No. 10-1819

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

UNITED STATES OF AMERICA, ex rel. MICHAEL K. DRAKEFORD, MD,

Plaintiff-Appellee,

v.

TUOMEY HEALTHCARE SYSTEM, INC.,

Defendant-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA

BRIEF FOR APPELLEE UNITED STATES OF AMERICA

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STATEMENT OF JURISDICTION

The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1345. The court entered a final judgment on July 13, 2010. Joint Appendix (JA) 139. Tuomey Healthcare System, Inc. (Tuomey), filed a notice of appeal on July 16, 2010, within the time specified under Fed. R. App. P. 4(a)(1)(B).

STATEMENT OF THE ISSUES

1. Whether the jury properly rendered a verdict that Tuomey's compensation arrangements with 19 specialty physicians violated the Stark Law.

2. Whether, based upon the jury's verdict, the district court properly entered judgment on the government's theories of payment by mistake and unjust enrichment.

3. Whether the Stark Law question was fully tried and properly submitted to the jury.

4. Whether the district court properly relied upon the unrebutted testimony of the government's damages expert in determining the amount of relief awarded to the government under its common law theories.

STATEMENT OF THE CASE

This case concerns compensation arrangements that Tuomey entered into with 19 referring physicians. Relator Michael K. Drakeford, MD, brought this civil action under the qui tam provisions of the False Claims Act, 31 U.S.C. §§ 3729-33 (the FCA). The United States of America intervened and added common law claims. A jury found that the arrangements violated the physician self-referral prohibition of the Medicare Act, commonly known as the Stark Law, 42 U.S.C. §

1395nn.[1] Based on the verdict, the district court entered judgment against Tuomey under the government's common law theories of payment by mistake and unjust enrichment. JA 136-39. The district court ordered Tuomey to re-pay the government $44,888,651, plus prejudgment interest, for reimbursements Tuomey had improperly received from the Medicare Trust Fund. Id. Tuomey appeals the judgment.

STATEMENT OF FACTS

I. The Stark Law and Regulations

The Stark Law was intended by Congress to eliminate the corrupting influence of money on medical decisionmaking. See JA 181 (R. Kusserow) (former Inspector General of the Department of Health and Human Services (HHS)). Enacted as amendments to the Social Security Act, the Stark Law establishes the clear rule that the United States will not pay for items or services ordered by any physician having a "financial relationship" with a hospital, unless the relationship meets the requirements of a statutory or regulatory exception. 42 U.S.C. §§ 1395nn(a)(1), (g)(1); see United States v. Rogan, 459 F. Supp. 2d 692,

[1]The jury found no FCA violation, but the district court granted the government's post-verdict motion for a new trial on that count based on the erroneous exclusion of certain key evidence. JA 135. Tuomey unsuccessfully sought interlocutory review of the new trial order in this Court. Case No. 10-254, Docs. 20, 22.

711 (N.D. Ill. 2006), aff'd, 517 F.3d 449 (7th Cir. 2008). The Stark Law is a strict liability statute, with no scienter requirement. Any amounts reimbursed by Medicare in violation of the Stark Law must be repaid. 42 U.S.C. § 1395nn(g)(1); 42 C.F.R. § 411.353(d); see Rogan, 517 F.3d at 453.

The Stark Law broadly defines prohibited "financial relationships" to include "compensation arrangements" in which any "remuneration" is paid by a hospital to a referring physician "**directly or indirectly, overtly or covertly, in cash or in kind**." 42 U.S.C. §§ 1395nn(a)(2)(B), (h)(1) (emphasis added); 42 C.F.R. § 411.354(c).

The government alleged that the arrangements at issue in this case were indirect compensation arrangements because two for-profit companies wholly-owned by Tuomey (the Tuomey LLCs) stood between the non-profit hospital and the referring physicians. The Stark regulations provide that an indirect compensation arrangement exists if the following criteria are met:

> (1) an unbroken chain of financial relationships exists between the referring physician and the hospital;
>
> (2) the referring physician receives aggregate compensation from the person or entity within the chain with which the physician has a direct financial relationship that **varies with, or otherwise takes into account, the volume or value of referrals** or other business generated by the referring physician for the hospital; and

> (3) the hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the arrangement meets the second criterion.

See 42 C.F.R. § 411.354(c)(2)(i)-(iii) (emphasis added). Below, Tuomey contested only the second element of this test and conceded the others.[2]

Once the government established that an indirect compensation arrangement existed, Tuomey then bore the burden of showing that the arrangement fell within the applicable exception. United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 95 (3d Cir. 2009); Rogan, 459 F. Supp. 2d at 716. The indirect compensation exception requires, among other things, that physician compensation be (1) "fair market value for services and items actually provided"; (2) "not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician" for the hospital and (3) "commercially reasonable even if no referrals are made" to the hospital. 42 C.F.R. § 411.357(p).

The jury heard evidence over three weeks. The district court then instructed the jury as to the disputed elements of the indirect compensation definition and exception, drawing its instructions almost verbatim from the language of the

[2]Without objection from Tuomey, the district court instructed the jury only as to the second element of the regulatory definition. JA 982-86, 1006-09. Thus, Tuomey conceded that the first and third elements of the definition were met. See also JA 39.

statute and regulations. JA 982-86. The jury was given an agreed-upon verdict form. JA 965-67, 995. As indicated on the completed form, the jury found that Tuomey violated the Stark Law. JA 117-18.

II. Facts Relevant to the Existence of a Prohibited Indirect Compensation Arrangement Between Tuomey and the Physicians

The evidence established that Tuomey's contracts with 19 surgeons and gastroenterological (GI) physicians were indirect compensation arrangements that met no exception to the Stark Law.

A. Competition and Its Cost to Tuomey

Tuomey Hospital is a non-profit hospital located in Sumter, South Carolina. Approximately 40 percent of Tuomey's business is derived from the Medicare program. JA 291.

Tuomey entered into the physician contracts at issue here because, for the first time, it faced competition in its service area for the lucrative facility fees generated by referrals of outpatient procedures. The sole GI group in Tuomey's service area was considering performing endoscopies in the group's offices instead of at the hospital. JA 225-26. The GI group and other specialty physician groups in the area also were considering taking their outpatient procedures from Tuomey to the Wesmark Ambulatory Surgery Center (Wesmark ASC), which had recently been built by the local urology practice. JA 204-08, 231-32. Two studies

– one by the hospital's chief financial officer (CFO), Paul Johnson, and the other by an outside firm called Cejka Consulting (Cejka) – concluded that the hospital could lose anywhere from $6 to $9 million or more in revenues just from the relocation of GI procedures. JA 282, 284-85, 1289-91.

The possibility of losing these revenues so concerned the hospital that it opposed the urologists' efforts to obtain a state license for their ASC (JA 1327-31), stopped assisting the urology group with their efforts to recruit additional urologists to serve the community's needs, and threatened to withdraw the urologists' admission privileges at the hospital, even though there was no other urology group in the vicinity to serve Tuomey's patients. JA 209-10, 215-20, 280-82, 402-04, 1369-70. The hospital also threatened relator Dr. Michael Drakeford and his group with the same type of "serious repercussions" if they opted to invest in Wesmark, rather than enter into an exclusive arrangement with Tuomey, even though Drakeford's group were the only orthopedic surgeons in the community. JA 427-31, 1563, 1575-76; Govt Tr. Ex. 426.[3]

---

[3]The parties have stipulated that, for ease of review by the Court, transcripts of recordings that were played at trial, and which were used as demonstrative exhibits, are part of the record on appeal and can be part of the Joint Appendix. However, Tuomey has not stipulated to the accuracy of the transcripts or the punctuation in the transcripts and is free to identify and notify the Court about any perceived inaccuracies. The recordings themselves remain the best evidence. By order dated February 17, 2011, the Court granted leave to file the recordings with (continued...)

B. The Physician Compensation Arrangements

To dissuade the physicians from moving their outpatient referral business to the Wesmark ASC or into their own offices, either of which would have been less costly for both insurers and beneficiaries[4], Tuomey offered the physicians contracts solely for the performance of their outpatient procedures. JA 174-79. These contracts paid the physicians cash and non-cash remuneration that greatly exceeded the fair market value of their services. JA 433-34, 1691, 1693. In exchange, the physicians agreed to perform their outpatient procedures exclusively at Tuomey for a period of 10 years and not to compete with Tuomey within a 30-mile radius for another 2 years after contract termination. E.g., JA 1134-42, 1175-83, 1193-1201, 1212-20. The contracts were written by Tim Hewson of the Nexsen Pruet law firm, based upon a compensation model devised by Cejka under Hewson's direction. JA 639-40, 1676-82.

