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THE USE OF THE FALSE CLAIMS ACT IN QUALITY OF CARE CASES

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The False Claims Act ("FCA") is the government's "primary litigative tool for combating fraud."[1] The FCA empowers both the Attorney General and private persons to institute civil actions to enforce the Act.[2] The FCA imposes liability on those who, inter alia, "knowingly" present, or cause to be presented, "a false or fraudulent claim for payment."[3] "Knowingly" is defined to mean, among other things, that the provider acted in "deliberate ignorance" or in "reckless disregard" of the truth or falsity of the information.[4]

In 1986, Congress substantially amended the FCA to encourage actions (known as *qui tam* actions) brought by private persons (known as relators). As a result of Congress's expansion and liberalization of the FCA, the government's recoveries under the FCA have skyrocketed. As of federal fiscal year 2000, the government has recovered almost $7 billion under the FCA since the 1986 amendments.[5] In federal fiscal year 2000 alone, the government recovered $1.5 billion and over half that amount arose from health-related FCA cases.[6] Part A providers — hospitals,[7] home health agencies,[8] and long-term care facilities[9] — have all been subjected to numerous FCA actions.

One growing area of FCA jurisprudence concerns the use of the FCA to police the quality of care provided to Medicare and Medicaid beneficiaries. Relevant recent cases are described below as well as applicable FCA defenses. Additionally, constitutional limitations on the use of the FCA in quality of care cases are discussed. This paper concludes that courts have appropriately restricted the application of the FCA to only those cases in which there is a total failure of care, as opposed to a mere lack of quality care, and that in light of recent cases, there may be constitutional limitations on the amount of penalties the government can obtain in these actions.

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1 *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 745 (9th Cir. 1993) (quoting Senate Judiciary Committee, False Claims Amendments Act of 1986, S. REP. NO. 345 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266).

2 31 U.S.C. § 3730.

3 *Id.* § 3729(a)(1).

4 *Id.* § 3729(b).

5 *See* Jack A. Meyer and Stephanie E. Anthony, *Reducing Health Care Fraud: An Assessment of the Impact of the False Claims Act* at 9 (September 2001).

6 *Id.*

7 *See, e.g.*, *United States ex rel. Dhawan v. New York Medical College*, 252 F.3d 118 (2d Cir. 2001); *United States v. Texas Tech Univ.*, 171 F.3d 279 (5th Cir. 1999); *Hindo v. University of Health Sciences/The Chicago Medical School*, 65 F.3d 608 (7th Cir. 1995); *Covington v. Sisters of the Third Order of St. Dominic of Hanford, Cal.*, No. 93-15194, 1995 U.S. App. LEXIS 20370 (9th Cir. July 13, 1995); *United States ex rel. Obert-Hong v. Advocate Health Care*, No. 99 C 5806, 2001 U.S.Dist.LEXIS 3767 (N.D. Ill. Mar. 27, 2001); *United States ex rel. McCarthy v. Straub Clinic and Hospital, Inc.,* 140 F.Supp.2d 1062 (D. Haw. 2001); *United States ex rel. Mathews v. HealthSouth Corp.*, 140 F.Supp.2d 706 (W.D. La. 2001); *United States ex rel. Cherry v. Rush-Presbyterian/St. Luke's Medical Center*, No. 99 C 06313, 2001 WL 40807 (N.D. Ill. Jan. 16, 2001); *United States ex rel. Goodstein v. McLaren*, No. 97-CV-72992-DT, 2001 U.S.Dist.LEXIS 2917 (E.D. Mich. Jan. 3, 2001); *United States ex rel. Amin v. George Washington Univ.*, 26 F. Supp. 2d 162 (D.D.C. 1998); *United States ex rel. Thompson v. Columbia/HCA Health Care*, 20 F. Supp. 2d 1017 (S.D. Tex. 1998); *United States ex rel. Cox v. Iowa Health System*, 29 F. Supp. 2d 1022 (S.D. Iowa 1998).

8 *See, e.g.*, *United States ex rel. Russell v. Epic Health Care Management Group*, 193 F.3d 304 (5th Cir. 1999); *United States ex rel. Waris v. Staff Builders, Inc.*, No. 96-1969, 1999 U.S. Dist. LEXIS 15247 (Oct. 4, 1999); *United States ex rel. Smith v. First American Health Care of Georgia*, No. 1:97-CV-780, 1999 U.S. Dist. LEXIS 6181 (W.D. Mich. Apr. 26, 1999); *United States ex rel. Okeke v. Home Care Services, Inc.*, No. 3:97-CV-2738-H, 1999 U.S. Dist. LEXIS 5177 (N.D. Tex. Apr. 9, 1999); *United States ex rel. Joslin v. Community Home Health of Maryland, Inc.*, 984 F. Supp. 374 (D. Md. 1997); *United States v. American Health Enters., Inc.*, NO. 94-cv-450-RCF, 1996 U.S. Dist. LEXIS 7494 (N.D. Ga. Apr. 29, 1996).

9 *See, e.g.*, *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149 (W.D. Mo. 2000); *United States ex rel. Swan v. Covenant Care, Inc.*, No. C-97-3814, 1999 U.S. Dist. LEXIS 15287 (N.D. Cal. Sept. 21, 1999); *United States ex rel. Eaton v. Kansas Health care Investors*, 22 F. Supp. 2d 1230 (D. Kan. 1998); *United States v. Chester Care Center*, No. 98 CV-139, 1998 U.S. Dist. LEXIS 4836 (E.D. Pa. Feb. 4, 1998).

I. RECENT QUALITY OF CARE CASES

Two recent cases shed important light on the government's ability to prosecute quality of care cases. In one case, *United States ex rel Mikes v. Straus*,[10] the Second Circuit restricted the government's ability to employ the FCA to police the standard of medical care while in the other, *United States v. NHC Healthcare Corp.*,[11] a district court permitted the government to enforce the FCA in a quality of care case.

A. Narrow Construction of the FCA regarding the Standard of Care: *United States ex rel. Mikes v. Straus*

In *United States ex rel Mikes v. Straus*, the relator, a pulmonologist, alleged that defendants submitted false reimbursement requests to the federal government for spirometry services.[12] Spirometry is an "easy-to-perform pulmonary function test used by doctors to detect both obstructive (such as asthma and emphysema) and restrictive (such as pulmonary fibrosis) lung diseases."[13] The defendants' spirometers measure "the pressure change when a patient blows into a mouthpiece, thereby providing the doctor with on-the-spot analysis of the volume and speed by which patients can exhale."[14]

The relator alleged that the submission of Medicare reimbursement claims for spirometry procedures not performed in accordance with the relevant standard of care violated the FCA.[15] Specifically, the relator alleged that American Thoracic Society ("ATS") guidelines recommend daily calibration of spirometers by use of a three liter calibration syringe, the performance of three successive trials during test administration, and the appropriate training of spirometer technicians.[16] The relator contended that the defendants' performance of spirometry did not conform to the ATS guidelines and thus would yield inherently unreliable data.

