

evidence that Tuomey submitted claims to Medicare for designated health services that resulted from “referrals,” as defined by Stark. Alternatively, this Court should grant a new trial because the jury’s verdict is against the clear weight of the evidence and allowing the verdict to stand will result in a miscarriage of justice.

This motion is supported by the attached memorandum of law and exhibits.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
 DISTRICT OF SOUTH CAROLINA
 COLUMBIA DIVISION

United States of America, ex rel,)	
Michael K. Drakeford, M.D.,)	C.A. No: 3: 05-cv-2858-MBS
)	
Plaintiff,)	
)	DEFENDANT TUOMEY’S
vs.)	MEMORANDUM IN SUPPORT OF
)	ITS MOTION FOR JUDGMENT
Tuomey Healthcare System, Inc.)	AS A MATTER OF LAW, OR IN
)	THE ALTERNATIVE, FOR A
Defendant.)	NEW TRIAL
_____)	

INTRODUCTION

The Stark Law was intended to create “bright line” rules which can only be violated by one’s actual conduct, not intent. *See United States ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 693 (W.D. Ky. 2008). The Fourth Circuit, in the previous appeal of this case, “agree[d] with the *Villafane* court that intent alone does not create a violation.” *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 675 F.3d 394, 409 n.25 (4th Cir. 2012). The Court explained that the Government’s burden was to prove to the jury that the part-time employment agreements between physicians and Tuomey (“the Contracts”) on their face took into account the volume or value of anticipated referrals. *Id.*

However, the Government failed to present any evidence that the actual compensation under the Contracts took into account the volume or value of anticipated referrals. Instead, the Government capitalized on Stark’s complexity and invited the jury to use an alternate (and improper) analysis—that Tuomey had bad intent and violated the Stark Law, 42 U.S.C. § 1395nn (“Stark”) by considering the financial impact on the hospital’s operations in deciding whether to offer the physicians part-time employment agreements.

Moreover, during its closing argument the Government quoted sections of opinion letters that discussed the intent element of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (“AKS”). But Tuomey was not on trial for violating the AKS. Rather, Tuomey was accused of violating one of Stark’s “bright line” rules. Despite the Fourth Circuit’s instruction that “the question ... is whether the contracts, on their face, took into account the value or volume of anticipated referrals,” *Drakeford*, 675 F.3d at 409, the Government implored the jury to look beyond the face of the Contracts and judge Tuomey’s intentions. Therefore, in the end, it did not matter to the jury how the physicians were paid under the terms of the Contract. Nor did it matter to the jury that Tuomey’s lawyers constructed the Contracts, with the assistance of a reputable fair market value appraisal firm, to comply with Stark, or that Tuomey followed the advice of its attorneys.

There was absolutely no evidence to support a finding that the actual compensation paid to the physicians under the Contracts varied with or took into account the volume or value of referrals to Tuomey. Instead, the indisputable evidence established that because the physicians were compensated based upon their personally performed professional services and nothing more, Stark did not apply to the Contracts.

In addition, there was no evidence of any claims submitted by Tuomey to Medicare that resulted from Stark-prohibited referrals. The claims forms upon which the Government exclusively relied in an attempt to prove referrals do not identify the referring physician, nor can the identity of the referring physician be inferred from any other information on the forms. The trial evidence established that the only way to identify the referring physician is to review a patient’s medical records. This was not done. The jury’s interrogatory answers about the number

of claims that violated the False Claims Act and the dollar value of those claims were therefore based on pure speculations.

Moreover, the underlying data the Government's summary witness relied on to add up his conclusions about the number and value of claims was unreliable and inadmissible under Federal Rule of Evidence 1006. Thus, not only did the Government fail to prove any referrals, it also failed to prove any claims. There cannot be a violation of the False Claims Act without proof of claims, and there cannot be a violation of Stark without proof of referrals. Moreover, the Government failed to prove any financial loss or damages resulting from the claims that were allegedly submitted in violation of Stark and the False Claims Act, 31 U.S.C. § 3729 ("FCA").

The undisputed evidence further established that Tuomey sought the advice of experienced health care lawyers in good faith and followed that advice. Therefore, there was not a legally sufficient evidentiary basis from which the jury could have found that Tuomey had the required scienter to violate the FCA. Even the Government acknowledged in closing argument that Tuomey acted in good faith reliance upon counsel up until Dr. Drakeford requested that Tuomey agree to have Kevin McAnaney issue a written opinion. The Government offered the jury a lower damages number if it wished to give Tuomey "the benefit of the doubt" on the knowledge element of the FCA claim, which the jury accepted. Thus, the jury implicitly concluded that Tuomey had followed the advice of its lawyers up to that point.¹ But uncontradicted evidence clearly established that Tuomey sought and followed the advice of its counsel in addressing Drakeford's request and further acted reasonably by obtaining an independent legal opinion from a professor of health law at one the nation's largest healthcare law firms.

¹ In fact, the jury implicitly found that Tuomey reasonably relied on counsel through September 30, 2005 by excluding the number and value of the 2005 claims from its verdict.

Because the Government failed to present sufficient evidence from which a reasonable jury could find that Tuomey knowingly submitted false claims to the Government in violation of the FCA, Tuomey is entitled to judgment as a matter of law. Alternatively, this Court should order a new trial under Rule 59 because the verdict is against the clear weight of the evidence and to avoid a miscarriage of justice.

ARGUMENT

To establish Tuomey's liability under the FCA, the Government was required to prove that Tuomey (1) submitted a claim to Medicare for payment, (2) that was false, and (3) Tuomey knew the claim was false when it submitted it, (4) the falsehood was material, and (5) the false claim caused the Government to pay out money to Tuomey. *See Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999) (*Harrison I*); 31 U.S.C. § 3729. In this case, the Government contends that Tuomey submitted claims to Medicare for services performed pursuant to referrals by the contracting physicians, that those claims were false because the contracts violated Stark, and that Tuomey knew the contracts violated Stark.

The Government's proof fails on all counts. First, there is not a legally sufficient evidentiary basis for the jury's finding that the Contracts violated Stark. The evidence in the record is clear and unrefuted that the contracting physicians were paid for their personally performed professional services and that the rate of compensation did not vary with or take into account the volume or value of referrals or other business generated by the physicians for Tuomey. Second, the Government failed to present admissible evidence of even a single claim that resulted from a Stark-prohibited referral by one of the contracting physicians. Without evidence of referrals, there can be no violation of Stark. Without evidence of claims, there can be no FCA liability. Third, the overwhelming evidence established that Tuomey acted on the advice of its counsel, thereby negating any knowledge of falsity as a matter of law. In sum, a reasonable

jury could not have found Tuomey liable for a violation of the FCA.² Finally, even if Tuomey were not entitled to judgment as a matter of law on liability, it is entitled to judgment on the issue of damages because there is not a legally sufficient evidentiary basis to support the jury's finding that the Government suffered actual damages.

I. TUOMEY IS ENTITLED TO JUDGMENT AS A MATTER OF LAW.

The Court should grant judgment as a matter of law if “the court finds that a reasonable jury would not have a legally sufficient basis to find for the party on the issue.” Fed. R. Civ. P. 50. Judgment as a matter of law is proper “if a reasonable jury could reach only one conclusion based on the evidence,” or if the jury's verdict was necessarily “based on speculation or conjecture.” *Myrick v. Prime Ins. Syndicate, Inc.*, 395 F.3d 485, 489 (4th Cir. 2005). A party is entitled to judgment as a matter of law if the Court “determines, without weighing the evidence or considering the credibility of the witnesses, that substantial evidence does not support the jury's findings.” *Konkel v. Bob Evans Farms, Inc.* 165 F.3d 275, 279 (4th Cir. 1999). The evidence must be viewed in the light most favorable to the non-moving party, but a mere “scintilla” of evidence is not enough; the plaintiff must “adduce substantial evidence in support of [its] claim.” *Demaine v. Bank One*, 904 F.2d 219, 220 (4th Cir. 1990). The Court is not a “rubber stamp convened merely to endorse the conclusions of the jury, but rather ha[s] a duty to reverse the jury verdicts if the evidence cannot support [them].” *Price v. City of Charlotte*, 93 F.3d 1241, 1250 (4th Cir. 1996).

² If no reasonable jury could find against Tuomey, one must wonder why this jury found Tuomey liable. Tuomey submits that the Government confused the jury with irrelevant and misleading evidence of intent, misstated the Stark law in its closing argument, and improperly implored the jury to ignore the terms of the Contracts, which were carefully designed by Tuomey's lawyers to comply with Stark and other governing health care laws. *See infra* Part II.E.

A. The Government failed to prove the contracts were subject to Stark, because, as a matter of law, there was no proof that physician salaries varied based on the volume or value of referrals.

Stark provides that a physician who has a prohibited financial relationship with a hospital may not make a referral to the hospital for inpatient or outpatient hospital services (“the referral prohibition”), nor may the hospital make a claim to Medicare for payment for those services (“the claim prohibition”). *See* 42 U.S.C. § 1395nn(a)(1). A financial relationship includes a “compensation arrangement.” *Id.* § 1395nn(a)(2)(B). The regulations implementing Stark promulgated by the Centers for Medicare and Medicaid Services (CMS) further define the universe of “compensation arrangements” to include direct or indirect compensation arrangements. 42 C.F.R. § 411.354(c). If there is neither a direct nor indirect compensation arrangement as defined in the regulations, Stark does not apply and there can be no Stark violation as a matter of law. Pratt (5/3/13) at 93-96 (attached hereto as Exhibit J); Def. Ex. 232 at 11-15 (attached hereto as Exhibit M).

An indirect compensation arrangement exists when (1) the hospital and the physician are connected by an unbroken chain of entities with financial relationships between them; (2) the aggregate compensation received by the physician “varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician”; and (3) the hospital has knowledge of the fact that the physician’s compensation so varies. 42 C.F.R. § 411.354(c)(2). In regulatory commentary, CMS has repeatedly stated the knowledge element of the indirect compensation arrangement definition requires the same proof required for an FCA violation, namely actual knowledge, deliberate ignorance, or reckless disregard. *See* 69 Fed. Reg. 16054, 16058 (Mar. 26, 2004); 72 Fed. Reg. 51012, 51026 (Sept. 5, 2007).

In this case, an indirect compensation arrangement was not and could not be proven because the only evidence is that the aggregate compensation paid under the Contracts, as

carefully designed by Nexsen Pruet, did *not* vary with or take into account the volume or value of referrals or other business generated by the contracting physicians. Furthermore, the evidence at trial irrefutably establishes that Tuomey's attorneys told Tuomey that the compensation did not vary with or take into account the volume or value of the physicians' referrals, which means that the knowledge element of the indirect compensation arrangement definition was also not met. *See infra* Part I.C. In an effort to avoid this failure of proof, the Government improperly argued that the so-called "1 to 1" correlation between physicians' professional services and the hospital's technical component proved that the Contracts did violate the volume-or-value standard, because "every time a doctor got paid, Tuomey got paid." Acker (5/7/13) at 78-79 (attached hereto as Exhibit K). However, this "1 to 1" correspondence merely reflects the fact that Medicare pays hospitals and physicians separately for the services each provides. When the Government's sinister spin on the evidence is disregarded, the only feasible conclusion is that aggregate compensation under the Contracts did not vary with or take into account the volume or value of referrals, and thus an indirect compensation arrangement did not exist. The Contracts are not encompassed within the definition of financial relationship and therefore are not subject to Stark.

1. Compensation under the Contracts does not vary with the volume or value of referrals.

It is clear from the face of the Contracts and the uncontradicted evidence presented at trial that the aggregate compensation received by the physicians under the Contracts did not vary with the volume or value of referrals because the physicians' compensation was based solely on collections for *personally performed professional services*. The Stark regulations provide that a physician's personally performed services are not "referrals" under Stark. 42 C.F.R § 411.351. It follows that compensation based only on such services cannot vary with the volume or value of

referrals. Nexsen Pruet attorney Tim Hewson, who drafted the contracts, testified that the Contracts, by intent and design, paid physicians only for their personally performed services. Hewson (4/30/13) at 90-91, 119-20 (attached hereto as Exhibit H).

