UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, EX REL. PETER ROST,	)	
Plaintiffs	)	
v.	)	CIVIL ACTION NO. 03-11084-PBS
PFIZER, INC. and PHARMACIA CORPORATION,	)	
Defendants.	)	

MEMORANDUM AND ORDER

September 14, 2010

Saris, U.S.D.J.

In June 2003, relator Peter Rost filed a qui tam complaint under seal charging defendants Pfizer, Inc. and Pharmacia Corporation with violating the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733. Rost alleged that the defendants engaged in illegal off-label marketing of a growth hormone deficiency medication called Genotropin, that they provided illegal "kickbacks" to physicians, and that these illegal activities caused pharmacies to submit false claims to state Medicaid agencies. The United States declined to intervene in this case in and the Court (Tauro, J.) unsealed relator's complaint in November 2005. (See Docket Nos. 34, 35.) Following dismissal of his original complaint, relator appealed to the First Circuit,

where the case was remanded with instructions to allow relator to amend his complaint. United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720 (1st Cir. 2007). The amended complaint was filed in 2008 and the parties conducted discovery limited to claims for pediatric off-label indications in Indiana and Kentucky.[1] Following the completion of discovery, defendants filed a motion for summary judgment [Docket No. 149]. Briefing on this motion has revealed that the relator's theories of recovery have changed now that discovery is complete. First, he argues that defendant caused one physician to prescribe Genotropin "off label" because she only used one test, rather than two, before diagnosing a patient with growth hormone deficiency. Relator's second theory is that defendant caused doctors to prescribe on-label and off-label by providing the doctors with kickbacks, including "boondoggle" trips. After hearing and a review of the record, the defendants' motion for summary judgment is **ALLOWED**.

I. BACKGROUND

When all reasonable inferences are drawn in favor of the non-moving party, the record contains the following facts, which, unless noted, are undisputed.

[1] In ruling on Pfizer's motion to dismiss the amended complaint, the Court limited discovery to pediatric off-label claims in the Indiana sales region, which includes Kentucky, because the Complaint alleged only these claims with particularity under Fed. R. Civ. P. 9(b). (Hr'g Tr. 39, Mar. 8, 2010.)

A. Genotropin

Pharmacia Corporation, later acquired by Pfizer, Inc. (together, the "Defendants"), manufactures and markets Genotropin, a recombinant human growth hormone ("rhGH"). Genotropin is also known by its chemical name, somatropin. The drug was first approved by the Food and Drug Administration ("FDA") in 1995. (Decl. of Mark Mosier ("Mosier Decl."), Ex. 1 (Genotropin Label).) Since Genotropin's initial approval in 1995, the FDA has approved other somatropin products that are chemically identical to Genotropin. As of 2004, five rhGH products, all known by the name somatropin, were available in the United States. (Decl. of Dr. Lynne Levitsky ("Levitsky Decl.") ¶ 22.)

Genotropin has been approved by the FDA for pediatric treatment of five indications: (1) the treatment of pediatric patients who have slow growth due to a deficiency of growth hormone (approved for this indication in August 1995); (2) treatment of pediatric patients who have growth failure due to Prader-Willi syndrome, a rare genetic disorder that causes short stature and other disabilities (approved June 2000); (3) treatment of growth failure in children born small for gestational age and who fail to manifest catch-up growth by age two (approved July 2001); (4) pediatric treatment of growth failure due to Turner syndrome, also a genetic disorder causing

short stature and other disabilities (approved April 2006); and (5) treatment of growth failure due to Idiopathic Short Stature (approved June 2008). (See Levitsky Decl. ¶¶ 9, 12, 14-19.)

The Medicaid agencies in both Indiana and Kentucky require prior authorizations for prescriptions of Genotropin for any indication.[2] Prior authorization is "a cost containment measure that provides full payment of health benefits only if the hospitalization or medical treatment has been approved in advance." (Def.'s SUF ¶ 15.) In Indiana, "[i]n order for a reimbursement claim submitted by a pharmacy to be paid by Indiana Medicaid after January 7, 2002, a physician must have submitted a prior authorization form and authorization must have been given by the [Indiana Family and Social Services Administration]." (Mosier Decl., Ex. 6 (Decl. of Carl Shirley).) Indiana's prior authorization form required the physician to provide a medical diagnosis for the patient and "clinical summary" that included "[a] current plan of treatment and progress notes as to the necessity, effectiveness and goals of the treatment." (Id.) Kentucky's Medicaid program first adopted prior authorization procedures in 1976. (Mosier Decl., Ex. 7.) When Genotropin was first approved by the FDA in 1995, it was placed on Kentucky's list of medications requiring prior authorization. (Id.)

