UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES ex rel. A.) SCOTT POGUE)	
Plaintiff,)	
v.)	Civil Action No. 99-3298 (RCL)
DIABETES TREATMENT) CENTERS OF AMERICA, et al.)	
Defendants.)	

MEMORANDUM OPINION

Now before the Court comes defendant Diabetes Treatment Centers of America's Motion for Summary Judgment [167] and Motion to Strike [189]. Upon consideration of the motions, the entire record herein, and the applicable law, the Court will GRANT defendant's Motion for Summary Judgment as to claims under the Stark Law and DENY defendant's Motion as to all other claims. The Court will further GRANT defendant's Motion to Strike.

I. <u>BACKGROUND</u>

Relator A. Scott Pogue filed this suit under the False Claims Act¹ against defendants

Diabetes Treatment Centers of America, American Healthcorp, Inc., West Paces Medical Center,

Dr. Paul C. Davidson, Dr. Bruce W. Bode, Dr. Judson G. Black, Dr. Robert Dennis Steed, and

Dr. Anthony E. Karpas, alleging presentation of false Medicare and Medicaid claims to the

¹31 U.S.C. § 3729.

United States Department of Health and Human Services. After almost fourteen years of litigation, Diabetes Treatment Centers of America remains as the lone defendant. Relator seeks redress in the form of damages, pursuant to the False Claims Act, stemming from defendant's alleged violation of the Anti-Kickback Statute² and Stark Law³. Defendant's Motion for Summary Judgment and Motion to Strike are currently before the Court.

A. <u>Factual Background</u>

Relator filed suit in 1994 in the United States District Court for the Middle District of Tennessee. In 1999, the Judicial Panel on Multidistrict Litigation transferred the action to this Court. Since first appearing before this Court, the parties have engaged in almost nine years of exhaustive discovery and have advanced substantially toward a final resolution of this protracted dispute.

Defendant Diabetes Treatment Centers of America ("DTCA") began in 1984 to establish treatment centers at various hospitals throughout the United States. (Opp. 80.) Through management of these centers, DTCA aimed to coordinate specialized care for diabetes patients. (*Id.*) Between 1984 and May 20, 1996, the time period germane to this action, DTCA contracted with about 120 hospitals, agreeing to establish treatment centers in the facilities in exchange for remuneration. (Opp. 81.) Only practicing physicians were able to admit patients to DTCA's treatment centers. (Williams Dep. 130:13-15.)

DTCA contracted with physicians to serve as medical directors at the various treatment

²42 U.S.C. § 1320a-7b.

³42 U.S.C. § 1395nn.

centers.⁴ (Mot. Summ. J. 5.) DTCA retained at least one medical director for each of its treatment facilities. (*Id.*) Between 1984 and 1996, 276 physicians served as medical directors. (*See* Reply Ex. 1.) DTCA also hired program managers to aid in coordinating efforts at its treatment centers. (Mot. Summ. J. 5.) Program managers enjoyed the primary day-to-day contact with DTCA's medical directors. (Cigarran Dep. Vol. 2, at 121:6-16.)

The relationship between DTCA and its medical directors constitutes the focal point of this dispute. Relator alleges that a purpose of DTCA's compensation of medical directors was to induce referrals to its treatment centers. (*See* Compl. ¶¶ 26-34.) Only by contracting with physicians to secure sufficient admissions to its treatment centers could DTCA guarantee hospitals that establishing a diabetes treatment center would be in their best financial interest. (*See id.*) In contracting with medical directors to induce referrals to treatment centers, relator alleges DTCA caused false Medicare and Medicaid (collectively "Medicare") claims to be submitted to the United States government, in violation of the False Claims Act ("FCA"), Anti-Kickback Statute ("AKS"), and Stark Law. (*See* Compl. ¶¶ 34, 45.) Relator further alleges that DTCA knowingly and willfully caused these false claims to be submitted to the Government. (*See* Compl. ¶ 34.) In redress for these harms, relator seeks an award of treble the amount of the United States' damages plus a civil penalty of \$10,000 for each false claim submitted to the Government. (Compl. Prayer for Relief.)

⁴The precise role of these medical directors serves as the heart of this dispute. Defendant argues that the medical directors were compensated for legitimate duties, which generally involved overseeing management of the treatment facilities. Relator contends that the medical directors were remunerated primarily for their referrals to the centers.

B. <u>Statutory Background</u>

1. False Claims Act

The FCA imposes liability to the government on 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." 31 U.S.C. § 3729(a)(1) (2008). To satisfy the statute's knowledge requirement, a person must "ha[ve] actual knowledge of the information, act[] in deliberate ignorance of the truth or falsity of the information, or act[] in reckless disregard of the truth or falsity of the information," but "no proof of specific intent to defraud is required." *Id.* § 3729(b).

Though affording no wholly private right to bring suit under the statute, the FCA allows a person to "bring a civil action for a violation of Section 3729 for the person and for the United States government... in the name of the Government." 31 U.S.C. § 3730(b)(1) (2008).

The Supreme Court has affirmed an aggressive reading of the FCA. *See Cook County*, *Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003). Indeed, the Court explained that "Congress wrote expansively, meaning to 'reach all types of fraud, without qualification, that might result in financial loss to the government." *Id.* (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)).

2. Anti-Kickback Statute

The AKS imposes liability on anyone who

knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b) (2008).