The outpatient procedures at issue generated two billings: one by the physician for his or her professional services (the "professional fee") and a second

[3](...continued)
the Joint Appendix. The recordings are Government Trial Exhibits 417, 421, 424, 426, 437, 446 and 461, and are cited herein as "Govt Tr. Ex. ___."

[4]Medicare and private insurers reimburse ASCs about 60 percent of what they pay hospitals for the same outpatient procedure. JA 203, 303-04. Dr. Scott McDuffie agreed that it generally costs patients more to have an endoscopy performed in the hospital than in a doctor's office. JA 231.

by the hospital or other facility for providing the space, the nurses, the equipment, etc. (the "technical component" or "facility fee"). JA 305-06. Under the Tuomey contracts, the Tuomey LLCs collected the physicians' professional fees from Medicare, other insurers and patients. The LLCs then paid the physicians a base salary tied to their collections, plus a "productivity bonus" totaling 80 percent of their collections, and up to an additional 5.6 percent of their collections for meeting certain quality measures. See JA 1314, 1317. Thus, under this formula, each time a physician performed an outpatient procedure on a Medicare beneficary, the physician received increased compensation from Tuomey. The hospital also received a corresponding referral of the technical component of each procedure, for which it could bill Medicare for a facility fee. JA 305-06, 353-54, 731-33. Because of this one-to-one relationship, the physicians' compensation, by design, "varie[d] with . . . the volume or value" of the physicians' referrals. 42 C.F.R. § 411.354(c)(2)(ii).

The evidence also established that the compensation Tuomey paid to the physicians "[took] into account the volume or value" of the physicians' referrals to the hospital. 42 C.F.R. § 411.354(c)(2)(ii). Kim Saccone, the former Cejka employee who developed the physician compensation plans for Tuomey, testified that, for each physician, she calculated the "net present value of the non-compete clause" included in their contracts. She arrived at this figure by calculating the

value of each physician group's outpatient referrals that Tuomey feared losing and wanted to keep, dividing that figure by the number of physicians in the group, and using the resulting amount as a "benchmark" for determining each physician's total compensation. JA 312-44, 374-75, 1289-96. Tuomey's CFO Paul Johnson and the then-secretary of its Board of Trustees, Janet Odom, admitted that Tuomey was paying the physicians in part for the value of the "non-compete clause." JA 284-87, 309-10, 425. A December 2004 memorandum from Tuomey Chief Operating Officer (COO) Gregg Martin to the Tuomey Board of Trustees, seeking approval of the physician compensation arrangements, expressly described both the base salary and the 80% productivity bonus as including "partial consideration for the covenant not to compete." JA 1676-77.

C. Tuomey's Physician Recruitment Efforts

In 2003 and 2004, Tuomey recorded a number of meetings it held with the doctors it was trying to recruit. These recordings made clear that Tuomey was offering to use the contracts as a vehicle to share with the physicians a portion of the facility fees the hospital received from their outpatient referrals – in clear violation of the Stark Law.

At an August 27, 2003 meeting, Hewson and his law partner, Al Pollard, described the proposed arrangements to the physicians. Also in attendance were Tuomey's Chief Executive Officer (CEO), Jay Cox, and its COO, Gregg Martin.

Throughout the meeting, the lawyers repeatedly stressed that any employment would simply be "technical" – "something that sort of acts like ownership, but we call it an employment relationship" – but it really would function like "phantom stock" or "phantom ownership" in the hospital's outpatient surgery center. Govt Tr. Ex. 437; JA 1231, 1253 (Pollard), 1274-75 (Hewson).

Hewson acknowledged the Stark Law's restrictions and told the doctors that it was "illegal" to "be in a situation where we're paying for referrals," but that nevertheless, the purpose of the proposed contracts with the doctors was to reward doctors "who have been and continue to be loyal to Tuomey in terms of referrals." JA 1242-44, 1248. Pollard added that Tuomey was "trying to protect the mission of this medical center by sharing revenues with those people who might otherwise, frankly, go out and compete with us by trying to build their own center. . . ." JA 1251-52. He stressed to the doctors that the purpose of the proposed contracts was to "reward you economically for using the ambulatory surgery center, to take your patients there to work on them. . . ." JA 1249-50. He also said that "you get paid for giving up the right to go elsewhere." JA 1257.

At the same meeting, Cox admitted to the physicians that the proposed contracts took into account the volume of their referrals to the hospital. He explained that the deals were being offered to the surgeons and gastroenterologists, but not to the radiologists and anesthesiologists, because "it

wouldn't make any sense for us to do some of the volume-driven things with them because they don't create the volume. Y'all create the volume. They just do the work that's ordered. . . ." JA 1283.

A few months later, at a December 15, 2003 meeting, a doctor asked COO Gregg Martin if the compensation was "indirectly tied to volume," and Martin replied, "yes, yes." Govt Tr. Ex. 417; JA 1403. Cox interrupted Martin. He confirmed that the compensation was indirectly tied to volume and that it changed from year to year. Cox then told the doctors:

> I've got to keep saying read between the lines. None of you all ever want to be sitting on the stand, and all we're trying to do is help everybody through this. If we find a way to get legally dollars into your hand that you can somehow go sit down with a pencil yourself and say, 'Ah ha!' You know, I just want to figure out the legal way to do it right. . . . And you know that we – we did extremely well at the end of the year because the place ran efficiently, I've got a feeling you're – you are incentive [sic], even if I cannot tie it directly to that. I'm just trying to make sure we keep each other out of trouble. That's all I'm trying to do.

JA 1404. Cox's statement urging the doctors to "read between the lines" clearly suggested that the real reason for the arrangements was to pay the doctors for their referrals, but to do so indirectly and covertly so as to gloss the relationship with the veneer of legality.

At a meeting held on January 19, 2004, the Tuomey executives and lawyers more overtly connected the physician contracts to the volume and value of the

physicians' referrals. Hewson explained to the physicians that even though Tuomey might lose money on the proposed contracts, it would still be reasonable because "the hospital has other sources of revenue." Govt Tr. Ex. 426; JA 1714, 1734-35. Martin observed that the hospital would be losing money on these contracts, and the doctors would be making more money. Dr. Murrell Smith (an OB-GYN who later signed one of the illegal contracts) confirmed his understanding of what Martin had just said: "Just, you're taking a facility fee, which is what we – and we participate in that a little bit . . . ." JA 1739.

Moreover, Hewson admitted outright that the hospital was taking into account the volume and value of referrals: "Because of the Stark and Anti-kickback laws, you can't explicitly say, 'Well, it's because we're getting all the referrals for these patients,' and of course that's what we're doing. And that's not a legal consideration." Govt Tr. Ex. 424; JA 1422, 1470.

In mid-2004, Cejka prepared a series of powerpoint presentations to show the hospital executives and doctors how the compensation plans would work – and how much each physician could expect to receive above the total amount of their personal collections. Cejka estimated that, on average, the physicians would be paid 19 percent above their individual outpatient collections in cash and benefits, not including health insurance, at an annual cost to the hospital of $968,000. JA 311, 349-58, 1314, 1319.

III. Facts Relevant to the Indirect Compensation Exception

A. The Physicians' Compensation Exceeded Fair Market Value

Tuomey paid the 19 specialty physicians total remuneration that substantially exceeded the fair market value of their services to Tuomey. The GI physicians and the ophthalmologist were over-compensated in cash, while the OB-GYN physicians and the general surgeons were over-compensated in benefits. JA 452-68, 1691, 1693, 1785, 1787. At trial, both parties called expert witnesses to testify about whether the Tuomey arrangements complied with the fair market value requirement. The experts agreed that the proper standard for "fair market value" was the definition of the term set forth in the Stark regulations. JA 435, 725-26. "Fair market value" is defined as:

> the value in arm's-length transactions, consistent with the general market value. "General market value" means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party**, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party,** on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is. . . the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, **where the . . . compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.**

42 C.F.R. § 411.351 (emphasis added).

Saccone issued fair market value letters for each of the physicians purporting to use the regulatory definition of fair market value. JA 360-61, 648-50. However, she lacked the expertise to render fair market value opinions. Essentially, Saccone generated the "opinion" letters using a standard format that her supervisor, Doug Cardinal, had developed. JA 359-60, 381-87. She also used Cardinal's concept, rejected by both parties' trial experts, that the compensation could be justified as long as it did not exceed 150% of the 90th percentile – the highest level of physician pay reported in the market data. JA 347-49, 648, 651-63, 1310, 1365, 1367[5]; cf. JA 482-93, 790-91. The parties' trial experts agreed, however, that fair market value compensation generally falls between the 50th and 75th percentiles. JA 447-50, 749-50.

