Corporate Integrity Agreements can be the basis for a False Claims Act Case

by Suzanne E. Durrell, Esq.

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Who should read this paper

- Presented by Atty. Suzanne E. Durrell at the 15th Annual Pharma Congress www.PharmaCongress.com in Washington D.C. in the Fall of 2014 when she joined the QUI TAM ROUNTABLE, this paper offers valuable insights to a large corporate audience – notably Compliance Officers, and other corporate officers and directors, as well as in-house legal counsel of health care providers, medical device and pharmaceutical companies, manufacturers, distributors, and others.
- In this paper, Atty. Durrell explores how provisions in Corporate Integrity Agreements could lead False Claims Act liabilities.

Corporate Integrity Agreements Can be the Basis for a False Claims Act Case

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Numerous health care providers have been parties to Corporate Integrity Agreements ("CIAs") over the past several years. Among them are many pharmaceutical companies/manufacturers. Typically these CIAs contain terms requiring, *inter alia*, the provider to notify HHS OIG of "Reportable Events," including "overpayments" from health care programs, and to submit to HHS OIG Annual Reports including a certification by the company's Compliance Officer that it was in compliance with all of the requirements of the CIA.

These (and other) CIA provisions raise the issue of when, if ever, violation of a CIA can give rise to liability under the False Claims Act, 31 U.S.C. §§ 3729, *et. seq*. Of particular relevance is 31 U.S.C. § 3729(a)(7), as amended an renumbered as § 3729(a)(1)(G) by the Fraud Enforcement & Recovery Act of 2009, § 4(b)(3), 123 Stat. at 1623 (May 20, 2009) ("FERA"). This section prohibits: (1) making a false statement that is material to an obligation to pay money to the Government; (2) concealing an obligation to pay money to the Government; and (3) improperly avoiding or decreasing an obligation to pay money to the Government.

Any one of these clauses could arguably serve as the basis for an FCA complaint. For example, a company's Annual Report could contain a "false statement" that is material to an "obligation" to pay money, a company could "conceal" its "obligation" to pay money by failing to notify HHS OIG of a "reportable event," and/or it could improperly avoid or decrease an "obligation" to pay money by not returning an overpayment. Key in all of these scenarios is the term "obligation" which is now defined by the FCA to mean:

> An established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.

31 U.S.C. § 3729(b)(3) (added by FERA).

The last clause of the definition of "obligation" is tied to retaining an "overpayment." The term "overpayment" was defined by The Patient Protection and Affordable Care Act ("PPACA"), Pub. L. 111-148, 124 Stat. 119 (Mar. 23, 2010), as "any funds that a person receives or retains under [Medicare] or [Medicaid] to which the person … is not entitled." 42 U.S.C. § 1320a-7k(d) (emphasis added). PPACA requires

that overpayments be reported and returned no later than 60 days after they are identified; in addition, providers must disclose the reason for the overpayment. 42 U.S.C. § 1320a-7k(d)(1) and (2). Any overpayment that is retained beyond the 60-day deadline becomes an "obligation" for purposes of the FCA. 42 U.S.C. § 1320a-7k(d)(3). Moreover, CIAs often contains a definition of "overpayment" that is very similar to PPACA's.

Since PPACA, HHS acting through its Centers for Medicare and Medicaid Services ("CMS"), has made several pronouncements about a provider's obligation to identify and refund overpayments. *See, e.g*., Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9179-9187 (February 16, 2012) (Proposed Rule pertaining to Parts A and B); Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29918-29925 (May 23, 2014) (Final Rule pertaining to the Medicare Advantage (MA) program (Part C) and the Prescription Drug Benefit Program (Part D)).