[2] Indiana required prior authorization for prescriptions of Genotropin after January 7, 2002, and Kentucky required prior authorization during the entire relevant period. (Def.'s SUF ¶ 16.)

Kentucky's prior authorization form required the patient's "diagnosis and prognosis." (Id.) To get prior authorization, a doctor has to sign a statement of medical necessity that is submitted by the patient to a specialty pharmacy to get the prescription. (Hr'g Tr. 24.)

B. Off-Label Promotion

Relator has abandoned his allegations about false claims made with respect to off-label prescriptions for Idiopathic Short Stature. (Hr'g Tr. 10-11.) His only remaining allegations with respect to claims being false as a result of being filled for off-label indications relate to a number of prescriptions written by Dr. Pamela Clark for the treatment of growth hormone deficiency ("GHD") where she only conducted one diagnostic test rather than two prior to making a diagnosis of GHD. Relator alleges that Dr. Clark only performed one test for approximately eight pediatric patients for whom she prescribed Genotropin. (See Pl.'s Statement of Undisputed Facts ("SUF") ¶¶ 40, 42.) Rost alleges that Genotropin prescriptions for GHD are "off-label" if the underlying diagnosis is not based on two tests. This is a new theory not alleged in the Complaint.

It is undisputed that the FDA approved Genotropin for the treatment of GHD as an "on-label" indication in 1995. (Id. ¶ 24.) However, Rost alleges that prescriptions of Genotropin to treat GHD are not "on-label" unless accompanied by a diagnosis of

GHD where a physician has administered two "stimulation tests" for which the results were positive. (Id.) The record is not entirely clear as to what a stimulation test is, but relator's Statement of Undisputed Facts [Docket No. 158] suggests that it is a test in which a "secretion inducing substance[]" is "used to attempt to stimulate the pituitary gland to release growth hormone." (Id. ¶ 25.) The levels of growth hormone released after the introduction of the stimulus allow physicians to diagnose GHD. Relator attributes the above-quoted statement to Dr. Ora Pescovitz, "a leading prescriber of Genotropin in the Indiana region," but the statement appears nowhere in the deposition transcript provided to the Court. (See Decl. of Mark Labaton ("Labaton Decl."), Ex. 4 (Pescovitz Dep.).) Indeed, Dr. Pescovitz testified that "there's no such thing as a definitive test" and that she is "highly skeptical of these tests." (Id. at 142-43.)

The only other evidence that relator offers in support of his allegation that Dr. Clark's Genotropin prescriptions for GHD were "off-label" is the testimony of Rost in his own deposition. Dr. Rost testified that a stimulation test is a "test that you do with a couple of substances to ensure that the patient actually has growth hormone deficiency, and if the value is below 10, two tests, then you are regarded during this time period as having had growth hormone deficiency." (Labaton Decl., Ex. 6, 80 (Rost

Dep.).) Although Dr. Rost does hold a medical degree, this opinion was given "based on [his] lay understanding in [his] capacity as a marketing executive." (Id.)

Defendants provided the Court with the FDA-approved labeling for Genotropin, which states that, for adult patients, "confirmation of the diagnosis of adult growth hormone deficiency . . . involves an appropriate growth hormone provocative test." (Mosier Decl., Ex. 1 at 2.) In the label's "Indications and Usage" section for pediatric patients, no testing requirement is mentioned or required. (Id.) Even if two tests were required, there is no evidence that defendants encouraged or influenced doctors to do only one test through any promotional materials.

