under the FCA's public disclosure rule, 31 U.S.C. § 3730(e)(4)(A). The Sixth Circuit found the complaint filed in a prior California case (the Wiese action) "sufficient to qualify as a public disclosure of fraud . . . [and] sufficient to put . . . the government on notice of

[5]On November 3, 2008, and again on December 10, 2008 (five days prior to the hearing on the motions to dismiss), Poteet sought leave to file a Second Amended Complaint. In this third iteration of her Complaint, Poteet proposes to add Medtronic and MSD as defendants, and to join Bobbie Vaden, a former employee of MSD's Memphis accounting department, as a relator. The first coterie of defendants moving for dismissal filed on July 22, 2008. Poteet filed her opposition on August 14, 2008. Several other defendant groups then filed dispositive motions. Poteet filed a final opposition brief on October 31, 2008. The motion to file a Second Amended Complaint will be DENIED as unduly delayed and prejudicial to defendants. See Steir v. Girl Scouts of the USA, 383 F.3d 7, 12 (1st Cir. 2004). The reinsertion of Medtronic and MSD as defendants in the case would, in any event, be futile in light of the government's settlement agreement with Medtronic.

[6]"Specifically, Poteet claimed that MSD had paid the defendant physicians large amounts of money and provided them with lavish travel and recreational opportunities – "'upgraded lodging for physicians, dinners, entertainment and activities such as golf, snorkeling, sailing, fishing, shopping trips, horse-back riding and hiking,' etc. – in connection with sham consulting contracts and royalty agreements. In return the defendant physicians and hospitals purportedly purchased MSD products for use in their patients' surgeries." Poteet, 552 F.3d at 508.

potential fraud by MSD and its physician customers."[7] In asking whether the Poteet I Complaint was "supported by" the Wiese filings (a requirement of the public disclosure rule), the Sixth Circuit found a "substantial identity" between the two filings, noting that an "'action based even partly upon public disclosures will be jurisdictionally barred." Poteet, 552 F.3d at 514.

This court invited post-hearing briefing to assess the impact of the Sixth Circuit's decision on Poteet's current claims. In responding, Poteet indicated that her "aim" is to "confine" herself to Count II of the Amended Complaint, and the wrongful promotion by the doctor defendants of off-label uses of INFUSE™.[8] Defendants argue that Count II is infected with the same fatal public disclosure flaw that was identified by the Sixth Circuit in Poteet I – in that there is no meaningful difference between paying kickbacks to doctors to use a product off-label or paying them to use it on-label.[9] See 31 U.S.C. § 3730(e)(4).

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[7]Wiese, a former Regional Sales Manager for MSD, filed a wrongful termination suit against Medtronic and MSD in the California Superior Court. Wiese alleged that he was fired after he refused to engage in illegal sales and marketing tactics designed to induce MSD's physician customers to use and promote MSD products.

[8]Poteet also stated in a letter to the court on January 14, 2009, that "[t]he purpose of this letter is to emphasize the point that we have dismissed all allegations that would be subject to the coverage of the reasoning of the Sixth Circuit leaving intact only our 'off-label promotion' allegations, which, of course, had never been the subject of any previous 'public disclosure' or any previously filed False Claims Act action." See Docket # 187. However to date, she has not done so.

[9]Defendants also argue for dismissal under the "first-to-file" rule, 31 U.S.C. § 3730(b)(5). Prior to Poteet's acknowledgment that the Sixth Circuit opinion terminates Counts I and III in this case, defendants also asserted defenses of collateral estoppel; misjoinder; the alleged failure to properly plead the elements of a violation of the Stark Statute, 42 U.S.C. § 1395nn; and an alleged failure to comply with Fed. R. Civ. P. 9(b). Defendants also argued that actions brought under the FCA cannot be predicated upon violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), or the Federal Food,

DISCUSSION

"The 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. 31 U.S.C. § 3729(a)(1)(b)." United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004). Submission of a false claim for payment is the proof necessary for liability under the statute; no proof of an intent to defraud is required. See 31 U.S.C. § 3729(b); Karvelas, 360 F.3d at 225.