A breach of contractual duties under a CIA has been found to be a basis for FCA liability (even before FERA added the definition of "obligation" to the FCA). In *United States ex rel. Matheny v. Medco HealthSolutions, Inc.*, 671 F.3d 1217 (11th Cir. 2012), the court held that "[a]n express contractual obligation to remit excess government property is a definite and clear obligation for FCA purposes." *Id.* at 1223.[1] In *Matheny*, the 11th Circuit Court of Appeals reversed a district court's dismissal of an FCA case in which relators alleged that a pharmacy services provider had failed to disclose and refund overpayments as required by a CIA. The court found that the relators had sufficiently alleged a violation of the pre-FERA "reverse false claims" provision of the FCA, which imposed liability on a person who "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7), amended and renumbered as § 3729(a)(1)(G) by the Fraud Enforcement & Recovery Act of 2009, § 4(a), 123 Stat. 1617, 1621-22 (2009). In *Matheny*, the alleged false statement was a Certification of Compliance that defendant submitted to the government to attest that it was in compliance with the terms of the CIA. The court upheld a complaint asserting that the defendants violated section 3729(a)(7) (now renumbered as § 3729(a)(1)(G)), by falsely certifying compliance with the CIA while knowingly failing to report and refund overpayments. 671 F.3d at 1229.

Another case involving allegations of false certifications of compliance with a CIA is currently pending in the Eastern District of Tennessee. *United States ex rel.*

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[1] *Matheny* was decided under the pre-FERA version of the FCA, which did not include the definition of "obligation" currently found in § 3729(b)(3), which specifically includes duties arising from an express or implied contractual relationship.

Stratienko v. Chattanooga-Hamilton County Hospital Authority, 1:10-CV-00322-CLC-WBC, United States District Court for the Eastern District of Tennessee at Chattanooga. *See generally Id*. at 958 F.Supp.2d 846 (2013) (court dismissed all but the count alleging violation of CIA as basis for FCA liability subject to further analysis). In that case, the relator alleged that the hospital violated its CIA (and thus the FCA) by allegedly failing to have signed, written agreements for any new or revised payment arrangements with doctors and providers and making false certifications of compliance with the CIA.

The Department of Justice has submitted two Statements of Interest (SOIs) in that case. The first cited *Matheny* for the proposition that a reverse false claim in violation of the FCA may be sufficiently alleged "by showing that a defendant has submitted a false Certification of Compliance with a CIA." United States' Statement of Interest in Response to Defendant's Motion to Dismiss, Document 42, 1:10-CV-00322-CLC-WBC (October 2, 2012). DOJ later submitted a second SOI, which took exception to the defendant's assertion that the claim should be dismissed because the relator failed to allege that the person who signed the Certification of Compliance had knowledge of the conduct that rendered the certification false. United States' Statement of Interest in Response to Defendant's Motion to Dismiss Relator's Second Amended Complaint, Document 77, 1:10-CV-00322-CLC-WBC (October 31, 2013). DOJ stated:

> For purposes of evaluating potential False Claim Act liability … the relevant knowledge is Defendant's knowledge as a corporate entity, and **a corporation may be held liable even if the certifying employee was unaware of the wrongful conduct of other employees**. *See Grand Union Co. v. United States*, 696 F.2d 888, 890-91 (11th Cir. 1983) (reversing grant of summary judgment in favor of grocery store in False Claims Act case on basis that evidence permitting inference that check-out cashiers knowingly permitted purchase of ineligible non-food items with food stamps precluded summary judgment, even in absence of evidence that head cashier, who certified that stamps were not accepted for ineligible items, was aware of ineligible transactions). Accordingly, the court should not grant Defendant's motion to dismiss simply because the allegations of the Complaint may not show that the certifying employee(s) had personal knowledge that certifications were false, but rather should separately determine whether the allegations are sufficient to support a conclusion that the Defendant, as an entity, acted with the requisite scienter.

Id. at 2-3 (emphasis added).

