IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

UNITED STATES OF AMERICA, *ex rel.* JOHN THOMAS — PLAINTIFF

v. — No. 4:06CV00465 JLH

MICHAEL M. BAILEY; BAILEY MANAGEMENT GROUP, INC.; FOUNDATION FOR ORTHOPEDIC AND SPINE EDUCATION AND RESEARCH; INNOVATIVE HEALTH SOLUTIONS, INC.; MOTIONTEK, INC.; BLACKSTONE MEDICAL, INC.; OMNI360 LLC; and OMNI360 MANAGEMENT, INC. — DEFENDANTS

OPINION AND ORDER

John Thomas brought this qui tam action pursuant to the False Claims Act, 31 U.S.C. § 3729 *et seq*., against Patrick D.S. Chan, M.D., Michael M. Bailey and four corporate entities with which he is affiliated (the "Bailey Defendants"), Blackstone Medical, Inc., and Synthes, Inc. After the government filed a notice of election to decline intervention pursuant to 31 U.S.C. § 3730(b)(4)(B), the Court unsealed the case and directed the plaintiff to serve summons and complaint. Each of the defendants filed a motion to dismiss. Pursuant to Rule 15(a)(1) of the Federal Rules of Civil Procedure, Thomas filed an amended complaint without leave of court. Each of the defendants then filed another motion to dismiss. Thereafter, Thomas and the government reached a settlement agreement with Dr. Chan as a result of which the claims against him were dismissed. The Court then heard argument on the pending motions to dismiss. During that same time, Thomas sought to depose Dr. Chan for use in his claims against the remaining defendants. At oral argument, the parties agreed that the most appropriate course of action would be for Thomas to file a motion for leave to file a second amended complaint – one with which he would live or die – and then he could be permitted

to depose Dr. Chan.[1] All parties understood that the defendants reserved the right to oppose the motion for leave to file a second amended complaint on the ground that it did not state a claim upon which relief can be granted and therefore permitting it to be filed would be futile.

Thomas has filed his motion for leave to file a second amended complaint with the proposed second amended complaint attached. The second amended complaint does not name Synthes, Inc., as a defendant, and an agreed order of dismissal has been entered dismissing Synthes. The second amended complaint named Orthofix International, N.V., but that defendant also has been dismissed by agreement of the parties. Blackstone and the Bailey Defendants remain. They have responded to the motion for leave to file an amended complaint by arguing that the proposed amended complaint does not state a claim upon which relief can be granted, so the motion should be denied and the action dismissed with prejudice.

I.

THE FACTUAL ALLEGATIONS IN THE SECOND AMENDED COMPLAINT

Thomas formerly sold instruments and devices used in spinal surgery, primarily products manufactured by Medtronic Sofamor Danek, Inc. Blackstone and Medtronic are competitors. Thomas alleges that Blackstone and the Bailey Defendants entered into a scheme with Dr. Chan that violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the violation of the Anti-Kickback Statute caused Dr. Chan and the hospitals where he performed surgeries to submit false or fraudulent claims to the government for payment.

[1] *See United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 559-61 (8th Cir. 2006) (holding that discovery may not be permitted to allow a relator to plead with sufficient particularity to satisfy Rule 9(d)).

According to the second amended complaint, from 2001 until the fall of 2002, Dr. Chan used cervical plating devices (screws, plates, and other such items) manufactured by Medtronic in cervical surgeries at two hospitals in Searcy, Arkansas, where he performed surgeries. During that time, Thomas's brother, Bob Thomas, worked for the Bailey Defendants. Sometime in 2002, Bob Thomas was at Michael Bailey's office when Bailey came in with Eric Hansen, a regional sales manager for Blackstone, who had a copy of a Blackstone consulting agreement to present to Dr. Chan. The second amended complaint alleges, "Hansen and Bailey discussed the fact that this was the agreement for Dr. Chan and that they were going to get more business in Arkansas." The contract amount was $25,000. There were no performance standards or description of the work to be done. In the fall of 2002, Dr. Chan ceased using Medtronic cervical plating products. When Thomas inquired as to why he had ceased using Medtronic products, Dr. Chan said that he had become a consultant for Blackstone and had to use Blackstone products. Other persons, including members of Dr. Chan's staff, also told Thomas that Dr. Chan had entered into a consulting agreement with Blackstone and was required to use Blackstone products.[2] The second amended complaint further alleges that Michael Bailey was the Blackstone sales representative who secured consulting

[2] Paragraph 49 of the second amended complaint alleges that the neurosurgery coordinator at one of the hospitals and a purchasing manager the other also told Thomas that Dr. Chan had entered into a consulting agreement with Blackstone and was required to use Blackstone products. However, in his brief in support of the motion for leave to file second amended complaint, Thomas has said that he "makes no allegation in this lawsuit that the hospitals . . . knew that these claims covered surgical procedures involving items that had been procured in violation of the AKS. Thus, Relator has not alleged that the hospitals are liable under the False Claims Act." (Br. in Sup. of Mot. for Leave to File Sec. Am. Compt. (Document #174) p. 6.) The argument on the motion for leave to file the second amended complaint has proceeded on the assumption that the hospitals did not know that Blackstone and Dr. Chan had entered into an agreement that violated the Anti-Kickback Statute, so the Court will rule based upon that assumption, notwithstanding the allegations in paragraph 49 of the second amended complaint regarding the knowledge of the neurosurgery coordinator at one hospital and the purchasing manager at the other.

agreements between Dr. Chan and Blackstone; that Bailey served as the Blackstone sales representative for Dr. Chan from 2002 through 2005; and that Bailey signed Blackstone's paperwork approving payments to Dr. Chan. In addition, the second amended complaint alleges that Bailey provided gratuities to Dr. Chan or his staff, including paying for a honeymoon trip for one of Dr. Chan's nurses and giving the nurse an expensive wedding trip; and providing an employee to babysit with Dr. Chan's children, to care for Dr. Chan's wife after surgery, and to perform personal tasks and errands for Dr. Chan and his family.

