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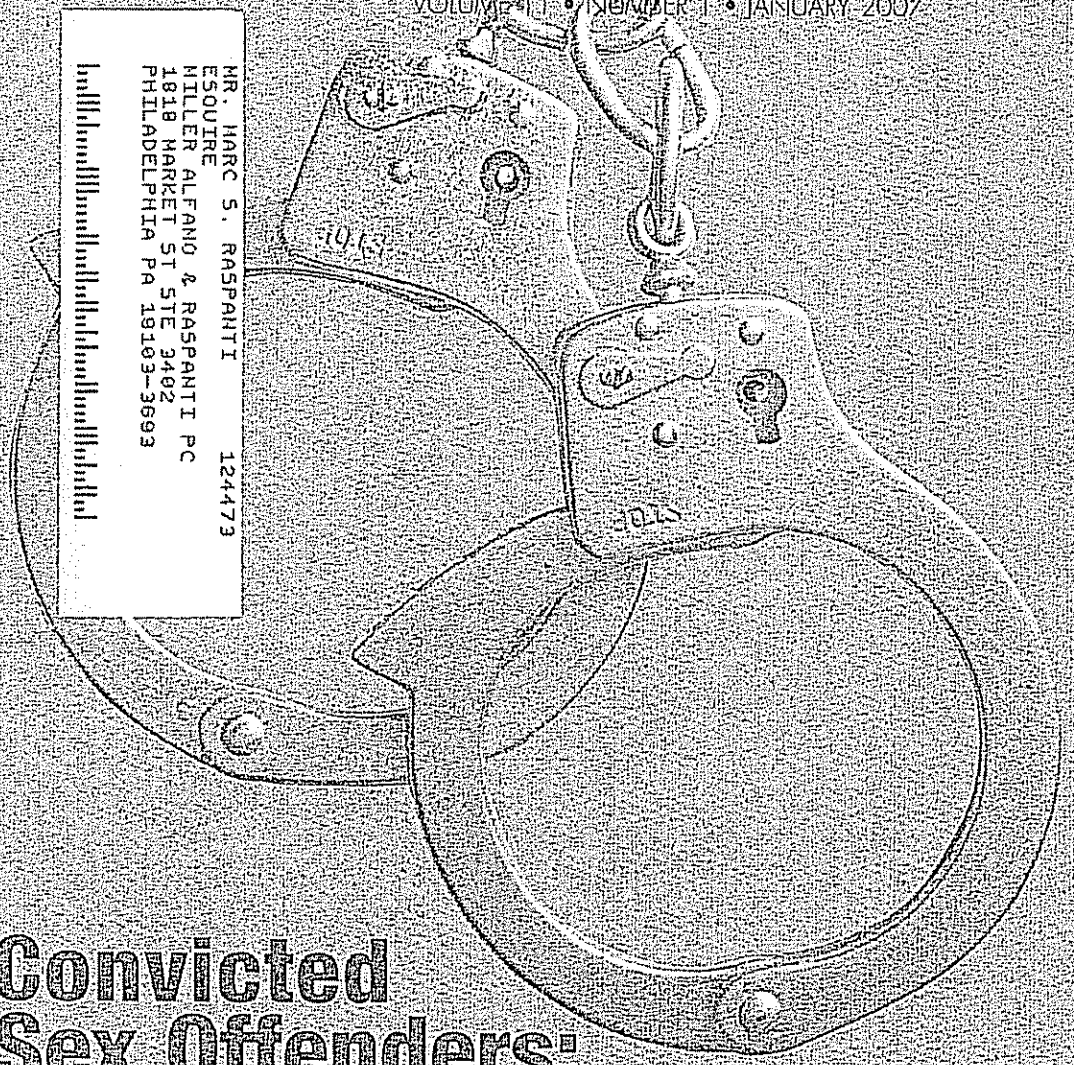

Convicted Sex Offenders:

Ramifications for Long Term Care—8

Modern False Claim Act Liability: Cradle to Grave Liability?—Part II—42

Focus On Consultants & Expert Witnesses— Page 29

HEALTH LAW ANALYSIS
JANUARY 2007

Modern False Claims Act Liability: Cradle to Grave Liability?—Part II

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I. INTRODUCTION

This article is the second in a two-part series examining the potential for "cradle to grave liability" under the modern False Claims Act (FCA), namely from the inception of the receipt of federal funds until termination of participation in a federally funded program. The first part of this article, published last month, provided a brief overview of FCA liability principles and began the discussion of FCA theories of liability. This article completes that discussion by examining the other major theories of expanding liability under the FCA.

