UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, EX REL. JACQUELINE KAY POTEET and BOBBIE VADEN, Plaintiffs, v. LAWRENCE G. LENKE, M.D., ET AL., Defendants.	Civil Action No. 1:07-cv-10237-RGS

MEMORANDUM IN SUPPORT OF THE PHYSICIAN DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

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INTRODUCTION

This motion is brought by a group of some 82 physicians and clinics (the "Physician Defendants"),[1] which includes many of the most renowned and respected orthopedic surgeons and neurosurgeons in the nation. Two former employees of Medtronic Sofamor Danek ("MSD") have brought unsupported claims under the federal False Claims Act, 31 U.S.C. §§ 3729-3731 ("FCA"), alleging, in a 66-page complaint, that this group - among the 143 named defendants - is liable under the FCA, medicare anti-kickback statute ("AKS"), Food and Drug Administration proscriptions against off-label promotion, and the Stark Law.

The essential facts of this suit have formed the basis for at least three separate previously-filed actions. Indeed, a similar qui tam suit by Relator Jacqueline Poteet against MSD ("*Poteet I*") was dismissed with prejudice, on motion of the government, by the U.S. District Court for the Western District of Tennessee only two weeks before Relators filed this action. Frustrated by her failure to extract any money from her former employer in *Poteet I*, Poteet invites another federal district court to impose liability on 143 physicians and distributors for the alleged submission of false claims for reimbursement under the Medicare program.

Relators' action is jurisdictionally barred by the first-to-file pleading rule of the FCA, runs afoul of the bar against claims based on prior public disclosures, and is collaterally estopped by the court's rulings in *Poteet I*. Dismissal is thus required under Rule 12(b)(1) of the Federal Rules of Civil Procedure ("FRCP"). Relators' Amended Complaint (the "Complaint") also lacks even a modicum of the specificity required under FRCP 9(b). Even in the absence of these defects, dismissal would be required under FRCP 12(b)(6), because the Complaint fails to state a

[1] The Physician Defendants are represented jointly by the undersigned counsel. A list of these defendants, on whose behalf this Motion is brought, is attached as Ex. A. Relators have agreed at our request to voluntarily dismiss their claims against non-physicians Bradley T. Estes, Ph.D. and Christian Puttlitz, Ph.D., as well as Ronald Lehman, M.D., a physician in the armed forces, who is scheduled to be deployed overseas shortly.

claim under the FCA on which relief can be granted. Finally, the Complaint should be dismissed on the ground that Relators have abusively misjoined the 143 unrelated defendants under FRCP 20(a), without even alleging that they were involved in any common transactions. The Physician Defendants ask the Court to dismiss the case with prejudice on these grounds.

FACTS

I. HISTORY OF PRIOR SUITS AND PUBLIC DISCLOSURES

The history of this action dates back to October 3, 2001, when a former employee of MSD, Scott Wiese, filed a wrongful termination suit (the "*Wiese*" suit) against MSD and its parent company, Medtronic, Inc., alleging that he was fired for refusing directives to pay illegal kickbacks to physicians in exchange for their business. *See United States ex rel. Poteet v. Medtronic, Inc.*, No. 07-5262 (6th Cir. 2008) (*Poteet I Appeal*), Government's Brief at 5-6 (Ex. B). Later, in September 2002, an unidentified relator filed a separate qui tam complaint alleging that MSD, through its sales and marketing efforts, had induced a number of defendants/physicians to use MSD products in violation of the FCA and the AKS. *United States ex rel. Doe v. Medtronic, Inc. et al.*, No. 2:02-cv-0279-BBD (W.D. Tenn. Sept. 11, 2002) (under seal) (the "*Doe*" action).[2] According to the *Doe* complaint (Ex. C), the kickbacks allegedly took the form of travel arrangements, "sham" consulting agreements, royalties and other perquisites. The *Doe* complaint identifies Poteet as the head of the travel department that made the allegedly improper arrangements. (Ex. C ¶ 46.)

The *Doe* action received significant public exposure. On September 5, 2003, Medtronic announced the government's investigation in its 10-Q SEC filing (Ex. D at 27), noting that a qui tam relator had alleged "certain payments and other services provided to physicians by MSD

[2] The names of the relator and the individual defendant physicians are unknown, as the *Doe* complaint remains under seal, and only a redacted version is publicly available. (*See* Ex. C.)

constituted improper inducements under the federal Anti-Kickback Statute." Several national media outlets reported on the filing, including the allegation that a Medtronic subsidiary had "offered kickbacks to doctors." *See, e.g., Inquiry into Possible Kickbacks at Medtronic Unit*, N.Y. Times, Sept. 8, 2003 (Ex. E); *An Operation to Ease Back Pain Bolsters the Bottom Line, Too*, N.Y. Times, Dec. 31, 2003 (discussing both the *Wiese* suit and the *Doe* complaints) (Ex. F).

Notwithstanding the public nature of the allegations, Poteet filed her first qui tam suit in the Western District of Tennessee against certain physicians associated with MSD (*Poteet I*), on December 29, 2003. *United States ex rel. Poteet v. Medtronic, Inc.*, Case No. 03-2979 D/A. Between March 2004 and July 2004, Poteet amended the complaint three times to name Medtronic, Inc. and MSD as additional defendants. In her suit she accused Medtronic, MSD, sixteen physicians, and nine clinics of violating the FCA and the AKS by accepting, between 1998 and 2003, illegal kickbacks in the form of travel junkets, sham consulting and royalty agreements, and other perquisites. (*Poteet I*, Third Amended Complaint, Ex. G at ¶¶ 35-46.) Poteet further specifically alleged that MSD paid kickbacks, not only to induce physicians to purchase its products, but also "in return for their agreements to assist MSD in the unlawful promotion of its products among potential physician users." *Id.* at 38. In October 2005, she filed a "Supplemental Complaint" asserting that the violations alleged in her Third Amended Complaint were continuing. *Poteet I*, Supplement to Third Amended Complaint (Ex. H). The *Poteet I* litigation was itself the subject of significant national publicity. *See Company News; Medtronic Says a 2nd Suit is Filed Over Alleged Kickbacks*, N.Y. Times, Sept. 3, 2004 (Ex. I); *Whistleblower Suit Says Device Maker Generously Rewards Doctors*, N.Y. Times, Jan. 24, 2006 (Ex. J).

In July 2006, following a widely-publicized settlement with Medtronic, the government filed a motion to dismiss *Poteet I* on the grounds that *Poteet I* was duplicative of *Doe*, thus violated the first-to-file rule, and was based on allegations previously publicly disclosed. *See* DOJ Press Release (Ex. K); *Medtronic Will Settle Accusations on Kickbacks*, N.Y. Times, July 19, 2006 (Ex. L). The district court entered an order granting the government's Motion to Dismiss on January 23, 2007 (Ex. M, redacted as filed), and a further order denying Poteet's Motion for Reconsideration on February 1, 2007 (Ex. N).

Poteet appealed the dismissal of *Poteet* I to the Sixth Circuit. *See United States ex rel. Poteet v. Medtronic, Inc.*, No. 07-5262 (6th Cir. Jan. 31, 2008.) Oral argument took place on June 5, 2008, and the Sixth Circuit has yet to issue a ruling on her case. *See Poteet I Appeal*, Oral Argument Certified Transcript (Ex. O). Nevertheless, on February 7, 2007 - just six days after the court denied Poteet's reconsideration motion - Relators filed the instant qui tam suit under seal in federal District Court for the District of Massachusetts ("*Poteet II*"). Although Medtronic and MSD are not named in the new Complaint, Relators have forced thirteen of the sixteen physicians dismissed in *Poteet I* to again defend against the same allegations, and forced 113 additional physicians and physician group, and 18 distributors, to defend against the same claims previously rejected by the federal district court in Tennessee. Four months after the suit was filed the United States declined to intervene, and the Complaint subsequently was unsealed. *See* Notice of Election to Decline Intervention (June 7, 2007) [Docket No. 15].

II. RELATORS' COMPLAINT

The Complaint alleges that Relator Jacqueline Poteet began working at MSD in 1995, and that she was the Senior Manager for Travel Services from 1998 to 2003. (Compl. ¶ 4.) Relator Bobbie Vaden worked in MSD's accounting department from 1991 to 2007. (Compl.

¶ 6.) Relators claim to know about "substantial financial relationships existing between [MSD] and many of its physician-customers." (Compl. ¶ 4.) Like the complaint in *Poteet I*, the Complaint here alleges that physicians and MSD entered into "sham" consulting arrangements to disguise the receipt of monetary payments and other perquisites in exchange for promoting certain MSD products. (Compl. ¶ 157.)