C. Kickbacks

Rost alleges that the defendants, in order to gain a competitive edge for Genotropin, provided illegal kickbacks to physicians that ultimately caused the submission of false claims to the Kentucky Department of Medicaid Services and the Indiana Family and Social Services Administration in violation of the FCA. Genotropin prescriptions in Indiana and Kentucky are filled at specialty pharmacies. These pharmacies are the parties that submit the claims to Medicaid for payment and reimbursement. These alleged kickbacks took three forms: (1) remuneration and personal benefits for physicians for attendance and participation at Pharmacia-sponsored events; (2) paid participation in the Kabi

International Growth Study (KIGS); and (3) participation in the Bridge Program. (Pl.'s SUF ¶ 4.) Defendants point out that, during the relevant time period, Pharmacia had a written policy that stated:

> The cornerstone rule of the fraud and abuse laws is as follows: No Pharmacia employee may offer or provide anything of value to any individual health care professional or institution as an inducement or in exchange for an agreement - written, unwritten or implied - to purchase, recommend the purchase of, or prescribe Pharmacia products.

(Mozier Decl., Ex. 17 at PFIZER001891 (emphasis in original).) In addition, there is evidence that Pharmacia employees received extensive communication about and training on the anti-kickback laws. (Def.'s SUF ¶¶ 47-52.)

As noted earlier, Relator's claims have been limited by this Court to pediatric prescriptions written for off-label indications in the Indiana sales region. Relator has identified[3] 10 patients for whom Medicaid paid a total of 122 claims for Genotropin prescribed for the off-label treatment of Idiopathic Short Stature.[4] (Pl.'s SUF ¶¶ 30-39; Labaton Decl., Ex. 49.) These prescriptions were written by one of eight physicians. Drs. John Fuqua, Henry Rodriguez, Erica Eugster, Linda DeMeglio,

---

[3] As a preliminary point, defendants argue that the relator has not adequately identified those claims that he alleges were false as a result of illegal kickbacks. The Court agrees that the record lacks clarity.

[4] The FDA eventually approved Genotropin for this use in June, 2008.

Nancy Johnson, Emily Walvoord and James Wright (the "Riley Doctors") are pediatric endocrinologists employed by the Riley Hospital for Children, which is associated with the Indiana University Medical Center. (Pl.'s SUF ¶ 28.) Dr. Pamela Clark is a pediatric endocrinologist who, from 1996 to 2005, was associated with the University of Louisville Medical Center. (Id. ¶ 29.)

1. Pharmacia Conferences

Relator identifies a number of Pharmacia-sponsored conferences that allegedly constituted illegal kickbacks to physicians who prescribed the claims at issue in this case. While relator goes into great detail about a number of conferences, the Court focuses only on those events that were attended by Dr. Pamela Clark. There is no evidence in the record that the Riley Doctors attended any Pharmacia-sponsored conferences.

Dr. Clark attended five conferences sponsored by Pharmacia between 1998 and 2003 in nice places like Nice, France, Puerto Rico, and Kona, Hawaii. (Pl.'s SUF ¶ 11.) Pharmacia's policy was to provide airfare, lodging and meals for physicians attending its conferences. (Labaton Decl., Ex. 12 at 9.)

Relator alleges that payments to compensate Dr. Clark for attendance at the conferences were illegal kickbacks. Defendants' expert disagreed, stating they "provided substantial

educational benefits to pediatric endocrine physician attendees by bringing them up-to-date on the newest findings in regard to growth disorders and effects and side effects of growth hormone." (Levitsky Decl. ¶ 38.) Relator retorts that the conferences were "run by" the marketing department. (Labaton Decl., Ex. 2 at 182 (Wajnrajch Dep.).) In his view, the meetings failed to meet a "standard of scientific objectivity." (Labaton Decl., Ex. 11 at 8-9 (Brock Report).)

In addition, beginning in 1998, Dr. Clark received $2500 per year from Pharmacia for sitting as a consultant for a National Committee, which met twice a year. (Pl.'s SUF ¶ 11.)

Pharmacia's records indicate that Dr. Clark prescribed Genotropin to approximately 90% of her new growth hormone patients in 2000 and 2001. (Labaton Decl., Ex. 36.) In 2000, Genotropin's market share (as compared to chemically equivalent somatropin drugs) was 12%, and in 2001 it rose to 18%. (Id., Ex. 17.)

