UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel.)
SUSAN HUTCHESON AND
PHILIP BROWN,

Petitioners,

v.

CIVIL ACTION NO. 06-11771-WGY

BLACKSTONE MEDICAL, INC.

Respondent.

MEMORANDUM AND ORDER

YOUNG, D.J. March 12, 2010

I. INTRODUCTION

Relators Susan Hutcheson and Philip Brown ("Relators") sued Blackstone Medical Inc., ("Blackstone") in a <u>qui tam</u> action under the False Claims Act, 31 U.S.C. § 3729 <u>et seq.</u> (the "Act"). The claim arises out of Blackstone's alleged nationwide fraudulent scheme to increase the use of its medical devices in spinal surgeries by payment of kickbacks to physicians in violation of the Medicare and Medicaid Patient Protection Act, 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute"). Relators allege that this fraudulent behavior caused the submission by hospitals and doctors of false claims for payment by Medicare, Medicaid, and

other federally-funded government healthcare programs in violation of the False Claims Act.

Blackstone moved to dismiss Relators' complaint on the basis that: (1) it fails to state a claim under Federal Rule of Civil Procedure 12(b)(6) and (2) the alleged fraud is not pled with sufficient particularity under Federal Rule of Civil Procedure 9(b). Blackstone also moved to dismiss Relators' complaint under two jurisdictional bars contained within the False Claims Act: (1) the Act's first-to-file rule, 31 U.S.C. § 3730(b)(5) and (2) the Act's public disclosure bar, 31 U.S.C. § 3730(e)(4)(A).

Blackstone also moved to transfer the case to the Eastern District of Arkansas where another <u>qui tam</u> action against Blackstone and others, alleging violations of the False Claims Act, was filed six months prior to the filing of Relators' complaint with this Court.

II. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

On September 29, 2006, Relators filed, under seal, a <u>qui tam</u> complaint against Blackstone¹ for violation of the False Claims

Act, 31 U.S.C. § 3729. Six months earlier, on April 14, 2006,

John Thomas ("Thomas") filed a <u>qui tam</u> action for violation of the False Claims Act against Blackstone and seven other

defendants including an Arkansas surgeon, Dr. Patrick Chan, in

¹ The original complaint was filed against Blackstone and its parent company, Orthofix International NV. On June 4, 2009, the day that Relators filed their first amended complaint, this Court terminated Orthofix International as a party.

the Eastern District of Arkansas.² <u>United States, ex rel. Thomas</u> v. <u>Bailey</u>, No. 06-00465 (E.D. Ark. filed Apr. 14, 2006).

Thomas's complaint similarly alleged the existence of a fraudulent kick-back scheme including Blackstone, its agents, and the other defendants. It alleged that as a result of the kick-backs, false claims were submitted to federally funded healthcare programs by defendant Dr. Chan. Thomas Compl. ¶ 5 [Thomas Doc. No. 1].³ It also stated on information and belief, that the corporate defendants have and continue to enter into consulting agreements with other physicians in Arkansas and other states in violation of the Anti-Kickback Statute. Thomas Compl. ¶ 57.

Thomas's original complaint contained two counts, alleging violations of 31 U.S.C. § 3729(a)(1) and (2) and conspiracy under 31 U.S.C. § 3729(a)(3). Thomas Compl. ¶¶ 58-62. On April 18, 2007, Thomas moved for partial voluntary dismissal against all defendants except Dr. Chan [Thomas Doc. No. 15]; on April 26, 2007, Thomas withdrew this motion [Thomas Doc. No. 17].

On April 23, 2007 the United States filed an <u>ex parte</u> motion for a partial lifting of the seal in Relators' case to enable it to disclose the existence and allegations contained in Relators'

 $^{^2}$ The seven defendants included Blackstone, Dr. Patrick D.S. Chan, Michael M. Bailey and four corporate entities with which he was affiliated, and Synthes, Inc. <u>U.S. ex rel. John Thomas</u> v. <u>Bailey</u>, No. 06-00465, 2008 WL 4853630, *1 (E.D. Ark. Nov. 6, 2008).

Thomas also alleged that Dr. Chan violated the False Claims Act on the basis that he performed surgeries that were not medically necessary and personally submitted claims for payment for those surgeries to Medicare and Medicaid. Thomas Compl. ¶ 4.

complaint to Thomas. The government's stated rationale was the potential overlap between allegations made in both complaints.

U.S. Ex Parte App. to Part. Lift Seal at 2 [Doc. No. 9]. Judge Lasker granted the application.⁴

On June 20, 2007 - over two months after the partial seal on Relators' complaint was lifted - Thomas amended his complaint, stating that Blackstone entered into improper consulting agreements and other kickback arrangements "throughout the United States," resulting in violations of the False Claims Act. Thomas Am. Compl. ¶ 4 [Thomas Doc. No. 73].

On November 24, 2008, Relators' complaint was unsealed.⁵ In response to Blackstone's first motion to dismiss, Relators amended their complaint on June 4, 2009 [Doc. No. 47]. In their amended complaint, they allege that:

• Blackstone utilized a business model, at the direction of senior management, which consisted of paying surgeons across the United States, in cash and in kind, to use its products in their surgeries. Am. Compl. ¶¶ 65, 69-70.

⁴ On November 21, 2008 the United States filed notice that it was not intervening at that time [Doc. No. 25]. The government informed the Court that its investigation would continue and requested that under 31 U.S.C. § 3730(b)(1), should the court dismiss the suit, the Attorney General be allowed to give written consent. <u>Id.</u> To date, the United States has not intervened in this action; but on September 2, 2009 it filed a statement of interest regarding the defendant's motion to dismiss [Doc. No. 60].

⁵ The initial complaint here also contained a second count, retaliation and wrongful discharge in violation of 31 U.S.C. § 3730(h). Compl. ¶¶ 81-83 [Doc. No. 3]. Relators' amended complaint did not include this second count. [Doc. No. 47].

