McDermott Will & Emery

Tuomey's Appeal of $237M False Claims Act Judgment Denied by the Fourth Circuit

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SPECIAL REPORT

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The U.S. Court of Appeals for the Fourth Circuit affirmed the trial court's May 2013 decision that Tuomey Healthcare System, Inc., a hospital and health system based in Sumter, South Carolina, submitted 21,730 false claims, claims prohibited by the Stark Law, to the Medicare program. The court rejected Tuomey's request for a new trial based on multiple errors by the trial court and Tuomey's constitutional challenges to the trial court's award of damages and civil penalties totaling $237 million. Although concurring with the Fourth Circuit's opinion, Judge Wynn described this case as "troubling," explaining that "even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act." *United States ex rel. Drakeford v. Tuomey*, No. 13-2219, 2015 U.S. App. LEXIS 11460, at *69 (4th Cir. Jul. 2, 2015) (Wynn, J., concurring).

Background

Unless an exception applies, the Stark Law prohibits referrals by a physician to an entity for the furnishing of designated health care services (DHS) (including hospital services) if the physician or an immediate family member has a financial relationship with the entity. In addition, the Stark Law prohibits Medicare claims *and the payment of Medicare claims* for DHS furnished pursuant to referrals prohibited by the Stark Law. The federal civil False Claims Act (FCA) creates liability for the submission of false or fraudulent claims to the United States, and provides for treble damages and penalties of $5,500 to $11,000 per claim. Individuals (referred to as relators) can bring lawsuits under the FCA on behalf of the United States, and are eligible for 15 percent to 25 percent of the judgment if the United States intervenes, and up to 30 percent if the United States does not.

Based on public filings, in response to a competitive threat from an ambulatory surgery center in 2005 and 2006, Tuomey, through subsidiaries, entered into 19 part-time employment contracts with surgeons and proceduralists in reliance on the advice and counsel of its local lawyer, Tim Hewson of Nexsen Pruet. The contracts were unusual because the physicians continued to maintain their private practices and only worked as part-time employees of Tuomey when performing *outpatient* surgeries at Tuomey. The physicians' part-time contracts obligated the physicians to perform all of their outpatient cases at Tuomey; had terms of 10 years; and included a two-year, 30-mile non-compete upon termination of the contract. The contracts provided for Tuomey to bill and collect for the surgeries, and to pay the physicians a guaranteed base salary that was modified year-to-year based on professional collections from the prior year. The bulk of the compensation, however, was a productivity bonus equal to 80 percent of the collections from Tuomey's charges for the professional component of the surgeries. The physicians were also eligible for an incentive bonus of up to 7 percent of their earned productivity bonus. Tuomey also assumed certain of the physicians' private practice costs, including professional liability insurance, employment taxes, and billing and collections.

Michael Drakeford, an orthopedic surgeon, was offered one of these part-time employment contracts in 2005, but declined to enter into the contract based on the advice of his lawyer, Greg Smith. Drakeford contended that the contract was not on fair-market-value terms and thus would be viewed by regulators as illegal payments for referrals. To address his concerns, Tuomey proposed an alternative in the form of an investment in a joint venture that would manage the hospital's outpatient surgery center. Drakeford rejected this alternative.

Seeking to resolve the parties' impasse over the legality of the part-time employment contracts, the parties jointly engaged Kevin McAnaney to review the contracts and give them his opinion. In May 2005, McAnaney advised the parties that the contracts raised significant "red flags" under the Stark Law and that the joint venture alternative raised separate concerns under the Anti-Kickback Statute. McAnaney was critical of the contracts' chances of surviving governmental scrutiny for fair market value. A fourth lawyer, Steve Pratt of Hall Render, also opined on the legality of the part-time contracts, issuing two favorable letters, and Tuomey had months earlier sought the advice of Richard Kusserow, former inspector general of the U.S. Department of Health and Human Services. While stating in a letter that the contracts did not raise "significant Stark issues," Kusserow noted that aspects of the contracts raised "potentially troubling issues" that had not been fully addressed. Tuomey instructed McAnaney that they would not

need his opinion in writing and terminated the engagement by September 2005.

