No. 13-2219

IN THE

United States Court of Appeals for the Fourth Circuit

UNITED STATES EX REL. MICHAEL K. DRAKEFORD, M.D.,

Plaintiff-Appellee,

v.

TUOMEY HEALTHCARE SYSTEM, INC.,

Defendant-Appellant.

On Appeal from the United States District Court
for the District of South Carolina

BRIEF OF AMICI CURIAE AMERICAN HOSPITAL ASSOCIATION AND SOUTH CAROLINA HOSPITAL ASSOCIATION IN SUPPORT OF DEFENDANT-APPELLANT

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Pursuant to Fed. R. App. P. 26.1 and Local Rule 26.1, amicus curiae the American Hospital Association ("AHA") makes the following disclosures:

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5. Does this case arise out of a bankruptcy proceeding? No.

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STATEMENT OF INTEREST OF AMICI CURIAE

The American Hospital Association and South Carolina Hospital Association respectfully submit this brief as amici curiae in support of Tuomey Healthcare System, Inc. ("Tuomey").[1] Tuomey has consented to the filing of this brief, and the Government and Relator do not oppose it.

[1] Pursuant to Fed. R. App. P. 29(c)(5), amici state that no party or party's counsel authored this brief in whole or in part; no party or party's counsel made a

The American Hospital Association ("AHA") represents more than 5,000 hospitals, health care systems, and other health care organizations, plus 42,000 individual members. AHA members are committed to improving the health of communities they serve and to helping ensure that care is available to and affordable for all Americans. The AHA educates its members on health care issues and advocates to ensure that their perspectives are considered in formulating health policy.

The South Carolina Hospital Association ("SCHA") is a private, not-for-profit organization made up of some 100 member hospitals and health systems and about 900 personal members associated with the institutional members. SCHA was created in 1921 to serve as the collective voice of the state's hospital community.

AHA and SCHA are particularly interested in this case because of its implications for an issue of major importance to their members: the extent to which hospitals can rely on legal advice—obtained in good faith and based on full information—to ensure that their business transactions comply with the many complicated and challenging regulatory regimes governing the delivery of health care. Many hospital boards (like Tuomey's in this case) are composed entirely of

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monetary contribution to fund the preparation or submission of this brief; and no person, other than AHA, SCHA, and their members or counsel, made a monetary contribution to fund the preparation or submission of this brief.

non-lawyers. Instead, hospital boards often include community volunteers, physicians, accountants, business leaders, and others who have no legal training or expertise in health care law. These individuals depend on the hospital's counsel to provide advice about the hospital's compliance with the law.

The Ethics in Patient Referrals Act, more commonly known as the Stark Law, is one of the health care compliance regimes where the advice of counsel is most crucial. At its most general level, the Stark Law provides that if a hospital has a "financial relationship" with a physician, a referral prohibition applies to the physician and a billing prohibition applies to the hospital, unless the hospital-physician relationship satisfies an exception. See, e.g., 66 Fed. Reg. 856, 864 (Jan. 4, 2001) (a "financial relationship" is "the factual predicate for triggering" the Stark Law's prohibitions). While that may sound straightforward, the combination of the statute, the multiple phases of implementing regulations, and the voluminous agency guidance regarding the meaning of the term "financial relationship" and the scope of the law's exceptions is anything but.

Hospitals and their boards devote significant resources to understanding their obligations under, and complying with, the Stark Law. Because the community members and doctors who sit on hospital boards are frequently not health care lawyers, hospitals depend on lawyers to guide them through the statute and the complicated set of prohibitions and exceptions in its implementing

regulations. When a hospital provides its lawyers with full and accurate information and then relies in good faith on those lawyers' advice, such good faith reliance is a strong indication that a hospital intends to follow the law. That intent is clear even if the government disagrees at some later date with the substance of the legal advice that the hospital obtained.

This case involves a judgment against Tuomey for nearly a quarter of a billion dollars based on various physician contracts that Tuomey's attorneys told the hospital were compliant with the Stark Law. Permitting hospitals to be penalized in this draconian fashion for obtaining and following the advice of legal professionals will jeopardize the ability of hospitals to meet the health care needs of their communities, especially in rural, medically underserved locations. It would also leave hospitals in an untenable catch-22: Without expert advice hospitals cannot ensure that their transactions comply with the Stark Law, but even if they obtain and rely on such advice they are still in jeopardy. AHA and SCHA are thus greatly interested in the advice-of-counsel issue at the core of this case.