In evaluating whether the defendants submitted false claims to the government the court pointed out that the statutory term "false or fraudulent" is not defined in the Act. In giving content to the phrase, the court reasoned:

> A common definition of "fraud" is "an intentional misrepresentation, concealment, or nondisclosure for the purpose of inducing another in reliance upon it to part with some valuable thing belonging to him or to surrender a legal right." Webster's Third New International Dictionary 904 (1981). "False" can mean "not true," "deceitful," or "tending to mislead." Id. at 819. The juxtaposition of the word "false" with the word "fraudulent," plus the meanings of the words comprising the phrase "false claim," suggest an improper claim is aimed at extracting money the government otherwise would not have paid.[17]

In evaluating whether the defendants spirometry claims were false, the court found that there are three types of falsity that could trigger liability under the FCA: (a) false express certification which represents compliance with a federal statute or regulation or a prescribed contractual term; (b) false implied certification under which defendants implicitly represents

10 274 F.3d 687 (2d Cir. 2001).
11 115 F.Supp.2d 1149 (W.D.Mo. 2000).
12 274 F.3d at 693.
13 *Id.* at 694.
14 *Id.*
15 *Id.* at 696.
16 *Id.* at 694.
17 *Id.* at 696 (citation omitted).

entitlement to payment notwithstanding the breach of some rule or regulation that is not referenced in the certification; (c) false representation that specific goods or services were submitted to the United States when they were not. The court found that none of these types of falsity was present under the facts and circumstances in the action.

1. The Relator's Theory Based Upon Express False Certification

In formulating its rule regarding whether the defendants' claim for payment for the spirometry on the HCFA-1500 breached the FCA because the defendants tendered a false certification, the court held that it would "join the Fourth, Fifth, Ninth, and District of Columbia Circuits in ruling that a claim under the Act is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment."[18] Under this test, two separate elements must be satisfied: (1) the party must certify compliance with a specific statute or regulation and (2) the party's certification and compliance with the statute or regulation must be a precondition of governmental payment.

In *Straus*, the court found that the second element was clearly satisfied. Both the HCFA-1500, which provides "No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations," and the Medicare Regulations, *see* 42 C.F.R. § 424.32, state that certification is a precondition to Medicare reimbursement. However, the court found that the first element was not satisfied because the HCFA-1500 did not contain any express certification regarding the quality of the spirometry services.

Specifically, as the court pointed out, a person certifies on the HCFA-1500 that "the services shown on this form were **medically** indicated and **necessary** for the health of the patient and were **personally furnished** by [the person] or were furnished incident to [the person's] professional service by [the person's] employee under [the person's] immediate personal supervision."[19] The court ruled that the relator could neither establish that the services lacked medical necessity nor that the physician did not personally furnish the service.

As an initial matter, the court found that the relator's objections to defendants' spirometry tests did not implicate the standard set out in the HCFA-1500 form that the procedure was dictated by "medical necessity" because the medical necessity standard relates to the level of service provided, not its quality.[20] Specifically, the court reasoned:

> The term "medical necessity" does not impart a qualitative element mandating a particular standard of medical care, and [the relator] does not point to any legal authority requiring us to read such a mandate into the form. Medical necessity ordinarily indicates the level — not the quality — of the service. For example, the requisite level of medical necessity may not be met where a party contends that a particular procedure was deleterious or performed solely for profit, *see United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 41-42 (D. Mass. 2000*)* (procedures chosen solely for defendants' economic gain are not "medically necessary" as required by claim submission form), or where a party seeks reimbursement for a procedure that is not

18 *Id.* at 697 (citing *United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.,* 214 F.3d 1372, 1376 (D.C. Cir. 2000); *Harrison v. Westinghouse Savannah River, Co.,* 176 F.3d 776, 786-87, 793 (4th Cir. 1999)*; United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.,* 125 F.3d 899, 902 (5th Cir. 1997); *United States ex rel. Hopper v. Anton,* 91 F.3d 1261, 1266-67 (9th Cir. 1996)). According to the court, its holding "is distinct from a requirement imposed by some courts that a false statement or claim must be material to the government's funding decision." *Id.* (citation omitted). It reasoned that a "materiality requirement holds that only a subset of admittedly false claims is subject to False Claims Act liability" and "that not all instances of regulatory noncompliance will cause a claim to become false." *Id.* (citation omitted). Consequently, the court declined to "address whether the Act contains a separate materiality requirement." *Id.*

19 *Id.* at 698 (emphasis supplied).

20 *Id.*

> traditionally covered, *see Rush v. Parham,* 625 F.2d 1150, 1156 (5th Cir. 1980) (upholding state's exclusion of experimental medical treatment from definition of "medically necessary" services under Medicaid).
>
> This approach to the phrase "medically necessary" — as applying to ex ante coverage decisions but not ex post critiques of how providers executed a procedure — would also conform to our understanding of the phrase "reasonable and necessary" as used in the Medicare statute, 42 U.S.C. § 1395y(a)(1)(A) (1994) (disallowing payment for items or services not reasonable and necessary for diagnosis or treatment). *See New York ex rel. Bodnar v. Sec'y of Health & Human Servs.,* 903 F.2d 122, 125 (2d Cir. 1990) (acknowledging Secretary's authority, in determining whether procedure is "reasonable and necessary," to consider type of service provided and whether service was provided in appropriate, cost-effective setting); *Goodman v. Sullivan,* 891 F.2d 449, 450-51 (2d Cir. 1989) (per curiam) (affirming exclusion of experimental procedures from Medicare coverage pursuant to requirement that procedures be "reasonable and necessary"); *see also Friedrich v. Sec'y of Health & Human Servs.,* 894 F.2d 829, 831 (6th Cir. 1990) (noting that the Health Care Financing Administration, when determining whether a procedure is "reasonable and necessary," considers the procedure's safety, effectiveness, and acceptance by medical community).[21]

The court concluded that "[i]nasmuch as [the relator] challenges only the quality of defendants' spirometry tests and not the decisions to order this procedure for patients, she fails to support her contention that the tests were not medically necessary."[22]

Finally, as to the defendants' representation on the certification that services are "rendered under the physician's immediate personal supervision by his/her employee," which the court noted covers the medical assistants' performance of spirometry at defendants' direction, the court ruled that the relator did not tender "evidence to support an allegation that the defendants did not 'personally furnish' the spirometry tests as required by the HCFA-1500 form."[23] Hence, the court held that the "plaintiff's cause of action insofar as it is founded on express false certification is without merit."[24]

2. The Relator's Theory Based Upon an "Implied" False Certification

Besides the relator's theory that the defendants submitted an expressly false certification, the relator, in the alternative, asserted that the defendants, in submitting the HCFA-1500, made an implied false certification. The court pointed out that under some case law authority a certification can be implicitly false based upon the notion that "the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment."[25]

However, the court specifically declined to expand this doctrine into the healthcare context because such an expansion would cause the FCA to conflict with local or private regulation of medical issues concerning the standard of care:

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21 *Id.* at 698-99.
22 *Id.* at 699.
23 *Id.*
24 *Id.*
25 *Id.* (citation omitted). Specifically, the court cited to *Ab-Tech Construction, Inc. v. United States,* 31 Fed. Cl. 429 (Fed. Cl. 1994), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1995) (unpublished table decission). *Id* at *26-*27.