2. KIGS Data Entry Payments

KIGS stands for Kabi International Growth Study and was administered by Pfizer and Pharmacia, which had acquired the company Kabi International. (Mozier Decl., Ex. 24.) Launched in 1987, KIGS is an ongoing, open-label, data surveillance study that surveys pediatric patients who take Genotropin for growth hormone deficiency. (Id.) The data collected focuses on the

long-term safety and growth response to Genotropin. (Id.) The KIGS database is populated by physicians, or investigators, who enter patient data into the database and update data points through continued monitoring of the patient. (Mozier Decl., Ex. 24.) Dr. Clark was a "Lead Investigator" and the Riley Doctors were "Co-Investigators" with the KIGS program during the relevant time period. (Labaton Decl., Ex. 13.)

For a physician to participate in the KIGS program, he or she needed to sign a clinical trial agreement with Pharmacia. (Mozier Decl., Ex. 26.) These agreements typically required approval of the academic institution with which the physician was affiliated and review of the KIGS protocol and informed consent by the institution's Institutional Review Board. (Mozier Decl., Ex. 25 at 207-08 (Wajnrajch Dep.).) Both institutions here - Indiana University and the University of Louisville - signed the clinical trial agreements. The agreements were reviewed and approved by the institutional review board and the grants office. (Mozier Decl., Ex. 22 at 167-69 (Pescovitz Dep.); id., Ex. 11 at 149 (Clark Dep.).)

Defendants remitted payments to these institutions for KIGS participation by physicians. (Mozier Decl., Exs. 26, 27.) Upon execution of the clinical trial agreement, each institution received $1,000 as compensation for the 15-20 hours required to review the protocol and approve the agreement. (Id.; Mozier Decl., Ex. 25 at 211 (Wajnrajch Dep.).) The institution also

received $100 per patient update, with a cap of two updates per year. (Mozier Decl., Exs. 26, 27.) This payment compensated for the half hour that it took to input the patient data. (Mozier Decl., Ex. 11 at 150 (Clark Dep.).) No physicians received payments for their participation in the KIGS study. (Mozier Decl., Exs. 26, 27.)

Relator alleges that the $100 payments overcompensated physicians participating in the KIGS program. (Pl.'s SUF ¶ 7.) Although the first data entry for a patient required approximately a half hour of data entry, subsequent entries only required the physician (or other designee) to enter the patient's height, weight, dose of Genotropin, pubertal status, and the date of the return visit. (Labaton Decl., Ex. 2 at 38 (Wajnrajch Dep.).) Relator also alleges that, although KIGS payments were made directly to the universities, they constituted "significant personal benefits to the prescribing physicians" because "physicians who work at academic medical centers are expected to raise money for research projects . . . . [and their] success or failure in doing so is known to department heads, and is an important factor in the advancement, promotion, and financial compensation of medical school faculty members." (Pl.'s SUF ¶ 7.)

3. Bridge Program

Defendants' expert Dr. Levitsky describes Pharmacia's Bridge

Program as follows:

> The Bridge Program was developed to assist patients and physicians with rhGH treatment and is similar to programs available from the other major growth hormone manufacturers, including Genentech, Eli Lilly, and Novo Nordisk. Personnel at the Bridge Program are available to facilitate growth hormone therapy in the busy pediatric endocrinologist's office. Our nurses use this program and other similar ones from other growth hormone companies to make sure that their patients get the coverage that they need in order to afford the necessary medical treatment. The Bridge Program does this by making sure the nurses provide all the necessary clinical data required by the insurers in addition to the [Statements of Medical Necessity] prepared by the doctors' offices. The Bridge Program will also carry out the intense follow-up many insurers require. The Bridge Program has also facilitated arranging for transitional rhGH therapy before the approval process is complete, which is particularly useful in children whose families are transitioning insurers because of job changes and the like. The Program can arrange for uninterrupted therapy, which greatly benefits the children receiving rhGH treatments.

(Levitsky Decl. ¶ 40.)