Thomas alleges that between 2002 and 2006 he continued to call on Dr. Chan and asked for his business but that Dr. Chan refused and told him that to win the business back he would need to provide Dr. Chan some type of consulting agreement.

Thomas contends that Blackstone's consulting agreement with Dr. Chan was a sham and that the real purpose of the consulting agreement was to compensate Dr. Chan for using Blackstone's products in spinal surgeries.

According to the second amended complaint, the sham consulting agreement between Blackstone and Dr. Chan was part of a nationwide strategy whereby Blackstone entered into unlawful consulting agreements and other kickback arrangements with physicians and staff members in return for use of Blackstone products. In support of that contention, the second amended complaint says that the consulting agreement that Bob Thomas saw in 2002 was a corporate form rather than an agreement generated in Arkansas for use only with Dr. Chan, and the second amended complaint describes five instances of allegedly improper arrangements or offers described to Thomas by others over a period of four years. One of those instances involved in a neurosurgeon in Jackson, Mississippi, who switched his use of surgical devices to Blackstone after Bailey hired the

neurosurgeon's girlfriend as a sales representative. Another instance involved a neurosurgeon in Jonesboro, Arkansas, whose brother was hired by Bailey as a salesman and paid a commission even though the brother lived in another state and never did any work. A third instance involved a neurosurgeon in Fayetteville, Arkansas, who switched the majority of his surgical devices to Blackstone after Bailey offered him consulting opportunities on behalf of Blackstone. A fourth instance involved Dr. Richard Jordan, a neurosurgeon in North Little Rock, Arkansas. The second amended complaint alleges that Geffrey Yielding, a licensed practical nurse working for Dr. Jordan, was placed in charge of Dr. Jordan's surgery schedule and the selection of his surgical products, after which Blackstone hired Yielding as an educator and sent him to various places to make presentations regarding Blackstone products. By 2003, Dr. Jordan's office had discontinued use of Medtronic products and switched business to Blackstone. According to the second amended complaint, Yielding then received payments from Blackstone that were characterized as training stipends. Thomas alleges that on several occasions between 2003 and 2006, Yielding told Thomas that he (Yielding) could get Thomas back in Dr. Jordan's rotation for the purchase of products if Thomas made it worth his while. In addition, the second amended complaint alleges that in early 2006 Blackstone offered kickbacks to unnamed physicians in Springfield, Missouri, in return for their use of Blackstone products.

Although the neurosurgeon decides which cervical plating devices to use during spinal surgery, the neurosurgeon does not purchase the devices from the manufacturer or supplier. Instead, the neurosurgeon tells the hospital which devices to have available for use during spinal surgery, and the hospital then purchases those devices from the manufacturer or supplier.

If the patient is a beneficiary of a federal program, the hospital is not reimbursed for cervical plating devices used during surgery on an item-per-item basis. Instead, the hospital submits a Form CMS-1450 with information that describes the services provided and the patient's diagnoses, as well as other required information. Based on the information on the CMS-1450, the claim is assigned to a Diagnosis-Related Group ("DRG"), and the government then reimburses the hospital on the basis of the particular DRG. According to the second amended complaint, the reimbursement rate set for each DRG is based, in part, on the costs typically incurred by hospitals in providing the services associated with the particular DRG. In other words, the hospital does not submit invoices for the products purchased for use during a surgery, but the reimbursement rate for the applicable DRG is set at an amount that is intended to include the typical cost of the surgical products purchased for the type of surgery that falls within that DRG.

Thomas contends that, during the time that Blackstone had the allegedly sham consulting agreement with Dr. Chan, whenever a hospital purchased a Blackstone product for use by Dr. Chan during neurosurgery and then submitted a claim for payment to Medicare, Medicaid, or another federal health program, that claim was false or fraudulent. Likewise, Thomas contends that whenever any hospital in the United States purchased a Blackstone product for use during spinal surgery because that product had been chosen by a physician who had entered into a sham consulting agreement with Blackstone and then submitted a claim for reimbursement to Medicare, Medicaid, or another federal health program, that hospital had submitted a false or fraudulent claim. Thomas contends that Blackstone caused these false or fraudulent claims by entering into agreements that violated the Anti-Kickback Statute. Although the physicians did not submit claims for reimbursement for the Blackstone products, Thomas contends that any claims that they submitted

to Medicare, Medicaid, or other federal health programs, for surgeries in which they had used Blackstone products while they had sham consulting agreements with Blackstone also were false or fraudulent claims and that Blackstone caused these false or fraudulent claims by entering into the agreements that violated the Anti-Kickback Statute. Thomas has identified in the second amended complaint twelve specific Medicare or Medicaid claims submitted by hospitals for surgery by Dr. Chan using Blackstone products in 2003, 2004, and 2005. He has also identified one claim submitted by Dr. Chan for surgery using Blackstone devices for a patient who was a Medicare and TRICARE[3] beneficiary. He has identified eight different claims submitted by Dr. Jordan to Medicare or Medicaid for surgeries using Blackstone devices in 2003 and 2004.