> [T]he False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations — but rather only those regulations that are a precondition to payment — and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the Act's reach. Moreover, a limited application of implied certification in the health care field reconciles, on the one hand, the need to enforce the Medicare statute with, on the other hand, the active role actors outside the federal government play in assuring that appropriate standards of medical care are met. Interests of federalism counsel that the regulation of health and safety matters is primarily, and historically, a matter of local concern.
>
> Moreover, permitting *qui tam* plaintiffs to assert that defendants' quality of care failed to meet medical standards would promote federalization of medical malpractice, as the federal government or the *qui tam* relator would replace the aggrieved patient as plaintiff. *See* Patrick A. Scheiderer, Note, Medical Malpractice as a Basis for a False Claims Action?, 33 Ind. L. Rev. 1077, 1098-99 (2000). Beyond that, we observe that the courts are not the best forum to resolve medical issues concerning levels of care. State, local or private medical agencies, boards and societies are better suited to monitor quality of care issues.[26]

Because of the poor fit of the FCA implied certification theory in the healthcare quality of care context, the court ruled that the "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid."[27] Accordingly, "[l]iability under the Act may properly be found therefore when a defendant submits a claim for reimbursement while knowing — as that term is defined by the Act, *see* 31 U.S.C. § 3729(b) — that payment expressly is precluded because of some noncompliance by the defendant."[28]

Under this interpretation of an implicit false certification, the court found that the relator's claim could not survive. The relator had asserted that compliance with §§ 1395y(a)(1)(A) and 1320c-5(a) of the Medicare statute is a precondition to a request for federal funds and that submission of an HCFA-1500 form attests by implication to the providers' compliance with both of those provisions.[29] Section 1395y(a)(1)(A) of the Medicare statute states that "**no payment may be made** under [the Medicare statute] for any expenses incurred for items or services which . . . are not **reasonable and necessary** for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[30] Because this section contains an express condition of payment — that is, "no payment may be made" — it explicitly links each Medicare payment to the requirement that the particular item or service be "reasonable and necessary."

The court rejected the relator's theory because the reasonable and necessary test did not address the quality of a service that was provided. Specifically, the court reasoned, consistent with its analysis of the relator's express certification claim, that "the requirement that a service be reasonable and necessary generally pertains to the selection of the particular

26 *Id.* at 699-700 (citations and internal quotations omitted).
27 *Id.* at 700 (citation omitted). *Accord In Re Genesis Health Ventures, Inc.*, 272 B.R. 558, 570 (Bkrtcy. D. Del. 2002) ("The notion of implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states that the provider must comply in order to be paid.… No specificity regarding the provision of credits for returned drugs to Medicaid as a condition of payment to a provider [exists]. Therefore, the claimant's cause fails under the 'legally false certification' theory") (citation omitted).
28 *Id.*
29 *Id.* at 700.
30 42 U.S.C. § 1395y(a)(1)(A) (emphasis supplied).

procedure and not to its performance…. While such factors as the effectiveness and medical acceptance of a given procedure might determine whether it is reasonable and necessary, the failure of the procedure to conform to a particular standard of care ordinarily will not."[31] Accordingly, because the relator had only contended that the "defendants' performance of spirometry was qualitatively deficient, her allegations that defendants falsely certified compliance with § 1395y(a)(1)(A) may not succeed."[32]

Similarly, the court rejected the relator's claim of an implicit false certification regarding section 1320c-5(a) of the Medicare Act. That section provides:

> It shall be the obligation of any health care practitioner . . . who provides health care services for which payment may be made . . . to assure, to the extent of his authority that services or items ordered or provided by such practitioner . . .
>
> (1) will be provided economically and only when, and to the extent, medically necessary;
>
> (2) will be of a quality which meets **professionally recognized standards of health care**; and
>
> (3) will be supported by evidence of medical necessity and quality . . . as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.[33]

The relator had contended that the ATS guidelines comprise a "professionally recognized standard of health care" for spirometry, and that the defendants had implicitly certified compliance with that standard when they submitted HCFA-1500 forms for spirometry tests. However, the court concluded that the relator's "allegations cannot establish liability under the False Claims Act because — unlike § 1395y(a)(1)(A) — the Medicare statute does not explicitly condition payment upon compliance with § 1320c-5(a)."[34] Specifically, the court found that this statutory provision simply authorizes the peer review organization to recommend sanctions, after reasonable notice and the opportunity for corrective action by the provider, and if HHS agrees that sanctions should be imposed, and further finds the provider unwilling or unable substantially to comply with its obligations, HHS may exclude the provider from the Medicare program or mandate the repayment of the cost of the noncompliant service to the United States "as a condition to the continued eligibility" of the health care provider in the Medicare program.[35] Accordingly the court ruled that because "§ 1320c-5(a) does not expressly condition payment on compliance with its terms, defendants' certifications on the HCFA-1500 forms are not legally false. Consequently, defendants did not submit impliedly false claims by requesting reimbursement for spirometry tests that allegedly were not performed according to the recognized standards of health care."[36]

Finally, on policy grounds, the court concluded that its interpretation of what constitutes an implicitly false claim conformed the FCA to the Medicare Act. Specifically, the court reasoned:

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31 *Id.* at 701 (citations omitted).
32 *Id.*
33 42 U.S.C. § 1320c-5(a) (emphasis added).
34 *Id.* at 701.
35 *Id.* at 702.
36 *Id.*

> Our holding — that in submitting a Medicare reimbursement form, a defendant implicitly certifies compliance with § 1395y(a)(1)(A), but not § 1320c-5(a) — comports with Congress' purpose…. Section 1395y(a)(1)(A) mandates that a provider's choice of procedures be "reasonable and necessary"; it does not obligate federal courts to step outside their primary area of competence and apply a qualitative standard measuring the efficacy of those procedures. The quality of care standard of § 1320c-5(a) is best enforced by those professionals most versed in the nuances of providing adequate health care.[37]

3. The Relator's Theory that the Defendants' Services were Worthless

The final issue the court considered was the relator's allegation that the defendants' service was so deficient that it was "worthless" and that the knowing submission of a claim for a worthless service breached the FCA.