Relator argues that the Bridge Program represented an illegal kickback to physicians for two reasons. First, relator claims that the program "enabled physicians to obtain - and then bill - new patients." (Pl.'s SUF ¶ 9.) Because the Bridge Program helped patients navigate the difficult process of obtaining insurance approval from third party payors, and because patients often remain on growth hormone treatment for between 4 and 18 years, relator argues that "if the Bridge program was successful in convincing an insurance [provider] to provide coverage for Genotropin, the prescribing physician could expect

periodic office visits from the patient for a number years," increasing that physician's remuneration. (Id.) Second, relator claims that the Bridge Program was valuable to physicians because it "saved them the time that they, or their staff, would have spent in seeking approval from third party payors." (Id.) Relator's expert, Dr. Dan Brock, wrote that these benefits were "intended to be an inducement for pediatric endocrinologists to prescribe Genotropin instead of any of the competing brands." (Labaton Decl., Ex. 11 at 5.)

Both Dr. Clark and the Riley doctors participated in the Bridge Program. (Labaton Decl., Ex. 15.)

II. DISCUSSION

A. Standard of Review

Summary judgment is appropriate when "'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.'" Barbour v. Dynamics Research Corp., 63 F.3d 32, 36-37 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)). To succeed on a motion for summary judgment, "the moving party must show that there is an absence of evidence to support the nonmoving party's position." Rogers v. Fair, 902 F.2d 140, 143 (1st Cir. 1990); see also Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986).

Once the moving party has made such a showing, the burden shifts to the non-moving party, who "'may not rest on mere allegations or denials of his pleading, but must set forth specific facts showing there is a genuine issue for trial.'" Barbour, 63 F.3d at 37 (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986)). The non-moving party must establish that there is "sufficient evidence favoring [its position] for a jury to return a verdict [in its favor]. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted." Anderson, 477 U.S. at 249-50 (internal citations omitted). The Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." Barbour, 63 F.3d at 36 (citation omitted).

B. False Claims Based on Off-Label Prescriptions

Relator argues that defendants violated the FCA through off-label marketing of Genotropin where the patient was diagnosed with GHD but the physician did not conduct two stimulation tests on the patient prior to making the diagnosis.

It is undisputed that the FDA approved Genotropin for the treatment of GHD as an "on-label" indication in 1995, and that Genotropin has been indicated for GHD treatment at all relevant times. (Pl.'s SUF ¶ 24.) Genotropin's FDA-approved label does not indicate that two stimulation tests are required for a

diagnosis of pediatric GHD or for the administration of Genotropin. (Mosier Decl., Ex. 1 at 2.)

Relator has produced no evidence suggesting that one of Genotropin's "on-label" indications is transformed to an off-label indication when both stimulation tests are not administered. Moreover, even if two tests were required, there is no evidence that defendants caused the submission of false claims based on inappropriate testing. Accordingly, there is no disputed issue of material fact and summary judgment will be allowed as to the purely off-label claims.

C. False Claims Act and Implied Certification Theory

Rost argues that defendants' payment of kickbacks to physicians caused false on-label and off-label claims to be submitted to the government. Defendants are liable under the False Claims Act if they "knowingly . . . cause[d] to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Claims may be "false or fraudulent" either factually or legally. See Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001); United States ex rel. Hutcheson v. Blackstone Medical, Inc., 694 F. Supp. 2d 48, 62 (D. Mass. 2010) (Young, J.). Factually false claims are claims involving "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." Mikes, 274 F.3d at 697. Legally false claims are those that falsely certify

compliance with applicable statutes and regulations when the government conditions payment on such compliance. United States ex rel. Conner v. Salina Regional Health Center, 543 F.3d 1211, 1217 (10th Cir. 2008); see also United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232 n.15 (1st Cir. 2004) ("A number of courts have also found FCA violations where a defendant falsely certifies compliance with certain conditions required as a prerequisite for a government benefit or payment in order to induce that benefit." (citing United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997))), abrogated on other grounds by Allison Engine Co., Inc. v. United States ex rel. Sanders, 553 U.S. 662 (2008). False certification can be express, where the claim is accompanied by an explicit statement of compliance, or implied, where the act of submitting the claim implies compliance. See, e.g., Conner, 543 F.3d at 1217-18; Hutcheson, 694 F. Supp. 2d at 62-63.

