CASE NO. 00-1288

IN THE
UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA, EX REL
JACK OBEYDEAN SWAFFORD, a/k/a
DEAN J. SWAFFORD,
Plaintiff-Appellant
v.
BORGESS MEDICAL CENTER, et al
Defendants-Appellees

On Appeal from the United States District Court
for the Western District of Michigan

BRIEF OF AMICI CURIAE AMERICAN MEDICAL ASSOCIATION AND MICHIGAN STATE MEDICAL SOCIETY IN SUPPORT OF DEFENDANTS-APPELLEES AND FOR AFFIRMANCE OF SUMMARY JUDGMENT

MICHAEL L. ILE
ANNE M. MURPHY
CAROLYN QUINN
AMERICAN MEDICAL ASSOCIATION
515 N. State Street
Chicago, IL 60610

RICHARD D. WEBER (P22073)
JOANNE GEHA SWANSON (P33594)
Kerr, Russell and Weber, PLC
Detroit Center
500 Woodward Avenue, Suite 2500
Detroit, MI 48226
313.961.0200

Attorneys for Amici Curiae
Michigan State Medical Society and
American Medical Association

DISCLOSURE OF CORPORATE AFFILIATIONS AND FINANCIAL INTEREST

Pursuant to Sixth Circuit Rule 26.1, Amici Curiae American Medical Association and Michigan State Medical Society make the following disclosures:

1. Are amici subsidiaries or affiliates of a publicly owned corporation? No.

2. Is there a publicly-owned corporation, not a party to the appeal, that has a financial interest in the outcome? No.

By: _____

Dated: September 1, 2000 Signature of Counsel

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER

CONCISE STATEMENT OF IDENTITY AND INTEREST OF AMICI CURIAE

Amicus the American Medical Association ("AMA") is a private, voluntary, nonprofit organization of approximately 300,000 physicians. Its members practice in all fields of medical specialization. The AMA was founded in 1847 to promote the science and art of medicine and the improvement of public health. It files this *amicus curiae* brief as a member of the American Medical Association/State Medical Society Litigation Center ("Litigation Center"), which was formed in 1995 as a coalition of the AMA and private, voluntary, nonprofit state medical societies to represent the views of organized medicine in the courts. Fifty state medical societies join the AMA as members of the Litigation Center.[1]

---

[1]The member organizations are: Medical Association of the State of Alabama, The Alaska State Medical Association, Arkansas Medical Society, California Medical Association, Colorado Medical Society, Connecticut State Medical Society, Medical Society of Delaware, Medical Society of the District of Columbia, Florida Medical Association, Medical Association of Georgia, Hawaii Medical Association, Illinois State Medical Society, Indiana State Medical Association, Iowa Medical Society, Kansas Medical Society, Kentucky Medical Association, Louisiana State Medical Society, Maine Medical Association, Massachusetts Medical Society, Michigan State Medical Society, Minnesota Medical Association, Mississippi State Medical Association, Missouri State Medical Association, Montana Medical Association, Nebraska Medical Association, New Hampshire Medical Society, Medical Society of New Jersey, New Mexico Medical Society, Medical Society of the State of New York, North Carolina Medical Society, North Dakota Medical Association, Ohio State Medical Association, Oklahoma State Medical Association, Oregon Medical Association, Pennsylvania Medical Society, Rhode Island Medical Society, South Carolina Medical Association, Tennessee Medical Association, Texas Medical Association, Utah Medical Association, Vermont State Medical Society, Medical Society of Virginia, Washington State Medical Association, West Virginia State Medical Association, State Medical Society of Wisconsin, Wyoming Medical Society.

Amicus the Michigan State Medical Society ("MSMS") is a professional association which represents the interests of over 14,000 physicians in the State of Michigan. Organized to promote and protect the public health and to preserve the interests of its members, MSMS is frequently called upon to act as amicus with respect to legal issues of significance to the medical profession. MSMS is also a member of the Litigation Center.

AMA/MSMS respectfully submit this brief to present their opinions concerning the proper scope and application of the False Claims Act. 31 U.S.C. § 3729 et seq. While AMA/MSMS wholly support an elimination of fraudulent medical billing practices, the associations contend that the instant case does not present facts amounting to a violation of the False Claims Act. Indeed, Defendants complied fully with the letter and the spirit of the law. The ruling invited by Plaintiff - which the District Court has already expressly rejected - would compel the Court to venture beyond the plain language of the False Claims Act and penalize Defendants for conduct that Congress never intended to punish. Of particular interest to the AMA/MSMS, Plaintiff essentially requests that this Court

render a judgment as to what does or does not constitute good medical practice. However, the FCA does not impose this obligation on the Court. Further, recent rulings from the United States Supreme Court reaffirm the accepted conclusion that issues of medical practice are reserved to the States.

