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The Salcido Report

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Key Points

- Learn what evidence the government or the relator must establish to prove that the defendant "recklessly" interpreted a statute or regulation in violation of the FCA.
- Understand the circumstances under which the defendant's reasonable interpretation of an ambiguous statute or regulation can provide the defendant with a dispositive defense under the FCA.
- Learn what additional evidence the government must establish to demonstrate that the defendant recklessly submitted a false claim, if the defendant's interpretation of a rule or regulation is objectively reasonable.

What Must the Government Prove to Establish that a Defendant Recklessly Interpreted a Statute or Regulation in Violation of the False Claims Act?

Any company conducting business with the government must master a wide array of rules and regulations. And, certainly, companies are duty bound to comply with all the government's rules and regulations when they conduct business with the government.[1]

Indeed, to ensure compliance, the government frequently requires that the company affirmatively certify that it is operating in compliance with all the government's rules and regulations. This certification, in turn, provides fertile ground for False Claims Act (FCA) actions. The FCA is an attractive vehicle to enforce regulatory compliance, because it provides the plaintiff, if successful, with treble damages and the prospect of obtaining massive civil penalties.[2] Additionally, private plaintiffs (known as "relators") may enforce the government's rules and regulations and receive a substantial bounty of up to 30 percent of the government's recovery.

However, notwithstanding a company's obligation to adhere to the government's rules and regulations, what happens when the government's rules and regulations are inherently vague and ambiguous? As one judge noted in the Medicare context, "Medicare regulations are among the most completely impenetrable texts within human experience."[3] The government's propensity to write ambiguous rules is not limited to the Medicare program.

In light of this, from an FCA perspective, several questions arise, such as, if the defendant develops a contemporaneous, reasonable interpretation of an ambiguous regulation, can it "knowingly" submit a false claim in violation of the FCA? What if the defendant's conduct merely conforms with a reasonable interpretation, but the defendant never formally reviewed the regulation until an FCA lawsuit was filed, does the answer change? And if the defendant demonstrates that it acted within a reasonable, plausible interpretation of a regulation, what evidence must the government or relator produce to demonstrate that notwithstanding the reasonable interpretation, the defendant "knowingly" submitted a false claim?

Three recent FCA cases—*United States ex rel. Purcell v. MWI Corp.*,[4] *United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*[5] and *United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*[6]—shed important light on these questions. These cases, either expressly or tacitly, rely upon the Supreme Court's ruling in *Safeco Ins. Co. v. Burr.*[7] In *Safeco*, the Court, in determining whether the defendant had recklessly interpreted the Fair Credit Reporting Act, ruled that the defendant's interpretation was not reckless, both because the interpretation was not "objectively unreasonable," even though the Court disagreed with the defendant's interpretation, and because there was no formal, authoritative guidance—such as an official government agency interpretation or a court decision—that might have "warned" the defendant away from the view it took.[8]

To better understand the implications of the *Safeco* precedent to the FCA, set forth below is a discussion of that case and a detailed analysis of court decisions applying the Supreme Court's precedent in *MWI Corp.*, *Fresenius* and *Anesthesia Assocs*. What this review illustrates is that, just as the defendants have a duty to understand the law and follow it, the government has an equal and reciprocal duty to promulgate and publish clear rules and regulations to guide and inform those who elect to do business with the government.[9]

What the recent case law demonstrates is that FCA litigation should not be a "gotcha" game, where the government or relator announces a novel interpretation of a regulation in the course of FCA litigation where the plaintiff is seeking to impose treble damages and substantial civil penalties on the defendant for failing to adhere to a rule or regulation that has never been published. In these cases, courts have sensibly informed the government and relators that, if they seek treble damages and substantial civil penalties and brand defendants as fraudsters, then they had better be able to demonstrate that the government proffered clear guidance that legitimately would warn the defendant away from its reasonable interpretation of the law.

I. Supreme Court Precedent

Although *Safeco* is not an FCA case, multiple courts, in FCA actions, have expressly relied upon the Supreme Court's decision in *Safeco Ins. Co. v. Burr*[10] to determine when a party's reading of a statutory term is "reckless."[11] In *Safeco*, in formulating a rule regarding when an interpretation is reckless, the Court ruled that an objective standard should be employed: "[w]hile the term recklessness is not self-defining, the common law has generally understood it in the sphere of civil liability as conduct violating an objective standard: action entailing an unjustifiably high risk of harm that is either known or so obvious that it should

be known . . . . It is this high risk of harm, objectively assessed, that is the essence of recklessness at common law."[12] The Court ruled, in applying this standard, that "a company subject to [the Fair Credit Reporting Act] does not act in reckless disregard of it unless the action is not only a violation under a reasonable reading of the statute's terms, but shows that the company ran a risk of violating the law substantially greater than the risk associated with a reading that was merely careless."[13]