II.

THE LEGAL STANDARDS FOR DETERMINING WHETHER THE SECOND AMENDED COMPLAINT STATES A CLAIM UPON WHICH RELIEF MAY BE GRANTED

Rule 8(a) of the Federal Rules of Civil Procedure provides that a pleading that states a claim for relief must contain a short and plain statement of the claim showing that the pleader is entitled to relief. Rule 9(b) provides that in alleging fraud a party must state with particularity the circumstances constituting fraud. Because the False Claims Act is an anti-fraud statute, complaints alleging violations of that act must comply with Rule 9(b). *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006).

> To satisfy the particularity requirement of Rule 9(b), the complaint must plead such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred,

[3] TRICARE is a federally funded medical insurance program for active and retired military personnel and certain of their dependents. *See* 10 U.S.C. §§ 1071-1107 and Department of Defense TRICARE Regulation 6010.8-R, 32 C.F.R. Part 199.

> who engaged in them, and what was obtained as a result. Put another way, the complaint must identify the "who, what, where, when, and how" of the alleged fraud.

Id. (citations omitted); s*ee also United States ex rel. Costner v. United States*, 317 F.3d 883, 888 (8th Cir. 2003). The Court must accept allegations of fact as true when considering a motion to dismiss, but the Court is free to ignore legal conclusions, unsupported conclusions, unwarranted inferences, and sweeping legal conclusions cast in the form of factual allegations. *Wiles v. Capital Indem. Corp.*, 280 F.3d 868, 870 (8th Cir. 2002). "The plaintiff must assert facts that affirmatively and plausibly suggest that the pleader has the right he claims . . . rather than facts that are merely consistent with such a right." *Stalley ex rel. U.S. v. Catholic Health Initiative*, 509 F.3d 517, 521 (8th Cir. 2007). In *Joshi*, the Eighth Circuit cited with approval an opinion from the Eleventh Circuit holding that a relator's duty to plead fraud with particularity requires that the allegations show sufficient "indicia of reliability" by providing an underlying basis for the relator's assertions. *Joshi*, 441 F.3d at 557 (quoting *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1013-14 (11th Cir. 2005)); *see also United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1357 (11th Cir. 2006); *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002).

III.

WHETHER THE SECOND AMENDED COMPLAINT SUFFICIENTLY ALLEGES A VIOLATION OF THE ANTI-KICKBACK STATUTE

The first issue is whether the second amended complaint alleges with sufficient particularity the fraudulent conduct in which Thomas contends Blackstone and the Bailey Defendants engaged. As noted above, the alleged fraudulent conduct is a violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B), which makes it a felony for any person knowingly and willfully to offer or pay any remuneration, directly or indirectly, to any person to induce that person to purchase, order,

arrange for, or recommend purchasing or ordering any item for which payment may be made in whole or in part under a federal health care program. The regulations create certain safe harbors, the most pertinent of which is:

> The following payment practices shall not be treated as a criminal offense under section 1128B of the Act[4] and shall not serve as the basis for an exclusion:
>
> * * *
>
> (d) Personal services and management contracts. As used in section 1128B of the Act, "remuneration" does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met –
>
> (1) The agency agreement is set out in writing and signed by the parties.
>
> (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
>
> (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
>
> (4) The term of the agreement is for not less than one year.
>
> (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
>
> (6) The services performed under the agreement do not involve the counselling [sic] or promotion of a business arrangement or other activity that violates any State or Federal law.

[4] Section 1128B of the Social Security Act is codified at 42 U.S.C. § 1320a-7b.

> (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.
>
> For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

42 C.F.R. § 1001.952(d) (footnote added).

The Anti-Kickback Statute does not create a private right of action for competitors who have lost business as a result of kickbacks or for other private persons, nor does Thomas contend that it does. Instead, he contends that Blackstone and Bailey are liable under the False Claims Act, specifically 31 U.S.C. § 3729(a)(1)-(3). Section 3729(a) provides, in pertinent part:

> Any person who –
>
> > (1) 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;
> > (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;
> > (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
> >
> > * * *
> >
> > is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages which the Government sustains because of the act of that person . . . .

31 U.S.C. § 3729(a). Thomas does not contend that Blackstone or Bailey submitted false or fraudulent claims to an officer or employee of the United States government. Instead, he contends that Blackstone and Bailey violated the Anti-Kickback Statute and thereby caused hospitals and physicians to present false or fraudulent claims to the United States government, caused false records or statements to get false or fraudulent claims paid or approved by the government, and conspired to defraud the government by getting false or fraudulent claims allowed or paid.

A. <u>As to Dr. Chan</u>.

As noted above, the second amended complaint alleges that in 2002 Eric Hansen, a regional sales representative for Blackstone, and Michael M. Bailey presented a written consulting agreement to Dr. Chan. The contract amount was $25,000. The agreement had no performance standards or description of the work to be done. Dr. Chan ceased purchasing products from Blackstone's competitors and told Thomas that he had become a consultant for Blackstone and had to use Blackstone products from then on. Thus, as to the alleged kickback arrangement with Dr. Chan, the second amended complaint alleges with particularity the "who, what, where, when, and how" of the kickback scheme. Who? Eric Hansen and Michael B. Bailey. What? a consulting agreement for $25,000 with no performance standards or description of the work to be done but with an understanding on the part of Dr. Chan that he must use Blackstone products. Where? in Dr. Chan's office. When? in 2002. How? a face-to-face meeting involving Hansen, Bailey, and Dr. Chan.