ARGUMENT

The False Claims Act ("FCA")[2] is a Civil War era statute enacted to combat corruption in the sale of war supplies to the union government.[3] Reduced to its essence, the intent of the FCA is to punish those who submit a claim for payment which they know to be false. See United States ex rel. Hagood v Sonoma County Water Agency, 81 F.3d 1465, 1478 (9th Cir. 1996).

Regrettably, some FCA-based suits concerning health care have alleged claims unrelated to the statute's original purpose of confronting fraud by government vendors. These claims assert a FCA violation based on allegations of failure to comply with anti-kickback statutes, failure to comply with regulatory requirements, or lack of adherence to the applicable standard of care. The relief sought by the *qui tam relator* in such cases may be inappropriate and misguided. This is especially so when the claim expresses the *qui tam relator's* personal disagreement with the manner in which the challenged services are provided, even though the manner of services are not defined by federal and state regulations and cannot otherwise be shown to violate them. Under such circumstances, *qui tam* actions are neither legally tenable nor, from a policy perspective, socially desirable. This is a case in point.

---

[2] 31 U.S.C. § 3729 et seq.

[3] See 132 CONG. REC. 22, 235 (1986).

Unlike the events which prompted passage of the FCA,[4] Plaintiff-Appellant Dean Swafford does not contend that Defendants submitted claims to the government for services they did not perform. Rather, this case arises from Mr. Swafford's subjective belief that Defendants' reading and interpretation of the results of venous ultrasound studies were of no value to the government because they were based upon insufficient information.[5] The question this Court must decide is whether an allegation of this nature is within the prohibition of the FCA.[6] The District Court held that it is not:

> [P]laintiff's disagreement with the qualitative nature and degree of review necessary for defendant physicians to

---

[4] "Testimony before the Congress painted a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war." United States v McNinch, 356 U.S. 595, 599 (1958).

[5] Plaintiff's Appeal Brief, p. 43 ("the issue is whether enough information is provided to Defendant physicians in order to make an 'interpretation' which is properly billable to the federal government").

[6] Mr. Swafford describes his allegations as follows:

> This action arises from Plaintiff-Appellant's allegations (and Defendants' admissions) that Defendant physicians did not review any hard copy data generated by/from any venous doppler ultrasound study reported by the technician as negative for a deep vein thrombosis (blood clot). In short, Defendant billing physicians simply reworded and/or plagiarized the vascular technician/technologist's "worksheet" in the form of a physician's ultrasound report and bill[ed] the federal government . . . for an alleged "reading or interpretation" of the study.

Proof Brief of the Appellant ("Swafford's Brief"), p 3.

> claim to "interpret" the technical component of a venous ultrasound study and then bill the government for the professional component fails to amount to either a false claim or a knowingly false claim under the FCA.

R. 131, Order Granting Defendants' Motions for Summary Judgment ("Order"), p. 24, Apx. p. . The AMA/MSMS urge this Court to affirm the judgment of the District Court and, like the lower court, reject Mr. Swafford's contention that the False Claims Act requires the judiciary to render decisions on the adequacy of medical care practiced by the Defendant physicians and hospital.

I. THE KNOWING FALSITY ELEMENT OF A FCA ACTION CANNOT BE ESTABLISHED ON THE FACTS OF THIS CASE.

The FCA describes the nature of the actions it was created to proscribe. Mr. Swafford's theory of liability is not among them.

The Act states in pertinent part:

> Any person who -
>
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
>
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; . . .
>
> is liable to the United States Government 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)-(3). To establish liability under the FCA, three elements must be shown: (1) the knowing submission of a claim for payment or approval; (2) the falsity of the claim; and (3) defendant's knowledge that the claim was false.[7] These elements are not easily established. Federal courts throughout the country have granted summary judgment to FCA defendants when the plaintiffs "fail[ed] to adduce enough evidence from which a reasonable jury could find that the claim at issue was objectively false, or that the defendant acted with the requisite intent." United States ex rel. Roby v Boeing Co. , 100 F.Supp.2d at 626(citing cases). The District Court in this case properly granted summary judgment on that same basis.

A. Mr. Swafford Cannot Establish That The Claims Were False.

The threshold issue for purposes of the present analysis is whether Mr. Swafford produced sufficient evidence to establish that the claims submitted by Defendants were false. At a minimum, the statute requires proof of objective falsehood. Hagood v Sonoma County Water Agency, 81 F.3d 1465, 1477-78 (9th Cir. 1996). In other words, the statement of fact must be one which can be said to be either true or false. Boisjoly v Morton Thiokol, Inc., 706 F. Supp. 796, 808 (D. Utah 1988).