- Blackstone knew that Medicare, Medicaid, and other federal program beneficiaries represent a significant percentage of spine surgery patients. <u>Id.</u> ¶ 66.
- The payments to surgeons were in excess of fair market value for any services the physicians contributed to Blackstone, and were essentially "kick-backs," taking the form of, inter alia, consulting agreements, payments for travel and accommodations, research grants and royalties. These kick-backs violated the Anti-Kickback Statute, 42 U.S.C. § 320a-7(b), which proscribes knowingly offering to pay any remuneration in cash or in kind in exchange for the referral of any product for which payment is sought from any federally-funded healthcare program. Id. ¶¶ 25, 33, 67.
- As a result of Blackstone's illegal inducements, physicians performed surgeries using its products on Medicare and Medicaid patients admitted to healthcare facilities around the country. $\underline{\text{Id.}}$ ¶ 24.
- Blackstone caused hospitals and doctors to submit false claims to federal healthcare programs because compliance with the Anti-Kickback Statute is a condition of payment for federallyfunded healthcare programs. Essentially, the claims submitted as a result of illegally-induced surgeries were false claims.
 Id. ¶ 64.

II. FEDERAL JURISDICTION

Federal jurisdiction is proper because this claim arises under the United States False Claims Act, 31 U.S.C. § 3729, giving the Court jurisdiction under 28 U.S.C. § 1331.

III. ANALYSIS

A. The Motion to Transfer

Blackstone moves pursuant to this section to transfer this action to the Eastern District of Arkansas. Under 28 U.S.C. § 1404(a), a district court may transfer any civil action to any other district where it may have been brought "[f]or the convenience of parties and witnesses, in the interests of justice." 28 U.S.C. § 1404(a). The burden of proof in a motion

to transfer rests with the party seeking transfer. <u>Coady</u> v. <u>Ashcraft & Gerel</u>, 223 F.3d 1, 11 (1st Cir. 2000).

The First Circuit has described 28 U.S.C. Section 1404(a) as a codification of forum non conveniens. Albion v. YMCA Camp Letts, 171 F.3d 1, 2 (1st Cir. 1999). Thus, in evaluating a motion to transfer, courts look to such factors as "the relative convenience to each of the parties, the 'relative ease of access to sources of proof,' the availability of compulsory process for attendance of unwilling' witnesses, and the relative availability of documentary and tangible evidence, as well as the public interest in the administration of justice, including trial efficiency." Veryfine Products, Inc. V. Phlo Corp., 124 F. Supp. 2d 16, 24 (D. Mass. 2000) (quoting Gulf Oil Corp. V. Gilbert, 330 U.S. 501, 508-09 (1947)). In terms of convenience to the parties and witnesses and availability of evidence, neither forum is favored. The Relators are both residents of Florida. Am. Compl. ¶¶ 10, 14. Blackstone, was a Massachusetts-based company, but now is located in Texas. Blackstone Mem. in Supp. Mot. Transfer at 13-14. More importantly, its relevant records are maintained electronically and can be produced in any jurisdiction with relative ease. Id. at 13. Finally, the ninety-one doctors alleged to have been involved in its alleged kick-back scheme are scattered across the country. Am. Compl. ¶ 84.

Ordinarily, there is a strong presumption in favor of the plaintiff's choice of forum. <u>Coady</u>, 223 F.3d at 11. There is sound empirical basis for this presumption. Studies confirm that

when a defendant can winkle a plaintiff out of her chosen forum, the defendant's likelihood of success increases markedly. See Kevin M. Clermont & Theodore Eisenberg, Exorcising the Evil of Forum-Shopping, 80 Cornell L. Rev. 1507, 1511-12 (1995) ("[T]he plaintiff wins in 58% of the nontransferred cases that go to judgment for one side or the other, but wins in only 29% of such cases in which a transfer occurred.").

Although the First Circuit has not ruled on the application of this presumption to nonresidents, this Court looks to Judge Wolf's decision in U.S. ex rel. Ondis v. City of Woonsocket, R.I., 480 F. Supp. 2d 434, 436 (D. Mass. 2007), as persuasive. In deciding to transfer the nonresident plaintiff's case, Judge Wolf cited 15 Wright, Miller & Cooper, Federal Practice and Procedure: Jurisdiction 3d § 3848 at 134-39 (2007) for the legal principle that plaintiff's choice of venue carries less weight when the district court has "no obvious connection to the case or the plaintiff is a nonresident." The "strong presumption" afforded plaintiff's choice of venue is based principally on the notion of convenience to the plaintiffs. See Nowak v. Tak How <u>Investments</u>, <u>Ltd.</u>, 94 F.3d 708, 718 (1st Cir. 1996). When plaintiffs choose a forum where they are not residents, this justification is diminished, and concerns of forum-shopping arise. See Williams v. Bowman, 157 F. Supp. 2d 1103, 1107 (N.D. Cal. 2001) ("The policy behind not deferring to a nonresident plaintiff's choice of venue appears tied into the notion that plaintiffs should be discouraged from forum shopping.").

Although the Relators' choice of venue carries less weight than if they were residents, Blackstone still carries the burden of convincing the Court that transfer is appropriate.

With no overriding concerns of convenience to the parties or witnesses, the Court turns to the arguments regarding the administration of justice. Blackstone argues strongly that "judicial economy" and comity dictate transferring this case to the Eastern District of Arkansas because that court already has invested so much time in the case. Blackstone Mem. in Supp. Mot. Transfer at 8-9. Not surprisingly, the Eastern District of Arkansas has narrowed the issues in Blackstone's favor. Relators point out that the Eastern District of Arkansas was not extensively briefed on the nationwide nature of Blackstone's activities, and that the Thomas and Hutcheson cases overlap only to the extent of detailing the illegal kickbacks associated with Drs. Chan and Jordan. Relators' Opp. to Mot. Transfer at 16.

Courts are justly wary of disputed claims of "judicial economy." Joint motions, or a claim that seeks judicial action from the judge then charged with responsibility for the case, are one thing. Other such claims usually involve thinly disguised efforts at forum shopping or seeking delay in the hope that some

⁶ The Arkansas court held that under either express or implied theories of certification, the False Claims Act is not triggered when an innocent third party submits a claim to the federal government, even if violations of the Anti-Kickback Statute have occurred somewhere in the chain of events leading up to the filing of the claim. Thomas, 2008 WL 4853630, at *13-14. As will be discussed, infra, this Court reaches the same conclusion, for the most part.

court somewhere will render a decision that would favor the moving party. See, e.g., Sabin Willett, Clericalism and the Guantanamo Litigation, 1 Northeastern U.L.J. 51, 56 (2009) (discussing the tactic of delay in the Guantanamo detainee cases). Both maneuvers are properly disfavored.