B. <u>The Alleged Nationwide Policy</u>.

The second amended complaint also alleges that Blackstone had a corporate policy, national in scope, to enter into sham consulting agreements and other arrangements with physicians that would violate the Anti-Kickback Statute and cause false or fraudulent claims to be presented to the United States government. The second amended complaint does not allege the "who, what, where, when, and how" of this alleged nationwide corporate policy. The second amended complaint does not identify who at Blackstone initiated, discussed, or adopted this alleged corporate policy; what the corporate policy was; where the corporate policy was adopted or in what documents it was reflected; when the corporate policy came into being or under what circumstances; or how the corporate policy was adopted or proposed to be communicated to salesmen and implemented

throughout the country. Instead, the second amended complaint alleges five episodes, anecdotal in nature, based on hearsay – in some instances from other salesmen who competed against Blackstone – reporting that Blackstone or Bailey offered kickbacks or hired a family member or friend of a physician. One of these anecdotes involved a physician in Jackson, Mississippi; one involved physicians in Springfield, Missouri; and three involved physicians in different cities in Arkansas. The second amended complaint specifies allegedly false claims with respect to only one physician other than Dr. Chan, *i.e.*, Dr. Jordan. The second amended complaint, therefore, does not allege, with sufficient particularity to meet the demands of Rule 9(b), a nationwide, corporate policy on the part of Blackstone to cause false claims to be submitted by entering into agreements with physicians in violation of the Anti-Kickback Statute.

IV.

WHETHER THE SECOND AMENDED COMPLAINT SUFFICIENTLY ALLEGES THAT FALSE OR FRAUDULENT CLAIMS WERE SUBMITTED TO THE GOVERNMENT FOR PAYMENT OR APPROVAL

For Thomas to prevail as a relator, he must plead and prove that one or more false claims were presented to the United States government for payment or approval. *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007) (the False Claims Act does not create liability for violations of federal law independent of any false claim); *United States ex rel. Karvelas v. Melrose Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004) ("Evidence of an actual false claim is 'the *sine qua non* of a False Claims Act violation.'") (quoting *Clausen*, 290 F.3d at 1311).

The theory advanced by Thomas is based on the notion that the person submitting a claim for payment to the government certifies or represents compliance with a federal statute, regulation, or prescribed contractual term. *See Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001). Some courts

have called this representation of compliance a "legally false" certification, to distinguish it from a "factually false" certification, which involves a claim for payment based upon an incorrect description of goods or services provided or a request for payment for goods or services that were never provided. *Id*. at 697; *United States ex rel. Conner v. Salina Regional Health Center, Inc.*, ___ F.3d ___, 2008 WL 4430668, at *4 (10th Cir. Oct. 2, 2008). Other circuits have recognized substantially the same legal theory, though not always using the terms "legally false" and "factually false." *See McNutt ex rel. U.S. v. Haleyville Med. Supplies*, 423 F.3d 1256, 1259-60 (11th Cir. 2005); *United States ex rel. Schmidt v. Zimmer, Inc*., 386 F.3d 235, 243 (3rd Cir. 2004); *United States ex rel. Augustine v. Century Health Servs., Inc*., 289 F.3d 409, 414 (6th Cir. 2002); *United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc*., 214 F.3d 1372, 1376 (D.C. Cir. 2000); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 786-87 (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, 1266-67 (9th Cir. 1996). The Eighth Circuit has not addressed this theory.

The Tenth Circuit has explained:

> The FCA recognizes two types of actionable claims-factually false claims and legally false claims. In a run-of-the-mill "factually false" case, proving falsehood is relatively straightforward: A relator must generally show that the government payee has submitted "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." By contrast, in a claim based on an alleged legal falsehood, the relator must demonstrate that the defendant has "certifie[d] compliance with a statute or regulation *as a condition* to government payment," yet knowingly failed to comply with such statute or regulation. Conner's claims fall in the latter category.
>
> In this circuit, legally false certification claims can rest one of two theories-express false certification, and implied false certification. An express false certification theory applies when a government payee "falsely certifies compliance with a

> particular statute, regulation or contractual term, where compliance is a prerequisite to payment." This promise may be any false statement that relates to a claim, whether made through certifications on invoices or any other express means.
>
> Under an implied false certification theory, by contrast, courts do not look to the contractor's actual statements; rather, the analysis focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment. If a contractor knowingly violates such a condition while attempting to collect remuneration from the government, he may have submitted an impliedly false claim.

Conner, 2008 WL 4430668, at *4 (citations omitted).

The second amended complaint alleges that compliance with the Anti-Kickback Statute is a necessary condition to the right of all health care providers, including physicians and hospitals, to receive payment from the Medicare, Medicaid, or TRICARE programs. Likewise, case law supports the proposition that compliance with the Anti-Kickback Statute is a condition of payment under these programs, so, when a health care provider presents a claim for payment pursuant to one of those programs, that health care provider certifies, either impliedly or expressly, that the health care provider is in compliance with the Anti-Kickback Statute. *McNutt*, 423 F.3d at 1259-60; *Zimmer*, 386 F.3d at 243; *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 17 (D. Mass. 2007); *United States v. Rogan*, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 616 (N.D. Ill. 2003), *aff'd* 517 F.3d 449 (7th Cir. 2008).