Although the Cejka compensation formulas cited the same market data that both parties' trial experts used, the compensation plans that Cejka devised deviated sharply from the standard valuation practices endorsed by the parties' experts. Saccone testified that in developing the physician compensation plans,

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[5]Cardinal conceded that his sole basis for using this 150% of the 90th percentile formulation was a 1997 letter written by a lawyer in response to questions raised by the Internal Revenue Service about an undisclosed physician practice's application for tax-exempt status. JA 1343-46. He had no evidence that the IRS or any other agency had ever approved this formulation. JA 654-60.

she did not consider what the physicians were earning before the contracts, nor did she conduct any analysis of the value of the fringe benefits Tuomey was providing under the contracts, nor did she make any connection between the physicians' actual level of productivity and what they could be paid. JA 365-73; cf. JA 749-50. Instead, she calculated the net present value of the physicians' future referrals, asked Tuomey to specify its "desired net gain" above collections for each physician, and then "backed into" the physicians' pay ranges. JA 346-47, 374-75, 1309-13.

As a result of Cejka's deviation from accepted valuation standards, Dr. James Goodson, the ophthalmologist, saw his income soar from a little over $500,000 annually before his Tuomey contract to as much as $1 million per year after the contract – with 70-80 percent of his outpatient collections coming from Medicare. JA 457-59, 473-74, 479-80, 1362, 1349. Dr. Scott McDuffie, a GI doctor, testified that while nothing had really changed in the way he worked, other than the addition of perhaps 10-15 hours per year of new administrative duties, his annual salary increased by $100,000 after he entered into the Tuomey contract. JA 242-45, 271-72, 475-79, 1649. Meanwhile, one of the gynecologists, Dr. Barney Williams, received salary and benefits that amounted to 700-800 percent of his outpatient collections because Tuomey paid him full benefits, including his entire malpractice insurance premium, even though he spent no more than 6 percent of

his time (about 2 hours per week) working under the Tuomey contract. Dr. Mark Crabbe, a general surgeon, received at least 129-144 percent of his personal collections for outpatient work, again because Tuomey was overly generous in providing him with full-time benefits for far less than full-time work. JA 441-46, 459-64, 1648, 1690, 1692. Thus, the evidence demonstrated that the Cejka-designed plans grossly exceeded fair market value for the physicians' work.

B. The Arrangements Were Commercially Unreasonable in the Absence of Referrals

Both parties' experts agreed that a "commercially reasonable" arrangement is one that "would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, **even if there were no potential [designated health service] referrals**." 69 Fed. Reg. 16054, at 16093 (Mar. 26, 2004) (emphasis added). JA 728-29. The Cejka letters did not opine on the commercial reasonableness of the contracts. Indeed, Saccone did not even know what the term meant. JA 373, 381-87.

The government's expert concluded that the Tuomey contracts were commercially unreasonable in the absence of referrals because, among other things, they did not protect the financial interest of the hospital. JA 469-70. Rather, the arrangements so grossly overpaid the physicians that the hospital lost

$1.5 million each year because of them, and was on track to lose as much as $14 million over the life of the contracts. JA 277-78, 881-82, 1689.

Cardinal testified that these deficits were "costs," not "losses," because the hospital offset the deficits with facility fees derived from the physicians' referrals. JA 666-68. This admission echoed a statement Hewson made in 2005 to Drakeford's counsel, Greg Smith. When Smith questioned Hewson about the legality of the arrangements, Hewson responded that Smith was "not going to want to hear this, but it is commercially reasonable because the hospital is getting the facility fees and other ancillary referrals from the doctors." JA 180. Tuomey CFO Paul Johnson conceded that although the physician contracts resulted in losses, in return, Tuomey obtained tens of millions of dollars in facility fees from Medicare, private insurance companies and patients. JA 299-301. This evidence demonstrated that the compensation plans were financially sustainable for the hospital only by taking into account the volume or value of the physicians' referrals and thus were not commercially reasonable in the absence of those referrals. See JA 892-94.

Tuomey's expert admitted that something didn't "quite look right" about the physician compensation arrangements. JA 793-94. He also conceded that if Tuomey had factored the value or volume of actual or anticipated referrals into the compensation it paid the physicians, the compensation could not meet the fair

market value and commercial reasonableness standards, and his opinions on those matters would be "null and void." JA 729-30, 801-03. As demonstrated, that is precisely what Tuomey did. Cox told the Board in 2003 that it would cost the hospital $1-2 million dollars per year to finance these contracts, but it would cost the hospital millions more to do nothing and to permit the physicians to take their outpatient referrals elsewhere. JA 1308. Guided by Cejka and Nexsen Pruet, Tuomey shared some of the value of the anticipated referrals in its payments to the physicians. For this reason, standing alone, these compensation plans could not possibly meet the standard of fair market value or commercial reasonableness. JA 482-85; see JA 729-30. The arrangements, therefore, could not qualify for the indirect compensation exception, and Tuomey was prohibited from making any claims to Medicare for any inpatient, outpatient or other services referred by these physicians.

STANDARD OF REVIEW

As the prevailing party under the jury's Stark Law verdict, the government is entitled to have all facts and reasonable inferences on that issue viewed in its favor. Duke v. Uniroyal Inc., 928 F.2d 1413, 1417 (4th Cir. 1991).

Findings of fact by the trial court are reviewed for clear error, while questions of law are reviewed de novo. Broughman v. Carver, 624 F.3d. 670, 674-75 (4th Cir. 2010); United States ex rel. Maddux Supply Co. v. St. Paul Fire &

Marine Ins. Co., 86 F.3d 332, 334 (4th Cir. 1996). The district court's qualification of expert witnesses is reviewed for abuse of discretion. United States v. Wilson, 484 F.3d 267, 273-74 (4th Cir. 2007).

SUMMARY OF ARGUMENT

The physician contracts at issue in this case were indefensible under any fair reading of the Stark Law and regulations. The whole purpose of these arrangements was for the hospital to thwart emerging competition by locking up the physicians' valuable outpatient referrals for a decade or more; the hospital told the physicians this was precisely its goal. To induce the physicians to sign up, the hospital devised a compensation plan that included a portion of the physicians' anticipated future referrals. As a result, the physicians were paid cash and benefits that far exceeded the fair market value of their work, and cost the hospital millions of dollars more than the physicians could actually bring in. For three weeks, a jury heard testimony and tape recordings and saw documentary evidence that confirmed the violation of law. The district court correctly instructed the jury as to each element of the Stark Law, including the applicable exception, hewing closely to the language of the statute and regulations. The jury returned a verdict finding that Tuomey had violated the Stark Law.

On appeal, Tuomey ignores the factual record entirely and relies upon convoluted interpretations of the law drawn from out-of-context snippets of the

agency commentary. As explained below, the Tuomey arrangements are precisely the type that Congress sought to ban through the enactment of the Stark Law, and the agency commentary is fully in accord with the government's interpretation of the law and regulations.

Tuomey also takes the position that because the government brought an action under the False Claims Act based upon the Stark Law violation, it is prohibited from recovering under the common law. However, binding precedent forecloses Tuomey's argument. Further, the False Claims Act provides a substantially different recovery from the common law theories because it is directed to the prevention of fraud in federal programs, not simply the recovery of government money paid out by mistake.

Tuomey contends that it is entitled to a "trial in equity" on the common law theories. But the government's common law theories sought damages and thus were legal claims. And because Tuomey's violation of the Stark Law was the factual predicate for both the False Claims Act count and the common law counts, the government was entitled to have that common issue decided by the jury in any event.

Tuomey's complaint about the district court's damages award lacks merit. The district court properly relied upon the unrebutted testimony of the government's expert witness for damages. In any event, Tuomey waived the right

to have the jury determine the common law damages because its counsel demanded that the damages line be removed from the verdict form.

ARGUMENT

I. The Jury's Verdict Was Proper and Amply Substantiated

The evidence at trial amply supported the jury's finding that Tuomey violated the Stark Law. The existence of an indirect compensation arrangement was established under both regulatory tests: (1) the physicians' compensation varied with the volume and value of their referrals to Tuomey because, by design, the physicians only earned money for work that simultaneously generated a referral in the form of a facility fee for the hospital, and their compensation rose in lockstep with these referrals; and (2) the compensation took into account the volume and value of the physicians' referrals by including a portion of the anticipated referral business (the "net present value of the non-compete clause"), which represented "phantom stock" in the revenues of Tuomey's outpatient surgery facility and was given as a reward for the physicians' "loyal[ty] to Tuomey in terms of referrals."

Likewise, the evidence overwhelmingly demonstrated that these arrangements could not qualify for the indirect compensation exception because the physicians' remuneration in cash and benefits took into account their referrals, far exceeded the fair market value standard and were commercially unreasonable

in the absence of referrals because they caused the hospital to "bleed money." See Govt Tr. Ex. 446; JA 1563, 1571-72.