Congress amended the statute in 1977 in an effort to expand its reach and make enforcement more vigorous. *See United States v. Greber*, 760 F.2d 68, 70-71 (3d. Cir. 1985). Concern about fraud and abuse in the Medicare system served as the primary impetus behind these amendments. *Id.* Of moment to this litigation, Congress viewed elimination of kickbacks as central to any efforts to combat Medicare fraud and abuse. *Id.*

3. Stark Law

In its current iteration, effective since 1995, the Stark Law prohibits physicians having a "financial relationship" with an entity from

mak[ing] a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health care services pursuant to a [prohibited] referral

42 U.S.C. § 1395nn(a) (2008). A "financial relationship" is defined as "a compensation arrangement [] between the physician [] and the entity." *Id.* "[A]ny arrangement involving any remuneration between a physician and an entity" constitutes a compensation arrangement. *Id.* § 1395nn(h).

An indirect compensation arrangement is most germane to this action. Such an arrangement embodies three key characteristics:

- (i) between the referring physician [] and the entity furnishing [designated health services] there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships [] between them (that is, each link in the chain has . . . a compensation arrangement with the preceding chain;
- (ii) the referring physician [] receives aggregate compensation from the person or entity in the chain with which the physician [] has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the [designated health

services]; and

(iii) the entity furnishing [designated health services] has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician [] receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the [designated health services].

Financial Relationship, Compensation, and Ownership or Investment Interest, 42 C.F.R. § 411.354(c)(2).

II. ANALYSIS

A. Standards for Summary Judgment

Summary judgment is appropriate where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c). Affording substantial deference to the nonmoving party, the summary judgment standard mandates that the court "draw all justifiable inferences in the nonmoving party's favor and accept the nonmoving party's evidence as true." *Brown v. Paulson*, 541 F. Supp. 2d 379, 383 (D.D.C. 2008).

Summary judgment must be entered "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "In such a situation, there can be no 'genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Id.* at 322-23.

The nonmoving party must clear a certain threshold in surviving a motion for summary judgment: "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment," and "[t]he mere existence

of a scintilla of evidence in support of the [nonmoving party's] position will be insufficient."

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 252 (1986); accord Matsushita Elec. Indus.

Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986) (holding that the nonmoving party "must do more that simply show that there is some metaphysical doubt as to the material facts").

Summary judgment is not appropriate "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson, 477 U.S. at 248. Thus, the proper focus of the inquiry is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Id. at 251-52.

The judge's role at the summary judgment stage is limited. *See id.* at 249. As the Supreme Court in *Anderson* explained, "the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Id.* Accordingly, the judge may not "assess the credibility of witnesses" at the summary judgment stage. *United States v. Project on Gov't Oversight*, 454 F.3d 306, 313 (D.C. Cir. 2006). Indeed, "[e]valuation of the credibility of witnesses must be left to the factfinder"

B. Legal Analysis

Defendant in its motion for summary judgment advances five principal arguments as to why summary judgment is appropriate here: (1) actions alleging violations of the AKS may not properly be pursued under the FCA; (2) relator has failed to produce evidence of claim presentment; (3) relator has failed to produce evidence that defendant sought to induce physician referrals; (4) relator has failed to produce evidence showing that defendant knowingly and willfully caused false claims to be presented to the U.S. government; and (5) relator has failed to

produce evidence to show that defendant violated the Stark Law. Though the Court agrees with defendant's fifth argument, it finds the first four unpersuasive. The Court will examine each argument in turn.

1. The AKS and Stark Law under the FCA

Apparently unperturbed by two adverse rulings in this litigation alone with respect to an identical argument, defendant first contends that an action alleging violations of the AKS cannot proceed under the FCA. Specifically, defendant asserts that a claim submitted to the government in violation of the AKS is not "false" pursuant to the FCA, since an offending provider may still receive reimbursement for Medicare claims even though it violated the statute. (*See* Mot. Summ. J. 22-29.) Unfortunately for plaintiff, a panoply of case law holding the opposite renders the current iteration of this argument as unsuccessful as its previous attempts.

Three elements must exist for permissible imposition of FCA liability: "(1) the defendant submitted a claim to the government; (2) which was false; and (3) which the defendant knew was false." *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 57 (D.D.C. 2007). A claim can meet the falsity requirement if it is either factually false or legally false. *Id.* at 64. "It may be factually false if it incorrectly describes the goods or services provided or a request for goods or services provided, or it may be legally false because of an express false certification or an implied false certification." *Id.*

The theory of implied certification is most relevant to this action. Such a theory rests on the principle that "where the government pays funds to a party, and would not have paid those funds had it known of a violation of a law or regulation, the claim submitted for those funds contained an implied certification of compliance with the law or regulation and was fraudulent."

United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., 238 F. Supp. 2d 258, 264 (D.D.C. 2002) [hereinafter Pogue II]. This Court in Pogue II engaged in a lengthy discussion of implied certification, the most salient of which will be repeated here.

A cursory glance at the current form for submission of claims to Medicare provides compelling evidence for rejecting defendant's argument. The form requires certification that "payment of a claim by Medicare or other federal health care programs is conditioned on the claim and the underlying transaction complying with such laws, regulations, and program instructions (including the anti-kickback statute and the Stark [L]aw)." *Id.* Even though this language was not added until 2001, and hence is not directly applicable to the claims at issue in this action, it nevertheless possesses "evidentiary value . . . in proving that the government would not have paid the claims had it known of the alleged violations." *Id.* at 264 n.2. Indeed, this Court noted that such a certification as found in the current Medicare claim submission form "comports with even the most parsimonious application of the implied certification theory." *Id.* at 264.

Legion other cases have held violations of AKS and Stark can be pursued under the FCA, since they would influence the Government's decision of whether to reimburse Medicare claims. *See, e.g., United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 33 (D.D.C. 2003) ("[C]ompliance with [AKS] and Stark laws would affect the government's decision to pay."); *United States ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp. 2d 8, 13 n.5 (D.D.C. 2003) ("Compliance with these laws [AKS and Stark] is a condition for reimbursement under Medicare, and [defendants] impliedly certified compliance with these laws[s] in submitting claims to Medicare."). At least one court has scoffed at the absurdity of

defendant's argument, noting that accepting such a position "would put the government in the position of funding illegal kickbacks after the act." *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 615 (N.D. Ill. 2003).