United States ex rel. Luckey v Baxter Healthcare Corp., 183 F.3d 730 (7th Cir. 1999), cert denied, 145 L.Ed.2d 439, is instructive. In that case, the *qui tam relator* believed that her employer should have used a total protein test to determine whether incoming plasma units contained saline (the presence of which could lead to false negatives for hepatitis and HIV testing), rather than tests she considered inadequate.

---

[7] Courts are split over whether a fourth element - damage suffered by the Government as a result of the false claim - must also be shown. See, R. 131, Order, p.6, Apx. p , .

She asserted that her employer's representations that the plasma had been tested for hepatitis and HIV were false because inadequate testing was tantamount to no testing at all. The Court refused to find the allegations actionable under the FCA:

> Only in Humpty Dumpty's world of word games would anyone apply the label "fraud" to the kind of representations Baxter made.

183 F.3d at 732.

Mr. Swafford's claims are of the same genre. He asserts that Defendants falsely billed for their "reading and interpretation" of venous ultrasound studies although they did no more than review and reword the worksheet findings of the vascular technicians who performed the tests.[8] According to Mr. Swafford, Defendants should have reviewed hard copy test data (photos and video tapes) made while the study was being performed, before billing for their interpretations.[9] As in Luckey, however, Mr. Swafford failed to present any evidentiary basis upon which to assert that the failure to do so rendered the claims "false." Summary judgment was properly granted.

---

[8] Mr. Swafford is a registered vascular technologist formerly employed by certain of the Defendants.

[9] That the studies were conducted according to nationally recognized protocols is not disputed by Mr. Swafford. These protocols required the technician to examine each segment of the venous system for certain specified characteristics, the presence, absence or combination of which were diagnostic indicators for deep vein thrombosis. Test protocols were designed to elicit a "negative" or "positive" finding with respect to each component. However, the technician was not required to grade or evaluate the findings. Only a vascular surgeon has the necessary qualifications to understand the medical significance of variations in overall results. Thus, physicians would review the technician's worksheet, and in some cases, other materials, and prepare a final report of their findings and conclusions. (R. 131, Opinion Granting Defendants' Motions for Summary Judgment ("Order"), pp. 2-3. Apx. pp.).

1. Falsity Cannot Be Predicated on the "Administrative Regulations" Mr. Swafford Relies Upon.

a. The Mere Violation of Administrative Regulations is Not Actionable Under the FCA.

The District Court properly concluded that the "FCA is not an appropriate vehicle for policing technical compliance with administrative regulations," quoting U.S. ex rel. Lamers v City of Green Bay, 168 F.3d 1013, 1020 (7th Cir. 1999) (R. 131, Order, pp. 11-12, Apx. pp.). This conclusion is abundantly supported. Numerous courts have held that mere noncompliance with a statute or regulation, in the absence of a certification of compliance, is not a false statement within the meaning of the FCA. See, e.g., United States ex rel. Hopper v Anton, 91 F.3d 1261, 1266-67 (9th cir. 1996), cert. denied, 136 L.Ed.2d 844, 117 S.Ct. 958 (1997); United States ex rel. Luckey v Baxter Healthcare Corp., 183 F.3d 730, 733 (7th Cir. 1999) (citing Lamers); United States ex rel. Joslin v Community Home Health of Maryland, Inc., 984 F. Supp. 374, 383 (Md. 1997); United States ex rel. Lum v Vision Service Plan, 104 F.Supp.2d 1237 (Hawaii 2000); United States ex rel. Thompson v Columbia/HCA Healthcare Corp., 125 F.3d 899 (5th Cir. 1997).

Further, the certification of compliance cannot be implied. In United States ex rel. Siewick v Jamieson Science and Engineering, Inc., 214 F.3d 1372, 1375 (D.C. Cir. 2000), the Court deemed the implied certification theory a "non-starter" doomed by the rule, "adopted by all courts of appeals to have addressed the matter," that a false certification of compliance with a statute or regulation cannot serve as the basis for a *qui tam* action under the FCA unless payment is conditioned on that certification. Id.[10] The rationale was articulated in Joslin:

[10] There was no such certification or certification requirement in this case.

> The FCA is not intended "to operate as a stalking horse for enforcement of every statute, rule, or regulation." Pogue, 914 F. Supp. At 1513. To hold that the mere submission of a claim for payment, without more, always constitutes an "implied certification" of compliance with the conditions of the Government program seriously undermines this principle by permitting FCA liability potentially to attach every time a document or request for payment is submitted to the Government, regardless of whether the submitting party is aware of its noncompliance.