Much of the evidence regarding the Stark Law violation was undisputed and presented through Tuomey's own agents and documents, including the self-taped conversations. Indeed, the evidence of Tuomey's Stark Law violation was so one-sided that judgment should have been granted as the government requested in its Motion for Partial Summary Judgment (District Court Docket (Dkt) 291, 327) or as the government requested at the close of the evidence under Rule 50(a). JA 814. However, the district court submitted the question to the jury, and the jury arrived at the correct result. Tuomey has not – and cannot now – challenge the sufficiency of the evidence supporting the jury's verdict on the Stark Law.

Tuomey, however, urges the Court to ignore the jury's verdict and the overwhelming evidentiary record that supports it, contending that no "financial relationship" existed between Tuomey and the physicians. Tuomey's position lacks merit.

A. The Physicians' Compensation Under the Contracts, By Design, Varied with the Volume and Value of Referrals

The evidence at trial demonstrated that Tuomey structured the physician contracts in an attempt to avoid the purview of the Stark Law. Instead of entering into these contracts directly, it set up two LLCs to employ the physicians

indirectly. Also, it structured the compensation formula to be based on a proxy for referrals, instead of on referrals themselves. In other words, Tuomey attempted to **covertly** pay the physicians for referrals, rather than do so overtly.

The Stark Law defines "financial relationship" as either an "ownership or investment interest" or a "compensation arrangement." 42 U.S.C. § 1395nn(a)(2). In the case at bar, the applicable part of the definition is the "compensation arrangement." The Stark Law defines a prohibited "compensation arrangement" very broadly:

> (A) The term "compensation arrangement" means **any** arrangement involving **any** remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C).
>
> (B) The term "remuneration" includes **any** remuneration, **directly or indirectly**, **overtly or covertly**, **in cash or in kind**.

42 U.S.C. § 1395nn(h)(1) (emphasis added). This language makes clear that Congress intended the definition of "financial relationship" to include **any** type of financial relationship in which physicians receive **any** remuneration of **any** kind from a hospital, **directly or indirectly**, **overtly or covertly**.

As demonstrated above and conceded at trial by Saccone, who designed the plans, and by Steven Rice, Tuomey's fair market value expert, the operation of the contracts themselves fulfilled the indirect compensation definition because each

and every time the physicians performed a Medicare-covered procedure under their Tuomey contract, the cash components of the physicians' salaries increased, and so did the volume or value of their Medicare referrals for the hospital. JA 305-06, 731-33. Tuomey concedes this fact in its brief. Tuomey Br. at 21. No more is required to bring these arrangements within the scope of the Stark Law.

"'Absent explicit legislative intent to the contrary,'" this Court "give[s] the words of a statute their 'plain and ordinary meaning.'" Broughman, 624 F.3d at 675 (quoting Carbon Fuel Co. v. USX Corp., 100 F.3d 1124, 1133 (4th Cir. 1996)). And it is axiomatic that any regulation must be interpreted consistently with the statute that it is implementing. Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."). Where, as here, a governing regulation is unambiguous, there also is no need to resort to agency commentary. Chase Bank USA, NA v. McCoy, 131 S. Ct. 871, 881-82 (2011) (citing Christensen v. Harris County, 529 U.S. 576 (2000)).

The Stark statute plainly covers "indirect" compensation arrangements, and the implementing regulation plainly states that such an arrangement exists if the compensation "varies with, or otherwise takes into account, the volume or value of referrals or other business generated by the referring physician." 42 C.F.R. §

411.354(c)(2)(ii). The clearest and most sensible interpretation of this regulation is that any relationship in which the physician's compensation goes up and down as his or her referrals go up and down is included in this definition. As Tuomey concedes, that is true in this case.

Applying this common-sense understanding of the words "varies with" does not necessarily mean that physician compensation that rises and falls with referrals will be prohibited in every instance. But it does mean that such arrangements fall within the purview of the Stark Law. The statutory and regulatory scheme is designed to define "financial relationships" broadly, and then to filter out acceptable relationships through analysis of the exceptions. See Kosenske, 554 F.3d at 95; Rogan, 459 F. Supp. 2d at 716. Tuomey attempts to "put the cart before the horse" by conflating the two steps of the analysis, an approach that was recently rejected by a district court considering a similar indirect compensation arrangement. United States ex rel. Singh v. Bradford Reg. Med. Center, ___ F. Supp. 2d ___, 2010 WL 4687739, at *23-26 (W.D. Pa. Nov. 10, 2010).

The relevant statutory and regulatory provisions applicable in this case were clear and unambiguous without resort to the agency commentary. But even if one goes beyond a plain reading of the statute and regulation and considers the preamble and commentary to the regulation (as Tuomey urges), Tuomey's

interpretation of the regulation still fails.[6] Contrary to Tuomey's assertions, the government does not argue, and has never argued in this case, that the physicians' personally performed services constitute referrals. However, the corresponding technical component of those services, and the resulting facility fees, **do** constitute referrals. This distinction is recognized in the preamble and comments to the regulations:

> We have concluded that when a physician initiates a designated health service and personally performs it him or herself, that action would not constitute a referral of the service to an entity under section 1877 of the Act. **However, in the context of inpatient and outpatient hospital services, there would still be a referral of any hospital service, technical component, or facility fee billed by the hospital in connection with the personally performed service.**

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[6]Contrary to Tuomey's assertions, and those of amicus American Hospital Association, the government never urged the district court to interpret the Stark Law in conflict with the preamble or commentary to the Stark regulations. The government merely objected to proposed jury instructions by Tuomey that consisted of incomplete, misleading and confusing snippets from the commentary that were not helpful to the jury. Plt. Opp. to Deft's Proposed Jury Instructions, Dkt No. 492. The trial court did not abuse its considerable discretion in deciding to omit these instructions from its charge. See, e.g., Boyle v. United States, 129 S. Ct. 2237, 2243 (2009); Lohrmann v. Pittsburgh Corning Corp., 782 F.2d 1156, 1164 (4th Cir. 1986). In any event, because the language of the applicable statute and regulations were unambiguous, there was no need to resort to the commentary.

66 Fed. Reg. 856, 941 (Jan. 4, 2001) (emphasis added).[7] Thus, the technical components for the outpatient procedures that the physicians performed under their contracts, for which Tuomey could bill a facility fee, constituted "referrals." See United States v. Campbell, 2011 U.S. Dist. LEXIS 1207, at *19-20 (D.N.J. Jan. 4, 2011).

Tuomey also contends that the rules regarding productivity bonuses exempted their financial arrangements with these physicians from Stark. This contention is wrong for several reasons. The productivity bonus rules come into play only at the **exception** stage and do not affect the question whether, as an initial matter, the financial relationship falls within the scope of the Stark Law. 69 Fed. Reg. at 16066-68. Second, such bonuses are subject to the fair market value requirement and to the requirement, absent from the Tuomey contracts, that patients, or their insurers, may elect a different location for the procedure. 69 Fed. Reg. at 16087, 16089. Third, the productivity bonus rules do not apply to base salaries. In the contracts at issue here, it was not only the "productivity" and "quality" bonuses paid to the physicians that varied with the volume or value of

[7]The same concept applies to non-Medicare services, in which the technical component or facility fee constitutes "other business generated" by the physician. See 69 Fed. Reg. at 16067.

their outpatient referrals to Tuomey; rather, the base salaries also varied with referrals.

Indeed, the GI physicians' base salaries were expressly determined by the number of outpatient procedures they performed at Tuomey. If a GI physician performed fewer than 615 procedures in a given contract year, his base salary would reduced by half the next year. JA 362, 1189. Thus, the base salaries for these physicians was directly tied to a pre-established volume of referral-generating procedures performed at Tuomey.

Similarly, the base salary scales for the ophthalmologist (Dr. Goodson) and the general surgeons were set in such a way that as the physician performed more procedures under the contracts, he captured not only a large dollar amount, but also a greater percentage, of the professional fees that Tuomey's LLC collected for his work. If Dr. Goodson performed procedures that generated $150,000 in professional collections in one year, he received a base salary of $10,000 the next year, or 6.7% of his collections. But if he performed enough procedures to generate $525,000 in professional collections, his salary the next year would rise to $75,000, or 14.3% of his collections. JA 1207, 1667. Thus, even under Tuomey's unduly narrow interpretation of the regulation, these contracts qualified as indirect compensation arrangements.

B. **The Compensation Paid to the Physicians "Took into Account the Volume and Value" of Their Referrals.**

The evidence established that Tuomey entered into these limited-purpose contracts in order to secure the physicians' outpatient surgery referrals and to share with the physicians the associated revenues the hospital received in the form of technical components. Thus, not only did the compensation "var[y] with the volume and value" of the physicians' referrals to Tuomey, but it also satisfied the alternate test for indirect compensation arrangements because it "[took] into account the volume or value of their referrals" to the hospital.