In late 2005, Drakeford, on behalf of the United States, sued Tuomey under the FCA. Drakeford alleged that Tuomey falsely certified to the Medicare program that its claims were in compliance with the Stark Law, thereby causing the Medicare program to pay thousands of false claims. The United States intervened in the case in 2007 and added equitable claims of unjust enrichment and payment by mistake. The case went to trial in 2010, and the jury found that Tuomey violated the Stark Law but was not liable under the FCA. On post-verdict motions, the court granted the United States' motion for a new trial on the basis that the court had erroneously excluded from the trial deposition testimony of Gregg Martin, Tuomey's senior vice president and chief operating officer. The court thus set aside the jury's FCA verdict and ordered a new trial on the entire FCA cause of action, *including* the issue of whether Tuomey violated the Stark Law. Based on the jury's verdict that Tuomey violated the Stark Law, and that the Stark Law requires a refund of payments prohibited by the law, however, the court entered a $45 million judgment for the United States based on its two equitable claims. Tuomey appealed this judgment to the Fourth Circuit.

In 2012, the Fourth Circuit vacated the trial court's $45 million judgment based on the United States' two equitable claims and remanded the case to the trial court for a new jury trial. The Fourth Circuit held that when the trial court set aside the jury's FCA verdict, it also set aside the jury's finding of a Stark Law violation, and therefore the trial court's judgment on the equitable claims deprived Tuomey of its Seventh Amendment right to a jury trial on the question of whether it violated the Stark Law.

Separate and apart from the Seventh Amendment holding, the Fourth Circuit addressed two threshold questions of law raised on appeal that the district court would be called upon to address upon retrial. First, the court addressed the question of whether the hospital facility component of a surgery is personally performed by the operating physician and thus not a "referral" for Stark Law purposes. Citing commentary by the Centers for Medicare & Medicaid Services (CMS), the court concluded that the facility component of a surgery is separate from the professional component performed by the operating surgeon, and that because the facility component is ordered and requested by, but not itself performed by, the operating surgeon, it constitutes a referral by the surgeon. The court's conclusion meant that Tuomey's argument that the physicians did not make "referrals" to Tuomey for surgery because the physicians personally performed the surgery would fail.

Second, the court examined the question of whether the Stark Law's volume/value standard applied to *anticipated* referrals in addition to actual referrals. The Stark volume/value standard was applicable here to determining whether the physicians had indirect compensation arrangements with Tuomey (because they were employed by Tuomey subsidiaries) and, if so, whether the indirect compensation arrangements qualified for an exception. To prove that the part-time contracts created indirect compensation arrangements between Tuomey and the physicians, the United States had to prove (i) that the aggregate employment compensation paid to the physicians varied with or took into account the volume or value of the physicians' referrals to Tuomey, and (ii) that Tuomey knew or should have known that the aggregate compensation paid to the physicians varied with or took into account the volume or value of the physicians' referrals to Tuomey. If the United States proved that the contracts created an indirect compensation arrangement, the burden of proof would shift to Tuomey to prove that the compensation qualified for an exception, including compliance with the exception's volume/value standard.

The Fourth Circuit agreed with the United States that the volume/value standard relates to both actual and anticipated referrals. This would mean that, at retrial, the United States could prove that the compensation under the part-time contracts *took into account* the volume or value of referrals to Tuomey by proving that the compensation was based in part on the anticipated value of such referrals, even if the compensation did not vary or fluctuate with actual referrals. Arguably confusing things, however, the Fourth Circuit concluded its discussion as follows:

> Accordingly, the question, which should properly be put to a jury, is whether the contracts, *on their face*,

took into account the value or volume of anticipated referrals.

United States ex rel. Drakeford v. Tuomey Healthcare Sys., 675 F.3d 394, 409 (4th Cir. 2012) (emphasis added). Compensation that takes into account *anticipated* referrals is compensation that does not vary or fluctuate with *actual* referrals, but is inflated or designed to reflect or recognize the value of the physician's referrals. This necessarily means looking *behind* the contract, not on its face, for the rationale or basis for the compensation.