Finally, the text of the Stark Law expressly brings it under the compass of the theory of implied certification: "[n]o payment may be made under this subchapter for a designated health service which is provided in violation of section (a)(1) of this section." 42 U.S.C. § 1395nn(g)(1).

Defendant attempts to escape this seemingly inexorable rejection of its argument, but these attempts likewise fail. It first argues that this Court's reasoning in *Hockett* mandates that relator produce evidence showing that the Government would not have reimbursed defendant for claims had it known of alleged violations. (*See* Reply 37-41.) However, this Court in *Hockett* expressly contrasted the rejection of the implied certification theory in that case (with respect to a different issue at hand) with the embracing of the same theory in the AKS context. 498 F. Supp. 2d at 69. Indeed, the Court voiced its approval of the conclusion reached in *Pogue II*, which was relied upon in the preceding discussion. *Id.* at 68.

Defendant further maintains that the deposition testimony of Eric Yospe, who worked for the Government and oversaw reimbursement of Medicare claims, shows that a violation of the AKS would not have affected the Government's decision to reimburse submitted claims. (*See* Mot. Summ. J. 47-51.) First of all, Yospe in his deposition expressly declared that he was testifying on behalf of himself and was not representing the U.S. government in any capacity. (*See* Yospe Dep.) Moreover, other courts have found similar testimony to be of no moment in the litigation. *See*, *e.g.*, *United States v. Rogan*, 517 F.3d 449, 452 (7th. Cir. 2008). The *Rogan*

court stated that the determination of falsity for purposes of the FCA is an objective standard, and "[t]estimony of a claims-processing officer along the lines of 'I follow the law' is not required." *Id.* The court further expounded on its disregard of testimony, similar to Mr. Yospe's, that an officer would have reimbursed a claim submitted in violation of the AKS:

[a]nother way to see this is to recognize that laws against fraud protect the gullible and the careless - perhaps especially the gullible and the careless - and could not serve that function if proof of materiality depended on establishing that the recipient of the statement would have protected his own interests.

Id.

Finding near unanimity in support of relator's argument that actions alleging violations of the AKS and Stark Law may proceed under the FCA, the Court rejects as meritless defendant's arguments to the contrary.

2. Violations of the AKS

In order to prove a violation of the AKS, a party must show that the defendant "knowingly and willfully made a payment or offer of payment as an inducement to the payee to refer an individual to another for the furnishing of an item or service that could be paid for by a federal healthcare program." *United States v. Miles*, 360 F.3d 472, 479-80 (5th Cir. 2004). In other words, relator here must show that defendant (1) caused claims to be submitted to the Government, (2) remunerated physicians with a purpose to induce referrals, and (3) knew that its actions violated the AKS. The Court finds that relator has satisfied his burden of presenting evidence supporting all three allegations such that there exists a genuine issue of material fact that a finder of fact must resolve.

a. Submission of Claims to the Government

Defendant argues that relator has produced no evidence showing the presentment of Medicare claims to the Government by hospitals with which it contracted. (*See* Mot. Summ. J. 18-21.) Such evidence is either entirely lacking in probative value or is inadmissible, according to defendant. The Court accepts as evidence electronic data of presented claims as authenticated by Mr. Frank Cippoloni. Therefore, it is unnecessary to analyze further the admissibility of other contested exhibits proffered by relator.

Evidence showing the submission of an actual claim to the Government is the "sine qua non of a[n] [FCA] violation." *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002). Indeed, "a central question in [FCA] cases is whether the defendant ever presented a 'false or fraudulent' claim to the government." *Id.* The nonmoving party "is not required to produce evidence in a *form* that would be admissible at trial," but "the evidence still must be capable of being converted into admissible evidence." *Gleklen v. Democratic Congressional Campaign Comm.*, 199 F.3d 1365, 1369 (D.C. Cir. 2000). *See also Greer v. Paulson*, 505 F.3d 1306, 1315 (D.C. Cir. 2007) ("[S]heer hearsay [] counts for nothing on summary judgment.") (internal quotation marks omitted).

A declaration or affidavit made by an official who actually produced claims data is sufficiently authenticated to constitute reviewable evidence for purposes of resolving a summary judgment motion. *See United States v. Rogan*, 459 F. Supp. 2d 692, 727 n.17 (N.D. Ill.), *aff'd*, 517 F.3d 449 (7th Cir. 2008). The court in *Rogan* held that testimony from an official at the Centers for Medicare & Medicaid Services ("CMS"), regarding the transfer of claims data to a CD and subsequent submission to relator, was sufficient to satisfy admissibility standards. *Id*.

Relator has produced a declaration of Frank Cippoloni, an official at CMS. (*See* Cippoloni Decl.) Mr. Cippoloni stated that he responded to relator's subpoena by assembling claims data on a CD and providing it to relator. (*Id.*) This data included Medicare claims submitted to the Government by hospitals with which defendant contracted, and the data was confined to claims made with respect to patients referred by defendant's medical directors. (*Id.*) Since Mr. Cippoloni could testify to this information at trial, this evidence may be permissibly considered by the Court, in accord with the reasoning of *Rogan*. *See* 459 F. Supp. 2d at 727 n.17. The information contained on the CD is sufficient to meet the first requirement of proving an AKS violation: defendant's causing of submission of claims to the Government.⁵

Even if consideration of the CD is allowed, defendant argues that the Court should grant summary judgment with respect to claims against the 187 medical directors whose patients' Medicare claims do not appear on the disc. (*See* Reply 12-13.) Rejecting arguments similar in tenor to that of defendant, courts have found it unnecessary for relators to produce evidence of every single claim submitted to the Government, provided relators can highlight sufficient

⁵Defendant filed along with its reply in support of the Motion for Summary Judgment a Motion to Strike certain enumerated exhibits submitted by relator. (*See* Docket No. 189.) The Court will grant defendant's Motion to Strike. The Court notes that the admission of the Cippoloni Declaration as evidence ultimately renders immaterial the effect of the disposition of the Motion to Strike.