A qui tam relator's standing to bring suit is a threshold issue of subject matter jurisdiction. Rockwell Int'l Corp. v. United States, 549 U.S. 457, 468 (2007). The FCA encourages citizens with first-hand knowledge of fraud to file private enforcement suits, but limits "opportunistic plaintiffs from bringing parasitic lawsuits" by barring all but original claims based upon non-public fraud.[10] Walburn v. Lockheed Martin Corp., 431 F.3d 966, 970 (6th Cir. 2005). A non-qualified plaintiff deprives the court subject matter jurisdiction to hear the case. "[S]tatutes such as the FCA which confer jurisdiction on federal courts

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Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 355, 357.

[10]"A whistleblower sounds the alarm; he does not echo it. The Act rewards those brave enough to speak out in the face of a 'conspiracy of silence,' and not their mimics." United States v. Northrop Corp., 59 F.3d 953, 966 (9th Cir. 1995), quoting S. Rep. No. 345, 99th Cong., 2d Sess. 2-3 (1986), reprinted in 1986 U.S.C.C.A.N. at 5271.

'are to be strictly construed, and doubts resolved against federal jurisdiction.'" United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 551 F. Supp. 2d 100, 103 (D. Mass. 2008). The burden of proving subject matter jurisdiction on a motion to dismiss rests with the plaintiff as the party asserting jurisdiction. In re New Motor Vehicles Canadian Exp. Antitrust Litig., 522 F.3d 6, 14 (1st Cir. 2008).

Public Disclosure Provisions of the FCA

Congress has specified that a relator is barred from filing a qui tam claim 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). Courts analyze the public disclosure bar using 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).

Allegations of fraud are publicly disclosed when they are "placed in the public domain." Id. at 730-731; United States ex rel. Doe v. John Doe Corp., 960 F.2d 318, 322 (2d Cir. 1992). While the allegations of fraud need not be accessible to all members of the public, there must be exposure outside of the government itself. Rost, 507 F.3d at 728.

Allegations in a civil or criminal suit that are on file in a court clerk's office, or that are publicized in the news media are "publicly disclosed" for purposes of section 3730(e)(4)(A). See United States v. Johnson Controls, Inc., 457 F.3d 1009, 1013 (9th Cir. 2006) (civil complaint filed in state court). See also United States ex rel. Wilson v. Graham County Soil & Water Conserv. Dist., 528 F.3d 292, 301 (4th Cir. 2008) ("Public disclosures in a congressional, administrative, or GAO report, hearing, audit, or investigation . . . strip[ ] federal courts of jurisdiction over qui tam actions."); Battle v. Bd. of Regents for Georgia, 468 F.3d 755, 762 (11th Cir. 2006) (action based upon information publicly disclosed in prior state government audits); Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1047 (8th Cir. 2002) (allegations "based upon" civil filings and newspaper accounts); United States ex rel. Mistick PBT v. Hous. Auth. of City of Pittsburgh, 186 F.3d 376, 385 (3rd Cir. 1999) ("[A] FOIA request has been made public through the administrative process and cannot form the basis of a qui tam action.").[11]

The allegations and transactions that form the basis of Poteet's Amended Complaint (the unlawful promotion of MSD products through "kickbacks") were widely aired in the civil courts and in the news media prior to her current qui tam filing. In Wiese, the assertion was that MSD improperly paid physicians to use MSD products. Poteet I alleged that MSD paid physicians to purchase and "unlawfully promote" its products. A New York Times article published on January 24, 2006, was devoted to Poteet I and its allegations that

[11]The First Circuit has more tentatively noted that "a filing to a government body such as a court (not under seal) where all records are public could be public disclosure." Rost, 507 F.3d at 728 n.5.