The case was retried in May 2013, and the jury found that Tuomey both violated the Stark Law and was liable for false claims under the FCA. Specifically, the jury found that Tuomey's hospital claims to Medicare pursuant to surgeries by the contracted physicians were false commencing with the date that Tuomey terminated McAnaney's engagement. The damages of the United States were determined to be $39,313,065, which, as mandated by the FCA, was trebled by the court. To this was added $119,515,000, which is the product of multiplying the 21,730 false claims by $5,500 per claim, the minimum per-claim penalty allowed under the FCA, for an award of $237,454,195. Tuomey appealed to the Fourth Circuit.

Tuomey's Second Appeal to the Fourth Circuit

Tuomey's appeal challenged the trial court's grant of a new trial on the FCA liability issue and asked the Fourth Circuit to either (i) grant it judgment on the Stark and FCA counts because a reasonable jury could not have found that the part-time contracts violated the Stark Law or that Tuomey knowingly submitted false claims, or (ii) grant it a new trial because of jury instruction errors by the trial court. Finally, Tuomey challenged the trial court's calculation of the damages and challenged the amount of the damages award on constitutional grounds.

The Trial Court's Grant of a New Trial

The *first* trial ended in a jury verdict that Tuomey was not liable under the FCA. Although the trial court entered a judgment of $45 million based on the United States' equitable claims of payment by mistake and unjust enrichment, prevailing on the FCA counts was a victory for Tuomey, until the trial court granted the United States a new trial on the issue of FCA liability. Tuomey did not appeal this grant of a new trial on FCA liability in its first appeal to the Fourth Circuit, but it did so in this second appeal.

The Fourth Circuit affirmed the trial court's grant of the new trial on FCA liability, but on different grounds than the trial court. The trial court granted the United States' motion for a new trial based on its finding that it had erred in excluding certain deposition testimony by a Tuomey executive (Martin). Martin's deposition involved his recollections of discussions with Hewson, Tuomey's lawyer, regarding conference calls Hewson had with McAnaney, Smith and Pratt. Martin's deposition testimony indicated that he was made aware of McAnaney's negative opinion of the part-time contracts. The United States argued that the Martin testimony was necessary evidence on the FCA "knowledge" element—whether Tuomey had actual knowledge or showed a reckless disregard or deliberate ignorance of the falsity of its Medicare claims pursuant to referrals by the part-time physicians. After reviewing the deposition testimony, the Fourth Circuit disagreed, finding "that the probative value of this particular evidence is weak at best, and excluding it did not negatively affect the government's substantial rights." *Tuomey*, 2015 U.S. App. LEXIS 11460, at *17. Martin's recollections, the court found, were hazy and lacking in specifics, since the conversations occurred four years prior to the depositions.

The Fourth Circuit, however, affirmed the trial court's grant of a new trial on FCA liability on alternative grounds, agreeing that the United States was substantially prejudiced by the trial court's exclusion of McAnaney's testimony and "related evidence of his warnings to Tuomey regarding the legal peril that the employment contracts posed." *Id.* at *19. The United States had the burden of proving not only that Tuomey had compensation arrangements with the physicians and violated the Stark Law's prohibition on Medicare claims for DHS furnished pursuant to referrals by such physicians, but also that it submitted claims prohibited by the Stark Law to Medicare with actual knowledge of, or a reckless disregard or deliberate ignorance of, the fact that the claims were