Defendant in its reply in support of the Motion to Strike vigorously argues that the Court may not permissibly consider the declaration of Mr. Cippoloni, since the attachment of this document to relator's Opposition to the Motion to Strike purportedly constitutes an "egregious" discovery violation. Defendant's impassioned rhetoric about the sanctity of the discovery process overlooks the stark truth: accepting its argument would jeopardize relator's suit, which has been working its way through the civil justice system for over fourteen years, owing solely to the violation of a procedural nicety. The Court will not allow enforcement of such a technicality to hinder the delivery of justice. *See Foman v. Davis*, 371 U.S. 178, 181-82 (1962) (reasoning that strict enforcement of the technicalities of the Federal Rules of Civil Procedure must not deprive parties of a decision on the merits of the case).

evidence of claim submission in general. *See, e.g., United States ex rel. El-Amin v. George Washington Univ.*, 522 F. Supp. 2d 135, 141-42 (D.D.C. 2007). The court in *El-Amin* expressly rejected the defendant's argument that relators' allegations should be dismissed with respect to claims submitted for which they had not produced Medicare forms: "[d]efendant is essentially asking the Court to evaluate the strength of Relators' evidence, which is not a proper consideration on a motion for summary judgment." *Id.* The court emphasized the role of the jury, stating that "[t]he number of false claims submitted by defendant, if any, will be determined by the factfinder." *Id.* Finding clear guidance from the opinion in *El-Amin*, the Court will not grant summary judgment as to claims stemming from referrals by medical directors whose patients' claims do not appear on the CD. Such a determination is properly left to the jury in determining whether defendant violated the FCA, and, if so, in ascertaining the appropriate amount of damages.

b. Inducement of Referrals

Defendant contends that relator has not compiled sufficient evidence to show that it compensated physicians with a purpose to induce referrals to DTCA centers. (*See generally* Mot. Summ. J.) Instead, defendant continues, relator relies on sweeping allegations that may be adequate to survive dismissal, but must be disposed of at the summary judgment stage. (*Id.*) The Court rejects defendant's arguments and concludes that relator has produced sufficient circumstantial evidence to support its claim that defendant remunerated physicians with a purpose to induce referrals; a reasonable jury could find for relator on this issue.

Inducement serves a central role in assessing claims of Medicare fraud. *See Polk County, Tx. v. Peters*, 800 F. Supp. 1451, 1455 (E.D. Tex. 1992) ("The gravamen of Medicare fraud is

inducement."). "Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient." *Id.* Courts strictly enforce the inducement prohibitions codified in the AKS. *See United States v. Bay State Ambulance and Hosp. Rental Serv., Inc.*, 874 F.2d 20, 30 (1st Cir. 1989). In view of this aggressive reading of the statute, "the issue of sole versus primary reason for payments is irrelevant since *any* amount of inducement is illegal." *Id.*; *accord United States v. Greber*, 760 F.2d 68, 72 (3d. Cir. 1985) (finding that payment to physicians violated AKS if, in addition to compensating the physicians for legitimate duties, it was also intended to induce referrals).

Though lacking a "smoking gun," relators may survive summary judgment if they have produced sufficient circumstantial evidence to create a jury question as to whether a defendant violated the AKS. *See Rogan*, 459 F. Supp. 2d at 719. Relator here has certainly met that burden and has thereby highlighted genuine issues of material fact.

Legion courts have held that, absent a few exceptions not at issue here, compliance with the AKS requires that a provider pay fair market value to a physician for his services. *See, e.g., id.* at 722-23 (emphasizing physicians' receipt of payment was far in excess of market value for contractual duties performed in finding violation of AKS); *United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045, 1049 (N.D. Ill. 2002). Indeed, "[p]ayment exceeding fair market value is in effect deemed payment for referrals." *Am. Lithotripsy Soc'y v. Thompson*, 215 F. Supp. 2d 23, 27 (D.D.C. 2002). The AKS statute itself states that impermissible remuneration to physicians includes "transfers of items or services for free or other than fair market value." 42 U.S.C. § 1320a-7a(i)(6).

Relator in his opposition produced a detailed fair market value analysis of medical

director fees from the time period germane to this action. (*See* Opp. Ex. 105.) Ms. Kathy McNamara, Senior Manager at the firm Mayer, Hoffman, McCann, PC ("MHM"), performed the analysis. (*Id.*) The report unequivocally stated that defendant paid its medical directors fees far in excess of the fair market value commensurate with their duties:

Our findings demonstrate that DTCA's [medical director agreement] terms were not commercially reasonable and the fees paid did not reflect the fair market value of the services rendered. The scope of the directors' work, the prevailing rates of compensation for comparable positions in comparable concerns, the existence of a potential conflict of interest and the salary policy as to all DTCA's employees and internal inconsistency in compensation paid to medical directors are some of the factors that establish DTCA's medical directors were generally unreasonable and did not reflect general market value.

(*Id.*) MHM also determined that defendant failed until 1995 to make even a primitive attempt at ascertaining fair market value of services performed by medical directors. (*Id.*) The MHM report certainly constitutes grounds for a reasonable jury to find that a purpose of defendant's remuneration to its medical directors was to induce referrals to its centers.