As set forth in the exhibits and unrefuted testimony at trial, the Contracts established a formula for the physicians' base salary that was derived from the data regarding the physician's historical collections, which is directly related to his or her personally performed professional services. For the gastroenterologists, this base amount was expressed as a minimum number of procedures rather than as a dollar amount, but in all cases the base salary formula was designed to ensure that the contracting physicians performed services commensurate with the compensation they were receiving. Hewson (5/2/13) at 44-45 (attached hereto as Exhibit I). By tying the physicians' compensation to what the market paid in terms of collections and by reducing the base salary of a physician who did not work hard, the base salary formula actually ensured that physicians were paid and would continue to be paid at fair market value levels for their own work. *Id.* at 68-70; Saccone (4/18/13) at 144-45 (attached hereto as Exhibit B).

The productivity bonus, like the base salary component, was tied directly and exclusively to an individual physician's collections, not to the volume or value of referrals. Pratt (5/3/13) at 95-96. CMS has specifically endorsed productivity bonuses calculated as a percentage of collections. *See* 73 Fed. Reg. 48434, 48709 (Aug. 19, 2008) (stating that "physicians can be paid a percentage of revenues or collections for *personally performed services*" (emphasis in original)).

Hall Render attorney and law professor Steve Pratt reviewed the compensation formula in the Contracts and agreed that the formula compensated physicians only for their own personally performed professional services. Pratt (5/3/13) at 96. Pratt set forth his analysis in two written

legal opinions on which Tuomey relied. Def. Ex. 204 (attached hereto as Exhibit L); Def. Ex. 232. Pratt confirmed his analysis during his trial testimony. Pratt (5/3/13) at 156-57. Two of the contracting physicians, doctors Moses and McDuffie, testified that they were only paid for the services they performed. McDuffie (4/22/13) at 135 (attached hereto as Exhibit D); Moses (4/22/13) at 49. No component of the physicians' pay depended on the amount of Tuomey's charges or collections for facility fees; the physicians received the same amount of pay regardless of whether, or how much, Tuomey collected. McDuffie (4/22/13) at 135; Moses (4/22/13) at 49-50. In fact, there were at least two occasions when Tuomey was presented with suggested modifications to the arrangements which, if added, would have resulted in technical fees being a component of the physicians' compensation. Hewson (5/2/13) at 15. These requests were denied. Hewson (5/2/13) at 15-16; McDuffie (4/22/13) at 154; Watkins (4/29/13) at 64-65.

Unable to refute this evidence, the Government resorted to claiming that the supposed 1:1 correlation between the physicians' personally performed professional services and Tuomey's technical component billings was evidence that compensation did vary with or take into account the volume or value of referrals. Acker (5/7/13) at 78-79. This argument is a misstatement of the law. *See* 73 Fed. Reg. 48434, 48709 (Aug. 19, 2008) (stating that "physicians can be paid a percentage of revenues or collections for *personally performed services*" (emphasis in original)). Indeed, Tuomey's attorneys objected to the Government's questions along these lines and the Court properly sustained the objection. Johnson (4/19/13) at 52 (attached hereto as Exhibit C).

First, the Government's claim is factually false, because a hospital is not paid for every procedure performed but rather receives a single payment based on the patient's discharge diagnosis. *See infra* Part II.D.2.a. Thus, even though a contracting physician may perform a procedure on a patient admitted by another physician, Tuomey cannot bill a separate technical

fee for that procedure. It simply is not true that Tuomey can bill a technical fee each time a doctor submits a fee for a personally performed service. *See infra* Part II.D.2.a.

Second, payment of a productivity bonus based on a physician's personally performed professional services is allowed even if the payment is "inevitably linked to a facility fee" paid to the hospital. 69 Fed. Reg. at 16088-89. The Phase II commentary describes a scenario in which a physician employed in a hospital's outpatient clinic is paid for each patient seen. At the same time, the hospital can bill a facility fee for each of those patient visits. Given that "the payment to the physician is inevitably linked to a facility fee," the question was "whether the payment to the physician would be considered an improper productivity bonus based on a ... referral (that is, the facility fee)." *Id.* CMS's response to this inquiry pulls the linchpin out of the Government's theory in this case:

The fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may receive a productivity bonus (subject to the fair market value requirement).

Id. at 16089. As a matter of law, then, the correlation between the payments to the contracting physicians for their personally performed services and Tuomey's facility fee does not mean that compensation paid to the physicians under the Contracts was based on the volume or value of the physicians' referrals to Tuomey. Therefore, the existence of the "1 to 1 ratio" decried by the Government in this case does not create a Stark violation. Moreover, when advising Tuomey about the Contracts, Hewson specifically relied on this official commentary by CMS and considered it to have the force of law. Hewson (5/2/13) at 50-55; Def. Ex. 419 (for identification only) (attached hereto as Exhibit N).

Finally, it is worth noting, a finding that Stark does not apply to the Contracts is entirely consistent with the intent of the law and regulations. Stark is targeted at financial relationships between physicians and entities that "may result in overutilization" of designated health services.

66 Fed. Reg. 856, 860 (Jan. 4, 2001). The prototypical example of overutilization is a physician ordering lab work to be performed by others, when the physician is part owner of the lab and has a financial interest in the resulting income stream. In such cases, the physician can multiply his income by the stroke of the pen. This danger simply does not exist when a physician's compensation is based on personally performed professional services, because there is a limit on the amount of work one physician can do. *See United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045, 1051 (N.D. Ill. 2002) (holding that when "percentage compensation is based on personally performed services, not referrals, there is no economic inducement to refer patients.").

2. Compensation under the contracts did not take into account the volume or value of referrals.

In *Drakeford*, the Fourth Circuit held that "if a hospital provides 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 physicians' referrals, ... such compensation by necessity takes into account the volume or value of such referrals." *Drakeford*, 675 F.3d at 409. At trial, the Government attempted to prove that compensation under the Contracts "took into account" the volume or value of referrals by arguing that (1) Cejka analyst Kim Saccone calculated the net present value of the technical fees Tuomey would lose if the physicians performed their outpatient procedures somewhere else, and then (2) included a portion of that value in the physicians' compensation. Saccone (4/18/13) at 22-24. The Government questioned Saccone regarding a spreadsheet she prepared as a business planning document in the course of her work for Nexsen Pruet. Pl. Ex. 47 (attached hereto as Exhibit O). On that spreadsheet, Saccone calculated (1) the net present value of "the money Tuomey would lose" (*i.e.*, the technical component) if the gastroenterologists began doing 80

percent of their endoscopies in their offices, as well as (2) the net present value of professional fees the doctors would earn for those procedures. Saccone (4/18/13) at 37. Saccone explained, without contradiction, that this was an “initial analysis” that “was not used in any compensation plan.” *Id.* at 42. She further testified that she performed this “typical business planning” analysis in 2003, at Hewson’s request. *Id.* at 153-54. Saccone analyzed the potential in-office earnings for each of the specialist surgery groups, but in no case did that analysis contain any calculations related to Tuomey’s technical fees. *Id.* at 155-59; Pl. Ex. 48 (attached hereto as Exhibit P); Pl. Ex. 530 (attached hereto as Exhibit Q). As to all of these analyses, Saccone testified repeatedly and unequivocally that they were not used to calculate the physicians’ compensation. Saccone (4/18/13) at 146-63.³

³ Q: So does [Plaintiff’s Exhibit 53 (attached hereto as Exhibit R)] reflect that you calculated the base salaries for each of these plans based on the MGMA data and the doctor’s historical net collections for personally performed professional services?

A: Yes, those base salary ranges were originally came from [the] 15th [and] 25th percentile MGMA data.

Q: So there’s nothing involving any technical fees or referrals to the hospital involved in the base salary?

A: No

Q: And the base salary as described in this plan, it also has nothing to do with plaintiff’s Exhibit 47, the which was non-compete unanimous for the GI doctors? [sic]

A: No, that’s never used again.

Q: That wasn’t used in any way as part of any of [these] compensation plans was it?

A: No.

Q: And you weren’t asked to do anything like that?

A: No.

Saccone (4/18/13) at 143.

Although the Government tried to suggest otherwise, this testimony was entirely consistent with Saccone's testimony in the previous trial. In the first trial, Kim Saccone testified that she determined how much the physicians in each group would earn if they performed 80 percent of their outpatient procedures somewhere other than at Tuomey, *i.e.*, the cash flow the physicians could expect if they did not enter into the proposed contracts. 2010 Trial Tr. at 672-74, (attached hereto as Exhibit Y). She then discounted that figure to present value and divided by the number of physicians in the group to arrive at a per-physician estimate of "the amount that would be needed to match those future cash flows." *Id.* at 674. The result represented the value of each physician's personally performed services for outpatient procedures, *i.e.*, the amount each physician could earn for those procedures. *Id.* at 684. On the same spreadsheet, Saccone estimated the net present value of Tuomey's revenues from those procedures during the life of the contracts. *Id.* at 664. Saccone testified then, as she did at this trial, that this figure was used for business analysis purposes. *Compare* 2010 Trial Tr. at 664 *with* Saccone (4/18/13) at 152-53.

However, during the first trial, the Government asked an ambiguous question to elicit testimony from Saccone that appeared to show that she arrived at compensation figures based in part on the "net present value" of the physicians' referrals to Tuomey.⁴ On the basis of Saccone's

⁴ At the very end of Saccone's direct examination, and after lengthy questioning on other topics, the Government returned to the topic of the spreadsheets and asked a rapid-fire series of questions without giving Saccone an opportunity to look at the spreadsheets themselves:

Q: Earlier we looked at documents that showed that you calculated a net present value for the non-compete clause for each of the physicians, correct?

A. Correct.

Q. And the amount that represented the value of their business to Tuomey Hospital, is that right?

A. Yes.

Q. And you used that number as a benchmark in developing their compensation plans, is that right?

answer to an unclear question (what is “that number”?), the Government argued to the Fourth Circuit that Saccone had used the net present value of the “lost” facility fees as a “benchmark” in calculating the physicians’ base salary (thereby taking into account the value of the physicians’ referrals to Tuomey). See Br. for Appellee United States (Doc. 45), *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, No. 10-1819 (4th Cir. filed May 7, 2011). In reality, Saccone had done no such thing.

When the Government attempted to elicit the same testimony in this trial, Saccone made clear that she had been confused by the Government’s questions at the first trial and that she had never intended to convey the impression the net present value of the facility fees had any role in her determination of the physician compensation formula. Saccone (4/18/13) at 49-50, 56. Moreover, Saccone testified numerous times with absolute clarity that her calculations in creating the physician compensation formula did not include any part of Tuomey’s facility fees. *E.g., id.* at 69, 71-72, 73, 125-26, 135, 143.

It is critical to understand the importance of Saccone’s testimony. The Government’s assertion that compensation under the Contracts took into account the volume or value of referrals rests entirely on its assertion that Saccone used the net present value of the non-compete clause to calculate compensation under the Contracts. Similarly, the reasoning of the Fourth Circuit’s decision directly reflects the Government’s mischaracterization of Saccone’s testimony. The Court noted the Government’s contention that Tuomey “included a portion of the anticipated facility component referrals in the physicians’ fixed compensation.” *Drakeford*, 675 F.3d at 407. And, the Court held that “if a hospital provides 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

A. Yes.
2010 Trial Tr. at 730.

account additional revenue the hospital anticipates will result from the physicians' referrals, ... such compensation by necessity takes into account the volume or value of such referrals." *Id.* at 409.