As an initial matter, the court concurred with the relator that if the defendants' spirometry was so deficient as to be "worthless," the defendants' claims would be false. However, the court found no liability because the relator "makes no showing that defendants knowingly — as the Act defines that term — submitted a claim for the reimbursement of worthless services" and "adopted the Ninth Circuit's standard that the 'requisite intent is the knowing presentation of what is known to be false' as opposed to negligence or innocent mistake."[38]

Specifically, the court noted that the "[t]he notion of presenting a claim known to be false does not mean the claim is incorrect as a matter of proper accounting, but rather means it is a lie."[39] The court concluded that the relator could not satisfy that test because the defendants tendered evidence of their "genuine belief that their use of spirometry had medical value" such as the fact that spirometers' instruction manual which — contrary to the ATS guidelines — indicated that daily calibration is not required and that individual spirometers had been sent out for periodic servicing. Because of this "good faith belief that their spirometry tests were of medical value," the court concluded that the relator's "unsupported allegations to the contrary [did] not raise a triable issue of fact sufficient to bar summary judgment."[40]

B. Broad Construction of the FCA regarding the Standard of Care: *United States v. NHC Healthcare*

The second recent case that sheds light on the quality care issue is *United States v. NHC Healthcare Corp.*[41] There the government alleged that two residents at the defendant nursing home did not receive care that satisfied Medicare and Medicaid program standards. Specifically the government contended that "these residents developed pressure sores, incurred unusual weight loss, were in unnecessary pain … and ultimately died because of this care."[42] The defendant contended that the claims it submitted to the government were not false or fraudulent and that it could not have "known" that the claims were false.

The court, however, rejected defendant's contention, ruling that as a condition of receiving a per diem payment "the care facility agrees in principle to 'care for its residents in

37 *Id.*
38 *Id.* at 703 (citing *Hagood v. Sonoma County Water Agency,* 81 F.3d 1465, 1478 (9th Cir. 1996)).
39 *Id.* (citation omitted).
40 *Id.* at 704 (citation omitted).
41 115 F.Supp.2d 1149 (W.D.Mo. 2000).
42 *Id.* at 1151.

such a manner and in such an environment as will promote maintenance or enhancement of the quality of life'. 42 U.S.C. § 1396r(b) (quotation from Nursing Home Reform Act which all Medicare and Medicaid recipients are required to adhere to)."[43] Therefore, the Court held that in order for the United States to prove that it was fraudulently billed for the care given to the two residents at issue in this lawsuit it must demonstrate that the patients were not provided the quality of care which promotes the maintenance and the enhancement of the quality of life.[44]

The district court conceded that the standard it established was "amorphous" and "in need of further clarification."[45] However, the court clarified that the billing dispute in the case was "not **how** the Defendant turned, bathed, administered drugs to, and fed the two residents in question, but **whether** the Defendant did these things at all."[46] The court pointed out that it "would not find a cognizable claim under the FCA if the United States simply disagreed with a reasonable medical or care treatment administered by the Defendant. In that case, the Defendant would obviously be innocent of fraud in its billing practices, but rather it would simply be at odds with the entity that pays the treatment it provided."[47]

However it noted that "at this stage of the litigation the plaintiff need … only plead a sufficient cause of action" and that the court "cannot say as a matter of law that no set of facts which could be reasonably demonstrated by the Government could not result in FCA liability."[48] The court concluded that it "may indeed be a very difficult burden of proof for the Government to show that the Defendant did not provide the minimum level of care necessary under its obligation to the United States, but difficulty in proving a cause of action should not bar the cause from even being litigated."[49]

Subsequently, upon defendants' summary judgment motion, the court revisited the issue of whether the government stated a cause of action.[50] As part of the record before the court on defendants' motion for summary judgment was evidence that the defendants had received complaints from staff, residents, surveyors and family member regarding staffing levels and inadequate care. The court thus rejected the defendants' motion for summary judgment because the court found that based "upon complaints from staff, residents, surveyors and family members the Defendants knew or should have known that they had a staffing shortage that impinged upon their ability to properly care for their patients. Defendants also knew or should have known that if they did not have sufficient staff to properly care for their residents, then they should not have submitted bills to Medicare and Medicaid which represented that they provided such care."[51] Significantly, the court seemingly imposed an affirmative duty upon the defendants that once they received complaints to investigate those complaints or otherwise to be charged with knowingly submitting false claims.[52]

As these cases demonstrate, the government and *qui tam* relators have contended that if health care providers fail to satisfy professionally recognized standards of health care,

43 *Id.* at 1153.
44 *Id.*
45 *Id.*
46 *Id.* at 1155 (emphasis supplied).
47 *Id.* at 1153.
48 *Id.* at 1153-54.
49 *Id.* at 1154.
50 *United States v. NHC Health Care Corp.*, 163 F.Supp.2d 1051 (W.D. Mo. 2001).
51 *Id.* at 1058 (footnote omitted).
52 *See id.* ("If Defendants had knowledge that they had severe staffing shortages at their facility, then they had a duty to investigate to see whether all their residents, including Residents 1 and 2, were getting the minimum standard of care to which they were entitled. A reasonable jury could conclude from the record before this Court that Defendants knew that the claims for reimbursement which they submitted were false because [the defendant long term care facility] acted in reckless indifference as to whether Residents 1 and 2 were receiving all the care they were entitled to under Medicare and Medicaid. Finally, the Court holds that an entity who is charging the Government for a minimum amount of care provided to its residents should question whether understaffing might lead to undercare. The knowledge of the answer to that question is charged to the Defendants when they submitted their Medicare and Medicaid claim forms.")

they violate the FCA. Courts have rejected this theory of FCA liability. Although both the *Straus* and *NHC* courts concluded that the FCA may properly be invoked if the defendants' services are worthless, they also agreed that the FCA should not be used to call into question a health care provider's judgment regarding a specific course of treatment. By striking this balance, courts have appropriately limited the FCA from becoming a federal malpractice statute and courts into specialized medical panels evaluating whether the care provided could have somehow been better while appropriately penalizing those who fail to provide care altogether.

C. Additional Defenses in Quality of Care Cases

Besides defenses referenced in *Straus* and *NHC*, defendants should consider whether any of the following defenses are applicable in a quality of care case.