The Court ruled that the defendant's reading was not "objectively unreasonable," because, (a) even though the Court disagreed with the defendant's interpretation, the defendant's reading had a foundation in the statutory text sufficient that the district court had agreed with it, and (b) the court of appeals and Federal Trade Commission had not offered contrary guidance "that might have warned it away from the view it took."[14] "Given this dearth of guidance and the less-than-pellucid statutory text, [defendant's] reading was not objectively unreasonable, and so falls well short of raising the 'unjustifiably high risk' of violation the statute necessary for reckless liability."[15]

II. Recent D.C. Circuit Authority

The D.C. Circuit applied the Supreme Court's *Safeco* rule to the FCA in *United States ex rel. Purcell v. MWI Corp.*[16]

In *MWI Corp.*, the defendant submitted certifications to the Export-Import Bank to secure loans of $74.3 million to finance the defendant's sale of water pumps to Nigeria.[17] The defendant was required to certify in a Supplier's Certificate that it had not paid "any discount, allowance, rebate, commission, fee or other payment in connection with the sale," except "*[r]egular commissions* or fees paid or to be paid in the ordinary course of business to [its] sales agents."[18]

The government alleged that the certification was false because **nonregular** commissions had been paid, pointing to $28 million in commissions — more than 30 percent of the loan amount — that the defendant had paid to its long-term (more than 12 years) Nigerian sales agent, Alhaji Indimi. The government alleged that those commissions were so great that the defendant should have disclosed them to the government as payments other than "regular commissions."[19]

The court ruled that the precise legal question regarding the meaning of "regular commissions" is ambiguous and that the defendant's interpretation was reasonable.[20] The court noted that the term "regular commission" could imply at least three different inquiries: What is a regular commission industrywide? What is a regulator commission for the company? What is a regular commission as to the company and the specific agent it used?[21] The court found that the defendant's interpretation — that the regular commission it had paid this particular agent over their long-standing (12 years) relationship was the appropriate benchmark — was objectively reasonable.[22] The court noted that the defendant only learned that the government possessed a different interpretation once the government announced the term's meaning in the litigation.

Once the court found that the interpretation was objectively reasonable, it turned, under the *Safeco* test, to the second inquiry: whether the government set forth sufficient evidence that the defendant was

warned away from its interpretation. The court found that the government could not satisfy this test. The government failed to identify guidance from the court of appeals or the relevant agency, and it was undisputed that the government had never published any written guidance on what the term meant.[23]

The government did point to other evidence that it believed "warned" the defendant away from its interpretation, but the court ruled that the information the government identified was insufficient. Specifically, the government pointed to informal guidance the company had received from an agency employee that the commission should be around 5 percent, but the court found that this type of informal guidance was insufficient to warn a regulated defendant away from an otherwise reasonable interpretation that it adopted.[24] The government also pointed to the testimony of defendant employees who stated that they knew the company had applied the wrong definition, and expressed concerns about disclosing the agent's commission to the government. But the court responded that, in "the face of an undefined and ambiguous regulatory requirement, it is no wonder that employees of the regulated entity were concerned."[25] Moreover, the court noted that, even if that testimony demonstrated that the defendant held its interpretation in bad faith, under the Supreme Court's test in *Safeco*, "subjective intent — including bad faith — is irrelevant when a defendant seeks to defeat a finding of knowledge based on its reasonable interpretation of a regulatory term."[26] Instead, under "the FCA's knowledge element, . . . the court's focus is on the objective reasonableness of the defendant's interpretation of an ambiguous term and whether there is any evidence that the agency warned the defendant away from that interpretation."[27]

Finally, the court rejected the viewpoint that the defendant acted recklessly by failing to seek a legal opinion to determine what constituted a regular commission.[28] The court noted that there was no guidance from the government that would provide the defendant with any "particular reason to formally inquire about these commissions."[29] Ultimately, the court reasoned that, if the government wanted a particular interpretation of its rule, then it could have defined the term, but if it failed to do so because it desired flexibility, "then the FCA may cease to be an available remedy if the government concludes after the fact that a particular commission is not 'regular' because it is too high."[30]

III. Other Court Applications of Safeco Doctrine in Recent FCA Cases

Other courts have also recently studied the issue of what are the FCA implications when the defendant has developed a reasonable interpretation of a rule, but there is no formal authority to warn the defendant away from its interpretation. They have ruled that, under these circumstances, the defendant cannot "knowingly" submit a false claim.