Defendant does not dispute the relevance of the fair market value analysis, but it instead attempts to call into question the findings. (*See* Reply 19-20.) Defendant contends that alleged inaccuracies in Ms. McNamara's formulaic analysis led to unconvincing results. (*Id.*) This argument overlooks the limited role of the Court in analyzing motions for summary judgment. It is emphatically the province of the finder of fact to weigh evidence and assess the credibility of witnesses. *See Anderson*, 477 U.S. at 249. As such, consideration of defendant's criticism of the fair market value analysis is inappropriate at the summary judgment stage.⁶

⁶The Court also notes the breadth of Ms. McNamara's experience in health care, as she has been working in the field for over eighteen years. (Opp. Ex. 105.) Moreover, Ms. McNamara in her deposition discussed the holistic nature of the fair market value analysis and vigorously defended the methods used. (*See* McNamara Dep. 216-23.) Her analysis, then, is not

Though the preceding discussion of market value is perhaps alone sufficient to create a jury question out of the inducement element of an AKS violation, relator has produced a wealth of additional evidence supporting his claims. The very foundation of DTCA's business model was built chiefly on concerns of census - the number of patients treated on a particular day. (See LaRue Dep. 135:1-2.) As the president of DTCA wrote to a fellow DTCA official, the chief objective of the business consisted of fostering census growth. (See Opp. Ex. 77; see also Beard Dep. 28:5 ("Ultimately our goal was census enhancement.").) Defendant communicated these goals of increased patient discharges to its contracting hospitals in a number of letters. (See, e.g., Opp Ex. 1 ("Our goal is to assist you in increasing the number of discharges for people with diabetes from one year to the next."); Opp. Ex. 2 ("Our primary goal . . . is to significantly increase the volume of business at your center.").) Hospitals, in turn, recognized that DTCA aimed to provide them with an increased number of patients. (See Opp. Ex. 4.) Indeed, one hospital proposed to defendant a revised contract term, stating that its purpose was "to incent DTCA to increase the volume over and above existing levels." (Id.) At least one medical director voiced concerns over defendant's excessive and "obvious concern about profit rather than giving services." (Opp. Ex. 9.)

From its inception, DTCA sought to "increase census" by hiring medical directors who could provide its facilities with the necessary patients through referrals. (*See* Opp. Ex. 113.) An early contract expressly stated that a medical director's performance would be "evaluated . . . by measuring census levels generated by his work in establishing quality programs and the credibility of the programs among referral sources" (*Id.*) Defendant added importance to

so egregiously baseless that the Court must disregard it at this juncture, as defendant suggests.

the outcome of these evaluations by stipulating that "[i]n the event that [the medical director] is unable to accomplish and maintain the above census levels, Company may, at its option, terminate this Agreement" (*Id.*) Later medical director form contracts required physicians to perform two primary referral-related duties:

(ii) assist Center in development of referral sources for the Center, to include the medical community, and other community organizations and individuals which can enhance the referral patterns of the area . . . [and] (iv) identify and encourage other physicians and referral sources whose patients could benefit from services offered by Center to utilize the Center.

(Opp. Ex. 12.) As in the original form of the contract, defendant had the right to terminate the agreement in the event the medical director did not meet the referral requirements. (*Id.*)

Furthermore, many medical director contracts awarded compensation to the physicians based on a percentage of annual gross revenue of DTCA centers. (Opp. Ex. 113.) A medical director thus had incentive to increase revenue, and hence his compensation, by referring more patients to defendant's facilities.

Relator has further produced evidence tending to show that defendant was focused on referral numbers when conducting contract negotiations with both medical directors and hospitals. In one example, a DTCA official recommended offering a medical director position to a physician who would contribute at least seven admissions per month to DTCA facilities. (Opp. Ex. 29.) Another DTCA official worried that reducing compensation owed to an existing medical director would create a risk that "he [would] not support the program and may take one-third of his patients elsewhere." (Opp. Ex. 26.) In a particularly salient showing of DTCA's intent to induce physician referrals to its centers, a 1991 contact chart describes ongoing negotiations with a reluctant hospital. (*See* Opp. Ex. 22.) Though the hospital initially worried

that an arrangement with DTCA would not be sufficiently lucrative, DTCA converted these doubts into enthusiasm by retaining a medical director who "promised to call [a hospital official] to express his willingness to admit all primary diabetes and as many secondary as feasible on a case by case basis." (*Id.*) Such negotiations underscored defendant's attempts to interact with medical directors "as customers" by actively soliciting their referrals. (*See* Opp. Ex. 52.) The chief problem with this approach, however, was that defendant was at the same time paying these directors, thereby in effect providing remuneration for referrals.

In addition to the preceding discussion of probative evidence, relator has produced a few "smoking guns." A former medical director at DTCA, Dr. Melvyn Kramer, shed light on the relationship between defendant and its medical directors:

my understanding of what I was required to do as a medical director was to refer patients to the Diabetes Treatment Center located at Waltham Weston Hospital and Medical Center and admit them for inpatient care . . . DTCA ostensibly paid us for our referrals. That was part of the arrangement.

(Ex. 115 (emphasis added).) Additionally, a DTCA program manager, Ms. Mary Beard, testified that DTCA hired medical directors in an effort to "solicit potential admissions." (Beard Dep. 45:4-9.) Ms. Beard expressly stated that DTCA's intent in retaining medical directors "was to solicit the participation, either contractual or through their admitting practices, to admit patients . . . to the center." (*Id.* 11:20-24.) Even DTCA's president, Mr. Jim Deal, admitted that a purpose of retaining medical directors was to induce their referrals:

Q: In other words, the purpose of recruiting a medical director in part was to secure that medical director's admissions?

A: The purpose was - that would be the result of recruiting him. That wouldn't be the only purpose. May not even be the first purpose.