A. <u>By the Hospitals</u>.

Thomas first contends that the hospitals where Dr. Chan performed surgeries submitted false or fraudulent claims when they submitted requests for payments to federal health care programs for the costs associated with surgeries involving Blackstone products that Dr. Chan requested that they purchase during the time that he had a consulting agreement with Blackstone. Thomas contends that

the hospitals submitted false or fraudulent claims when they submitted requests for reimbursement on Form CMS-1450 to Medicare, Medicaid, and TRICARE. He also alleges that the hospitals incorporated the costs associated with the surgical procedures on their annual cost reports, which also are claims resulting in a final annual payment from the government. *See Rogan*, 459 F. Supp. 2d at 708. Thomas contends that the claims submitted by the hospitals were false or fraudulent either under an implied certification or an express certification theory of liability under the False Claims Act.

If the hospitals either impliedly or expressly certified that Dr. Chan's selection of products was untainted by violation of the Anti-Kickback Statute, then it follows from the holding in the preceding section that the second amended complaint sufficiently alleges that the hospitals submitted false or fraudulent claims. The issue, then, is whether the hospitals impliedly or expressly certified that Dr. Chan's selection of products was untainted by violation of the Anti-Kickback Statute.

Thomas first argues that the hospitals submitted false claims under the implied certification theory when they sought reimbursement for surgeries for which they had purchased Blackstone products to be used by Dr. Chan while he had a consulting agreement with Blackstone. In other words, Thomas argues, in effect, that by submitting these claims for payment the hospitals impliedly certified that Dr. Chan's selection of products to be used during the surgeries was untainted by violation of the Anti-Kickback Statute.

The Court agrees that a hospital's act of submitting a claim for payment to the government impliedly certifies that the hospital has complied with the Anti-Kickback Statute, which is essentially the holding in *McNutt* and other cases cited above; but, it is another matter to say that a hospital's act of submitting a claim for payment is an implied certification that a person who is not employed

by the hospital, is not an agent or subcontractor of the hospital, and who does not act under the hospital's control, complied with the Anti-Kickback Statute. Thomas has cited no authority for the proposition that the hospital's right to be reimbursed by one of the federal health care programs depends on whether the attending physician complied with the Anti-Kickback Statute. The most apposite regulation appears to be 42 C.F.R. § 424.520, which provides:

> (a) Certifying compliance. CMS enrolls and maintains an active enrollment status for a provider or supplier when that provider or supplier certifies that it meets, and continues to meet, and CMS verifies that it meets, and continues to meet, all of the following requirements:
>
> (1) Compliance with title XVIII of the Act and applicable Medicare regulations.
>
> (2) Compliance with Federal and State licensure, certification and regulatory requirements, as required, based on the type of services or supplies the provider or supplier type will furnish and bill Medicare.
>
> (3) Not employing or contracting with individuals or entities--
>
> (i) Excluded from participation in any Federal health care programs, for the provision of items and services covered under the programs, in violation of section 1128A(a)(6) of the Act; or
>
> (ii) Debarred by the General Services Administration (GSA) from any other Executive Branch procurement or nonprocurement programs or activities, in accordance with the Federal Acquisition and Streamlining Act of 1994, and with the HHS Common Rule at 45 CFR part 76.
>
> (b) Reporting requirements. Following enrollment, a provider or supplier must report to CMS any changes to the information furnished on the enrollment application and furnish supporting documentation within 90 calendar days of the change, with the exception of DMEPOS suppliers which are required to report changes of information within 30 days as specified in § 424.57(c)(2), or a change of ownership or control of the provider or supplier that must also be reported within 30 calendar days. Failure to do so may result in the deactivation or revocation of the provider or supplier's Medicare billing privileges.

Thus, to be eligible as a Medicare provider, a hospital is required to certify that it is in compliance with the laws and regulations governing the Medicare program and that it does not employ or contract with persons excluded from participation; but neither this nor any other regulation brought to the Court's attention requires a hospital to certify that physicians who admit patients to the hospital are in compliance. It may be that a hospital submitting a claim to the government for payment would be ineligible for payment if the hospital knew of a violation of the Anti-Kickback Statute by the physician who attended the patient receiving the services; but, as noted above, Thomas has expressly disclaimed making any allegation that the hospitals where Dr. Chan performed surgery knew that Dr. Chan had violated the Anti-Kickback Statute. Thomas has offered no support for the proposition that the hospitals where Dr. Chan performed surgery impliedly certified that his selection of surgical products was untainted by violation of the Anti-Kickback Statute.

In the alternative, Thomas argues, in effect, that the hospitals made an express certification that Dr. Chan's selection of surgical products was untainted by violation of the Anti-Kickback Statute when they submitted their annual cost reports. The annual cost reports are submitted on Form CMS-2552-96. The certification on that document provides:

> 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 WERE 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.
>
> CERTIFICATION BY OFFICER OR ADMINISTRATOR OF PROVIDER(S)
>
> I HEREBY CERTIFY that I have read the above statement and that I have examined the accompanying electronically filed or manually

> submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by _____ (Provider Name(s) and Number(s)) for the cost reporting period beginning _____ and ending _____ and that to the best of my knowledge and belief, it 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 provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.
>
> (Signed)_____
> Officer or Administrator of Provider(s)
>
> _____
> Title
>
> _____
> Date