Actually, there are neutral principles on which a claim of judicial economy may be evaluated. As Relators argue, the statistics maintained by the Administrative Office of the United States favor denying the motion to transfer. Relators' Opp. to Mot. Transfer at 14. The Eastern District of Arkansas has five authorized judgeships (one of which is vacant) and, on a per judge basis, the second highest caseload of all the ninety-four United States District Courts. 2008 Federal Court Management Statistics, Administrative Office of the United States, 111. In light of this heavy caseload, it is no surprise that the Eastern District of Arkansas has 1,630 civil cases over three-years old. Id.

The District of Massachusetts, with thirteen authorized judgeships (one of which is vacant)⁷, on a per judge basis has a

⁷ <u>But see</u> Report of the Proceedings of the Judicial Conference of the United States, March 17, 2009, at 23. As I have written:

[[]F]rom time to time the Judicial Conference takes upon itself the authority to advise the President not to nominate judges to fill vacancies it deems superfluous. It makes this decision by fixing an arbitrary cutoff point based upon the court's "weighted caseload," derived by a methodology that has been sharply (and accurately) criticized by independent observers. . . . While the "weighted caseload" ranking may be modified by various gestalt factors, none of them have anything to do with

far lighter caseload and only 197 civil cases over three-years old. <u>Id.</u> at 38. Any rational calculus of actual judicial economy thus strongly favors keeping this case in the judicial workload of the District of Massachusetts.

The most relevant performance criteria confirm this judgment. Among the forty-three district courts with six or more judges, the District of Massachusetts ranks ninth⁸ in time actually spent on the bench conducting evidentiary hearings and fifteenth in total time out on the bench actually engaging in the

the actual work being performed by the judges of the affected court, i.e. the on bench and trial time of those judges.

Even putting aside the larger issues of the separation of powers - the fact that the Judicial Conference is, in effect, advising the President not to enforce a law passed by Congress setting the number of district judges within each judicial district and is interfering with the Senate's constitutional prerogative to advise and consent to such nominations - what message does this communication send to the people of the affected district? Cf. S. Rep. No. 110-427, at 2-5, 20-21 (revealing the extent of the Judicial Conference's influence over Congress's power to constitute the lower courts, and including Sen. John Cornyn's objections on behalf of his district to the Administrative Office's recommendations). Can it be that the speed and quality of justice is too high in those locations and we need to And what of the active judges in such a district, knocking themselves out to try the cases before them and help other courts as well? Each one must know that, should she falter or fail, it is the official policy of the Judicial Conference that her seat shall lie vacant and her courtroom go dark.

William G. Young, <u>A Lament for What Was Once and Yet Can Be</u>, 32 B.C. Int'l. & Comp. L. Rev. 305, 317-318 n.72 (2009) ("Lament") (internal citations omitted).

⁸ The Eastern District of California ranks first.

adjudication of disputes. Rankings derived from Table C-12, Trials and Trial Days for Each Place of Holding Court During the Twelve Month Period Ended June 30, 2009, Judicial Business of the United States Courts. Today the average active district judge tries only five civil cases per year, the average district

[As reported in the publicly accessible Federal Court Management Statistics the Judicial] Conference has debased the term "trial." The term once denoted a jury or bench proceeding that led to a verdict; now it encompasses any disputed evidentiary hearing. Thus a criminal case with a motion to suppress, a Daubert hearing, a genuine trial, and a sentencing hearing counts as four "trials," as does a civil patent case with a preliminary injunction hearing, a Markman hearing, a genuine trial, and a separate damages hearing. result, the Administrative Office inflates the actual number of trials by approximately 33%. However much this may impress Congress, such imprecision renders the term "trial" essentially meaningless, a result not lost on scholars and the knowledgeable press.

Lament at 317 (footnotes omitted) (citing Zach Lowe, <u>Federal</u> <u>Court Statistics</u>, <u>or: How Numbers Can Drive You Mad</u>, Law.com, Sept. 2, 2008, http://www.law.com/jsp/law/LawArticleFriendly.jsp?id=1202424181868 (last visited Apr. 16, 2008) and Theodore Eisenberg & Margo Schlanger, <u>The reliability of the Administrative Office of the U.S. Courts Database: An Initial Empirical Analysis</u>, 78 Notre Dame L. Rev. 1455, 1470-73 (2003) (comparing the Administrative Office's database records and case

⁹ Again, the Eastern District of California ranks first.

¹⁰ Yet again, the Eastern District of California ranks first. The District of Montana ranks first in criminal trials with nineteen such trials per active district judge. The Southern District of Iowa ranks first overall with twenty-three civil and criminal trials per active district judge as compared to thirteen for the Eastern District of Arkansas and ten for the District of Massachusetts. The Court is well aware that the 2008 Federal Court Management Statistics report, under "Actions per Judgeship - Trials Completed" that each active judge in the Eastern District of Arkansas completed twenty-three "trials", see id. at 111, and each such judge in Massachusetts completed twenty "trials." See Id. at 38. Unfortunately, these figures do not reflect reality.

judge in the Eastern District of Arkansas tries eight such cases, and the average district judge in the District of Massachusetts tries seven. Rankings derived from Table T-1, Civil and Criminal Trials by District, during the Twelve Month Period Ended June 30, 2009, Judicial Business of the United States Courts.

Considered on the basis of neutral principles and accurate measures of productivity, therefore, the disparity in caseload alone as between the Eastern District of Arkansas and the District of Massachusetts strongly counsels against transfer.

For all of these reasons, the motion to transfer is denied.

B. False Claims Act's First to File Rule

The False Claims Act prohibits false or fraudulent claims for payment to the federal government and permits civil actions based on such claims to be brought by the Attorney General or by private individuals, called "relators," acting in the government's name. 31 U.S.C. § 3730(a), (b). Where the government elects not to intervene, the so-called <u>qui tam</u> plaintiff may proceed with the action as the government's assignee. 31 U.S.C. § 3730(c)(3).

Under the Act, liability attaches 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. 31 U.S.C. § 3729(a)(1)-(2); United States ex rel. Rost v. Pfizer,

dockets in PACER for tort and inmate cases, and concluding that the Administrative Office method of recording judgments created disparities in the data)).

Inc., 507 F.3d 720, 727 (1st Cir. 2007). The Act was adopted following a congressional investigation into the sale of munitions and provisions to the war department. <u>United States</u> v. McNinch, 356 U.S. 595, 599 (1958). The investigation revealed that the United States had been over-charged for goods, and billed for goods that were never delivered or were worthless.

Id. The Supreme Court has made it clear that the Act was not designed to reach all types of fraud performed upon the Government. Id.

"The threshold question in a False Claims Act claim is whether the statute bars jurisdiction," Rost, 507 F.3d at 727.

