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WHAT'S INSIDE

FALSE CLAIMS ACT/IMPLIED CERTIFICATION

U.S. says Supreme Court should affirm Medicaid implied-certification ruling

By Phyllis L. Skupien, Esq., Managing Editor, Westlaw Journals

The government is asking the U.S. Supreme Court to rule that health care providers submitting claims under federally insured health care programs can be held liable when they falsely imply they have complied with all the government's requirements.

Universal Health Services Inc. v. United States ex rel. Escobar, No. 15-7, oral argument scheduled (U.S. Apr. 19, 2016).

The government says the high court should affirm a ruling by the 1st U.S. Circuit Court of Appeals that reinstated a suit alleging a mental health facility submitted false claims to Medicaid because it had not complied with the program's certification requirements.

At issue is whether "implied certification" is a basis for an action under the False Claims Act, the government's primary tool for defending the public fisc against fraud.

The Supreme Court will hear oral arguments in the case April 19, and its decision will likely have implications for claims outside the medical context, including for any government contractor.

UNDERLYING DISPUTE

The case involves Yarushka Rivera, a 17-year-old patient at an Arbour Counseling Services facility in Lawrence, Massachusetts.

In 2009, Rivera was initially treated by two counselors but her parents, Carmen Correa and Julio Escobar, later learned that neither had been licensed to perform psychotherapy, according to court documents.

Rivera was later assigned to a "doctor," who diagnosed her with bipolar disorder, but the counselor actually was not a medical doctor, the government's brief says.

As Rivera's condition continued to deteriorate, her parents asked for a psychiatrist to see her

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EXPERT ANALYSIS

Supreme interest: Cases pending at the Supreme Court could change the scope of FCA litigation

B. Kurt Cooper, J. Andrew Jackson, Heather O'Shea and Danielle Scoliere of Jones Day analyze pending disputes before the U.S. Supreme Court that involve the False Claims Act and how the decisions could affect health care providers and government contractors.

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Supreme interest: Cases pending at the Supreme Court could change the scope of FCA litigation

By B. Kurt Copper, Esq., J. Andrew Jackson, Esq., Heather M. O'Shea, Esq., and Danielle L. Scoliere, Esq.
Jones Day

The ongoing rise of False Claims Act cases and news stories regarding massive settlements resulting from them continue to earn the attention of those who do business with the Government, including health care providers and Government contractors. In part, the FCA's increased utilization stems from a lack of uniform framework for courts to use when interpreting and applying the Act.

The results are startling. The Justice Department has collected over $3.5 billion from FCA cases in each of the last four years, and 638 qui tam actions were filed by relators in fiscal year 2015, compared to just 30 actions filed in FY 1987.

Yet while FCA cases are becoming more prevalent, the law has become less, not more, clear. Issues regarding implied certification, the applicable scienter standard, the consequences of breaching the FCA's seal requirement, and the application of Rule 9(b) at the pleading stage have all split lower courts. And the U.S. Supreme Court has started to take notice.

In the upcoming term, the Court has the opportunity to bring clarity to the FCA in three different cases that address these issues, and each will be closely watched. *U.S. ex rel. Escobar v Universal Health Servs., Inc.*, 780 F.3d 504 (1st Cir.), *cert. granted in part*, 136 S. Ct. 582 (2015); *U.S. ex rel. Rigsby v. State Farm Fire & Cas. Co.*, 794 F.3d 457 (5th Cir. 2015); *U.S. ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112 (D.C. Cir. 2015).

ESCOBAR AND THE VIABILITY OF THE IMPLIED CERTIFICATION DOCTRINE

For years, courts have struggled to apply a consistent framework in FCA cases that allege legally false, as opposed to factually false, claims. Often a complaint asserts factually false claims by alleging that a provider supplied an incorrect description of goods or services provided, or requested reimbursement for goods or services never provided. A complaint asserting legally false claims, on the other hand, often alleges that a claim for payment was submitted and a provider falsely certified compliance with some statute, regulation or contractual provision. Such theories of legal falsity under the FCA have become the focus of private relators and Government plaintiffs.

When alleging an FCA claim based on legal falsity, the key requirement is the provider's certification of compliance with an applicable statute or regulation. *U.S. ex rel. Spicer v. Westbrook*, 751 F.3d 354, 365 (5th Cir. 2014). Some courts, however, have not limited the requirement to express certifications of compliance. Instead, many relators have argued, and several lower courts have adopted the position, that even if a provider made no express statement of compliance with a particular statute, regulation or contractual provision, the provider may have impliedly certified compliance with the provision when it submitted claims for payment.

Courts have justified this "implied certification" theory by citing "Congress' expressly stated purpose that the Act include at least some kinds of legally false claims, and [] the Supreme Court's admonition that the Act intends to reach all forms of fraud that might cause financial loss to the government." *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001) (internal citations omitted). This implied certification doctrine has created both huge potential liabilities for defendants, and significant questions for courts. Fortunately, the Supreme Court recently agreed to decide a case that could help resolve the debate.