- *No falsity* – without any falsity, there can be no violation of the FCA. Hence, as axiomatic as it seems, the defendant should first ascertain what specific regulatory or contractual breach the plaintiff alleges occurred, and if there was no such breach, the defendant will prevail as a matter of law.[53]

- *Negligence* – mere negligence does not result in FCA liability. Accordingly, if the alleged breach resulted from negligence, the plaintiff's action should be dismissed.[54]

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53 *See United States ex rel. Bondy v. Consumer Health Foundation*, No. 00-2520, 2001 U.S.App.LEXIS 24238 at *13-*15 (4th Cir. Nov. 9, 2001) (the relator could not establish falsity because the relator did not demonstrate that "HCFA disapproved of [the apportionment statistic] method [the defendant used on its cost report] or that the method chosen was not in accordance with HCFA's established procedures"); *United States ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1073–74 (9th Cir. 1998) (no falsity when defendants' acts conformed with Veteran Administration payment guidelines); *United States ex rel. Lindenthal v. Gen. Dynamics Corp.*, 61 F.3d 1402, 1412 (9th Cir. 1995) (whistleblower's FCA claims for payment based on work that satisfied contractual obligations "could not have been 'false or fraudulent' within the meaning of the [False Claims Act]"); *United States ex rel. Glass v. Medtronic, Inc.*, 957 F.2d 605, 608 (8th Cir. 1992) (a statement cannot be false or fraudulent under the FCA when the statement is consistent with regulations governing the program); *United States ex rel. Bidani v. Lewis*, No. 97 C 6502, 2001 U.S. Dist. LEXIS 9204 at *14-*16 (N.D. Ill. June 29, 2001) (rejecting relator's claim that defendants breached the FCA because they breached the assignment rules by receiving payment rather than the patient because the relator "points to no regulation requiring that the patient also sign a separate assignment form nor any evidence that defendants were aware that they were violating any regulation. Since relator has not provided evidence (or a sufficient argument) in support of his assignment claim, he will not be permitted to file an amended complaint raising that claim"); *United States ex rel. Mathews v. HealthSouth Corp.*, 140 F. Supp. 2d 706, 710-13 (W.D. La. 2001) (rejecting the relator's claim that the defendant rehabilitation hospital's cost report certification was false because it failed to comply with "[m]edicare regulations and criteria [that] require" rehabilitation hospitals "to provide to all patients intensive rehabilitation service, which is defined as a minimum of three hours of therapy a day, five days a week," when the relator could not point to any such statute or regulation and hence had "failed to allege a fraudulent course of conduct or falsity in connection with [defendant's] certification of compliance in its … annual cost reports"); *United States ex rel. Ben-Shlush v. St. Luke's-Roosevelt Hosp.*, 97 Civ. 3664 (LAP), 2000 U.S. Dist. LEXIS 3039 at *8-*9 (S.D.N.Y. Mar. 10, 2000) (the court rejected the relator's contention that the defendant had falsely certified to the government that it had a written plan of discharge for plaintiff when, in fact, its written discharge plan was inadequate because "a review of the regulations cited by plaintiff does not support his position" in that plaintiff did not cite "any regulations mandating certification to [D]HHS regarding discharge planning" or "specify any information to be included in such a plan" and thus "plaintiff's allegations do not support a False Claims Act claim"); *United States ex rel. Swafford v. Borgess Med. Ctr.*, 98 F. Supp. 2d 822, 827-28 (W.D. Mich. 2000) (the court rejected the relator's allegation that defendant physicians breached their certification that the services they provided were "personally furnished" by them or by an "employee under [their] personal direction" when they billed for interpreting venous ultrasound studies by merely rewording the vascular technologist's worksheet summary when the technologist reported the results as either negative or negative with abnormality (and did not review the technologist's hard copy data (video tape results)) because no regulations mandated that the physicians must review the hard copy data in order to bill for the interpretations) (citation omitted), *aff'd*, 2001 U.S. App. LEXIS 26669 (6th Cir. Dec. 12, 2001); *United States ex rel. Gathings v. Bruno's Inc.*, 54 F. Supp. 2d 1252 (M.D. Ala. 1999) (the court rejected the relator's allegation that the defendants, which were pharmacies, defrauded the government by charging lower dispensing fees for Blue Cross/Blue Shield patients than they did for Medicaid patients, allegedly contrary to a contractual provision mandating that the Medicaid program be charged the same amount as the general public, because the defendants' practice did not breach any Medicaid standard regarding the amount of the dispensing fees); *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, No. 96-1380 *et al.*, 1999 U.S. Dist. LEXIS 13036 at *30-*32 (E.D. La. Aug. 20, 1999) (court dismissed relator's allegation that defendant submitted false claims when it billed the government for a price higher than it billed its best customers, because the relator could not point to any "statute or regulation imposing the obligation it asserts defendant has breached" and the "statute does not state that providers must charge Medicare the lowest rate billed to anyone"); *United States ex rel. Cox v. Iowa Health Sys.*, 29 F. Supp. 2d 1022, 1026 (S.D. Iowa 1998) (where defendant engages in a "standard billing practice within an industry" and relator can point to "no controlling authority" which would require defendant to bill in a contrary fashion, the court "must dismiss th[e] action" because the relator "cannot pursue a FCA allegation without a legitimate false claim"); *United States ex rel. Joslin v. Cmty. Home Health*, 984 F. Supp. 374, 379 (D. Md. 1997) (where defendants' practices conformed to the law "any representation to the Federal Government . . . is correct . . . and did not violate the FCA"); *cf. Gublo v. Novacare, Inc.*, 62 F. Supp. 2d 347 (D. Mass. 1999). In *Novacare,* relators alleged, in part, that defendant's claims were false because it overstated its Medicare fee schedule by failing to reduce it by the amount of the discounts it furnished to substantial customers other than Medicare, thus misrepresenting its "actual charge." The court dismissed relators' claims under Fed.R.Civ.P. 9(b), stating "relators fail to point to any section of the regulations that requires [the defendant] to factor discounts given to private insurers into the determination of its 'actual charges' for government billing purposes."

54 *See, e.g.,* 132 CONG. REC. 20,536 (Aug. 11, 1986) (Congress settled upon the "reckless disregard" standard "to assure that mere negligence, mistake, and inadvertence are not actionable under the False Claims Act") (statement of Sen. Grassley). Included below is only a brief summary of the applicable defenses. For a more comprehensive discussion of the defenses and interpretative case law, *see* Robert Salcido, FALSE CLAIMS ACT & THE HEALTHCARE INDUSTRY: COUNSELING & LITIGATION (American Health Lawyers Ass'n 1999) [hereinafter Salcido, FALSE CLAIMS ACT COUNSELING]; *see also* Robert Salcido, FALSE CLAIMS ACT & THE HEALTHCARE INDUSTRY: COUNSELING & LITIGATION: NOVEMBER 2000 SUPPLEMENT (American Health Lawyers Ass'n 2000) [hereinafter Salcido, FALSE CLAIMS ACT COUNSELING: NOVEMBER 2000 SUPPLEMENT].