The implied false certification theory of liability under the FCA is an evolving area of the law. Two courts have deferred ruling on its very validity. See, e.g., United States ex rel. Marcy v. Rowan Companies, Inc., 520 F.3d 384, 389 (5th Cir. 2008) (deferring decision on validity of implied false certification theory); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 786 n.8 (4th Cir. 1999) (declining to address validity of implied false certification theory). Other circuits have

accepted the theory under varying conditions. See Conner, 543 F.3d 1211, 1218 (10th Cir. 2008) (explaining that "under an implied false certification theory . . . the analysis focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment); United States ex rel. Augustine v. Century Health Servs., Inc., 289 F.3d 409, 415 (6th Cir. 2002) (holding that "false implied certification may constitute a false or fraudulent claim even if the claim was not expressly false when it was filed" and that "liability can attach if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned"); Mikes, 274 F.3d at 699-700 (concluding that implied false certification is appropriately applied "in limited circumstances" where the underlying statute or regulation expressly states that payment is conditioned on compliance); United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc., 214 F.3d 1372, 1376 (D.C. Cir. 2000) (adopting the rule "that a false certification of compliance with a statute or regulation cannot serve as the basis for a qui tam action under the FCA unless payment is conditioned on that certification") (citing United States ex rel. Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996)).

Alternatively, other courts have held that plaintiffs only need to show that the implied certification related to compliance with applicable statutes and regulations which, if not complied

with, would cause the government to withhold payment. United States ex rel. Pogue v. Diabetes Treatment Centers of America, 565 F. Supp. 2d 153, 158-59 (D.D.C. 2008)(involving Medicare).

The difficult legal question in this case is whether or not the claims submitted by the innocent third parties, the pharmacies, can be "false or fraudulent" under a theory of implied certification when the drug manufacturer allegedly violated the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b, by paying kickbacks to doctors to induce them to prescribe their drugs in violation of the AKS. The relator alleges that the pharmacies' implied certifications were false because the claims resulted from violations of the AKS by defendants and the prescribing physicians. The defendants argue that the pharmacies' implied certification related only to their own compliance and did not reach back to the defendants' conduct or the conduct of the prescribing physicians.

The Supreme Court has long held that a person may be liable under the FCA for causing an innocent third party to submit a false claim to the government without knowing it is false. See, e.g., United States v. Bornstein, 423 U.S. 303, 313 (1976) (holding that a subcontractor, which made three shipments of falsely branded electron tubes to prime contractor which caused prime contractor to submit false claims to the United States for radio kits, was liable under the FCA); United States ex rel. Marcus v. Hess, 317 U.S. 537, 539-43 (1943) (holding that

provisions of the FCA "indicate a purpose to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government"); United States v. Rivera, 55 F.3d 703, 706-07 (1st Cir. 1995) ("Although, from [the innocent party's] perspective, the claim it presented may not have been 'false or fraudulent,' that claim was inflated by defendants' earlier fraud; and the case law allows the United States, in such circumstances, to sue defendants under the FCA for having 'caused' the filing of a 'false' claim against the government."). However, "a violation of the federal antikickback provision is not a per se violation of the FCA." United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 54 (D. Mass. 2001). "While Defendant's payment of kickbacks may well be illegal, a claim under the FCA will fail unless Relator alleges that [the defendant] caused or induced a doctor and/or pharmacist to file a false or fraudulent certification regarding compliance with the anti-kickback statute." Id. at 55. A claim cannot be false merely because the activity underlying the claim was illegal, "[i]t is the false certification of compliance which creates liability." United States ex rel. Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996).

This Court has previously had occasion to address the issue of implied certifications, albeit in a factually dissimilar case. In In re Pharmaceutical Industry Average Wholesale Price

Litigation, 491 F. Supp. 2d 12 (D. Mass. 2007), the Court denied a motion to dismiss an allegation that a pharmaceutical company caused the submission of false claims for reimbursement based on fictitious "average wholesale prices" to state Medicaid programs by inducing the submission of those false claims through kickbacks. Pointing out that the issue had been poorly briefed, the Court held:

> The FCA is violated when a Medicaid claim is presented to the state government in violation of the Anti-Kickback statute, even if there is no express certification of compliance with the statute.

Id. at 18. The Court did not address a situation where, as here, the claim itself was not factually false (i.e., because of a false price) but where the AKS was violated.

