FALSE CLAIMS ACT
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MID-YEAR IN REVIEW

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1. United States *ex rel.* Salingo v. Wellpoint Inc., et al., No. 16-56400, 2018 WL 4403407 (9th Cir. March 8, 2018)

In this *qui tam*, the Ninth Circuit reversed in part the dismissal of a False Claims Act suit against several Medicare Advantage organizations. Unlike Medicare fee-for-service, Medicare Advantage employs a capitation payment system. This means that an amount is paid to the Medicare Advantage Organization per patient. The per-month fee fluctuates depending on the acuity level of the patient. The acuity level, in turn, is based upon a beneficiaries "risk adjustment data," which reflect several factors that can affect healthcare costs including medical diagnoses.

As the court noted, "Medicare regulations require risk adjustment data to be produced according to certain best practices." In addition, Medicare regulations establish data certification requirements including that certifications that the risk adjustment data is accurate, complete, and truthful. In United States *ex rel.* Swoben v. United Healthcare Ins. Co., 848 F.3d 1161, 1169 (9th Cir. 2016), the Ninth Circuit held that a certification is thus false when the Medicare Advantage organization has actual knowledge of the falsity of the risk adjustment data *or* demonstrates either reckless disregard or deliberate ignorance of the truth or falsity of the data.

In this case, the relator is a former compliance officer and director of provider relations for Mobile Medical Examination Services ("MedXM"). MedXM employs healthcare professionals to conduct in-home health assessments of Medicare beneficiaries on behalf of Medicare Advantage organizations. The relator alleges that the Medicare Advantage organizations "retained MedXM to fraudulently increase, or at least maintain, their capitation payments for enrollees whose risk scores were set to expire and revert to the unadjusted Medicare beneficiary average." Specially, the relator alleged that Med XM:

- used inappropriate software so that it could edit health records to exaggerate medical diagnoses;
- used nurse practitioners and physician assistants not legally authorized to make conclusive medical diagnoses;

- "Systematically fabricated complex diagnoses that its medical examiners could not have possibly confirmed during an in-home assessment."
- Regularly produced diagnostic information that was not the result of face-to-face medical encounters.

The relator contends that the Medicare Advantage organizations made false claims for payment by using the information from MedXM to support risk adjustment submissions to CMS with knowledge or reckless disregard or deliberate indifference as to their validity. The relator contends that the claims were both factually false because they were premised on invalid risk adjustment data and legally false because of false compliance certifications.

While the district court permitted the claims against MedXM to survive, it dismissed the claims against the Medicare Advantage organizations. In reversing the district court, the Ninth Circuit first found that the operative complaint satisfied Rule 9(b)'s heightened pleading requirement. The court held that "[e]ach of the defendant organizations allegedly had separate contracts with MedXM, and each of them allegedly passed on MedXM's inflated diagnosis information in the same way" and, accordingly, no way for the relator to "differentiate among those allegations that are common to the group." In so holding, the court rejected defendants' contention that the complaint did not allege a sufficient factual basis to link MedXM's misconduct to the Medicare Advantage organizations' actual submission of claims or certifications to CMS. The Court also rejected defendants' argument that the relator did not plead knowledge of the alleged fraud sufficient to satisfy Rule 8, including allegedly obvious indicia of problems with MedXM's health assessment reports.

2. United States *ex rel.* Silver v. Omnicare, No. 16-4418, 2018 WL 4201631 (3d Cir. Sept. 4, 2018)

Relator, a former owner of a nursing home and a pharmacy, filed a *qui tam* action against PharMerica, a long-term care pharmacy, alleging it engaged in a swapping scheme, in violation of False Claims Act, by offering nursing homes below market prices for drugs to patients insured by Medicare Part A in exchange for referrals of prescriptions for nursing home patients insured by Medicare Part D or by Medicaid, and thereby defrauded the federal government when it submitted Medicare and Medicaid claims for reimbursement which falsely certified its compliance with the Anti-Kickback Statute. The United States District Court for the District of New Jersey granted the defendant summary judgment, based on FCA's public disclosure bar. Relator appealed. The Court of Appeals held that inference of fraud was not publicly disclosed at time of suit and the case was reversed and remanded.