Medtronic and MSD "induce[d] the physician through any financial means necessary to use its devices."[12] Reed Abelson, Whistle-Blower Suit Says Device Maker Generously Rewards Doctors, N.Y. TIMES, January 24, 2006, at A2. A medical malpractice case filed in 2005 in the Minnesota state court described Dr. David Polly's off-label use of INFUSE™ and his consulting contract with Medtronic.[13] See Hemmingson v. Polly, No. 05-014665 (Minn. 4th Dist. 2005). In July of 2006, the Department of Justice posted on its website a settlement agreement with Medtronic and MSD that obligated the firms to pay $40 million to settle claims that between 1998 and 2003 they had paid illegal kickbacks to physicians to induce them to use MSD spinal products. See http://www.usdoj.gov/opa/pr/2006/July/06_civ_445 (last visited March 12, 2009).

The Sixth Circuit summarized the relevant law succinctly: "[A] public disclosure reveals fraud if 'the information is sufficient to put the government on notice of the likelihood of related fraudulent activity.'" Poteet, 552 F.3d at 512. Applying that test, the Sixth Circuit found that the public disclosures in Wiese (filed in October of 2001), effectively barred the claims of fraud alleged in Poteet I (filed in December of 2003).[14] The

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[12]The article quotes a Poteet I pleading alleging that the "'bribery program' as it was described in the suit, 'has not only failed to cease, but continues unabated with increased payments made to many physicians.'" Id. at 3. The article then describes payments made to Dr. Hallett Mathews (who was not named in the Poteet I Complaint), which increased from $75,000 in 2004, to $700,000 in 2005. Dr. Mathews is named as a defendant in this case.

[13]Poteet named Dr. Polly a defendant in this case.

[14]The Sixth Circuit, however, rejected the government's argument that the Medtronic 10-Q reports filed with the Securities and Exchange Commission (SEC), as well as numerous media reports about the government's investigation of the Doe complaint, constituted "public disclosures." The Court found that SEC filings and news reports

analysis is instructive.

> First, as a filing in a California civil action, the Wiese complaint clearly was a "public" disclosure. See, e.g., [United States ex rel.] McKenzie [v. BellSouth Telecomm., Inc.], 123 F.3d at 939; Bledsoe I, 342 F.3d at 645 ("There is little doubt that [a] complaint, filed in Tennessee state court, qualifies as a public disclosure."). Moreover, the allegations contained in the Wiese complaint were sufficient to put to the government on notice of potential fraud by MSD and its physician customers. In his complaint, Wiese alleged that he had been terminated because he had "refused his supervisors [sic] directives to pay illegal kickbacks and bribes to [MSD's] customers in exchange for business." J.A. at 386. Wiese explained that these illegal payments took the form of "hunting and/or fishing trips" and other "extravagant trips for doctors and their families" which would be disguised as "Think Tanks." J.A. at 380-81. Wiese claimed that, while these "Think Tanks" were "touted as a way to brainstorm among doctors and other professionals in the medical device industry regarding current trends and technology," in reality, they "were nothing more than additional perks offered to doctors in exchange for their business." J.A. at 381. Wiese further described how MSD made "illegal payments to doctors in the guise of 'consulting contracts,'" under which doctors would perform "little work." J.A. at 382. In short, Wiese provided a detailed description of how MSD and its physician customers were covertly violating the Anti-Kickback statute. While Wiese did not directly allege that the doctors accepting kickbacks from MSD submitted fraudulent reimbursement claims to the federal government, his description of the manner in which these doctors and MSD were attempting to disguise these illegal kickbacks as legitimate business activities strongly suggested that these physicians were not disclosing such information - which would have disqualified them from receiving Medicare or Medicaid reimbursement-when submitting insurance claims to the government. The Wiese complaint "presented enough facts to create an inference of wrongdoing," Jones, 160 F.3d at 332, and thereby was sufficient to "put the government on notice of the 'possibility of fraud.'" Gilligan, 403 F.3d at 390.