prohibited by the Stark Law and thus false (the "knowledge" element of the FCA). McAnaney, hired by Tuomey (as part of a joint engagement with Drakeford), gave Tuomey his opinion of the Stark Law risk posed by the part-time contracts, and his testimony as to his advice to Tuomey "was a relevant, and indeed essential, component of the government's evidence on that [knowledge] element, and Tuomey offered no good reason why the jury should not hear it." *Id.* at *19–20. (Asserting an advice-of-counsel defense, Tuomey waived the attorney-client privilege with respect to the advice that it received from its lawyers, including McAnaney, and so it could not bar McAnaney's testimony on that ground.) The court recounted McAnaney's specific testimony at the *second* trial as evidence of its relevance for the "knowledge" element, noting that "it is difficult to imagine any more probative and compelling evidence regarding Tuomey's intent than the testimony of a lawyer hired by Tuomey, who was an undisputed subject matter expert on the intricacies of the Stark Law, and who warned Tuomey in graphic detail of the thin legal ice on which it was treading with respect to the employment contracts." *Id.* at *23. Rejecting Tuomey's legal arguments that the trial court properly excluded McAnaney's testimony in the first trial under federal rules governing the exclusion of evidence, and having found that the United States was substantially prejudiced in the first trial by the exclusion of McAnaney's testimony, the Fourth Circuit affirmed the trial court's grant of a new trial on FCA liability.

Tuomey's Request for Judgement as a Matter of Law on the Stark Law and FCA Issues

On appeal from the second trial, Tuomey asked the Fourth Circuit to reverse the trial court's denial of its motion for a favorable judgment, as a matter of law, on both the Stark and FCA issues. This required the Fourth Circuit to consider whether a reasonable jury could rule *only* in favor of Tuomey. The Fourth Circuit held, however, that a reasonable jury *could* rule against Tuomey on the Stark and FCA issues. The Stark Law and FCA issues are each discussed separately below.

THE STARK ISSUE

On appeal, Tuomey contended that no reasonable jury could have found that it violated the volume/value standard of the Stark Law. The Fourth Circuit held that a reasonable jury could find that Tuomey violated the volume/value standard of the Stark Law, however, because Tuomey "paid aggregate compensation to physicians that varied with or took into account the volume or value of actual or anticipated referrals to Tuomey." *Id.* at *26. Tuomey argued that, based on the Fourth Circuit's first opinion in this case, the only question that should have been put to the jury was "whether the contracts, on their face, took into account the value or volume of anticipated referrals." *Id.* at *27. Tuomey contended that because the compensation under the part-time contracts was based solely on collections for personally performed professional services, it did not take into account the volume or value of anticipated referrals. The Fourth Circuit disagreed with Tuomey's reading of its first opinion, stating that the "district court properly understood that the jury was entitled to pass on the contracts as they were actually implemented by the parties . . . ," noting that it had said as much in its prior opinion: "On remand, a jury must determine, in light of our holding, whether the aggregate compensation received by the physicians under the contracts *varied with*, or took into account, the volume or value of the facility component referrals." *Id.*

Applying its interpretation of the volume/value standard, the court concluded that a "reasonable jury could have found that Tuomey's contracts in fact compensated the physicians in a manner that *varied with* the volume or value of referrals." *Id.* (emphasis added). Specifically, the court noted that the more procedures the physicians performed at the hospital, the more hospital facility fees Tuomey collected, and the more compensation the physicians received in productivity bonuses and increased base salaries (adjusted annually based on the prior year's professional collections). In other words, the court's specific instruction that the volume/value standard is to be evaluated based on the *face of the contract* was not intended to foreclose the trial court from considering the effect of the contract's compensation terms in the "real world." If, as here, the collections-based compensation meant that the physicians would take home compensation that would "vary

with" their referrals to the hospital, the compensation fails the volume/value standard.[1]

Tuomey and the court wrangled over the implications of the following CMS commentary:

> *Comment:* A commenter presented the following scenario. A hospital employs a physician at an outpatient clinic and pays the physician for each patient seen at the clinic. The physician reassigns his or her right to payment to the hospital, and the hospital bills for the Part B physician service (with a site of service reduction). The hospital also bills for the hospital outpatient services, which may include some procedures furnished as "incident to" services in a hospital setting. The commenter's concern is that the payment to the physician is inevitably linked to a facility fee, which is a designated health service (that is, a hospital service). Accordingly, the commenter wondered whether the payment to the physician would be considered an improper productivity bonus based on a DHS referral (that is, the facility fee).
>
> *Response:* The fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement).

69 Fed. Reg. 16,054, 16,088–89 (Mar. 26, 2004). The Fourth Circuit conceded that a productivity bonus to a *bona fide* surgeon employee (or physician that has a "meaningful administrative relationship" with the hospital) based on the fair market value of the physician's *personally performed work* would not offend the volume/value standard. The court limited the scope of this commentary to direct employment arrangements, however, and found that it was not applicable here.