SUMMARY OF ARGUMENT

Faced with a complex and ever-changing set of legal obligations, hospitals regularly seek out and rely on legal counsel to help them meet their obligations under complex legal regulatory regimes like the Stark Law. Structuring the relationship between hospitals and physicians requires case-by-case analysis under

the Stark Law's byzantine requirements, and hospitals need help from lawyers to do this analysis.

To be liable under the False Claims Act, a person or entity must "knowingly" engage in the prohibited conduct. See 31 U.S.C. § 3729(a)(1). A hospital that provides its lawyers with full and accurate information and relies on their advice is making every effort to comply with the law, not to violate it. The Court should hold that when a hospital relies in good faith on its qualified counsel's determination that a particular transaction is legally permissible under the Stark Law that is a strong indication that the hospital did not knowingly violate the law.

ARGUMENT

I. Hospitals Routinely Rely On Legal Advice To Achieve Compliance With The Stark Law.

The Stark Law is part of a broader Medicare statutory regime that this Court has numbered "among the most completely impenetrable texts within human experience." Rehabilitation Ass'n of Va., Inc. v. Kozlowski, 42 F.3d 1444, 1450 (4th Cir. 1994). The Stark Law itself has been described as " 'confusing,' 'complicated,' 'over-reaching, too complex, and intrusive;' . . . ambiguous; 'arcane'; and 'very vague . . . '." Steven D. Wales, The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals, 27 Law & Psychol. Rev. 1, 22 (2003) (footnotes omitted). And the already confusing statute has only been made more complex by the Centers for Medicare and

Medicaid Services' issuance of extensive and comprehensive regulations in three phases. See 66 Fed. Reg. 856-965 (Jan. 4, 2001); 69 Fed. Reg. 16,054-146 (Mar. 26, 2004); 72 Fed. Reg. 51,012-99 (Sept. 5, 2007).

The evolving regulations have rendered compliance with the law "a moving target." Wales, The Stark Law, 27 Law & Psych. Rev. at 21. And the resulting regulatory regime, which is comprised of "numerous volumes of complex rules, regulations and exceptions," Patrick A. Sutton, The Stark Law in Retrospect, 20 Annals of Health L. 15, 15 (2011), has transformed the relationship between hospitals and physicians. The law, moreover, "does not treat violators kindly." Jo-Ellyn Sakowitz Klein, The Stark Laws: Conquering Physician Conflicts of Interest?, 87 Geo. L.J. 599, 503 (1998).

Faced with such impenetrable and thorny legal obligations, achieving full compliance with the Stark Law can be a "troublesome and elusive goal." United States ex rel. Villafane v. Solinger, 543 F. Supp. 2d 678, 687 n.8 (W.D. Ky. 2008) (internal quotation marks and citation omitted). Indeed, hospitals and physicians acting "with the best of intentions and efforts" often struggle to understand what the law requires of them. Wales, The Stark Law, 27 Law & Psychol. Rev. at 22 (quoting Molly Tschida, Stark Raving Mad: Beaten Down by Ambiguous Self-Referral Laws, Providers Now Face the Prospect of Harsh Penalties, Mod. Physician, May 1, 1999, at 3). And despite these best efforts, "the likelihood of

'technical' Stark Law violations . . . is high." Sonnenschein Nath & Rosenthal LLP, The Stark Law: A User's Guide to Achieving Compliance at 350 (2d ed. 2009).

In the face of such uncertainty, the only rational way for hospitals to proceed is to seek expert assistance from lawyers who specialize in health care compliance issues. See Lawrence F. Wolper, Physician Practice Management: Essential Operational and Financial Knowledge at 485 (2012) (recommending that medical practices "ensur[e] that effective legal counsel with specialized expertise review[ ] the compensation methodology"); Barbara Landy, et al., Beware of Stark Law "Self-Dealing," 57 Long-Term Living at 35 (August 2008) (advising that health care providers "seek appropriate professional legal . . . assistance . . . to comply with the law"). The reason hospitals seek legal advice regarding the Stark Law is obvious: The statute and its regulations are incredibly complicated, ambiguous, and difficult to apply to real world situations. Hospitals want to comply with the law, and they want to know whether transactions they are considering are lawful. Hospitals need lawyers to help them comb through hundreds of pages of far-from-straightforward regulations and commentary to answer those questions.