Tuomey simply refuses to acknowledge what was shown at trial, largely through Tuomey's own employees and consultants: that the compensation paid to the physicians was designed to exceed their personal collections for the work they did and included an amount that represented a portion of their anticipated future referrals as "partial consideration for the covenant not to compete." Tuomey did not merely "think about" referrals. Through Cejka, it calculated the value of those referrals precisely and included a slice of that value in the physicians' compensation. Nothing in the statute, the regulations, or the agency commentary authorizes such a blatant payment for physician referrals. To the contrary, the agency commentary makes clear:

> Arrangements under which a referring physician receives compensation tied to the volume or value of his or her referrals or

> other business generated for the DHS entity [i.e., the hospital] are the very arrangements at which section 1877 of the act is targeted.

66 Fed. Reg. at 868.

Tuomey urges the Court to consider only the express language of the agreements, and not their actual operation. Thus, merely because physicians' "personally performed" work was the stated driver of their compensation, Tuomey argues the Court should ignore the fact that Tuomey covertly incorporated a portion of the value of the physicians' anticipated referrals in their compensation. Tuomey also argues that the Court should disregard the fact that the services that generated this compensation for the physicians simultaneously, and invariably, generated valuable referrals for Tuomey.

Tuomey cites United States ex rel. Villafane v. Solinger, 543 F. Supp. 2d 678 (W.D. Ky. 2008), in support of its position that a court may not look beyond the four corners of the contract to determine whether physician compensation "takes into account" the volume or value of referrals. However, even a generous reading of that case does not support Tuomey's proposition. The Villafane court stated that where the "face of the arrangement" does not raise any question about either "fair market value" or contain a "provision allowing for increases or decreases in payment based on the number of referrals made," the court would not rule against the hospital "on the basis of intent alone." Id. at 693. However, in the

case at bar, there **was** evidence on the face of the contracts themselves both that the doctors were likely getting paid in excess of fair market value – indeed, the formula indicated that the physicians would likely be paid more than 100% of the value of their professional collections, when all their incentives and benefits were added up – and that their salary would increase or decrease, depending on the number of referrals made. These features of the Tuomey plans are the kind that should raise a concern, even under the Villafane ruling.

Other courts have not hesitated to look beyond the four corners of a contract to determine the true nature and design of an arrangement. In United States ex rel. Roberts v. Aging Care Home Health, Inc., 474 F. Supp. 2d 810, 818 (W.D. La. 2007), the court agreed that it had to "look behind the terms of the formal arrangement and focus on the actual relationship between a physician and [the health care entity paying the physician]." The court did exactly that and granted the government partial summary judgment because the compensation took into account referrals, and the doctors were not truly being paid just for the work that was described in the contract.

Another district court recently rejected virtually the same arguments Tuomey makes here and granted partial summary judgment against the hospital for violating the Stark Law. Bradford Reg. Med. Center, 2010 WL 4687739, at *18.

Like Tuomey, the hospital in Bradford became concerned when a physician group that had traditionally referred its patients to the hospital for diagnostic tests acquired a nuclear camera and began performing tests in its own office. The hospital first threatened to revoke the physicians' privileges. Then, it entered into a "sublease" for the physicians' camera that included a non-compete clause. The compensation paid to the physicians under the sublease was based upon the referral business the hospital anticipated receiving from the physicians due to the sublease. The hospital's CEO admitted that his purpose in entering the sublease agreement was to capture those referrals. Id. at *19-20.

The Bradford court then considered the Stark regulations, as well as portions of the commentary, and held that by including the value of anticipated referrals in the sublease compensation – just as Tuomey did here with the outpatient compensation – the hospital had taken into account the volume and value of the physician's referrals, thereby creating an indirect compensation arrangement. Id. The court went on to find that the fair market value standard was not met because – again, just as here – the compensation had been "determined in [a] manner that took into account the volume and value of anticipated or actual referrals" from the physicians to the hospital, and thus the indirect compensation exception did not apply. 42 C.F.R. 411.351; Bradford,

2010 WL 4687739, at *30. The Bradford decision is correct, and this Court should follow the same course here.

Tuomey's insistence that this Court ignore the actual functioning of the arrangements has no basis in law or logic. Indeed, Tuomey's interpretation, if adopted, would create a loophole to the Stark prohibition that could devour its very basis. With a wink and a nod – much like this case – providers could easily evade a standard that prohibited only compensation based explicitly on the value or volume of referrals. That outcome would defeat Congress' intent to broadly capture within Stark's purview all compensation schemes between hospitals and referring physicians that involve any type of remuneration, even if paid "indirectly" or "covertly." 42 U.S.C. § 1395nn(h)(1)(B); 42 C.F.R. § 411.351.

C. The Agency Commentary Does Not Help Tuomey

Tuomey cites two sections of the commentary that it contends stand for the proposition that a mandatory referral requirement in a hospital-physician contract does not violate the Stark Law. Tuomey Br. at 27-28. One need read no further than the quoted sections, however, to see that Tuomey misinterprets the commentary.

The agency said in a comment quoted by Tuomey that it does not "consider the volume or value standard to be implicated by **otherwise acceptable**

compensation arrangements for physician services solely because the arrangement requires a physician to refer to a particular provider as a condition of payment." 66 Fed. Reg. at 877. Tuomey omits the key qualification set forth in the same comment that for an arrangement to be "otherwise acceptable," it must be "consistent with fair market value for the services performed (that is, the payment does not take into account the volume or value of the anticipated or required referrals) and otherwise compl[y] with the requirements of the applicable exception. . . ." Id. Thus, this comment confirms that the Tuomey arrangements, which failed the fair market value and commercial reasonableness requirements of the indirect compensation exception, were not "otherwise acceptable."

Tuomey also mischaracterizes the comments regarding exclusivity provisions. The comment Tuomey cites specifically addressed exclusive arrangements with hospital-based physicians (such as radiologists, anesthesiologists, pathologists and emergency room physicians), who typically do not refer business for a hospital like the surgeons in this case did, as Cox acknowledged at one of the recruitment meetings when he told the surgeons that radiologists and anesthesiologists "don't create the volume. Y'all create the volume." JA 1283. Moreover, the comment notes (and Tuomey's citation omits) the critical restrictions that "[i]f the payments reflect or take into account non-personally performed services, they may raise concerns under the statute and

would merit a case-by-case determination, regardless of the apparent fixed payment," and any payments also would be subject to the fair market value requirement. 69 Fed. Reg. at 16088.

Additionally, Tuomey's argument ignores the commentary's warning about non-compete clauses in combination with exclusive referral arrangements, as in the contracts at issue here: "In other words, a covenant not to compete might prevent a physician from setting up a private practice or offering services that compete with the entity that purchased his or her practice. **If an agreement also included the requirement that the physician refer business to the purchaser, the agreement would be suspect under the anti-kickback statute."** 66 Fed. Reg. at 879 (emphasis added); 69 Fed. Reg. at 16069-70 ("As we cautioned in Phase I, mandatory referral arrangements could still implicate the anti-kickback statute depending on the facts and circumstances."). Compliance with the anti-kickback statute, 42 U.S.C. § 1320a-7b, is required for an arrangement to meet the indirect compensation exception, 42 C.F.R. § 411.357(p)(3), and, of course, is mandatory in any event.

For the same reasons, United States ex rel. Obert-Hong v. Advocate Health Care, 211 F. Supp. 2d 1045 (N.D. Ill. 2002), is inapposite. Obert-Hong dealt with physician compensation arrangements where – unlike the Tuomey arrangements –

the physicians did not earn more than their personal collections, and where there was no other basis to presume that the physicians were being paid for actual or anticipated referrals. Indeed, the court in Obert-Hong specifically noted that the fair market price of a physician practice must **not** include the value of anticipated referrals in order to comply with the anti-kickback statute, and that any value paid in excess of fair market value must be presumed to be an illegal inducement for referrals. Id. at 1049 nn.2 & 3. Further, the court dismissed the complaint on Rule 9(b) grounds because there was no basis to believe that the physicians' salaries reflected the volume or value of their referrals. Here, of course, as in the more relevant Bradford case, there is abundant evidence that the physicians were paid above-fair market compensation that was inflated to account for their anticipated referrals to the hospital.

As demonstrated here, the commentary – fairly read – does not help Tuomey. The agency has repeatedly made clear that the technical components and facility fees associated with outpatient procedures are referrals, and that physician compensation must be fair market value and commercially reasonable in the absence of referrals. The trial record established that the Tuomey arrangements failed to meet these requirements.