A. Frensenius

In *United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*,[31] the relator alleged that the defendant billed Medicare for overfill — a surplus volume of Epogen and Zemplar contained in vials received from manufacturers — from 2005 through 2006 in violation of Medicare rules and regulations prohibiting reimbursement for drugs that providers receive for free.[32] The Court bifurcated the summary judgment briefing schedule to first consider whether the submission of a request for payment for overfill administration satisfied the FCA falsity element — that is, whether overfill administration was reimbursable under Medicare rules and regulations.[33] The court ruled that the defendant was not

permitted to bill Medicare for Epogen and Zemplar overfill during the relevant time period and hence submitted false claims.[34] At that point the court did not consider whether the defendant "knowingly" submitted any false claim.

After the parties moved for summary judgment on the FCA's knowledge element, the court ruled that no reasonable jury could find that the defendant acted knowingly or recklessly such that it could be held liable under the FCA.[35] The court primarily relied upon two factors in ruling that the defendant did not act with reckless disregard. First, the court noted that the relevant rules and regulations regarding overfill billing were silent and that no rule or regulation expressly prohibited billing for administered overfill during the relevant time period.[36] Second, viewing Medicare law and policy generally, the court concluded that whether billing was permitted was ultimately ambiguous: "One could have deduced from the Medicare policy on discarded drugs that overfill was free, and thus should not be billed even if administered. But one could alternatively, reasonably assume that by prohibiting overfill billing only when overfill is discarded, Medicare implicitly recognized that overfill can be billed when administered."[37]

Faced with this ambiguity, and notwithstanding that the court had previously ruled that a better interpretation of Medicare law is that the defendant violated the law when billing for overfill, the court found that the defendant did not "recklessly" interpret the law, because the evidence in the record showed that the defendant believed — and its counsel advised — that administered overfill was reimbursable. The court ruled that, whether right or wrong, the defendant's interpretation was plausible, because (1) although some facts existed that could have led the defendant to conclude that overfill billing was impermissible, the defendant's lawyers believed that billing was permissible and so advised the company;[38] (2) although the defendant never disclosed its billing practice to CMS, the defendant informed the OIG that it was billing for overfill under its Corporate Integrity Agreement and stated that it was utilizing (and implicitly billing for) overfill in its SEC filings;[39] and (3) although simply acting in conformity with others in the industry does not absolve government contractors of FCA liability, the evidence revealed that others in the industry routinely billed overfill and believed that it was permissible, including the relator's own expert.[40]

Ultimately, the court concluded that, although the defendant's interpretation of the rule was wrong, and even negligent, the defendant's interpretation was not recklessly wrong, because it was consistent with its communication to the government and conformed to industry practices:

> Perhaps Relator is correct. Fresenius's exploitation of silence or ambiguity in the Medicare rules or regulations, capitalizing on a loophole in the regulatory fabric, certainly has an unsettling dimension to it. The Court agrees with Relator that "as the recipient of substantial largesse from the Government," Fresenius had an obligation to act with integrity and not abuse its position as government contractor. And the Court credits Relator's position that the presumption in Medicare reimbursement practices is that a provider does not bill for something it received for free. The record thus supports a reasonable inference that Fresenius negligently failed to recognize the relationship between various Medicare principles, rules and regulations, and failed to properly

investigate whether overfill was a reimbursable drug product or instead no different than a free sample. Also based on this record, a jury could decide that sophisticated companies such as Fresenius were not blindsided when CMS proposed to prohibit overfill billing. Indeed, issues involving overfill extraction, administration, and billing had bubbled to the surface time and again for decades — in the context of patient safety and reentry protocols, alleged kickbacks and improper marketing, wastage, and of course, billing for overfill administration. And viewed in the light most favorable to Relator, Fresenius knew free items were not reimbursable.

Nonetheless, Fresenius's failure to connect the dots — to fully appreciate that overfill was to be treated just like a free sample for reimbursement purposes — although arguably negligent, does not support a finding of recklessness based on this record. Instead, the record shows that Fresenius adopted a plausible interpretation of the Medicare rules and regulations, consistent with its communications with OIG and CMS and with some in the industry (including Relator's own expert). CMS could presumably have timely and successfully attempted to recover overpayments based on overfill reimbursement prior to 2011. But to expose Fresenius to treble damages in an FCA action would only be appropriate if Fresenius recklessly disregarded or alternatively fraudulently with intent disregarded the fact that overfill was simply not reimbursable. On this record, no reasonable jury could make such a finding.[41]

B. Anesthesia Associates of Kansas City

In *United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*,[42] another district court construed what evidence the FCA plaintiff must present to demonstrate that the defendant recklessly interpreted an ambiguous rule or regulation.