Saccone's testimony in this trial—as corroborated by Hewson, who designed the Contracts—made absolutely clear that the compensation formula was “based solely on the value of the services” the contracting physicians were expected to perform. Saccone (4/18/13) at 125. Thus, the unrefuted testimony is that compensation under the Contracts simply did not take into account the revenue Tuomey anticipated would result from the physicians' referrals.⁵

Stark's “take into account” terminology does not prohibit Tuomey from evaluating the financial impact on the hospital of the loss of facility fees if physicians started performing the outpatient procedures elsewhere. *See* Hewson (5/2/13) at 74 (testifying that “there was nothing improper” about Tuomey's Board discussing competitive threats because “hospitals are allowed to compete”). Nor does “take into account” prohibit a cost-benefit analysis of offering employment to physicians. *See id.* at 73 (testifying that Tuomey's Board has “a fiduciary duty to monitor these charitable assets and ... to understand overall operations of the hospital and whether they can operate with sufficient margins to support the hospital's mission to provide care for everyone in the community regardless of their ability to pay”). In fact, CMS's 2007 amendment of the Stark regulations supports Tuomey's analysis. In those amendments, CMS clarified the regulatory language by replacing the term “otherwise reflects” which appeared from

⁵ It is permissible to incorporate non-compete provisions in a hospital-physician contract. CMS expressly stated in the Stark Phase II commentary that “non-compete covenants in employment contracts generally do not take into account the volume or value of referrals [as long as the] payment for [the] non-compete covenant [is] fair market value.” 69 Fed. Reg. at 16088. Hewson testified that he specifically relied on this legal authority when he designed the Contracts and advised Tuomey that they complied with Stark. Hewson (5/2/13) at 57-58. Therefore, there was nothing wrong with Saccone calculating the net present value of a non-compete clause. In fact, it was a necessary part of Tuomey's ongoing efforts to comply with the law.

time to time to “takes into account.” 72 Fed. Reg. at 51087. CMS explained that the terms had been used interchangeably in the regulations, and this was a non-substantive change “to clarify that we do not interpret ‘otherwise reflects’ and ‘takes into account’ (with respect to referrals and as these terms are used in certain exceptions) as having separate and different meanings.” *Id.* at 51027. Thus, “takes into account” does not and cannot refer to what the parties were thinking when they negotiated or agreed upon compensation. Rather, it can only refer to an *objective* analysis of how the compensation is paid under the terms of the agreement. *See Villafane*, 543 F. Supp. 2d at 693. This is why the Fourth Circuit said in its mandate that the jury had to decide *on the face of the Contract* whether the compensation varied with or took into account the volume or value of referrals. *Drakeford*, 675 F.3d at 409.

Even under the Government’s incorrect construction of the term “take into account,” hospitals can still consider the financial consequences of a course of action without violating Stark. The Government’s fundamental premise—that Stark forbids hospitals from competing for business or evaluating the financial impact of employment decisions—is simply wrong. CMS has cautioned that “while [Stark] must be implemented to achieve its intent, we should be cautious in interpreting its reach so broadly as to prohibit potentially beneficial financial arrangements.” 66 Fed. Reg. at 860; *see id.* (“[W]e believe that compliance with ... this rulemaking should not cause undue disruption of the health care delivery system.”). Nothing in Stark, or the Medicare statute more generally, prohibited Tuomey’s Board from performing its fiduciary duty to preserve and promote Tuomey’s financial viability. *See United States ex rel. Williams v. Renal Care Group, Inc.*, 696 F.3d 518, 528 (6th Cir. 2012) (rejecting government argument that a dialysis provider violated the FCA by forming a subsidiary “for the sole purpose of increasing its profit margins” and stating, “Why a business ought to be punished solely for

seeking to maximize profits escapes us.”); *United States ex rel. Colucci v. Beth Israel Med. Ctr.*, 785 F. Supp. 2d 303, 314 (S.D.N.Y. 2011) (“The worst that can be said of [Beth Israel] is that it took advantage of the uncertainty in the regulations to maximize its Medicare billings. This is not fraud.”).

Stark is not a “thought crime.” Except for the knowledge element of the indirect compensation arrangement exception, it is a strict liability civil statute. Pratt (5/3/13) at 97-99, 147-48. As CMS stated in the Phase I commentary, “we have attempted, as much as possible, to establish “bright line” rules so that physicians and healthcare entities can ensure compliance and minimize administrative costs.” 66 Fed. Reg. at 860. CMS specifically applied this bright-line concept to the to the volume-or-value standard. *Id.* at 865-66. To construe “taking into account” to mean that a hospital violates Stark by considering the financial impact of any business proposal is absurd. Yet, the Government’s expert McNamara (who is not an attorney) made repeated statements that it was improper to consider referral dollars when entering into contracts with referring physicians. McNamara (4/23/13) at 75, 106, 114 (attached hereto as Exhibit E). And, the Government in closing argument argued that Tuomey violated Stark by considering or talking about referral dollars. Acker (5/7/13) at 88-94. The Government played excerpts from various tapes to the jury and even misquoted law from a letter from former OIG director Richard Kusserow (who is also not an attorney) that addressed the AKS, not Stark. Then the Government implored the jury to disregard the terms of the Contracts and focus instead on Tuomey’s intent or reason for entering into the agreements. *E.g.*, Acker (5/7/13) at 100-01. When Tuomey pointed out that the intent section of Kusserow’s letter addressed the AKS and that Tuomey was not accused of violating the AKS, Daniel (5/7/13) at 132-33, the Government’s rebuttal argument compounded the error by arguing that Kusserow said that AKS and Stark are closely related,

Acker (5/7/13) at 165. As CMS stated in the Phase I commentary: “the approach taken by the Congress in enacting [Stark] results in important differences between it and other anti-fraud and abuse measures, especially the [AKS].” 66 Fed. Reg. at 863. The jury’s verdict was the product of confusion brought about by the Government’s inaccurate presentation of Stark. Because there was not a legally sufficient evidentiary basis to support the jury’s verdict, Tuomey is entitled to judgment as a matter of law that Stark did not apply to the Contracts. *See Konkel*, 165 F.3d at 279.

B. Tuomey is entitled to judgment as a matter of law because there was no evidence of any Stark-prohibited referrals by any of the contracting physicians.

Even if Stark applied to the Contracts in this case—which it does not—Tuomey is still entitled to judgment as a matter of law because the Government failed to introduce any evidence of referrals, and thus failed to provide evidence of “the *sine qua non* of a False Claims Act violation”: submission of a false claim. *United States ex rel. Schubert v. All Children’s Health Sys., Inc.*, 2013 WL 1651811, at *2 (M.D. Fla. Apr. 16, 2013).⁶ (attached hereto as Appendix 3). Failure by the Government to prove “a real false claim, either in the form of the false claim itself or evidence sufficient to identify such a claim,” is failure to prove a violation of the FCA. *See United States ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 1003 (9th Cir. 2002). Moreover, it is not enough for the Government to present evidence from which it might be inferred “that false claims must have been submitted”; the Government must prove “*actual submission* of a ... false claim” to Medicare. *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 434 (3d Cir. 2004) (emphasis added).

⁶ As explained below, there was also insufficient evidence for the jury to find that *any* claims were submitted to the Government. *See infra* Part II.C.

The Government's theory is that Tuomey submitted claims that were false because they sought payment "for designated health services furnished pursuant to a referral" by one of the contracting physicians. 42 U.S.C. § 1395nn(a)(1).⁷ A "referral" is "the request or establishment of a plan of care by a physician which includes the provision of the designated health service."⁸ 42 U.S.C. § 1395nn(h)(5)(B). The "designated health service" at issue in this case is the technical component, *i.e.*, the space, services, and equipment provided by the hospital for which Tuomey bills a facility fee. Therefore, to prove Tuomey made a "claim" under the FCA, the Government was required to prove that one of the contracting physicians referred a patient to Tuomey for a service and that as a result, Tuomey subsequently billed for the technical component associated with the service referred by the physician. As this Court correctly observed at the pretrial motions hearing, "the plain wording of the [Stark] statute ... prohibits payment if those claims are a *result* of referrals from physicians with whom the hospital has a financial relationship." Hearing Tr. (Doc. 737) at 41 (emphasis added).

Ruben Steck's conclusions about the number and dollar value of claims that the Government used to support its damages demand were based on his calculations of how many times one of the contracting physicians was listed on the Medicare claims forms as an attending

⁷ By making this argument, the Government is essentially advancing a legally insufficient "implied certification" theory to support its FCA claim. "The theory of implied certification ... is 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., Inc.*, 238 F. Supp. 2d 258, 264 (D.D.C. 2002). The Fourth Circuit has not adopted this theory. *See Harrison I*, 176 F.3d at 787 n.8 (explaining that Fourth Circuit precedent holding that "there can be no False Claims Act liability for an omission without an obligation to disclose ... makes questionable an implied certification claim in the Fourth Circuit").

⁸ The definition in § 1395nn(h)(A) does not apply because it applies only to physicians' services reimbursed under Medicare Part B. Hospital services, which are reimbursed under Medicare Part A, are encompassed by the definition in (h)(5)(B).

physician or an operating physician.⁹ Steck (4/24/13) at 139, 141-42 (attached hereto as Exhibit F). In its jury instructions, the Court defined the terms “attending physician” and “operating physician” based on CMS definitions as follows: “An ‘attending physician’ is the individual who has overall responsibility for the patient’s medical care and treatment reported in a claim/encounter. An ‘operating physician’ is the individual with the primary responsibility for performing the surgical procedure.” Jury Instructions (Doc. 810) at 9. The Government consented to the Court defining these terms in the Jury Instructions. Steck (4/24/13) at 125. Agreed-upon jury instructions form the law of the case. *United States v. Romero*, 136 F.3d 1268, 1272 (10th Cir. 1998); *Jabat, Inc. v. Smith*, 201 F.3d 852, 857 (7th Cir. 2000).

There is nothing in these definitions that identifies a referring physician. As established by the unrefuted testimony of Therese Janus, the UB-92 form only contains fields to list the “attending physician” and “other physician.” Janus (4/30/13) at 54; Def. Ex. 351 (attached hereto as Exhibit S). The UB-04 form contains fields for “attending,” “operating,” and “other” physicians. Janus (4/30/13) at 56; Def. Ex. 352 at 254977 (attached hereto as Exhibit T). There is no field for “referring physician” on either form. The UB-04 form instructions refer to a “DN” qualifier code that purportedly can be used to identify a referring provider. Janus (4/30/13) at 57. But, Tuomey’s Medicare intermediary does not permit Tuomey to use this qualifier. *Id.* at 58. Thus, there could not be anything in the hospital claims data that Steck reviewed which would identify a referring physician as Stark defines that term.

This comports with the testimony of Troy Barsky from CMS, whose 30(b)(6) deposition was read to the jury. Barsky testified that CMS does not track the identity of referring physicians

⁹ Steck was also not qualified as an expert by the Court because his work was not the product of reliable principles and methods as required by Federal Rule of Evidence 702. Steck (4/24/13) at 120-21. This makes the Government’s claims evidence even more suspect.

for Stark purposes. Barsky Depo (Doc. 798) at 171.¹⁰ Likewise, CMS witness Fred Rooke testified that hospitals are not required to identify referring physicians on Medicare Part A claims forms.¹¹ Rooke Depo. (Doc. 788) at 23.

The jury's interrogatory answers about the number of claims that violated the FCA and the dollar value of those claims were based solely on Steck's testimony and were therefore pure speculation. The data Steck relied upon to reach his conclusions was derived from the Medicare claims forms for hospitals, which do not identify the referring physician. As Janus said, the only way to identify the referring physician would be to review the medical record. Janus (4/30/13) at 63; *see* Pratt (5/3/13) at 154 ("Usually you look in the medical records to determine if there's been a referral."). But Steck never looked at any medical records. Steck (4/24/13) at 145. Neither did Thomas MaCurdy, who gave Steck the Medicare data that Steck analyzed. MaCurdy (4/22/13) at 165. Nor was the jury provided with a single medical record.¹² Consequently, the trial record contains no evidence from which the jury could possibly identify any claims resulting from referrals by contracting physicians—a necessary and essential element of a Stark violation,

¹⁰ Barsky's 30(b)(6) testimony is binding on the Government. *QBE Ins. Corp. v. Jorda Enters., Inc.*, 277 F.R.D. 676, 690 (S.D. Fla. 2012); *Ierardi v. Lorillard, Inc.*, 1991 WL 158911, at *2 (E.D. Pa. Aug. 13, 1991).

¹¹ In contrast, the CMS 1500 form, which is used to submit physician claims to Medicare, contains a specific field to identify the "referring physician" using a definition that tracks the Stark definition almost word-for-word. Janus (4/30/13) at 62-63; Def. Ex. 350 (attached hereto as Exhibit U). However, Steck testified that he only used hospital claims to perform his summary calculations. Steck (4/24/13) at 132. Thus, to the extent that the 1500 form identified the referring physician, it had no bearing on the numbers that Steck gave to the jury.