The FCA's public disclosure bar generally disallows *qui tam* actions that are based on allegations that are, at least in substantial form, already known to the public. The public disclosure bar, prior to March 23, 2010, provided that "[n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions of fraud …."

What Constitutes the Public Disclosure of Allegations or Transactions of Fraud ?

The first question presented in this case is how specific the publicly disclosed allegations need to be. The relator argued that the district court improperly barred his case by treating public disclosures concerning the general risk of swapping in the nursing home industry as a bar to his specific allegations, supported by nonpublic information, that PharMerica was actually engaging in swapping.

To determine whether the public disclosure bar applies, courts employ the following algebraic formula:

> "If X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed."

In this case, the partied agreed that the allegedly "misrepresented" set of facts [X] is that PharMerica was complying with the Anti-Kickback statute, and that the allegedly "true" state of facts [Y] is that PharMerica was in fact engaging in the fraudulent practice of swapping, which violates the statute. PharMerica argued — and the District Court found — that a number of publicly available reports and documents, upon which relator testified that he relied to deduce the fraud, discussed swapping in the nursing home industry and accordingly both X and Y were publicly disclosed.

On appeal, the Third Circuit disagreed: "Neither of [two alleged public disclosures], alone or considered together with the rest of the public documents, disclose the fraudulent transactions that [relator] alleges, not least of which because the documents do not point to any specific fraudulent transactions directly attributable to PharMerica. In addition, the disclosures alone would not support an allegation against PharMerica. Instead, relator had to add non-public information in order to support his allegations. The Court "h[e]ld that the FCA's public disclosure bar is not implicated in such a circumstance, where a relator's non-public information permits an inference of fraud that could not have been supported by the public disclosures alone." In this case, the relator's non-public knowledge of the per diem rates that PharMerica was charging nursing homes allowed him to take publicly known information – including the possibility of swapping in general and PharMerica's reported financial performance -- and to deduce that PharMerica must be charging less than its actual cost for the Part A drugs.

The Third Circuit went on to state that, in order for prior disclosures to have preclusive effect, they have to be sufficient, if pled in a complaint, to meet the heightened requirements of Rule 9(b). Since, in this case, a complaint based only on the publicly available information would not satisfy Rule 9(b), the public disclosure bar did not apply.

When is an Action Based Upon a Prior Public Disclosure ?

Next, the Third Circuit addressed what it means for a suit to be "based upon" a prior public disclosure. The Court held that the mere fact that relator admitted that he referred to the prior disclosures and even relied on them in concluding that PharMerica committed fraud did not implicate the public disclosure bar because the information in the prior disclosures did not, in and of itself, disclose the fraud. In assessing whether the bar might apply, a court should first determine whether the prior disclosures amount to a "public disclosure" before it addresses whether the relator's suit is "based upon" the disclosures.

Because there were no public disclosures that relator's suit could be based upon, the public disclosure bar did not apply and the Third Circuit reversed and remanded the case.

3. United States *ex rel.* Streck v. Allergan, Inc., et al., Civ. No. 17-1014, 2018 WL 3949031 (3d Cir. Aug 16, 2018)

This case involves allegations against several drug manufacturers, which were referred to as "Service Fee Defendants," underpaid rebates to multiple states under the Medicaid Drug Rebate Program. Under the Medicaid program, states are entitled to certain rebates from drug manufacturers. Those rebates are based on a number of factors, which take into account the drug's Average Manufacturer's Price ("AMP"), which is generally defined as the price wholesalers pay to manufacturers for their drugs. Relator, a CEO of a drug wholesaler, alleged that the Service Fee Defendants engaged in a scheme that lowered rebates to Medicaid programs and, therefore, constituted false claims. Specifically, he alleged that the SFD Defendants would give drug wholesalers credits for certain purchases, but that they would exclude those credits when making their AMP calculations. Relator alleged that, by excluding these credits from the AMP calculation, the defendants lowered the calculated AMP, which he alleged resulted in lower rebates that would be paid to the state Medicaid programs. Therefore, according to the Relator, the reported AMPs were "false claims."