The Complaint asserts three counts, but the purported factual and legal bases for these counts are anything but clear. Count I alleges that consulting fees and royalties MSD paid the more than 100 physicians named as defendants for their time and expertise were "kickbacks" or "bribes" meant to induce them to purchase or recommend the purchase of MSD products. (Compl. ¶ 157.) Count II essentially repeats that allegation, but focuses on a particular product that the physicians allegedly purchased and improperly promoted: the INFUSE™ Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device (the "INFUSE™ device"). (Compl. ¶ 327.) INFUSE™ is a protein that promotes bone growth for spinal fusion and eliminates the need for an autogenous bone graft to be harvested from the patient's hip. Relators allege that MSD paid thousands of dollars in kickbacks to physicians to get them to unlawfully use and promote MSD products such as INFUSE™. Count III alleges that the defendants violated the Stark Law, 42 U.S.C. § 1395nn, by making improper self-referrals that resulted in the submission of false claims. (Comp. ¶ 331.)

Notwithstanding 66 pages and 334 largely repetitive, rote paragraphs of allegations, the Complaint fails to allege a single improper claim for reimbursement from a federally-funded healthcare program and indeed, is so convoluted as to leave Defendants confused as to even who supposedly submitted the false claims for reimbursement, to whom they were submitted, and how they are false.

Because the Complaint violates the jurisdictional filing requirements of the FCA, fails to meet the specificity requirements of Rule 9(b), does not properly state a claim under the FCA, and improperly joins 143 unrelated defendants, all three counts should be dismissed with prejudice. Poteet's repeated and abusive attempts to obtain an unjustified windfall must be put to rest once and for all.

ARGUMENT

I. SUBJECT MATTER JURISDICTION IS LACKING

The False Claims Act is a unique statute, which confers standing on private citizens to bring claims on behalf of the United States and share in the recovery, notwithstanding that they have no stake of their own in the claims asserted. In establishing this extraordinary right of action Congress sought to discourage parasitic lawsuits brought by citizens with no new information to contribute, by imposing strict jurisdictional prerequisites that must be met before any FCA action can proceed. *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 224-225 (1st Cir. 2004). Thus, the "threshold question in any FCA case is whether the statute bars jurisdiction." *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007).

A relator who sues under the FCA bears the burden of proving that the Court has jurisdiction to hear her claims. *Murphy v. United States*, 45 F.3d 520, 522 (1st Cir. 1995). Moreover, the statute does not permit "claim smuggling," but rather, the relator must prove jurisdiction as to each separate claim asserted. *Rockwell Int'l Corp. v. United States*, --- U.S. ---, 127 S. Ct. 1397, 1410 (2007) (stating that the joinder of claims in a single lawsuit does not "rescue claims that would have been doomed by [the jurisdictional limits of the FCA] if they had been asserted in a separate action"). In evaluating a motion to dismiss for lack of subject matter

jurisdiction under Rule 12(b)(1), a court may consider extrinsic evidence without converting the motion into one for summary judgment. *Aversa v. United States*, 99 F.3d 1200, 1210 (1st Cir. 1996); *see also United States ex rel.Gagne v. City of Worcester*, Civ. No. 06-40241-FDS, 2008 WL 2510143, at *3 (D. Mass. June 20, 2008). Statutes such as the FCA, which confer jurisdiction on federal courts, "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 (D. Mass. 2008) (emphasis added).

Relators' claims run afoul of both the "first-to-file" requirement of the FCA, 31 U.S.C. § 3730(b)(5), and the "public disclosure" bar, 31 U.S.C. § 3730(e)(4). Relators are, furthermore, collaterally estopped by the decision of the Tennessee district court in *Poteet I* from even asserting that they have met these jurisdictional prerequisites.

A. RELATORS ARE NOT THE "FIRST TO FILE"

The FCA prohibits private plaintiffs from "bringing related actions based on the same underlying facts." *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187 (9th Cir. 2001) (citing 31 U.S.C. § 3730(b)(5)). This "first to file" requirement eliminates repetitive claims, while rewarding only those relators who first provide the government with notice of the alleged fraud. *Id.* at 1187. This requirement, furthermore, "encourage[s] potential relators to file *qui tam* suits by reducing the prospect of having to share recovery with opportunistic third parties filing 'copycat suits'." *Poteet I*, Order Granting United States' Motion to Dismiss (Ex. M) at 6 (citing *Grynberg v. Kock Gateway Pipeline Co.*, 390 F.3d 1276, 1279 (10th Cir. 2004)).

The prohibition against bringing repetitive lawsuits is "exception-free." *Lujan*, 243 F.3d at 1187. A relator is not excused from the first-to-file requirement even if she was also the relator in the previous case. *United States ex rel. Smith v. Yale-New Haven Hosp., Inc.*, 411

F. Supp. 2d 64, 75 (D. Conn. 2005) (citing *Grynberg*, 390 F.3d at 1279). Thus, a relator is not permitted to file one lawsuit, discover additional information during the pendency of that suit, and then bring a second, derivative suit adding or varying the details of the original action. *Id.*

The first-to-file rule bars not only those claims that are the same as the claims asserted in a prior action, but all claims "arising from events that are already the subject of existing suits." *LaCorte*, 149 F.3d at 232.

> A later case need not rest on precisely the same facts as a previous claim to run afoul of this statutory bar. Rather, if a later allegation states all the essential facts of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim, *even if that claim incorporates somewhat different details.*

Id. at 232-33 (emphasis added). In other words, the first-to-file rule "precludes a subsequent relator's claim that alleges the defendant engaged in the same type of wrongdoing as that claimed in the prior action, even if the allegations cover a different time period or location within a company." *Lujan*, 243 F.3d at 1188.

This bar prohibits derivative lawsuits by private relators, but of course does not apply to the government. 37 U.S.C. § 3730(b)(5). Thus, although the United States is free to bring a subsequent, related claim alleging a different time period, new defendants or other legal theories arising from the same scheme, private relators are prohibited from doing so since the government already has been put on notice. *See United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs, Inc.*, 149 F.3d 227, 234 (3d Cir. 1998) ("[D]uplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds.").

In dismissing *Poteet I* under the first-to-file requirement, the Tennessee district court found that both the *Doe* complaint and the *Poteet I* complaint alleged that a group of physicians, Medtronic and MSD had violated the FCA and the AKS by paying or accepting kickbacks to use

and recommend the use of MSD products. *Poteet I*, Order Granting United States' Motion to Dismiss (Ex. M) at 1, 6. The court acknowledged that the two complaints differed in that the *Poteet I* complaint added new defendants and additional specific details, but nevertheless held that *Poteet I* was barred by the first-to-file rule because its allegations "pertain to the same kickback scheme addressed in [the *Doe* complaint]." *Id.* at 8. The court found that the additional parties and factual details provided in *Poteet I* were "merely variations" on the *Doe* complaint. *Id.* at 8. In reaching this conclusion, the Court was unmoved by the allegations asserted in Poteet's "supplement" to the Third Amended Complaint, in which she claimed to be asserting a unique scheme of kickbacks purportedly continuing into 2005. *Poteet I*, Order Granting United States' Motion to Dismiss (Exhibit M) at 7-8 (stating that "[h]er allegations regarding MSD's ongoing activities should be of considerable interest to the government and its ongoing investigation and settlement negotiations with MSD," but finding that these claims nonetheless pertained to "the same kickback scheme" as that addressed in *Doe*).

The Sixth Circuit Court of Appeals noted the same defect during the June 5, 2008 oral argument on Poteet's appeal. The court noted that it had made a side-by-side chart comparing the allegations asserted in *Doe* with those set forth in *Poteet I*, and found them to be nearly identical. (*Poteet I Appeal*, Oral Argument Certified Transcript, Ex. O at 5: "I'll be darned if I can find anything of substance that's in your complaint that isn't in the in the John Doe complaint except the names of a few additional doctors.")

Worse, the Relators' Complaint in this case mirrors *both* the *Doe* and *Poteet I* complaints in all material respects. This lawsuit is predicated on the same alleged kickback scheme as that alleged first in *Doe*, and again in *Poteet I*. Like the complaints in those cases, the Complaint here asserts that the Physician Defendants violated the FCA and the AKS by receiving kickbacks

from MSD for using or promoting the use of MSD products. The Relators in this case allege that false claims were submitted to the government because MSD provided physicians with improper "consulting fees, patent interests, expense reimbursements, MSD stock, grants and fellowships" as compensation for purchasing or promoting its products. (Compl. ¶ 331.) Similarly, the *Doe* complaint asserted that MSD provided a "multitude of illegal kickbacks . . . to improperly induce physicians to use MSD products," and that these improper inducements "cause[d] the submission of false claims for payment in violation of the False Claims Act." *Doe* Complaint (Ex. C) at 3. *Doe* further alleged that MSD paid the kickbacks in various forms, including sham consulting and royalty/product development agreements. *Id.* Poteet likewise asserted, in *Poteet I*, that MSD paid kickbacks to physicians in violation of the FCA in the form of "sham consulting contracts," "royalties" and travel expense reimbursements, in exchange for their agreement "to conduct business with MSD" and to "assist MSD in the unlawful promotion of its products among potential physician users." *Poteet I* Third Amended Complaint (Ex. G) ¶¶ 37, 38, 41, 42.