The implications of the Fourth Circuit's volume/value analysis for the health care industry are addressed below under the discussion of the jury instructions on the volume/value standard.

THE FCA ISSUE

Tuomey argued on appeal that a reasonable jury could only rule in its favor on the "knowledge" issue under the FCA. Its argument had two components—a traditional FCA *scienter* argument and an advice-of-counsel defense argument, each of which is discussed separately below.

Tuomey argued that it did not have actual knowledge of, or show a reckless disregard for or deliberate ignorance of, whether its claims were prohibited by the Stark Law and thus false. ("Knowingly" will hereinafter refer to any one of the above states of knowledge or *scienter*.) The court disagreed, concurring with the trial court that "a reasonable jury could have found that Tuomey possessed the requisite *scienter* once it determined to disregard McAnaney's remarks." *Tuomey*, 2015 U.S. App. LEXIS 11460, at *31. A reasonable jury, the court observed, "could indeed be troubled by Tuomey's seeming inaction in the face of McAnaney's warnings, particularly given Tuomey's aggressive efforts to avoid hearing precisely what McAnaney had to say regarding the contracts." *Id.* at *31–32. Notably, McAnaney's warnings to Tuomey did not include a statement or conclusion by him that the contracts did not meet a Stark exception. He warned that procuring a fair market value opinion is not conclusive on the issue of fair market value, and that it would be hard to convince the government that paying a physician substantially above his or her collections is fair market value. Such compensation, he warned, was "basically a red flag to the government." *Id.* at *22. He noted that such compensation had been prosecuted before, but the cases had settled. He also pointed out that the 10-year term and two-year/30-mile non-compete would reinforce the government's view that Tuomey was paying above fair market value for referrals. His conclusion was that the

[1] A key term of the contract that the court did not specifically call out was that the physicians would *only* be paid their collections bonus for personally performed procedures if the physicians referred the procedures *to Tuomey*. This term of the contract is what caused the contracted compensation, *on its face*, to be determined in a manner that takes into account referrals for the hospital facility component; but for the referrals *to Tuomey* for the hospital facility component, there would be no compensation for the physician's professional component services, and the very amount of compensation would most definitely vary with the volume, if not always the value, of these hospital facility component referrals *to Tuomey*.

contracts would not pass the "red face test," and warned that the government would find this "an easy case to prosecute." *Id.* at *23. Taken together, McAnaney clearly communicated to Tuomey that he believed that the contracts presented a significant degree of litigation risk for Tuomey.

Tuomey had conflicting opinions, however, and had to pick an opinion in order to act. Presumably, the fact that Tuomey picked the opinion with which the government and the jury ultimately disagreed was not the basis for finding that Tuomey violated the Stark Law's claims prohibition knowingly. Rather, what supported a reasonable finding by the jury that Tuomey knowingly submitted prohibited claims was Tuomey's lack of diligence in understanding and weighing the merits of McAnaney's opinion, especially in light of his background and credentials, and not ensuring that all the consulted lawyers had the benefit of each other's analysis and fact-finding. The court's reasoning suggests that if Tuomey had carefully and deliberately considered McAnaney's legal analysis, fully disclosed all of the lawyers' analysis *and fact finding* to all of the other lawyers engaged to review the Stark Law issue, and then, after carefully weighing the multiple opinions and analyses at the highest levels of the organization, declined to follow McAnaney's counsel, then arguably Tuomey would have been more likely to have prevailed on the "knowledge" issue.