984 F. Supp. at 384.

b. Further, There Are No Applicable Regulations Which Require a Physician to Review Hard Copy Data of a Venous Ultrasound Study in Order to Bill for Reading and Interpreting the Test Results.

Although Mr. Swafford alleged that Defendants falsely certified, through the billing process, that their interpretation of venous ultrasound studies complied with applicable federal and state regulations, Mr. Swafford admitted that Medicare had not promulgated regulations which govern that service. (R. 131, Order, p. 9, Apx. p.).[11] Nor could Mr. Swafford identify any other federal or state regulation which required a physician to review the hard copy data of a venous ultrasound study in order to "read and interpret" the results. Thus, there is no basis upon which to establish that billing for the services Defendants did perform - reviewing the technicians' worksheets,

---

[11] Defendant Dr. Jain directed a Freedom of Information Act request to Medicare for any published guidelines governing the interpretation and reading of venous studies and was advised that there were none. See July 9, 1998 Correspondence to Advanced Vascular Surgery, R. 112, Appendix B, filed in Support of Defendants Motion to Dismiss and/or for Summary Judgment.

evaluating the results, and stating their findings or conclusions - constituted a "false" claim within the meaning of the FCA.

The District Court of Georgia reached this conclusion in United States ex rel. Cox v Memorial Medical Center, Inc., No. CV-497072 (S.D. Ga., April 6, 1998). In Cox, a helicopter pilot filed a FCA action asserting that defendants overcharged the government for air ambulance services by billing in statute miles rather than nautical miles. The Court held that plaintiff could not show that submission of claims in statute miles was a false claim because "[t]here is simply no law, regulation or guideline which requires that the submission of miles be in nautical miles rather than statute miles." (Emphasis in original).

Nonetheless, Mr. Swafford urged the District Court to find a requirement in the HCFA Carriers Manual, or to evaluate Defendants' representations in light of other HCFA regulations which govern the billing of radiology services, x-rays, and other procedures.[12] The District Court was not persuaded:

---

[12] The Health Care Financing Administration ("HCFA") administers the Medicare program partly through the use of private contractors who serve as fiscal intermediaries for the submission of provider claims. Guidelines for submitting claims are summarized in a Provider Handbook. Reimbursement guidelines are provided to contractors in a Carriers Manual. All of these guidelines are published in the Federal Register. At a minimum, the billed-for services are to be identified with five-digit billing codes established by the AMA and published in the AMA publication "Current Procedural Terminology." (R. 131, Order, p. 4, Apx. p.). However, it is up to HCFA and the private contractor carriers to furnish physicians with any and all directives that affect how the CPT codes are to be processed and paid. AMA Policy Compendium, H-70.943; Res. 838, A-98. The majority of venous ultrasound studies at issue in this case were billed using the following global codes: 93970 - duplex scan of extremity veins or a complete bilateral study, and 93971 - a unilateral or limited study, each with a "26 modifier." This modifier signifies the "professional," as distinguished from the "technical," component of the study, and the "global" service, which includes both. (R. 131, Order, p.5, Apx. p.). Moreover, no specific or defining directives have been issued.

> Given the lack of specific billing regulations concerning venous ultrasounds, the Court is not persuaded by plaintiff's arguments. As a matter of law, the Court concludes plaintiff's position on this issue is insufficient to establish a genuine issue of material fact. Plaintiff concedes HCFA has not promulgated specific regulations relating to the submission of reimbursement claims for venous ultrasounds, but proposes the Court instead employ HCFA Carriers Manual regulations on radiology as governing venous ultrasounds. The case law makes clear, however, that the Carriers Manual is merely a guide for fiscal intermediaries between Medicare and physicians, and lacks "the binding effect of law or regulation." National Medical Enterprises v Bowen, 851 F.2d 291, 293 (9th Cir. 1988). Moreover, the Carriers Manual is intended to instruct carriers as to whether to pay a claim and is not routinely provided to physicians. Indeed, by its terms the Carriers Manual does not purport to address the physician's decision to submit a claim for reimbursement, and most importantly, does not dictate whether physicians are required to review the hard copy data of venous ultrasounds. Hence, the Court declines to judge the truth or falsity of defendants' representations in light of the Carriers Manual.

(R. 131, Order, pp. 10-11, Apx. pp.) (Emphasis supplied).

The District Court also rejected Mr. Swafford's attempt to advance alternative regulations as controlling, finding that Mr. Swafford had neither established that compliance with the standards was a prerequisite to Medicare reimbursement for venous ultrasounds, nor presented any facts from which one could infer that the physicians knew or believed that the regulations were applicable.