Under the False Claims Act's first-to-file bar, "[w]hen a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5).

"The first-to-file rule furthers the policy of the [False Claims Act] 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.'" United States ex rel. Duxbury v. Ortho Biotech Products, L.P., 551 F. Supp. 2d 100, 110 (D. Mass. 2008) (Zobel, J.) rev'd on other grounds, 579 F.3d 13 (1st Cir. 2009) (quoting United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1187 (9th Cir. 2001)).

The question for the Court, therefore, is whether Relators' case is "a related action based on the facts underlying" the Thomas action, and therefore jurisdictionally barred under the

False Claims Act's first-to-file rule. In an August 2009 case, the First Circuit interpreted Section 3730(b)(5) to "bar a later allegation [if it] states all the <u>essential facts</u> of a previously-filed claim or the same <u>elements</u> of a fraud described in an earlier suit." <u>Duxbury v. Ortho Biotech Products</u>, 579 F.3d 13, 32 (1st Cir. 2009) (quoting <u>United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.</u>, 149 F.3d 227, 232-33 (3d Cir. 1998)) (internal quotes omitted). It also held that "[u]nder this 'essential facts' standard, § 3730(b)(5) can still bar a later claim 'even if that claim incorporates somewhat different details.'" <u>Id.</u> (quoting <u>LaCorte</u>, 149 F.3d at 232-33.)

Therefore, under <u>Duxbury</u>, this Court must examine whether Relators' complaint contains the same "essential elements" and determine whether this action is barred because the <u>Thomas</u> complaint served its purpose - to put the federal government on notice of the essential facts of a fraudulent scheme. 579 F.3d at 32. In order to ascertain the essential elements of both complaints, this Court compares the factual allegations made against Blackstone in the Thomas complaints with Relators' amended complaint currently before this Court.¹¹

¹¹ Thomas filed four complaints in total. The first was filed on 4/14/2006. An amended complaint was filed on 6/20/2007 [Thomas Doc. No. 73]; a second amended complaint was filed on 11/20/2008 [Thomas Doc. No. 228]; and a third amended complaint was filed on 12/29/2008 [Thomas Doc. No. 240]. Importantly, the allegations of a "nationwide policy" against Blackstone appeared in the amended complaint, but did not appear in the second or third amended complaints. Despite this pleading irregularity, The District Court of Arkansas referred to the "nationwide scheme" allegations as though they were made in the second amended complaint, and made a ruling dismissing Thomas's claims

Thomas Complaint (E.D. Ark.) (April 14, 2006): Thomas alleged that: (1) Dr. Chan had a consulting agreement with Blackstone which required him to use Blackstone products, Thomas Compl. ¶ 44; (2) a Blackstone employee paid for the honeymoon of one of Dr. Chan's nurses and gave the nurse an expensive wedding gift, id. ¶ 46; and (3) upon information and belief that Blackstone had in the past and was continuing to enter into consulting agreements "with other physicians in Arkansas and other states that illegally induce those physicians to use their products in spinal surgical procedures, in violation of the Anti-Kickback Statute." Id. ¶ 57 (emphasis added).

Hutcheson Complaint (D. Mass.) (September 9, 2006): Relators alleged that Blackstone engaged in a fraudulent scheme of kickbacks to physicians throughout the United States in the form of sham consulting agreements, research grants, entertainment, travel, and other illegal incentives in order to increase its market share, and in doing so caused violations of the False Claims Act. Compl. ¶¶ 1-2.

Thomas Amended Complaint (E.D. Ark.) (June 20, 2007): Thomas alleged that: (1) the contract amount of the Blackstone

pertaining to a nationwide fraudulent scheme for failing to plead with particularity as required by Federal Rule of Civil Procedure 9(b). See Thomas, 2008 WL 4853630, at *8. In the interest of thoroughness, this Court compares the factual allegations made in all four Thomas complaints with those made in Relators' complaint and amended complaint.

consulting agreement presented to Dr. Chan was for \$25,000 and featured no performance standards or description of the work to be done, Thomas Am. Compl. ¶ 45; and (2) Blackstone's "practice of entering into unlawful consulting agreements and other kickback arrangements with physicians was a matter of corporate policy that extended to other physicians in Arkansas and elsewhere in the United States." Id. ¶ 52 (emphasis added). In support of this, the complaint alleged that the Blackstone consulting agreement presented to Dr. Chan was a "corporate form" agreement, and listed alleged kickback arrangements between Blackstone and several other doctors in Arkansas, Missouri, and Mississippi. Id. ¶¶ 45, 55-61.

Thomas Second Amended Complaint (E.D. Ark.) (November 20, 2008):
Thomas alleged that: (1) Dr. Chan was a paid member of
Blackstone's "Medical Advisory Board," Thomas 2d Am. Compl. ¶ 39;
and (2) an agent of Blackstone provided childcare and homecare
services and performed personal tasks and errands for Dr. Chan.

Id. ¶ 49. This version of the complaint contained no allegations
of a "nationwide scheme."

Thomas Third Amended Complaint (E.D. Ark.) (December 29, 2008):

This complaint reiterated the factual allegations made in the second amended complaint pertaining to Blackstone's alleged kickbacks to Drs. Chan and Jordan, and again contained no allegations of a "nationwide scheme."

<u>Hutcheson Amended Complaint (D. Mass.)(June 4, 2009):</u> Relators allege that Blackstone: (1) entered into "sham" consulting agreements with consultants across the United States in order to increase the number of surgeries performed using BMI products, Am. Compl. ¶¶ 2, 73, 86; and (2) this consulting scheme included kickbacks such as (a) an "education grant" to a surgeon for "sponsorship" of his website, id. ¶ 120; (b) paying surgeons to engage in sham research studies long after BMI products had been researched, developed, and launched, <u>id.</u> ¶¶ 134, 147, 86; (c) offering per diem "studies" on a per-patient basis to incentivize surgeons to use its products, id. ¶ 207; (d) paying royalties to surgeons for the development of certain products, id. ¶ 205; (e) paying surgeons to perform cadaver labs demonstrating Blackstone products to sales representatives, id. ¶ 208; (f) paying surgeons in stock rather than cash, <u>id.</u> ¶¶ 209-10; (g) lavishing entertainment and VIP travel on consultants and their families, id. ¶¶ 213-17; and (h) providing cash incentives to consultantsurgeon's staff. Id. ¶ 223. In support of their claim that Blackstone had a nationwide kickback program, Relators allege that at least ninety-one doctors from across the United States received some sort of kickback from Blackstone. Id. ¶ 84.