II. Evidence That A Hospital Reasonably And In Good Faith Obtained And Followed The Advice Of Counsel As To Stark Law Compliance Works Against A Finding That The Hospital "Knowingly" Violated The False Claims Act.

The False Claims Act provides, in relevant part, that "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" can be held liable for "a civil penalty of not less than $5,000 and not more than $10,000 . . . plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1). The term "knowingly" is defined to cover a person who "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." Id. § 3729(b)(1).

As this Court and many others have recognized, the False Claims Act does not punish reasonable resolutions of disputed legal questions or good faith interpretations even if the government later disagrees with them. See, e.g., United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 377 (4th Cir. 2008) ("differences in interpretation growing out of a disputed legal question are . . . not false" within the meaning of the False Claims Act); Hagood v. Sonoma Cnty. Water Agency, 81 F.3d 1465, 1478 (9th Cir. 1996) ("To take advantage of a disputed legal question, as may have happened here, is to be neither deliberately ignorant nor recklessly disregardful." (citation omitted)). Just as a company's

good faith reliance on "faulty calculations [is] not actionable under the False Claims Act," United States ex rel. Yannacopoulos v. Gen.l Dynamics, 652 F.3d 818, 833 (7th Cir. 2011), neither is a hospital's good faith reliance on expert advice that the government views as "faulty." Cf. United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co. 612 F.3d 724, 733 (4th Cir. 2010) (an estimate only qualifies as "knowingly false" if it is "made by one who either knows of no facts that would support the estimate or has knowledge of facts that preclude the estimate"); United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc., 214 F.3d 1372, 1378 (D.C. Cir. 2000) (a faulty estimate or opinion can qualify as a false statement under the FCA only "where the speaker knows facts 'which would preclude such an opinion' ").

Legal advice is no different from these other contexts. If a hospital does not know of any facts or circumstances that would preclude it from relying on the legal advice it receives, it should be able to do so without risking False Claims Act liability. Liability only accrues for a False Claims Act violation predicated on a Stark Law violation if the hospital "knowingly" violated the Stark Law; and good faith reliance on legal advice from multiple attorneys specializing in health care that a contract complies with the Stark Law is a very strong indicator that the hospital did not "knowingly" violate the law. See United States v. Newport News Shipbuilding, Inc., 276 F. Supp. 2d 539, 565 (E.D. Va. 2003) ("[G]ood faith

reliance on the advice of counsel may contradict any suggestion that a contractor 'knowingly' submitted a false claim, or did so with deliberate ignorance or reckless disregard."). That is because "a provider that, in good faith, solicits legal advice regarding a questionable practice cannot seriously be accused of being 'deliberately ignorant' or 'recklessly disregardful' of the commands of the law." Robert Salcedio, Application of the False Claims Act "Knowledge" Standard: What One Must "Know" To Be Held Liable Under the Act, 8 Health Law. 1 (1996).

To the contrary, deciding to seek out legal advice demonstrates intent to follow the law, not violate it; and relying on the opinion of qualified counsel demonstrates an understanding that the resulting conduct is lawful, not unlawful. Hospitals that seek legal advice, provide full and accurate information to their attorneys, and follow the reasonable advice they receive from counsel are doing their best to ensure care is available in their communities while staying within the bounds of the law. Punishing a hospital with crippling liability because the government disagrees with the legal advice given to the hospital's board by attorneys who told the hospital the transaction was Stark-compliant is not consistent with the letter or the spirit of the law.