¹² The government did not even attempt to provide the jury with the CD containing its insufficient and unreliable claims data evidence. Without the claims in evidence, "the jury has no evidence upon which to determine that any false claims were submitted." *United States ex rel. Gonzalez v. Fresenius Med. Care N. Am.*, 748 F. Supp. 2d 95, 114 n.32 (W.D. Tex. 2010) (observing that "the electronic claims forms ... are not in evidence, nor is any substitute document or testimony about them, so the jury has no evidence upon which to determine that any false claims were submitted ...").

which was the sole predicate of the Government's FCA claim. Tuomey is entitled to judgment as a matter of law for this reason alone.¹³ See *Price*, 93 F.3d at 1249; *Wheatley v. Wicomico Cnty., Md.*, 390 F.3d 328, 332 (4th Cir. 2004).

For all of these reasons, Tuomey is entitled to judgment as a matter of law because there was not a legally sufficient evidentiary basis for the jury to conclude that false claims had been submitted to Medicare.

C. Based on the uncontradicted evidence presented as to Tuomey's reliance on the comprehensive advice of counsel, no reasonable jury could have found that the Government met its burden of proof as to the element of scienter.

The FCA is intended to punish wrongdoing, not honest mistakes. *Colucci*, 785 F. Supp. 2d at 316. Accordingly, a defendant may be held liable under the FCA only for *knowing* submission of a false claim. See *Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 917 (4th Cir. 2003) (*Harrison II*). “[C]laims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA.” *Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 475 (5th Cir. 2012) (internal quotation marks omitted). In this case, the Government was required to prove that Tuomey knew that the Contracts violated Stark and, therefore, that claims resulting from referrals by the contracting physicians were false. Evidence that a defendant relied on advice of counsel in good faith negates the requisite intent needed to establish violation of the FCA. *United States v. Newport News Shipbuilding, Inc.*, 276 F. Supp. 2d 539, 565 (E.D. Va. 2003); see also, *United States v. Polytarides*, 584 F.2d 1350, 1353 (4th

¹³ As explained *infra* Part II.C, the data underlying Steck's summary exhibits was extracted from databases to which only a select few are granted access. Tuomey was never given access to these databases at any time during this litigation, in contravention of Fed. R. Evid. 1006 (“The proponent [of a summary exhibit] must make the originals or duplicates available for examination ...”). Moreover, the very person who extracted the data, Thomas MaCurdy, admitted that it was likely incomplete and inaccurate. Accordingly, in addition to being inadequate to prove referrals, the claims data was inadmissible.

Cir. 1978) (“The basis for the defense of action taken on the advice of counsel is that, in relying on counsel’s advice, defendant lacked the requisite intent to violate the law.”); *cf. United States v. Miller*, 658 F.2d 235, 237 (4th Cir. 1981) (stating that the reliance defense “is designed to refute the government’s proof that the defendant intended to commit the offense”).

There can be no doubt that Tuomey reasonably relied on Nexsen Pruet’s advice. The trial evidence, discussed in more detail *infra* Part II.B.1.c., is clear that Tuomey relied on its counsel in good faith and accordingly the Government failed to prove scienter. Hewson provided extensive testimony over the course of three days about the comprehensive legal advice provided to Tuomey about the physician contracts over the course of several years. Hewson and Nexsen Pruet have extensive experience in health care law and Stark law issues, Hewson (4/30/13) at 68-75, and the firm’s advice to Tuomey was a collaborative effort of numerous attorneys including Hewson, Al Pollard, Matthew Roberts, Ralph Barbier, Joe Kahn, Mindy Staley, and others, *id.* at 76-78.

The Tuomey Board did not simply take Hewson’s advice at face value; rather, it actively and thoroughly questioned him regarding all issues surrounding the legality of the Contracts. *E.g.*, Moses (4/22/13) at 100, 106-07; Watkins (4/29/13) at 75 (attached hereto as Exhibit G); Glenn (4/29/13) at 197-98, 207-08. There is no evidence that anyone at Tuomey believed that Nexsen Pruet’s advice was unsound. *See S.E.C. v. Prince*, ____ F. Supp. 2d ____, 2013 WL 1831841, at * 29 (D.D.C. May 2, 2013) (noting that reasonableness of reliance was supported by the absence of evidence that anyone at the defendant company thought counsel’s advice was incorrect) (attached hereto as Appendix 2). Attorneys Hewson and Pratt both repeatedly advised Tuomey the Contracts were legal. During their trial testimony, both strongly reaffirmed that advice without qualification or reservation. Hewson (4/30/13) at 95-96; Pratt (5/3/13) at 95-96;

Def. Exs. 59 (attached hereto as Exhibit X), 204, 232. Unrefuted evidence also established that Cindy Hutto with Nelson Mullins helped design the gastroenterologists' contracts and approved them. Hewson (4/30/13) at 93-94. The testimony is clear that Tuomey followed the advice of its counsel throughout the conception, design, and implementation of the Contracts. Hewson (4/30/13) at 95-96; Watkins (4/29/13) at 74; Glenn (4/29/13) at 188, 207.

The only possible evidence the Government could point to in support of its allegation that Tuomey knew the Contracts violated Stark was McAnaney's testimony. However, his testimony does not satisfy the Government's burden to present "substantial evidence" of scienter. *DeMaine*, 904 F.2d at 220 (citing *Business Dev. Corp. v. United States*, 428 F.2d 451, 453 (4th Cir. 1970) ("[A] district court should direct a verdict for the defendant if the plaintiff has failed to adduce substantial evidence in support of his claim.")). McAnaney never opined or testified the contracts violated Stark. McAnaney (4/19/13) at 116-18. At most, he expressed concern that the Government might not like the concept of paying physicians more than their collections. *Id.* Even this concern was presented with the caveat that McAnaney was not a fair market value analyst. *Id.* at 108. Nevertheless, Tuomey followed Nexen Pruet's advice about responding to McAnaney's comments by asking Pratt to review the Contracts. The result was a studied, written opinion from a preeminent health care law firm stating that Stark did not even apply to the Contracts. Def. Ex. 232. In light of Pratt's opinion, it was more than reasonable for Tuomey to rely on the opinions it received from highly qualified counsel concerning the import of McAnaney's comments.

Tuomey was entitled to ask its attorneys to fit its objectives with respect to the Contracts into a legally acceptable arrangement. *See United States v. DeFries*, 129 F.3d 1293, 1309 (D.C. Cir. 1997) ("Fitting a client's objective into a legally acceptable formula is a large part of

lawyering.”). The fact that McAnaney may have suggested to Hewson that Tuomey should act more cautiously than the law requires, or that the Contracts could potentially be scrutinized, does not mean Tuomey acted unreasonably in following Hewson’s advice in going forward with the Contracts. *See id.* (“If we were to conclude that a client did not ‘rely’ on his attorney’s advice in good faith anytime he disregarded one of his attorney’s suggestions, the scope of the advice-of-counsel defense would be very narrow indeed.”); *see also* Hewson (5/3/13) at 27 (testifying that “there’s no way to eliminate risk from a hospital financial relationship”); Pratt (5/3/13) at 151-52.

Moreover, Nexsen Pruet had already retained industry-expert Cejka Consulting, which had arrived at a compensation formula that was fair market value and reasonable. Hewson (4/30/13) at 116. Tuomey relied on Cejka’s analysis on the advice of Hewson and Pratt, that payment over collections was commercially reasonable and the Contracts did not violate Stark. *Id.* at 98; Pratt (5/3/13) at 88-89, 112. Tuomey sought the advice of counsel in good faith and followed this advice precisely in every respect. The mere fact that the Government contends this advice is incorrect does not prove Tuomey “knowingly” submitted false claims or acted with deliberate ignorance or reckless disregard of the claims falsity. *See Mead Data Cent., Inc. v. Toyota Motor Sales, U.S.A., Inc.*, 875 F.2d 1026, 1028 (2d Cir. 1989) (“[E]ven if the attorney’s professional advice had been wrong, it does not follow that ... reliance on that advice would have constituted bad faith.”); *Pharmacia Corp. v. Alcon Labs., Inc.*, 201 F. Supp. 2d 335, 376 (D.N.J. 2002) (holding that a defendant can rely on counsel’s advice even if that advice was ultimately determined to be wrong).

D. Tuomey is entitled to judgment as a matter of law because the Government failed to prove damages.

In this case, the amount of damages as alleged by the Government is the value of claims submitted by Tuomey based on referrals by the contracting physicians. Therefore, the Government could not prove damages unless it proved the number of referrals and the value of payments received by Tuomey from such referrals. Because the Government failed to offer any such proof, as discussed above, there is no evidence of damages and Tuomey is entitled to judgment as a matter of law.

However, there is a more fundamental problem with the damages evidence in this case. Under the FCA, which was the only cause of action tried to the jury, the Government is entitled to recover from a defendant an “amount of *damages* which the government sustains because of the act of that person.” 31 U.S.C. 3729(a)(1) (emphasis added). Under the FCA, damages means actual, economic loss, calculated as “the amount the government paid over and above what the government would have paid if not for the fraudulent activity.” *United States ex rel. Bunk v. Birkart Globistics GMBH*, 2012 WL 488256, at *5 (E.D. Va. Feb. 14, 2012) (*Bunk II*). In this case, it simply cannot be said that the Government received nothing of value in exchange for its payments to Tuomey. It received exactly the medical services it paid for, and it paid exactly the same amount it would have paid had the services been performed by another hospital.

This case is similar to *Harrison II*, which, like this case, rested FCA liability on a false certification theory.¹⁴ *Harrison II*, 352 F.3d at 912-13. In *Harrison II*, the defendant’s false certification caused the government to award a subcontract for which the defendant was actually ineligible. *See id.* at 914-15. The question for the court was how to measure FCA damages.

¹⁴ In *Harrison II*, the defendant falsely certified compliance with conflict-of-interest rules. In this case, the Government alleged that Tuomey falsely certified compliance with Stark.

Recognizing that the general measure of FCA damages is “the amount of money the government paid by reason of the false statement above what it would have paid absent the false statement,” *id.* at 922, the Fourth Circuit held that Harrison was required to prove “how much more the government paid [the defendant] to perform the subcontract than it would have paid another firm absent the false ... certification.” *Id.* at 923. Because the work was actually performed, there was “no evidence that the government did not get what it paid for or that another firm could have performed the work for less.” *Id.* Thus, there were no actual damages under the FCA.¹⁵

Applying *Harrison II* to this case requires a conclusion that the Government suffered no damages at all. There was no evidence presented that the Government suffered any actual loss resulting from any of the claims submitted by Tuomey. The Government did not attempt to prove, because it could not, that Tuomey provided services that were not medically necessary or that it overcharged for the services it provided. To the contrary, the only testimony on this point at trial established that every claim submitted by Tuomey was for a medically necessary service and was properly charged. *See Moses* (4/22/13) at 54; *McDuffie* (4/22/13) at 134. Every outpatient procedure performed under the Contracts would have been performed *even if the Contracts had never been entered into*. The same is true of the inpatient procedures, which were not covered by the Contracts for outpatient surgical services. In sum, there is no dispute that valuable and medically necessary services were provided by Tuomey exactly as described on the face of each claim form. *Cf. United States v. Jain*, 93 F.3d 436, 441-42 (8th Cir. 1996) (reversing

¹⁵ The Fourth Circuit thus rejected the rationale adopted by the Seventh Circuit in *United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008), on which the Government relies. In *Rogan*, the court found it immaterial that the United States would have paid for medically necessary procedures regardless of Stark and AKS violations, stating only that “[w]hen the conditions” set by Medicare “are not satisfied, nothing is due.” *Id.* at 453. A leading treatise on the FCA has characterized the result in *Rogan* as “extremely harsh” and its analysis as “perfunctory and superficial.” John T. Boese, *Civil False Claims & Qui Tam Actions* § 3.01[B].

“honest services” mail fraud conviction because the patients who were allegedly the victims of the kickback scheme received excellent, medically necessary care).