Various circuit views and the opportunity to clarify implied certification

Lower courts' treatment of the implied certification doctrine has varied by circuit. For instance, some circuits have accepted the implied certification theory and held that a requirement need not expressly be identified as a condition of payment. *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 387–88 (1st Cir. 2011); *U. S. v. Triple Canopy, Inc.*, 775 F.3d 628, 636 (4th Cir. 2015); *U.S. v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010). These courts have found that a statute, regulation, or contractual requirement may constitute a condition of payment, and thus can lead to FCA liability, even if the requirement's text

This expert analysis was written for The Government Contractor by *(L-R)* **B. Kurt Copper**, **J. Andrew Jackson**, **Heather M. O'Shea** and **Danielle L. Scoliere** of **Jones Day**. The authors are attorneys from the Columbus, Ohio; Chicago; and Washington offices of Jones Day who defend investigations and litigation brought under the FCA.

does not explicitly state it is a condition of payment.

For example, in *Escobar*, the relator argued to the First Circuit that a Massachusetts counseling services center presented false claims to Medicaid by failing to comply with state regulations requiring, among other things, that mental health centers employ individuals who are licensed in psychiatry, psychology, social work and psychiatric nursing, or are supervised by "a fully qualified professional staff member trained in one of [those] disciplines." 780 F.3d at 507 (citation omitted) (internal quotations omitted).

Although the district court dismissed the FCA claim because the state regulations, according to the district court, were mere "conditions of participation" in the Medicaid program and not conditions of payment, the First Circuit reversed. It held that although the particular state regulations did not expressly state they were conditions of payment, other state regulations made clear that compliance was a condition of payment, and FCA liability could flow from submitting claims for payment to the Medicaid program when the defendant was not in compliance with the state regulations.

"Preconditions of payment," the First Circuit held, "may be found in sources such as statutes, regulations, and contracts," and "need not be expressly designated. Rather, the question whether a given requirement constitutes a precondition to payment is a fact-intensive and context-specific inquiry involving a close reading of the foundational documents, or statutes and regulations, at issue." *Id*. at. 512 (internal citations and quotations omitted). See also *U.S. ex rel. Badr v. Triple Canopy, Inc.*, 775 F.3d 628, 636–38, n.5 (4th Cir. 2015) (recognizing implied certification doctrine and rejecting argument "that implied representations can give rise to liability only when the condition is expressly designated as a condition of payment").

Other circuits, including the Second and Sixth, have taken a "middle-ground" approach. While those courts recognize that a defendant might, in an appropriate case, impliedly certify compliance with a statute or regulation, FCA liability is possible only if the Government *expressly* conditions payment on compliance. *Mikes*, 274 F.3d at 701 (holding plaintiff's allegations cannot establish liability under the FCA because "the Medicare statute does not explicitly condition payment upon compliance"); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011) (rejected implied certification claim because plaintiff did not allege that was an "express[] require[ment] to comply with those standards as a prerequisite to payment of claims").

The Fifth Circuit has likewise recognized that if implied certification claims did exist, such claims would require that the Government expressly condition payment on compliance. *U.S. ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262 (5th Cir. 2010). For example, a regulation would have to state explicitly that the Government would not pay a provider who fails to comply in order to trigger FCA liability. A provider's mere noncompliance would not suffice. This middle-ground view provides greater protection to FCA defendants than those views that require no statement to find a condition of payment, but it still creates risk even if a provider has not expressly told the Government that it is complying with the particular requirement at issue.

> While FCA cases are becoming more prevalent, the law has become less, not more, clear.

In contrast, the Seventh Circuit seemingly rejected the implied certification doctrine in a recent case, stating that the concept lacked a "discerning limiting principle." *U.S. v. Sanford-Brown, Ltd.*, 788 F.3d 696, 711 (7th Cir. 2015). In *Sanford-Brown*, the relator worked at a for-profit university. He contended that the defendant violated, among others, participation agreement provisions that (a) prohibit paying incentive compensation to certain types of employees involved in admissions and recruiting; and (b) require universities to repay the Department of Education portions of payments for certain students who failed to complete at least 60 percent of a term.

When the U.S. declined to intervene, the relator proceeded with the suit and asserted an implied certification theory, contending that Sanford-Brown presented false claims for payment by breaching provisions of the agreement while simultaneously submitting claims for payment. Although the participation agreement does not state that compliance with the provisions is a condition of payment, the relator relied on the implied certification doctrine to allege that the defendant knowingly defrauded the Government. The defendant contended that the suit is more properly termed a breach of contract case, not one based in fraud.

The Seventh Circuit held that because compliance with all of the Title IV regulations in the participation agreement was merely a condition of continued participation in the program, rather than a condition of payment necessary to be eligible for subsidies, the defendant had not violated the FCA. The court examined other circuits' treatment of implied certification claims, including those where courts found certain legal requirements conditions of payment even when not expressly identified as conditions of payment, and explained, "[a]lthough a number of other circuits have adopted this so-called doctrine of implied false certification, we decline to join them . . .." *Id*. at 711–12 (internal citation omitted).

The Seventh Circuit cautioned against a situation where "any of the conditions in the [agreement] that are not met by the institution would have the potential to impose strict liability on it under the FCA." *Id*. at 711. Indeed, the court expressed particular concern that "thousands of pages of federal statutes and regulations" could be incorporated by reference into the participation agreement and thus create liability under the FCA. *Id*. The FCA, the court made clear, "is simply not the proper mechanism for government to enforce" compliance with any and every Government statute, regulation, and contract. *Id*. at 712.

