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United States ex rel. Gacek v. Premier Med. Management,
2017 WL 2838179 (S.D. Ala. June 30, 2017)

This case was before the court on the defendants' motion to dismiss relator's first amended complaint in intervention. Relator originally filed his complaint in July 2014. Relator, a physician, was a former employee of Premier from 1997 until April 2013 (about 1 ½ years before filing his qui tam complaint). The government conducted a three-year investigation and declined to intervene.

Relator's False Claim Act complaint alleged that he had been terminated for repeatedly complaining about alleged "healthcare fraud and unethical medical practices." Relator alleged that (1) Premier presented or caused to be presented false or fraudulent claims, (2) Premier created false records or material statements to secure payments, (3) Premier retaliated against relator, (4) Premier and its employees conspired to violate the law, and (5) Premier was involved in "reverse false claims" by failing to timely return alleged overpayments. Specifically regarding the fifth count, Relator alleged that, as a result of an alleged kickback scheme, Premier had an obligation to reimburse the government for payments received for services that were performed by certain physicians as a result of the alleged kickbacks.

Relator alleged that Premiere billed for certain types of medical tests instead of other equally or more effective medical tests because they were more profitable and sometimes conducted and billed for both tests. He also alleged that Premiere would up-code procedures to obtain higher levels of reimbursement, giving an example of a procedure billed to a private insurance plan, but alleging that he had been informed that other physicians had raised concerns that government funded health care programs were also were the subject of up-coding. Relator

claimed, on information and belief, that Premiere had billed for and received payment from the government for these alleged fraudulent schemes and that the false claims and statements "are in the exclusive control of Premiere." He also alleged an intra-corporate conspiracy to submit false claims. Finally, he alleged that physicians paid cash gifts to front desk personnel to schedule more patients on the physicians' calendars and that Premiere billed for those "tainted and illegal procedures."

Among other arguments, Premiere asserted that relator's complaint lacked the necessary sufficiency required by Rule 9(b). Premiere argued that the complaint failed to identify specific statements, in specific documents, submitted by specific people, presented to specific government programs, and failed to identify payments from the government for those claims. Relator did not contradict that position, but instead argued that a False Claims Act complaint could meet the 9(b) requirements where it provides "other indicia of reliability."

The district court agreed with relator that the "other indicia of reliability" standard is applicable to False Claims Act cases, however, also noted that a more lenient standard is not applied in False Claims Act cases simply because "evidence of fraud was uniquely held by the defendant." The court found that, in applying a case-by-case approach to the heightened pleading requirements, "several principles emerge." Specifically, a relator with direct knowledge of submission of false claims gained through employment "may have a sufficient basis for asserting that the defendants actually submitted false claims," but that someone without such first-hand knowledge was unlikely to have a sufficient basis for such a claim. However, "at a minimum" a relator mush explain the basis for making an allegation that fraudulent claims were submitted and this must be more than a bald assertion that the relator is aware of such practices.

Even though relator in this case was an insider, he did not claim to have any knowledge of its billing practices or that he submitted or knew that others submitted false claims. As a result, it would require the court to speculate that there was an actual submission of false claims. Therefore, the court dismissed these claims.

Premier also moved to dismiss the retaliation claims, because there was no fear of litigation for Premier. However, the court held that retaliation claims related to FCA claims are not required to satisfy the heightened pleading requirements of a fraud based claim. As a result, as long as relator's allegations that Premiere feared being reported are plausible, then the complaint satisfies the pleading requirements. The court found such a claim plausible.

Regarding the conspiracy claims, the court agreed that the "intracorporate conspiracy doctrine" typically bars conspiracy claims that are premised on the theory that individuals within an organization conspired with one another. However, this doctrine applies only in the civil context, not to criminal conspiracies. The court found that this exception applies in the civil context when the alleged civil conspiracy also would constitute a crime. The court reasoned that, because the alleged conduct in relator's complaint could give rise to criminal liability if proved at trial, the intracorporate conspiracy "cannot and does not bar" relator's civil conspiracy claim. Nonetheless, relator's complaint still lacked sufficient detail of an agreement to satisfy Rule 9(b).

Finally, Premier moved to dismiss relator's claims based on alleged kickbacks. The court found that relator's kickback theory, although "convoluted" according to the court, appeared to be based on a theory that there was an "internal unlawful kickback scheme" whereby some physicians paid appointment clerks to shift patient appointments to the physicians' calendars. It is not clear from the opinion whether any of these claims would have been billed for the services

of another Premier provider. Nonetheless, Relator argued that, after becoming aware of this scheme, Premiere had an obligation to return payments that were tainted by that scheme to the government. Premiere moved to dismiss, asserting that relator failed to allege facts that Premiere knowingly avoided or decreased an obligation to pay the government. However, the court found that the complaint contained sufficient facts and a corresponding statutory responsibility to repay the government for overpayments and denied the motion to dismiss the reverse false claim under this anti-kickback theory.

United States ex rel. Smith v. Van Dyck,
2017 WL 3428096 (9th Cir. 8/10/17)

In this case, the 9th Circuit affirmed the district court's denial of relators' request to intervene holding that a criminal forfeiture action does not constitute an "alternate remedy" to a civil *qui tam* action under section 3730 (c) (5) of the False Claims Act entitling a relator to intervene in the criminal action and recover a share of the proceeds.

Neil Van Dyck was a licensed podiatrist who owned and operated a podiatry practice until October 2014. Relator Wendy Johnson worked as his medical assistant from 1986 to 2008, and Relator Nancy Smith worked as his medical assistant and biller from 2006 to 2012.