Tuomey next argued that no reasonable jury could find that it was liable based on its advice-of-counsel defense. In the case of fraud allegations, the advice-of-counsel defense is an absolute defense against liability when all the criteria of the defense are met. Tuomey argued that its factual disclosures to and good faith reliance on the advice of Tim Hewson met its burdens of proof on the advice-of-counsel defense. The advice-of-counsel defense, however, requires that the defendant prove that it acted in good faith reliance on the advice of *all* of the lawyers from whom it sought advice, after making a full disclosure of all of the pertinent facts to *all* of these lawyers. The court agreed with the trial court that "a reasonable jury could have concluded that Tuomey was, after September 2005, no longer acting in good faith reliance on the advice of counsel when it refused to give full consideration to McAnaney's negative assessment of the part-time employment contracts and terminated his representation." *Id.* at *33. Tuomey contended that its retention of Pratt, a health care regulatory lawyer with a national practice, evidenced that it was acting in good faith and not ignoring McAnaney's warnings. The court, however, pointed to relevant facts that it stated were not disclosed to Pratt, most notably the details of the fair market value opinion, what the doctors earned prior to the contracts, and the extent of the projected "losses" on the part-time contracts before accounting for hospital facility revenue. The court found that, on balance, there were sufficient flaws with Tuomey's advice-of-counsel defense for a reasonable jury to reject it.[2]

Tuomey's Requests for a New Trial Based on Jury Instruction Error

Tuomey argued that the trial court issued four erroneous jury instructions. Each is discussed separately below.

VOLUME/VALUE STANDARD INSTRUCTION

Tuomey contested the trial court's handling of the volume/value standard in its instructions. The trial court instructed the jury to consider both the indirect compensation exception *and* the employment exception, both of which have volume/value standards. The jury was instructed that if the compensation satisfied *either* exception, the Stark Law was not violated. This meant that the jury was left to reach a verdict on the volume/value issue under the indirect compensation exception and the employment exception and its productivity bonus exception to the volume/value standard without any guidance but the text of the exceptions and the evidence admitted at trial, which included evidence of Tuomey's intent and purpose in entering into the employment contracts. Tuomey argued that the trial court's failure to instruct the jury that the volume/value question is "whether the contracts, on their face, took into account the value or volume of anticipated referrals . . ." erroneously allowed the jury "to consider extrinsic evidence of intent in determining whether the physicians' compensation took into account the volume or value of referrals." *Id.* at *38.

[2] In his concurring opinion, Judge Wynn agreed that a reasonable jury could have found that Tuomey was no longer acting in good faith reliance on the advice of counsel when it refused to give full consideration to McAnaney's negative assessment.

As modified by its second opinion, the Fourth Circuit's position on the admissibility of evidence on the volume/value issue ostensibly appears to be that evidence on the issue of intent is admissible, but that evidence alone is insufficient. This appears to mean that, as the court asserted in *United States ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678 (W.D. Ky. 2008), to make out an indirect compensation arrangement (which, by definition, requires that the compensation vary with, or take into account, the volume or value of referrals or other business generated by the physician), the government must prove more than an intent to induce, pay for or recognize the value of referrals; it must adduce evidence that the fixed compensation was above fair market value, or that the amount of the aggregate compensation payable under the contract varies (increases or decreases) with the volume or value of referrals or other business generated by the physician.

This apparent limitation on the use of intent evidence for the volume/value issue was seemingly undone, however, by the Fourth Circuit's clearly articulated position that "fixed compensation to a physician that is not based solely on the value of the services the physician is expected to perform, but also takes into account additional revenue the hospital anticipates will result from the physician's referrals, . . . by necessity takes into account the volume or value of such referrals." *Tuomey*, 675 F.3d at 409. The only way for the government to prove that fixed compensation (*e.g.*, $200,000 per year) takes into account the volume or value of referrals to the hospital employer is by introducing evidence of intent to secure, pay for or recognize the value of referrals. Even if a federal district court should feel constrained by *Tuomey* to require something more than evidence on the issue of intent when evaluating whether a party has met its burden of proof on the volume/value standard, *Tuomey* arguably stands for the proposition that the fair market value issue can be resolved solely on the basis of evidence of intent to secure, pay for or recognize the value of referrals.[3] This position eliminates any hope of a "bright-line" fair market value standard under the Stark Law and creates a "back door" for the government and relators to bring in evidence of intent. Given the current state of the case law, the notion of any bright-line fair market value or volume/value standard appears to be illusory, and the industry should assume that every conversation, e-mail, letter, valuation opinion or other communication suggesting that referrals were a consideration by the parties in setting or adjusting compensation could be admissible and considered by the jury on the issue of fair market value and volume/value issues.