Poteet, 552 F.3d at 513. The allegations in Poteet I and this case are virtually identical: both complaints allege fraud in the form of kickbacks to doctors disguised as consulting

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"consist[ed] of little more than headlines announcing that someone was alleging illegal kickbacks to doctors by MSD." Poteet, at 513 n.6. "Such rumors of reported fraud are not the kind of 'allegations or transactions' which the FCA requires in order for a public disclosure to bar jurisdiction." Id.

fees and "perquisites."[15] That there was prior disclosure is evident.

Courts have not settled on a single standard for judging the second inquiry: whether and when a fledgling qui tam action is "based upon" a public disclosure.[16] The minority view, shared by the Fourth Circuit and Seventh Circuits, is that "based upon" means "derived from," in other words, it requires that the qui tam allegation originate from the public disclosure. See United States ex rel. Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1348 (4th Cir. 1994); United States v. Bank of Farmington, 166 F.3d 853, 863 (7th Cir. 1999). The "majority rule" states that an action is "based upon" a public disclosure "when the supporting allegations are similar to or the same as those that have been publicly disclosed . . . regardless of where the relator obtained his information." Wilson, 528 F.3d at 308; see also Allina Health Sys., 276 F.3d at 1044-1047. Within this district, three judges have adopted the "minority rule." See United States ex rel. Rost v. Pfizer, Inc., 446 F. Supp. 2d 6, 19 (D. Mass. 2006) (Tauro, J.), vacated on other grounds, Rost, 507 F.3d at 734; United States ex rel. LeBlanc v. Raytheon Co., 874 F. Supp. 35, 41 (D. Mass. 1995) (Lindsay, J.); United States ex rel. LaValley v. First Nat. Bank of Boston, 707 F. Supp. 1351 (D. Mass. 1988) (Wolf, J.). Two judges have followed the "majority rule." See Duxbury, 551 F. Supp. 2d at 107 (Zobel, J.); United States ex rel. O'Keefe v. Sverdup Corp., 131 F. Supp. 2d 87, 92 (D. Mass. 2001) (Saris, J.). See also United States ex rel. Ondis v. City of Woonsocket, R.I., 582 F. Supp. 2d 212, 218-219 (D.R.I. 2008) (Torres,

[15]Attached to the Affidavit of Lousene Hoppe is a useful chart comparing "key allegations" in Doe, Poteet I, and this case. (Docket #190, Ex. B).

[16]The First Circuit has not yet addressed the issue.

J.) ("This Court finds the majority view to be more consistent with both the text of the statute, read as a whole, and its underlying purpose.").

I agree with the majority view (which is the only one Poteet discusses in her brief), although the difference in views would seem of little significance in the case at hand. The Complaint in Poteet I (as finally perfected in the Third Amended Complaint and Supplement) maintained that MSD/Medtronics kickback scheme was "continu[ing] unabated." The allegations in Poteet I, in other words, have sufficient identicality to those in the present Amended Complaint to satisfy either the minority or the majority view. While Poteet argues that neither Wiese nor Poteet I "mention the INFUSE™ off-label promotion scheme," "[n]ot a single circuit has held that a *complete* identity of allegations, even as to time, place, and manner is required to implicate the public disclosure bar; rather all have held, at a minimum, that dismissal is warranted where the plaintiff seeks to pursue a claim, the essence of which is 'derived from' a prior public disclosure."[17] United States ex rel. Boothe v. Sun Healthcare Group, Inc., 496 F.3d 1169, 1174 (10th Cir. 2007) (emphasis in original). See also Bledsoe I, 342 F.3d at 646 ("[A] person who bases any part of an FCA claim on publicly disclosed information is effectively precluded from asserting that claim in a qui tam suit.").