However, the Seventh Circuit's opinion did provide possible fodder for some relators to argue that the court did not fully reject the implied certification theory. Although the court stated that it "decline[d] to join" other circuits who had adopted the implied certification theory, it also stated it was "join[ing] the Fifth Circuit." *Id*. at 711–12.

But the Fifth Circuit has not yet ruled regarding whether it accepts the implied certification theory, as the complaints it has examined did not suffice even if it did allow implied certification claims. See, e.g., *U.S. ex rel. Steury v. Cardinal Health, Inc.*, 735 F.3d 202 (5th Cir. 2013); *Steury*, 625 F.3d 262. In any event, the Seventh Circuit's approach avoids allowing aggressive relators to turn

run-of-the-mill regulatory violations into FCA claims absent an express statement of compliance by the defendant.

The inconsistency of the circuits' treatment of implied certification claims has created an opportunity for the Supreme Court to provide clarification. The Court took advantage of this opportunity by granting certiorari in the *Escobar* case on two issues: (1) whether the "implied" certification theory of legal falsity under the FCA is viable; and (2) if an "implied certification" theory is viable, whether an FCA plaintiff must show that the defendant violated a statute, regulation or contractual provision that *expressly* states that it is a condition of payment.

RIGSBY PROVIDES TWO KEY FCA QUESTIONS

Beyond *Escobar* and implied certification, the Supreme Court also recently requested the views of the solicitor general regarding a petition for certiorari pending in another FCA before the Court, *State Farm v. U.S. ex rel. Rigsby*. Petition for Writ of Certiorari, *State Farm Fire & Casualty Co. v. U.S. ex rel. Rigsby* (No. 15-513).

The case presents two key issues for the Court's consideration: (1) what standard determines dismissal for a relator's violation of the FCA's seal requirement, 31 USCA § 3730(b)(2); and (2) under what standard an organization can be deemed to have "knowingly" submitted a false claim "based on the purported collective knowledge or imputed ill intent of employees other than" the employee who chose to present the claim. *Id*. The request reflects the Court's interest in the topics, which may signal that the case could be taken.

The inconsistency of the circuits' treatment of implied certification claims has created an opportunity for the Supreme Court to provide clarification.

Following the grant of certiorari, the U.S. recently filed its merits brief as amicus curiae, advocating for a broad reading of the FCA. The Government argues that "[j]udicial references to the 'implied certification' theory of FCA liability are best understood as shorthand for the established principle that a communication can be materially misleading, and can give rise to liability for fraudulent misrepresentation, if the requisite scienter is established, even though it contains no explicit false statement." Brief for the U.S. as Amicus Curiae Supporting Respondents, *Universal Health Servs., Inc. v. U.S. ex rel. Escobar* (No. 15-7).

The Government thus rejects numerous courts of appeals' holdings and contends that no condition of payment requirement exists for legally false claims. Instead, the Government argues that FCA liability can stand for a defendant who submits a claim for payment while in violation of *any* statute, regulation or contractual provision, so long as the provision is deemed "material" under the FCA's diluted definition of "material" and the defendant is acting "knowingly" (which includes reckless disregard). *Id*.

Needless to say, if the Supreme Court were to adopt such an approach, the standard could increase potential liability for many providers, Government contractors and others who conduct business with the Government.

Rigsby*'s background*

The relators in *Rigsby* alleged that State Farm Fire and Casualty Co. submitted false claims to the U.S. Government for payment on flood insurance policies. Relators contended that following the massive damage to homes by Hurricane Katrina, State Farm fraudulently submitted to the U.S. a flood claim for payment, although the damage was caused by wind. In response, State Farm has argued that all three claims adjusters assigned to the particular claim shared a good faith belief that the home suffered flood damage, meaning they did not have the requisite intent for a FCA claim.

The relators' initial complaint was filed under seal on April 26, 2006, and was not lifted until Aug. 1, 2007. During that time, relators' counsel violated the FCA seal requirement by disclosing the complaint to several news outlets through e-mails and interviews, including e-mailing sealed evidence to ABC News to use for a 20/20 story. The district court found that these actions did not require dismissal of the case, and proceeded to trial. At trial, the jury found for relators. On appeal, State Farm argued, among other things, that it could not have acted "knowingly" because the claims adjusters believed in good faith that the claim was based on flood damage, not wind damage, and any evidence of wind damage was developed only after the claims were submitted. The Fifth Circuit affirmed, and State Farm has sought certiorari from the Supreme Court.

The seal requirement

Under the FCA, a relator's complaint "shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders." 31 USCA § 3730(b)(2). This seal requirement allows the Government to investigate and determine whether to intervene, and it protects the defendant's reputation until further investigation is done. Despite uniform recognition of the important role this requirement plays in FCA claims, courts of appeals have differed regarding the consequence of violating the requirement.