The District Court's ruling is entirely consistent with existing law. In Cox, for example, the Court rejected plaintiff's assertion that Federal Aviation Association regulations, which require that aviation distances be stated in nautical miles, should govern the billing of air ambulance services. "Although the FAA governs the

requirements for air travel," the Court said, "it does not follow that it governs how air ambulance providers submit their bills to Medicare."

c. FCA Liability Cannot Be Established by Regulatory Terms Which Are Vague and Indefinite.

Further, Mr. Swafford's assertions that Defendants' services did not comply with the definition of "professional services" contained in the Provider's Manual do not demonstrate a violation of the FCA. The Manual defines the professional component of physician-delivered services as "the interpretation or reading of the results of the test performed." Medicare Part B Provider Handbook for Michigan, I-27 (March 1997).[13] As the District Court noted, whether such services were rendered is a dispute over the meaning of terms which is insufficient to establish falsity under the FCA. (R. 131, Order, p. 20, Apx. p.).

The law is quite clear on this point. Imprecise statements "or differences in interpretation growing out of a disputed legal question" are not "false" within the meaning of the FCA. United States ex rel. Lamers v City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999). As the Court explained in Roby:

> Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false.

100 F. Supp. at 625. See also, United States ex rel. Milam v Regents of the University of California, 912 F. Supp. 868, 886 (Md. 1995) ("Disagreements over scientific methodology do not give rise to False Claims Act liability"). More

[13] The "technical component" of a professional service is the actual performance of the test. It does not require the expertise of a physician and is normally performed by the office or hospital staff. Medicare Part B Provider Handbook for Michigan, I-27.

importantly, Defendants provided the claimed "professional services." By billing with the 26 modifier, Defendants informed the Government that they were seeking payment for "the interpretation or reading of the results of the test performed." It is undisputed that Defendants evaluated the worksheet results of the venous ultrasound studies, and, as noted in Defendants' brief, the evaluation was not a simple reiteration of the technicians' work:

> "[T]he overall results of the [ultra-sound] study include significant variations from patient-to-patient. (*See*, R. 113, Renewed Motion to Dismiss and/or for Summary Judgment, Ex. 19 (Munn dep.) at pp. 23-25, JA ___). These variations range from studies which are incomplete because of limitations on the technician's ability to test all of the areas required by the protocol, to studies in which evidence of non-DVT-related pathologies or abnormalities are found, to studies showing "positive" characteristics consistent with the presence of an acute DVT, to purely normal studies in which no abnormalities are found during the course of the test. (Id. *See also*, R. 113, Renewed Motion to Dismiss and/or for Summary Judgment, Ex. 6-10 (examples of test reports), JA ___). To ensure the results of every test are evaluated by someone qualified to understand the medical implications of every possible result (rather than a piecemeal approach where "simple" tests are evaluated by a technician and "complicated" tests are reviewed by a vascular surgeon), the protocols require physician interpretation of all tests. (R. 113, Renewed Motion to Dismiss and/or for Summary Judgment, Ex. 14 (Jain aff.), JA ____ .) Only the vascular surgeons - not the technicians - have the necessary qualifications."

Proof Brief of Defendants-Appellees Advanced Vascular Surgery, P.C., et al., pp. 9-10. Thus, Defendants accurately reported the services they provided.

2. Allegations That the Billed-For Services Violated the Applicable Standard of Care Do Not Establish Falsity Within the Meaning of the FCA.

Mr. Swafford's attempted reliance on expert testimony to establish that the claims were false because the services violated a standard of care was appropriately rejected by the District Court:

> [A]s a matter of law, plaintiff cannot demonstrate the falsity of defendants' claims under the FCA by proving their delivery of services fell short of the requisite standard of care. Although the Sixth Circuit has not spoken directly to this issue, the Seventh Circuit rejected a similar argument when it was presented upon similar facts in Luckey v Baxter Healthcare Corp., 183 F.3d 730 (7th Cir. 1999).

(R. 131, Order, p. 16, Apx. p.). Thus, assuming arguendo that Defendants' services violated the applicable standard of care, Plaintiff could not demonstrate a genuine issue of material fact with respect to the alleged falsity of the claims under the FCA. Id. at p. 18. In any event, there is no evidence of sub-standard care in this case. Defendants rendered their physician services according to protocols accepted and practiced nationwide.

The District Court's conclusion on this issue is abundantly supported by the results reached in several similar recent cases. The following decisions recognized that allegations that billed-for services violated the applicable standard of care or deviated from commonly-accepted scientific practices were insufficient to establish falsity under the FCA. United States ex rel. Mikes v Straus, 84 F.Supp.2d 427, 433 (S.D.N.Y. 1999); Luckey v Baxter Healthcare Corp., 2 F.Supp.2d 1034, 1047 (E.D. Ill. 1998); Hagood v Sonoma County Water Agency, 81 F.3d 1465, 1478, cert. denied

519 U.S. 865; United States ex rel. Milam v Regents of the University of California, supra; United States ex rel. Wang v FMC Corp., 975 F.2d 1412 (9th Cir. 1992).