Relator's claims were originally filed in 2008. The federal government and the states declined to intervene, but Relator was undeterred and filed several amendments to his complaint. In 2011, the SFD Defendants moved to dismiss Relator's Fourth Amended Complaint. The District Court granted that motion, finding that Relator had failed to plead sufficient facts that SFDs knowingly violated the False Claims Act. The appeal centered on whether the SFDs acted with the requisite mental state to support a False Claims Act violation.

The Third Circuit explained that the FCA imposes liability on a defendant who "knowingly" makes a false claim. "A defendant acts 'knowingly' if he or she 'acts in reckless disregard of the truth or falsity…of information.'" *Streck,* 2018 WL 3949031, at *3. Notably, the Third Circuit repeated that the FCA "does not reach an innocent, good faith mistake about the meaning of an applicable rule or regulation." *Id.* Although courts have taken different approaches to this, the Third Circuit also explained that the FCA does

not reach claims that are "based on reasonable but erroneous interpretations of a defendant's obligations." *Id.*

Relying on this standard, the Third Circuit then considered the decision by the SFDs to exclude certain credits for purposes of calculating AMP and, if that was problematic, whether excluding those credits was "objectively unreasonable." The court explained that,

> basing a defense on a reasonable, but erroneous, interpretation of a statute includes three distinct inquiries:
>
> (1) whether the relevant statute was ambiguous;
> (2) whether a defendant's interpretation of that ambiguity was objectively unreasonable; and
> (3) whether a defendant was 'warned away' from that interpretation by available administrative and judicial guidance.

Id.

Applying these principles, the court then undertook a statutory interpretation regarding the calculation of the AMP. The court observed that Congress's definition of AMP had changed repeatedly from 1997-2007. During those changes, Congress recognized that certain items could be excluded from the calculation of AMP, such as prompt-pay discounts (e.g., a discount for paying within a specified period of time). However, none of the definitions of AMP specifically addressed how to account for the type of credit of which Relator complained.

Because the credit was not specifically addressed in the statute, the court undertook an interpretation of the statute itself and whether it should be interpreted to include the credits about which Relator complained. On this issue, the court determined that the statute was ambiguous. As a result, the court considered whether defendants' interpretation was "objectively unreasonable." The district court found that the interpretation that the price initially paid to defendant was not objectively unreasonable. The Third Circuit agreed, finding that the statute itself did not have a temporal connection.

The court then considered whether there was anything that warned the defendants away from their interpretation of the relevant statutes. Relator argued that the guidance available during the relevant time period should have warned defendants away from their conduct because it provided broad examples of the type of price concessions that should be included in the calculation of AMP. The court agreed that the guidance could be read as construed by Relator. However, the court could not conclude that it was "so clear as to warn the SFDs away from an interpretation that excluded price-appreciation credits from AMP. Rather, we are convinced that the available scattershot guidance failed to articulate a coherent position on AMP and, specifically, price appreciation credits." *Id.* at *5. Importantly, the court focused on OIG guidance in 2005 that noted confusion in the industry regarding proper calculations of AMP and suggested that CMS consider addressing the concerns raised by industry, but these issues were not addressed until 2012, but even that guidance did not require that the credits be considered as part of the AMP calculation. It was in light of this noted confusion that the court determined that the SFD Defendants had not been warned away from their alleged wrongful conduct. The court found that "[a]lthough we are not prepared to say that this is the best interpretation of the statute, we nevertheless are confident that – at the very least – it was not objectively unreasonable to act in accordance with such an interpretation between 2004 and 2012." *Id.* at 6. Therefore, the Third Circuit affirmed the district court's dismissal of Relator's claims.

4. United States *ex rel.* Vaughn v. United Biologics, No. 17-20389, 2018 WL 4268423 (5th Cir. Sept. 7, 2018)

In this declined *qui tam*, relators sought to voluntarily dismiss their case with prejudice as to themselves and without prejudice as to the United States. The defendant challenged the "without prejudice" dismissal as to the government, seeking to include the United States in the "with prejudice" dismissal.