II. FCA THEORIES OF LIABILITY

While courts have addressed a variety of liability theories under the FCA, there are certain major theories of liability to be considered in connection with almost any modern FCA case. Last month, we examined FCA theories of liability based on fraudulent inducement of a contract and on false certification of compliance with federal or state law. This month, we will delve into the other major FCA theories of liability including for providing "worthless services," for inadequate quality of care, for off-label uses of prescription drugs, and for failure to comply with contract requirements.

A. FCA Liability for Providing "Worthless Services"

Another developing theory of liability under the FCA is known as "worthless services." This theory is based on the assertion that, although some or all services were actually provided, the services were of "no value" or essentially "worthless." A growing number of courts have recognized the viability of this theory. For example, as held by the U.S. Court of Appeals for the Ninth Circuit in *United States ex rel. Lee v. SmithKline Beecham, Inc.*:

> [K]nowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under § 3729, regardless of any false certification conduct.
>
> * * *
>
> If . . . a party to a government contract knowingly or with deliberate ignorance charged the government for worthless services, then there would be fraud on the government that may be pursued under the FCA.

United States ex rel. Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001). As also held by the U.S. Court of Appeals for the Second Circuit:

> We agree that a worthless services claim is a distinct claim under the [False Claims] Act. It is effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided. In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all.

Mikes, 274 F.3d at 703 (citation omitted); *see also In re Genesis Health Ventures, Inc.*, 112 Fed. Appx. 140, 143 (3d Cir. 2004) (nonprecedential opinion) ("Case law in the area of 'worthless services' under the FCA addresses instances in which either services literally are not provided or the service is so substandard as to be tantamount to no service at all."); *United States ex rel. Nudelman v. Int'l Rehab. Assocs., Inc.*, Civ. A. No. 00-1837, 2006 WL 925035,

at *15 (E.D. Pa. Apr. 4, 2006) (quoting *Genesis Health Ventures*); *United States ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1221 (E.D. Cal. 2002) (recognizing existence of worthless services claim but dismissing claim because plaintiff "does not allege that [Defendant's] neglect of its patients was so severe that, for all practical purposes, the patients were receiving no room and board services or routine care at all . . . ."). Participants in government-funded programs, therefore, must be aware of a potential claim that the services provided were so deficient as to be deemed "worthless." In the context of any "worthless services" claim, the key inquiry will be whether any value was provided by the putative defendant.

B. FCA Liability for Inadequate Quality of Care

A corollary to the theory of "worthless services" is based on allegations that a medical provider failed to provide sufficient "quality of care" to patients. In *United States ex rel. Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc.*, the court held that such allegations sufficiently stated a claim under the FCA:

> Statutes and regulations governing the Medicaid program clearly require health care providers to meet quality of care standards, and a provider's failure to meet such standards is a ground for exclusion from the program.
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> * * *
>
> In this case, the second amended complaint alleges that [Defendant] charged the government for in-patient care of children and adolescents "who were subjected to unreasonable risks of physical and mental harm, including sexual perpetration" and "the risk of harm was sufficiently unreasonable, and the risks of harm known by [Defendant] were sufficiently frequent and blatant, that it was improper for [Defendant] to admit government insured patients into such an environment and to bill the Government Payors for the care of these patients." The Court declines to hold that these allegations, if proved, cannot form the basis of an FCA claim.

United States ex rel. Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc., 945 F. Supp. 1485, 1488-89 (W.D. Okla. 1996) (citation omitted). Similarly, in *United States v. NHC Healthcare Corp.*, although recognizing the difficulties in proof the government might have in ultimately pursuing the claim, the court, nevertheless, denied a defendant's motion to dismiss the FCA "quality of care" claim, holding that:

> Unlike performing medical tests, when caring for the infirmed it is not the end product result that it [sic] crucial, it is the dignity and quality of life provided through the care process. The Government has alleged that this essential agreement was grossly violated and the Court finds that for purposes of a motion to dismiss, this allegation satisfies the requirements under the FCA.