- *Ambiguity* — If the underlying rules or regulations are ambiguous and the defendant relies upon a reasonable interpretation of the rules and regulations, there is no violation of the FCA.[55] Hence in each quality of care case, even if the defendant's interpretation of a rule is erroneous, if the defendant can show that it at least acted in conformance with a reasonable interpretation of the rule, there is no FCA liability.

- *Subjective standards* – Courts, in some contexts, have rejected the view that a claim can be false when compliance with the underlying legal standard or certification requires subjective judgment because, under these circumstances, there is no objective basis to use to ascertain whether the submitted claim is actually accurate or false.[56] Hence this defense may apply in quality of care cases that use standards such as requiring the provider to "promote maintenance or enhancement of the quality of life" because compliance with such a standard is inherently subjective.

55 *United States v. Krizek,* 859 F. Supp. 5, 9-10 (D.D.C. 1994) (because the relevant provision of the CPT itself, during the relevant time frame, was "ambiguous," the government could not state an FCA cause of action), *aff'd, in part, rev'd in part*, 111 F.3d 934 (D.C. Cir. 1997). *See also Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1477 (9th Cir. 1996) (when statute grants government discretion to allocate costs, contractor's reliance on the government's exercise of discretion in allocating costs does not render claim false because all that existed was proof of "a disputed legal issue," which is not enough "to support a reasonable inference" that the claim "was *false* within the meaning of the False Claims Act"); *United States v. Data Translation, Inc.*, 984 F.2d 1256 (1st Cir. 1992) (when supplier's actions conformed with industry practice and were otherwise reasonable, the government could not state a cause of action under the FCA); *United States ex rel. Swafford v. Borgess Medical Center*, 98 F. Supp. 2d 822, 831-32 (W.D. Mich. 2000) (where the relator had contended that in order to bill for an "interpretation or reading" of the "results of the test" of ultrasound studies the defendant physicians must do more than merely rely upon the findings of the technician and independently review the supporting data from which the technician arrived at her conclusions, the court rejected the relator's claim because it found that those terms were undefined and ambiguous and that the relator's position "devolves to a dispute over the meaning of the terms governing the delivery of the professional component of physicians services" and that such a "legal dispute is . . . insufficient" to establish FCA liability), *aff'd,* 2001 U.S. App. LEXIS 26669 (6th Cir. Dec. 12, 2001); *United States v. Napco Int'l, Inc.*, 835 F. Supp. 493, 498 (D. Minn. 1993) (because underlying regulation was ambiguous, the court would not permit the government to apply "an interpretative afterthought by the agency" against the contractor in an FCA action). *Cf. United States v. Southland Management Corp.*, No. 00-60267, 2002 U.S.App.LEXIS 6751 at *62 (5th Cir. Apr. 11, 2002) (pointing out that a "number of courts have recognized that, while a legitimate dispute regarding the meaning of a regulatory or statutory provision might preclude FCA liability, the government can nonetheless prove the falsity of a claim by establishing the unreasonableness of the defendant's interpretation of the regulation or contractual provision").

56 *See, e.g., United States ex rel. Mikes v. Straus*, 84 F.Supp.2d 427, 432 (S.D.N.Y. 1999), *aff'd other grounds,* 274 F.3d 687 (2d Cir. 2001); *United States ex rel. Swafford v. Borgess Medical Center*, 98 F.Supp.2d 822 (W.D.Mich. 2000), *aff'd,* 2001 U.S. App. LEXIS 26669 (6th Cir. Dec. 12, 2001). In *Swafford*, the relator contended that defendant physicians had breached a standard of care because, in interpreting the results of some vascular ultrasound tests, they relied upon a summary worksheet prepared by the vascular technologist rather than review the underlying data of the ultrasound studies (such as photographs, prints, or videotape of the ultrasounds). The relator contended that this practice amounted to "inadequate and pathetic patient care" and breached applicable standards of care, and thereby rendered the physicians' underlying claims to Medicare to be "implicitly" false even if no express rule or regulation precluded the physicians from engaging in this practice. *Id.* at 829-30. The court rejected the relator's theory, pointing out that the implicitly false theory has only prevailed when "the defendant's compliance with statutory or regulatory authority is so essential for reimbursement that, if the government had been aware of the defendant's non-compliance, it would have refused payment" and that "claims that fail to meet the relevant standard of care are nevertheless insufficient to establish falsity under the FCA." *Id.* at 831 (citations omitted). Thus the court concluded that the relator "cannot demonstrate a genuine issue of material fact with respect to false claims under the FCA, even if he can demonstrate defendants' practice failed to conform to the standard of care applicable to the interpretation of venous ultrasounds." *Id. See generally Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 731 (7th Cir.), *cert. denied* 120 S.Ct. 562 (1999). There the relator asserted that defendant's representation that it had tested incoming plasma for hepatitis and human immunodeficiency virus ("HIV") was false because its testing procedures were flawed and could be improved by adding one additional test to the plasma to ensure that the plasma was not contaminated with saline before testing it for hepatitis and HIV. The Seventh Circuit rejected this contention. It pointed out that experts could debate regarding whether the testing was "effective." *Id.* at 732. It concluded, however, that when the record reveals only "a dispute about whether [the defendant's] testing protocols could be improved," even an "affirmative answer to that question would not suggest that [the defendant's] representations to the United States in years past were false or fraudulent." *Id.* at 733. *But see United States v. Southland Management Corp.*, No. 00-60267, 2002 U.S.App.LEXIS 6751 at *56-*57 (5th Cir. Apr. 11, 2002) (rejecting the defendants' contention that the certification that housing is "decent, safe, and sanitary" is too inherently subjective to determine objectively whether a claim was true or false because the phrase in the certification has "a commonsense 'core of meaning' such that it is capable, without additional definition, of being understood by a factfinder called upon to evaluate whether a certification of compliance with this standard is objectively true or false"); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F.Supp.2d 35, 43 (D.Mass. 2000) (ruling that the government can state a cause of action that the defendants' claims breached 42 U.S.C. § 1320c-5(a)(1)'s mandate that healthcare services be "economically" provided, even though they did not certify compliance with that mandate, because "[s]ubmitting a claim under the false pretense of entitlement is fraudulent" and "the entitlement to Medicare reimbursement depends upon fulfilling an obligation to perform services economically," and thus the "government may proceed on this theory").