In *Anesthesia Assocs*., the relator contended that the defendant's anesthesiologists violated the "Seven Steps" regulation setting forth the conditions of payment for Medically Directed anesthesia services by failing to personally participate in a patient's emergence from anesthesia in the operating room.[43] Specifically, the regulation provided that the anesthesiologist must personally participate in the most demanding aspects of the anesthesia plan, including, if applicable, induction and **emergence**.[44] If this condition is not satisfied, the procedure must be billed at a lower rate.

The regulation did not define what "emergence" means, or when emergence begins or ends, and neither CMS, in subregulatory guidance, nor its agents defined emergence.[45] The court also pointed out that no national or state anesthesiology organization had defined "emergence," because "emergence is a process, and each patient is different. Some patients take longer than others to recover from the effects of anesthesia, and there are different levels of emergence."[46] The court noted that the University of Kansas Hospital, where some of the defendant's anesthesiologists and CRNAs received their education and training, taught its anesthesiology residents and nurse anesthetist students that emergence occurs over a period of time and may take an hour or more.[47]

In light of this regulatory void, the defendant and the relator offered conflicting definitions of when emergence occurs. For example, the defendant defined "emergence" to include the patient's recovery in

the recovery room.[48] The defendant's anesthesiologists attempted to comply with the emergence requirement for each patient, either by visiting the patient during the patient's emergence in the operating room, in the hallway during the patient's transfer to the recovery room or after the patient arrived in the recovery room.[49]

The relator, by contrast, viewed emergence as excluding time in the recovery room.[50] In support, the relator proffered two board-certified expert anesthesiologists, who disagreed with the proposition that an anesthesiologist is present at "emergence" if he examines the patient in the recovery room. One expert anesthesiologist, for example, opined that:

> It defies the widespread practice and common sense to argue that an anesthesiologist need NOT be present during . . . emergence in the operation room. This is in direct contrast to the intent and letter of the law, and the general understanding of the law in the anesthesiology community, as it pertains to Medical Direction.[51]

Not surprisingly, for FCA purposes, the parties derived different legal conclusions stemming from the ambiguity regarding the meaning of emergence. For example, the defendant contended that the ambiguity regarding what constitutes emergence demonstrated that the relator cannot establish that the defendant **knowingly** submitted false claims. Specifically, the defendant noted that its interpretation that emergence extends into the recovery room is reasonable and that the 8th Circuit has held recently that a defendant's "reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA."[52]

The relator, by contrast, pointed out that the FCA requires it to show only that the defendant submitted a false claim with "reckless disregard" or "deliberate indifference" and that reimbursement regulations do not have to be drafted with impossible specificity or mathematical precision.[53] Instead, the relator contended that "emergence" should be interpreted according to its common meaning in the medical community, and it pointed out that it has placed evidence in the record demonstrating that the government and the medical community understand that being present for emergence means being present in the operating room as the patient is weaned from anesthesia.[54] The relator suggested that, even if the regulation is ambiguous, it need only show that the defendant knew that CMS interpreted the regulation in a certain way and that its actions did not comply with this interpretation.[55]

In reaching its ruling, the court engaged in a three-step inquiry: Was the regulation ambiguous? If so, did the defendant have a reasonable (or plausible) interpretation of the ambiguous rule? If so, was there formal guidance that would warn the defendant away from its reasonable (plausible) interpretation?

As to ambiguity, the court concluded that the regulation is ambiguous, because what constitutes "personally participates in . . . emergence" is not clear. Specifically, the court noted:

> "Emergence" is not defined by CMS, a National Coverage Determination, a binding Local Coverage Determination, or any national or state anesthesiology organization. Although there is a

> consensus within the anesthesiology community that emergence begins in the operating room with the cessation of the delivery of anesthetic agents, there is no agreement on when it ends. Relator's two experts and Palmetto GBA, the nationwide Medicare carrier for railroad retirees, view emergence as ending once the patient is turned over to the staff in the recovery room. But it is uncontroverted that anesthesiologists consider emergence to be a process that occurs over a period of time and may take an hour or more to complete, depending on the patient. The absence of a clear definition of when emergence ends means the regulation is ambiguous. *See Ketroser*, 729 F.3d at 831.[56]

As to reasonableness, the court concluded that the defendant's interpretation was reasonable. The defendant defined "emergence" to include the patient's recovery in the recovery room. The court noted that, although the defendant's interpretation of emergence may not be the most widely held or most reasonable definition of "emergence," it was a plausible definition, and, thus, its "view that the regulation is satisfied by seeing the patient in the recovery room is a reasonable interpretation."[57]