The Fifth Circuit first addressed the question of whether the non-intervening Government may be dismissed without prejudice when relators voluntarily dismissed themselves with prejudice. (This situation occurs often, but is rarely litigated.) The Court held that relators' decision to dismiss does not bind the Government because it would leave the Government "powerless to vindicate the public's interests in other actions that may have a stronger basis or a relator more able to shoulder the burdens of litigation." Id. at *6.

The court next rejected the defendant's contention that the Government and the Court had an obligation to provide a written explanation to support the dismissal. The Court held that the False Claims Act requires "written consent," but does not require the court or Government to provide written reasons for the dismissal. The Court noted that it as well as other circuits had previously concluded that the "Government retains *absolute* discretion to consent (or withhold consent) to as dismissal under § 3730(b)(1)—even when it does not intervene in the litigation." In so holding, the Fifth Circuit noted that the district court had held a hearing to discuss the matter and required the Government's attendance.

Finally, the court rejected the defendant's challenge to the dismissal as an abuse of discretion. In so holding, the court rejected defendant's argument that relators sought dismissal so as to avoid "an imminent adverse result on the merits" or that dismissal was inappropriate because the defendant had expended "significant resources" on the matter.

5. United States *ex rel.* Wood v. Allergan, Inc., 899 F.3d 163 (2d Cir. 2018)

The FCA's "first-to-file bar" prohibits a person from bringing a "related action" when an FCA suit is "pending." In this interlocutory appeal, the issue presented -- a question of first impression for the Second Circuit and the subject of a circuit split -- was whether a violation of the FCA's first-to-file bar can be cured by the filing of an amended complaint after the first-filed related action is no longer pending.

The "first-to-file bar," provides that "[w]hen a person brings an action under [the FCA], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." The first-to-file bar ensures that only one relator shares in the Government's recovery and encourages potential relators to file their claims promptly. A second action is 'related,' within the meaning of [the FCA] if the claims incorporate 'the same material elements of fraud' as the earlier action, even if the allegations incorporate additional or somewhat different facts or information." In other words, to be related, the cases must rely on the same "essential facts." If the first-filed complaint ensures that the Government "would be equipped to investigate" the fraud alleged in the later-filed complaint, then the two cases are related within the meaning of Section 3730(b)(5).

Wood filed his suit in July 2010. At that time, two prior suits raising essentially the same claims had already been filed. These earlier suits remained pending in 2010, but by 2016, when the government declined to intervene in Wood's action, the two cases had been dismissed. The government declined to intervene in both prior cases and the relators never pursued the claims.

Wood argued that the first-to-file bar did not apply because the prior complaints did not adequately plead fraud and that his claims were broader and more detailed. The Second Circuit disagreed, holding first that Wood's complaint was "related to" the first filed complaint: "Lampkin and Wood both allege a scheme where Allergan provided free cataract surgery recovery kits to induce increased use of Allergan products." That Wood's allegations were more detailed did not make a difference.

Similarly, whether the first-filed complaint met the requirements of Rule 9(b) was immaterial, since "Nothing in the language of Section 3730(b)(5) incorporates the particularity requirement of Rule 9(b) …. [and] Rule 9(b) and Section 3730(b)(5) serve different purposes, the former intending to protect defendants in fraud cases from 'frivolous accusations' and the latter designed to reward a *qui tam* relator for putting the Government on notice of a potential fraud without the dilution of 'copycat actions that provide no additional material information.'"

Finally, the Second Circuit disagreed that Wood could cure the first-to-file problem by amending his action after both prior actions had been dismissed and were therefore no longer "pending." While other circuits are split on this issue, the Second Circuit held that "The first-to-file bar is thus clear: an action **cannot be brought** while a first-filed action is pending…. [A]mending or supplementing a complaint does not bring a new action, it only brings a new complaint into an action that is already pending."

The Second Circuit went on to discuss at length how adopting Wood's interpretation of the first-to-file bar "would pose serious administrative concerns and disrupt the orderly operation of the FCA… . create problematic inefficiencies … [and] …essentially make any statute of limitations obsolete."