- *Advice of Counsel* — If the defendant can show that it relied upon the advice of counsel, courts will generally find that the defendant did not act with reckless disregard or deliberate ignorance of the law.[57]

- *Government knowledge* – Similarly, the FCA arguably does not apply when the government knows of the defendant's practices and notwithstanding that knowledge pays on the defendant's claims.[58]

II. THE CONSTITUTIONALITY OF THE FCA

It appears that the *qui tam* provisions of the FCA are constitutional. The two prime challenges to the constitutionality of the *qui tam* provisions have centered on whether relators have standing to sue on behalf of the United States when in fact they have not suffered any personal injury and whether the *qui tam* provisions impermissibly privatizes law enforcement. As to the standing issue, the Supreme Court has recently ruled that relators have constitutional standing to file *qui tam* actions.[59] As to the relator's ability to enforce federal law, several circuits have ruled that the relator's ability to institute litigation on behalf of the United States does not unconstitutionally infringe upon the Executive's Branch's

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57 *Cf. United States ex rel. Bidani v. Lewis*, No. 97 C 6502, 2001 WL 32868 (N.D. Ill. Jan. 12, 2001), *reh'g granted in part, denied in part,* 2001 U.S.Dist. LEXIS 9204 (N.D. Ill. June 29, 2001). In *Bidani*, the defendant doctor owned a dialysis facility that provided outpatient home dialysis services commonly known as "Method I" and a dialysis supply company that would contract with dialysis patients to provide necessary dialysis equipment and related supplies for self-administered home dialysis under a program commonly known as "Method II." *Id.* at *5. The defendant doctor and his owned dialysis facility would refer patients to his owned dialysis supply company for participation in the Method II program. *Id.* The defendant doctor and his owned companies had fully apprised their lawyers of the structure of the arrangement and had never been informed that the arrangement was unlawful until the Stark Law became operational, at which time the arrangement ceased. *Id.* at *10. The relator contended that the defendant doctor and his owned companies breached the FCA because the referrals breached the Anti-Kickback Statute and that they breached the FCA because the dialysis supply company did not qualify as a proper supplier because of the doctor's common ownership of both companies. The court ruled that the relator could not prove that the defendants acted with the requisite intent to violate the FCA because, based upon advice of counsel, they had a good faith belief that the arrangement complied with the applicable laws and regulations. Specifically, in granting summary judgment to the defendants, the court reasoned that because of the level of communications flowing from the defendants to their attorneys regarding Medicare rules and regulations, the relator could not prove that the defendants "knowingly presented or knowingly caused to be presented any false Medicare claims":

> The undisputed evidence establishes that [the defendant doctor] sought the advice of attorneys in purchasing [the hospital's] dialysis facility, incorporating [the dialysis supply company] and [the facility company], and regarding the operations of [the supply company] as a dialysis supplier. The attorneys, who also did the incorporation work for [the supply company and the facility], were fully aware of the ownership relationship between the two entities and that one functioned as a Method I dialysis facility and one as a Method II dialysis supplier. There is no indication that [the defendant doctor] hid from the attorneys any pertinent facts regarding the ownership relationship. [The defendant doctor] was continually advised that his operations were lawful and, when advised of changes in applicable statutes and regulations, [he] accordingly revised his conduct. When finally advised that the ownership relationship would be unlawful under a new statute [i.e., the Stark law], [the supply company] ceased operations before the new statute went into effect. The only reasonable inference that can be drawn from the undisputed evidence is that [the defendant doctor] (and the entities he controlled) had no actual knowledge during the pertinent time period that the common ownership either prohibited [the defendant doctor] from referring patients to [the supply company] or that [the supply company] failed to qualify as a dialysis supplier because of the common ownership. Neither can it be inferred that [the defendant doctor] deliberately ignored or acted in reckless disregard of the truth. Therefore, it cannot be found that [the defendant doctor] knowingly presented or knowingly caused to be presented any false Medicare claims and defendants are entitled to summary judgment on the remaining FCA claims.

Id. However, when there is no reliance on counsel and the person submits an unsupportable fact to the government, the court may impose FCA liability. *See, e.g., United States v. Medco Physicians Unlimited*, No. 98 C 1622, 2001 WL 293110 (N.D. Ill. Mar. 26, 2001). In *Medco*, the person signing the cost report had affixed an addendum stating that the disputed meal and transportation costs had been included in the cost report because he believed that such inclusion was consistent "with regulations issued in February, 1994." *Id.* at *3. The court found that the person's statement was knowingly false because, when challenged, he could not "cite to any regulations in 1994" that supported his contention. For a summary of the case law specifically applying these defenses, *see* Salcido, FALSE CLAIMS ACT COUNSELING §§ 2:03, 2:05; Salcido, FALSE CLAIMS ACT COUNSELING: NOVEMBER 2000 SUPPLEMENT at 10-27, 30-37.

58 *See United States ex rel. David Bennett v. Benetics & IVF Institute*, No. 98-2119, 1999 U.S.App.LEXIS 27911 (4th Cir. Oct. 28, 1999) (although the defendant's contract mandated that, in conducting paternity testing, it conduct two tests, it informed the government entity that it would perform only one test [since DNA testing was more accurate than the previously used serology testing] both before the contract was awarded and after it was awarded but before performance began; the court affirmed the district court's determination that no reasonable jury could conclude that the defendant had the requisite intent under the FCA because the government knew of defendant's practices and had not objected); *United States ex rel. Durcholz v. FKW, Inc.*, 189 F.3d 542, 545 (7th Cir. 1999) ("If the government knows and approves of the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim. In such a case, the government's knowledge effectively negates the fraud or falsity required by the FCA"); *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999) (When the governmental entity had fully reviewed defendant's practices [including the alleged violations], the "notion that [it] was somehow being duped by the [defendant] at this point in the process is absurd….[The relator], it seems, wants to use the FCA to preempt the [agency's] discretionary decision not to pursue regulatory penalties against the [defendant]. But the FCA is not an appropriate vehicle for policing technical compliance with administrative regulations. The FCA is a fraud prevention statute; violation of the [agency's] regulations are not fraud unless the violator knowingly lies to the government about them"); *but see United States v. Southland Management Corp.*, No. 00-60267, 2002 U.S.App.LEXIS 6751 at *49-*52 (5th Cir. Apr. 11, 2002) (holding that in "the context of government-initiated FCA actions, [the court] would permit a 'government knowledge defense' primarily in the rare situation where the falsity of a claim is unclear and the evidence suggests that the defendant actually believed his claim was not false because the government approved and paid the claim with full knowledge of the relevant facts" and finding that because "the record indicates that the Defendants … had actual knowledge" that their certifications were false, "a factfinder could determine on this record that the Defendants knowingly submitted false claims to the government"); *Shaw v. AAA Engineering & Drafting Inc.*, 213 F.3d 519, 534 (10th Cir. 2000) (rejecting the government knowledge defense when it was the relator who disclosed the underlying practice *to the government* (not her employer), and the employer was evasive when questioned about the practice by the government).