Although Relators have sought to camouflage this recycled lawsuit with a few new bells and whistles, the gravamen of the alleged fraud upon the government in each case is the same. Poteet has revised the *Poteet I* complaint by omitting Medtronic and MSD from the caption, and, instead, including as defendants the distributors of Medtronic products and a long list of the nation's most highly regarded surgeons. Both cases, however, assert claims that physicians who consulted with MSD, participated in its conferences, and received royalty payments for their contributions to its patents violated the FCA. Indeed, thirteen of the individual physicians named in *Poteet I* are also named as defendants in this lawsuit for the same alleged conduct.[3] In dismissing *Poteet I*, the Tennessee court explicitly held that the addition of new defendants did

[3] They include Drs. George Picetti, Lawrence Lenke, K. Daniel Riew, Regis Haid, Gerald Rodts, Jr., Mathew Gornet, Edward Pratt, Kevin Foley, Maurice Smith, Kenneth Burkus, Rick Sasso, Gerald Girasole, and Vincent Treynelis.

not distinguish it from *Doe*. *Poteet I*, Order Granting United States' Motion to Dismiss (Ex. M) at 7-8 ("Ms. Poteet directly names many more doctors than are named in [*Doe*]. . . .The names of additional players and the additional particulars offered by Ms. Poteet, while no doubt helpful to the government, are 'merely variations' on the prior complaint.") The multiplication of defendants here adds nothing as the allegations are not particularlized but rote recitations of formulaic accusations.

Poteet has also attempted to tweak her prior complaint by asserting that the defendants engaged in off-label promotion and violated the Stark law. But neither of these counts alters the fundamental nature of the claims alleged. In support of their Stark claim, Relators assert, "All of the defendant physicians have been compensated for their purchase or promotion of MSD products in the form of some or all of the following conduits: consulting fees, patent interests, expense reimbursements, MSD stock, grants and fellowships. . ." (Compl. ¶ 331.) As discussed below, these allegations do not, in fact, support a claim under Stark, and the factual predicate of this claim and the claims asserted in *Poteet I* are the same.

Relators' off-label allegations similarly spring from the previously asserted claim that MSD compensated physicians for improperly promoting its products. While the complaint in *Poteet I* charged the physician defendants with assisting MSD in the "unlawful promotion" of its products, *Poteet I* Third Amended Complaint (Ex. G) at 38, the Complaint in this case asserts that the off-label use of MSD's products is what allegedly makes the promotional activities "unlawful." Relators attempt in vain to distinguish this case from *Poteet I* by focusing on a particular MSD product, INFUSE™, which they allege a small handful of the defendants improperly promoted. But this added color does not change the subject of the lawsuit. *See LaCorte*, 149 F.3d at 232-33.

Finally, it should be noted that although Relators purport to assert the promotion of off-label uses through the kickback scheme against all of the "Defendants" to the lawsuit (Compl. ¶¶ 326-29), the factual allegations concerning the alleged off-label promotion of MSD products do not even pertain to the vast majority of the defendants.[4] The assertion of this claim based on such a thin factual basis is a transparent attempt to circumvent the first-to-file rule and should not be countenanced.

B. RELATORS' CLAIMS ARE PRECLUDED BY PRIOR PUBLIC DISCLOSURES

Relators' claims are also precluded by the "public disclosure" provision of the FCA, which establishes a jurisdictional hurdle that is distinct and separate from the first-to-file requirement. This provision deprives courts of jurisdiction to hear *qui tam* suits that are "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 evaluate whether a case is barred by this provision under a four-part test:

> (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 with the "original source" exception as defined in § 3730(e)(4)(B).

Rost, 507 F.3d at 728. The answers to all four questions here require dismissal.

[4] Of the 143 defendants, 133 are not mentioned at all in the off-label allegations in the Complaint. (Compl. ¶¶ 285-291.)

1. Relators' Allegations Have Been Publicly Disclosed.

"To be considered 'public,' a disclosure need not be widespread or reach 'all members of the community,' but there must be 'some act of disclosure to the public outside the government.'" *In re Pharm. Indus. Average Wholesale Price Lit.*, 538 F. Supp. 2d 367, 376-77 (D. Mass. 2008) (quoting *Rost*, 507 F.3d at 728 n.6). "[I]t is generally accepted that publicly available documents, such as a complaint filed in conjunction with a civil lawsuit, qualify as public disclosures under the statute." *Id.* at 377 (citations omitted).

The Relators' allegations in this case have been the subject of substantial public disclosures, through court filings, media reports, and government press releases—all of which fall within the statutory prohibition. As the district court in *Poteet I* noted in its dismissal order, the *Wiese* complaint "described in considerable detail the company's alleged practice of providing lavish travel arrangements, bogus consulting agreements, and company-sponsored 'think tanks' to doctors to ensure their continued use of the company's products." *Poteet I*, Order Granting United States' Motion to Dismiss (Ex. M) at 2. Because those allegations became a part of the public domain when *Wiese* filed his complaint, the court found that the fraud and kickback allegations underlying *Poteet I* already had been publicly disclosed. *Id.* at 11. In reaching this conclusion, the court noted that even though the *Wiese* complaint "was not focused on wrongdoing by doctors compromised by being bribed by MSD through the alleged kickback scheme . . . the inference of such wrongdoing is direct and immediate." *Id.* The court thus rejected Poteet's argument that her suit was distinct because it was focused on false claims—which *Weise* did not assert in his lawsuit.

Here, the case for public disclosure is even stronger, because the allegations that underpin Relators' claims have been the subject of numerous newspaper articles and press releases

published after *Poteet I* was filed. *See, e.g., Whistle-Blower Suit Says Device Maker Generously Rewards Doctors*, N.Y. Times, Jan. 26, 2006 (Ex. J) ("The suit . . . accuses Medtronic of giving spine surgeons 'excessive remuneration, unlawful perquisites and bribes in other forms for purchasing goods and medical devices.'"); *Medtronic: Don't Write that $40 Million Check Just Yet*, Wall Street Journal, Aug. 1, 2006 (Ex. P) ("The Minneapolis-based company agreed last month to pay the money to settle the accusations . . . that the company's spinal implant division paid kickbacks to doctors to induce them to use its products."); DOJ Press Release (Ex. K) (stating that the settlement involved "allegations that [MSD] paid kickbacks to doctors to induce them to use MSD's spinal products" and that "Medtronic paid kickbacks in a number of forms, including sham consulting agreements, sham royalty agreements, and lavish trips to desirable locations."). These publications put the factual assertions in Relators' complaint directly into the public domain.

Furthermore, Relators' off-label promotion claims add nothing new to the public discourse. That physicians have used and written about INFUSE™ is widely-known, and has been the subject of several publications. *See, e.g., Medtronic Applies for FDA Approval for Bone Growth Protein*, Memphis Business Journal, Sept. 29, 2005 (Ex. Q) ("Surgeons enjoy the freedom to use products for purposes beyond their FDA clearance, and some have been using [INFUSE™] for off-label treatment."). Indeed, the journal publications alleged in Relators' Complaint as evidence that certain defendants promoted INFUSE™ for off-label treatment, (*see* Compl. ¶ 291), themselves constitute public disclosures of both the off-label use and the promotion of that use by the publishing authors.

2. The Disclosures Were Made as Specified in the Statute.

The FCA describes many different ways in which a public disclosure can occur, including through civil hearings and in the media. 31 U.S.C. § 3730(e)(4)(A). As discussed above, the factual underpinnings of this lawsuit have been the subject of at least three prior civil actions, and numerous newspaper stories, journal articles, and press releases. These disclosures fall within the statutory bar.

3. Relators' Claims are "Based Upon" the Publicly Disclosed Allegations.

Although a circuit split currently exists as to the proof required to meet this element, eight of federal circuit courts have adopted the view that an action is "based upon" a prior public disclosure "when the allegations in the relator's complaint are similar to, supported by, or the same as those that have been publicly disclosed . . . *regardless of where the relator obtained his information.*" *In re Pharm. Indus.*, 538 F. Supp. 2d at 377 (emphasis in the original). A minority of courts hold that an action is 'based upon' a public disclosure 'only when the allegations supporting the action' are actually derived from it. *See, e.g., United States ex rel. Rost v. Pfizer, Inc.*, 446 F. Supp. 2d 6, 19 (D. Mass. 2006), *vacated on other grounds*, *Rost*, 507 F.3d at 734.

At least three cases in the District of Massachusetts (decided by two judges) have adopted the majority view. *See Duxbury*, 2008 WL 24434 at *5 (reasoning that the majority view "better comports with both the policies underlying the provision and the Supreme Court's recent *Rockwell* decision"); *In re Pharm,* 538 F. Supp. 2d at 379 (court "continue[s] to follow" majority rule); *United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 92-93 (D. Mass. 2001) (reasoning that the majority view is "consonant with the structure and policies of the FCA," while the minority interpretation "would contravene the congressional policy of

prohibiting *qui tam* actions where the government has sufficient information to pursue the false claim itself").