II. The Jury's Finding Required the District Court to Enter Judgment on the Common Law Theories as a Matter of Law

The Stark Law makes clear that Medicare will not pay for any claims submitted in violation of its provisions, and any reimbursements received for claims that violate the Stark Law must be refunded. 42 U.S.C. § 1395nn(a)(1), (g)(1); 42 C.F.R. § 411.353(d). Thus, under the statute and regulations, once the jury concluded that Tuomey had violated the Stark Law, Tuomey was obligated to repay all the improper reimbursements it had received. The government sought recovery of these amounts under theories of payment by mistake and unjust enrichment. JA 42, 72-74. Tuomey contends that it was entitled to a "trial in equity" after the jury returned its verdict. But the only issue relevant to the common law claims that was not resolved by the jury verdict was the amount of the government's damages for the Stark Law violation. Because the factual record was complete on that question, the district court properly determined the government's damages and entered judgment in the government's favor under its common law theories.

A. <u>The Government Was Entitled to Judgment on Its Payment by Mistake Count</u>

The Supreme Court has long recognized that "[t]he Government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid. 'No statute is necessary to authorize the United

States to sue in such a case. The right to sue is independent of statute. . . .'" United States v. Wurts, 303 U.S. 414, 415-16 (1938) (footnote omitted) (quoting United States v. Bank of the Metropolis, 15 Pet. 377, 401 (1841)). Further, "the Government's right to recover funds, from a person who received them by mistake and without right, is not barred unless Congress has 'clearly manifested its intention' to raise a statutory barrier." Wurts, 303 U.S. at 416 (citation omitted).

The obligation to refund to the Treasury money paid in error or without legal authorization will not be excused, even if the party who erroneously received it acted in "good faith" and could suffer "hardship" if required to return the funds. See, e.g., Weiss v. United States, 296 F.2d 648, 649-50 (5th Cir. 1961) (collecting cases). The government retains the right to sue for recovery of moneys paid by mistake "even if the payment resulted from the carelessness of a government official." Mt. Vernon Coop. Bank v. Gleason, 367 F.2d 289, 291 (1st Cir. 1966).

Significantly for this case, "where the disbursement of public funds is concerned, the government is not under the obligation of showing either that the recipient was unjustly enriched or that the balance of equities otherwise lies in its favor." Id. This principle has been widely recognized for many years. See United States v. Burchard, 125 U.S. 176, 181 (1888) ("This is a case where the disbursing officers, supposing that a retired officer of the navy was entitled to more than it turns out the law allowed, have overpaid him. Certainly, under such

circumstances, the mistake may be corrected."); United States v. Lahey Clinic Hosp., Inc., 399 F.3d 1, 15–16, n.16 (1st Cir. 2005) (in case involving Medicare overpayments, discussing United States' "longstanding" right to recover monies wrongfully paid out of the Treasury); United States v. Mead, 426 F.2d 118, 124 (9th Cir. 1970) (holding, where government failed to prove defendant acted "knowingly" under FCA, "The government's alternative theory of recovery is under the common law doctrine of payment by mistake. This remedy is available to the United States and is independent of statute."); United States v. Borin, 209 F.2d 145, 148 (5th Cir. 1954) ("[W]e agree that payments made on invalid claims can be recaptured, and that the invalidity of the claim may be established in the action brought to recapture such payments."); see also Stone v. United States, 286 F.2d 56, 58–59 (8th Cir. 1961) ("Where monies are erroneously paid by agents of the United States, whether the error be one of fact or of law, the Government may always recover the money improperly paid."); United States v. Indep. Sch. Dist. No. 1 of Ok-Mulgee County, Okl., 209 F.2d 578, 580-81 (10th Cir. 1954) (holding that federal, not state law, governs action by United States to recover erroneously paid funds, and "[w]hether . . . the asserted remedy be for money had and received or restitution for unjust enrichment, the right to recover under controlling federal law is plain"). Indeed, even where the Fifth Circuit described the government's changed enforcement policy regarding defaulted student loans as "schizophrenic"

and "less than admirable," it nevertheless followed Wurts and upheld the lower court's ruling granting recovery under the doctrine of payment by mistake. LTV Educ. Sys., Inc. v. Bell, 862 F.2d 1168, 1175 (5th Cir. 1989).

The Stark Law could not be clearer in prohibiting a hospital from submitting claims to Medicare for services referred by doctors with whom the hospital has an improper financial relationship. The jury found that Tuomey's contracts with the physicians violated the Stark Law. That violation rendered Tuomey ineligible to receive any reimbursement from Medicare for services referred by the physicians – whether those services were for inpatient or outpatient procedures, and regardless of whether the services were medically necessary or actually performed. As explained in Rogan:

> Nor do we think it important that most of the patients for which claims were submitted received some medical care – perhaps all the care reflected in the claim forms. . . . [The defendant hospital] did not furnish any medical service to the United States. The government offers a subsidy (from the patients' perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due. Thus the entire amount that [the defendant hospital] received on these 1,812 claims must be paid back.

517 F.3d at 453.

As the district court correctly recognized, the Supreme Court's decision in Wurts controls this case. The government is plainly entitled, where a jury has heard evidence for three weeks and found a violation of the Stark Law, to recover

for the Medicare Trust Fund all the moneys "wrongfully, erroneously, or illegally paid" to Tuomey.

B. The Government Was Also Entitled to Judgment on Its Unjust Enrichment Count

While the district court's judgment can be affirmed on the basis of the Wurts principle alone, it should also be affirmed based on the government's alternative claim of unjust enrichment. This Court has identified the elements of an unjust enrichment claim as follows: (1) the plaintiff had a reasonable expectation of payment, (2) the defendant should reasonably have expected to pay, **or** (3) "society's reasonable expectations of person and property would be defeated by nonpayment." Provident Life & Accident Ins. Co. v. Waller, 906 F.2d 985, 993-94 (4th Cir. 1990); accord Rogan, 459 F. Supp. 2d at 728. Here, the government's and society's expectations are fully aligned because the Stark Law specifically prohibits the submission to, and payment by, Medicare of claims for hospital services arising from improper physician referrals. The purpose of the Stark Law is to preserve the integrity of the Medicare program by eliminating financial incentives to physicians that may override medical judgments made in the patient's best interest. Congress intended to protect both the Treasury and the millions of beneficiaries who rely upon the Medicare program from the pernicious influence of money upon medical decisionmaking.

Aside from the clear statutory prohibition on the submission and payment of claims arising from improper referrals, the Stark regulations, as noted above, specifically require the prompt refund to Medicare of moneys paid out for all such ineligible claims. 42 C.F.R. § 411.353(d). Johnson, Tuomey's CFO, who signed the hospital's Medicare Provider Agreement and its annual cost reports, understood that all claims for payment submitted by the hospital had to comply with the Stark Law. JA 291-98. Hewson stated at one of the recorded meetings that a consequence of violating the Stark Law would be the hospital's obligation to return the payments received to Medicare. Govt Tr. Ex. 426; JA 1714, 1763-65. Accordingly, not only **should** the hospital have reasonably expected to repay Medicare for the improper reimbursements it received, but it actually **did** expect to repay this money. The district court properly required Tuomey to fulfill this obligation.

C. The Government's FCA Claim Did Not Displace Its Right to Proceed Under the Common Law

The addition of statutory remedies under the FCA to the government's arsenal of legal theories allowing it to recover wrongfully-paid taxpayer dollars did not, of course, eliminate the government's pre-existing right to seek such recoveries under the common law or equitable theories, so long as there is only one recovery. See United States v. Moffitt, Zwerling & Kemler, P.C., 83 F.3d

660, 667 (4th Cir. 1996) ("We start from the premise that federal statutes do not, by implication, abrogate the government's right to bring common law suits."); United States v. Silliman, 167 F.2d 607, 610-11 (3d Cir. 1948) ("The defendant offers us no reason, and we see none, for concluding that because [the FCA statute] enlarged the liability of the defendant, it abrogated the right which the sovereign otherwise has to pursue common law remedies against tort-feasors in its own courts."); Pooler v. United States, 127 F. 519, 520 (1st Cir. 1904) ("The right in this case . . . was not created by Congress, but existed at common law; and it is plain that whatever remedies are afforded to the United States by the provisions of the Revised Statutes which the plaintiff in error cites are cumulative, so that it is at the option of the United States which to elect."); see also Lahey, 399 F.3d at 8 (where government sought recovery of Medicare overpayments through payment by mistake and unjust enrichment theories, holding that administrative procedures created under Medicare Act did not "displace[] the underlying common law causes of action relied on by the government in this case to recover payments wrongfully made out of the public fisc.").