59 *See Vermont Agency of Nat. Res. v. United States*, 120 S. Ct. 1858 (2000).

duties under Article II's Take Care Clause, which commands that the Executive "take Care that the Laws be faithfully executed."[60]

However, an issue that will become widely litigated in quality of care cases – where the computation of damages is amorphous at best – is whether the FCA's penalty is so disproportionate to the government's damages as to render the application of the FCA to be in violation of the Eighth Amendment proscription on excessive fines.

The FCA provides that the United States may obtain treble damages and civil penalties of $5,000 to $10,000 for each violation of the statute.[61] Recently, courts have evaluated how to apply the FCA's treble damage and civil penalty provisions when the government's demonstrated damages are substantially below the judgment the plaintiff would obtain by operation of the FCA. Specifically, because of the Supreme Court's characterization of FCA damages as being "essentially punitive in nature,"[62] courts have declined to automatically apply the FCA's treble damage provisions and civil penalty provisions when the government's recovery would be substantially disproportionate to its damages.

The latest case applying this principle is *United States v. Mackby*.[63] There the Ninth Circuit concluded that "the civil sanctions provided by the False Claims Act are subject to analysis under the [Constitution's] Excessive Fines Clause because sanctions represent a payment to the government, at least in part, as punishment. Inquiry must be made, therefore, to determine whether the payment required by the district court is so grossly disproportionate to the gravity of [the defendant's] violation as to violate the Eighth Amendment."[64] Additionally, the court concluded that the FCA's treble damages provision was similarly subject to scrutiny to determine whether it was unconstitutionally excessive. Specifically, the court concluded that "the FCA's treble damages provision, at least in combination with the Act's statutory penalty provision, is not solely remedial and therefore is subject to an Excessive Fines Clause analysis under the Eighth Amendment. Accordingly, we remand to the district court for its consideration of the question whether a treble damage award in this case would be unconstitutionally excessive."[65]

Other courts have also recently applied this principle to limit the government's recovery under the FCA.[66] If the rule gains wide-spread application, it may have a significant impact on quality of care FCA cases. For example, in *Straus* had the plaintiff prevailed in establishing that the defendants' spirometry services were substandard and accordingly been awarded a civil penalty of $5,000 for each service, the plaintiff's recovery

60 *See United States ex rel Stone v. Rockwell*, 282 F.3d 787, 806 (10th Cir. 2001) ("we agree with the Fifth, Sixth, and Ninth Circuits, and hold that at least where the Government intervenes, the *qui tam* provisions of the FCA do not violate the separation of powers by transgression of the Take Care Clause") (citations omitted); *United States ex rel. Riley v. St. Luke's Episcopal Hosp*., 252 F.3d 749, 753-57 (5th Cir. 2001); *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 747–59 (9th Cir. 1993); *United States ex rel. Kreindler & Kreindler v. United Techs. Corp*., 985 F.2d 1148, 1153–55 (2d Cir. 1993); *United States v. Gen. Elec*., 41 F.3d 1032, 1041 (6th Cir. 1994).

61 For violations committed on or after Sept. 29, 1999, the defendant is liable for treble damages plus penalties ranging from $5,500 to $11,000 per claim. *See* Civil Monetary Penalties Inflation Adjustment, 64 Fed. Reg. 47,099, 47,103–47,104 (1999) (to be codified at 28 C.F.R. pt. 85). However, the statute also contains voluntary disclosure provisions under which a provider's exposure to liability is limited to double the government's damages and civil penalties.

62 *Vermont Agency of Nat. Res.*, 120 S.Ct. at 1869.

63 261 F.3d 821 (9th Cir. 2001).

64 *Id.* at 830 (citation omitted).

65 *Id.* at 831 (citations omitted).

66 *See, e.g., United States ex rel. Garibaldi v. Orleans Par. School Bd.*, 46 F.Supp.2d 546, 564-65 (E.D.La. 1999), *vacated on other grounds* 244 F.3d 486 (5th Cir. 2001). There, the district court noted that the Fifth Circuit, in *Peterson v. Weinberger*, 508 F.2d 45, 55 (5th Cir. 1975), had previously ruled that courts can exercise their discretion to ensure that the penalties assessed "reflect a fair ratio to damages" and that the "Government completely recoups its losses." The district court believed that, notwithstanding the 1986 legislative amendments to the FCA mandating civil penalties of $5,000 to $10,000 per violation, the *Peterson* ruling remained "good law" in the circuit. Applying that standard, the court found that, in a case in which the jury verdict was $7.4 million (which would be trebled to $22.8 million) and the civil penalties equaled $7,850,000, the judgment was "excessive;" thus, the court exercised its discretion to reduce the forfeiture from $7,850,000 to $100,000. The court noted that a "penalty of $100,000 is an adequate forfeiture, as the automatic trebling of the verdict as prescribed in the statute has already resulted in a judgment for $15.8 million more than was actually falsely claimed by the [defendant]." *Cf. United States v. Cabrera-Diaz*, 106 F.Supp.2d 234 (D.P.R. 2000). In *Cabrera-Diaz*, upon granting the United States' motion for a judgment of default, the district court applied the treble damage provision in computing the amount of the judgment but expressly refused to apply any civil penalties because the number of penalties would be "excessive." *Id.* at 242 ("If this Court was to imposed [sic] civil penalties of between $5,000.00 to $10,000.00 for each of the one of the 455 false claims, in addition to the treble damages, the same would range between $2,275,000.00 and $4,550,000. We deem this amount to be excessive and therefore no civil penalties are hereby imposed").

would be substantially disproportionate to the government's damages – even assuming that the government's full damages would be the amount it paid for the service – because the charge for the service is substantially less than $5,000. Under these circumstances, the government may win the battle (a court finding a violation of the FCA) but lose the war because the court declines to grant any measurable recovery to the government.[67]

III. CONCLUSION

Consistent with the overall trend in FCA actions, courts in the future will review an increasing number of quality of care FCA actions. However, a solid foundation is beginning to take shape to evaluate these claims. Specifically, consistent with the approach developed in *Straus* and *NHC*, courts should consider whether there was a total failure of care – rather than a mere lack of quality care – in determining whether the defendant knowingly submitted a false claim. Further, consistent with the Eighth Amendment of the Constitution, courts should carefully evaluate whether the plaintiff's recovery in these cases is proportionate to its damages.

67 Under these circumstances, however, the defendant's victory may be short-lived because if the court found a substantial violation of the law, the government would presumably exercise its discretion to exclude the provider from participation in federal health care programs.