In April 2011, Van Dyck was notified by SafeGuard Services, LLC, a Medicare contractor, that his billing patterns for surgical nail avulsions and other procedures were under investigation and requested certain of his medical records for patients seen between March 2010 and February 2011.

Van Dyck submitted incomplete records and SafeGuard, together with the Department of Health and Human Services (HHS) continued to pursue records. In 2011, Relator Smith talked with SafeGuard about the record production, seeking clarification of what was sought and why.

Shortly after Van Dyck received the SafeGuard request for records, he down-graded his billing claims to more routine foot care.

In February 2012, HHS received an anonymous complaint about Van Dyck's billing. The anonymous caller was later identified as Relator Smith.

In July 2014, the Government interviewed Relator Smith to determine her role, if any, in Van Dyck's billing.

Based on SafeGuard's and HHS's investigation, the Government sought a warrant to search Van Dyck's office and during the execution of the warrant, Van Dyck confessed to the fraud.

In September 2015, Van Dyck was charged with health care fraud and, as part of his plea agreement, he agreed to forfeit funds from his retirement account. On October 27, 2015, the district court issued a personal forfeiture money judgment for $1.23 million, the estimated amount of the fraud.

In July 2012, over a year after the SafeGuard investigation began, the relators filed their sealed *qui tam* action.

The Government attempted to resolve the civil *qui tam* but settlement negotiations broke down and, in February 2016, the Government declined to intervene. At the time of this decision, the civil *qui tam* was still pending in district court.

The 9th Circuit, in rejecting the relators' request to intervene in the criminal proceeding, said that they simply asserted "unliquidated, undetermined and speculative interest on the forfeited money." The Court relied on the fact that the Government's investigation preceded the *qui tam* filing, and that the Government's investigation – rather than the relators' information – prompted the criminal forfeiture action.

The Court rejected the relators' argument that the Government had chosen the criminal forfeiture as an alternate remedy. The 9th Circuit held that their "sole remedy" was to commence their *qui tam* action and the conclusion of the criminal forfeiture does not preclude relators from going forward. The Court acknowledged the practical concern of the possibility of Van Dyck being

rendered judgment proof, but that did not provide the relators with the right to intervene in a criminal action. "The question of collection on a judgment is separate from an intervention right." See also United States v. Couch, 2017 WL 3016923 (S.D. Ala. July 13, 2017)

Finding no provision in the Federal Rules of Criminal Procedure for intervention by a *qui tam* relator in a criminal forfeiture proceeding, the district court ruled that the proceeds of such an action are not an "alternate remedy" under the FCA and a relator is not entitled to seek a share thereof.

United States ex. Rel. Brian Wall v. Circle C Construction, LLC,
2017 WL 4477367 (6th Cir., Aug. 18, 2017)

The Sixth Circuit recently awarded a defendant $468,704 in attorney's fees, despite the government winning its FCA suit. The Court found that the defendant was entitled to recover its fees under the plain language of the Equal Access to Justice Act ("EAJA"), even though it was not the prevailing party, because the government's demand for $1.6 million in damages was "unreasonable" and "substantially in excess" of the final judgment of $14,748.

Over the course of nearly a decade of litigation, the United States sought treble damages in connection with 42 warehouses Circle C built for the United States Army based on $9,900 in underpayments to two electricians by Circle C's subcontractor. Specifically, the government argued that claims for all 42 warehouses were "tainted" by the underpayments because the underpayments resulted in Circle C's submission of false compliance statements and invoices. The United States prevailed and was awarded $763,000 by the trial court. On appeal, the Sixth Circuit rejected the tainted claims theory and reduced the damages to just $14,748.

Circle C subsequently moved for recovery of its legal fees under the EAJA, which provides that "if, in a civil action brought by the United States,…the demand by the States is substantially in excess of the judgment finally obtained by the United States and is unreasonable when compared with such judgment", the court must "award to the [defendant] the fees and other expenses related to defending against the excessive demand." 28 U.S.C. § 2412(d)(1)(D). The district court denied the motion on grounds that the government's damages theory was "not unreasonable."

In a 2-1 decision, the Sixth Circuit reversed, holding the district court failed to consider the actual merits of the government's position and that the EAJA was unambiguous. To the Sixth Circuit the application of the EAJA was clear: the final judgment amounted to less than 1% of the government's initial demand; thus, it "could hardly be plainer" that the government's demand was "substantially in excess" of the judgment, and the demand was then clearly "unreasonable." Indeed, the Court characterized the government's proposed damages as "fairyland rather than actual," and noted that the government received the benefit of its bargain "every minute of every day" through use of the electricity in the 42 buildings.

Turning to the exceptions to the EAJA, the Court found that none of the stated exceptions applied because the Defendant had not "committed a willful violation of law or otherwise acted in bad faith", and the government had not shown that any "special circumstances make an award unjust." The Court reasoned that, while Circle C's underpayment was "reckless," it was neither willful nor in bad faith. The Court batted away the government's argument that an award of legal costs would chill its efforts to "vigorously enforce" the FCA; noting, "One should hope so."

Judge John M. Rogers dissented, arguing that "it is a matter of judgment" whether the government's position was reasonable and that the government had provided numerous examples of cases in which similar tainted claims arguments were found to be reasonable. As a result, Judge Rogers argued, the district court's decision should be given substantial deference and its denial of fees should be affirmed.