II. ALTERNATIVELY, TUOMEY IS ENTITLED TO A NEW TRIAL.

“If the court grants a renewed motion for judgment as a matter of law, it must also conditionally rule on any motion for a new trial by determining whether a new trial should be granted if the judgment is later vacated or reversed.” Fed. R. Civ. P. 50(c)(1). This Court may grant a new trial “on all or some of the issues...for any reason for which a new trial has heretofore been granted in an action at law in federal court.” Fed. R. Civ. P. 59(a). Rule 59(a) allows the Court to set aside the verdict and order a new trial if “(1) the verdict is against the clear weight of the evidence, or (2) is based upon evidence which is false, or (3) will result in a miscarriage of justice even though there may be substantial evidence” that otherwise would preclude a directed verdict under Rule 50. *Atlas Food Sys. & Servs., Inc. v. Crane Nat’l Vendors, Inc.*, 99 F.3d 587, 594 (4th Cir. 1996). The first two prongs of the analysis present “purely factual questions” that require the Court to compare “the factual record and the verdict to determine their compatibility.” *Id.* “The third prong requires a policy analysis” in which the Court brings to bear its “unique vantage point and day-to-day experience with such matters.” *Fairshter v. Am. Nat’l Red Cross*, 322 F. Supp. 2d 646, 650 (E.D. Va. 2004) (internal quotation marks omitted). In considering a motion for a new trial, the Court may “weigh the evidence and consider the credibility of the witnesses.” *Knussman*, 272 F.3d at 647.

A. The jury’s determination that Tuomey violated Stark is against the clear weight of the evidence, which showed Stark does not apply.

Tuomey is entitled to a new trial because the jury’s finding of a Stark violation is simply incompatible with the evidence presented at trial. Hewson testified that in reliance on specific provisions of the Stark statute, regulations, and official commentary, he and his colleagues at

Nexsen Pruet designed the Contracts to compensate physicians only for their own work. Hewson (5/2/13) at 50-55. Not one witness said otherwise—not even McAnaney, who was concerned that compensation exceeded collections, but not with the manner in which compensation was determined. McAnaney (4/19/13) at 94-95.

Knowing that it had no evidence of an actual Stark violation, the Government muddied the waters. Over Tuomey's objection, the Government played snippets of recorded discussions that took place years before the Contracts were signed and that involved completely different potential arrangements—including a joint venture agreement under which sharing facility fees would have been perfectly legal. Hewson (5/3/13) at 54-57, 59-62. The Government also repeatedly raised the specter of the AKS, with its intent-based—and wholly inapplicable—standard of guilt.¹⁶ *E.g.*, Hewson (5/2/13) at 121; Pratt (5/3/13) at 148; Bassett (4/17/13) 164-65 (attached hereto as Exhibit A); Kusserow (4/17/13) at 77, 82, 114, 142; Acker (5/8/13) at 79, 81, 100-01, 165. Finally the Government insinuated that Tuomey was wrong to worry about the competitive effect of the Wesmark ASC—as though charitable institutions have no right to be concerned about the bottom line.

The jury may have bought into the Government's intent-based theory, but it is contrary to the law. Under Stark, the proper inquiry is whether compensation under the contract *in fact* varied with, or took into account, the volume or value of referrals. Of this, there is no evidence at all. If Tuomey is not entitled to judgment as a matter of law, at the least it should receive a new trial.

¹⁶ The AKS does not apply to *bona fide* employment contracts, *see* 42 U.S.C. 1320a-7b(b)(3)(B), so it is completely irrelevant to this case. Furthermore, the OIG has issued an advisory opinion stating that part time employment contracts like those at issue in this case would not implicate the AKS. OIG Adv. Op. 08-22. <http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-22.pdf>.

B. The jury's rejection of Tuomey's advice of counsel defense is against the clear weight of the evidence.

The evidence presented by Tuomey of its good faith reliance on counsel was overwhelming and far outweighed any evidence offered by the Government. Allowing the present jury verdict to stand precludes reliance on the advice of counsel defense if there are any differing views among attorneys (even in the absence of competing legal opinions), thereby eviscerating the right to rely on advice of counsel. Such a precedent would have profound negative implications on a client's right to rely on counsel, the practice of law, the attorney-client relationship, and the administration of justice—especially in the exceedingly complex area of health care law. Accordingly, the Court should grant Tuomey a new trial because allowing the jury verdict to stand would be against the clear weight of the evidence and would result in a miscarriage of justice.

1. Tuomey proved it relied on the advice of counsel.

To negate the scienter requirement of an FCA claim by asserting advice of counsel, the defendant must prove (1) the advice of counsel was sought in good faith; (2) the client provided full and accurate information to counsel; (3) the client receives that advice which can be reasonably relied upon, and (4) the client faithfully follows this advice. *Newport News Shipbuilding, Inc.*, 276 F. Supp. 2d at 565.

a. Tuomey sought the advice of counsel in good faith.

As early as 2000, Tuomey executives learned of the significant trend developing across the country in which specialist surgeons who had previously performed all inpatient and outpatient procedures at a hospital were beginning to perform more and more outpatient procedures in their offices or off-site surgery centers. *Watkins* (4/29/13) at 26. This trend created an environment in which physicians no longer needed the hospital and could thus give up their

inpatient privileges. By giving up their hospital privileges, the doctors were relieved of the burden of taking emergency room call. *Id.* at 26-27.

In addition to this growing trend, the rigorous call schedule of the surgical specialists made recruitment increasingly difficult. As surgeons began to retire, the other physicians in the practice were required to account for his or her portion of on call nights until a new surgeon could be recruited to the group. Thus, as the number of surgeons retiring increased, so did the number of nights other surgeons in a specific group were on call. Moses (4/22/13) at 38; *id.* at 39 (“[W]hile I had no plans [to] leave, had we gotten down to a three-man group and unable to recruit I would very much have been looking at alternative sources of employment.”). This increase exacerbated the difficulty Tuomey had in recruiting new surgical specialists. Recruitment challenges were further compounded by the presence of an adverse payor mix. In Sumter, the majority of the population has Medicare/Medicaid/Tricare or is uninsured. Glenn (4/29/13) at 193-94. Thus, Tuomey was faced with the growing challenge of recruiting surgical specialists to a small, rural city where they would be taking call much more often than would be required in a larger urban city and the reimbursement they received for their personally performed services would in large part be comprised of Medicare/Medicaid/Tricare rates—if they received any reimbursement at all.

To address these issues, the Board created the Surgical Services Strategic Committee (“Surgical Committee”) comprised of a surgeon from each of the specialty groups and several Tuomey administrators. Beginning in February 2001, the Surgical Committee began to address immediate and long-term concerns of the surgeons and Tuomey. For the next year and a half, the committee researched and discussed ways in which to address immediate operational efficiencies faced by the physicians, including on-time starts, turn-around time, and block scheduling. By

increasing the efficiency in operating rooms, Tuomey was able to more quickly accommodate the growing number of patients requiring surgery at Tuomey. Watkins (4/29/13) at 27-31.

Knowing that increasing operational efficiency was not a long term solution to the growing population, the Surgical Committee retained an outside consultant with experience consulting for hospitals nationwide, to assess what the demand for operating rooms at Tuomey would be over the next five to ten years. Based on her report, and the risk of not having enough surgical specialists available to meet the need at Tuomey, the Surgical Committee recommended to the Board to increase operating room capacity, as well as engage the physicians in some type of contractual arrangement. Watkins (4/29/13) at 31.

Recognizing this need and the challenges Tuomey faced, Tuomey turned to Tim Hewson and his colleagues at Nexsen Pruet for advice on how to accomplish its goals in a legal manner. Watkins (4/29/13) at 31, 33-34; Hewson (4/30/13) at 79-88; *see DeFries*, 129 F.3d at 1309 (“Fitting a client’s objective into a legally acceptable formula is a large part of lawyering.”). Nexsen Pruet’s solution was the employment contracts that are the subject of this action. Hewson (4/30/13) at 88; Watkins (4/29/13) at 36.

b. Tuomey provided full and accurate information to its counsel.

Throughout the entire process, Tuomey provided its counsel with any and all information requested by its counsel. Glenn (4/29/13) at 206. Tim Hewson testified he was granted full access to anything he requested from Tuomey. In addition, after Cejka was retained at the advice of Hewson, Tuomey provided Kim Saccone with full and accurate information each time it was requested. Watkins (4/29/13) at 34.

Furthermore, having given Hewson all of the information he requested, Tuomey relied on him to pass this information along to McAnaney and Pratt. Odom (4/22/13) at 183. Hewson testified at trial that he provided McAnaney with all of the information needed for him to

perform his assessment and likewise, gave Pratt all of the information he needed for his opinion. Hewson (5/3/13) at 86. Tuomey never withheld information or provided inaccurate information to counsel.

c. Tuomey reasonably relied on counsel's advice.

Having provided its counsel with accurate and complete information, Tuomey relied on experienced counsel to develop contracts that complied with the law. This reliance was reasonable for several reasons. First and foremost, Tuomey retained counsel with extensive experience dealing with physician contracts and Stark. Glenn (4/29/13) at 188-89. Nexsen Pruet had served as Tuomey's lawyers for over 20 years, and its attorneys had advised Tuomey regarding other issues such as health care law, taxes, and benefits. *Id.*; Hewson (4/30/13) at 76; *see Prince*, 2013 WL 1831841, at *28 (considering length of relationship between the defendant and counsel as evidence of the defendant's good faith in seeking counsel's advice). Nexsen Pruet's advice to Tuomey was a collaborative effort of numerous attorneys including Hewson, Al Pollard, Matthew Roberts, Ralph Barbier, Joe Kahn, Mindy Staley, and others. Hewson (4/30/13) at 76-78. Specifically, Hewson's practice had focused entirely on healthcare law since 1990. *Id.* at 70. A major portion of his practice was dedicated to ensuring hospital-physician contracts complied with state and federal law, and advising clients on Stark was part of his daily practice. *Id.* at 72-73. Based on Hewson's vast experience ensuring the compliance of hundreds of physician contracts with Stark and his frequent dealings with fair market value analysts, it was reasonable for Tuomey to rely on his advice to retain Cejka. Hewson (04/30/13) at 112. Moreover, it was reasonable for Tuomey to rely on Hewson's and Pratt's assessment that Cejka had done a thorough, credible job. Hewson (4/30/13) at 92.

Tuomey reasonably relied on the thoroughly researched and carefully considered advice of counsel:

- Nexsen Pruet researched, designed, drafted, and recommended Tuomey enter into the Contracts, *id.* at 89;
- Nexsen Pruet advised Tuomey that the contracts complied with all laws, including Stark, *id.*;
- Nexsen Pruet advised Tuomey that the compensation did not vary with or take into account the volume or value of referrals or the hospital's technical fees, but rather paid the physicians for personally performed professional services, *id.* at 90, 91;
- Nexsen Pruet engaged Cejka, a fair market value consulting firm, to work on the Contracts and recommended that Tuomey rely on Cejka's opinion that the physicians' compensation was both fair market value and reasonable, *id.* at 91-92, 112;
- Nexsen Pruet engaged Richard Kusserow and evaluated his comments on the proposed agreements, *id.* at 92-93;
- Hewson advised Tuomey that Cindy Hutto of Nelson Mullins had negotiated and approved the gastroenterologists' contracts, further demonstrating that the Contracts complied with Stark, *id.* at 93-94;
- Tuomey provided Nexsen Pruet with all information needed for the firm to give its legal advice, never pressured Nexsen Pruet for a certain result, and never asked for anything improper, *id.* at 96-97;
- Hewson considered McAnaney's comments and concerns (made in a phone call to which Tuomey was not a party) but fundamentally disagreed with McAnaney. He discussed this with Tuomey and continued to advise Tuomey that the Contracts complied with the law and that compensation in excess of collections did not violate Stark, *id.* at 97-98;
- Nexsen Pruet intended for Tuomey to rely on his advice about McAnaney's comments and the "Drakeford letter," and Tuomey did rely on that advice, *id.* at 98-99;
- Hewson stands by all his advice to Tuomey and its Board that the Contracts were entirely legal, *id.* at 99.

Tuomey relied on Hewson's comprehensive legal advice throughout the entire process, and Hewson made sure Tuomey was well-informed on the progress of the contract formation. Hewson provided regular updates and drafted memoranda describing in detail the many steps taken to ensure that the Contracts complied with the law. Specifically, Hewson explained the purpose and legality of each of the relevant contract provisions, including every component of compensation, with specific reference to Stark authorities supporting each one. Those authorities

included commentary from CMS published in the Federal Register that Hewson specifically relied on when formulating the contracts. Hewson (5/2/13) at 49-58; *see* 69 Fed. Reg. at 16088. Hewson testified that Cejka was engaged to work for Nexsen Pruet and that Cejka's opinion letters and other work product were reviewed and approved by him from a legal standpoint. Hewson (5/2/13) at 58-67. Hewson testified that Cejka's methodology and work product—including documents criticized by the Government as raising Stark law issues, *see* Pl. Exs. 53, 84, 47, 530—did not present any Stark problems. Hewson (5/2/13) at 58-67. Hewson advised Tuomey that it should rely on Cejka's opinions. Hewson (4/30/13) at 92.