Consequences for violation of the seal requirement

The strictest view is that a violation of the FCA's seal requirement mandates dismissal. *U.S. ex rel. Summers v. LHC Grp., Inc.*, 623 F.3d 287, 298 (6th Cir. 2010). The Sixth Circuit explained that, "[g]iven that the very existence of the *qui tam* right to bring suit in the name of the Government is created by statute, it is particularly appropriate to have the right exist in a given case only with the preconditions that Congress deemed necessary for the purpose of safeguarding the Government's interests." *Id*. This rule provides a strong deterrent for potential violators, and offers the best protection to Government investigations and FCA defendants.

Other circuits, however, have held that dismissal is not automatic; instead, they have held that multiple factors must be evaluated. See *U.S. ex rel. Pilon v. Martin Marietta Corp.*, 60 F.3d 995 (2d Cir. 1995); *Smith v. Clark/Smoot/Russell*, 796 F.3d 424, 430 (4th Cir. 2015); *U.S. ex rel. Lujan v. Hughes Aircraft Co.*, 67 F.3d 242 (9th Cir. 1995).

For example, the Second Circuit calls for a more general inquiry into whether the relator's actions "incurably frustrated" the interests served by the under-seal rule, which include shielding defendants from meritless

lawsuits. *Pilon*, 60 F.3d at 996 (holding "[b]ecause this failure incurably frustrated the statutory purpose underlying these requirements, we agree that the complaint should have been dismissed").

The Ninth Circuit offers even less protection to defendants, as it uses a three-factor balancing test to evaluate whether dismissal is proper: (1) whether the disclosure actually harmed the Government; (2) the nature and severity of the violation (for example, disclosing underlying facts in general terms in a newspaper, a minor violation, versus completely failing to file the complaint under seal, a major violation); and (3) the presence or absence of bad faith or willfulness. *Lujan*, 67 F.3d at 245–46.

The Fifth Circuit's approach

In *Rigsby*, the Fifth Circuit analyzed other circuits' approaches and adopted the view that "a seal violation does not automatically mandate dismissal." *Rigsby*, 794 F.3d at 471. The court embraced the Ninth Circuit's test and explained that "the 1986 amendments to the FCA were intended to encourage more, not fewer, private FCA actions. Holding that any violation of the seal requirement mandates dismissal would frustrate that purpose, particularly when the government suffers minimal or no harm from the violation." *Id*. After finding that the Government was not likely harmed by the disclosures to news organizations, the court held that the seal violation did not merit dismissal.

The balancing test adopted by the Fifth and Ninth circuits appears to treat the seal requirement as a mere suggestion, rather than as a text-based requirement of FCA litigation. As a practical matter, it often is difficult for FCA defendants to prove harm to the Government, particularly if the Government has a financial incentive not to weigh in on the issue.

What does it mean for an organization to act 'knowingly'?

The second question the Supreme Court may address in the *Rigsby* case is a key issue for FCA defendants: Can an organization be held liable for "knowingly" acting if the person who submits the claim for payment does so in good faith? Again, courts of appeals have taken various stances on the FCA's scienter requirement.

For instance, the D.C. Circuit and the Fourth Circuit have rejected a "collective knowledge" approach that would allow "a plaintiff to prove scienter by piecing together scraps of 'innocent' knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds." *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 918, n.9 (4th Cir. 2003); *SAIC*, 626 F.3d at 1275.

The *Rigsby* petitioner argues that the Fifth Circuit's approach stands in contrast, as the Fifth Circuit held that scienter was satisfied based on an alleged generalized intent of a group of employees.

Such a "collective knowledge" approach would ignore the fact that the FCA is a unique statute designed to target only those who knowingly defraud the Government, not any organization who submits a claim for payment later found to be errant — or worse, merely inadequate. Needless to say, in organizations with thousands of employees, monitoring the knowledge of every employee and predicting how such knowledge could be pieced together would be impossible. On the other hand, defending an FCA case by relying on the good faith of the employee submitting the claims could become more viable if the Supreme Court adopts a more exacting standard.

RULE 9(B) AND THE CHALLENGE TO COURTS ADDRESSING FCA COMPLAINTS

The third FCA case pending before the Supreme Court is currently at the certiorari stage, and if certiorari is granted, the case could solidify a key defense in FCA cases: the application of Federal Rule of Civil Procedure 9(b). *Heath*, 791 F.3d 112. Rule 9(b) provides a fundamental safeguard for defendants of fraud claims, as it requires that a party pleading fraud must "state with particularity the circumstances constituting fraud." It serves to weed out some unsupported FCA claims and protect against improper settlement pressure. Ultimately, it can save millions of dollars in discovery costs by mandating dismissal of claims brought by relators who have not done their homework.

Yet courts have been inconsistent in judging FCA complaints under Rule 9(b). In particular, courts have differed regarding whether a relator must plead "with particularity" the details of a *claim for payment*, or merely the details of a broader *fraudulent scheme*. On one hand, the FCA's text requires false claims for payment to sustain liability, so many courts have recognized the need to link broad alleged schemes to actual claims for payment in order to proceed in an FCA case. *See, e.g., U.S. ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 457–458 (4th Cir. 2013); *U.S. ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116 (1st Cir. 2013); *U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007); *U.S. ex rel. Dunn v. N. Mem'l Health Care*, 739 F.3d 417, 420 (8th Cir. 2014); *U.S. ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1308 (11th Cir. 2002).