While the First Circuit has not yet weighed in on the circuit split, this Court should apply the majority interpretation for several reasons. As the *O'Keeffe* court concluded, the majority interpretation is more consistent with the policies underlying the public disclosure bar, since a *qui tam* complaint loses its value to the government if the information it reveals is already publicly available. 131 F. Supp. 2d at 93. Furthermore, as the *Duxbury* court concluded, the majority view is also more consistent with the Supreme Court's analysis in *Rockwell*, on the related issue of what it means to be an original source:

> It is difficult to understand why Congress would care whether a relator knows about the information underlying a publicly disclosed allegation . . . when the relator has direct and independent knowledge of different information supporting the same allegation . . . . Not only would that make little sense, it would raise nettlesome procedural problems, placing courts in the position of comparing the relator's information with often *unknowable* information on which the public disclosure was based.

127 S.Ct. at 1407-08 (emphasis in the original). The original source exception to the public disclosure bar would be entirely superfluous if the bar applied only to claims that actually arise from publicly-disclosed information. No District of Massachusetts case has adopted the minority rule since *Rockwell.*

Finally, for the reasons discussed in greater detail below, collateral estoppel bars Relators from re-litigating issues that were already decided by the court in *Poteet I.* The district court in that case applied the majority rule, and held that the public disclosure bar applies if "substantial identity" exists between the publicly disclosed allegations or transactions and the *qui tam* complaint. *Poteet I*, Order Granting United States' Motion to Dismiss (Ex. M) at 11-12. Relators should not be allowed to shop for an alternative forum by refiling their claims in

Massachusetts in hopes of finding a court that will apply a more favorable test to the public disclosure issue.

Moreover, whether the Court chooses to adopt the majority view or the minority position, Relators cannot establish that their claims are not based on publicly disclosed information. The allegations here are so similar to the information that has been disclosed publicly as to create a strong presumption that the Relators actually derived their claims from those disclosures. The Court, therefore, should find that the public disclosure provision bars their claims unless they meet the "original source" exception.

4. Relators Are Not Original Sources.

An "original source" is someone with "direct and independent knowledge of the information on which the allegations are based and [who] has voluntarily provided the information to the government before filing" a *qui tam* complaint. 31 U.S.C. § 3730(e)(4)(B). A relator's knowledge is "direct" if she acquired it through her own efforts, without an intervening agency or through another person; it is "independent" if it is not dependent on the public disclosure. *O'Keeffe*, 131 F. Supp. 2d at 93; *United States ex rel. Barth v. Rigedale Elec., Inc.* 44 F.3d 699, 703 (8th Cir. 1995). A relator may not bootstrap her claims onto those of a co-relator; rather, each relator must be able to prove an independent right to bring suit. *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 51 n.14 (D.D.C. 2007).

In her first lawsuit, Poteet did not even argue that she was an original source. *Poteet I*, Order Granting United States' Motion to Dismiss (Ex. M) at 8. Here, too, she is unable to assume that status - particularly since she admits she did not work at MSD during most of the time period covered in the Complaint. (Compl. ¶ 4.) Moreover, neither relator was in a position

to know the value of the services provided by the Physician Defendants in exchange for any payments they may have received from MSD—a necessary component of any accusation that the payments were "kickbacks." Finally, Relators have not attempted to conceal their lack of knowledge pertaining to *any* false claim that may have been submitted: "Relator cannot identify at this time all of the false claims which were caused by defendants' above-described conduct. The false claims were submitted by many physicians with whom the Relator had no dealings and the records of the false claims are not within the Relator's control."[5] (Compl. ¶ 333.) Obviously, a person who seeks to obtain information concerning a key element of her claims through the discovery process is not an "original source" of that information.

The allegations in the Complaint are the subject of multiple prior public disclosures, and Relators cannot establish direct and independent knowledge of the information contained in those allegations. The public disclosure bar thus deprives the Court of jurisdiction and the Complaint must be dismissed.

C. RELATORS ARE COLLATERALLY ESTOPPED FROM RELITIGATING ISSUES DECIDED IN *POTEET I*

The doctrine of collateral estoppel, or "issue preclusion," bars litigants from retrying issues that were litigated in a prior case. *Keystone Shipping Co. v. New England Power Co.*, 109 F.3d 46 (1st Cir. 1997). A party invoking the doctrine must show that: (1) there was a final judgment in the prior action; (2) the party against whom preclusion is asserted was a party or in privity with a party to the prior action; and (3) the issue in the prior action was the same as the issue in the current action. *In re Sonus Networks, Inc.*, 499 F.3d 47, 57 (1st Cir. 2007).

The district court's dismissal in *Poteet I* for lack of subject matter judgment is a final and binding judgment with preclusive effect. *See Sonus*, 499 F.3d at 59 (holding that dismissal for

[5] The repeated use of the singular "Relator" suggests that the current complaint was cut and pasted from *Poteet I*.

lack of jurisdiction is preclusive); *In re Kane*, 254 F.3d 325, 328 (1st Cir. 2001) (holding that a judgment is entitled to preclusive effect even if on appeal). Moreover, both cases were brought by a common relator—Poteet. Although Ms. Vaden was not a party to the prior lawsuit, she is in privity with the United States, and the United States is the real party in interest in both qui tam lawsuits. *See, e.g., United Seniors Ass'n, Inc. v. Philip Morris*, 500 F.3d 19, 24 (1st Cir. 1007); *U.S. ex rel. Rodgers v. State of Ark.*, 154 F.3d 865, 869 (8th Cir. 1998) (stating that a relator "stands in the shoes" of the government in FCA qui tam cases). Relators are therefore barred from relitigating any issue that was decided by the district court in *Poteet I.*

The Tennessee district court decided several key issues that operate to bar Relators' claims in this case. The court determined that Poteet's core allegation—that MSD violated the FCA and the AKS by paying kickbacks to physicians as inducements to use and recommend the use of MSD products—was duplicative of prior lawsuits such that the first-to-file requirement barred her claims. *Poteet I*, Order Granting United States' Motion to Dismiss (Ex. M) at 8. Relators are similarly precluded in this case from relitigating claims predicated on that same alleged kickback scheme. The *Poteet I* court further held that the addition of new defendants and specific details did not avoid the first-to-file rule. *Id.* at 7-8. That determination has preclusive effect in this case.

The Tennessee district court also determined that the allegations asserted in *Poteet I* were barred under the public disclosure rule, because the core fraud and kickback allegations were substantially the same as those that had been disclosed publicly in the *Wiese* complaint. *Id.* at 11-12. In reaching that conclusion, the court determined that a claim is "based upon" a prior public disclosure if there is "substantial identity" between the publicly disclosed allegations and the *qui tam* complaint. *Id.* at 11. Because the core kickback scheme alleged in *Poteet I* is the

same as the scheme alleged here, each of these key determinations has preclusive effect and must not be addressed again in a different forum. Relators are collaterally estopped from arguing the most essential elements of their claims, and therefore, the Complaint must be dismissed.

II. THE COMPLAINT DOES NOT SATISFY RULE 9(b)

FRCP 9(b) requires plaintiffs to state allegations of fraud with particularity. The Physician Defendants move to dismiss the Complaint on grounds that the allegations it asserts against them fall far short of this requirement. As a threshold matter, the Complaint fails to identify a single false claim filed as a result of the purportedly improper conduct alleged. *See Karvelas*, 360 F.3d at 232-33 (requiring relators to plead, as to at least some reimbursement claims, the dates, form numbers, identification numbers, amounts billed, individuals involved, services provided, and other details). Relators here fail to identify - even in the most general terms - who supposedly submitted a false claim, to whom, when the claim was filed, and what claim was made. The Complaint even confuses whether the alleged false claims were billed to Medicare (as asserted in some paragraphs) or Medicaid (as asserted in others). It also fails to state whether any Medicare claims at issue were submitted under Part A or Part B, and whether reimbursement was claimed for goods or for services. The Complaint should be dismissed on these grounds alone.

In support of their motion on these and other grounds, the Physician Defendants join in the memoranda and arguments submitted by the Distributor Defendants (Bahler Medical, Inc., *et al.*). The Physician Defendants raise the following additional 9(b) deficiencies in the Complaint as asserted against them.

A. THE COMPLAINT FAILS TO ALLEGE KEY FACTS CONCERNING THE PHYSICIAN DEFENDANTS' CONDUCT

Conclusory allegations are insufficient to state a claim under the FCA. *Rost*, 507 F.3d at 731. Despite the length of the Complaint, it lacks particularized allegations about the nature of any alleged fraudulent conduct or misrepresentations by Physician Defendants. Of the 334 paragraphs in the Complaint, 138 paragraphs merely list the names and addresses of the defendants. (Compl. ¶¶ 8-145.) Formulaic allegations that defendants earned money under consulting or royalty agreements with MSD comprise another 121 paragraphs. (Comp. ¶¶ 157-279). The Complaint, when stripped of its identifying data, contains very little specific information and provides insufficient support for the broad accusation that each of the Physician Defendants did not earn the fees or royalties he allegedly was paid. Relators do not claim that the consulting fees were excessive when compared with the cost of similar consulting services by skilled practitioners, nor do they provide any detail about the market value of the services Physician Defendants provided to MSD. Instead, they appear to assert that every time MSD made a payment to any physician, such necessarily was an illegal kickback. Without particularized information concerning the allegedly illegal payments, it is impossible to defend against such broad allegations. Rule 9(b) compels dismissal.