The case should serve as a strong warning to government lawyers inclined to pursue overly aggressive damages theories.

United States v. Persaud,
866 F.3d 371 (6th Cir. 2017)

This case arises from a criminal action against Harold Persaud, a cardiologist. Persaud's practice focused primarily on the treatment of coronary artery disease (CAD). As the court explained, diagnosing CAD can involve a variety of tests, each with advantages and disadvantages. When the tests reveal potential problems, a physician may prescribe different invasive procedures, such as the insertion of a stent. Insertion of a stent is permanent and can cause additional medical problems, such as blood clotting and narrowing of a stented artery.

The government alleged that Persaud ordered "unnecessary tests," "systematically overestimated the degree of arterial blockage … in order to justify costly interventional procedures such as 'stenting'" and engaged in "up-coding" by over-reporting "the complexity of his patients' medical issues." Persaud would see patients for 10 minutes, but would document in medical records that he spent 30-35 minutes with them. Also, when his practice came to the attention of auditors "he began to edit existing patient files that the auditors had selected for review, adding additional notes and observations to support his inflated CPT codes."

Testimony at trial included the fact that Persaud required his patients to undergo unnecessary procedures, and that he was able to increase his profits from these certain testing because he owned the equipment for performing the tests. To justify the tests, he used a "pre-populated template form that assigned his patients the same litany of vague symptoms." "In some instances, Persaud used wheel-chair assisted replacement patients in treadmill-based NST's…" He also "allegedly falsified his patients' NST results in order to convince them to undergo additional catheterization testing at local hospitals." Demonstrating that experts might disagree

regarding interpretations of certain studies, the court explained that "[a]lthough interpreting angiograms is an inexact science subject to reasonable differences in professional opinion" however, also noted that "most cardiologists who interpret the same angiogram will indicate similar levels of blockage." An expert at the trial testified that the variability between 2 cardiologists is typically about 10%, but that Persaud overestimated blockages by about 40-50% and used this to justify additional invasive procedures.

The matter came to light when another physician, the chief cardiologist at St. John's Medical Center, had been assigned to monitor one of Persaud's patients until surgery could be scheduled. The physician and a nurse noticed that Persaud's records "severely overestimated the extent of the patient's arterial blockage." As a result of subsequent testing, the physician concluded that there was no reason for the patient to undergo bypass surgery. The physician then undertook a review of 12 tests that Persaud had performed at St. John Medical Center during the 3 months before the falsely referred bypass patient and, of the 11 images he was able to recover, he identified problems with 7 of those cases. Subsequent investigation by the hospital led them to conclude that 43 out of 65 stent procedures were "completely unnecessary." Publicity regarding this issue triggered the government investigation.

After a month-long trial, the jury convicted the defendant of all counts, with the exception of 1 of 14 counts of making false statements relating to health care matters. The court sentenced the defendant to 20 years imprisonment, a $1,500 special assessment, and restitution in the amount of $5,486,857.03.

The court characterized Persaud's argument on appeal as a claim that he was "an overprotective cardiologist who is guilty of nothing more than relying on outdated practice

methods in treating his patients." However, the court stated that "he is effectively asking this court to re-weigh the expert testimony that was presented at trial." The court found that Persaud was not arguing that the expert testimony was insufficient, but instead that the expert witnesses were wrong "either because they relied on incomplete information or made incorrect assumptions about the standards of professional medical care." The court stated that, after testimony has been properly admitted, it is for the jury to decide whether to accept it.

As the court explained, Persaud attempted to present information on appeal that was never before the jury. For example, he attempted to provide information that his practice of testing patients on an annual basis "is, at best, obsolete, and not a sign of healthcare fraud" and then proceeded to provide patient-by-patient information to justify procedures for some of his patients. However, the court found that this information was never presented to the jury. The court also observed that the government put forward ample uncontested evidence that supported the conviction and again commented on the fact that Persaud used "wheelchair bound patients in treadmill based" tests to fill a quota of patients—a fact which Persaud did not challenge. The court also observed that Persaud argued that, because he knew the details of his patients' lives, he was better positioned to determine if their symptoms merited further testing and that the government's experts lacked sufficient information to properly analyze his use of the tests.

Despite the fact that experts could disagree regarding the appropriateness of Persaud's conduct, the court explained that "the jury was entitled to accept the view of the government's experts over those of Persaud's experts." In this case, the fact that experts might disagree would not preclude a conviction. Instead, the court's task was confined to deciding whether a rational

jury could conclude, based on the record that was presented before the jury, that Persaud's conduct was indicative of healthcare fraud. The court concluded that Persaud failed to demonstrate his burden of demonstrating that the conviction was not supported by sufficient evidence.

United States ex rel. Smith v. Carolina Medical Center, et al.,
(Civil Action No. 11-2756, ED Pa., Aug. 2, 2017)

In the 1990s, Melchor Martinez owned and operated three outpatient mental health clinics in Pennsylvania. His wife Melissa Chlebowski was an administrator at these clinics.

In 2000, the Commonwealth of Pennsylvania convicted Martinez of Medicaid fraud for billing for services not rendered and falsification of records. Martinez was then excluded for 10 years as a provider for the Medicare and Medicaid program.

Martinez transferred his ownership in the clinics to Chlebowski and they created a new corporation, Northeast Community Mental Health Centers, Inc.

Since 2000 and despite the exclusion, Martinez, with Chlebowski, operated and expanded their business, opening new clinics in Pennsylvania and North Carolina.