In Mikes, plaintiff alleged that defendants' failure to calibrate and test certain equipment violated the standard of care, led to inaccurate test results, and rendered false the claims submitted for performance of the tests. Granting summary judgment for defendants, the Court held that the submission of a claim for negligent medical care is not actionable under the FCA. 84 F.Supp.2d at p. 433. "Submitting a claim to the Government for a service that was not provided in accordance with the relevant standard of care . . . , without more, does not render that claim false or fraudulent for FCA purposes." Id.

In Milam, plaintiff filed a FCA suit alleging that defendants submitted grant applications to the National Institutes of Health and received funds based on falsified research data. To establish falsity, plaintiff in part asserted that defendants "employed practices that irreconcilably deviated from those that are commonly accepted within the scientific community . . ." In rejecting this theory, the Court said:

> At most, the Court is presented with a legitimate scientific dispute, not a fraud case. Disagreements over scientific methodology do not give rise to False Claims Act liability.

912 F. Supp. at 886.

The plaintiff in Wang was a mechanical engineer who alleged that his former employer defrauded the government in its performance of various defense contracts. However, he presented evidence of no more than innocent mistakes or negligence. In granting summary judgment for defendant, the Court said the case "betray[ed] a serious misunderstanding of the Act's purpose."

> The Act is concerned with ferreting out "wrongdoing," not scientific errors. . . What is false as a matter of science is not, by that fact, wrong as a matter of morals.

975 F.2d at 1421.

B. Mr. Swafford Cannot Establish That Defendants Knew That the Claims Were False Within the Meaning of the FCA.

Pursuant to the FCA, knowingly means "that a person (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information..." 31 U.S.C. § 3729 (b). Proof of a specific intent to defraud is not required, Id, but an untrue statement is not by itself sufficient. United States ex rel. Roby, 100 F. Supp. 2d 619, 626 (S.D. Ohio 2000). A plaintiff must present facts which establish more than innocent mistake or negligence. "The requisite intent is the knowing presentation of what is known to be false." Hindo v University of Health Sciences, 65 F.3d 608, 613 (7th Cir. 1995), quoting United States ex rel. Hagood v Sonoma County Water Agency, 929 F.2d 1416, 1420 (9th Cir. 1991). In other words, the claim must be "a lie." United States ex rel. Wang v FMC Corp., supra. As the District Court concluded, Mr. Swafford's proofs fell far short of these requirements.

Assertions of purported familiarity with HCFA regulations and statements in the Carriers Manual are "insufficient to create an inference of reckless disregard on the part of defendants," the Court explained, "because the reckless disregard must be of applicable regulations to the submission of claims." R. 131, Order, p. 22, Apx. p. . Mr. Swafford's proofs similarly fell "short of creating an inference of deliberate ignorance." The District Court said:

> Plaintiff offers his affidavit testimony that internal discussions occurred that indicated defendant physicians' awareness that their claims rested upon uncertain ground, and that only Dr. Jain investigated what regulations actually govern the interpretation of venous ultrasounds. (Pl. Ex. 18). However, plaintiff concedes that on at least three occasions defendant Jain contacted HCFA, including a Freedom of Information Act request, seeking any "published guidelines specific to procedures 93970-93971 with a 26 modifier." (Pl. Ex. 7). The answer defendant Jain received: "[w]e have no published guidelines specific to procedures 93970-93971 with a 26 modifier," does not give rise to an inference of either deliberate indifference or reckless disregard. (Pl. Ex. 7)
> . . . Moreover, the evidence of internal discussions plaintiff points to cuts against his argument that defendant physicians were deliberately ignorant, and instead suggests defendants evinced concern and investigated the question of what procedures were required to submit a proper claim for reimbursement.

R. 131, Order, p. 23, Apx. p. (emphasis added).

Other courts have reached similar conclusions on analogous facts. With respect to defendant's efforts to investigative the challenged billing prerequisites in X Corp. v John Doe, 816 F.Supp. 1086, 1093 (E.D.Va. 1993), for example, the Court said, "[F]ar from ignoring the compliance concerns, X Corp. acted to investigate the matter in order to ensure regulatory compliance." The same analysis negated scienter in United States ex rel. Mikes v Straus, supra. Although the court noted that one of the defendants was aware of possibly regulatory noncompliance, he had responded to the relator's concerns by asking her to investigate the matter further. 84 F.Supp.2d at pp. 438-9.