The Complaint leaves numerous other questions unanswered regarding the Physician Defendants' alleged liability for false claims: Who paid royalties to which defendants at what time, and what were the terms of the agreements under which they were paid? How do the off-label promotion claims apply to the 134 defendants for whom no promotional activities concerning off-label uses are even alleged? Equally confusing is Relators' failure to explain who submitted the allegedly false claims to the government. Was it Physician Defendants, their unidentified "employers", the hospitals where the surgeries were performed, or other

unidentified providers? In several paragraphs of the Complaint, Relators admit that the Physician Defendants never submitted false claims to the government directly, but allege they somehow benefited "indirectly" from the submission of false claims by third parties. (Compl. ¶¶ 149, 155, 329, 334.) Elsewhere, however, Relators appear to assert that Physician Defendants and their "agents, employers, and employees" submitted false claims to the Medicare or Medicaid programs directly. (Compl. ¶¶ 1, 319.) The plaintiffs should not be allowed to throw alternatives and theories into a complaint in the hope that *something* will stick. Such imprecision and contradiction makes it impossible for Physician Defendants to discern the nature of the allegations against them and to respond appropriately. *See Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir. 1996) (reciting purposes of heightened fraud pleading requirement to include: giving notice to defendants of the plaintiffs' claim, protecting defendants' reputation from meritless fraud claims, and preventing filing of suits for the purpose of conducting fishing expeditions during discovery) (citation omitted).

B. RELATORS' ALLEGATIONS AS TO INDIVIDUAL DEFENDANTS ARE DEFICIENT

Although named in the caption, Drs. James Ogilvie, Langston Holly, and Reginald Davis are not even mentioned in the body of the Complaint. Relators have simply failed to assert any claims against them. Similarly, a large number of the Physician Defendants are named in the caption and accused summarily of receiving "sham" consulting fees, but they appear nowhere in the allegations concerning any purported conduct beyond the rote recitation that they received remuneration.[6] Thus, the Complaint identifies no specific acts of these Physician Defendants

[6] These individuals include Drs. Muwaffak Abdulhak, Neel Anand, Hyun Bae, John Bendo, Randal Betz, Christopher Comey, Jeffrey Deckey, Francis Denis, Bradley Estes, Jean-Pierre Farcy, Joe Flynn, Jr., Timothy A. Garvey, Gerald J. Girasole, Edward Goldberg, Jason Hubbard, Louis Jenis, Reginald Knight, Donald Kucharzyk, Vivek Kushwaha, Ronald Lehman, Baron Lonner, Michael MacMillan, Frederisk F. Marciano, Amir Mehbod, Jean-Pierre Mobasser, Robert Myles, Russ Nockels, Paul Pagano, Sylvain Palmer, Joseph Perra, Manuel Pinto, Eric Potts,

that could constitute fraud under the FCA. Moreover, Relators include no allegations that the payments purportedly received by these individuals were even related to the alleged kickback scheme. Relators fail to state any fraud claim—particularized or not—against these Physician Defendants.

On the other hand, a number of Relators' factual allegations involve the conduct or representations of physicians who are not even named as defendants in the Complaint's caption. For example, Relators insinuate that "Dr. Zdeblick," who is neither listed in the caption nor identified as a party, received consulting fees and royalties for promoting off-label use of the INFUSE™ device. (Compl. ¶¶ 288-89, 306.) Similarly, a physician identified as "Dr. Dorchak" is mentioned repeatedly as one of the principal clinical investigators of rhBMP-2 (the primary component of the INFUSE™ device), and as a recipient of kickbacks for publishing questionable studies and promoting off-label uses. (Compl. ¶¶ 292, 294, 306-07.) But Dr. Dorchak is neither named nor identified as a party in the Complaint. Several other non-party physicians are also accused of receiving illegal kickbacks, including: Drs. Dickman, Papadopoulos, and Sandhu. Relators cannot rely on acts of other non-parties to bolster claims for false representations by the Physician Defendants.

Relators appear to have drafted their Complaint with casual indifference to the very real, injurious effect that their accusations would have on the individual physicians forced to defend against them. The inclusion of dozens of the nation's most respected orthopedic surgeons and neurosurgeons in a lawsuit alleging misrepresentation and fraud - without factual support - reflects an appalling lack of concern for the substantial financial costs and potential damage to

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Daniel Riew, Joseph Riina, James Robinson, David Rouben, Sean Salehi, Thomas Conrad Schuler, Frank Schwab, John Shiau, Hal Silcox, Stanley Skinner, Jeffrey Silber, Jeffrey Spivak, Brian Robert Subach, George Teitelbaum, and Lytton Williams.

reputation they have visited upon these individuals. Relators should not be permitted to proceed any further with their claims.

C. RELATORS ADMIT THEY CANNOT SATISFY RULE 9(B) AND SHOULD NOT BE ALLOWED TO RE-PLEAD

Relators acknowledge -- but attempt to compensate for -- their pleading failures by presumptuously excusing themselves from the law, namely the particularity requirement of Rule 9(b): "Given the vast number of false claims, their scope and complexity, Realtor [*sic*] is excused from the requirement of specifying each false claim." (Compl. ¶ 328.)[7] Relators' assertion is erroneous.

The First Circuit has explained that an FCA plaintiff *must* identify particular false claims for payment in order to satisfy Rule 9(b). *Karvelas*, 360 F.3d at 232-33. Prior decisions of this Court are consistent with that ruling. *United States ex rel. Gublo v. Novacare, Inc.*, 62 F. Supp. 2d 347, 354 (D. Mass. 1999) (Stearns, J.) (dismissing plaintiffs' FCA claims for fraudulent billings for prosthetics because they failed to identify a single specific instance of a fraudulent billing for that category of device). Other Massachusetts district courts have done the same. *See, e.g., United States ex rel. Driscoll v. Serono*, 2008 WL 728939, at *3 (D. Mass. Mar. 18, 2008) (O'Toole, J.) (dismissing FCA and state false claims act allegations against pharmacy defendants because complaint "fail[ed] to identify a single particular false claim submitted for payment by any of the pharmacy defendants to any governmental agency at any time").

Relators try to obfuscate the lack of detail regarding any false claims by implying that they have provided such details with regard to some. For instance, they state that they "cannot identify at this time *all* of the false claims which were conducted by defendants' conduct."

[7] Poteet made the same faulty excuse for her pleading failures in *Poteet I:* "At the present time ... it is impossible to plead the fraud perpetrated upon the United States with respect to every false claim filed with greater particularity than furnished herein." *Poteet I*, Third Amended Complaint (Ex. G) at ¶ 45.

(Compl. ¶ 328.) In fact, they have not identified *any* claims for reimbursement whatsoever.

Relators admit that they have provided all the detail they are capable of providing with respect to the false claims alleged. It is not enough. Given Relators' admission that pleading with greater particularity is impossible, the Complaint should be dismissed with prejudice in its entirety, without leave to amend. *See, e.g., Serono*, 2008 WL 728939 at *4 (holding that leave to amend complaint further is futile when discovery would be necessary for relators to satisfy particularity requirement); *accord United States ex rel. Frazier v. IASIS Healthcare Corp.*, --- F. Supp. 2d ----, 2008 WL 1808332, at **7-8 (D. Ariz. 2008).

III. THE COMPLAINT FAILS TO STATE CLAIMS UPON WHICH RELIEF MAY BE GRANTED

Although Relators assert purported violations of the AKS, FDA standards addressing off-label promotion, and the Stark Law, they do not have standing to bring a private right of action under any of these laws. Rather, the only legal basis available to private citizens seeking recompense for alleged violations of these laws is through the FCA. For Relators to make out a proper claim under the FCA and survive a motion to dismiss under Rule 12(b)(6), however, they must at a minimum plead the elements of the FCA and set forth sufficient factual allegations to establish an entitlement to relief. *See* 31 U.S.C. § 3730.

Even assuming for purposes of this motion that the facts of the Complaint are true, (which the Physician Defendants vigorously dispute) each of the Relators' three counts against the Physician Defendants fails to state a claim for relief under the FCA. Specifically, Counts I and II allege that the Physician Defendants violated the FCA by presenting or causing another to present claims for reimbursement to the federal government based on an implied certification that they or their unidentified employers had complied with all applicable laws and regulations, presumably including the AKS and the Food, Drug, and Cosmetic Act ("FDCA") or FDA rules

and regulations addressing off-label promotion. However, nowhere in Counts I or II of the Complaint do the Relators identify a specific false or fraudulent claim nor do they sufficiently allege the necessary nexus between an illegal kickback or off-label promotional activity and a claim for reimbursement. While the Complaint repeatedly makes the claim that the physician defendants impliedly falsely certified compliance with all applicable laws and regulations when causing claims to be submitted to the federal government, it fails to allege any set of facts from which this Court could find that the Relators would be entitled to relief, much less meet the higher standard now required by *Twombly, infra.*

Similarly, in Count III of the Complaint, the Relators fail to allege the necessary elements of a Stark law violation, nor do they provide an adequate factual framework to support any entitlement to relief. For these reasons, and as detailed more fully below, the Complaint must be dismissed in its entirety as it fails to state any cause of action upon which relief can be granted.