Finally, as to formal guidance that would warn the defendant away from its interpretation, the court found that there was none:

> Although exactly what constitutes "deliberate ignorance" or "reckless disregard" is somewhat uncertain, the Eighth Circuit has made clear what does not constitute "deliberate ignorance" or "reckless disregard." The Eighth Circuit recently held in *United States ex rel. Ketroser v. Mayo Foundation* that where a regulation is unclear, a defendant's "reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA." 729 F.3d 825, 832 (8th Cir. 2013). This is consistent with its 2010 decision in *United States ex rel. Hixson v. Health Management Systems, Inc.* that a bill submitted "based on a reasonable interpretation of a statute cannot support a claim under the FCA if there is not authoritative contrary interpretation of that statute. 613 F.3d at 1190. To prevail in an FCA action the relator "must show that there is no reasonable interpretation of the law that would make the allegedly false statement true." *Id.* at 1191.[58]

The Court also concluded that its analysis is not altered by the fact that the defendant had a financial motive to reach its interpretation, because, regardless of the defendant's opportunistic interpretation, the relator could not establish the FCA knowledge element:

> Of course, Defendant's interpretation is opportunistic because it has a financial motive to interpret the regulation this way. Under Relator's definition of "emergence," thousands of the procedures Defendant's anesthesiologists performed should have been billed at the lower Medical Supervision rate. But there is "no authoritative contrary interpretation" of the regulation here, and the Eighth Circuit has ruled that "a defendant does not act with the requisite deliberate ignorance or reckless disregard by 'taking advantage of a disputed legal question.'" *Hixson*, 613 F.3d at 1190-91 (quoting *Hagood*, 81 F.3d at 1478). While Relator has arguably put forth a more reasonable interpretation of the regulation, this is not enough. Relator must carry its burden of

showing "that there is no reasonable interpretation of the law that would make the allegedly false" claim valid. *Id.*[59]

Conclusion

So, what is the teaching of this growing body of FCA case law for those operating corporate compliance departments, in-house lawyers advising the company regarding its government contracts and payments, and lawyers defending FCA actions?

First, stay actively abreast of governmental rules and regulations regarding government payment and form a reasonable understanding of what those rules require. **Second**, when applicable, communicate that understanding to the government whenever the issue arises (for example, in informal conversations with government representatives, routine audits, SEC filings or other public reports). **Third**, monitor official governmental pronouncements and court decisions to evaluate whether that guidance contains any information that would "warn" the company "away" from its reasonable interpretation.

This growing body of case law is a paradigm shift. The best defense argument is always that the defendant's conduct conformed to the plain language of the government's rule. However, when the defendant's fallback position has been that the government's rule is ambiguous, but that the defendant relied upon a reasonable interpretation, the Department of Justice's response historically has been, in essence, "Oh my God, if the rule is ambiguous, why did you not seek out guidance from the government instead of interpreting the rule in a fashion that furthered your financial interest? That is the epitome of 'reckless disregard' or 'deliberate ignorance,' which should subject you to liability under the FCA." Now, the courts have offered the defendant a dispositive response when the rule is ambiguous, which is as follows: What formal guidance — in either official agency action or court decision — have you, the government, promulgated that you contend should have warned us away from our reasonable interpretation of an ambiguous rule? If the government cannot identify any, the case law is teaching that the government should receive, if its interpretation of the rule is correct, no more than single damages on an overpayment claim, but not treble damages and substantial civil penalties under the FCA, because, under these circumstances, the government cannot satisfy the FCA's knowledge element.

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October 28, 2015 – Minimizing Exposure to Stark Law Liability in False Claims Act Cases by Isolating Those Who Determine Fair Market Value From Those Who Measure Contribution Margin or Other Similar Operational Data

October 1, 2015 – When a Violation of a Rule or Regulation Becomes an FCA Violation: Understanding the Distinction Between Conditions of Payment and Conditions of Participation

September 25, 2015 – False Claims Act Public Disclosure Alert

About the Author

Robert Salcido is a leading FCA practitioner.