The requisite scienter has also been held to be absent when, as in this case, the billing prerequisites were subject to interpretation and there was no evidence that

defendant knew its interpretation was incorrect. See e.g., United States ex rel. Hockman v Nackman, 145 F.3d 1069, 1076 (9th Cir. 1998) ("Without sufficient evidence to support an inference that the defendants understood that they were interpreting the Affiliation Agreements incorrectly. . . , the plaintiffs' claim must fail"); United States ex rel. Oliver v The Parsons Co., 195 F.3d 457, 464 (9th Cir. 1999) ("A contractor relying on a good faith interpretation of a regulation is not subject to liability, not because his or her interpretation was correct or 'reasonable' but because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met").

Mr. Swafford's inability to raise a genuine issue of material fact that the challenged claims were knowingly false demonstrates the total impropriety of a FCA claim in this context. Mr. Swafford begins and ends with a personal belief that a physician should review hard copy data of negative venous ultrasound exams in order to bill for interpreting the study results. The facts necessary to fashion that belief into a FCA claim simply do not exist. As the Court concluded in Luckey upon reaching a similar result:

> All this record reveals is a dispute about whether Baxter's testing protocols could be improved. An affirmative answer to that question would not suggest that Baxter's representations to the United States in years past were false or fraudulent.

183 F.3d at 733.

II. BROADENING THE SCOPE OF THE FCA IS NEITHER LEGALLY, LOGICALLY, NOR SOCIALLY DESIRABLE POLICY.

Mr. Swafford's suit asks this Court to decide whether, as a matter of public policy, the contours of appropriately reimbursable medical care can and should be established through a FCA action. Defendants and amici have attempted to demonstrate that such a request would draw the Court well-beyond the simple prohibition established by the FCA, i.e., false claims cannot be knowingly submitted for remuneration. This Court need not venture beyond the clear proscription erected by the FCA.

In fact, recent authority indicates that this Court should not render a judgment which would require it to determine whether a physician's decision-making process in rendering care to the patient constituted a fraudulent claim. In Pegram v Herdrich, 530 U.S. _____; 120 S. Ct. 2143; 147 L. Ed. 2d 164 (2000), the United States Supreme Court ruled that the decision of a physician-owned HMO, acting through a doctor, to deny a certain form of care to a patient, did not constitute a breach of fiduciary duty under the Employee Retirement Income Security Act (29 U.S.C. sec 1001 et seq.) In relevant part, the Supreme Court observed that the allegedly actionable decision by the physician was not a fiduciary responsibility envisioned by ERISA, but rather, involved the exercise of medical judgment by a physician. Congress did not intend ERISA to encroach upon the authority to legislate standards of medical care traditionally reserved to the states, the Supreme Court ruled.

Here, too, the claims asserted by Mr. Swafford, particularly as they allege that Defendants failed to meet the standard of care for rendering decisions based on venous ultrasound studies, fall far outside the intended reach of the FCA. Whether the physicians in this case did or did not adhere to standards of medical care is entirely irrelevant to the resolution of this case. It is also an issue that is correctly decided as a matter of state law.

Further, a finding of a FCA violation can have far reaching consequences. An individual or entity found to have violated FCA may be ordered to pay damages of up

to three times the amount of the claim, as well as mandatory penalties of between $5,000 and $10,000 per claim, regardless of its size. 31 U.S.C. §3729(a)(7).[14] There are collateral consequences as well, including exclusion from participation in the federally funded health care programs (Medicare, Medicaid and the Civilian Health and Medical Program of the Uniformed Services), loss of medical licensure, and loss of hospital staff privileges.

Given the severity of these consequences, no target of a FCA claim, however certain of the propriety of his or her conduct, would take such a threat lightly. For this reason, even the most avowedly innocent are encouraged to settle claims which advance untested and aggressive legal theories. As a consequence, many aspects of the law have "never face[d] the winnowing effects of judicial scrutiny."[15] Frivolous actions thrive in such an environment because deterrents, such as requiring an unsuccessful relator to pay the opposing party's legal fees, do not exist.

An overly expansive reading of FCA, like the one suggested by Plaintiff, is not the proper mechanism to set medical reimbursement standards. Other negative consequences could also follow. Changes in the provision of medical services would be driven by something other than medical propriety and scientific knowledge.

In this case, Mr. Swafford has not alleged that requiring vascular surgeons to view videotapes or other hard copy data of negative venous ultrasound exams would have aided their reading and interpretation of the exam results, would have resulted in fewer instances of missed diagnoses, or would have otherwise affected in any way the

---

[14] Effective September 29, 1999, inflationary adjustments raised the civil penalties to a minimum of $5,500 and a maximum of $11,000. See Boese, Can Substandard Medical Care Become Fraud? The Brief, Vol. 29, No. 4, p. 30, 32 (Summer 2000).