Following the Kusserow call, Hewson provided the Tuomey Board with several memoranda, with the Kusserow Letter attached, that explained how the comments of non-lawyer Kusserow were being vetted and, if warranted, addressed in the Contracts so as to ensure Tuomey complied with Stark. Hewson (4/30/13) at 93; Hewson (5/2/13) at 67. Similarly, Hewson discussed his call with McAnaney with Tuomey and assured Tuomey that paying physicians more than they collect was legal. Hewson (4/30/13) at 98; Pratt (5/3/13) at 88-89, 112. To alleviate any residual doubt, Tuomey retained Steve Pratt on the advice of Hewson to render an opinion on the legality of the Contracts. Pratt provided Tuomey with two well-researched opinions in which he concluded that Stark did not apply to the Contracts, but even if it did, the Contracts fell within an exception and were thus legal. Pratt (5/3/13) at 92-96; Def. Exs. 204, 232. Tuomey's reliance on counsel was particularly reasonable given the overwhelming evidence that the Stark statute, regulations, and commentary are confusing and unsettled. Even the Government's witnesses and representatives acknowledged the complexity and uncertainty inherent within Stark and regulations. McAnaney (4/19/13) at 105; Barsky Depo (Doc. 798) at 61.

Similarly, Tuomey's reliance on Steve Pratt and the Hall Render law firm was reasonable. Pratt began working for Hall Render and spent 14 years practicing healthcare law until 2000, when he left to be in-house counsel for Ascension Health, the parent company for a group of approximately 100 hospitals in 25 states. After four years as in-house counsel, Pratt returned to Hall Render and continued to advise clients as to Stark, as well as other healthcare laws and regulations. Hall Render is the largest healthcare firm in the country, and nationally renowned for its expertise in healthcare law. McAnaney also acknowledged that Hall Render is a very respected and well-known national healthcare firm. McAnaney (4/19/2013) at 103. In addition, Pratt has been a law professor since 2000 and presently teaches a class on Stark at Indiana University School of Law. Pratt (5/3/13) at 63-67.

Pratt's preliminary opinion concluded that the Contracts complied with applicable IRS rules, the AKS, and Stark. As part of his Stark analysis, Pratt concluded that the Contracts were "commercially reasonable." Specifically, Pratt explained:

We understand that it is very likely that the Practice will not generate a profit from the services that will be rendered by the employed physicians. We considered whether an employment arrangement that is not profitable could qualify as "commercially reasonable," and we conclude that it can. In our experience, most physicians who are directly or indirectly employed by a hospital do not generate a profit. It is common for a hospital owned physician practice group to operate at a financial loss. Generating a profit is only one of many factors that needs to be considered when determining whether an arrangement is "commercially reasonable."

Def. Ex. 204. This legal opinion is significant because it directly contradicted McAnaney's basic premise that the Government regulators would question the commercial reasonableness and fair market value of physician compensation arrangements that paid a physician more than collections for personally performed services. Pratt was admittedly experienced and qualified to provide this commercial reasonableness opinion, as he not only analyzes the commercial

reasonableness of compensation arrangements as part of his daily legal practice, but he also teaches law students how to do the same.

Hall Render issued its final opinion letter to Tuomey on September 20, 2005. Def. Ex. 232. In this letter, Pratt confirmed his preliminary opinions that the Contracts were legally compliant and commercially reasonable. Pratt advised Tuomey that Stark did not apply to the Contracts because Tuomey did not have an indirect financial relationship with the physicians:

[I]n order for the Physicians to have an indirect compensation arrangement with Tuomey, the aggregate compensation paid to the Physician by the Practice Group must vary with or otherwise reflect the volume or value of DHS referrals or other business generated by the Physician for Tuomey. It does not The aggregate compensation paid to the Physicians is determined by the services that are personally performed by the Physician These services do not constitute “referrals” as the Stark law defines “referrals.”

Id. at 12. Tuomey was entitled to rely on this written advice from an eminently qualified healthcare lawyer and professor of Stark. McAnaney’s comments did not even rise to the level of a competing legal opinion. Even so, Pratt carefully considered McAnaney’s comments and responded to them. The result was a carefully reasoned, credible legal opinion that Stark did not even apply to the Contracts. Therefore, McAnaney’s comments do not preclude Tuomey’s right to rely on counsel’s advice.

d. Tuomey faithfully followed the advice of its counsel.

There is not a shred of evidence that Tuomey did not faithfully follow the advice it was given by counsel. Instead, it actively sought out competent legal counsel, asked the tough questions, provided its counsel with full and accurate information, and only then entered into the Contracts. Glenn (4/29/13) at 195-99, 205-08. Based on their attorneys’ advice that compensation had to be fair market value, Chal Glenn and Sherri Watkins testified that they refused to offer more compensation to a physician than what Cejka had determined was fair market value. Glenn (4/29/13) at 199; Watkins (4/29/13) at 63. Dr. Moses similarly testified that each time the

gastroenterologists asked for an increase in pay, Tuomey adamantly adhered to keeping the compensation within the fair market value range established by Cejka. Moses (4/22/13) at 44. Moreover, when McAnaney assessed the Contracts in June 2005, Tuomey faithfully followed Hewson's advice in retaining Pratt and based on his opinions did not unwind the Contracts.

Yet, despite the overwhelming evidence of reliance on advice of counsel, the jury erroneously concluded that the existence of uncertainty or conflicting views as to Stark negated advice of counsel. Such a conclusion is fatally flawed and would, if allowed to stand, gut the viability of advice of counsel and be a miscarriage of justice. After all, advice of counsel has little use when the rules are clear. The point of seeking legal advice is to get guidance when the law is *not* clear. So long as the client actually relies on counsel and that reliance is reasonable, the protections of advice of counsel should apply. In this instance, the jury evidently believed that the very circumstances that most required counsel's advice actually made the defense unavailable to Tuomey. The Court should not allow this error to stand.¹⁷

2. The Government failed to introduce any evidence to undermine Tuomey's advice of counsel defense.

At trial, it was not disputed that Tuomey acted on the advice of counsel. Rather, the Government challenged the correctness of the advice and argued that Tuomey was not entitled to rely on the well-founded legal advice of its counsel. However, as discussed above and herein, the

¹⁷The trial evidence showed that the Government's claims calculations were made on a Government fiscal year basis. The Government's fiscal year runs from October 1st through September 30th. By acknowledging that Tuomey relied on counsel through September 30, 2005, the jury's verdict imposing liability and damages after that date is completely inconsistent with the evidence. There was no evidence that Tuomey received any legal advice beyond September 30, 2005 that conflicted with the advice it had received before that date. The last evidence in the record regarding Tuomey's advice of counsel was Steve Pratt's written legal opinion, dated September 20, 2005, which stated that the Contracts did not violate Stark because the law did not apply. Def. Ex. 232. Thus, by acknowledging that Tuomey relied on advice of counsel through September 30, 2005, the jury clearly and plainly erred in not finding advice of counsel to be a complete defense, because there was not substantial evidence.

greater weight of the evidence clearly shows that Tuomey's reliance on counsel was reasonable. Perhaps the most vivid demonstration of how one-sided and compelling the evidence was regarding the reasonableness of Tuomey's reliance was the willingness of the Government to effectively concede the applicability of advice of counsel until McAnaney became involved. Acker (5/7/13) at 110-11. This admission not only highlights the strength of Tuomey's evidence, but also necessarily is a concession that all of the "intent" evidence introduced by the Government prior to June 2005 was not sufficient to prove scienter.

In light of this concession and the jury verdict, the relevant inquiry becomes what, if any, evidence the Government presented to strip Tuomey of the advice of counsel defense after June 2005. The answer is that no such evidence was introduced. At most, the Government can point to McAnaney, whom Tuomey and Dr. Drakeford's practice retained to provide a neutral assessment (not a legal opinion) of the Contracts. McAnaney (4/19/13) at 100-01; Pratt (5/3/13) at 105-06. However, the Government's reliance on McAnaney to undermine the reasonableness of Tuomey's reliance on advice of counsel must fail because Tuomey reasonably relied on Hewson and Pratt to evaluate McAnaney's comments. Moreover, McAnaney did not offer a legal opinion on the Contracts in 2005 or at trial, and the evidence showed that his assessment was not neutral.

McAnaney was not retained to, and did not, provide a legal opinion to Tuomey as to whether the single contract he examined complied with Stark. McAnaney (4/19/13) at 103; Hewson (5/2/13) at 78. Within the limited scope of his engagement, McAnaney provided Hewson with his assessment of how government regulators would view the agreements—that government would likely think the compensation paid to the physicians over their collections was for referrals. *Id.* at 109. However, McAnaney also told Hewson that the mere fact that

physicians are paid more than collections is not determinative of whether compensation is fair market value. *Id.* at 110. McAnaney never stated that the Contracts violated Stark.

Hewson considered McAnaney's thoughts, but McAnaney's assessment did not change his opinion on the legality of the Contracts, and he accordingly advised Tuomey to proceed. Hewson (5/2/13) at 85. Based on his experience and understanding of the law, Hewson fundamentally disagreed with McAnaney's view that physicians could not be paid a salary of more than their collections for personally performed services. Likewise, Pratt testified that it was permissible under Stark for an organization like Tuomey to employ a physician who operates at a loss. Pratt (05/03/2013) at 89. In fact, Pratt's experience is that physician-employment contracts are net losers for a hospital 95 percent of the time. *Id.* Having received opinions from two reputable healthcare attorneys that the contracts complied with Stark, Tuomey's reliance on their advice was reasonable. Such reasonableness is not defeated by McAnaney's oral assessment, which amounted to little more than an off-the-cuff observation that the Government would not like payment to the doctors that was more than their collections—although no statute, regulation, or official commentary forbids it. This is especially true given that McAnaney's comments related to fair market value, on which he was not an expert.

Furthermore, McAnaney was retained by Tuomey and Dr. Drakeford's practice to serve as a *neutral* third party because there was a disagreement among attorneys. However, as made clear by the evidence at trial, McAnaney was not neutral. Rather, it became obvious to Hewson during his calls with McAnaney that McAnaney's view of the arrangements was biased. From the outset of the June 22 and 23 calls with McAnaney it became clear to Hewson that McAnaney was against the contracts. Pratt's testimony of his participation in the June 23 call mirrors Hewson's impression of McAnaney. As explained by Pratt, it was apparent McAnaney was

against the under-arrangements; however, after an hour of discussing the reasoning and operation of the arrangements McAnaney was acknowledging the legal legitimacy of the arrangements. Pratt (5/3/13) at 83-84.

Following the calls with McAnaney, Hewson summarized McAnaney's assessments and expressed to Tuomey his impression that the "well had been poisoned."¹⁸ Glenn (4/29/13) at 211. Hewson informed the Board of McAnaney's assessment concerning payment of compensation over the amount of collections. However, Hewson explained that he had researched the issue thoroughly and based on his assessment, compensation exceeding collections was legal where the compensation was based only on personally performed services. Thereafter, Dr. Drakeford sent the July 19, 2005 letter to the Board allegedly summarizing McAnaney's views. The "Drakeford letter" parroted McAnaney's primary concern that paying more than collections could not be fair market value. The letter noted no other concerns regarding the legality of the Contracts, which is consistent with Hewson's testimony. Pl. Ex. 148 (attached hereto as Exhibit V). Although Dr. Drakeford's summary was self-serving and contained numerous false statements, Hewson nevertheless advised Tuomey to take the allegations seriously. Accordingly, Nexsen Pruet advised Tuomey to ask Hall Render for advice on the legality of the Contracts in light of the allegations, and to convene a Board meeting to obtain legal advice on the issues. Tuomey faithfully followed Nexsen Pruet's legal advice concerning each and every step taken in response to the Drakeford letter, including Tuomey's decision not to ask for a legal opinion from McAnaney. Hewson (5/2/13) at 88-93.