(Deal Dep. 236:11-237:2.)

After formally retaining the services of medical directors, defendant closely monitored the directors' contribution to the census, citing a need to "maximize utilization [of DTCA centers] among the directors." (Opp. Ex. 3.) The DTCA Marketing Manual succinctly tied a medical director's referral patterns to his compensation: "[t]he ultimate Goal = to increase census, which increases revenues, which increase your bonus." (Opp. Ex. 7.) The manual also gave medical directors questions to answer in order to evaluate their performance: "How many patients came in this month? How many new patients came in this month? What is the change since last month? What is the change since this month last year?" (*Id.*) In a brutally candid letter, a DTCA official exhorted medical directors to "join with us in taking whatever steps are necessary to increase volume." (Ex. 8.)

Defendant made clear to its medical directors that their compensation and continuing employment was inextricably linked to the number of patients they provided to the centers. To that end, defendant created an incentive-based compensation system, where medical director performance was articulated in terms of admissions. (*See* Opp. Ex. 107 (Monthly Report).) As a DTCA official said in a letter to a medical director, "[i]ncreased activity will, of course, result in increased value for you." (Opp. Ex. 41.) That promise came into fruition through raises doled out to medical directors who showed a "significant impact on the census." (*E.g.*, Opp. Ex. 40.) In brainstorming ways to further the incentive-based compensation system to increase referrals, DTCA officials recommended giving stock to a medical director to "create a feeling of ownership in him" and make him "see . . . what a good census at the Center means to him." (Opp. Ex. 30.) Such a program "would perhaps encourage him to take a very active part in census building." (*Id.*)

In addition to giving incentives to medical directors in an effort to increase referrals to its centers, defendant actively monitored medical director activity to make sure it was comporting with the goals of increased census. (*E.g.*, Opp. Ex. 21 ("Spoke with the 3 medical directors, informed them of current status. Asked them to contact Pat and express their support and potential admissions.").) Defendant was not hesitant to approach medical directors whose centers had seen a noticeable lapse in discharges. (*E.g.*, Opp. Ex. 106 ("Dr. Hellman has continued to vocalize support of the center, although his census is not reflecting the support.").) In a particularly salient example of defendant's conduct to this end, a DTCA official met with two medical directors:

substance of the dinner was to inform [medical director] that: (1) his admissions to the Center were the least representative in the division; (2) the inability of his office to accommodate emergency referrals and admissions forces us to utilize other physicians . . . [the medical director] asked how many patients it would take to "keep the Center." My answer was at least 15 patients everyday in the Center would be necessary, and how did he plan to facilitate that census.

(Opp. Ex. 24.)

Even when medical directors were performing satisfactorily, defendant nevertheless continued to seek referrals in its neverending drive for profit. Indeed, a DTCA official described company policy as necessitating "incremental census to justify any expense" (Opp. Ex. 37.) In a profitability analysis, defendant listed ways in which the company could enlarge its profit, one of which involved convincing medical directors to increase admissions to the centers. (*See* Opp. Ex. 31.; *accord* Opp. Ex. 44 (recommending that DTCA officials "[v]isit each Medical Director weekly, at their office, to encourage DTC admissions" in order to increase profit).)

Defendant's need for medical director referrals was great, owing to the contractual relations with its hospital customers. These form contracts based the amount of remuneration to

defendant on the number of discharges or Medicare patient days. (*See, e.g.*, Opp. Ex. 82, 120, 121.) A typical example is a 1990 contract between defendant and a hospital: "[h]ospital shall pay DTCA, for services rendered pursuant to this Agreement, amounts as follows based upon the hospital's total diabetes discharges." (Opp. Ex. 121.) Such fee structures provided defendant with a powerful incentive to induce referrals from its medical directors.

Defendant attempts to mitigate the significance of relator's evidence by insisting that the Court impose a greater burden for relator to meet to resist summary judgment. (*See* Reply 26-35.) Defendant first suggests that FCA claims relying on circumstantial evidence must meet a higher bar to survive motions for summary judgment, relying on *Klaczak v. Consol. Med.*Transp., 458 F. Supp. 2d 622 (N.D. Ill. 2006), for this proposition. (*See* Reply 5-6.) Defendant ignores the context of the *Klaczak* court's imposition of a seemingly heightened circumstantial evidentiary threshold. The court applied a raised standard only because relator had produced no evidence showing that the defendant was familiar with the AKS and knew it might be violating the statute. *See Klaczak*, 458 F. Supp. 2d at 681. Reliance on this discussion is inapposite in this action, since relator has produced evidence supporting its claim that defendant knowingly violated the provisions of the AKS. *See* discussion *infra* Part II.B.2.c.

More important, defendant fundamentally mischaracterizes the applicable summary judgment standards. Relator is under no burden to prove with absolute certainty his claims, as defendant throughout its filings seems to suggest. *See Anderson*, 477 U.S. at 248-49. Indeed, the Court's discussion is based on the facts as viewed in a light favorable to relator, and all justifiable inferences are drawn in his favor, as mandated by the rules of summary judgment. *See Paulson*, 541 F. Supp. 2d at 383. Viewed through this prism, relator's evidence must be

sufficient to raise a genuine issue as to material facts such that a reasonable jury could find for relator, and the Court must not inject its own factfinding judgments into the analysis. *See Anderson*, 477 U.S. at 248-52. In sum, the Court finds that relator has produced a wealth of evidence supporting his claim that defendant compensated physicians for their referrals to DTCA centers, and a reasonable jury could decide the issue in relator's favor. As such, summary judgment as to the inducement element of the AKS is patently inappropriate.

c. Knowledge

Defendant argues that its conduct does not satisfy the knowledge standard codified in the AKS. Though defendant admits that it knew it would be illegal to induce referrals, it asserts a good-faith defense. (*See* Mot. Summ. J. 39-42.) Defendant contends that since it relied in good faith on its counsel's advice as to its contractual relations with medical directors, its conduct necessarily cannot meet the knowledge requirement of the AKS. (*See id.*) The Court finds defendant's argument unpersuasive.