[15] Klein, Protection or Persecution? New Applications Link the False Claims Act's Onerous Penalties to Kickback and Quality Lapses, Raising Concerns About the Law's Scope, AMNews (Feb. 15, 1999).

quality of care provided. Yet, viewing such data would undoubtedly take additional time, adding to the cost of the service and decreasing the time the physicians would have to devote to other procedures.[16]

Such changes would not be uniformly implemented from one region to the next. If standard of care was permitted to be the touchstone for falsity, the reimburseability of medical services would vary on a geographic basis.[17] Additionally, it is not inconceivable that *qui tam relators* could simultaneously pursue opposing goals and achieve conflicting results. This would unquestionably complicate the reimbursement process, increase the resources required of the Government to sort through the inconsistencies, and overly enmesh the courts in medical issues which are not appropriate for resolution by a judge or a jury.

Health care may also be affected. As commentator John Boese explained in "Can Substandard Medical Care Become Fraud?":

> Ironically, the dual pressures of aggressive government and *qui tam* FCA enforcement threaten to *decrease* the quality of care. Resources that would otherwise be directed to patient care are sapped as providers are forced to deal with burdensome regulations and fend off *qui tam* suits that may be frivolous or involve de minimis regulatory violations.

---

[16] Even if Swafford argued that the present practice resulted in substandard care, "it simply makes no sense for federal prosecutors, no matter how well intentioned or expert, to establish clinical care norms. It is unnecessary because an array of expert federal, state and private authorities are already responsible for monitoring quality of care concerns, and, moreover, have recently demonstrated renewed energy toward improving quality of care." Fabrikant and Solomon, Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry, 51 Ala. L. Rev. 105, 106.

[17] Thus, if a health care provider migrates from one region of the country to another, services which were appropriately billed in one region may not be proper in another and would expose the provider to FCA liability.

> Moreover, some providers are choosing to opt out of federal health care programs or to shut down altogether, thereby reducing patient choice and perhaps negatively affecting quality of care at remaining institutions.

The Brief, Vol. 29 at p.31. See also, Fabrikant and Solomon, supra, 51 Ala. L. Rev. 105, 159.

CONCLUSION

AMA/MSMS request that the Court resist suggestions to use the onerous context of a FCA action to impose subjective conclusions about the standard of care upon the medical community. Health care providers are subject to an innumerable array of federal and state regulations, many of which are vague and subjective. The potential that the FCA will be abused as an enforcement tool under such circumstances is great. As Mr. Boese explained:

> When FCA liability can be imposed for alleged violations of ambiguous and aspirational regulations governing subjective qualities, defendants are at enormous risk. When *qui tam* relators are given this power, the risk is even greater. These relators may be motivated by grief, ignorance of medical facts, conflicts with the provider, or simple greed.

The Brief, Vol. 29 at p. 36. Further, relators have no incentive to exercise the prosecutorial discretion that sometimes causes the government to refrain from pursuing lawsuits that are not good policy. This is such a case. The District Court acted properly in dismissing it. This Court should affirm.

Dated: September 1, 2000

KERR, RUSSELL AND WEBER, PLC

By:_____
RICHARD D. WEBER (P22073)
JOANNE GEHA SWANSON (P33594)
Detroit Center, 500 Woodward Avenue, Suite 2500
Detroit, MI 48226
313.961.0200

Attorneys for Amici Curiae
Michigan State Medical Society and
American Medical Association

MICHAEL L. ILE
ANNE M. MURPHY
CAROLYN QUINN
AMERICAN MEDICAL ASSOCIATION
515 N. State Street
Chicago, IL 60610

CERTIFICATE OF COMPLIANCE

The undersigned counsel for Amicus Curiaes American Medical Association and Michigan State Medical Society hereby certify that, according to Corel WordPerfect computer-generated word volume count, this brief, from the Statement of Concise Identity and Interest of Amici Curiae through the Conclusion, consists of 6,440 words in 14 point, Times New Roman font.

Dated: September 1, 2000

KERR, RUSSELL AND WEBER, PLC

By:_____

RICHARD D. WEBER (P22073)
JOANNE GEHA SWANSON (P33594)
Detroit Center, 500 Woodward Avenue, Suite 2500
Detroit, MI 48226
313.961.0200

Attorneys for Amici Curiae
Michigan State Medical Society and
American Medical Association

MICHAEL L. ILE
ANNE M. MURPHY
CAROLYN QUINN
AMERICAN MEDICAL ASSOCIATION
515 N. State Street
Chicago, IL 60610