A. LEGAL STANDARD

When considering a motion to dismiss for failure to state a claim under Rule 12(b)(6), a court must view all allegations stated in the complaint as true and construe all inferences in the light most favorable to the plaintiff. *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984); *Cooperman v. Individual, Inc.*, 171 F.3d 43 (1st Cir. 1999). The district court may only properly consider facts and documents that are part of or incorporated into the complaint, *Trans-Spec Truck Service, Inc. v. Caterpillar, Inc.*, 524 F.3d 315, 320 (1st Cir. 2008), and "eschew any reliance on bald assertions, unsupportable conclusions, and opprobrious epithets." *Chongris v. Bd. of Appeals of the Town of Andover*, 811 F.2d 36, 37 (1st Cir. 1987) (citation and internal quotation omitted).

To survive a motion to dismiss for failure to state a claim, a complaint must contain factual allegations sufficient to "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, --- U.S. ---, 127 S.Ct. 1955, 1965 (2007); *Dixon v. Shamrock Financial Corp.*, 522 F.3d 76 (1st Cir. 2008). "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 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 127 S.Ct. at 1964-65 (quoting Fed. R. Civ. P. 8(a)(2)) (alteration in original) (citations omitted); *see also Wash. Legal Found. v. Mass. Bar Found.*, 933 F.2d 962, 971 (1st Cir. 1993) (stating court, in performing Rule 12(b)(6) analysis, is free to reject "unsupported conclusions or interpretations of law").

B. COUNTS I AND II FAIL TO ALLEGE FALSE CLAIMS UNDER A FALSE CERTIFICATION THEORY OF LIABILITY

In Count I of the Complaint, Relators allege that the consulting fees MSD paid to the Physician Defendants for their time and expertise were merely "kickbacks" or "bribes" meant to induce the physicians to purchase, or recommend the purchase, of MSD products in violation of the AKS. (Compl. ¶¶ 157, 319.) In Count II of the Complaint, Relators allege that the Physician Defendants promoted MSD products for use to Medicare providers, purportedly in violation of the FDCA and FDA rules and regulations concerning off-label marketing and promotion. (Comp. ¶¶ 326-29.)

"FCA liability attaches only to a 'false or fraudulent claim for payment' or to a 'false record or statement [made] to get a false or fraudulent claim paid' by the government." *Duxbury*, 551 F. Supp. 2d at 103. In Count I of the Complaint, the Relators assert that the Physician Defendants accepted kickbacks from MSD and then leap to the unsupported inference that this alleged conduct must have resulted in the submission of false claims in violation of the

FCA. Similarly, in Count II of the Complaint, the Relators baldly assert that the Physician Defendants promoted off-label uses of INFUSE™ and then leap to the unsupported inference that this alleged conduct must have caused false claims for reimbursement. Relators' allegations regarding the alleged kickbacks and alleged off-label promotion are insufficient to state a claim upon which relief can be granted because they fail to allege any factual basis for the supposition that any claim linked to such alleged conduct constitutes the submission of a false claim to the federal government.

1. The False Claims Act Statute

The FCA is a highly punitive statute, and as such is meant to be directed only against those who are clearly "out to cheat the federal government," *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999), by employing an outright "lie." *Hindo v. Univ. of Health Sys.*, 65 F.3d 608, 613 (7th Cir. 1995). Liability for an FCA violation occurs only when a person:

> (1) knowingly presents or causes to be presented, to an officer or employee of the United States Government. . . a false or fraudulent claim for payment or approval; [or]
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government[.]

31 U.S.C. § 3729(a). To set forth a claim that the Physician Defendants engaged in an "act" that allegedly violates the FCA under Section (a)(1), the Relators must establish that:

> (1) the defendants presented or caused another to present a "claim" for payment or approval to the United States;
> (2) the claim is "false or fraudulent;
> (3) the defendants acted knowing that the claim is false; and
> (4) the false claim is material to the government's payment.

See, e.g., United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 55 (D. Mass. 2001) (citing *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999)). The

four requirements of Section (a)(1) are also applicable to liability under Section (a)(2). However, Section (a)(2) also requires making or using (or causing someone to make or use) a false record to cause a false claim to be paid or approved. Thus, the record supporting the claim must be false and the record must be made or used for the purpose of causing the false claim to be paid. *See, e.g., United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 675 (5th Cir. 2003) (en banc) ("There is no liability under this Act for a false statement unless it is used to get [a] false claim paid."); *United State ex rel. Franklin v. Parke-Davis*, No. Civ. A. 9611651PBS, 2003 WL 22048255, at *1 (D. Mass. Aug. 22, 2003) (holding that Section 3729(a)(2) contains a "double-falsehood requirement").

As stated above, the Relators have failed to identify any specific claim for payment presented to the federal government. Moreover, as discussed in more detail below, the Complaint fails to set forth a factual basis to support a finding that any claim submitted to the federal government for reimbursement was "false or fraudulent."

2. Relators Have Failed to State a False Certification Theory

In Counts I and II of the Complaint, the Relators appear to advance an "implied certification" theory to establish that claims which were "false and fraudulent" under the FCA were submitted by the defendants to the federal government.[8] Liability for implied false certification is based on the notion that, under certain circumstances, the act of submitting a claim for reimbursement itself implies compliance with federal statutes or rules. *See Ab-Tech Construction v. United States*, 31 Fed. Cl. 429, 429-34 (Fed. Cl. 1994). While an "implied certification" theory has been recognized as a basis for liability under the FCA, case law makes it

[8] The Relators do not claim that the defendants expressly certified compliance with either the AKS, FDCA, or FDA rules and regulations concerning off-label promotion. For this reason, the Physician Defendants focus here on implied certification and do not address express certification in detail. The Physician Defendants note, however, that Relators have not made any specific factual allegations that would support any such claim.

clear that the statute "was not intended to operate as a stalking horse for enforcement of every statute, rule or regulation." *United States ex. rel. Showell v. Philadelphia AFL, CIO Hosp. Assoc.*, 2000 WL 424274 at *7 (E.D. Pa. Apr. 18, 2000); *United States v. McNinch*, 356 U.S. 595, 599 (1958) (FCA not designed to reach every kind of fraud allegedly practiced on the government).

Most courts that have addressed this issue have held that claims for services rendered in violation of a particular statute or regulation do not *per se* constitute false or fraudulent claims under the implied false certification theory. *See, e.g., United States ex rel. Mikes v. Strauss*, 274 F.3d 687, 700 (2d Cir. 2001); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997). Rather, at a minimum, courts require a showing that the government *actually conditioned* payment of a claim upon a claimant's express or implied certification of compliance with that statute or regulation. *Thomson*, 125 F.3d at 902. Moreover, the Second Circuit has recognized implied false certifications as a basis for FCA liability in the health care context only when "the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Mikes*, 274 F.3d at 700 (emphasis in the original).[9]

Neither the AKS nor the FDCA and its implementing regulations contain express language requiring compliance with their provisions in order to submit claims for reimbursement to Medicare for items or services otherwise properly provided. As such, these statutes, rules and regulations cannot form the basis for a *qui tam* suit under the FCA based on an implied certification theory under *Mikes*. The Relators' claims also fail because the Relators have not -

[9] In *Mikes*, the Second Circuit reasoned that limiting application of the false implied certification theory was appropriate in health care cases, because use of the theory as a "blunt instrument" to enforce compliance with all medical regulations would improperly broaden the FCA's reach. *Id.* at 699. The court further reasoned that a limited application of the theory in this context takes into account the "active role actors outside the federal government play in assuring that appropriate standards of medical care are met." *Id.* at 700.

and cannot - set forth how the government actually conditioned payment of specific claims on Physician Defendants' compliance with the AKS, the FDCA, or FDA regulations. *See, e.g., Pogue II,* 238 F. Supp. 2d 258, 264-65 (D.D.C. 2002) (certification of compliance with statute or regulation at issue must be so important that the government would not have paid the claim if it were aware of the violation). Nowhere in the Complaint do the Relators allege the necessary connection between the purported illegal "kickbacks", "bribes", or off-label promotional activities to claims submitted for reimbursement by the federal government.