Although the United States typically obtains a positive monetary recovery in more than 90 percent of the FCA actions it institutes, see 114 COLUM. L. REV. at 1991, Mr. Salcido has been lead counsel in several FCA actions in which he successfully defended clients in FCA actions the government filed at trial or summary judgment, including:

- Mr. Salcido was lead counsel for Golden Living in an FCA action where the federal government had sued Golden Living's predecessor company Beverly Enterprises ("Beverly") for $895 million, alleging that Beverly had engaged in an unlawful kickback scheme with McKesson Corp. in violation of the Anti-Kickback Act and the FCA. After 14 days of trial, the court ruled that Beverly and McKesson did not violate the FCA or the Anti-Kickback Act, because their business negotiations were fair and reasonable and were conducted in good faith. *See United States of America ex rel. Jamison v. McKesson Corp*., 900 F. Supp. 2d 683 (N.D. Miss. 2012).
- Mr. Salcido was lead counsel for Aegis Therapies and a Golden Living skilled nursing facility where the federal government had alleged that defendants provided medically unnecessary rehabilitation therapy. The district court granted defendants' summary judgment motion, ruling that the government had used the wrong standard to assess whether the services were medically necessary and failed to prove that defendants' certification regarding medical necessity was objectively false. *See United States ex rel. Lawson v. Aegis Therapies, Inc.*, 2014 U.S. Dist. LEXIS 45221 (S.D. Ga. Mar. 31, 2015).
- Mr. Salcido was lead counsel for a defendant physician and multispecialty group practice that the government accused of FCA violations. The district court dismissed all the government's claims on summary judgment. Ultimately, because the United States' action lacked "substantial justification," the United States was ordered to pay defendants more than $500,000 in legal fees. In making the ruling, the court ruled that Medicare fraud law is an area of expertise and ruled that it was undisputed that Mr. Salcido possessed such expertise. *See United States v. Prabhu*, 442 F. Supp. 2d 1008 (D. Nev. 2006).
- Mr. Salcido was lead counsel for Golden Living in an action where the relator and the government sued multiple defendants, alleging that they violated the FCA because they knowingly created and operated a supply company in violation of Medicare Supplier Standards. The district court granted defendants' FCA summary judgment motion regarding the Supplier Standards allegations, finding that the government's prior administrative proceedings demonstrated that the defendant supply company was entitled to payment. *See United States ex rel. Jamison v. McKesson Corp*., 784 F. Supp. 2d 664 (N.D. Miss. 2011).

Mr. Salcido has authored a number of books and chapters in leading publications (including the American Health Lawyers Association, BNA Books and Bloomberg BNA) regarding the application of the FCA, including:

- FALSE CLAIMS ACT & THE HEALTHCARE INDUSTRY: COUNSELING & LITIGATION (2d ed. American Health Lawyers Ass'n 2008) (with annual supplements) (3d edition forthcoming in 2016)
- *The False Claims Act in Health Care Prosecutions: Application of the Substantive, Qui Tam, and Voluntary Disclosure Provisions*, in HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, Ch. 3 (3d ed. BNA Books 2013) (with annual supplements)
- *False Claims Act: Health Care Applications and Defenses* in Bloomberg BNA Health Law & Bus. Series No. 2650 (2012) (with annual supplements).

Because of his work successfully defending a number of FCA lawsuits, he has been recognized in:

- *The National Law Journal*, in its Inaugural 2014 Litigation Trailblazers & Pioneers, named Mr. Salcido as one of 50 "people who have made a difference in the fight for Justice" for his outstanding work in defending FCA lawsuits.
- *Chambers USA: America's Leading Lawyers for Business* (2006-2014). In the 2011-2014 editions of *Chambers USA*, Mr. Salcido is listed under Healthcare: Regulatory & Litigation, Leading Individuals (Nationwide) (Band 1) and as Healthcare Leading Individuals (District of Columbia) (Band 1).
- *Law360* MVP (2012) for Health Care selected Mr. Salcido as one of the four Health Care MVPs for 2012 based upon a successful trial verdict obtained in the Golden Living FCA/Anti-Kickback Act lawsuit).

Before entering private practice, he served as trial counsel for the U.S. Department of Justice Civil Fraud section, which has nationwide jurisdiction over the FCA, where he led several successful prosecutions of the FCA on the United States' behalf.

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[1] *See, e.g., Heckler v. Community Health Servs. of Crawford Cnty., Inc.*, 467 U.S. 51, 63-64 (1984) ("As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements for cost reimbursement.").

[2] The FCA imposes liability on those who "knowingly" submit false claims or statements. "Knowingly" is defined to reach, at a minimum, those who act in "reckless disregard" or in "deliberate ignorance" of the truth or falsity of their claims. *See* 31 U.S.C. § 3729(b).

[3] *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 770 (N.D. Tex. 2003).

[4] 807 F.3d 281 (D.C. Cir. 2015).

[5] No. 1:10-CV-1614, 2015 U.S. Dist. LEXIS 156924 (N.D. Ga. Oct. 30, 2015).

[6] No. 4:12-CV-0876, 2015 U.S. Dist. LEXIS 74239 (W.D. Mo. June 9, 2015).

[7] 551 U.S. 47 (2007).

[8] *Id.* at 70.