The balancing test adopted by the Fifth and Ninth circuits appears to treat the seal requirement as a mere suggestion.

On the other hand, some courts have cautioned that Rule 9(b) should not be a "straitjacket," so if a court can infer that claims for payment were likely submitted to the Government, even if the complaint does not plead details of those claims with particularity, an appropriate FCA case may still proceed. *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (holding that even if a relator "cannot allege the details of an actually submitted false claim, [the case] may nevertheless survive"). See also *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (stating "it is hard to reconcile the text of the FCA, which does not require that the exact content of the false claims in question be shown, with the "representative samples" standard); *U.S. ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854–55 (7th Cir. 2009); *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998–99 (9th Cir. 2010); *U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010).

The *Heath* case would allow the Supreme Court to provide clarity on this key issue. Petition for Writ of Certiorari, *AT&T, Inc. v. U.S. ex rel. Heath* (No. 15-363).

In *Heath*, the relator alleged that the defendant fraudulently overbilled a Government fund administered by the

Federal Communications Commission from 1997 to 2009 by failing to offer schools mandatory discounts on services. The relator did not allege specific instances of fraud, but rather more generally asserted that the defendant did not train its employees on the applicable price requirement, and as a result, the fund was fraudulently overbilled.

AT&T moved to dismiss and argued that the FCA complaint was not pled with sufficient particularity. The district court dismissed the case on unrelated grounds. On appeal, the D.C. Circuit reversed. While the relator's complaint failed to provide details regarding even one particular claim for payment, the D.C. Circuit held that the complaint satisfied Rule 9(b) because it sufficiently alleged "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Heath*, 791 F.3d at 126 (citation omitted) (internal quotations omitted).

The Court explained that it "join[ed] our sister circuits in holding that the precise details of individual claims are not, as a categorical rule, an indispensable requirement of a viable False Claims Act complaint." *Id*.

An understanding of the specificity needed in a complaint under Rule 9(b) is even more important in the FCA context than in other types of litigation. As the *Heath* court noted, the incentive structure of qui tam actions under the FCA "can give rise to opportunistic and abusive behavior" because of the possibility that the relator could share in any settlement or judgment amount. *Id*. at 116. The problem is further exacerbated by both the drastic penalties defendants face in FCA litigation, and the significant costs involved to defend an FCA suit through discovery.

Rule 9(b) thus serves as an essential procedural check on plaintiffs' ability to pursue meritless and expensive fishing expeditions. It "serves to discourage the initiation of suits brought solely for their nuisance value, and safeguards potential defendants from frivolous accusations of moral turpitude." *Id*. at 123. Without that check, FCA plaintiffs know that they can assert broad vague allegations, and then attempt to justify broad, and costly, discovery.

In addition, relators would face a lower burden in turning allegations of regulatory or contract breaches into an FCA claim that could survive a motion to dismiss.

Given that landscape, the Supreme Court in *Heath* has an important opportunity to refocus courts on the text of the FCA and, in particular, require the pleading of actual claims for payment (which are "sine qua non" of an FCA violation) before allowing cases to proceed into discovery. See *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 878 (6th Cir. 2006). The Supreme Court in other contexts has already recognized that, without proper enforcement of pleading standards, "the threat of discovery expense" in large-scale litigation "will push cost-conscious defendants to settle even anemic cases." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007). In *Heath*, it may recognize those same risks for FCA defendants.

CONCLUSION

The current landscape at the Supreme Court could allow for new clarity and uniformity in FCA litigation. The Court has already agreed to decide the implied certification question in *Escobar*, and that case will be closely watched given its potentially huge ramifications for all who do business with the Government. The Court has the opportunity to craft a rule that avoids confusion and excessive application of the FCA to commonplace regulatory disputes.

Moreover, the Court has called for the views of the solicitor general on the seal and scienter issues in *Rigsby*, which signals its interest in additional questions that often arise in FCA litigation and investigations. And in *Heath*, the Supreme Court also has the chance to set the Rule 9(b) standard which governs every FCA complaint. While in theory Congress could amend the FCA's terms to correct certain misinterpretations, such action remains unlikely given the current legislative environment. Health care providers and others who do business with the Government should keep abreast, as the scope of FCA litigation may take a significant turn. WJ

Novartis must face case over another company's generic drug, appeals court says

(Reuters) – A California appeals court has ruled that Novartis Pharmaceuticals Corp. must face negligence claims from twins who say their developmental disabilities were caused by off-label use of a generic asthma medication their mother took nearly six years after Novartis sold its stake in the drug.

REUTERS/Arnd Wiegmann

T.H. v. Novartis Pharmaceuticals Corp., No. D067839, 2016 WL 916387 (Cal. Ct. App., 4th Dist. Mar. 9, 2016).

On March 9 California's 4th District Court of Appeal reversed a lower court and said that although Novartis was not the manufacturer of the drug that allegedly caused the unnamed minor twins' developmental disabilities, it could be liable for negligence if it knew about the dangers involved in its off-label uses but failed to adequately warn the public.