The Relators' claims concerning the alleged off-label promotion of devices are particularly tenuous. Relators would have this Court believe that all physician prescriptions for drugs or devices outside the FDA-approved indications are violations of the law. That is not the case. Prescribing drugs and devices for off-label use is not only legal, but is an important aid in treating patients and advancing medical research. *See e.g., Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350-51 (2001) (prescribing off-label "is an accepted and necessary corollary to the FDA's mission to regulate without directly interfering with the practice of medicine."); 21 U.S.C. § 396 ("Nothing in [the FDCA] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition of disease within a legitimate health care practitioner-patient relationship."). Indeed, in recognition of the important right of physicians to exercise independent medical judgment, Medicare reimbursement for devices is *not* conditioned on whether they are prescribed or recommended for an approved ("on-label") indication. Instead, Medicare covers items that are "reasonable and necessary" for the care and treatment of patients. 42 U.S.C. 1985y(a)(1)(A). Relators' Complaint proceeds from the faulty premise that all off-label prescribing behavior by physicians is illegal. Moreover, Relators fail to set forth how the

government actually conditioned payment of specific claims on Physician Defendants' prescribing for only "on-label" indications.

These fatal deficiencies in the Complaint are compounded by the Relators' failure to tie any alleged unlawful conduct – whether the acceptance of kickbacks or off-label promotion – to any specific claims for reimbursement. Evidence of a false claim is "the *sine qua non* of a False Claims Act violation." *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002), *cert. denied,* 537 U.S. 1105 (2003). Relators should not be allowed to proceed, because they have neither identified any particular false claims nor articulated how any alleged claims were "false or fraudulent" under a false certification theory.

3. Physician Defendants Cannot be Liable for False Certifications by Third Parties

Although Relators fail to identify the particular claimants who purportedly sought reimbursement in violation of the FCA as a result of the Physician Defendants' conduct, they concede that "defendants did not submit the false claims and did not directly receive the payments [from the government]." (Compl. ¶ 329, 334.) Instead, Relators appear to base their claims against Physician Defendants on the theory that somehow they caused *other* physicians or hospitals to make false certifications of compliance with the law. (*See* Compl. ¶ 149, "The defendants did not directly provide MSD products to the Medicare program. Instead, they embarked on a course of unlawful conduct that they knew would lead to the submission by physicians (or their hospitals) of thousands of Medicare claims for MSD products. . . .".)

This district has rejected a similar attempt to extend the dubious theory of third-party false certification to an FCA claim based on a violation of the AKS. *See United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 55 (D. Mass. 2001) (finding neither case law nor allegations in the complaint sufficient to support the theory of third party false certification).

The court's ruling in *Franklin* makes sense: To state a claim under the FCA using a false certification theory, the plaintiffs must establish that the claimant made a claim for reimbursement based on a certification of compliance that is in some way false. Here, however, the unidentified third party claimants are neither alleged to have submitted any untruthful information to obtain reimbursement nor alleged to have violated any law or regulation. Whatever violations of the AKS, the FDCA, or FDA rules and regulations may be alleged to have been attributable to the Defendants, they cannot be attributable to the unknown third party providers, so as to render any certification they may have made untrue in any respect. Like the *Franklin* defendants, Physician Defendants here have uncovered no case law that extends the theory of legally false certification to cover claims filed not by the defendants themselves, but by third parties, as Relators advance in the Complaint.

Thus, even assuming Relators' allegations set forth a violation of the AKS, the FDCA, or FDA rules and regulations (which the Physician Defendants strongly deny), their third-party false certification theory under the FCA fails because they have not alleged that the Physician Defendants caused or induced another doctor or entity to file a false or fraudulent certification of compliance with the law, and have pointed to no claim for reimbursement that is false on its face.

4. Relators' Failure to Identify Any False Claims for Reimbursement Requires Dismissal Under Rule 12.

Nowhere in the Complaint do the Relators advance the necessary factual basis linking or connecting the alleged "kickbacks" or "bribes" received by the Physician Defendants (or the alleged off-label promotional activities) to the claims submitted for reimbursement by the federal government. The Complaint noticeably avoids any mention of this necessary nexus because, as the Relators well know, they are wholly unable to make the connection. In *United States ex rel. Hess v. Sanofi-Synthelabo Inc.*, the court found the same deficiencies that plague this Complaint

to be fatal: "Plaintiff does not allege that Defendant made any misrepresentations to doctors, to the Government or to anyone else regarding [the drug in question]; . . . Plaintiff does not allege a single doctor prescribed [the drug] improperly; that . . . any doctors who may have prescribed [the drug] and sought reimbursement from Medicare made any misrepresentation to Medicare[.]" Civ. No. 05-570, 2006 WL 1064127, at *4 (E.D. Mo. Apr. 21, 2006). The *Hess* court, accordingly, dismissed the FCA claims under Rule 12. *Id.* at *9. The court found that without an allegation of deliberate falsehoods to providers or Medicare, the relator's allegations could not state a cognizable FCA claim. *Id.*

The Complaint asserts no allegations linking any specific conduct of the Physician Defendants to violations of law, as is required to survive a motion to dismiss. *See Twombly*, 127 S.Ct. at 1964-65. Therefore, Counts I and II should be dismissed in their entirety for failure to state a claim under the FCA.

C. COUNT III DOES NOT PROPERLY ALLEGE A STARK LAW VIOLATION

In Count III, Relators allege that Defendant Physicians caused false claims to be filed as a result of unlawful self-referrals under the Stark Law. The Stark statute prohibits a physician from referring a patient to an entity for certain designated health services ("DHS") that are covered by a federal health care program if the physician has a financial relationship with that entity, unless an exception applies. 42 U.S.C.A. § 1395nn(a)(1) (Westlaw 2008). In addition, an entity "may not present or cause to be presented a claim . . . to any individual, third party payor, or other entity for designated health services furnished pursuant to a [prohibited referral]." 42 U.S.C.A. § 1395nn(a)(1)(B). Therefore, the elements of a Stark law violation include:

(1) a financial relationship between a physician and a DHS entity;
(2) physician referral of a Medicare/Medicaid recipient to the entity for DHS;
(3) the entity's submission of a billing claim for the DHS; and

(4) the absence of an applicable exception.[10]

See United States ex rel. Villafane v. Solinger, 543 F. Supp. 2d 678, 684-685 (W.D. Ky. 2008).

Title 42, Part 411, Subpart J of the Code of Federal Regulations implements the Stark Law. The regulations more explicitly define the term "entity." An entity is:

> A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, not-for-profit corporation, or unincorporated association that furnishes DHS.

42 C.F.R. § 411.351. A person or entity furnishes DHS when it "is the person or entity to which CMS makes payment for the DHS" or "is the person or entity to which the right to payment for the DHS has been reassigned . . . ." 42 C.F.R. § 411.351(1)(i) & (ii). Because they are not "entities" receiving payment or assignment of payment from CMS, medical device manufacturers, such as MSD, are not implicated under the Stark law. The statute lists eleven categories of DHS, including: durable medical equipment (DME) and supplies; and inpatient and outpatient hospital services. *See* 42 U.S.C. 1385nn(h)(6).

For their proposed Stark claim, Relators allege:

> [Defendants] intentionally colluded with MSD [a non-party to this lawsuit] and decided to participate in improper marketing practice to promote MSD products, the Defendants knew or should have known that thousands of physicians (chiefly through their hospitals under applicable DRGs) would routinely and necessarily file false claims with the federal government when they sought federal reimbursement for MSD products. But for Defendants' actions most, if not all, of the false claims for the purchase of MSD products would never have been filed.

(Compl. ¶155.) Much later in the Complaint, Relators incorporate these allegations into Count III and attempt to state the elements of a Stark violation:

> The defendants have caused the submission of false claims in violation of the Stark law by referring their own patients and the patients of other physicians to

[10] There are numerous exceptions, *i.e.* situations that would otherwise qualify as "compensation arrangements," that do not give rise to violation of the Stark Law. Due to a lack of clarity in the Complaint regarding the alleged compensation arrangements, it is impossible to determine if any of these exceptions apply.

> DHS entities (the hospitals where the surgeries are performed) with whom the defendants have indirect compensation arrangements, and who are paid money by MSD, the manufacturer.

(Compl. ¶332.) Relators' Stark Law claim fails, because they have not properly alleged: (1) that there is a "financial relationship" under the Stark law between physician defendants and any DHS entity; (2) that physician defendants made any improper Stark referrals; and (3) that any entity submitted a claim for the DHS.

1. **Relators have not Alleged a Financial Relationship with a DHS Entity.**

Unless Relators properly plead the existence of a financial relationship with a DHS entity, no Stark violation exists. A "financial relationship" includes:

> (A) an ownership or investment interest in the entity; or
> (B) a "compensation arrangement" between the physician and the entity.

42 U.S.C.A. § 1395nn(a)(2). Compensation arrangements that violate the Stark Law include any arrangement involving remuneration between a physician and an entity. The Stark regulations explain that a "compensation arrangement" can be either direct (i.e. the referring physician receives remuneration directly from the DHS-furnishing entity) or indirect. An indirect compensation arrangement requires: (1) an unbroken chain of any number of persons or entities between the referring physician and the DHS entity with linked compensation arrangement; (2) that the referring physician received aggregate compensation from the next link in the compensation chain that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS; and (3) that the DHS entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives the aggregate compensation in requirement (2). 42 C.F.R. 411.354(c)(2).