A violation of the AKS under the FCA "must have been made 'knowingly,' which can be proven by actual knowledge, deliberate ignorance, or reckless disregard." *Pogue II*, 238 F. Supp. 2d at 266. "Summary judgment is appropriate where [relator] produces no evidence sufficient to support a finding of the requisite scienter." *Hockett*, 498 F. Supp. 2d at 57-58. Courts do, however, recognize a good-faith defense to claims pursued under the AKS and FCA. *See United States v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996).

Relator's evidence shows panoplied warnings from counsel to defendant about potential violations of AKS. (*See, e.g.*, Opp. Ex. 108 (documenting attorneys' advice to defendant regarding potential fraud and abuse claims with respect to its business arrangements and

highlighting over fifty relevant documents).) In a 1989 letter to DTCA, counsel bluntly summarized its fears about the company's business practices:

we are receiving an increasing number of requests - several each week - involving different methods of compensating doctors who happen to be the source, or the potential source, of substantial referrals. While some of these proposals are doubtless clean, *some are not* and the mere volume of the transactions casts a shadow even upon those that might otherwise past [sic] muster. Thus we have an increasing concern about your ability to successfully defend all of the arrangements which are now in place and many of the arrangements for which our opinion has been sought. . . . We get the feeling that some of your people who are negotiating contracts may not fully appreciate all of the considerations that go into dealing with this problem.

(Opp. Ex. 35 (emphasis added).) Attorney Jay Hardcastle actively kept DTCA officials apprised of the latest developments in relevant case law and made recommendations in accordance with judicial demands. (*See* Opp. Ex. 53 (recommending that directors should be made to perform defined duties to mitigate potential charges of fraud and abuse); Ex. 55.; Ex. 62 ("Thus the problem becomes more difficult and our prior advice to you and others at Healthcorp that contracts should be based upon services to be performed and compensation that is reasonable for those services is again underscored.").) Mr. Hardcastle began keeping a "Fraud & Abuse" file in which to record his various warnings to defendant, and he at one point summarized his efforts: "[advised DTCA officials] that their payments to medical directors (along with their occasional physician recruitment assistance, lease payments, etc.) constitute possible violations of the anti-kickback provisions of the Medicare laws, and that these possible violations were especially dangerous after the Kats and Bay State decisions." (Opp. Ex. 70.)

As time went on, counsel called on defendant with vigor, advising that it systematically revise its contracts with medical directors: "it is becoming more and more difficult to sell your product, since legal counsel (who in the recent past would not have raised the issue) are

commonly raising fraud and abuse issues." (Opp. Ex. 72.) A key component of attorneys' advice to defendant centered on the necessity of conducting a fair market value analysis of medical directors' services in addition to requiring the directors to maintain time logs detailing their work. (*See*, *e.g.*, Opp. Ex. 14 ("I would strongly advise that you engage a consultant with experience in this area to assist you in determining a fair market value of compensation for DTCA's medical directors."); Ex. 57 ("I cannot overstress the importance of keeping [time records]. *These sorts of records are absolutely critical in order to demonstrate that [a medical director] is in fact working for his stipend and not being paid for referrals.*") (emphasis added); Ex. 100 (detailing concerns that contracts with medical directors discuss payments that do not reflect market value for services provided).)

Even contracting hospitals expressed concern to defendant that contractual provisions that take into account the volume of referrals may lead to imposition of AKS liability. (*E.g.*, Opp. Ex. 81.) Attorney Hardcastle told DTCA officials that one hospital was uncomfortable with the medical directorship arrangement, since it felt that such a relationship might lead to prosecution against the hospital and DTCA under Medicare fraud and abuse laws. (Opp. Ex. 83.) Hospitals reacted to these concerns by insisting upon insertion of amendments to their existing contracts with DTCA, which expressly provided that payment would not be proportional to hospital revenue. (*See* Opp. Ex. 86.)

At first, it seemed as though defendant, recognizing it was on the brink of unlawfulness, was ready to heed the advice of counsel and take measured steps to avoid violations of the AKS. The president of DTCA sent out a letter in 1989 highlighting the company's concern about the current state of Medicare regulations and judicial precedent:

[w]e do not necessarily believe that this is a proper interpretation of Medicare laws, but it is clear to us that the Medicare program and the courts are taking an aggressive opposite position. This is one time when, even if we are right, we could win the battle but lose the war.

(Opp. Ex. 58.) Shortly thereafter, defendant decided it would make an attempt to force medical directors to complete time logs. (*See* Opp. Ex. 16; Stone Dep. 218:16-18.) Furthermore, the highest ranking DTCA officials engaged in regular discussions about the current state of the Medicare fraud and abuse laws in an effort to determine an appropriate course of action to ensure compliance. (*See* LaRue Dep. 118:16-21.) One such official testified he felt at the time that "any payment based upon a census had some risk." (*Id.* 198:14-18.)

Ultimately, however, defendant's apparent concern about violations of the AKS amounted to nothing more than bluster. Confronted with a multitude of alarms regarding potential fraud and abuse allegations, defendant nevertheless decided to deliberately ignore these warnings and continue to carry out its business as usual. One attorney working for defendant noted DTCA officials' propensity "not [to] deal in any substantive way with the issues" he had raised. (Opp. Ex. 60; *see also* Opp. Ex. 73 ("I advised [a DTCA official] of the Medicare risk involved in this arrangement, and he decided to proceed anyway.").) In fact, defendant did not even make an initial attempt until 1995 to clearly define medical director duties and ascertain fair market value for their services. (*See* Williams Dep. 92:10-21; Black Dep. 81-84.) Far from a cogent professional evaluation of appropriate market rates for payment, the 1995 market value "analysis" was based on one DTCA official's "personal judgment" and use of his purported "rule of thumb." (Williams Dep. 243:9-16.)