Relators in *U.S. ex rel. Booker v. Pfizer, Inc.*, No. 10-11166-DPW, 2014 WL 1271766 (D. Mass. Mar. 26, 2014) took yet another tack, alleging that Pfizer made "reverse" false claims in violation of 31 U.S.C. § 3729(a)(1)(G), by failing to comply with CIA provisions requiring Pfizer, after reasonable opportunity for review, to report to

OIG certain qualifying “reportable events,” including violations of law applicable to federal health care programs or violation of FDA requirements relating to the promotion of government-reimbursed products. Relators alleged that by failing to report an event that should have been reported, Pfizer's behavior constituted avoidance of its obligation to pay the CIA’s “Stipulated Penalties” of $2,500 per day for failure to report a qualifying event. However, the Court was persuaded that because the CIA provided that Pfizer's failure to comply “may lead to the imposition” of the Stipulated Penalties if the OIG “determin [es] that Stipulated Penalties are appropriate,” there was no obligation to pay the United States, and thus there could be no violation of the FCA reverse false claims provision. (“The mere fact that Pfizer's failure to report “might result in a fine or penalty is insufficient” to establish an “obligation” to pay the government under § 3729(a)(1)(G). *U.S. ex rel. Bahrani v. Conagra, Inc.*, 465 F.3d 1189, 1195 (10th Cir.2006). When “potential fines depend on intervening discretionary governmental acts, they are not sufficient to create ‘obligations to pay.’ ” *U.S. ex rel. Marcy v. Rowan Companies, Inc.*, 520 F.3d 384, 391 (5th Cir.2008). “). Booker, 2014 WL 1271766 at *9.

The Booker Court distinguished the cases cited by relators because those cases involved clear obligations to pay money or transmit property to the government that defendants sought to avoid. For example, as to *U.S. ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217 (11th Cir.2012), discussed above, the Booker court found that it “involved a pharmaceutical company's failure to report government overpayments, which defendant was contractually obligated to return, 671 F.3d at 1223–24; the pharmaceutical company thus had a contractual obligation to transmit money to the government, which it avoided by failing to return the overpayments.” 2014 WL 1271766 at *10.

Given the number of companies under CIAs and the 2009 and 2010 amendments to the FCA, one can expect more FCA cases to be brought based at least in part on violation(s) of a CIA.

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About Suzanne E. Durrell, Esq.

Suzanne E. Durrell, founder and principal of Durrell Law Office, has represented relators in False Claims Act *qui tam* cases for over a decade. She associates with attorney Robert M. Thomas, Jr. of Thomas & Associates in Boston as part of the Whistleblower Law Collaborative. Their success rate and notable cases can be found at the firm's website listed below.

Ms. Durrell is the former Chief, Civil Division of the United States Attorney's Office in Boston. During her distinguished 12 years career with the Department of Justice, she supervised all of the office's False Claims Act litigation, and prosecuted a number of such cases including a then record setting health care fraud case. She received several honors including the *Attorney General's Award for Exceptional Service*, the most prestigious recognition bestowed by the Department of Justice. She also held the position of Deputy Associate Attorney General at the Justice Department in Washington, D.C.

Prior to joining the U.S. Attorney's Office, Ms. Durrell was an Assistant Attorney General for the Commonwealth of Massachusetts, an associate at the Boston law firm of Hill & Barlow in Boston (1978-1984), and a Staff Assistant to the Honorable Patrick J. Leahy, United States Senator (D-VT) (1975-1976).

Ms. Durrell is a 1978 *cum laude* graduate of Georgetown University Law Center and a graduate with honors from Swarthmore College in 1975. She is a member of the bar of the Commonwealth of Massachusetts, the United States District Court for the District of Massachusetts, the United States Court of Appeals for the First Circuit, and the United States Supreme Court.

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The Whistleblower Law Collaborative is the association of Thomas & Associates and Durrell Law Office to represent whistleblowers nationwide under the United States False Claims Act and other federal and state whistleblower/Qui Tam Laws. Headquartered in Boston Massachusetts, the collaborative offers whistleblower clients a commanding and unique collaboration of two preeminent attorneys: Robert M. Thomas Jr. and Suzanne E. Durrell.

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