In 2011, Karen Smith, a former clinical director at a mental health clinic in North Carolina, filed a qui tam complaint alleging that Martinez, an excluded provider, was improperly managing the clinic and concealing his involvement. Smith named as defendants the three corporations run by Martinez. The Government intervened with an expanded complaint, naming the three corporations as well as Martinez, his wife Chlebowski, and three clinic administrators.

The Government's complaint in intervention alleges that Martinez: hired and fired staff; instructed staff on billing; ordered staff to alter doctors' notes; monitored the productivity of the clinics' therapists and psychiatrists; set schedules; trained therapists; monitored patient intake; directed the implementation of new electronic medical records; and directed other activities.

The complaint also alleges that Chlebowski's name was put on legal documents to disguise Martinez's involvement yet Martinez earned over $35,000/month in rent alone from the clinics. It also alleges that Martinez traveled on the companies' credit cards. On yearly Medicare and

Medicaid enrollment forms Chlebowski certified multiple times that no excluded person was an "operator, director, manager, agent, consultant or owner of the clinics."

The Government's complaint alleges that in addition to submitting false claims as a result of Martinez's involvement, the clinics also overbilled for services such as "med checks" billed as longer psychiatric services and billed for services rendered by non-qualified personnel. The Government alleges that the false and fraudulent statements in the enrollment forms about Martinez's involvement in the clinics resulted in False Claims Act violations for all claims subsequently submitted.

In this decision, Judge Stengel, now Chief Judge for the Eastern District of Pennsylvania, denied Defendants' Motions to Dismiss finding that under both the Pre and Post 2010 amendments to the False Claims Act the Governments' allegations were sustained.

For claims submitted before the amendments, the Court rejected Defendants' argument that the Escobar "implied false certification" theory must control, and instead found that, "based on a theory of fraudulent inducement, a claimant can be held liable for express false certifications in enrollment documents." Here the Government and the relator alleged sufficient facts showing false statements and omissions that induced the Government to enroll the clinics in Medicare and Medicaid.

The 2010 amendments made FCA liability for fraudulent inducement even more explicit. The Court, following a lengthy discussion of materiality, conditions of payment, administrative guidance, Government knowledge and conditions of participation, found that such liability could be imposed and denied Defendants' motions on that basis.

The Court then addressed the question of the sufficiency of the factual pleadings to hold the three individual administrators liable, finding that their individual actions caused the submission of false claims.

The Court also rejected Defendants' materiality challenges to the "med check" upcoding allegations, saying that "because the Government alleges the Pennsylvania Medicaid administrator recouped overpayments as a result of the clinics' failures to document start and end times for the visits, it has sufficiently alleged facts showing materiality."

The Court sustained the Government's claims of liability for unqualified therapists despite Defendants' argument that the Government knew of the therapists' deficiencies and paid anyway, finding that "while materiality is violated where the government pays current claims it knows to be fraudulent, it is not defeated on a motion to dismiss by the suggestion in the complaint that healthcare administrators did not seek redress for past improper billings."

The Court also sustained the Government's claims regarding false claims for unsupervised therapists, finding sufficient particularity in the pleadings.

The Court's decision also contained a discussion of piercing the corporate veil, finding that veil-piercing is appropriate under these facts as the corporations were created as shells to hide Martinez's involvement.

United States ex rel. Brown v. Pfizer, Inc.,
2017 WL 1344365 (E.D. Pa.. April 12, 2017)

In a prior decision, *United States v. Pfizer, Inc*., No. 05-6795, 2016 WL 807363 (E.D. Pa. Mar. 1, 2016), the court dismissed the relator's claims under the "first-to-file" rule. The court allowed the relator to file an amended complaint, which it did, again alleging that Pfizer improperly caused the submission of false claims related to its product Vfend. In the instant decision, the court denied Pfizer's motion to dismiss the amended complaint.

Pfizer make four principal arguments in support of dismissal:

1. Relators lacked subject matter jurisdiction because they are required to file a separate action in order to cure the first-to-file bar and any such separate action would be time-barred;
2. The off-label use of Vfend on neutropenic patients and for empiric therapy is covered by Medicare and other healthcare programs;
3. Relators have failed to state a claim that Defendant paid kickbacks because the challenged practices are protected by a safe harbor regulation; and,
4. Relators have failed to state a claim under implied false certification theory and failed to satisfy the materiality requirement of the FCA because the government continued to pay for Vfend after Relators' allegations in 2005.

First-to-File

The court held that since the prior-filed action was dismissed, it was no longer "pending" and no longer imposed a "first-to-file" bar. The court relied on the First Circuit -- the only circuit court to have addressed this issue – decision in *U.S. ex rel. Gadbois v. PharMerica Corp*., 809 F.3d

1 (1st Cir. 2015), in which a relator whose case had been dismissed under the first-to-file rule was able to resurrect his case after the first-filed action was dismissed. In this case, since the first-filed matter was dismissed, it was no longer "pending" for purposes of the first-to-file rule under the FCA, and Relators were permitted to file an amended complaint.

As to the statute of limitations, the court determined that the amended complaint related back to the original complaint, which was filed in 2005, so that the statute had not run. Rule 15(c) provides that "[a]n amendment to a pleading relates back to the date of the original pleading when ... the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading." The court held that Relators' allegations in the amended complaint arose out of the conduct that Relators alleged in their original complaint, namely that Pfizer promoted Vfend for impermissible off-label uses and that the original complaint gave Defendant fair notice of the general fact situation that Relators allege in the amended complaint.