[9] *See generally United States v. Cooperative Grain and Supply*, 476 F.2d 47, 60 (8th Cir. 1973) (noting in FCA action that "[o]bviously a citizen cannot digest all the manifold regulations, nor can the Government adequately and individually inform each citizen about every regulation, but there is a corresponding duty to inform and be informed").

[10] 551 U.S. 47 (2007).

[11] In addition to *MWI Corp.* and *Fresenius*, discussed here, *see, e.g., United States ex rel. K&R Ltd. P'ship v. Mass. Hous. Fin. Agency*, 530 F.3d 980, 983 (D.C. Cir. 2008) (granting summary judgment to defendant because relator "never explains why [defendant's] interpretation . . . . was unreasonable, much less why its interpretation constituted reckless disregard. While the unreasonableness of [defendant's] interpretation is merely evidence, the absence of which does not preclude a finding of knowledge, . . . [the relator] points to nothing else 'that might have warned [the defendant] away from the view it took'") (quoting *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 (2007)); *United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 592-93 (E.D. Pa. 2012) (same); *United States ex rel. Pritzker v. Soldexho, Inc.*, No. 03-6003, 2009 U.S. Dist. LEXIS 51469, at *53-54 (E.D. Pa. Mar. 6, 2009) ("[L]ack of clarity regarding the proper interpretation of the regulations indicates that no basis exists for imposing FCA liability on [d]efendants, who merely adopted a reasonable interpretation of regulatory requirements which favored their interests.") (citing *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47 (2007)), aff'd, 364 F. App'x 787 (3d Cir. 2010). *See generally*, *United States ex rel. Hixson v. Health Mgmt. Sys.*, Inc., 613 F.3d 1186, 1191 (8th Cir. 2010) (citing *Safeco*).

[12] 551 U.S. at 68 (internal, citations and footnote omitted).

[13] *Id.* at 69.

[14] *Id.* at 70.

[15] *Id.* (footnote omitted).

[16] 807 F.3d 281 (D.C. Cir. 2015).

[17] *Id.* at 283.

[18] *Id.* at 284.

[19] *Id.*

[20] *Id.* at 288.
[21] *Id.*
[22] *Id.* at 284, 288-89. The court noted that "the definition of 'regular' makes clear that something can be 'regular' either because it is not unusual in relation to societal norms or because it is not unusual for that individual. *See, e.g., The American Heritage Dictionary of the English Language* (5th ed. online 2015). Consequently, [the defendant] could reasonably have concluded that Indimi's commissions were regular because they were consistent with what [the defendant] had been paying him for over twelve years and were calculated using the same formula [the defendant] used to determine commissions for all of its agents." *Id.* at 288-89.
[23] *Id.* at 289.
[24] *Id.* at 289-90.
[25] *Id.* at 290.
[26] *Id.* (citation omitted).
[27] *Id.* (citation omitted).
[28] *Id.*
[29] *Id.* Other courts have similarly rejected the notion that defendants have a duty to seek legal advice whenever they act in accordance with a reasonable interpretation of an ambiguous regulation. *See, e.g., United States ex rel. K&R P'ship v. Mass. Hous. Fin. Agency*, 530 F.3d 980, 984 (D.C. Cir. 2008) (rejecting relator's position that defendant's failure to obtain a legal opinion or prior HUD approval showed that defendant acted recklessly because relator pointed to no "evidence of anything that might have given [the defendant] reasons to do so" and defendant had "made no secret of the [issue] and during a HUD audit the next year [defendant] specifically brought the [issue] to HUD's attention, albeit for a somewhat different issue . . . There is no evidence HUD expressed any concerns and, in fact, HUD continued (and continues) to pay [defendant] even after [relator] filed this lawsuit. Although the fact that the government continues to pay claims might not preclude a finding of knowledge, here that fact at least suggests [defendant] did not act with reckless disregard"); *United States ex rel. Quirk v. Madonna Towers, Inc.*, 278 F.3d 765, 768 (8th Cir. 2002) (holding that "failing to secure a legal opinion, without more, is not the type of deliberate ignorance that can form the basis for an FCA lawsuit"); *United States ex rel. Rose v. E. Tex. Med. Ctr.*, No. 2:05 CV 216, 2008 U.S. Dist. LEXIS 65660 at *23 (E.D. Tex. Aug. 25, 2008) (rejecting relator's contention that defendant should have sought outside legal advice regarding the legality of its participation in the program when it relied upon the advice of statewide advocacy and leadership organization, which the state had selected to implement the program, because, even though statewide organization had a financial interest in advising defendant, its "failure to seek independent legal advice under the facts [did] not rise to the level of reckless disregard needed for an FCA claim," but, at most, "would constitute negligence, which is insufficient to assert a claim under the FCA").
[30] *Id.* at 291.
[31] No. 1:10-CV-1614, 2015 U.S. Dist. LEXIS 156924 (N.D. Ga. Oct. 30, 2015).
[32] *Id.* at *21-22. Regarding overfill, the court noted that manufacturers of Epogen and Zemplar distribute the drugs in individual vials, with the amount of drug contained in the vial labeled on the vial itself. "However, consistent with industry standards and federal regulations, the manufacturers also include in each vial a surplus volume of each drug, referred to as 'overfill'… The overfill ensures that the nurses administering the drug will be able to extract at least the labeled amount from the vial." *Id.* at *11.
[33] *Id.* at *22.
[34] *Id.* at *22-24 (citing *United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 972 F. Supp. 2d 1339 (N.D. Ga. 2013).
[35] *Id.* at *26.
[36] *Id.* at *113.
[37] *Id.* at *113-14.
[38] *Id.* at *27-34. *See generally United States ex rel. Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1061-62 (11th Cir. 2015) (holding that the defendant school did not act with reckless disregard when the individual testified that, when he signed a certification of compliance with the Rehabilitation Act, even