United States v. NHC Healthcare Corp., 115 F. Supp. 2d 1149, 1155 (W.D. Mo. 2000).

Decisions subsequent to *Aranda*, however, have refused to recognize an FCA claim based on quality of care issues. *See, e.g., Sweeney v. ManorCare Health Servs., Inc.*, No. CO3-5320RJB, 2005 WL 4030950, at *5 (W.D. Wash. Mar. 4, 2005) ("[Plaintiff's] first claim, that because [Defendant's] quality of care is so poor it is violating the FCA, fails to state a claim upon which relief can be granted.[1] [Plaintiff's] claim in essence is based on alleged regulatory violations."); *United States ex rel. Bailey v. Ector County Hosp.*, 386 F. Supp. 2d 759, 766 (W.D. Tex. 2004) ("[T]he False Claims Act should not be used to call into question a health care provider's judgment regarding a specific course of treatment . . . . Thus, the Court finds the Relator has not pled a cognizable claim under [the] False Claims Act regarding his quality of care claim."). The rationale for not allowing purportedly deficient "quality of care" to constitute an FCA violation is that allowing such a claim:

> would promote federalization of medical malpractice, as the federal government or the *qui tam* relator would replace the aggrieved patient as a plaintiff. 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.

Mikes, 274 F.3d at 700 (citation omitted).

In connection with a potential "quality of care" FCA claim, the key debate will be whether the particular service simply constitutes a "medical judgment" rather than compliance with a statutory, regulatory, or contractual obligation or failure to render a mandated service. If a party can frame the issue as the former, it may defeat the attempted FCA claim. If the court views it as the latter, the "quality of care" claim will be allowed to proceed at least through discovery. In the healthcare context, therefore, "quality of care" remains an FCA issue.

C. FCA Liability for Off-Label Uses of Prescription Drugs

The reach of the FCA also has extended to claims based on the marketing and promotions of so-called "off label" prescription medications under the federal Medicare/Medicaid Programs. "Off label" uses of medications are those "which are different than those approved by the FDA [Food and Drug Administration]." *Parke-Davis*, 147 F. Supp. 2d at 44.

In *Parke-Davis*, the court held that a plaintiff sufficiently stated a claim for violation of the FCA for "off label" prescription medications, holding that:

> Relator alleges more than a mere technical violation of the FDA's prohibition on off-label marketing. The gravamen of Relator's claim is that Parke-Davis engaged in an unlawful course of fraudulent conduct including knowingly making false statements to doctors that caused them to submit claims that were not eligible for payment by the government under Medicaid. Thus, the alleged FCA violation arises—not from unlawful off-label marketing activity itself—but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct.

Parke-Davis, 147 F. Supp. 2d at 52. *Id.* at 48 (complaint "describ[es] a scheme of fraud designed to increase the submission of off-label prescriptions for [the drug] for payment by Medicaid" and "false statements made to physicians to induce off-label prescriptions"). Equally significant, the court further held that: "The fact that such prescriptions are for an off-label use is material because, as the Defendant does not dispute, the government would not have paid the claim if it had known of the use to which they were being submitted." *Id.* at 53. As recognized by the court in *Parke-Davis*: "Relator's theory of liability takes the parties into territory that is not well chartered by the existing decisional law." *Id.* Nevertheless, the court allowed the FCA claim to proceed.[2]

Recently, in *United States ex rel. Hess. v. Sanofi-Synthelabo Inc.*, Civ. A. No. 4:05 CV 570; 2006 WL 1064127 (E.D. Mo. Apr. 21, 2006), the court distinguished the *Parke-Davis* decision and granted a defendant's motion to dismiss an FCA action. The court concluded that the plaintiff failed to allege sufficiently: (1) the materiality of the allegedly false misrepresentations (*i.e.*, the misrepresentations were critical to the decision to pay) (*id.* at *7-8); (2) the necessary intent required under the FCA because "[p]laintiff neither alleges that Defendant deliberately lied nor the data provided by Defendant either to its sales representatives or to doctors was incorrect or false" (*id.* at *9); (3) the identity of specific physicians contacted by the defendant who allegedly then submitted false claims to Medicare (*id.* at *10); and (4) "how" the defendant allegedly induced impermissible "off-label" uses of the drug at issue (*id.*). The *Hess* decision, therefore, while recognizing the viability of a potential FCA claim, demonstrates that any such claim must be supported with detailed factual allegations about the alleged fraud.