The court acknowledged that it was at odds with many other states' views that the makers of brand-name drugs should not be held liable for injuries allegedly caused by generic versions.

But California law views such claims differently, the ruling said, pointing to the 1st District's 2008 ruling in *Conte v. Wyeth*, 168 Cal. App. 4th 89, holding that a brand-name drugmaker could reasonably foresee that a patient could be injured by relying on information it provided, even if the alleged injury involved another company's generic, and "shoulder its share of responsibility at least in part."

The 2013 suit involves terbutaline sulfate, approved by the Food and Drug Administration in the 1970s to treat asthma. A Swedish report in the 1970s suggested it could be used for tocolysis — preventing premature labor — but subsequent research disputed those benefits while highlighting the risks it could pose to the mother and fetus.

The ruling is at odds with many other states' views that the makers of brand-name drugs should not be held liable for injuries allegedly caused by generic versions.

Novartis acquired the new-drug application, or NDA, to the drug, which gave it control over the label. It sold the drug under the brand name Brethine until 2001, when it divested the product.

In 2007, according to the complaint, the twins' mother was prescribed a generic form of Brethine to prevent premature labor while pregnant with them. Three years after their birth, the twins were diagnosed with developmental disabilities and subsequently autism.

The twins' father filed a lawsuit on their behalf against Novartis — along with the mother's health care providers and the companies that made the version of Brethine she ingested — in San Diego. The suit alleged that while Novartis held the rights to the drug, it had a legal duty to update its label to warn about the risks to developing fetuses. Had it done so, the mother's doctor may not have prescribed it, the suit said.

Novartis filed a demurrer seeking to dismiss the claims against it, saying it had no duty to plaintiffs since it did not make the drug their mother took. The trial court granted the motion. Plaintiffs appealed, saying Novartis' duty was established by Conte.

The 4th District sided with plaintiffs. Although Novartis, unlike the defendant in Conte, did not own the NDA at the time of the alleged injury, the same legal duty applied, they wrote.

"If the minors can prove Novartis failed to adequately warn about fetal risks it knew or should have known were associated with tocolytic use before it divested the product in 2001, they may be able to establish Novartis' conduct bore some direct relationship to the alleged harm in this case," wrote Justice Judith McConnell, joined by Justices Gilbert Nares and Joan Irion.

A lawyer for plaintiffs, Ben Siminou, said he was pleased with the decision's "sensible and obvious application of California's longstanding law." Novartis was not immediately available for comment. WJ

(*Reporting by Jessica Dye*)

Attorneys:
Plaintiffs: Benjamin Siminou and Kevin Quinn, Thorsnes Bartolotta McGuire, San Diego, CA

Defendant (Novartis): Eric Lasker, Hollingsworth, Washington DC; Erin Bosman and Julie Park, Morrison & Foerster, San Diego, CA

Related Court Document:
Opinion: 2016 WL 916387

Testosterone plaintiffs can pursue off-label fraud claims for generic products

(Reuters) – A federal judge in Illinois has partly reversed a previous decision in consolidated litigation over testosterone products that found plaintiffs' state law claims over generic versions of the drugs were preempted by federal law.

In re Testosterone Replacement Therapy Products Liability Litigation, No. 14-cv-1748, MDL No. 2545, 2016 WL 861213 (N.D. Ill. Mar. 7, 2016).

In a March 7 ruling, U.S. District Judge Matthew Kennelly in the Northern District of Illinois said plaintiffs could move forward after all with claims that defendants who sold generic testosterone drugs fraudulently promoted them for off-label use, reversing his November ruling that those claims were preempted along with others regarding the adequacy of the products' labeling.

Judge Kennelly is overseeing multidistrict litigation against multiple makers of brand-name and generic drugs prescribed to men to boost flagging testosterone production.

Plaintiffs allege that pharmaceutical companies selling the products failed to warn that they could increase users' risk for heart attack, stroke and early death. More than 4,800 cases have been filed since the MDL was created in 2014.

In November, Judge Kennelly granted a motion from several defendants — Pfizer and its Pharmacia & Upjohn subsidiary, and Endo International's Auxilium Pharmaceuticals — to dismiss claims over their generic testosterone drugs as preempted by federal law, pursuant to the U.S. Supreme Court's 2011 ruling in *Pliva Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharmaceutical Co v. Bartlett*, 133 S. Ct. 2466 (2013).

Judge Kennelly said together those rulings barred plaintiffs from pursuing state law claims for failure to warn and design defect involving generic products, because their labels are required by federal law to match those on the brand-name version. Since generic drug makers cannot unilaterally change their drugs' design or warnings

REUTERS/Brendan McDermid

A spokeswoman for co-defendant Pfizer said the ruling "only allows a narrow set of plaintiffs' claims to move forward" and does not disturb the previous ruling on labeling issues.

without violating federal law, those claims are preempted, Judge Kennelly ruled. *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14-cv-1748, 2015 WL 6859286 (N.D. Ill. Nov. 9, 2015).

Plaintiffs asked the judge to reconsider and clarify certain points of his ruling, including whether claims based on defendants' allegedly fraudulent off-label marketing of the product should survive the preemption analysis.