Defendant responds to this evidence by arguing that since an attorney never told it with certainty that it would be found liable for an AKS violation, it acted in accord with the requisite standard demanded by the good-faith defense. (See Mot. Summ. J. 39-42.) Not only does this argument again conveniently overlook the appropriate summary judgment standards, see discussion *supra* Part II.B.2.c, but it also ignores the assumptions under which defendant's counsel operated. Indeed, attorney Hardcastle explicitly stated that in his legal analysis he assumed that "aggregate compensation paid to the medical director over the term of the agreement will be consistent with fair market value in arms length transactions and will not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties." (Opp. Ex. 56.) Such assumptions were dubious at best. See discussion supra Part II.B.2.b. Attorney Hardcastle further testified that he relied almost completely on statements from DTCA officials in carrying out his analysis and was under the impression that no part of the compensation paid to medical directors was tied to referrals. (Hardcastle Dep. 268:15-22, 445-48; see also Mills Dep. 67:18-68:1 (stating all understanding regarding duties actually performed by medical directors and the commensurate fair market values of such services came from defendant).) Attorney Smith made pellucid the assumptions under which he labored for defendant:

[d]id I search beyond the four corners? No. Do I have a recollection of a specific conversation with [DTCA officials] about the specific activities that were being done? No. . . . I have no knowledge of the conduct that may have been done by my client or others beyond the four corners of this agreement. So I can't comment on any conduct that may have been done because I don't know what that was.

(Smith Dep. 180:14-19, 182:1-11.) In view of relator's production of evidence regarding defendant's conduct during the relevant time period, it seems as though defendant's counsel may have been misled by the company when analyzing the contracts. Perhaps this was the only reason why most attorneys did not explicitly say that a given contract was patently illegal.

Relator has certainly produced sufficient evidence of defendant's knowledge or reckless disregard of available information about its potential violation of the AKS. The evidence is sufficient for a reasonable jury to find that defendant acted with the requisite level of culpability for imposition of liability under the AKS and FCA.

3. Violations of the Stark Law

Relator further alleges that defendant violated the Stark Law with respect to its conduct between January 1, 1992 and May 20, 1996. This claim must be dismissed, however, in view of relator's failure to produce sufficient evidence showing that contracting hospitals had the requisite knowledge of defendant's payment scheme.

To support an actionable claim under the Stark Law and survive summary judgment, relator must point to evidence showing three key characteristics:

- (i) between the referring physician [] and the entity furnishing [designated health services] there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships [] between them (that is, each link in the chain has . . . a compensation arrangement with the preceding chain;
- (ii) the referring physician [] receives aggregate compensation from the person or entity in the chain with which the physician [] has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the [designated health services]; and
- (iii) the entity furnishing [designated health services] has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician [] receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the [designated health services].

42 C.F.R. § 411.354(c)(2).7 The Court finds defendant has failed to create a genuine issue of

⁷Relator relies on *Rogan* in arguing that these regulations cannot be applied to this action, since they were promulgated after 2000 and cannot be applied retroactively. However, the Court agrees with the *Rogan* court in concluding that these regulations, though not technically binding, constitute persuasive authority and provide excellent guidelines with which to analyze the Stark

material fact as to the third element, and so analysis of the preceding factors is unnecessary.

In stark contrast to the mountain of evidence produced with respect to defendant's alleged AKS violations, relator produces almost no evidence to support a conclusion that the hospitals contracting with defendant (i.e. "the entit[ies] furnishing designated health services") had knowledge of, or acted in reckless disregard or deliberate ignorance of, defendant's compensation schemes. Indeed, relator's discussion of this element is confined to a single sentence in its 166-page opposition memorandum: "[h]ere, the hospitals were directly contracted with DTCA and were well aware of the business model - they paid DTCA to cultivate the business in question." (Opp. 164.) Though such a conclusory allegation may survive a motion to dismiss, it must be disposed of at the summary judgment stage. Concluding that no reasonable jury could find that the evidence supports a finding that hospitals acted with requisite knowledge pursuant to the Stark Law, the Court finds summary judgment is appropriate with respect to all claims under the Stark Law.

C. Suggestion of Remand

This action was originally filed in the U.S. District Court for the Middle District of Tennessee. The Judicial Panel of Multidistrict Litigation ("JPML") subsequently transferred the case to this Court in 1999.

The Court finds that consolidated and coordinated pretrial proceedings have concluded, and pursuant to JMPL Rule 7.6(c)(ii), this Court suggests that the JPML consider remand of this action to the Middle District of Tennessee. Under the multidistrict litigation statute, a case "shall be remanded by the panel at or before the conclusion of such [coordinated or consolidated]

Law claims at issue. See Rogan, 459 F. Supp. 2d at 712-15.

pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated." 28 U.S.C. § 1407(a). Because both discovery and all necessary proceedings before trial have concluded, this Court suggests that the JPML remand this matter to the Middle District of Tennessee for all remaining purposes.

III. <u>CONCLUSION</u>

For the foregoing reasons, the Court concludes that defendant's Motion for Summary Judgment will be GRANTED as to claims under the Stark Law and DENIED as to all other claims. The Court further concludes that defendant's Motion to Strike will be GRANTED.

A separate order shall issue this date.

Signed by Chief Judge Royce C. Lamberth, on July 21, 2008.