6. United States *ex rel.* Polukoff v. St. Mark's Hospital, 895 F.3d 730 (10th Cir. July 9, 2018)

This case centers on a physician's medical judgment, CMS rules regarding reasonable and necessary treatments, and whether such judgment may ever serve as the basis for False Claims Act liability. Relator filed this False Claims Act suit against Dr. Sorenson, a cardiologist with whom he worked, and Intermountain Healthcare Inc. and St. Mark's Hospital, hospitals at which both physicians worked. Relator claimed that Dr. Sorenson engaged in a widespread practice of performing a high number of cardiac procedures and that those procedures were not consistent with industry guidance and even that, on some occasions, they were conducted for entirely unproven treatments. Relator also alleged that, because Sorenson knew that Medicare and Medicaid would not pay for the procedures if Sorenson provided the actual diagnosis information, Sorenson would represent that the procedures had been done in accordance with industry guidance.

Relator claimed that Sorenson's practices were widely known within Intermountain Hospital. Several physicians at the hospital objected to Sorenson's procedures and alleged that he was violating internal policies. Intermountain then conducted its own audit of 47 of the relevant procedures performed by Sorenson in one month and the audit revealed that "the guidelines had been violated in many of the 47 cases." *Polukoff*, 895 F.3d at 738. Initially, Intermountain suspended Sorenson's cardiac privileges for two weeks. However, when he returned, Sorenson continued to violate hospital internal guidelines for the procedures. Ultimately, Intermountain suspended Sorenson. Sorenson resigned and moved his practice to St. Mark's Hospital. Relator then began working for Sorenson while at St. Mark's. Relator alleged that, while working at St. Mark's, he observed Sorenson actually create the condition that the procedure was designed to correct, even though the patient did not have the condition previously. Based on this alleged conduct, Relator alleged that Sorenson, Intermountain, and St. Mark's all submitted false claims for these unsupported procedures.

Reviewing these allegations, the district court dismissed Relator's complaint. The district court explained that Relator must show that the defendants "knowingly made an objectively false representation to the government that caused the government to remit payment." *Id.* at 739 (citations omitted). The district court found that "because [o]pinions, medical judgments, and conclusions about which reasonable minds may differ cannot be false for purposes of an FCA claim ... Dr. Sorenson's representations to the government could not be false absent a regulation that clarifies the conditions under which it will or will not pay for [the procedure]." *Id.* (citations and internal quotations omitted). Relator appealed.

On appeal, the Tenth Circuit was particularly focused on the district court's conclusions that (1) "medical judgment" and "conclusions about which reasonable minds might differ" cannot be false for purposes of FCA liability and (2) that a physician's certification that a procedure was "reasonable and necessary" could not be false absent a regulation clarification the conditions under which the government will or will not pay. The Tenth Circuit first found that it had not created a bright-line rule that medical judgment can never serve as a basis for FCA liability. It explained: "First, we read the FCA broadly … Second, the fact that an allegedly false statement constitutes the speaker's opinion does not disqualify it from forming the basis of FCA liability … [and] Third, claim for medically unnecessary treatment are actionable under the FCA." *Id.* at 742 (citations and internal quotations omitted). The court found that, because a physician certifies in a claim for reimbursement that the procedure was reasonable and necessary, for a claim to be reimbursable, it must meet the government's definition of "reasonable and necessary." *Id.* The Court found that this definition of reasonable and necessary is contained in the Medicare Program Integrity Manual and includes such factors as being "safe and effective," "not experimental or investigational," "furnished in accordance with accepted standard of medical practice…," among other factors. *Id.* at 742-43 (citing CMS, Medicare Program Integrity Manual, § 13.5.1). The court noted that it was aware that concerns about such a broad definition of "false or fraudulent" could expose physicians to more liability under FCA, it found that "concerns about fair notice and open-ended liability

can be effectively addressed through strict enforcement of the [FCA]'s materiality and scienter requirements. Those requirements are rigorous." *Id.* at 743 (citing *Universal Health Servs., Inc. v. United States ex rel. Escobar*, ___ U.S. ___, 136 S. Ct. 1989 (2017))

Although the Tenth Circuit had previously noted in its opinion that the industry guidelines were "inconclusive," Relator relied on those guidelines to define the medical community standards. The court then found that Relator had adequately pleaded that Sorenson performed unnecessary procedures including the allegations that (1) Sorenson performed an unusually large number of procedures, (2) the procedures violated both industry standards and internal hospital guidelines, (3) other physicians objected to Sorenson's procedures, (4) Intermountain had audited Sorenson and concluded that its own guidelines had been violated, and (5) Sorenson knew that Medicare would not reimburse his procedures if they knew the true reason, so he falsely represented that the procedures were consistent with industry guidance.