In a potential FCA action based on "off-label" prescription medications, the initial key inquiries will be: (1) the identification of purportedly false information to promote a specific drug for "off-label" uses; (2) whether the purportedly false information was material to coverage under the Medicare and/or Medicaid Programs; and (3) whether FDA approval exists or was not necessary for the particular "off-label" drug at issue.

D. FCA Liability for Failure to Comply with Contractual Requirements

Under certain circumstances, the simple failure to perform a service required by contact can result in liability under the False Claims Act. This was the result reached in *Shaw v. AAA Engineering & Drafting, Inc.*, 213 F.3d 159 (10th Cir. 2000). In *Shaw*, the defendant undertook to: "provide the equipment necessary for silver recovery and was required to dispose of the used filter and other chemicals in accordance with Environmental Protection Agency ('EPA') guidelines and standard." *Shaw*, 213 F.3d at 527.

The U.S. Court of Appeals for the Tenth Circuit refused to set aside the jury verdict of FCA liability, holding that the plaintiff "presented sufficient evidence demonstrating AAA [the defendant] submitted invoices for full payment on the contract knowing it had failed to comply with the silver recovery contract requirement[.]" *Shaw*, 213 F.3d at 533; *see generally United States ex rel. Hunt*, 336 F. Supp. 2d at 439, 440 ("Medco billed Blue Cross and hence the Government for services it was required to render in accordance with its contract and with state law—any claims submitted that do not fulfill these prerequisites are false."); *United States ex rel. Stebner v. Stewart & Stevenson Servs., Inc.*, 305 F. Supp.2d 694, 700-01 (S.D. Tex. 2004) ("[A] contractor's mere request for full payment inherently represents that he has tendered a complete and conforming performance. . . . [A] request for full payment becomes a material misrepresentation when the Government does not receive the benefit of its bargain. Indeed, an FCA violation occurs when the contractor 'knowingly' makes a material misrepresentation."); *United States ex rel. Fallon v. Accudyne Corp.*, 921 F. Supp. 611, 621 (W.D. Wis. 1995) ("If a contractor knowingly fails to perform testing as required by a contract, and tenders the untested goods, making a claim for full payment it has surely submitted a false claim. Under such circumstances a false claim may arise from not advising of a failure to perform a material part of the contract.").

The legal conclusion that FCA liability results from claims for services not provided in accordance with contractual

requirements has support in the legislative history for the False Claims Act, which states that: "[A] false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation." S. Rep. No. 99-345 at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274.

Where the contract specifically requires compliance with federal and state law, a defendant's failure to comply with such laws may give rise to FCA liability. *See, e.g., United States ex rel. Holder,* 296 F. Supp. 2d 1167, 1176-77 (C.D. Cal. 2003) ("In the instant case, however, the contracts specifically state that SDI [the defendant] must comply with a series of laws and regulations . . . . The regulations were there for a reason.") ("[I]f SDI is ignoring important aspects of the contract in order to increase its profits, i.e. environmental and safety regulations, it is possible that a cause of action might lie under the False Claims Act."). Accordingly, strict compliance with contractual requirements and a mechanism for monitoring such compliance will be essential as any deviation may result in an FCA claim.

E. FCA Liability Based on Failure to Comply with Federal or State Law and Regulations

Historically, FCA liability did not arise for mere non-compliance with federal or state law and regulations. *See, e.g., United States ex rel. Cantekin v. Univ. of Pittsburgh,* 192 F.3d 402, 416 (3d Cir. 1999) ("[N]ot every regulatory violation is tantamount to making a knowingly false statement to the government."); *United States ex rel. Hopper v. Anton,* 91 F.3d 1261, 1266 (9th Cir. 1996) ("Violations of laws, rules or regulations, alone do not create a cause of action under the FCA."). A growing number of recent decisions, however, have recognized potential FCA liability for alleged violations of federal and state laws or regulations.