Thomas argues that the last sentence of the certification constitutes an express certification that the physicians complied with the Anti-Kickback Statute in selecting products for use in the surgeries identified in the cost report. He acknowledges that the previous sentence certifying the accuracy of the records is "to the best of my knowledge and belief," and is therefore a certification only as to what the certifier actually knows and believes; and he acknowledges that the first half of the last sentence ("I am familiar with the laws and regulations") presents a subjective statement regarding what the certifier knows; but he argues that the second half of the last sentence ("the services identified in this cost report were provided in compliance with such laws") is an objective certification that extends to matters that may not only be beyond the certifier's knowledge but even beyond what the certifier could possibly know. Because this certification is submitted in conjunction with an annual cost report, it must extend to every service for every patient for which reimbursement was sought from Medicare for an entire year, and so, according to Thomas's argument, the person signing it on behalf of the hospital would thereby certify that all of the physicians who practiced at

that hospital, no matter how large the number, had complied with the laws and regulations with respect to every medical service provided in conjunction with the hospital for every patient for an entire year. It is impossible that the person signing the cost report could have that knowledge, nor does Thomas argue otherwise. It is difficult to see why the government would require someone to certify to matters that are both beyond his knowledge and beyond what he could possibly know.

Form CMS-2552-96 states, "This report is required by law (42 USC 1395g; 42 CFR 413.20(b))." Nothing in either the statute or the regulation suggests that the hospital is required to certify that every physician who rendered care to patients in the hospital during the year covered by the annual cost report did so in compliance with the laws and regulations regarding the provision of health care services.

Thomas argues that a person can submit a false claim to the government without knowing that the claim is false, and of course that is true. See, for example, *United States v. Bornstein*, 423 U.S. 303, 96 S. Ct. 523, 46 L. Ed. 2d 513 (1976), where the defendant was a subcontractor who provided nonconforming electron tubes to a prime contractor, who incorporated them into radio kits that it sold to the government. Even though the prime contractor did not know that the tubes were nonconforming, having been "[d]uped into accepting the tubes as genuine," *id.* at 320, 96 S. Ct. at 533 (Rehnquist, J., concurring), the subcontractor was held liable under the False Claims Act. *Id.* at 313, 96 S. Ct. at 530; *see also United States v. Rivera*, 55 F.3d 703, 706-07 (1st Cir. 1995) (defendant caused Merrill Lynch to present false claims to the government "[a]lthough, from Merrill Lynch's perspective, the claim it presented may not have been 'false or fraudulent'"); *United States v. Lagerbusch*, 361 F.2d 449, 449-50 (3d Cir. 1966) (where employee of government contractor cheated his employer, thus inflating costs that were passed on to government, court states, "We have

no doubt that the False Claims Act covers such an indirect mulcting of the government."); *United States v. Ueber*, 299 F.2d 310 (6th Cir. 1962) (subcontractor inflated invoices, which prime contractor relied on in preparing vouchers to the government; no indication in opinion that prime contractor knew vouchers were inflated); *United States v. Rohleder*, 157 F.2d 126, 128 (3d Cir. 1946) (subcontractor who engaged in bid-rigging held liable under False Claims Act even though prime contractor forwarded tainted bids to Navy "without suspicion" that they were rigged); *United States v. Inc. Village of Island Park*, 888 F. Supp. 419, 440 (S.D.N.Y. 1995) (defendants caused "innocent mortgagees" to submit false claims that violated fair housing laws). Obviously, anyone can and everyone probably has at some time made a false statement without realizing that the statement was false. Just as obviously, whether a statement is false and whether it is knowingly false are separate questions. Nevertheless, those truisms do not translate into an argument that hospitals that submit claims to Medicare, Medicaid, or the TRICARE program either impliedly or expressly certify that the physicians who attended the patients receiving services from the hospital complied with the laws and regulations that govern those programs.

Thomas has called to the Court's attention 42 C.F.R. § 412.46(b), which requires that each hospital have on file an acknowledgment that the physician has reviewed the following notice:

> Notice to Physicians: Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fines, imprisonment, or civil penalty under applicable Federal laws.

Thomas also notes that Medicare imposes other conditions of participation on hospitals that demonstrate the unique relationship between hospitals and admitting physicians, including:

> The hospital's governing body determines which categories of practitioners are eligible for appointment to the medical staff, appoints the members of the medical staff, approves the medical staff bylaws, and ensures that the criteria for selection of medical staff are individual character, competence, training, experience, and judgment. *See* 42 C.F.R. § 482.12(a).
>
> The hospital's governing body ensures that each patient is admitted on the recommendation of a physician and that a physician is on duty or on call at all times. *See* 42 C.F.R. § 482.12(c).
>
> The hospital's governing body ensures the patient's rights to have physicians and other hospital staff comply with advance directives. *See* 42 C.F.R. § 482.13(b).
>
> The hospital must have a medical staff that is well organized and accountable to the governing body for the quality of medical care provided to patients. *See* 42 C.F.R. § 482.22(b).
>
> The medical staff bylaws must include criteria for determining the privileges to be granted to individual physicians and a procedure for applying the criteria to individuals requesting privileges. *See* 42 C.F.R. § 482.22(c).
>
> If the hospital offers surgical services, surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. *See* 42 C.F.R. § 482.51(a).

None of these regulatory provisions says that hospitals must certify, expressly or impliedly, that physicians have complied with the Anti-Kickback Statute.