Is the Challenged Use of Vfend Covered by Medicare ?

The court previously dismissed Relators' off-label Medicaid claims, but allowed Relators to amend the complaint to support the off-label Medicare claims. Pfizer argued that the court improperly relied on a Medicare provision that applied only to chemotherapeutics and biological drugs, but the court disagreed. Accordingly, the court continued to hold that Relators should be given the opportunity to engage in discovery to identify any statutorily-recognized compendium which states that Vfend is "not medically appropriate" for empiric therapy in Neutropenic Patients.

Are False Claims Resulting from Kickback Violations Properly Plead ?

Relators claimed that Pfizer "misrepresented and concealed the true import of the 608 Study which was used to obtain approval in 2004 for use of Vfend in treating invasive Candida fungal infections;" paid physicians to write and submit an article to the New England Journal of Medicine advocating for the off-label use of Vfend for empiric therapy when they "well knew that the 603 Study results showed that Vfend was not suitable for [such a] use;" distributed "misleading materials ... urging physicians to prescribe Vfend;" "encouraged its sales representatives to promote Vfend for 'early and aggressive therapy;' " and, "participated in, encouraged, and authorized the unlawful payment of illegal kickbacks to physicians and pharmacists in order to increase sales of Vfend, a substantial percentage of which were for 'off-label' uses." Pfizer argued that making such marketing activities illegal would render all pharmaceutical marketing improper. The court disagreed, however, since the Relators alleged that false and misleading statements were being used to market the product.

The court also disagreed with Pfizer's argument that its financial arrangements with physicians, consultants, and promotional speakers fell within the Personal Services safe harbor. The court required Pfizer to demonstrate that it met every element of this safe harbor – which Relators argued was impossible at the pleading stage – and held that Pfizer failed to show that the various payments made to the consultants were consistent with fair market value. "We are compelled to conclude that Relators' allegations call into question whether the types of compensation that Defendant paid to its medical agents was actually consistent with a fair market value. Accordingly, at this point Defendant's actions do not meet the safe harbor requirements."

Falsity and Materiality

The court found that Relators argued express falsity: "We find that Relators have sufficiently established the element of "falsity" pursuant to the FCA. We agree that Relators alleged that Defendant withheld or concealed adverse test results from the FDA, however Relators have also alleged that Pfizer made expressly false statements to the FDA for approval of Vfend in order to induce Medicare and Medicaid payments. Therefore, the falsity element is satisfied."

The court further found that the Relators alleged that Pfizer misrepresented the 608 Study by doing the following: falsely citing the 608 study as evidence that Vfend was more effective than other anti-fungal medications in treating Candida infections, claiming that the 608 Study revealed that Vfend was effective in treating a Candida infection despite the fact that the 608 Study showed the opposite results, misrepresenting the 608 Study results to add credibility to Pfizer's illegal marketing tactics, and supporting the publication of "ghost written" articles in medical journals, which cited the 608 Study as evidence that Vfend should be used to treat Candida infections. Relators alleged that Pfizer did that after the FDA first rejected its proposed use for Vfend. As a result, the court found that Relators pled sufficient facts to demonstrate that Pfizer's misleading and false statements were material to the FDA's approval of Vfend for treating Candida infections.

Finally, Pfizer argued that the fact that the government continues to pay for the challenged claims even though Relators filed this action in 2005 proves that the alleged falsity is not material to the payment decision. The court disagreed: "The mere fact that the government

has continued to pay and approve claims for Vfend even after Relators' allegations in 2005 is insufficient to establish that Relators' claims lack materiality. As the First Circuit held, mere knowledge of allegations regarding noncompliance is insufficient to prove actual knowledge of noncompliance. Moreover, Relators allege that the United States was "unaware of the false or fraudulent nature" of Pfizer's statements and actions, and therefore due to this ignorance, continued to pay for reimbursement claims for Vfend. Absent evidence that the government had actual knowledge of Defendant's fraud, we find the government's continued payments of Vfend claims insufficient to establish that Relators' claims fail for lack of materiality."

United States ex rel. Phalp v. Lincare Holdings, Inc.,
857 F.3d 1148 (11th Cir., 2017)

In this case, relators (former sales representatives for Lincare) alleged that Lincare's violations of certain regulations gave rise to a cause of action under the False Claims Act. Lincare supplied certain products and services to patients who suffered from Chronic Pulmonary Disease ("COPD"). Lincare also created a company called Diabetic Experts of America to sell diabetic testing supplies. Lincare had received assignment of benefit forms from Medicare beneficiaries in connection with Lincare's COPD operations. Relators alleged that Diabetic Experts of America would contact former Lincare customers. Relators also alleged that Diabetic Experts of America did not obtain assignment of benefit forms for these Medicare beneficiaries specifically for diabetic testing supplies, but relied on the assignment of benefit forms obtained by Lincare in connection with the COPD business.

Relators argued that this conduct gave rise to a False Claims Act cause of action because Lincare was non-compliant with Medicare regulations in two ways: 1) they failed to obtain specific authorizations for purchasing particular items, but relied on generic authorizations when ordering diabetic test strips and 2) they submitted claims that resulted from phone calls to Medicare beneficiaries that were in violation of Medicare "unsolicited telephone contact rules." Relators also provided the specific bills that were submitted in support of their complaint.