In their complaint, plaintiffs said defendants manufactured a fictitious condition known as low testosterone, or "low T," to boost their products' sales. In fact, testosterone products were only approved to treat a real medical condition, hypogonadism, in which the male sex glands fail to produce adequate amounts of testosterone, plaintiffs alleged.

Those claims had nothing to do with the products' labeling or design and therefore should not have been preempted, plaintiffs argued. Defendants countered that the broad federal definition of "labeling" included the sort of allegations underlying plaintiffs' claims.

Judge Kennelly sided with plaintiffs and, reversing his previous decision, said they could move forward with claims for fraud, consumer protection and unjust enrichment — all of which were based in part on allegations of fraudulent off-label promotion — and derivative claims for wrongful death, loss of consortium and punitive damages to the extent they addressed the off-label promotion.

"Nothing in the approved warning label for defendants' drugs requires them to promote those drugs for unapproved off-label uses," he wrote.

A lead lawyer for plaintiffs, Ron Johnson, said in a statement that the ruling "will give victims the right to hold pharmaceutical giants responsible for prioritizing company profits over the safety of consumers across the country."

Pfizer spokeswoman Neha Wadhwa said in a statement that the ruling "only allows a narrow set of plaintiffs' claims to move forward," and does not disturb the previous ruling on labeling issues. She said the company will continue to vigorously defend the litigation.

An Endo spokeswoman declined to comment. WJ

(*Reporting by Jessica Dye*)

Attorneys:
Plaintiffs: Trent B. Miracle, Simmons Hanly Conroy, Alton, IL; Ronald E. Johnson, Schachter Hendy & Johnson, Fort Wright, KY; Christopher A. Seeger, Seeger Weiss, New York, NY

Defendants (Pfizer and Pharmacia & Upjohn): Loren H. Brown and Cara D. Edwards, DLA Piper, New York, NY; Matthew A. Holian and Jessica C. Wilson, DLA Piper, Boston, MA

Defendant (Auxilium): Andrew K. Solow, Robert Grass and Pamela J. Yates, Kaye Scholer, New York, NY

Related Court Document:
Memorandum opinion and order: 2016 WL 861213

KICKBACKS

Chicago psychiatrist gets 9-month sentence for taking kickbacks

By Phyllis L. Skupien, Esq., Managing Editor, Westlaw Journals

A Chicago psychiatrist has been sentenced to nine months in jail for accepting nearly $600,000 in kickbacks to prescribe an antipsychotic drug to mental health patients.

United States v. Reinstein, No. 15-cr-44, defendant sentenced (N.D. Ill. Mar. 11, 2016).

Michael J. Reinstein, 72, of Skokie, Illinois, pleaded guilty last year to one count of violating the Medicare and Medicaid Anti-Kickback Statute, 42 U.S.C.A. § 1320a-7B(b)(1)(A).

"Reinstein abused his position of public trust as a physician and took advantage of the faith and trust of his mentally ill patients in order to enrich himself," Chicago U.S. Attorney Eric S. Pruitt said in a statement.

In addition to the prison term, U.S. District Judge Sharon J. Coleman of the Northern District of Illinois ordered Reinstein to forfeit the $592,000 he received in kickbacks and perform 120 hours of community service.

According to the Justice Department, Reinstein, who started practicing psychiatry in 1973, prescribed the drug clozapine to thousands of elderly patients in Chicago-area nursing homes and hospitals for many years.

In exchange he received consulting fees and entertainment expenses, including meals, tickets to sporting events and paid vacations, from the manufacturers, the government said.

The plea agreement does not specify a timespan for the illegal activity, but the U.S. attorney's office said that by the end of 2003, Reinstein was the largest prescriber of clozapine to Medicaid recipients in the country.

Clozapine, used to treat schizophrenia, has serious side effects, especially for elderly patients, as it may cause a fatal decrease in white blood cells, seizures and inflammation of the heart.

The deaths of three of Reinstein's patients have been linked to clozapine intoxication.

According to his plea agreement, Reinstein prescribed Clozaril, the brand-name version of the drug, long after less expensive generic brands were available because the manufacturer was paying him.

After the deal with the original manufacturer ended in 2003, Reinstein switched to prescribing the generic version, but only after its manufacturers, Ivax Pharmaceuticals and successor Teva Pharmaceuticals USA Inc., agreed to pay him a yearly $50,000 consulting fee and finance a research study.

> At one point in the early 2000s, the defendant was the country's largest prescriber of the antipsychotic drug clozapine to Medicaid recipients, the Justice Department said.

Reinstein previously agreed to pay the United States and the state of Illinois $3.8 million to settle a civil lawsuit. Teva and Ivax also paid $27.6 million to settle civil allegations they violated the False Claims Act, 31 U.S.C.A. § 3729. WJ

Illinois marketer convicted of taking bribes for referrals to home health agency

By Phyllis L. Skupien, Esq., Managing Editor, Westlaw Journals

A Chicago federal judge has convicted a marketer of receiving kickbacks for Medicare referrals and conspiring to pay or offer kickbacks in a bribery and fraud scheme involving an Illinois home health agency.

United States v. George et al., No. 12-cr-559-7, 2016 WL 1161269 (N.D. Ill. Mar. 22, 2016).