¹⁸ During discovery in this trial, Hewson learned Smith had drafted and sent to McAnaney a memorandum that misstated Hewson's analysis of the Contracts. Among other things, the memorandum recounts purported statements by Hewson that were "complete fabrication[s]." Hewson (5/2/13) at 81. Smith's memo is addressed to Hewson, but Smith did not copy Hewson on the email forwarding the memorandum to McAnaney, and in fact Hewson never received the memorandum. *Id.* at 78-79.

Pratt and Hewson advised Tuomey to reject the request of Greg Smith, Drakeford's lawyer, to ask McAnaney to put his opinions in writing. Pratt explained that there was genuine concern that McAnaney's understanding of Tuomey's intentions (an important factor under the AKS) had been adversely influenced by comments from Smith. Pratt also expressed concern that since McAnaney was jointly hired by Drakeford and Tuomey that the communication would not be protected by the attorney-client privilege. In addition, Pratt concluded that McAnaney would have a conflict of interest arising from the joint representation of both Drakeford and Tuomey because of the significant disagreement that had arisen between the parties. Pratt also noted that Tuomey had already engaged Hall Render to provide an opinion on the Contracts and Pratt did not believe that McAnaney had been thorough in his prior review. Def. Ex. 224, (attached hereto as Exhibit W).

Pratt also agreed with Hewson's assessment of the legality of the Contracts. While the Government attempted to discredit Pratt's analysis by implying Hewson withheld relevant information, this point is a red herring. Tuomey provided all of the relevant information to Hewson as he was formulating the contracts. Tuomey relied on Hewson to provide information to Pratt. Hewson did not withhold any information from Pratt, Hewson (5/2/13) at 23, but even if he had, the Government offered no evidence that Tuomey knew information had been withheld. Without such knowledge, there is no basis for a conclusion that Tuomey's reliance on counsel was unreasonable. More importantly, even after the Government pointed out all of the information allegedly withheld and concealed by Hewson, Pratt unequivocally testified his opinion *would not have changed*. Pratt (5/3/13) at 156-57; *see DeFries*, 129 F.3d at 1309-10 (recognizing that the advice of counsel defense does not require that counsel has perfect

knowledge of all facts). Accordingly, Tuomey is entitled to a new trial because the clear weight of the evidence illustrates Tuomey's reliance on counsel was reasonable.¹⁹

C. The jury's verdict that Tuomey violated the FCA is against the clear weight of the evidence.

For the reasons discussed in Part I, *supra*, Tuomey believes it is entitled to judgment as a matter of law on the issue of liability under the FCA. At a minimum, however, the jury's liability finding is against the clear weight of the evidence. The Government cannot prove FCA liability without proving submission of a false claim. But the "evidence" presented by the Government regarding claims was non-probative and inherently unreliable. Accordingly, Tuomey should be granted a new trial because the evidence weighs against a conclusion that Tuomey submitted claims pursuant to referrals by the contracting physicians.

The Government's only evidence of claims was Steck's summary evidence, which was in turn derived from inadmissible data that Thomas MaCurdy extracted from a database (the "Data Link" project) maintained by MaCurdy's company Acumen, a private contractor for the Department of Justice ("DOJ"). The Data Link project, for which MaCurdy is the project director, is a joint effort between HHS and the DOJ. MaCurdy (4/22/13) at 159. According to MaCurdy, the Data Link project is "the official government record for Medicare paid claims." *Id.* at 160.

MaCurdy's report, which was shown to him during his trial testimony, states that the data in the Data Link database was ultimately derived from the Medicare Common Working File ("CWF") and Standard Analytic File ("SAF"). His report describes these files as "depositories containing original claims" and goes on to say that Acumen processes these claims into a single

¹⁹ Claims submitted based on differences of interpretation growing out of disputed legal questions are not considered "false" under the FCA. *United States ex rel. Wilson v. Kellogg, Brown & Root, Inc.*, 525 F.3d 370, 377 (4th Cir. 2008).

database, *i.e.*, the Data Link project. Fred Rooke likewise described the CWF as a repository for Medicare claims data used by Medicare contractors when processing claims. Rooke Depo. (Doc. 788) at 23-26. Rooke further testified that after Medicare claims are processed, they go to the National Claims History File (“NCHF”). This is consistent with the testimony at the first trial by Chris Worrall, the CMS official in charge of Data Link, 2010 Trial Tr. at 338-42, and MaCurdy, *id.* at 1158 (describing Data Link as providing access to the SAF and NCHF).

Tuomey was not given access to any of these databases—Data Link, the SAF, or the NCHF—at any point during this litigation. Nor could it have been. CMS limits access to those databases to what it terms “routine uses” under the Privacy Act. These include access by the DOJ when the government is a party to litigation, and then only if CMS deems the records “relevant and necessary to the litigation.” 71 Fed. Reg. 64960 (Nov. 6, 2006); 71 Fed. Reg. 67141-42 (Nov. 20, 2006). These “routine uses” do not include access by private parties like Tuomey. According to Worrall, only Acumen and two other government contractors have access to the CWF and NCHF through Data Link. 2010 Trial Tr. at 347:4-8.

Furthermore, since 1980 CMS policy has prohibited release of payment amounts tied to individually identified physicians due to privacy concerns. *See* 45 Fed. Reg. 14703 (Nov. 28, 1980). This policy was adopted in partial response to a 1979 injunction barring the release of such information. That injunction was continuously in effect until last Friday, when it was vacated. *See Fla. Med. Ass’n v. Dept. of Health Educ. & Welfare*, 2013 WL 2382270 (M.D. Fla. May 31, 2013) (attached hereto as Appendix 1). But the court specifically left the 1980 CMS policy in effect, so Tuomey is still legally prohibited from accessing to data bases for the information extracted by MaCurdy and given to Steck.

For the reasons articulated in *United States ex rel. Bunk v. Birkart Globistics GmbH*, 2011 WL 5005313 (E.D. Va. Oct. 19, 2011) (“*Bunk I*”), the MaCurdy data was not admissible. Thus there was not a legally sufficient basis for the jury to find that any claims were submitted in violation of the FCA. In *Bunk I*, the district court concluded that the Government “failed to present evidence sufficient to allow the jury to determine without speculation the number of false claims that the ... defendants caused to be submitted to the government.” *Id.* at *1. The claims at issue were the vouchers submitted by the defendant, but the government neither introduced the actual vouchers nor presented direct evidence of the number of vouchers submitted. *See id.* at *7. Instead, the Government offered summary exhibits that purported to derive the number of false claims from a massive government database that was not produced or made available to the defendants. *See id.* The court concluded that the Government had failed to comply with the requirement of Federal Rule of Evidence 1006 “that the opposing party be given a fair opportunity to evaluate the accuracy and reliability of the summary exhibit against the source documents supposedly summarized in the summary exhibit.” *Id.* at 8.

The court also ruled that the Government’s summary exhibits were inadmissible because the underlying database was inadmissible, observing that the data

[W]as entered not by DFAS, but by an independent, private contractor There was no evidence from anyone with knowledge about the reliability or accuracy of the process used by the contractor to enter information into the database (as opposed to the reliability and accuracy of the information subsequently entered by DFAS based on its actual payments and other activities).

Id. at *8 n.13 (citations omitted). The court therefore concluded that there was insufficient evidence from which the jury could determine the number of false claims.

In this case, as in *Bunk I*, the Government attempted to prove claims with data that was inaccurate and unreliable, and hence inadmissible. Just like in *Bunk I*, the database from which the data was extracted was not provided to Tuomey. And, just as in *Bunk I*, the evidence

extracted from the database was not reliable. MaCurdy admitted that the data was only current as of September 30, 2009. MaCurdy (4/22/13) at 168. But because the information in the NCHF is “ever evolving,” MaCurdy was forced to admit that the data could have changed after the extraction date, making the data used at trial incomplete and inaccurate. *Id.* at 165. MaCurdy’s testimony that claims data is subject to change based on subsequent payment adjustments was corroborated by Fred Rooke, who testified that claims data is for 10 years. Rooke Depo. (Doc. 788) at 29-30. MaCurdy also admitted that the data he sent to Steck did not include claims information for Dr. Lauzon. MaCurdy (4/22/13) at 168-69. Steck nevertheless reported information about Dr. Lauzon, making his conclusions even more suspect and confirming the unreliable nature of the Government’s claims data.

Even CMS admits that the databases from which MaCurdy extracted his information are unreliable. In a disclaimer appearing on the CMS website²⁰ that must be signed by anyone who is allowed to access information from those databases (presumably including MaCurdy and the DOJ): “Some data fields that are not used for agency functions may contain incorrect or incomplete data. CMS has no responsibility for the data after it has been converted, processed, or otherwise altered. <http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/IdentifiableDataFiles/Downloads/CustomDisclaimer.pdf>.

D. Because the damage award could only rest on speculation, Tuomey is entitled to a new trial *nisi remittitur* on damages.

The Court must order a new trial on damages if the evidence would require the jury to speculate. *McCollum v. McDaniel*, 136 F. Supp. 2d 472, 476-77 (D. Md. 2001). A new trial on damages should be granted if “the amount is grossly excessive or monstrous, clearly not

²⁰ The Court may take judicial notice of information on government websites. *Tisdale v. S.C. Highway Patrol*, 2009 WL 1491409, at *1 n.1 (D.S.C. May 27, 2009), *aff’d*, 347 Fed. Appx. 965 (4th Cir. 2009).

supported by the evidence, or based only on speculation or guesswork.” *Harper v. City of Los Angeles*, 533 F.3d 1010, 1028 (9th Cir. 2008); *see also, Int’l Safety Access Corp. v. Integrity Worldwide, Inc.*, 2011 WL 6826855 at *3 (D.S.C. Dec. 28, 2011). The Government’s proof did not permit the jury to determine the number of false claims “based on just and reasonable inferences.” *Pine Ridge Coal Co. v. Local 8377, United Mine Workers of Am.*, 187 F.3d 415, 421 (4th Cir. 1999). Accordingly, the jury’s award of damages is against the clear weight of the evidence and Tuomey should be granted a new trial.

At a minimum, the Court should order a new trial *nisi remittitur*. Remittitur “is the established method by which a trial judge can review a jury award for excessiveness.” *Atlas Food Sys.*, 99 F.3d at 593. Remittitur offers the plaintiff a choice between accepting a reduced damages award or retrying the case. *Id.*; *see Sloan v. State Farm Mut. Auto. Ins. Co.*, 360 F.3d 1220, 1225 (10th Cir. 2004) (recognizing that giving a choice between remittitur and a new trial is necessary to preserve the plaintiff’s Seventh Amendment rights). “It is well established that remittitur should be ordered when the jury award will result in a miscarriage of justice.” *Robles v. Prince Georges County*, 302 F.3d 262, 272 (4th Cir. 2002) (internal quotation marks omitted); *see Atlas Food Sys.*, 99 F.3d at 593 (“[I]f a court finds that a jury award is excessive, it is the court’s duty to require a remittitur or order a new trial.”).

1. As a matter of law, the jury could only award damages for referrals pursuant to the employment contracts.

The potential universe of false claims is limited to facility fee claims by Tuomey arising from referrals by the contracting physicians pursuant to the Contracts, *i.e.*, for outpatient services. Accordingly, to arrive at an amount of damages the jury was required to determine which of the purported 21,730 claims (1) was for outpatient services that were (2) performed by Tuomey pursuant to a referral from one of the contracting physicians. *See* Jury Instructions (Doc.

810) at 14 (“If Tuomey violated the Stark Law, Tuomey was not allowed to submit claims for payment to Medicare for services that were referred by the physicians whose compensation arrangements violated the Stark Law.”). Any claim that did not meet those criteria was not “for designated health services furnished pursuant to a [prohibited] referral,” 42 U.S.C. § 1395nn(a)(1)(A), and therefore could not be included as damages.

2. Steck’s numbers are grossly inflated.

The jury awarded damages of \$39 million, based on 21,730 purported claims in which a contracting physician was either the attending or the operating physician. These numbers included claims that could not possibly have resulted from a referral by one of the contracting physicians, and thus grossly overstated the actual number of false claims that Tuomey could have submitted.

a. Steck’s data included claims when the contracting physician was not the attending physician.