In dismissing the first set of claims, the district court held that, when a defendant in a False Claims Act case asserts that the law is ambiguous, a relator is required to establish that there is "no reasonable interpretation of the law that would make the alleged false statement true." The district court explained that a "reasonable interpretation of any ambiguity inherent

in the regulations belies the scienter necessary to establish a claim of fraud under the FCA." The district court dismissed these claims on the basis of that ambiguity. The district court granted summary judgment on the telemarketing claims based on its finding that the specific calls identified were within an exception to the rule prohibiting such marketing calls.

The Eleventh Circuit Court of Appeals disagreed with the district court's holding regarding ambiguous statutes and regulations. The court first explained that relator's case was based on a False Certification theory, not an action to enforce Medicare regulations, noting that the False Claims Act "does not create liability for a healthcare provider's disregard of Government regulations…unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe." The court also explained the requisite scienter that a relator must show: "actual knowledge," "deliberate ignorance," or reckless disregard." Importantly, the court explained that liability attaches to those who fail to make such inquiry "as would be reasonable and prudent" under the circumstances.

Based on this, the court disagreed with the district court's explanation 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." The court held that the conclusion that "a finding of scienter can be precluded by a defendant's identification of a reasonable interpretation of an ambiguous regulation that would have permitted its conduct is erroneous." Such an interpretation is a relevant factor, but the court held that the requisite scienter can exist "even if a defendant's interpretation is reasonable." Instead, under the standard set forth by the Eleventh Circuit, courts must look at whether the defendant was aware of the proper interpretation of the statute or regulation at issue. Although the Eleventh Circuit held that the

district court had applied the wrong standard, it found that there was no evidence of scienter and also that there was "nothing in the plan language" of the regulation that would have put the company on notice that its conduct was not compliant with the regulations.

With respect to the telemarketing claims, the Eleventh Circuit agreed with the district court that the transactions proffered by relators were squarely within an exception to the prohibited "unsolicited telephone contacts" rule. The court correctly held that contacts by one company affiliated with another are permissible when the calls are within 15 months of the time that an affiliated company supplied a covered item to the individual. Although relators argued that, even if the exemplars provided were insufficient, they could survive summary judgment "based on facts known to them personally from their time as employees of Lincare affiliates." The Eleventh Circuit agreed with the district court's rejection of this argument and that the relator's evidence failed to create a "genuine dispute of material fact." As a result, it confined its review to the exemplars provided by relators.

United States ex rel. Scarlette Lutz, et al. v. Berkeley Heartlab, Inc., et al.,
2017 WL 1533434 (D.S. Car. April 27, 2017)

The Government filed a complaint in intervention against Defendants Blue Wave Healthcare Consultants, Inc., Floyd Calhoun Dent, III, LaTonya Mallory, Robert Bradford Johnson, and others, alleging violations of the Anti-Kickback Statute (AKS), and False Claims Act. The alleged violations arise from Blue Wave's marketing of laboratory tests for two laboratory companies. The Government alleged that Defendants violated the FCA when they orchestrated multiple kickback schemes to induce physicians to refer blood samples to certain of the Defendants for large panels of blood tests, many of which were medically unnecessary. One of the schemes was to pay processing and handling fees (P&H fees) to physicians.

In this decision, the district court addressed motions to compel the Government to provide more complete answers to several Requests for Production. Highlighted here are four of the motions.

First, Defendants sought production of "all witness statements of any kind related to this action…" The Government objected, arguing that it had already produced all sworn or verbatim statements of the key witnesses and that any other responsive memoranda of witness interviews are privileged or protected by the work product doctrine.

The Court ordered the production of interview notes, memoranda and other documents. The Government was allowed to withhold protected opinion work product but only after producing a log identifying such.

Second, Defendants sought the production of any settlement discussions between the Government and certain other parties. The Court rejected the Government's assertion of FRE 408, attorney-client privilege, work product and Government privilege and found that settlement

discussions may be relevant to the issue of damages. The Government was ordered to produce the settlement documents.

Third, Defendants sought the production of documents in which "any attorney, law firm or Government agency" opined on the legality of the payment of the P&H fees to physicians. The Government objected, arguing that these were internal Government deliberations and the Court agreed. Finding that these documents did not reflect the Defendants' state of mind, the Court did not order production.

Finally, Defendants sought "all documents relied upon or considered by the OIG" in issuing a Special Fraud Alert on the topic of these P&H fees. The Government asserted the deliberative process privilege and the Court, after assessing the three procedural steps required to assert the privilege, agreed with the Government. The three procedural requirements were:

1) Agency head must assert the privilege after personal consideration;

2) Agency head must state with particularity the information subject to the privilege; and

3) Agency must aver precise and certain reasons for preserving the confidentiality of the requested documents.

The Court found that the Government satisfied these requirements and that the withheld documents were both predecisional and deliberative.

See Also

United States ex rel. Lutz v. Berkeley Heartlab, Inc., 2017 WL 2972143 (D.S. Car. July 11, 2017) and United States ex rel. Lutz v. Berkeley Heartlab, Inc., 2017 WL 3131104 (D.S. Car. July 21, 2017)

In another series of pretrial discovery rulings in this case, the Court addressed the admission of expert testimony regarding the kickback scheme of paying P&H fees to physicians that was then included in their Medicare reimbursement. In response to the Government's expert testimony on this subject, the Defendants offered testimony of two experts regarding how charges for these services could be calculated and the fair market value for these services. Both of the above decisions granted the Government's motion to exclude one of the expert witnesses as failing to satisfy the *Daubert* standard.