Poteet's suit is therefore jurisdictionally barred unless she is the "original source" of the information regarding MSD's alleged kickback scheme. See Karvelas, 360 F.3d at 225 ("An FCA qui tam action may not be based on publicly disclosed information unless

[17]As defendants accurately state: "INFUSE" is just another MSD product – included in the group of products that Poteet previously publicly alleged MSD paid its physician customers to use and unlawfully promote."

the relator is the original source of that information."). See also United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys., 384 F.3d 168, 174 (5th Cir. 2004) (a qui tam suit does not benefit the government if the information about the fraud is already publicly known unless the plaintiff is an "original source"). An "original source" is "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. §3730(e)(4)(B). See also Rockwell, 549 U.S. at 470-471; Johnson Controls, Inc., 457 F.3d at 1013.

Poteet does not argue that she is an original source.[18] The only other relator named in the Amended Complaint is "John Doe," who is described as "a number of unidentified people with direct knowledge of the information contained in the allegations herein, and who have provided same to Ms. Poteet."[19] While within this undifferentiated mass of "John

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[18]In the Sixth Circuit case, Poteet also did not claim to be an original source.

> Poteet wisely does not contend that she qualifies as an original source. While Poteet, due to her former position as MSD's Senior Manager for Travel Services, arguably has direct and independent knowledge of most of the facts alleged in her complaint, she undisputedly failed to provide this information to the government before filing her complaint and before the filing of the Wiese complaint. Thus, she cannot qualify as an original source under the FCA.

Poteet, 552 F.3d at 515.

[19]For reasons that elude the court, Bobbie Vaden is listed by defendants and plaintiff (although not the government) in their chosen case caption, although she is not a party to the Amended Complaint. The defendants also inexplicably devote considerable space to discussing Vaden's role in the qui tam action, which in the relevant pleadings is nonexistent.

Does" there may well be someone who might lay claim to being an original source, anonymous broadside pleading is not acceptable for qui tam purposes. If it were, no sentient plaintiff could ever fail to plead an effective escape from the original source bar.

The FCA's "First-to-File" Rule

While Poteet's suit is clearly barred by the public disclosure rule, defendants in the alternative argue that it is also barred by the first-to-file rule. Under the FCA, "the relator must be a true 'whistleblower'; therefore, [she] is precluded from collecting a bounty . . . if someone else has filed the claim first." United States ex rel. Taxpayers Against Fraud v. Gen. Elec. Co., 41 F.3d 1032, 1035 (6th Cir. 1994). "The first-to-file rule furthers the policy of the FCA in that '[t]he first-filed claim provides the government notice of the essential facts of an alleged fraud, while the first-to-file bar stops repetitive claims.'" In re Pharm. Indus. Average Wholesale Price Litig., 2008 WL 2778808 *2 (D. Mass. July 15, 2008), quoting United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1187 (9th Cir. 2001).[20]

[20]The first-to-file bar is not confined to "identical" actions - [s]ection 3730(b)(5)'s plain language refers to "related" not "identical" actions. See Duxbury, 551 F. Supp. 2d at 105. See also United States ex rel. Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d 214, 217-218 (D.C. Cir. 2003). "[S]o long as a subsequent complaint raises the same or a related claim based in significant measure on the core fact or general conduct relied upon in the first qui tam action, § 3730(b)(5)'s first-to-file bar applies." Grynberg v. Koch Gateway Pipeline Co., 390 F.3d 1276, 1279 (10th Cir. 2004). See also Lujan, 243 F.3d at 1188-1189 n.13 ("[S]ection 3730(b)(5) bars a later claim unless: (1) it alleges a different type of wrongdoing, based on different material facts than those alleged in the earlier suit; and (2) it gives rise to a separate recovery of actual damages by the government."); Duxbury, 551 F. Supp. 2d at 111 (same). "As the Third Circuit has explained, a relator who merely adds details to a previously exposed fraud does not help 'reduce fraud or return funds to the federal fisc,' because 'once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds.'" United States ex rel. Branch Consultants v. Allstate Ins. Co., 2009 WL 388947, *6 (5th Cir. Feb.