The Tenth Circuit also found that Relator adequately pleaded that both Intermountain and St. Mark's "knowingly" submitted false certifications through its Hospital Cost Reports, that include the certification "I certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations." The Tenth Circuit found that these express certifications were knowingly false as to each hospital based on Relator's pleading. Relator had alleged that he had personally informed the CEO at St. Mark's about the reason for Sorenson's suspension from Intermountain. Intermountain's knowledge could be inferred from the fact that Intermountain knew that such procedures should be rare, but numerous physicians had complained to Intermountain about Sorenson's procedures. The court noted that "[a]t a minimum, the amended complaint adequately alleges that St, Mark's and Intermountain acted with reckless disregard as to whether [the procedures] Dr. Sorenson was performing were medically necessary." *Polukoff,* 895 F.3d at 744. Although the district court had also dismissed the claims against Intermountain because relator failed to allege sufficient details about the claims submitted by

Intermountain, the Tenth Circuit explained that such deficiencies can be excused when they "result from the plaintiff's inability to obtain information within the defendant's exclusive control" and that Intermountain would know which of its employees handled billing for procedures performed by Sorenson "during his decade there." *Id.* at 745. The court therefore reversed the district court's decision to grant Defendants motion to dismiss Relator's complaint.

7. United States v. Academy Mortgage Corp., No. 16-cv-2120, 2018 WL 3208157 (N.D. Cal. June 29, 2018)

After initially declining to intervene, the Government moved to dismiss relator's *qui tam* suit, contending that the litigation would "drain its resources." The relator asked for an evidentiary hearing. Applying the applicable standard in the Ninth circuit, the court required relator to "present some evidence that the Government's decision to dismiss was unreasonable, not a result of a full investigation, or based on arbitrary or improper considerations." The relator's evidence purportedly showed that "the Government performed only a limited investigation of the original complaint and appears not to have investigated the amended complaint at all." Having made that showing, the applicable Ninth Circuit law then shifted the burden to the Government to identify a valid government purpose and demonstrate a rational relation between dismissal and that purpose. However, the Government did not submit evidence in response to the Court's order. Accordingly, the Court denied the Government's motion to dismiss.

United States *ex rel.* Maldonado v. Ball Homes, No. 17-379, 2018 WL 3213614 (E.D. Ky. June 29, 2018)

After declining to intervene in February 2018, the Government moved to dismiss the action after relator served the complaint. While the Sixth Circuit had not spoken to the issue, the district court held that "the government has virtually unfettered discretion to dismiss a *qui tam* action." This holding is the same that the D.C. Circuit reached.

Applying this principle, the court dismissed the action. In doing so, the court noted that "the government has a valid interest in reining in weak *qui tam* actions." The court also held that the False Claims Act did not entitle relator to an evidentiary hearing absent exceptional circumstances. The court held that it was sufficient that it afforded the relator a hearing during which he could argue against the dismissal motion.

8. United States *ex rel.* Allen v. Alere Home Monitoring, Civil Action No. 16-11372-PBS, 2018 WL 4119667 (D. Mass. Aug. 29, 2018)

This case pertains to Medicare reimbursements for at-home blood testing kits. The kits allow patients on blood thinning medication to monitor their blood's clotting time at home rather than traveling to a hospital or clinic. The eight defendants all supply these kits to patients and get reimbursed through Medicare. However, defendants only provide kits to patients who test two to four times per month. According to Relator, this business practice of requiring two to four monthly tests as a precondition to providing kits induces doctors to order medically unnecessary tests. Thus, defendants run afoul of the FCA because they get reimbursed by Medicare for tests they know are not medically necessary.

The United States declined to intervene in November 2017, and the case was unsealed. Each of the eight defendants filed motions to dismiss.

Allegations Against the "Willing Providers"

The district court first sorted the defendants into two groups. The first group were "willing to provide" testing materials to relator, even though he never enrolled in their programs. The court dubbed these the "Willing Provider" Defendants.