United States ex rel. Penelow v. Johnson & Johnson, et al.,
2017 WL 2367050 (N.J. May 31, 2017)

Relators filed suit on behalf of the Government, twenty-seven states, and the District of Columbia against Janssen Products, L.P. and its parent company, Johnson & Johnson, alleging fifty-eight counts under the Federal False Claims Act ("FCA"), Federal Anti-Kickback Statute ("AKS"), and the false claims acts of various states. The claims related to Defendants' purported misconduct in connection with marketing two HIV/AIDS drugs: Prezista and Intelence. The Government declined to intervene in the matter. At issue was the Defendants' motions to dismiss.

With respect to Prezista, Relators alleged that Defendants' sales representatives and managers falsely promoted the drug as "lipid neutral," meaning that "the drug would not affect or increase a patient's cholesterol or triglyceride levels, contrary to Prezista's label." Relators further pled that because Prezista actually increases lipids in patients, it presents a serious risk of cardiovascular disease for patients. Additionally, Relators alleged that Defendants misrepresented Prezista as having superior "binding affinity," which relates to the drug's ability to prevent HIV from replicating. The Amended Complaint alleged that Prezista's worldwide sales increased substantially due to Defendants' misrepresentations.

As to Intelence, Relators alleged that Defendants improperly promoted and marketed the drug for unapproved once-daily dosage and treatment-naïve patients. Intelence, according to Relators, was actually intended for twice-daily dosing to patients who were treatment-experienced.

According to the Amended Complaint, Defendants also allegedly implemented a kickback scheme, used dinner programs with planted audience members to ask off-label questions, and

paid for speaking engagements to falsely promote Prezista and Intelence. As a result of Defendants' misleading marketing and kickback schemes, Relators alleged that false claims for reimbursement were submitted to the Government.

Is Prescribing for an FDA-approved Use "Reasonable and Necessary" ?

Janssen Products first argued that prescriptions written for Prezista's FDA-approved use were inherently "reasonable and necessary" and therefore could not result in false claims. Janssen further argued that the Amended Complaint's allegations of misbranding were conclusory and could not, therefore, give rise to FCA liability. The Relators argued that the fact that Prezista was prescribed for an approved use was immaterial, since they alleged that the prescription resulted from fraudulent statements made by Janssen to the prescribing physician.

The Government submitted a Statement of Interest, arguing that "a drug is not per se 'reasonable and necessary' simply because it was prescribed for a FDA-approved indication." Rather, the Government asserted, other factors are relevant to the "reasonable and necessary" determination, such as "whether a physician prescribed the drug." Additionally, the Government argued that "[f]raud directed at physicians may ... establish FCA liability if government reimbursement was a reasonably foreseeable result." The Government did not take a position as to whether Relators adequately pled under this theory. In response, Janssen contended that it was not advocating a per se rule for FDA-approved drugs.

The Court held that Relators adequately pled FCA violations involving prescriptions of Prezista for its FDA-approved use, relying on *United States ex rel. Petratos v. Genentech Inc*., 855 F.3d 481, 486 (3d Cir. 2017), in which the Third Circuit held that, "the 'reasonable and necessary' determination is a process involving the FDA, CMS, and individual doctors." Thus, FDA approval

alone does not per se render a drug "reasonable and necessary," but rather a drug "must also be 'reasonable and necessary for [the] individual patient' based on 'accepted standards of medical practice and the medical circumstances of the individual case.' " The Court held that Relators pled that, despite FDA approval, Prezista was not "reasonable and necessary" for certain patients and therefore they properly pled an FCA violation.

Were the Alleged False Claims Material ?

Jansen next argued for dismissal. Claiming that the alleged false claims were not material given that "there are no factual allegations showing that the Part D sponsor would not have reimbursed claims for on-label prescriptions of Prezista." The Court disagreed, noting that the Amended Complaint pled that: (1) each of Defendants' claims for government reimbursement, in connection with Prezista and Intelence, included false certifications rendering the claims "ineligible for reimbursement"; and (2) Defendants' "claims for prescriptions caused by [their] misconduct are not reimbursable." In so holding, the Court applied a low bar for establishing materiality, basically requiring a simple allegation that, absent the false certification, the claim would not have been paid.

Did Relators Plead Fraud with Requisite Specificity ?

Janssen next argued that the Relators failed to meet the heightened pleading standards of Rule 9(b) in that "they do not identify even one physician who wrote a prescription that was reimbursed by a government payor based on the[ ] allegedly false statements or when any such prescription was written."

The Court applied *Foglia v. Renal Ventures Mgmt*., *LLC*, 754 F.3d 153, 156 (3d Cir. 2014) ("To satisfy Rule 9(b) for a FCA claim, a plaintiff must allege "particular details of a scheme to

submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.") The Court held that Relators adequately pled the submission of false claims because the Amended Complaint alleged that "Defendants caused false claims to be submitted to the Government Health Care Programs for reimbursement," and that that Defendants utilized a nationwide scheme of misbranding and kickbacks to cause physicians to prescribe Prezista and Intelence, which resulted in substantial financial success for Defendants.

Did Relators Properly Plead Claims Against the Parent Company ?

Finally, the Court agreed with Johnson & Johnson's argument that Relators failed to plead specific allegations against it with sufficient particularity. By defining "J & J" as referencing both Defendants, Relators failed to provide Johnson & Johnson with the requisite notice as to what specifically was being alleged against it. Relators also did not allege facts to set forth agency liability in adequate detail, and the Court refused to consider factual allegations set forth in Relators' briefs or oral argument. As "mere ownership of a subsidiary does not justify the imposition of liability on the parent," the Court dismissed Relators' claims against Johnson & Johnson.