For example, in *United States ex rel. Franklin v. Parke-Davis,* 147 F. Supp.2d 39 (D. Mass. 2001), the court allowed an FCA claim to proceed against a pharmaceutical manufacturer based on alleged violations of the Federal Food, Drug, and Cosmetics Act (FDCA), 21 U.S.C. § 360aaa *et seq.*, despite the fact that the FDCA did not provide for a civil damage remedy, holding that:

> [T]he FCA *can* be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentations made to obtain a government benefit.
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> * * *
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> Thus, the failure of Congress to provide a cause [of] action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government in violation of 25 U.S.C. § 3729(a).

Franklin, 147 F. Supp.2d at 51. Courts have recognized potential FCA claims in connection with alleged violations of a variety of federal and state statutes and regulations. *See, e.g., United States ex rel. Hunt,* 336 F. Supp. 2d at 439, 440 ("Medco billed Blue Cross and hence the Government for services it was required to render in accordance with its contract and with state law—any claims submitted that do not fulfill these prerequisites are false."); *Pickens v. Kanawha River Towing,* 916 F. Supp. 702, 705-06 (S.D. Ohio 1996) (FCA action involving Clean Water Act); *United States ex rel. Fallon v. Accudyne Corp.,* 880 F. Supp. 636, 638 (W.D. Wis. 1995) (FCA action based on failure to comply with environmental standards); *United States v. Incorporated Village of Island Park,* 888 F. Supp. 419, 439-40 (E.D. N.Y. 1995) (FCA action based on failure to comply with non-discrimination requirements). *See generally United States ex rel. Augustine v. Century Health Servs., Inc.,* 289 F.3d 409, 415 (6th Cir. 2002) ("[L]iability can attach [under the False Claims Act] if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned."). In any FCA action involving a highly regulated industry, therefore, a thorough analysis of the possible application of federal and state laws or regulations (which is particularly likely in the area of healthcare) must be undertaken in any effort to establish, avoid, or diminish FCA liability.

F. FCA Liability Based on Allegedly False Status Reports

Participants in government-funded programs may be under the mistaken belief that FCA liability may exist only for actual requests for payment and related documents supporting the request for payment. An increasing number of decisions, however, have recognized potential FCA liability based on purportedly false "status reports," which provide details of the government program at issue. *See, e.g., United States ex rel. Bryant v. Williams Building Corp.,* 158 F. Supp.2d 1001, 1009 (D. S.D. 2001) (holding that reasonable jury could find daily reports and progress reports were false in violation of Section 3729(a)(1) and (a)(2) of the FCA). Status reports may result in FCA liability under Section 3729(a)(2) regardless of whether the reports are actual invoices or requests for payment:

> [T]he district court failed to consider that the individual progress reports, though not in themselves

> actual invoices, might constitute 'false claims' or 'statements' under the [FCA]. We hold that if, as [Plaintiff] alleges, [the defendant] knowingly submitted false progress reports stating that the software delivered during the same period was complete when in fact it was not, then these progress reports would constitute false statements in support of false claims and would trigger the [FCA's] civil penalty. That the progress reports are not invoices is immaterial.

United States ex rel. Schwedt v. Planning Research Corp., 59 F.3d 196, 199 (D.C. Cir. 1995). *See also United States v. TDC Management Corp.*, 24 F.3d 292, 298 (D.C. Cir. 1994) ("To prevail under [3729(a)(2) of] the False Claims Act, the government must prove either that [the defendant] actually knew it had omitted material information from its monthly progress reports or that it recklessly disregarded or deliberately ignored that possibility.").

In any FCA action, therefore, each and every submission to the government (or even to a government contractor or subcontractor) must be analyzed as a potential basis for an FCA claim. Simply labeling a submission as a "status report" or "progress report" may not avoid potential FCA liability. The accuracy, completeness (and significance and materiality) of the particular reports at issue will be critical inquiries in an FCA action.