The district court dismissed claims against the "Willing Providers" because plaintiff could not identify and did not allege any specific false claims that they submitted or caused to be submitted.

The district court also noted that the "Willing Providers" relied on certificates of medical necessity issued by independent physicians. Thus, in order to support an allegation that these providers acted with scienter, relator would have to sufficiently allege that each defendant knew or recklessly disregarded the risk that the physicians ordered medically unnecessary tests and that the provider induced the physician to do so. The court held that "… Relator has failed to [allege] a single example of the [willing provider] company submitting a claim for a test despite known or obvious risks that the enrollment form was false with respect to a particular patient's medical needs." The court did not believe that applying a "relaxed standard" for 9(b) that is applied in certain fraudulent inducement cases saved the relator's claims in this

case. “But even if the “more flexible” standard did apply, Relator has not provided enough additional evidence to strengthen the inference of fraud beyond the level of possibility based on the enrollment forms alone.” The claims against the “Willing Providers” were dismissed.

Defendant Specific Allegations

The relator made more specific allegations against providers with whom he had direct dealings (both as a customer and through telephone conversations with company representatives), some of which the court allowed to proceed. Notably, the relator did not identify specific false claims for all of these companies, but in some instances nonetheless stated specific and plausible claims and therefore met Rule 9(b).

For example, the court allowed claims against CardioLink to proceed. A Cardiolink representative allegedly told relator that he was free to test once a month, but the company would bill Medicare for four tests per month regardless. In addition, the representative told relator that the company used an instructional DVD for at-home testers, rather than in-person instruction, which relator alleged is required by Medicare.

The court also allowed allegations against ACS. ACS's enrollment form states that “Medicare recommends weekly testing,” and the company sent relator materials to reinforce this point. Relator alleged that this is untrue, which supported the claim that ACS was knowingly causing the submission of false claims. In subsequent communications, relator asked the ACS representative whether Medicare would cover weekly tests even though his doctor told him he only needed monthly tests. The representative allegedly replied, “Yes, Medicare covers our services.”

The court dismissed similar claims against another test kit provider, PHM, holding that a mere assertion by a representative that Medicare “requires” its patients to test weekly, was insufficient, as there was no allegation that PHM made the statement to any treating physician and therefore no plausible allegation that this false statement caused the submission of a false claim. Allegations regarding PHM's marketing material intending to increase revenue through more frequent testing also fell short absent a

specific example showing that this promise of a new revenue stream actually induced a doctor to enroll a patient in weekly testing despite the lack of medical necessity.

Finally, the court rejected claims against two providers whose representatives basically told relator when he called that they would not work with patients whose physicians did not order weekly testing. In those cases, the court noted that the alleged facts indicated that neither company caused the submission of false claims, but instead relied on the physician's determination that the patients required weekly testing.

In the end, relator's broad industry-wide attack was essentially limited to claims against companies that actually provided him testing kits and/or companies whose representatives essentially admitted that the company filed claims for services that were not ordered, or made misrepresentations to physicians that induced them to order weekly tests.

9. United States *ex rel.* Rose v. Stephens Institute, Civ. No. 17-15111, 2018 WL 4038194 (9th Cir. Aug. 24, 2018)

This case involves the extent to which a violation of regulations can satisfy the materiality standards enunciated by *Universal Health Servs., Inc. v. United States ex rel. Escobar*, ___ U.S. ___, 136 S. Ct. 1989 (2017). Realtors, all prior admissions personnel for the defendant, claimed that the Defendant had violated a federal incentive compensation ban, which prohibits schools from offering incentive compensation that is related to a person's success in securing enrollments or financial aid. The Ninth Circuit took this interlocutory appeal to address a number of legal issues in the wake of *Escobar*.