In <u>Duxbury</u>, upon an almost identical set of events, the First Circuit reversed the district court's dismissal of a second complaint under the first-to-file bar. Three paragraphs in a first-filed complaint alleged that pharmaceutical company Orthofix N.V. caused inflated claims for its product, Procrit, to

be submitted to Medicare by, <u>inter alia</u>, using cash payments to encourage physicians, clinics and hospitals to undertake "off label" uses of Procrit. <u>Duxbury</u>, 551 F. Supp. 2d at 111-12. A complaint from a second relator, filed one month later, alleged a promotional scheme of "off label" use, including:

(1) direct off-label marketing to medical professionals; (2) influencing the results of purportedly independent clinical studies; (3) illegal payments to medical professionals in the form of 'educational grants' and 'clerkships;' (4) payments to medical professionals for giving presentations on increased dosage of Procrit; (5) attending consulting conferences sponsored by OBP which pushed increased dosage of Procrit; and (6) rebate programs offered to induce increased prescriptions of Procrit.

Duxbury, 551 F. Supp. 2d at 113.

On appeal, the First Circuit held that the first complaint could not trump the second because it failed "to encompass the other allegations contained in the [second complaint] concerning [Ortho Biotech]'s 'off-label' promotion," and therefore it failed to "allege the 'essential facts' of the 'off-label' promotion scheme contained in the [second complaint]." <u>Duxbury</u>, 579 F.3d at 33.

Here, the first Thomas complaint made only passing "information and belief" reference to false claims arising out of illegal kickbacks beyond Arkansas. Moreover, it alleged a consulting agreement with only one doctor. The allegations contained in the Hutcheson complaint, including research engagements, VIP travel, stock payments and royalties involving at least ninety-one doctors across the United States are more

than simply "details," but essential elements of a <u>nationwide</u>

<u>fraudulent scheme</u>. The Hutcheson complaint is not barred,

therefore, because it does not allege "the same elements of a

fraud described in an earlier suit." For these reasons, the

Court denies Blackstone's motion to dismiss based upon the first

to file bar.

C. False Claim Act's Public Disclosure Rule

The False Claim Act's public disclosure bar provides that a district court does not have subject matter jurisdiction over any qui tam action that is "based upon the public disclosure of allegations or transactions" concerning the alleged fraud, unless, among other things, "the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A). A relator qualifies as an "original source" if she has "direct and independent knowledge" of the information supporting her claims and she "provided the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B).

In <u>Duxbury</u>, the First Circuit discussed the inquiries necessary to determine whether a claim is barred by an earlier public disclosure. <u>Duxbury</u>, 579 F.3d at 21. They are:

(1) whether there has been public disclosure of the allegations or transactions in the relator's complaint; (2) if so, whether the public disclosure occurred in the manner specified in the statute; (3) if so, whether the relator's suit is 'based upon' those publicly disclosed allegations or transactions; and (4) if the answers to these questions are in the affirmative, whether the relator falls within the 'original source' exception as defined in § 3730(e)(4)(B).

<u>Id.</u> (citing <u>Rost</u>, 507 F.3d at 728).

Blackstone contends that this suit is based upon public information and relators are not the original source of that information. Def.'s Mem. in Supp. Mot. to Dismiss at 6. Specifically, Blackstone asserts that Relators' allegations of its "campaign to induce physicians to perform surgeries utilizing its medical products by paying illegal kickbacks" were first publicly disclosed in an earlier complaint. Id. at 6-7.

In support of this proposition, Blackstone cites Berrios v. Blackstone Medical, Inc., No. 05-17339 (Brevard Co., Fla., filed May 16, 2005), a negligence and strict liability action brought by a patient who had faulty Blackstone devices implanted during spinal surgery. Blackstone points out that in her complaint, Berrios contended that Blackstone "routinely provides incentives to orthopedic surgeons to use their devices over those of their competitors, including, upon information and belief, offering practitioners paid travel and entertainment labeled as 'continuing medical education' and paying financial incentives to high-volume users under the guise of 'consulting' agreements." Def.'s Mem. in Supp. of Mot. to Dismiss at 7 quoting Berrios Compl. ¶ 10. Blackstone further contends that Hutcheson and Brown, the Relators here, have simply "declared" themselves relators and that such conclusory assertions do not meet Relators' burden of pleading facts that establish this Court's jurisdiction. Id. at 8.

Relators assert that: (1) the <u>Berrios</u> complaint was not a public disclosure of the "massive kickback fraud alleged by

relators in this case"; (2) Berrios' allegation regarding the Blackstone kick-back scheme was based on "information and belief" and therefore not "statutorily significant"; 12 (3) Relators' allegations were not "based upon" the Berrios complaint because they were not aware of the allegations contained within it; and (4) Relators are "original sources" on the basis that while employed by Blackstone they gained significant insider knowledge which formed the basis of their allegations. Pls.' Opp'n to Mot. to Dismiss at 5-9 [Doc. No. 58]. Relators further specify that they disclosed the allegations of the complaint, prior to filing, to the United States Attorney's Office for the Middle District of Florida in the summer of 2006 and disclosed the allegations of the complaint to the United States Attorney's Office for the District of Massachusetts in October 2006. Am. Compl. ¶ 8.

Although it was entirely unrelated either to the False Claims Act or Anti-Kickback Statute, the <u>Berrios</u> complaint publicly disclosed Blackstone's kickback scheme in the manner specified in the statute. The First Circuit has recognized that "a filing to a government body such as a court (not under seal) where all records are public could be public disclosure." <u>Rost</u>, 507 F.3d at 728, n.5.

Relators rely on a Texas district court, which held that it is difficult to claim that "one paragraph in a purely private litigation . . . actually put the government on notice of the scheme alleged by Relator." <u>United States ex rel. Smart</u> v. CHRISTUS Health, 626 F. Supp. 2d 647, 655 (S.D. Tex. Jan. 2009).

Here, however, Relators' complaint is not "based upon" the Berrios complaint. Under Rost, an "action is 'based upon' a public disclosure of allegations only where the relator has actually derived from that disclosure the allegations upon which his qui tam action is based." 446 F. Supp. 2d at 19 (quoting United States ex rel. Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1348 (4th Cir. 1994)).