Maxmed Healthcare, Inc. v. Thomas Price, Secretary, HHS,
860 F.3d 335 (6th Cir., 2017)

This is not an FCA case; instead, it involves the use of statistical sampling to support a Medicare overpayment demand.

Based on a MAC audit, HHS determined that the Medicare program overpaid Maxmed Healthcare, Inc. by almost $800,000 for home health care services. Maxmed sought judicial review, arguing principally that the extrapolation of the overpayment was in error. The district court granted summary judgment and denied Maxmed's motion to amend or alter the judgment. The Sixth Circuit affirmed.

Congress created the Medicare Integrity Program through which the Secretary contracts with private entities "for the purpose of identifying underpayments and overpayments and recouping overpayments[.]" *See* 42 U.S.C. § 1395ddd(a), (h)(1). Extrapolation is one permissible method of calculating overpayments. In particular, Congress authorized Medicare contractors to "use extrapolation to determine overpayment amounts" if the Secretary determines that "there is a sustained or high level of payment error." *Id.* § 1395ddd(f)(3)(A).

CMS has issued two key documents that govern the use of extrapolation. One document, Ruling 86–1, provides that sampling for extrapolation purposes "only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment." Following an overpayment determination based on extrapolation, the burden shifts to the Medicare provider, who "could attack the statistical validity of the sample, or [ ] could challenge the correctness of the determination in specific cases identified by the sample[.]" The second document is the Medicare Program Integrity Manual (MPIM), which sets out "[t]he major steps in conducting statistical sampling," and articulates a number of criteria that govern the specifics

of each step in the extrapolation process.

Providers who dispute an overpayment determination may challenge it in a lengthy, five-step appeal process. In Maxmed's case, that process took more than six years. Maxmed prevailed with an Administrative Law Judge, who invalidated the extrapolation. The ALJ found that the extrapolation methodology was fatally flawed in a number of ways, including (1) the failure to record the random numbers used in the sample; (2) the failure to properly define sampling units; (3) the failure to demonstrate the sampling units' independence; and (4) the failure to demonstrate average overpayment was normally distributed.

Undaunted, CMS appealed the ALJ's decision to the Medicare Appeals Council which, ruling *de novo*, reversed the ALJ's determinations and reinstated the entire overpayment. Maxmed then appealed to the district court, which affirmed the Council. Maxmed appealed.

Failure to Document Random Numbers is Not Fatal

Maxmed argued that the extrapolation was invalid because the MAC failed to document the random numbers used in the sample and how they were selected. The Court disagreed because, according to the MPIM, failure to record the random numbers used to generate the sample does not necessarily invalidate the extrapolation methodology. In this case, the MAC's chief statistician was able to replicate the sample of 40 claims using the information available to Maxmed.

Need for Sampling Units' Independence

Maxmed also argued that the MPIM requires the MAC to "obtain a statistically valid random sample of processed Medicare claims that are defined correctly and independent." Maxmed contended that the sampling was fatally "dependent" because the same Medicare

beneficiary could have multiple claims or claim lines in the sample. The ALJ's independent expert, Dr. Haller, found that using multiple claims for one beneficiary in the sample rendered the sampling units not independent. The Council criticized Dr. Haller's "effort to incorporate by reference academic standards that are not contemplated in CMS guidance or consistent with real-world Medicare practices." The Court agreed, noting that the MPIM does not actually have a strict "independence" requirement and expressly permits a sample to include multiple claims or claim lines from the same beneficiary.

Medicare's Rule of Thumb Does Not Apply to Post-Payment Audits

Maxmed next pointed to the CMS Medicare Benefit Policy Manual (MBPM), which provides that a "determination of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs." MBPM Chap. 7, § 20.3.3 This is referred to a "Rule of Thumb." Maxmed argued that the use of extrapolation violates the Rule of Thumb because extrapolation is not based on an assessment of each beneficiary's individual care needs. The Council rejected the argument because Maxmed "point[ed] to no authority for such a sweeping proposition." The district court affirmed for the same reason and also because Maxmed did not suggest "any alternative means to calculate the overpayment in this case that would not violate the 'Rule of Thumb.' " The Sixth Circuit affirmed, noting that he Rule of Thumb applied only to prepayment reviews and not post-payment audits and that the upshot of this argument would invalidate the use of extrapolation in all cases.

Having upheld the overpayment demand against Maxmed, the Sixth Circuit then launched into a (gratuitous) discussion of how unfair the Medicare appeals process is for providers. Hundreds of thousands of Medicare appeals are backlogged in agency proceedings. In 2016, a

district judge issued mandamus relief ordering the Secretary to resolve the backlog by 2020. The Secretary recently told that judge that it "has no means to, and therefore cannot, meet the reduction targets ...." As of June 2017, there were 607,402 pending appeals and the Secretary projects that there will be nearly 1 million pending appeals by the end of Fiscal Year 2021.

The Sixth Circuit lamented that most providers do not have the resources to underwrite six years of appeal and pointed out that the problem is made worse by the fact that private contractors are awarded bounties for finding purported overpayments and whose findings are presumed valid. Providers are then subjected to multiple tiers of *de novo* agency review, which render non-Council decisions and proceedings all but useless. Finally, if a provider endures until judicial review, the courts' highly deferential standards of review offer the vast majority of providers little hope of success. The Court concluded with a plaintive question: Are these redundant, time-consuming, and costly procedures worthwhile for program integrity or providers?

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