G. FCA Liability Based on Omission of Information

FCA liability also may arise where an entity either deliberately omits or recklessly fails to provide critical information regarding compliance with its obligations. In such circumstances, courts have recognized potential liability under the FCA. *See, e.g., United States v. TDC Mgmt. Corp.*, 288 F.3d 421, 426 (D.C. Cir. 2002) ("TDC [the defendant] thus defrauded the government by presenting reports in support of payment that omitted information indicating that it was acting in a manner that was contrary to the core terms of the Program"); *Ab-Tech Construction Inc. v. United States*, 31 Fed. Cl. 429, 434 (1994), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1985) ("[T]he Government was duped by Ab-Tech's active concealment of a fact vital to the integrity of that program. The withholding of such information—information critical to the decision to pay—is the essence of a false claim."); *BMY-Combat Systems Division of Harsco Corp. v. United States*, 38 Fed. Cl. 109, 125 (1997) ("[A]n implied representation on an invoice that work has been completed pursuant to the contract requirements may constitute a false claim for payment. In order for [a party] to show that an implied representation constituted a violation of the False Claims Act, [a party] must prove by a preponderance of the evidence that [a party] deliberately withheld information."). *See generally United States ex rel. Berge v. Board of Trustees of the Univ. of Ala.*, 104 F.3d 1453, 1460 (4th Cir. 1997) ("There can only be liability under the False Claims Act where the defendant has an obligation to disclose omitted information.").

Two important inquiries under this theory are whether: (1) the defendant, either as a matter of law or as a matter of contract, has an obligation to disclose information; and (2) whether the information that was known but yet withheld by the defendant arguably would have affected the payment decision. Under these circumstances, FCA liability may arise due to omission or non-disclosure by a putative defendant.

H. FCA Liability for Attempting to Conceal, Avoid, or Decrease an Obligation to the Government

In addition to direct liability under the FCA, there exists potential liability for the so-called "reverse false claim." A "'reverse false claim' is an attempt to 'conceal, avoid, or decrease' an obligation owed to the government by filing false documents." *United States ex rel. Hunecam, Inc. v. Medshares Management Group, Inc.*, 400 F.3d 428, 439 n.11 (6th Cir. 2005). *See also United States ex rel. Grynberg v. Praxair, Inc.*, 389 F.3d 1038, 1041 n.2 (10th Cir. 2004) ("A reverse false claim is documentation resulting in an underpayment to the Government, as opposed to a false claim, generally referring to an inflated or false bill for payment from the Government."). A claim under Section 3729(a)(7) "requires a plaintiff to prove a 'reverse false claim': that is, that the defendant made or used (or caused someone else to make or use) a false record in order to avoid or decrease an obligation to the federal government." *Schmidt*, 386 F.3d at 242.

A "reverse false claim" most likely will arise where a party seeks to avoid or evade contractual or statutory fines and penalties or to avoid disclosure of non-compliance with applicable statutes and regulations. *See, e.g., United States ex rel. Huangyan Import & Export Corp.*, 370 F. Supp. 2d 993 (N.D. Cal. 2005) (attempt to evade anti-dumping customs duties states Section 3729(a)(7) claim); *Hunt*, 336 F. Supp. 2d at 445 ("The instant that Medco's conduct falls below that contractually required of it, a penalty slams into place through the operation of the contract, without regard to *when* the penalty must be paid. Any efforts by Medco to cover-up its failure, therefore, are efforts that

'conceal, avoid or decrease an obligation to pay or transmit money or property to the Government,' in violation of 31 U.S.C. § 3729(a)(7)."); *United States v. Raymond & Whitcomb Co.*, 53 F. Supp. 2d 436, 445-47 (S.D.N.Y. 1999) (holding that commercial travel agent incurred reverse false claim act liability by using a favorable non-profit mailing rate). *See generally American Textile Mfrs. Inst. Inc. v. The Limited Inc.*, 190 F.3d 729, 737 (6th Cir. 1999) ("A statute or regulation might also impose a duty to pay or transmit property, and breaches of such a duty might expose a defendant to liability under the reverse false claims provision."). *See also United States v. Penco Aerplex, Inc.*, 195 F.3d 1234 (11th Cir. 1999) (reversing dismissal of reverse false claim holding that defendant had obligation to account for full value of any excess government property).