This is the third complaint (known to this court) in which unlawful payments by MSD or Medtronic to doctors are alleged to have resulted in false claims to Medicare and the second qui tam complaint of the same genre filed by Poteet. It is also the fifth reported case exploring ramifications of alleged illegal kickbacks to doctors by Medtronic. While at first glance, the first-to-file rule would seem preclusive of Poteet's Amended Complaint, as interpreted by some courts the rule applies more narrowly.

> One important caveat to this first-to-file rule, however, is that, in order to preclude later-filed *qui tam* actions, the allegedly first-filed *qui tam* complaint must not itself be jurisdictionally or otherwise barred. See Walburn, 431 F.3d at 972 (finding that an earlier filed complaint's failure to comply with Rule 9(b) rendered it legally infirm from its inception, and thus unable to preempt a later-filed action); Campbell v. Redding Med Ctr., 421 F.3d 817, 825 (9th Cir. 2005) (holding that "the first-to-file rule of § 3730(b)(5) bars only subsequent complaints filed after a complaint that fulfills the jurisdictional prerequisites of § 3730(e)(4)"). Indeed, if the first complaint is either jurisdictionally precluded, see 31 U.S.C. § 3730(e), or legally incapable of serving as a complaint, see Fed. R. Civ. P. 9(b)); United States ex rel. Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 504 (6th Cir. 2007) (hereinafter "Bledsoe II"), then it does not properly qualify as a "pending action" brought under FCA, 31 U.S.C. § 3730(b)(5).

Poteet, 552 F.3d at 516 (emphasis added).

All of the previously filed suits cited by defendants either were not qui tam actions (the first requirement cited by the Sixth Circuit), or were dismissed on jurisdictional grounds instead of on the merits (the second listed requirement). In quick summary: the 2001 Wiese wrongful termination suit made no claim under the FCA; the 2002 "John Doe" qui tam complaint was found barred by the public disclosure rule; Poteet's first 2003 qui

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18, 2009), quoting United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir.1998).

tam complaint against Medtronic, MSD, and some twenty-five doctors and health care providers, was dismissed under the public disclosure rule; and finally, the 2005 Hemmingson suit against Dr. Polly was a non-FCA medical malpractice action. Under the Sixth Circuit's interpretation of the first-to-file rule, none of these lawsuits would serve as a bar to Poteet's current action. I share the skepticism expressed by Judge McKeague in his concurring opinion in Poteet, whether the second of the first-to-file requirements found by the Sixth Circuit (dismissal on the merits) is an accurate (or wise) interpretation of the qui tam statute. Still, where as here, the public disclosure rule clearly bars the action, it is unnecessary for this court to blaze a new trail.[21]

Rule 9(b)

Finally, the distributor defendants argue that Poteet's Complaint fails under Fed. R. Civ. P. 9(b). FCA complaints must be sufficiently detailed to put defendants on notice of their essential allegations. In Karvelas, 360 F.3d at 227-228, the First Circuit made clear that claims under the FCA must also comply with Rule 9(b).

> [W]e reject Karvelas's argument that the False Claims Act is not a "fraud" statute because, under the statute, "liability depends on the defendant's knowledge, not on his fraud," and therefore only the second clause of Rule 9(b), which allows knowledge of fraud to be averred generally, applies. Under the FCA, liability depends upon the defendant's act (presentation of a false or fraudulent claim to the United States government) and mental state (knowledge, or deliberate ignorance or reckless disregard of the truth or falsity of the information presented). That Rule 9(b) allows "[m]alice, intent, knowledge, and other condition of mind of a person [to be] averred generally" does not mean that particularity requirements do not apply to FCA claims. Rather, it simply means that a qui tam relator need not plead with particularity

[21]The district court in Poteet I did dismiss the Complaint as barred by the first-to-file rule, although this ground of the district court's decision did not persuade the two-judge majority of the Sixth Circuit panel.