Under Count III, Relators claim that Physician Defendants referred patients to DHS entities "with whom the defendants had indirect compensation arrangements." No factual allegations or other statements in the Complaint support this allegation. On the contrary, throughout the Complaint, Relators have claimed improper compensation arrangements with MSD, not any hospitals or other such DHS entities. For example, they claim that "[a]ll of the defendant physicians have been compensated for their purchase or promotion of MSD products in the form of some or all of the following conduits: consulting fees, patent interests, expense reimbursements, MSD stock, grants and fellowships and other hidden forms of remuneration, all greatly in excess of fair market value." (Compl. ¶ 331.) In the "Factual Allegations," Relators identify these alleged consulting fees, paid by MSD to each defendant doctor, as "sham" payments and kickbacks. (*Id.* ¶¶ 157-280.) Relators also allege that Drs. Zdeblick, Mathews, and Boden were paid consulting fees and royalties by MSD for testimony at a hearing before the FDA Advisory Committee pursuant to which the device in question here was approved. (*Id.* ¶¶ 287-288.) In addition, Relators claim that MSD awarded a number of defendant doctors patents and/or consulting fees as kickbacks for promoting the INFUSE device. (*Id.* ¶¶ 293-297, 307.) Relators further aver that many of the doctors attend VIP meetings sponsored by MSD, the purpose of which is to promote on and off-label uses of MSD products, including INFUSE™. (*Id.* ¶¶ 305-306.) Finally, Relators claim that MSD's distributors also gave expensive gifts and perquisites to, and sponsored lavish meetings for, physicians, and that the bills for all these items and events were allegedly paid by MSD's accounting office. (*Id.* ¶¶ 309-310.)

Notably absent from Relators' list of allegations is any claim that the Physician Defendants had compensation arrangements with the medical facilities where they referred patients with spinal injuries or defects for treatment. Nor do they allege that MSD is a pass-

through entity for compensation from hospitals to the Physician Defendants. All that Relators have alleged are compensation arrangements between the Physician Defendants and MSD. MSD, however, is not a "DHS entity" under the Stark Law. 42 C.F.R. § 411.351(1)(i) & (ii).

Finally, Relators have not alleged behavior that corresponds to the three requirements for showing indirect compensation arrangements. First, nowhere does the Complaint state that there was an unbroken chain of entities between the referring physician and the DHS entity with a linked compensation arrangement. Second, the only allegation in the Complaint that the referring physicians received aggregate compensation based on the volume or value of referrals that the physicians generated is directed toward MSD, a non-DHS entity. (Compl. ¶ 156.) Finally, Relators make no allegations regarding whether the hospitals where the spinal implant surgeries took place knew about any such aggregate compensation.

2. Relators have not Alleged Prohibited Referrals.

Relators have made no claim that the Physician Defendants made any referrals that implicate the Stark prohibitions. Under the Stark statute, a referral means a request by a physician for a Medicare Part B item or service, including the request by a physician for a consultation with another physician or any test or procedure ordered by, to be performed by, or to be performed under the supervision of, the other physician. 42 U.S.C. § 1395nn(h)(5)(A). The regulations provide a two-fold definition; a Stark referral is either: (1) a request by a physician for, or ordering, or certifying the need for, Medicare Part B DHS, including a request for a consultation; or (2) a request by a physician for provision of DHS under Medicare, including establishment of a plan of care that includes a DHS. *See* 42 C.F.R. § 411.351. A "consultation" means a professional service, requested by another physician and furnished to a patient, including but not limited to a

physician's advice or opinion as to evaluation or management of a specific medical problem. 42 C.F.R. § 411.351. A "plan of care" arises when a physician establishes a course of diagnosis or treatment for a patient. 42 C.F.R. § 411.351. Thus, to properly plead a Stark violation, the Complaint must allege that the physician defendants referred specific patients to another physician or entity with which they have a financial relationship.

Relators allege no facts to support that any of the Physician Defendants made any referral meeting the standards outlined in the Stark regulations. The Complaint makes no allegation: (1) that Physician Defendants made any request to any other physicians to attend to a particular medical problem; (2) that Physician Defendants established a plan of care for a patient; (3) that Physician Defendants ordered or certified a Medicare Part B DHS; or (4) that Physician Defendants requested the provision of such DHS from another physician or entity. Although Relators baldly assert that Physician Defendants referred patients to "DHS entities (hospitals where the surgery is performed)," they make no factual allegation about which physicians referred what patients to which hospital for what procedures. (Compl. ¶ 332.) Therefore, Relators fail to meet this requirement for pleading a Stark Law violation.

3. Relators have not Alleged that any Entities Submitted Claims to CMS for the DHS.

In Count III, Relators fail to allege that the "hospitals where the surgery is performed" ever submitted claims under the Medicare or Medicaid programs for particular DHS services. Indeed, their lengthy Complaint fails to cite a single instance of a claim for DHS services that was submitted by a physician or entity for payment under the Medicare or Medicaid program. Relators have thus failed to plead the third element of a Stark violation.

In summary, Physician Defendants could not violate the Stark Law by referring their patients to hospitals for DHS while allegedly receiving remuneration *from MSD*—as opposed to the *hospitals* providing care. Relators' Complaint reflects a complete misunderstanding of the Stark Law and the conduct it was designed to regulate. Their Stark Law claim does not meet the standards required to survive a motion to dismiss under Rule 12(b)(6). *See Twombly*, 127 S.Ct. at 1964-65. Because the underlying activity alleged in Count III does not involve a violation of the Stark Law, Count III should be dismissed for failure to state a claim.

IV. THE COMPLAINT IMPROPERLY AND PREJUDICIALLY JOINS UNRELATED DEFENDANTS

As discussed above, the Complaint is so lacking in specificity as to mandate dismissal under both Rules 9(b) and 12(b)(6). This is no mere technical fault. The vagueness of the allegations is extremely prejudicial to each individual defendant, who is unable to discern from the Complaint exactly what he is accused of doing, and is forced to respond to an unfair, moving target. Relators, furthermore, have hidden behind that lack of specificity improperly to join 143 unrelated defendants in the same lawsuit. FRCP 20(a) allows multiple defendants to be joined in the same action only if: (1) "any right to relief is asserted against them jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence or series of transactions or occurrences"; *and* (2) "any question of law or fact common to all defendants will arise in the same action." Plaintiffs "cannot join defendants who simply engaged in similar types of behavior, but who are otherwise unrelated; some allegation of concerted action *between defendants* is required." *United States ex rel. Grynberg v. Alaskan Pipeline Co.*, 1997 WL 33763820, at *1 (D.D.C. Mar. 27, 1997) (emphasis added).

Here, the Relators have failed to identify *any* specific transactions to support their claims and thus cannot show that the defendants participated in same transaction or series of

transactions. A Florida court has discussed misjoinder in a case similar to this one, in which an FCA relator had joined six individual doctors and seven medical centers who were all affiliated with a single HMO. *United States ex rel. Citizens Untied to Reduce & Block Fed. Fraud, Inc. v. Metro Med. Ctr., Inc.*, 1990 WL 10519617 (S.D. Fla. Jan. 11, 1990). Although the court ultimately dismissed the case on FRCP 9(b) grounds, rather than on the basis of prejudicial joinder, it raised concerns about misjoinder of the defendants, stating, "the complaint amounts to no more than an assertion that several doctors, with some loose common affiliation, have each individually defrauded the government." *Id.* at *2. The court further reasoned that "the circumstances attending a fraudulent claim by a particular doctor differ from those surrounding one submitted by another doctor, simply because of the differences in each of their individual operations. A trial of such diverse factual issues would be inconvenient." *Id.*

The abusive joinder of so many defendants is prejudicial, not only because of the burdens of defending against a case of this magnitude, but also because it improperly tarnishes each defendant with the allegations against all others. Joinder transforms what would otherwise be a fairly simple case against any one of the defendants into a large, complex and expensive lawsuit.. That the Relators seek to use this tactic to their unfair advantage is evident from the face of the Complaint. For example, as noted above, Relators seek to impose liability against all of the defendants under Count II, yet make no factual assertions pertaining to Count II as to most of the defendants named. When the misjoinder of multiple, unrelated defendants is as blatant and egregious as it is in this case, dismissal with prejudice is warranted. *See Nassau County Ass'n of Ins. Agents v. Aetna Life & Cas. Co.*, 497 F.2d 1151, 1154 (2d Cir. 1974).

CONCLUSION

For the foregoing reasons, the Physician Defendants respectfully request that the claims against them be dismissed in their entirety, with prejudice.

Respectfully submitted,

Dated: August 15, 2008

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Certificate of Service

I hereby certify that the foregoing document will be sent electronically to the registered participants as identified in the Notice of Electronic Filing ("NEF") and that paper copies will be sent by United States Mail, first class, postage prepaid, to any non-registered participants, on August 15, 2008.

/s/ John W. Lundquist
John W. Lundquist

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*The Group of Physician Defendants included in this Motion are listed in Exhibit A (Attached). All 82 are represented by Fredrikson & Byron, P.A. Nutter, McClennen & Fish, LLP anticipates representing all but a few of the 82 doctors and clinics, and has been retained to date by 57 of them.