Could the government require such a certification from hospitals as a condition of receiving payment from federal health care programs? It could. But were it to do so, one would expect the language of the certification to say so unambiguously. The regulations, for example, specify the precise language of the physician acknowledgment statement that hospitals must keep on file. 42 C.F.R. § 412.46(b). That regulation is clear, precise, and unambiguous. The certification in the annual cost report, however, "contains only sweeping general language," *Conner*, 2008 WL 4430668, at *6, that the services identified in the cost report were provided in compliance with the

laws and regulations regarding provision of health care services; that certification is not an unambiguous declaration that the hospital certifies that all of the physicians attending patients at the hospital during the year did so in compliance with the Anti-Kickback Statute.

In summary, the hospitals impliedly certified that they were in compliance with the Anti-Kickback Statute; but they did not impliedly or expressly certify that the physicians who attended patients in their hospital complied with that statute. Thomas has expressly disclaimed any contention that the hospitals violated the Anti-Kickback Statute or knew that Dr. Chan had done so. Consequently, assuming all of the facts alleged in the second amended complaint as true, the claims submitted by the hospitals were not false or fraudulent claims within the meaning of the False Claims Act.

B. By Dr. Chan.

Thomas also alleges that the claims submitted by Dr. Chan to the Medicare, Medicaid, and TRICARE programs for surgeries in which he used Blackstone products while he had a consulting agreement with Blackstone were false or fraudulent claims. Dr. Chan's claims for reimbursement did not include claims for the costs of the Blackstone products. As noted above, those products were purchased by the hospitals, and any reimbursement for them would have been included within the reimbursement paid to the hospitals according to the rate of reimbursement for the applicable DRG. Nevertheless, Thomas alleges that Dr. Chan's claims for payment for those surgeries were false or fraudulent within the meaning of the False Claims Act.

A physician submits claims for reimbursement for these federal programs on Form CMS-1500. That form states, in pertinent part:

> I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare . . . regulations.[5]

That form does not include an express certification that the physician has complied with the Anti-Kickback Statute.

However, according to Thomas's second amended complaint, when a physician seeks to participate in the Medicare program, he must complete a Medicare Federal Health Care Provider/Supplier Enrollment Application, Form CMS-855I, which requires the physician to certify as follows:

> 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 my compliance with all applicable conditions of participation in Medicare.

Thus, when a physician submits a claim to Medicare, the physician impliedly certifies that the claim and the underlying transaction comply with the Anti-Kickback Statute. Assuming for purposes of ruling on the motion to dismiss that Dr. Chan's consulting agreement with Blackstone violated the Anti-Kickback Statute, the claims for payment submitted by Dr. Chan for surgeries using Blackstone products that he directed the hospital to purchase while he was in violation of the Anti-Kickback Statute were false and fraudulent claims within the meaning of the False Claims Act.

[5] This form was revised in August 2005. The record does not reflect the language of the previous version of the form. The defendants have made arguments in their brief based on the assumption that the certification before August 2005 was identical, and Thomas has not challenged that assumption.

The defendants argue that the second amended complaint fails to identify specific false claims, but that argument is incorrect. The second amended complaint identifies one specific claim submitted by Dr. Chan on January 21, 2003, to Medicare and TRICARE for surgery using Blackstone devices. That constitutes one representative example of a false claim. *See Joshi*, 441 F.3d at 557.

The defendants also argue that the falsity at issue was not material to the government's decision to make payment, but that argument is incorrect. "The government offers a subsidy (from the patients' perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due." *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008). One of those conditions is that the provider of services may not violate the Anti-Kickback Statute, and when that condition is not met, nothing is due. *See McNutt*, 423 F.3d at 1259; *Zimmer*, 386 F.3d at 243.

V.

WHETHER THE SECOND AMENDED COMPLAINT SUFFICIENTLY ALLEGES THE OTHER ESSENTIAL ELEMENTS

Until now, the discussion of the issues has not required that a distinction be made between Thomas's claims under subsections (a)(1), (a)(2), and (a)(3) of 31 U.S.C. § 3729. The analysis is the same for all three subsections on the issue of whether the second amended complaint sufficiently alleges a violation of the Anti-Kickback Statute and on the issue of whether the hospitals or Dr. Chan submitted false claims. Now, however, assuming that Thomas has sufficiently alleged that Blackstone and the Bailey Defendants violated the Anti-Kickback Statute by engaging in a sham consulting agreement with Dr. Chan, and assuming that they have sufficiently alleged that Dr. Chan presented false or fraudulent claims to the government for approval, it is necessary to address the

issue of whether Thomas has sufficiently alleged the other elements of a claim for relief for each of the three subsections.

A. Subsection 3729(a)(1).

Subsection 3729(a)(1) provides that any person who 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 is liable. The statute defines *knowing* and *knowingly* as follows:

> For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information –
>
> (1) has actual knowledge of the information;
>
> (2) acts in deliberate ignorance of the truth or falsity of the information; or
>
> (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(b). As noted above, Thomas does not allege that Blackstone or the Bailey Defendants presented false claims to the government. Instead, he alleges that they caused false claims to be presented and did so knowingly.