though he had not personally ensured that the company's nondiscrimination policies and grievance procedures complied with the Rehabilitation Act, because he "relied on the opinions of his subordinates, including those charged with compliance, and had no reason to believe that [the defendant's] policies violated the Rehabilitation Act or its implementing regulations" and "while he did not independently review the agreement or specifically review [the defendant's] policies for compliance with the Rehabilitation Act, [the defendant] had hired 'the kind of people that had integrity, that had experience, [and] that had knowledge'; the company also used a system where there were 'experts who ran the departments,' and they were responsible for ensuring [the defendant's] compliance" and the relator "adduced no evidence — either in the district court or on appeal — suggesting (much less showing) that [the individual's] reliance on his subordinates was unreasonable under the circumstances").

[39] Id. at *116. *See also United States ex rel. Gonzalez v. Planned Parenthood of L.A.*, 759 F.3d 1112, 1115-16 (9th Cir. 2014) (finding that, where the defendant had exchanged letters with state officials describing its billing process, it was billing at usual and customary rates and not at acquisition cost, and state officials did not object; when state later acknowledged that, regarding the definition of "at cost," the state had provided "conflicting, unclear, or ambiguous misrepresentations . . . to providers," the relator could not set forth a plausible FCA cause of action that the defendant knowingly presented false claims).

[40] *Id.* at *123-24. *See also United States ex rel. Williams v. Renal Care Grp.*, 696 F.3d 518, 531 (6th Cir. 2012) (holding that a defendant is not reckless when, in the face of ambiguous regulations, the defendant follows industry practice, consults and relies on advice of counsel, and was forthright with the government about its conduct). For a detailed history of the FCA's knowledge standard and a description of its case law, *see* Robert Salcido, False Claims Act & Healthcare Industry: Counseling & Litigation § 2:05 (American Health Lawyers Ass'n Supp. 2014); *see generally* Robert Salcido, False Claims Act & Healthcare Industry: Counseling & Litigation (2d ed. American Health Lawyers Ass'n 2008).

[41] *Id.* at *134-36.

[42] No. 4:12-CV-0876, 2015 U.S. Dist. LEXIS 74239 (W.D. Mo. June 9, 2015).

[43] *Id.* at *1-2.

[44] *Id.* at *6.

[45] *Id.* at *6, *14-15.

[46] *Id.*

[47] *Id.* at *15.

[48] *Id.* at *16.

[49] *Id.* at *16.

[50] *Id.*

[51] *Id.* at *16-17. The reason that the issue of where emergence occurred was potentially case-dispositive is that some defendant employees testified that defendant anesthesiologists were almost never present in the operating room for emergence. *Id.* at *17.

[52] *Id.* at *25 (quoting *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013)).

[53] *Id.* at *25.

[54] *Id.* at *25-26.

[55] *Id.* at *26.

[56] *Id.* at *29-30.

[57] *Id.* at *30 (footnote omitted).

[58] *Id.* at *26-27. In a Statement of Interest, the government entered the fray, asserting that "what steps the defendant took to ascertain the government's construction of an ambiguous regulation is also relevant to evaluating whether the defendant acted with knowledge." *Id.* at *28. The court rejected the government's Statement of Interest, noting that its alternate formulation was inconsistent with 8th Circuit case law that "a defendant is not liable under the FCA if the regulation is ambiguous and [the defendant's] statements would be true under a reasonable interpretation of the regulation." *Id.* at *28-29.

[59] *Id.* at *26-27.