This Court holds that the "original source" exception to the public disclosure bar applies to relator Hutcheson. Relator Hutcheson was a regional manager, employed by Blackstone between January 2004 and January 2006. She states that she observed Blackstone's business practices while in their employ, and was privy to meetings, conversations, and other internal communications. In the regular course of her job duties, she also had access to email and internal documents and data which reflected the conduct discussed in the complaint, including communications and documents circulated among upper management.

Am. Compl. ¶¶ 11-12.

Relator Brown's contribution to the complaint is comparatively weaker than Hutcheson's. Brown states that he was a distributor for Blackstone in 2004 and that part of his role was to develop a Blackstone consulting relationship with physicians in his territory. Am Compl. ¶ 15. Brown does not appear to have contributed significant facts or data, and acknowledges that his interactions with Blackstone representatives and physicians merely support and confirm many of

the allegations contained in the complaint. <u>Id.</u> On this basis, the Court agrees with Blackstone's contention that Brown's claim to be an "original source" is conclusory, and insufficient to meet his burden of pleading facts establishing the Court's jurisdiction.

The motion to dismiss based on the False Claims Act's public disclosure bar as to relator Hutcheson is denied on the basis that she is an "original source" under the Act. The motion to dismiss based on the False Claim Act's public disclosure bar as to relator Brown is allowed.

D. Motion to Dismiss for Failure to State a Claim

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) challenges a complaint on the basis that it fails to state a claim upon which relief can be granted. To survive a motion to dismiss under the Rule, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). A pleading that merely offers "labels and conclusions" or a "formulaic recitation of the elements of a cause of action" is insufficient. Id. at 555.

1. False Claims Act Standard of Review

An individual violates the False Claims Act when he "knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for

payment or approval." 31 U.S.C. § 3729(a)(1). To clarify the elements necessary to state a claim under the False Claims Act, numerous circuits have created specific tests. The Fourth, Fifth and Ninth Circuits enquire: "(1) whether 'there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim).'" United States ex rel. Longhi v. United States, 575 F.3d 458, 467 (5th Cir. 2009) (quoting United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 376 (4th Cir. 2008)); see also United States ex rel. Hendow v. University of Phoenix, 461 F.3d 1166, 1177-78 (9th Cir. 2006). The Second Circuit uses a five-part test requiring the individual to show (1) a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing its falsity, and (5) seeking payment from the federal treasury. United States ex. rel. Mikes v. Straus, 274 F.3d 687, 695 (2d Cir. 2001) (utilizing a five-part test where a violation of the FCA is shown when an individual). The First Circuit explained that:

[T]he [False Claims Act] 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.

<u>United States ex rel. Karvelas</u> v. <u>Melrose-Wakefield Hosp.</u>, 360 F.3d 220, 225 (1st Cir. 2004). In addition, the First Circuit

held that the false claim must be material in <u>United States</u> v.

<u>Data Translation</u>, <u>Inc.</u>, 984 F.2d 1256, 1267 (1st Cir. 1992). In an attempt to provide greater clarity on the necessary elements for a claim under the False Claims Act, this Court will break down the First Circuit requirements to separate specific elements. Thus, to state a claim under the False Claims Act, an individual must allege that the accused: (1) knowingly presented or caused to be presented, (2) a false claim, (3) to the United States government, (4) knowing its falsity, (5) which was material, (6) seeking payment from the federal treasury.

a. Knowingly Presented or Caused to Be Presented
There are two roads to submitting a false claim to the
government. An entity or person can actually submit the claim
itself or cause another entity or person to submit the claim.
The second road, the "causes to be presented" prong of the False
Claims Act, results when the submission was the reasonably
foreseeable result of a defendant's actions. Rost, 507 F.3d at
733 n.9 ("under the [False Claims Act] . . . [t]hat there were
allegedly intervening persons who actually submitted the claims
does not itself necessarily break the causal connection when the
claims are foreseeable").

b. False Claim

The next inquiry is whether the plaintiff sufficiently alleged the existence of a "false or fraudulent claim." There are three theories under which a claim may be "false or fraudulent" under the False Claims Act. They are: (1) factual

falsity; (2) legal falsity under an express certification theory; and (3) legal falsity under an implied certification theory.

i. Factual Falsity

A "factually false" claim is defined as a claim in which the goods or services provided are either incorrectly described, or make claim for a good or service never provided. Mikes v. Straus 274 F.3d 687, 697 (2d. Cir. 2001) (citing Robert Fabrikant & Glenn E. Solomon, Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry, 51 Ala. L. Rev. 105, 111-12 (1999)).

ii. Legal Falsity Under Express Certification

In amending the False Claims Act in 1986, Congress emphasized that the scope of false or fraudulent claims should be broadly construed such that "each and every claim submitted under a contract, loan guarantee, or other agreement which was originally obtained by means of false statements or other corrupt or fraudulent conduct, or in violation of any statute or applicable regulation, constitutes a false claim." S. Rep. No. 99-345, at *9 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5274. Thus, the coverage of the False Claims Act has been extended to cover claims that are legally false, that is where a party certifies compliance with a statute or regulation as a condition to government payment, but did not actually comply with the statute or regulation. See U.S. ex rel. Conner v. Salina Regional Health Center, Inc., 543 F.3d 1211, 1217 (10th Cir. 2008); U.S. ex rel. Quinn, v. Omnicare, Inc., 382 F.3d 432, 440-

41 (3d Cir. 2004); Mikes, 274 F.3d at 697; United States ex rel.

Siewick v. Jamieson Science & Engineering, Inc., 214 F.3d 1372,

1375-76 (D.C. Cir. 2000); Harrison v. Westinghouse Savannah River

Co., 176 F.3d 776, 785-87 (4th Cir. 1999); United States ex rel.

Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997); United States ex rel. Hopper v. Anton, 91 F.3d 1261,

1265-66 (9th Cir. 1996). The First Circuit has not defined legal falsity in the context of the False Claims Act, although it has recognized that other courts have found liability for legally false claims. See Karvelas, 360 F.3d at 232 n.15.