INDIRECT COMPENSATION DEFINITION INSTRUCTION

Tuomey correctly argued that the trial court did not include the "knowledge" element of the Stark Law's definition of an indirect compensation arrangement. To make out an indirect compensation arrangement, the United States had to prove that Tuomey had actual knowledge of, or acted with reckless disregard or deliberate ignorance of, the fact that the direct compensation arrangement in the chain of financial relationships between Tuomey and the physicians, *i.e.*, the part-time employment compensation, varied with or took into account the volume or value of the physicians' referrals or other business generated for Tuomey. The Fourth Circuit, however, concluded that this error was harmless, because the trial court had instructed the jury on the "knowledge" element of the FCA. The Fourth Circuit reasoned that if the jury found that Tuomey possessed the requisite knowledge of what it was doing under the FCA, it necessarily found that Tuomey knew that its contracts varied with or took into account referrals.

FAILURE TO INSTRUCT JURY ON RELEVANCE OF DISPUTED LEGAL QUESTIONS FOR "FALSITY" UNDER THE FCA

Tuomey argued that the trial court erred by not instructing the jury that claims to the government based upon differences of interpretation of disputed legal questions are not false under the FCA. The Fourth Circuit concluded that this instruction is only suitable when the question of the falsity of claims involves a subjective inquiry. Here, the court found, the falsity of Tuomey's claims turned solely on the inquiry into whether Tuomey's Medicare cost report certification of Stark Law compliance was objectively false or not. The jury had found that Tuomey violated the Stark Law, and thus Tuomey's certification of compliance with the Stark Law was false.

[3] For decisions taking a similar approach to the Stark fair market value issue, see *Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602, 620–33; *United States ex rel. Schubert v. All Children's Health Sys.*, 2013 WL 6054803 (M.D. Fla. Nov. 15, 2013) (order denying motion to dismiss).

Accordingly, the Fourth Circuit found that the trial court did not err by not giving this instruction.

NO INSTRUCTION TO JURY THAT TUOMEY COULD RELY ON WRONG LEGAL ADVICE

The Fourth Circuit found that the scope of the trial court's instruction on the "knowledge" element of the FCA was sufficient to cover the import of Tuomey's proposed instruction that it could rely on legal advice that later turned out to be wrong. The trial court's charge to the jury had "emphasized that the jury could *not* conclude that Tuomey had knowledge 'from proof of mistake, negligence, carelessness or a belief in an inaccurate proposition.'" *Tuomey*, 2015 U.S. App. LEXIS 11460, at *41 (emphasis added; emphasis in original omitted).

Other Implications of the *Tuomey* Decision for Hospitals and Stark Law Reform

While the facts in *Tuomey* are generally viewed as "bad" and uncommon, Tuomey's challenge to preserve an important service line of the hospital in the face of competition from its own medical staff is a challenge that the hospital industry faces every day. This challenge and the perceived need to make certain deals with physicians must, however, be checked by an equally compelling need to carefully and deliberately address the sometimes difficult and undesired Stark Law issues raised by such deals, and to ensure that these issues are raised to the highest levels of the organization. If *Tuomey* is a wake-up call for the hospital industry, it is especially a wake-up call for the boards of directors and "C" suites who must, in the exercise of their fiduciary duties to the hospital, ensure that the hospital properly balances perceived business imperatives and opportunities with the need to protect the organization from the monetary and reputational damage of investigations and litigation.

The magnitude of the damages award in *Tuomey* was troubling to Judge Wynn, who, while concurring in the court's opinion, was clearly concerned that the Stark Law, a strict liability statute, in combination with the FCA's treble damages and per-claim penalties, had become a "booby trap" in which even well-intentioned hospitals could find themselves caught. His discussion of the Stark Law's problems and the need to revisit the law's purposes and effects is timely, because Stark Law cases and investigations are clearly on the rise, and questions regarding the proportionality and fairness of Stark Law liability have never been more consequential for the industry.

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