> allegations concerning defendants' knowledge, reckless disregard, or deliberate ignorance of the submission of false claims. The characterization of a state of mind, after all, does not lend itself to detailed pleading. On the other hand, the details of the actual presentation of false or fraudulent claims to the government can and must be pled with particularity in order to meet the requirements of Rule 9(b).
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> Finally, every circuit court that has addressed this issue has concluded that the heightened pleading requirements of Rule 9(b) apply to claims brought under the FCA.

Id.

The distributor defendants argue that to comply with Rule 9(b), Poteet must identify at least some of the individual claims submitted for payment.[22] The Amended Complaint contains eight paragaraphs of allegations against the distributor defendants. See Amended Complaint ¶¶ 309-316. These paragraphs are devoid of specific allegations linking the distributor defendants to the general allegations of kickbacks and the filing of false claims with the government. Excepting three Medtronic internal emails (attached as Exhibit 5 to the Amended Complaint) from an Administrative Assistant in the Medtronic travel department (two indicating that gifts were purchased by someone at Venture Medical, and one suggesting that gifts were purchased by First Choice Medical), plaintiffs fail to specify which distributors were involved in the scheme, and how they were involved. Poteet does not identify whether the recipients of the gifts ever purchased Medtronic products or filed a claim for Medicare benefits. Nor does the Amended Complaint allege that these gifts

[22]Defendants also move to dismiss the Amended Complaint for failure to identify individual false claims for payment that were submitted to the government. When an FCA complaint alleges that a defendant caused false claims to be presented by a third party (i.e., through an alleged kickback or off-label marketing scheme), it must include facts that are sufficient to support an inference that false claims for payment were likely submitted to the government. Rost, 507 F.3d at 732.

caused a false filing with Medicare.

Paragraph 311 of the Amended Complaint alleges that "[e]ach year, thousands of MSD physician customers (neurosurgeons and orthopedic surgeons), including the physician defendants herein, attend hundreds of lavish meetings all over the world," and that "[i]n each such case, the entire cost of the physician customer's travel, lodging, food, beverage, and entertainment is defrayed by MSD's distributors, and not by MSD." Poteet does not allege any detail regarding these alleged "lavish meetings," or which distributor might have paid the costs. The Amended Complaint in other words contains "no factual or statistical evidence to strengthen the inference of fraud beyond possibility." See Rost, 507 F.3d at 733; Corsello v. Lincare, Inc., 428 F.3d 1008, 1011 (11th Cir. 2005) (dismissing a complaint on Rule 9(b) grounds where a former sales employee alleged that improper practices resulted in the submission of false claims "[b]ecause the complaint failed to provide any factual support that false claims were actually submitted to the government."). Accordingly, the claims against the distributor defendants can be dismissed for failure to adequately plead under Rule 9(b).[23]

ORDER

For the foregoing reasons, the motions to dismiss are ALLOWED. The court lacks

[23]The distributor defendants also argue that the public disclosure rule precludes suit against them. United States ex rel. Gear v. Emergency Med. Assocs. of Ill., Inc., 436 F.3d 726, 729 (7th Cir. 2006) ("We are unpersuaded by an argument that for there to be public disclosure, the specific defendants named in the lawsuit must have been identified in the public records."). Because Poteet has agreed to dismiss all claims against the distributor defendants there is no need to further discuss issues involving these defendants. See Docket 187 and 191, at 2 ("[R]elators will in due course voluntarily dismiss without prejudice to themselves and/or the United States' interest the claims now pending against these distributors.").

jurisdiction to hear this matter under the public disclosure rule. Poteet's Motion to file a Second Amended Complaint is DENIED. The Clerk will enter judgment for all defendants and close the case.

SO ORDERED.

/s/ Richard G. Stearns

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UNITED STATES DISTRICT JUDGE