In *Zimmer*, the Third Circuit applied ordinary causation principles from negligence law in finding that a qui tam complaint stated a cause of action against a manufacturer who allegedly engaged in a marketing program that violated the Anti-Kickback Statute. Following Restatement (Second) of Torts § 443, the court held that if a jury were to conclude that the manufacturer's marketing scheme was a "substantial factor" in bringing about the hospital's filing of a false claim, the manufacturer could be found to have caused and thus be responsible for that filing. *Zimmer*, 386 F.3d at 244-45. Furthermore, "[t]he alleged targets of this scheme were health care providers that [the manufacturer] knew to be participants in the Medicare program." *Id*. at 244. In the absence of

any contrary authority from the Eighth Circuit, the Court will follow *Zimmer*. The second amended complaint sufficiently alleges that Blackstone and the Bailey Defendants engaged in a scheme that they knew would violate the Anti-Kickback Statute and result in the submission of false or fraudulent claims to the government. A jury could find that that scheme was a substantial factor in bringing about Dr. Chan's submitting false and fraudulent claims when he sought payment for surgeries using Blackstone products while accepting payments from them under the allegedly sham consulting agreement. Therefore, the second amended complaint sufficiently alleges all of the essential elements of a claim for relief under 31 U.S.C. § 3729(a)(1).

B. Subsections 3729(a)(2) and (3).

Subsection 3729(a)(2) imposes liability on any person who 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. Subsection 3729(a)(3) imposes liability on any person who conspires to defraud the government by getting a false or fraudulent claim allowed or paid.

The United States Supreme Court interpreted these subsections in *Allison Engine Co., Inc. v. United States ex rel. Sanders*, ___ U.S. ___, 128 S. Ct. 2123, 170 L. Ed. 2d 1030 (2008). The Court said, "[w]hat § 3729(a)(2) demands is not proof that the defendant caused a false record or statement to be presented or submitted to the Government but that the defendant made a false record or statement for the purpose of getting 'a false or fraudulent claim paid or approved by the Government.'" *Id*. at 2130. The second amended complaint identifies no false records or statements that Blackstone or the Bailey Defendants made, used, or caused to be made other than the allegedly sham consulting agreement, and Thomas does not allege that the sham consulting agreement was made or used to get a false claim paid. *See* 1 JOHN T. BOESE, CIVIL FALSE CLAIMS AND *QUI TAM*

ACTIONS § 2.01[B], at 2-27 (3d ed. 2008) ("[E]ven though a false record may result in a criminal violation, it does not result in civil liability unless it is also made or directly used to get a false claim paid."). Thomas does not allege that the sham consulting agreement was presented, or intended to be presented, to anyone for the purpose of getting a claim paid. Therefore, the second amended complaint fails to state a claim upon which relief can be granted under 31 U.S.C. § 3729(a)(2).

In *Allison*, the Supreme Court's interpretation of subsection 3729(a)(3) was similar to its interpretation of subsection 3729(a)(2). "[I]t must be shown that the conspirators intended 'to defraud the government.'" *Allison Engine Co.*, 128 S. Ct. at 2130. Whereas it suffices under subsection 3729(a)(1) to show that the defendant knowingly caused false or fraudulent claims to be presented to the government, subsection 3729(a)(3) requires proof that the purpose of the conspiracy was "to defraud the government." Although the second amended complaint sufficiently alleges that the defendants knowingly caused false or fraudulent claims to be presented to the government for payment, it does not allege a conspiracy the specific intent of which was to defraud the government. As stated above, the second amended complaint sufficiently alleges that Blackstone and the Bailey Defendants knew that their conduct would result in Dr. Chan submitting false or fraudulent claims to the government; but it does not allege that they had the specific intent to defraud the government. Therefore, the second amended complaint fails to state a claim upon which relief can be granted pursuant to 31 U.S.C. § 3729(a)(3).

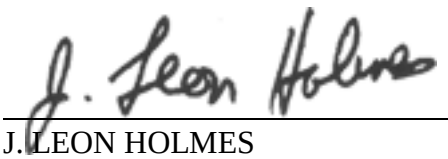
CONCLUSION

The second amended complaint states a claim upon which relief can be granted under 31 U.S.C. § 3729(a)(1) insofar as it alleges that the defendants knowingly caused Dr. Chan to submit false or fraudulent claims to the United States government for payment or approval. The second

amended complaint fails to state a claim for which relief can be granted insofar as it attempts to allege that Blackstone violated 31 U.S.C. § 3729 by engaging in a nationwide corporate policy of entering into unlawful consulting agreements and other kickback arrangements with physicians and their staff in return for the use of Blackstone products. The second amended complaint fails to state a claim upon which relief can be granted insofar as it attempts to allege that the defendants violated 31 U.S.C. § 3729(a)(1) by knowingly causing hospitals to present false or fraudulent claims for payment or approval. The second amended complaint fails to allege a claim upon which relief can be granted insofar as it attempts to allege violations of 31 U.S.C. § 3729(a)(2) and (3). If Thomas wishes to file a second amended complaint limited to the claim that the defendants violated 31 U.S.C. § 3729(a)(1) by knowingly causing Dr. Chan to present to the United States government false or fraudulent claims for payment or approval, he may file the second amended complaint with all allegations unrelated to that claim removed within fourteen days from the entry of this Opinion and Order; but he may not insert any allegations or amend the allegations pertaining to this one claim for relief. John Thomas's motion for leave to file the second amended complaint is therefore GRANTED IN PART and DENIED IN PART. Document #174.

Inasmuch as this action will proceed on one claim for relief alleged in the proposed second amended complaint pursuant to this Opinion and Order, the following motions are deemed moot: Documents #45, #60, #95, #97, #101, #103, #130.

IT IS SO ORDERED this 6th day of November, 2008.



J. LEON HOLMES
UNITED STATES DISTRICT JUDGE