At oral argument, the government relied heavily on Mason v. Medline Indus., Inc., ___ F. Supp. 2d ___, 2010 WL 653542 (N.D. Ill. Feb. 18, 2010), which held that a company was liable for engaging in a pattern of bribes and kickbacks, the necessary and foreseeable consequence of which was the submission of cost reports and accompanying certifications that expressly certified compliance with the AKS. Id. at *7 ("The wealth of case law supports the proposition that the FCA reaches claims that are rendered false by one party, but submitted to the government by another."). Here, however, there is no evidence of any false express certification of compliance with the AKS by either the pharmacies or the prescribing physicians who had to seek prior

approval.

The government argues that when you bill Medicaid you are impliedly certifying that no kickbacks have been paid in any of the underlying transactions. However, there are no statutes, regulations, or express certifications by pharmacists cited to support this argument.

The two courts that have directly addressed this issue have rejected an argument that a person who pays kickbacks to induce a factually truthful claim can be held liable under the FCA through an implied certification theory. See Hutcheson, 694 F. Supp. 2d at 66 (holding that "the certification is specific to the party seeking reimbursement" and that it is "not in itself a certification that the entire transaction complied with the Anti-Kickback statute"); United States ex rel. Thomas v. Bailey, No. 06-cv-00465, 2008 WL 4853630, at *9 (E.D. Ark. Nov. 6, 2008) ("[A] hospital's act of submitting a claim for payment to the government impliedly certifies the hospital has complied with the Anti-Kickback Statute . . . 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 does not act under the hospital's control, complied with the Anti-Kickback Statute."). Under the approach taken in Bailey and Hutcheson, the pharmacies that submitted the claims implicitly certified compliance with applicable statutes and regulations only with respect to themselves and those persons they control (e.g., employees).

In its statement of interest the government alternatively argues that "the payment of a kickback renders subsequent claims factually false under the FCA, without regard to who submits the claim or whether there is a certification that no such kickback was accepted." (Docket No. 173 at 2.) Relying on a conflict of interest theory that the claim itself is false if a kickback has been paid, the government claims, "[A]s a condition of its reimbursement, Medicaid requires that the physicians must render their services without the conflict of receipt of a kickback." (Id. at 5.) The government supports this theory by citing to United States v. Mississippi Valley Generating Co., a Supreme Court opinion from 1961 which held that a contract may be disaffirmed by the Government in the case of a conflict of interest, even without proof of actual additional costs to the government or proof that the conflicted agent acted differently than he would have without the conflict. 364 U.S. 520, 549-50 (1961). However, the D.C. Circuit has held, in the context of a False Claims Act case, that Mississippi Valley does not support a conflict of interest theory of FCA liability because its holding renders a contract voidable, as opposed to automatically void. Siewick, 214 F.3d 1372, 1377 (D.C. Cir. 2000); cf. Karvelas, 360 F.3d at 225 (holding that "[n]ot all fraudulent conduct gives rise to liability under the FCA. The statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment.").

The Court notes that the federal AKS, 42 U.S.C. § 1320a-7b,

was recently amended to include language stating that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the False Claims Act]." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 § 6402(f)(1) (2010). However, this language was not effective at the time the claims in question were submitted to the state Medicaid agencies.

Neither the government nor the parties have cited any cases that have stretched an implied certification theory to reach back to impose FCA liability on a payer of kickbacks where the person who submitted the claim was innocent of wrongdoing and where (a) the claim itself was not factually false, (b) the claim was not legally false due to an express certification of compliance with the AKS or (c) compliance with the federal statute was not an expressly stated precondition of payment. As other courts have stated, the implied certification theory should be applied with caution in only limited circumstances.

Accordingly, the Court finds that Rost cannot proceed on the present record with his implied certification theory of liability. Because the Court finds that relator's implied certification theory fails as a matter of law, the Court need not reach the difficult and important question of whether or not the payments to Dr. Clark to attend "boondoggle" conferences, which may have had some educational aspects, constitute illegal

kickbacks under the AKS.[5]

III. ORDER

The Court **ALLOWS** defendants' motion for summary judgment.

/s/ PATTI B. SARIS_____
PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

[5] Based on the undisputed evidence, though, I note that neither the KIGS program nor the Bridge program functioned as illegal kickbacks.