Stark defines the term “referral” as a “request or establishment of a plan of care by a physician which includes the provision of the designated health service constitutes a ‘referral’ by a ‘referring physician.’” 42 U.S.C. § 1395nn(h)(5)(B). The “designated health services” at issue in this case are hospital services. 42 U.S.C. §1395nn(h)(5)(K). A hospital does not bill “a la carte” for each service it provides to the patient (such as operating room space, lab tests, or x-rays). Instead, Medicare pays hospitals a flat rate on a per-case basis. 42 C.F.R. § 412.112; Janus (4/30/13) at 50.

Since a hospital receives only one payment for each admission, the Stark claim prohibition applies only to the hospital’s claim for payment that arises from payment that arises from that admission. The evidence at trial established that there can be only one “attending” physician per inpatient or outpatient hospital service, as explained above. Rooke Depo. (Doc.

788) at 20. And yet, Steck admitted that his numbers included claims where the contracting physicians were listed as operating physicians, but non-employed physician were listed as attending physicians.

As stated above, the claims forms do not necessarily establish that the “attending” physician for a claim is also the physician who ordered the patient’s admission. However, let us assume for the moment that this is so. Therefore, even if the attending physician on the claims form was the referring physician for Stark purposes, Steck should not have counted claims if the attending physician was not one of the contracting physicians.

b. Steck’s data included claims for patients admitted through the ER.

Stark does not prohibit Tuomey from making claims for payment when there has been no referral, even if a contracting physician performed some service for the patient. *See* 42 U.S.C. § 1395nn(a)(1)(B) (prohibiting claims for services performed “pursuant to a [prohibited] referral”). As CMS itself has explained in the Phase I commentary, “[T]he relevant inquiry is whether the physician [with a financial relationship covered by Stark] has made a referral, directly or indirectly, to the entity furnishing DHS, in other words, whether he or she is referring ‘to’ that entity.” 66 Fed. Reg. at 873. Furthermore, CMS stated in the same commentary: “The definition of ‘referral’ by a ‘referring physician’ in section 1877(h)(5) of the Act [Stark] focuses only on actions and requests for services that are *initiated* by physicians ...” 66 Fed. Reg. at 945 (emphasis added).

The testimony at trial established that patients admitted to a hospital through its emergency department are not “referred” by any physician; rather, such patients are “effectively ... self-referring themselves to the hospital.” Rooke Depo. (Doc. 788) at 36-37. Common sense dictates that in such cases, the patient’s choice to come to the hospital is not initiated by a

physician, it is initiated by the patient, the patient's family members, or a first responder like an ambulance company. Therefore, even if one of the contracting physicians were to treat a patient who presented to the emergency room, any resulting claim by Tuomey would not be "pursuant to a referral" by the physician and should not have been included in Steck's numbers.

c. Steck's data included outpatient claims when a contracting physician was not the referring physician.

The Fourth Circuit's ruling that the only relevant procedures in this case are outpatient procedures performed pursuant to the physicians' employment contracts is a key part of the mandate to this Court. *See Drakeford*, 675 F.3d at 405. Because there is no dispute that every procedure performed under the Contracts was medically necessary, the most harm the Government can argue it suffered stems from the possibility that some of the outpatient surgery procedures performed by the contracting physicians at Tuomey might have been performed at Wesmark. In the first place, such an assertion would be entirely speculative. There was absolutely no evidence presented at trial to show that (1) the patients or doctors would have chosen Wesmark over Tuomey; (2) Wesmark would have the capacity to handle those surgeries; and (3) the surgeries would have been clinically appropriate to perform at an ambulatory surgery center.

As discussed above, the universe of potential damages in this case is limited to claims resulting from referrals for hospital services pursuant to the Contracts, *i.e.*, the outpatient procedures only. The Government proved no referrals at all, but in any event the maximum number that could ever even possibly exist would be 10,663 referrals. Therefore, the jury's award of 21,730 claims and \$39,313,065 damages grossly exceeds the maximum amount of claims paid in violation of Stark.

Tuomey believes the Court should grant judgment as a matter of law on liability or damages, *see supra* Part I. But if the Court does not grant it a directed verdict, Tuomey respectfully requests that the Court order a new trial *nisi remittitur*. *See* Opposition to Gov't Motion for Damages and Penalties (Doc. 825) and accompanying exhibits.

E. Granting Tuomey a new trial is necessary to avoid a miscarriage of justice.

Even if the jury's verdict could be accepted in light of the overwhelming evidence supporting Tuomey, which it cannot, allowing the jury's verdict to stand would be a miscarriage of justice.

First, the evidence was clear that the physicians' compensation did not vary with or take into account their referrals to Tuomey, and thus that Stark did not apply to the Contracts. Pratt (5/3/13) at 95-96. Saccone testified that the compensation models she designed did not reflect any technical fee income to Tuomey. Saccone (4/18/13) at 40, 69-70. Hewson confirmed that the Contracts were designed to pay physicians only for their personally performed services. Hewson (5/2/13) at 90-91. Doctors Moses and McDuffie testified that they were paid only for their personally performed services and their compensation was not tied to Tuomey's technical fees. Moses (4/22/13) at 11; McDuffie (4/22/13) at 135. It is undisputed that the physicians were paid regardless of whether Tuomey received a facility fee related to the contracting physicians' surgeries. Moses (4/22/13) at 49-50; McDuffie (4/22/13) at 135, 137.

Second, the Government has not proved any referrals to Tuomey by the part-time physicians. The Government admittedly does not track physician referrals, and Ms. Janus' testimony that Tuomey is not even allowed to enter referring physician data on its electronic claims forms is not disputed. Janus (4/30/13) at 58. The CMS definitions of attending and operating physicians do not meet the Stark definition of a "referring" physician. The only way to determine the identity of a referring doctor is by gleaning the medical records, Janus (4/30/13) at

63, and it is clear that this was not done by either Steck or MaCurdy. Steck (4/24/13) at 145; MaCurdy (4/22/13) at 165.

Third, the jury's finding regarding the Government's claims and damages is clearly excessive and is based upon unreliable data. As noted by the Fourth Circuit in *Drakeford*, the relevant claims are those based upon the Contracts, i.e., only the outpatient surgical claims. There is simply no basis to support the jury's finding that Tuomey had 21,730 false claims for \$39 million dollars when there were only 10,663 outpatient claims for about \$6 million dollars.

Fourth and finally, the overwhelming evidence at trial established that Tuomey relied on advice of counsel in good faith throughout the conception, design, and implementation of the Contracts. Hewson (4/30/13) at 95-96; Watkins (4/29/13) at 74; Glenn (4/29/13) at 188, 207. Tuomey went to Nexsen Pruet, its long-time counsel, to help it fashion a solution to a growing problem with retaining and recruiting surgical specialists needed to protect the hospital's ability to provide a full array of surgical services and emergency room call coverage necessary to maintain its core mission to serve the Sumter community. Nexsen Pruet attorney Hewson pursued several options for Tuomey and proposed a legally compliant arrangement. Hewson (4/30/13) at 114. Tuomey followed Hewson's advice to the letter. And, Hewson's advice was confirmed repeatedly, including by Cindy Hutto (who participated in negotiations and advised her clients to enter into the Contracts) and Steve Pratt. *Id.* at 93-94; Pratt (5/3/13) at 95-96; Def. Exs. 204, 232.

Dr. Drakeford, in contrast, did not demonstrate good faith in his dealings with Tuomey. Drakeford's attorney raised concerns about the legality of the contracts only after Tuomey refused to pay him more than fair market value. Tuomey, in good faith and on the advice of Hewson, jointly hired former OIG attorney McAnaney to provide his assessment of the contract.

At the urging of Dr. Drakeford, Tuomey also hired attorney Steve Pratt of the Hall Render law firm to review both the under-arrangement and part-time contracts that were under consideration in the summer of 2005. Pratt (5/3/13) at 69-70, 78. Hall Render is one of the biggest health care law firms in the nation. *Id.* at 65. Pratt confirmed Hewson's assessment that McAnaney's attitude toward the Contracts was tainted. *Id.* at 74-75, 82-83, 147-48. In response to the July 19, 2005 "Drakeford Letter," which again set forth McAnaney's concern about whether the compensation was fair market value because the physicians' pay exceeded collections, Pratt issued a short written opinion to the Board stating that the contracts complied with Stark. Def. Ex. 204. On September 20, 2005, Pratt issued an extensive written opinion to Tuomey, concluding that Stark Law did not apply to the contracts, but, even if it did, then the indirect compensation arrangement exception and/or the employment exception would exempt the contracts from Stark. Def. Ex. 232.

Both Hewson and Pratt testified that Tuomey acted in good faith, provided all of the necessary information regarding the contracts, and followed their advice. Pratt (5/3/13) at 86; Hewson (4/30/13) at 95-96; Watkins (4/29/13) at 34. The only legal opinions in evidence state that Stark either did not apply to these contracts or the contracts complied with Stark. Under these circumstances, the advice of counsel defense was clearly and overwhelmingly proved.

The Government's response to this overwhelming evidence confused the jury and led it to think, incorrectly, that if Tuomey talked or thought about referrals then it had violated Stark and the FCA. In its closing, the Government displayed the following excerpt from Pratt's September 20, 2005 opinion letter:

[L]aw enforcement authorities, the courts and Congress have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of payments between healthcare providers and potential referral sources.

Def. Ex. 232 at 10.²¹ The Government then argued to the jury, “And that’s what you’re being asked to do, to look beyond just the formalities and look at the underlying reasons, the underlying purposes of the contract.” Trial Tr. (5/7/13) at 80. The Government then replayed audio of various segments of meetings and told the jury its job was to “scratch away the veneer” and look to the underlying purpose of the Contracts.²² “If something looks like a duck and quacks like a duck, it’s a duck. And what they are doing is they are paying for an ongoing stream of referrals.” *Id.* at 81.

It is obvious that the jury’s verdict resulted from of the Government’s use of intent evidence to confuse the jury into believing that Tuomey violated Stark by considering the financial impact on the hospital’s operations in deciding whether to offer the physicians part-time employment agreements. This Court permitted the Government to introduce evidence of intent “as to the physicians’ contracts and determinations of fair market value.” Hearing Tr. (1/15/13) at 50-51, (attached hereto as Exhibit Z). However, the Government’s proffered evidence of intent was not used for the purposes for which this Court allowed. Instead, the Government misused this evidence to support its theme that Tuomey had bad intent (*i.e.*, to stifle competition) and was greedy (*i.e.*, it wanted to force patients to pay more by having procedures done at Tuomey). Therefore, in the end, it did not matter to the jury how the physicians were paid under the terms of the contract, nor did it matter to the jury that Tuomey’s lawyers constructed these physician agreements, with the assistance of a reputable fair market value appraisal firm, and that Tuomey followed the advice its attorneys.

²¹ It should be noted that this excerpt related to the AKS, not to Stark.

²² Notably, the statement “scratch away the veneer” was not even made in reference to the part-time contracts. Rather, as Hewson testified, the comment related to an ASC services agreement that was rejected in favor of the safer employment model. Hewson (5/3/13) at 60. Thus, the Government twisted Hewson’s legitimate advice, which Tuomey reasonably relied on, and used the advice as a sword against Tuomey.

The Stark law is an undeniably complex and evolving set of regulations that are not easily understood even on the most basic level. Recognizing the obvious evidentiary deficiencies in its case, the government capitalized on this complexity and invited the jury to use an alternate (improper) analysis that was designed to emphasize irrelevant AKS evidence in the record. Compliance with AKS was not legally before the jury and it was not something Tuomey was asked to defend. However, it provided the Government with a means to mislead the jury to think the intent inquiry for the AKS was synonymous with Stark. The jury's verdict shows that the jury was in fact misled by the Government and was led to render a verdict that contradicts the great weight of the evidence presented during trial. To allow this verdict to stand which is the product of improper and misleading argument would be a grave injustice. Therefore, if the Court does not grant Tuomey judgment as a matter of law, it should grant a new trial.

CONCLUSION

For the reasons set forth above, Tuomey respectfully requests the Court to grant it judgment as a matter of law on liability and damages, or in the alternative a new trial.

Signatures on following page.

Respectfully submitted.

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