A claim is legally false under an express certification theory when the party making the claim expressly states that it has complied with the applicable statutes' regulations, where such compliance is a precondition of payment. Conner, 543 F.3d at 1217. This theory is satisfied any time a claimant expressly states compliance with prerequisites of payment -- there is no specific form of "certification" required. See Hendow, 461 F.3d at 1172 ("So long as the statement in question is knowingly false when made, it matters not whether it is a certification, assertion, statement, or secret handshake; False Claims liability can attach.").

iii. Legal Falsity Under Implied Certification

There appear to be three definitions of the implied

certification theory of legal falsity. Some courts hold that a

claim is legally false under an implied certification theory

where a claimant makes no express statement about compliance with

a statute or regulation, but by submitting a claim for payment implies that it has complied with any preconditions to payment. Conner 543 F.3d at 1218; <u>United States ex rel. Augustine</u> v. Century Health Systems, Inc., 289 F.3d 409, 415 (6th Cir. 2002); Mikes, 274 F.3d at 699. Other courts have held that the implied certification theory is essentially a materiality analysis where the government would not have paid funds had it known of a violation of a law or regulation. See United States ex rel. Poque v. Diabetes Treatment Centers of America, Inc., 238 F. Supp. 2d 258, 264 (D.D.C. 2002); see also In re Pharma. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 12, 18 (D. Mass. 2007) (Saris. J.) (holding that hospitals submitted legally false claims under an implied certification theory for Medicaid reimbursement when they failed to comply with the Anti-Kickback Statute because Medicare requires compliance with the Anti-Kickback Statute). Finally, there is a definition that implied certification exists where a statute requires express certification, but the claimant did not expressly certify. Siewick, 214 F.3d at 1376 (holding that courts will "infer certification from silence, but only where certification was a prerequisite to the government action sought"); Harrison, 176 F.3d at 787 n.8, 793.

This Court rules that the first definition is the proper definition for the implied certification theory. As to the second definition, because this Court holds that materiality is a separate element of a claim under the False Claims Act, analysis

of whether the claim is false <u>vel non</u> ought not be based on the materiality of the false statement. The third definition fits within either the express certification theory or the implied certification theory, but is not broad enough fully to define either theory completely. In adopting the first definition, this Court agrees with the logic of <u>Mikes</u> as to the implied theory of liability, restricting such liability to compliance with expressly stated preconditions of payment found in the relevant statute or regulations. 274 F.3d at 700.

c. Knowingly

The Act was amended in 1986 to clarify that specific intent is not required in order to find a violation of the Act. 31 U.S.C. 3729(b). Instead, "knowingly" means that the defendant had actual knowledge that the information is false, acted in deliberate ignorance of the truth or falsity of the information, or acted in reckless disregard of the truth or falsity of the information. Id.

d. Materiality

Numerous circuits have explicitly required a "materiality" element regarding the government's decision to pay a claim in False Claims Act cases. See Longhi, 575 F.3d at 470; United States v. Bourseau, 531 F.3d 1159, 1170-71 (9th Cir. 2008); United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc., 400 F.3d 428, 445 (6th Cir. 2005); United States ex rel. Costner v. U.S., 317 F.3d 883, 889 (8th Cir. 2003); Harrison, 176 F.3d at 785; Luckey v. Baxter Healthcare Corp., 183 F.3d 730,

732-33 (7th Cir. 1999); <u>Data Translation</u>, 984 F.2d at 1267 (holding that any jury instruction error was harmless because Government failed to show that alleged nondisclosure was material). While the Second Circuit has not adopted a materiality element in the claim requirements, it has stated that the False Claims Act "does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions." <u>Mikes</u>, 274 F.3d at 697.

Nonetheless, there is not a consistent definition of materiality and the First Circuit did not provide one in Data Translation. The Fourth, Sixth, Ninth Circuit and Fifth Circuits adopted a "'natural tendency test' for materiality, which focuses on the potential effect of the false statement when it is made rather than on the false statement's actual effect after it is discovered." Longhi, 575 F.3d at 470 (quoting Bourseau, 531 F.3d at 1171). In contrast, the Eighth Circuit relies upon an "outcome materiality test," which requires a showing that the defendant's actions (1) had "the purpose and effect of causing the United States to pay out money it [was] not obligated to pay," or (2) "intentionally deprive[d] the United States of money it is lawfully due." Bourseau, 531 F.3d at 1171 (quoting Costner v. <u>URS Consutlants, Inc.</u>, 153 F.3d 667, 677 (8th Cir. 1998)). justifying its decision to adopt the "natural tendency test," the Fifth Circuit explained that in passing the Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. No. 111-21, § 4, 123 Stat. 1617 (2009) (codified at 31 U.S.C. § 3729), Congress clarified

its intent for the False Claims Act by adding the following language to §3729 (b): "(4) the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." Longhi, 575 F.3d at 470 (quoting 31 U.S.C. § 3729(b)). This Court follows the reasoning of the Fifth Circuit and adopts the "natural tendency test" such that it considers whether the government likely would have declined to pay had they known of the fraud.

e. Seeking Payment from the Federal Treasury

Finally, the last element of a claim under the False Claims Act was defined in <u>Rivera</u>, where the First Circuit held that liability under the Act may occur even where a contractor "did not actually induce the government to pay out funds or to suffer any loss," but required a court to inquire whether "within the payment scheme, the [claim] has the practical purpose and effect, and poses the attendant risk, of inducing wrongful payment." 55 F.3d at 709-10.

2. Application

With the elements thus defined, the Court turns to whether the Amended Complaint states a claim under the False Claims Act. The Amended Complaint alleges that Blackstone paid doctors a fee to act as consultants. Am. Compl. ¶ 72. The doctors did no actual consulting for Blackstone, however, rather the payment was an inducement to the doctors to use Blackstone products in their spinal surgeries. Id. ¶ 73. The Amended Complaint alleges that this arrangement provided doctors a kick-back in violation of the

Anti-Kickback Statute, 42 U.S.C. § 320a-7b(b). The Amended Complaint alleges that Blackstone created and used this program as a means to increase the use of its products. Id. ¶ 68. It also alleges that Blackstone executives were aware that reimbursement would be sought from government health programs for many of the surgeries performed. Id. ¶ 66.

Both the doctors and hospitals submitted claims for reimbursements of many of these surgeries to Medicare, Medicaid, and other government health programs. <u>Id.</u> ¶ 243. The doctors submitted claims requesting reimbursement for their services, such as performance of the surgery, and the hospitals submitted claims for use of the hospital and reimbursement for the products, including Blackstone's products, used in the surgeries. <u>Id.</u> ¶¶ 51, 53.

Before seeking any reimbursement from Medicare, hospitals and physicians enter into a Provider Agreement to establish their eligibility to seek such reimbursement. <u>Id.</u> \P 57. The Provider Agreement states, in part:

I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback Statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Id. (quoting Form CMS-855A; Form CMS-855I) (emphasis added). In
addition, Hospitals must submit annual Hospital Cost Reports.