Where the government has not prevailed upon its statutory claim, it may obtain recovery under applicable common law theories. E.g., United States v. Applied Pharmacy Consultants, Inc., 182 F.3d 603 (8th Cir. 1999) (where jury found no liability under FCA, district court appropriately awarded relief to

government on its unjust enrichment claim); Mead, 426 F.2d 118 (where court found insufficient evidence to support liability under FCA, government was permitted to recover under its alternate theory of payment by mistake); Borin, 209 F.2d 145 (where statute of limitations for FCA claim had expired, government was permitted to pursue restitution of payments made for invalid claims under terms of Emergency Price Control Act and under theory of common law fraud). The Fifth Circuit observed in Borin, 209 F.2d at 147, "[t]he United States had, of course, a right to plead as many separate claims as it possessed, regardless of consistency, . . . and the court should grant the relief to which it is entitled even though not demanded in its pleadings. . . ." Citing Mead, Borin and Silliman, among other cases, this Court explained that

> [United States v. Texas, 507 U.S. 529 (1993),] is not alone in holding that common law actions are available to the government to supplement those remedies found in federal statutes, as long as the statute does not expressly abrogate those rights. This principle has been affirmed and re-affirmed many times.

Moffitt, 83 F.3d at 667-68 (collecting cases). Nothing in the FCA abrogates the government's right to pursue common law claims to recover improperly paid public monies.

In support of its claim that the FCA count ousted the government's right to proceed on it common law theories, Tuomey identifies a handful of district court

cases with little or no analysis of the subject. Tuomey Br. at 30-31.[8] By far the dominant view, expressed in numerous cases, including the circuit court rulings cited above, is that the government has the right to pursue common law theories alongside a claim under the FCA all the way to judgment. E.g., Roberts, 474 F. Supp. 2d 810 (in FCA case, awarding government summary judgment on its payment by mistake and unjust enrichment theories based on Stark Law violations, and holding that FCA claim, which required scienter showing not required by alternative common law claims, was not an adequate remedy); United States ex rel. Roberts v. Aging Care Home Health, Inc., 2008 WL 2945946 (W.D. La. July 25, 2008) (granting summary judgment to government under FCA, payment by mistake and unjust enrichment claims, but limiting damages to those awarded

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[8]The decision to dismiss the government's payment by mistake and unjust enrichment claims in United States v. United Technologies Corp., 51 F. Supp. 2d 167 (D. Conn. 1999), followed a full bench trial on the merits of all the government's claims; the district court in that case ruled that the government could recover under its breach of contract theory and therefore did not need to avail itself of the other causes of action. Id. at 200. The two Northern District of Illinois cases cited by Tuomey similarly involved contracts, in contrast to the present case, which does not. Compare United States v. Job Resources for the Disabled, 2000 WL 562444 (N.D. Ill. May 9, 2000); United States v. Hydroaire, Inc., 1995 WL 86733 (N.D. Ill. Feb. 27, 1995), with Rogan, 459 F. Supp. 2d at 727-28, and United States ex rel. Klaczak v. Consolidated Med. Transp., Inc., 2002 WL 31010850, at *5 (N.D. Ill. Sept. 9, 2002) (in case alleging kickbacks and violations of FCA, refusing to dismiss government's payment by mistake and unjust enrichment claims, notwithstanding "adequacy of legal remedy" argument by defendant, because rules allow pleading in the alternative).

under FCA to avoid double recovery); United States v. Stevens, 605 F. Supp. 2d 863, 870 (W.D. Ky. 2008) (rejecting "adequate remedy at law" argument and holding that because "the FCA claim against [defendant] has not been fully litigated, it would be premature to dismiss the alternative unjust enrichment claim"); Rogan, 459 F. Supp. 2d at 727-28 (after bench trial, finding defendant liable under FCA, payment by mistake and unjust enrichment, but setting aside relief under common law claims to avoid double redress for same wrong); United States ex rel. Purcell v. MWI Corp., 254 F. Supp. 2d 69, 78-79 (D.D.C. 2003) (in FCA case, refusing to dismiss unjust enrichment and payment by mistake claims, notwithstanding "adequate remedy at law" argument, because parties are permitted to plead alternate theories of recovery); United States v. United Techs. Corp., 255 F. Supp. 2d 779 (S.D. Ohio 2003) (in FCA case based upon government contract, rejecting argument on summary judgment that government's [equitable claims] should be dismissed notwithstanding "sufficient remedy at law" concept); United States ex rel. Zissler v. Regents of Univ. of Minn., 992 F. Supp. 1097, 1113 (D. Minn. 1998) (in FCA case alleging grant fraud, defendant failed to show that government's remedy at law – including damages for payment by mistake and unjust enrichment – was adequate, and government was permitted to proceed with disgorgement claim).

The "pursuit of consistent remedies, even to final adjudication" is permitted, "so long as the plaintiff receives but one satisfaction." Pennsylvania Nat'l Mut. Cas. Ins. Co. v. Pine Bluff, 354 F.3d 945, 950-51 (8th Cir. 2004); see generally Alexander v. Gardner-Denver Co., 415 U.S. 36, 49-50, 51 n.14 (1974) (observing that election of remedies doctrine does not prevent a plaintiff from prevailing on duplicative claims, but in cases where that happens, "judicial relief can be structured to avoid such windfall gains"). If on re-trial the government prevails on its FCA claim, then any payments Tuomey has made in satisfaction of the common law judgment at issue here will be credited against the FCA recovery, as provided by United States v. Bornstein, 423 U.S. 303, 314-17 (1976), thus avoiding double redress. See JA 137, 1030, 1121.

Notwithstanding the overwhelming weight of authority to the contrary, Tuomey maintains that the government was precluded from pursuing its payment by mistake and unjust enrichment theories in the same action as its FCA claim. As demonstrated, this is simply untrue. Further, it must be stressed that an FCA recovery is not merely a substitute for the common law rights the United States asserts here. The theories of payment by mistake and unjust enrichment have no scienter element. By contrast, the FCA requires a showing of knowledge, and that is precisely why there is a higher level of recovery (treble damages and penalties) under the FCA. 31 U.S.C. § 3729(a). The common law theories redress different

and lesser misconduct that does not involve knowing fraud. The FCA does not displace the government's well-established ability to sue for simple recovery of improperly paid public money.

III. The District Court Properly Submitted the Stark Law Question to the Jury

Tuomey complains about the procedure followed by the district court in rendering its judgment on the common law claims based upon the jury's verdict. But those complaints are empty. Tuomey consented to the Stark Law issue being submitted to the jury and included on the verdict form. Tuomey also consented to the instructions that were given on the disputed elements of the Stark Law, including the indirect compensation definition and exception. The trial court acted well within its broad discretion in formulating the verdict form and interrogatories. See Cunningham v. M-G Transp. Svcs., Inc., 527 F.2d 760, 762 n.1 (4th Cir.1975) ("The drafting of special interrogatories is largely a matter of common sense and local practice. . . . They may be as detailed as counsel and the district court wish to make them, and the particular verbiage used is of no great consequence so long as the questions were framed so that the jury knows what it is deciding."); accord Klein v. Sears Roebuck & Co., 773 F.2d 1421, 1426-27 (4th Cir. 1985); Tights, Inc. v. Acme-McCrary Corp., 541 F.2d 1047, 1060 (4th Cir. 1976).

There is, of course, no question that the FCA count was a jury-triable matter in its entirety, including the essential factual question whether Tuomey had violated the Stark Law. For this reason, the government was indisputably entitled to a jury trial upon the Stark Law question, and the jury's resolution of that question – its verdict – is binding under the Seventh Amendment.

Tuomey proceeds from the erroneous presumption that the government's theories of payment by mistake and unjust enrichment are equitable, rather than legal. The Supreme Court has held that monetary relief is generally "legal" in character, and of course, the government sought only monetary relief in this case. See Granfinanciera, S.A. v. Nordberg, 492 U.S. 33, 47-48 (1989) ("Where an action is simply for the recovery . . . of a money judgment, the action is one at law.") (internal citations omitted).[9] In particular, the payment by mistake cause of action has a more "legal" than "equitable" character when the United States is the plaintiff because, under Wurts, once the government has established that the defendant wrongfully received public money, the court is obligated to require the defendant to return that money to the Treasury. The Stark Law's mandatory refund obligation confirms the legal nature of the government's common law

[9]During the trial, government counsel did refer to the common law counts as equitable. However, having been afforded the opportunity to research and brief the question, government counsel discovered the Granfinanciera decision and brought it to the district court's attention. JA 1097-98.

claim in this case. As explained in Granfinanciera, where, as here, a plaintiff is entitled to the return of funds, and the court lacks discretion to refuse to enter an award for less than the amount sought, "any distinction that might exist between 'damages' and monetary relief under a different label is purely semantic, with no relevance to the adjudication of [the plaintiff's] Seventh Amendment claim." 492 U.S. at 49 n.7; see also In re Stansbury Poplar Place, 13 F.3d 122, 124-25 (4th Cir. 1993) (following Granfinanciera and holding that request for equitable accounting did not deprive defendants of constitutional right to jury trial on fraudulent conveyance claim).