The critical inquiry for a "reverse false claim" case is whether there is a sufficiently definite "obligation" owed to the government. *See, e.g., United States ex rel. Bain v. Georgia Gulf Corp.*, 386 F.3d 648, 657 (5th Cir. 2004) ("It is clear to us that, as the government argues, the reverse false claims act does *not* extend to the potential or contingent obligations to pay the government fines or penalties which have not been levied or assessed (and as to which no formal proceedings to do so have been instituted) and which do not arise out of an economic relationship between the government and the defendant (such as a lease or a contract or the like) under which the government provides some benefit to the defendant wholly or partially *in exchange* for an agreed or expected payment or transfer of property by (or on behalf of) the defendant to (or for the economic benefit of) the government.") (emphasis in original); *United States ex rel. American Textile Mfrs.*, 190 F.3d at 736 ("[a] reverse false claim action cannot proceed without proof that the defendant made a false record or statement at a time that the defendant owed to the government an obligation sufficiently certain to give rise to an action or debt at common law."). If the obligation is merely "potential" or "contingent," a party should not be subject to a Section (a)(7) FCA claim: "The obligation cannot be merely a potential liability: instead, in order to be subject to the penalties of the False Claims Act, a defendant must have had a present duty to pay money or property that was created by a statute, regulation, contract, judgment, or acknowledgment of indebtedness." *United States v. Q Int'l Courier*, 131 F.3d 770, 773 (8th Cir. 1997). Accordingly:

> Contingent obligations—those that will arise only after the exercise of discretion by government actors—are not contemplated by the statute. Examples of contingent obligations include those arising from civil and criminal penalties that impose monetary fines after a finding of wrongdoing; as opposed to quasi-contractual obligations created by statute or regulation (such as the imposition of a standard mailing rate), contingent obligations (such as the imposition of a civil penalty for an antitrust violation) attach only after the exercise of administrative or prosecutorial discretion, and often after a selection from a range of penalties.

American Textile Mfrs., 190 F.3d at 738.

For a "reverse false claim" FCA case, the key inquiries are: (1) whether there is any fixed, definite "obligation" owed to the government rather than a "contingent" or "potential" claim (either in the context of specific, agreed-upon fines and penalties in a contractual relationship) or a statute or regulation that specifically requires the payment of funds to the government under definite conditions (such as duties owed)); and (2) whether the defendant utilized specific means to "conceal, avoid or decrease" that obligation. Typically, the basis of a "reverse false claim" FCA case will be the reports or invoices submitted to the government where an individual or entity omits critical information regarding penalties, fines, or money or property due the government.

III. CONCLUSION

For participants in any government-funded program, the financial risk of such participation continues to expand. While substantial financial reward may be achieved through a government-funded contract, there is also substantial financial risk. Potential FCA liability exists during every moment of the relationship involving the receipt of government funds. In reality, any federal or state law or regulation applicable to the conduct at issue, as well as virtually every document submitted by a program participant, including invoices as well as any type of progress or status report, are "in play" as a source of FCA liability.

Simply stated, the breadth and scope of the theories of liability now available under the FCA have resulted in potential "cradle to grave liability." As a result, every aspect of the relationship may be subject to scrutiny from the response to a request for proposal, to the quality or completeness of any product or service provided, to specific contractual obligations, to any potentially applicable federal or state law or regulation, as well as to any express or implied certification of compliance.

For a plaintiff in an FCA action, every stone can and should be turned over while analyzing the program participant's conduct as a potential source of FCA liability. For a defendant in an FCA action, corporations, practitioners, and providers must be prepared to: (1) defend the accuracy and truthfulness of all submissions made

under the government-funded program; (2) establish the value and quality of all products and services provided; and (3) illusurate compliance with contractual, statutory and regulatory obligations. Given the potentially staggering financial consequences of an adverse decision in an FCA action, a defendant's financial survival may well depend on it.

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END NOTES

[1] For an overview of this entire area, *see generally* John R. Munich and Elizabeth W. Lane, "When Neglect Becomes Fraud: Quality of Care and False Claims," 43 ST. LOUIS U. L. J. 27 (1999).

[2] In a later decision, the *Parke-Davis* court denied a defendant's motion for summary judgment. *United States of America ex rel. Franklin v. Parke-Davis*, Civ. A. No. 96-11651, 2003 WL 22048255C (D. Mass. Aug. 22, 2003).