Good faith reliance on legal advice plays a similar role in other areas of the law. In the criminal context, for example, "the defense of criminal action taken on

the advice of counsel" is based on the premise that, "in relying on counsel's advice, defendant lacked the requisite intent to violate the law." United States v. Polytarides, 584 F.2d 1350, 1353 (4th Cir. 1978). Likewise, in the intellectual-property realm, "[p]ossession of a favorable opinion of counsel" is an "important" factor in determining whether patent infringement was willful. Electro Med. Sys., S.A. v. Cooper Life Scis., Inc., 34 F.3d 1048, 1056 (Fed. Cir. 1994). And for suits arising under 42 U.S.C. § 1983, reliance on legal advice "is compelling evidence" that an official's act was objectively reasonable. Wadkins v. Arnold, 214 F.3d 535, 542 (4th Cir. 2000).

To be sure, in any given case the question whether legal advice was sought and relied on in good faith is a factual one. And that question may be further complicated if the legal advice received is not entirely consistent. But the Stark Law's complexity and ambiguity effectively ensures that legal opinions about its application will not always be unanimous. Hospital board members will often receive advice that varies from lawyer to lawyer, and they will use their best judgment to decide how to proceed. That is no anomaly; that is how businesses operate every day. And so long as their evaluations of conflicting opinions are made in good faith, resulting violations of the law will seldom be made knowingly.

Ensuring a role for legal advice in the False Claims Act scienter analysis is especially important for hospitals trying to navigate the Stark Act's inscrutable

demands. For one thing, if reliance on legal advice were irrelevant to the scienter inquiry, hospitals would have little incentive to seek such advice in the first place. Lawyers, of course, are not inexpensive. Resources expended seeking legal opinions are well spent if hospitals can rely on those opinions. But if reliance on Stark-related legal advice does not protect a hospital from a finding of a "knowing" violation of the Stark Law, hospitals will have less reason to seek out such advice in the first place. They will, in effect, be stuck between a rock and a hard place: Hospitals need expert advice to comply with the law, but may not be able to justify the significant expenditure of resources necessary to obtain advice when that advice will not protect them.

Even more importantly, ensuring that hospitals can rely on legal advice is critical to maintaining the capability of a hospital to meet the health care needs of its community. Especially in sparsely populated areas, hospitals often struggle to find qualified physicians to serve their communities. See, e.g., Richard A. Crosby, et al., Rural Populations and Health: Determinants, Disparities, and Solutions at 138 (2012) (discussing causes of "the scarcity of rural physicians"). Innovative hospital-physician arrangements are important tools for bringing talent to these underserved populations. But hospitals, facing potentially massive liability for even a single misstep, will be reluctant to enter into such arrangements if they cannot rely on their lawyers' determinations that the arrangements comply with the

Stark Law. See, e.g., Statement of the AHA on the Importance of Clinical Integration to the Nation's Hospitals and their Patients, Federal Trade Commission, "Clinical Integration in Health Care: A Check-Up" (May 29, 2008) (explaining that confusion about the Stark Law impedes hospital-physician arrangements that would improve health care delivery).[2] Instead of embracing novel, lawful arrangements that would lower the cost and improve the availability of services, hospitals will be pushed to sacrifice those benefits out of fear of after-the-fact challenges. Without some assurance that hospitals can rely on legal advice, the threat of millions-upon-millions of dollars of liability makes this chilling effect all but inevitable.

To provide predictability for hospitals doing their best to simultaneously comply with the Stark Law's complex requirements, serve their communities, and avoid massive liability, this Court should reassure hospitals that they can continue to rely on their lawyers' advice. To that end, it should reaffirm the basic premise that good faith reliance on legal advice counsels against a finding that a hospital has knowingly violated the Stark Law. A contrary conclusion would do immeasurable harm to hospitals, physicians, and the communities they serve.

[2] Available at http://www.aha.org/aha/testimony/2008/080529-tes-ftc.pdf.

CONCLUSION

For the forgoing reasons, as well as those in Tuomey's brief, the Court should reverse the decision below.

Respectfully Submitted,

s/ Jessica L. Ellsworth

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December 10, 2013

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and Fed R. App. P. 29(d) because it contains 2,989 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Office Word 2010 in Times New Roman 14 point font.

s/ Jessica L. Ellsworth
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CERTIFICATE OF SERVICE

I certify that on December 10, 2013, the foregoing document was served on all parties or their counsel of record through the CM/ECF system. The following registered CM/ECF users were served:

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