Even if the government's payment by mistake and unjust enrichment theories were deemed "equitable", the district court still followed proper procedure in submitting all the contested issues of fact – including the Stark Law question – to the jury. When a case involves multiple causes of action, some of which are equitable and others legal, the Seventh Amendment requires that the legal claims be tried to a jury. Dairy Queen, Inc. v. Wood, 369 U.S. 469, 471-72 (1962). The jury's determination of common facts precludes an alternate finding by the court on the remaining elements, if any, of the equitable claims. Ross v. Bernhard, 396 U.S. 531, 537-38 (1970); Beacon Theatres, Inc. v. Westover, 359 U.S. 500, 508 (1959); Wade v. Orange County, 844 F.2d 951, 954 (2d Cir. 1988).

In Dairy Queen, the Court held that it was error for the district judge to refuse the plaintiff's demand for a jury trial upon its breach of contract claim, where the plaintiff sought, among other forms of relief, an "accounting." The Court held that since the issues involved in the breach of contract claim "are common with those upon which respondents' claim to equitable relief is based, the legal claims involved in the action must be determined prior to any final court determination of respondents' equitable claims." 369 U.S. at 479.

In order to properly safeguard a party's constitutional right to a jury trial, the proper procedure for a court entertaining related legal and equitable claims "requires submission of the case first to the jury to resolve liability and all legal damages. Thereafter, the court conducts a trial in equity to resolve all issues of equitable relief." Duke v. Uniroyal, Inc., 928 F.2d 1413, 1422 (4th Cir. 1991). However, the facts found by the jury will control the court's determination of the equitable claim. Ross, 396 U.S. at 537-38. The district court followed the order of procedure prescribed in Uniroyal precisely. The jury's verdict is, accordingly, valid and binding. U.S. Const. Amend. VII.

IV. The District Court's Damages Award Was Proper

At trial, the government introduced definitive – and unrebutted – evidence showing that, because of its Stark Law violation, Tuomey had improperly obtained $44,888,651 in Medicare reimbursements. JA 1674. This figure was determined

by Ruben Steck, whom the district court properly accepted as an expert in the field of Medicare and Medicaid claims analysis.

The relevant claims records were authenticated at trial by Stanford University Professor Thomas MaCurdy, whose company – Acumen – serves as a contractor to the Center for Medicare and Medicaid Services (CMS), the HHS component charged with administering the Medicare and Medicaid programs. Drawing on original CMS claim repositories, Acumen extracted and verified the electronically-stored records of Tuomey's claims to Medicare for inpatient and outpatient services provided between January 1, 2003 and June 30, 2009, as well as all the Medicare claims submitted by each of the physicians for services provided during those same dates. Acumen then provided the encrypted records to Steck. JA 506-18.

Steck, who has reviewed hundreds of millions of Medicare and Medicaid claims records in his 20-year career, used proprietary and non-proprietary software to analyze the CMS records. JA 532-34. Notwithstanding Steck's computer science education and highly specialized expertise in the analysis of Medicare and Medicaid claims records, Tuomey takes issue with the district court's qualification of Steck as an expert in this field. The trial judge probed Steck on his qualifications and was satisfied with his expertise. JA 529-48. The district court's qualification of Steck as an expert in the field of Medicare and Medicaid claims

analysis was well-founded and certainly not an abuse of discretion. Even if Steck had not been qualified as an expert, his testimony still would have been admissible under Federal Rule of Evidence 1006 as summary testimony. The government proffered his testimony under both FRE 702 and 1006. JA 540. In any event, Tuomey cannot demonstrate that the trial judge abused his discretion permitting Steck to testify about his analysis of Tuomey's Medicare claims involving the subject physicians. See, e.g., United States v. Wilson, 484 F.3d 267, 273-74 (4th Cir. 2007).

After analyzing the records, Steck produced charts showing the total number and value of the claims submitted by Tuomey where one of the subject physicians was identified as either the "attending" or "operating" physician for a service provided between the beginning date of his or her contract and June 30, 2009. JA 1674, 1675. Steck carefully explained how he verified the records he received from Acumen. He then walked through the information contained in each of the relevant fields of the records he analyzed, identifying the meaning of each field in the data set. JA 534-36, 549-66. He also testified that he selected the "attending" and "operating" physician fields based upon definitions for those fields provided by ResDAC, a data source for researchers hosted by the University of Minnesota and funded by CMS. JA 561-64. These two fields closely

correspond to the Stark Law's definition of "referring physician." The Stark Law and regulations define a "referral; referring physician" as:

- the request by a physician for an item or service, including a request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of), that other physician, or

- a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed by the referring physician.

See 42 U.S.C. § 1395nn(h)(5); 42 C.F.R. § 411.351. The "attending" physician is defined as "the physician who would normally be expected to certify and recertify the medical necessity of the services and/or who has primary responsibility for the beneficiary's medical care and treatment." The "operating" physician is "the physician who performed the principal procedure." JA 563-64. These two categories fall well within the broader statutory and regulatory definitions of "referring physician," as the district court in Rogan also concluded. Rogan, 459 F. Supp. 2d at 713 & n.11 (citing numerous official sources identifying the "attending" and "operating" physician fields as the "referring physicians" for purposes of the Stark Law).

Tuomey was required by law to identify the "referring physician," within the meaning of the Stark Law, on every claim it submitted for outpatient facility fees. 42 U.S.C. § 1395*l*(q)(1). There is no limitation on the number of physicians who could be designated a "referring physician" for purposes of the Stark Law, but there must be at least one listed on each claim form.[10] At trial, Tuomey failed to demonstrate that some field other than the "attending" and "operating" fields identified the "referring physicians" on its Medicare claims. Thus, Steck's testimony in this regard stood unrebutted, as the district court recognized in its oral ruling on damages. JA 1119-22.

Steck determined that Tuomey submitted 25,973 claims for services where one of the physicians was shown as the "attending" or "operating" physician, and where the service was provided between the start date of that physician's Tuomey contract and June 30, 2009. JA 1675. Steck concluded that Medicare paid Tuomey $44,888,651 for these claims. JA 1674. Tuomey offered no testimony or other evidence to contradict these conclusions.

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[10]It is entirely possible for multiple physicians to be "referring physicians," within the meaning of the Stark Law. The "attending" physician could be the patient's primary care physician, who refers the patient to an "operating physician" for a procedure, but oversees the patient's plan of care and certifies the medical necessity of the treatment. The "operating" physician would make a "referral" to the hospital by arranging for the procedure to take place at the hospital and by ordering any tests there in connection with the procedure.

Contrary to Tuomey's arguments, Steck was not required to review the medical records underlying each claim because the Stark Law is not concerned with the actual diagnosis and treatment provided; other portions of the Medicare law and regulations address those issues. The Stark Law is concerned with whether the referral itself is proper or improper. If the referral is improper, then Medicare will not pay the claim, even if it might otherwise be allowable. 42 U.S.C. § 1395nn(a)(1)(A); Rogan, 517 F.3d at 453.

As noted above, Tuomey's counsel insisted that the court, rather than the jury, decide the amount of the government's damages for the Stark Law violation. The government acceded to this request. JA 965-66, 1001-05. The district court's determination of damages is thus a factual finding subject to review only for clear error. See United States ex rel. Maddux Supply Co. v. St. Paul Fire & Marine Ins. Co., 86 F.3d 332, 334 (4th Cir. 1996). On this unrebutted record, the district court properly concluded that Tuomey was liable to refund the entire $44,888,651, plus accrued interest, to the Medicare Trust Fund. See JA 119-26 (computation of prejudgment interest due). Tuomey cannot demonstrate error – much less clear error – by the district court, and the damages award therefore should be affirmed.

CONCLUSION

For all the foregoing reasons, the district court's judgment in this case should be affirmed.

Respectfully submitted,

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March 7, 2011

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REQUEST FOR ORAL ARGUMENT

The United States of America requests oral argument.

Certificate of Service

I hereby certify that on this 7th day of March, 2011, I caused the required number of copies of the foregoing Brief of Appellee the United States of America to be filed with the United States Court of Appeals for the Fourth Circuit and served upon the following counsel of record for the Appellant and the Relator by by overnight commercial carrier (Federal Express):

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I also caused the Brief of Appellee to be filed with the Court and served upon the below-listed counsel for the Appellant and the Relator through the Court's electronic case filing system.

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UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

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