Id. ¶ 44 (citing 42 U.S.C. § 1395g(a); 42 C.F.R. § 413.20). The
Hospital Cost Report includes the following statement:

Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

 $\underline{\text{Id.}}$ ¶ 61 (quoting CMS Form 2552). The person certifying the report is required to sign a statement which reads:

To the best of my knowledge and belief, it [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provisions of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

Id. ¶ 62. In reimbursing hospitals for operating costs, Medicare pays according to a per-patient standardized rate, called the Diagnostic Related Group ("DRG") rate. Id. ¶ 40 (citing 42 U.S.C. § 1395ww(d)(3)(A), (D)). The hospital submits a claim for a surgery by identifying the DRG associated with the surgery. The DRG reimbursement rate is "intended to fairly compensate the hospital for all costs associated with the surgery, including the medical device costs." Id. ¶ 52. The Amended Complaint contains no allegations regarding certifications or requirements in other government health programs such as Medicaid or TRICARE.

Based on those facts, this Court holds that the Amended Complaint fails to state a claim for which relief can be granted.

Recognizing that it is not easy to break out each element when looking at a factual situation, the Court will attempt to be as clear as possible in explaining how the complaint fails. Numerous courts have held that reimbursement for Medicare requires compliance with the Anti-Kickback Statute. See Conner, 543 F.3d at 1223 n.8 (citing cases). The Court agrees with those decisions to the extent that they hold that the Provider Agreement creates an express certification of compliance with the Anti-Kickback Statute. 13 The Court further holds that as written, this certification is specific to the party seeking reimbursement. The certification states, "I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]." While the paragraph does state that the signatory "understand[s] that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback Statute and the Stark law) . . . , " that statement is not in itself a certification that the entire transaction complied with the Anti-Kickback Statute. The statement creates no obligation on the part of the signatory to determine whether the entire transaction

The Court does not hold that the Hospital Cost Report creates such an express certification because it simply acknowledges the civil and criminal liability of failing to comply with the Anti-Kickback Statute. The actual certification in the Hospital Cost Report is not specific enough to create False Claims Act liability for failure to comply with the Anti-Kickback Statute, as it refers broadly to "such laws and regulations." Contra Mason v. Medline Indus. Inc., No. 07-5615, 2010 WL 653542, at *5-6 (N.D. Ill. Feb. 18, 2010).

complied with the Anti-Kickback statute. 14 Moreover, the statement does not create a precondition to payment for purposes of the implied certification theory. This Court holds that the implied certification theory requires that a statute or regulation expressly state the preconditions to payment, such a precondition cannot be hidden in an enrollment form. The Medicare statutes and regulations do not expressly contain a precondition of compliance with the Anti-Kickback Statute. The Amended Complaint contains no allegations that the hospitals themselves received kickbacks, or that they knew or should have known about the kickbacks received by the doctors. As a result, the certifications submitted by the hospitals were not false.

The issue as to whether the ninety-one doctors identified in the Amended Complaint submitted false claims is a closer issue.

As with the hospitals, the doctors expressly certified compliance with the Anti-Kickback Statute. To the extent that they submitted any claims for surgeries performed using Blackstone

¹⁴ The Court can imagine a certification that does create such an obligation. If the form read, "I declare that the underlying transaction for which I seek reimbursement complied with such laws, regulations and program instructions (including the Federal Anti-Kickback Statute and Stark Law) at every step of the transaction," or some such statement, this Court would hold differently. With such a certification, the Court imagines that hospitals would require all employees and independent contractors to agree to indemnify the hospital should they violate any such laws or regulations. Interpreting the current language of Form CMS-855A and Form CMS-855I as certifying compliance at every step of a transaction not only goes beyond the plain language of the document, but it is a policy decision (holding hospitals responsible for such knowledge) that properly ought come from Congress or the Department of Health and Human Services, not the courts.

products while they received consulting fees, they did not comply with the Anti-Kickback Statute, and thus submitted a false claim. The Amended Complaint sufficiently alleges that through the consulting agreements, Blackstone knowingly caused the submission of these false claims. Whether or not any such Medicare claims from these doctors were paid, the doctors sought payment from the federal treasury. This Court holds, however, that the Amended Complaint does not sufficiently allege that the false statements were material. Contra Thomas, 2008 WL 4853630, at *14.

As explained above, the Court must determine whether the false claim had "a natural tendency to influence, or be capable of influencing, the payment or receipt of money." The Court assumes that had the hospital received a kick-back or known of the kick-back, such that its certification was false, the false certification by the hospital would have been material, despite the use of DRG pricing. Although the government did not lose any excess money by the use of Blackstone products, it likely would not have paid for the cost associated with the surgery, including the use of the Blackstone product, had it known of the kickback for such use. The request for reimbursement from the doctor is a little different. The doctor is not seeking reimbursement for the use of the Blackstone device at all, the doctor is purely seeking reimbursement for his services. The purchase of Blackstone devices are thus not an underlying transaction to the reimbursement request for the doctor. Had the Amended Complaint alleged that Blackstone induced doctors to perform medically

unnecessary surgeries for which they sought reimbursement from Medicare, this Court would reach a different conclusion. In that situation, the underlying transaction -- the sale of surgical services to a patient -- would have been tainted by a kickback, and the false statement would have had a natural tendency to influence the decision to pay.

III. CONCLUSION

For the reasons stated above:

- 1. The Court denies Blackstone's Motion to Transfer (Document No. 50).
- 2. The Court denies Blackstone's motion to dismiss based on the False Claims Act's first-to-file rule because the Relators' case is not "a related action based on the facts underlying" the Thomas action, and therefore not jurisdictionally barred under the False Claims Act's first-to-file rule.
- 3. The Court denies Blackstone's motion to dismiss based on the False Claims Act's public disclosure bar as to relator Hutcheson, but allows it as to relator Brown, on the basis that he is not an "original source" under the public disclosure bar of the False Claims Act.
- 4. The Court grants the motion to dismiss based on (Document No. 52) the failure to state a claim under the False Claims Act, under Federal Rule of Civil Procedure 12(b)(6) because the express certification by the hospitals in seeking payment for the use of Blackstone's devices was personal to the hospital and with no allegations that the hospital knew of the

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kick-backs, those claims were not false, and the false express certification by the doctors were not material.

Judgment shall enter for the defendant Blackstone.

SO ORDERED.

By the Court,

/s/ William G. Young
WILLIAM G. YOUNG
DISTRICT JUDGE