First, the Ninth Circuit addressed the issue of implied certification under *Escobar*. It explained that, under the implied false certification theory, a relator must satisfy a two-part test. Specifically, the claim must (1) not merely request payment, but must also make specific representations about the goods or services being provided and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *United States ex rel. Rose v. Stephens Institute*, ____ F.3d ____, 2018 WL 4038194, *4, (citing *Escobar*, 136 S. Ct. at 2001). Noting that Supreme Court did not say that these two conditions are the exclusive means of establishing a false claim, the Ninth Circuit concluded that it was bound by this interpretation unless and until the Ninth Circuit, en banc, interprets Escobar differently. *Rose*, 2018 WL at *4. The court found that, because the Defendant represented in Federal Stafford Loan School Certification forms that the student applying for federal financial aid is an "eligible student" and s "accepted for enrollment in an eligible program," because Defendant failed to disclose non-compliance with the incentive compensation ban, a trier of fact could conclude that these were misleading half- truths that satisfy the two-prong Escobar standard.

The court then considered whether the alleged non-compliance with the incentive compensation ban was material for purposes of False Claims Act liability, meaning "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. *Id.* at *5. The court relied on a prior decision in which it found that violations of the incentive compensation ban are material based on the fact that "the statute, regulation, and program participation agreement all explicitly conditioned payment on compliance with the incentive compensation ban". Id. The Ninth Circuit recognized that the Escobar court explained that "[w]hether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry." *Id.* (citing *Escobar*, 136 S.Ct. at 2001). It recognized that the non-compliance with the incentive compensation and may not be material in all cases.

The court then considered whether a reasonable trier of facts could find that the alleged violations in this case could be material to a government decision. The court first found that the fact that "triple-conditioning of Title VI funds on compliance" through statute, regulation, and contract, although not "sufficient, without more, to prove materiality, it is certainly probative evidence of materiality." *Rose* at * 6. The court then considered whether past Department of Education actions would support a finding of materiality. The court found no evidence that the Defendant was aware of the government refusing to make payments based on non-compliance with the incentive compensation ban. The court also found no evidence that the government had made payments despite actual knowledge that the Defendant was violating the incentive compensation ban. With respect to whether the government regularly pays a particular type of claim in full despite knowledge that certain requirements were violated, the court found evidence that the government does sometimes take action when it is aware of such a violation. For example, of 32 other schools that had been noted with substantial violations, the government ordered 25 to take corrective action, 2 of the 25 schools were required to pay fines totaling $64,000, and The government also identified $187 million in misspent student aid funds at 1 of the schools and recouped more than $16 million of that liability. Based on this history, the court found that a reasonable trier of fact could conclude that violations of the incentive compensation ban were material to the government.

The court also noted that, under Escobar, "materiality does not exist 'where noncompliance is minor or insubstantial.'" *Id.* at *8. The court found that, if the program involved $10 gift cards or free coffee, there would be no viable claim under the FCA. However, the court paid particular attention to the amounts at issue in the incentive compensation program, finding that in the 2006-2008 plan, representatives could gain as much as $30,000 and a trip to Hawaii. In 2009-2010, representatives could receive a salary adjustment of up to $23,000 for meeting enrollment goals. Finding that this was the type of conduct that the incentive compensation ban was meant to avoid, a trier of fact could found that this non-compliance was material.

In a lengthy dissent, Judge Smith believed that the court made three errors in reaching its conclusion and that he would have reversed the summary judgment decision and remanded the case for further discovery to develop a proper record for summary judgment. First, Judge Smith believed that the Ninth Circuit's decision regarding the materiality of the incentive compensation ban had been overruled by Escobar. He concluded that, after *Escobar*, the analysis must focus "not on *whether* payment is conditioned on compliance, but *whether* the government would truly find such noncompliance material to the payment decision." *Rose*, at *9. Judge Smith then found that Escobar requires a "'rigorous' and 'demanding' inquiry into the 'likely or actual behavior' of the Government to determine whether it 'would attach importance [to the misrepresentation] in determining [its] choice of action in the transaction.'" *Id.* at *10 (citation omitted). He found that the focus must be on alleged misconduct that is directly analogous to the conduct at issue in the specific case. Because the only evidence before the court was that the government sometimes does take action with respect to violations of the incentive compensation ban, demonstrating that "the Government *cares* in broad sense," and that compliance with the incentive compensation ban is a condition of payment, there was not sufficient evidence to meet the "rigorous" and "demanding" materiality standards under *Escobar*.