After a bench trial, U.S. District Judge John W. Darrah of the Northern District of Illinois found Jenette George, 62, guilty of two counts of violating the federal Medicare and Medicaid Anti-Kickback Statute and one count of conspiracy for taking bribes to refer elderly patients to Rosner Home Healthcare Inc.

George is the 11th person convicted in the U.S. District Court for the Northern District of Illinois as part of a federal investigation into Rosner's bribery scheme, according to a statement released by the U.S. attorney's office in Chicago.

Between January 2008 and July 2012, Rosner officials paid kickbacks and bribes to doctors, marketers, medical office employees and nurses to secure patient referrals, the statement said. Rosner then billed Medicare for the home health services subsequently provided, the statement said.

George ran Ttenej Senior Referral Agency and referred seniors to home health care agencies in the Chicago area. But evidence presented at trial in October 2015 showed she received about $500 from Rosner for each referral she made for the company, the U.S. attorney's office said.

George was also caught on surveillance video counting cash she received from a former Rosner employee, Edgardo Hernal, who was cooperating with the government in the investigation, the statement said. He pleaded guilty to a conspiracy charge in 2013.

According to prosecutors, Rosner nurses included false information in patient charts to make their services appear necessary even when they were not. Rosner has since closed, the U.S. attorney's office said.

Besides George and Hernal, the other defendants convicted in the investigation are:

- Ana Nerissa Tolentino, nurse and former part owner of Rosner
- Armando Tolentino, nurse and former part owner of Rosner
- Frederick Magsino, former part owner of Rosner
- Emmanuel Nwaokocha, physician
- Masood Syed, physician
- Jennifer Holman, medical office manager
- Titis Jackson, marketer
- Lionel Paul Gassmann, Rosner nurse
- Gloria Zisman, Rosner nurse

The U.S. attorney's office said Arthur Davida, a Bloomingdale, Illinois, physician, was also convicted of health care fraud in a related case involving false certification of patients for Rosner's home health services. He was sentenced to two years in prison.

George faces up to 15 years in prison and is scheduled to be sentenced Aug. 10. WJ

Hospitals must exhaust agency appeals despite 'grotesque' Medicare delays

By Michael Scott Leonard, Senior Legal Writer, Westlaw Journals

Hospitals challenging the size of their Medicare reimbursements cannot force administrative law judges to hear their cases within 90 days, a federal appeals court has decided, saying that despite "grotesque" delays, health care providers must exhaust their agency appeals before suing the government.

Cumberland County Hospital System Inc. v. Burwell, No. 15-1393, 2016 WL 860334 (4th Cir. Mar. 7, 2016).

In a March 7 ruling, a the 4th U.S. Circuit Court of Appeals panel found that although the Medicare Act, 42 U.S.C.A. § 1395ff, provides for an administrative law judge hearing within 90 days of a hospital's payment challenge, the statute also gives providers an adequate way to "escalate" appeals stuck at that stage.

More than 800,000 Medicare appeals are currently awaiting referral to an ALJ, the appeals panel noted.

But however maddening the backlog, hospitals cannot go to court against the U.S. Department of Health and Human Services until they have completed the full administrative process, the unanimous three-judge panel said, affirming dismissal of the suit by Cumberland County Hospital System.

The hospital group, doing business as Cape Fear Valley Health System, runs a number of facilities in eastern North Carolina. The group had sought a writ of mandamus ordering HHS to send its case before an ALJ.

"While we agree that the delay in the administrative process for Medicare reimbursement is incontrovertibly grotesque, the Medicare Act does not guarantee a health care provider a hearing before an ALJ within 90 days," U.S. Circuit Judge Paul V. Niemeyer wrote for the panel. "Rather, it provides a comprehensive administrative process — which includes deadlines and consequences for missed deadlines — that a health care provider must exhaust before ultimately obtaining [judicial] review ... within a relatively expeditious time.

"The issuance of a judicial order now, however, directing [HHS] to hear the hospital system's claims in the middle of the administrative process, would unduly interfere with the process and, at a larger scale, the work of the political branches," Judge Niemeyer added.

Moreover, the appeals court said, mandamus is an extraordinary remedy that is only appropriate when a government official or agency is shirking a clear, nondiscretionary duty. A writ of mandamus is a relatively rare type of court order compelling a government official or agency to do its job.

"Mandamus is a 'drastic' remedy that must be reserved for 'extraordinary situations,'" Judge Niemeyer wrote, citing *Kerr v. U.S. District Court*, 426 U.S. 394 (1976).

According to the panel's opinion, the case turned on the fact that the Medicare Act does not simply require an ALJ hearing within 90 days.

Instead, the statute established a multilevel process for escalating appeals within HHS, culminating in a final ruling by the agency's chief that is appealable in court. The law also allows health care providers to bypass steps if HHS misses deadlines, the appeals court noted.

By cutting off those administrative appeals prematurely, the courts would be interfering with the comprehensive regulatory scheme established by the Medicare Act, the panel found.

Cape Fear Valley Health System "would have the judiciary enforce an isolated deadline and thereby impose a process not contemplated by the Medicare Act — indeed, in conflict with it," Judge Niemeyer wrote. "The precedent established by this judicial intrusion would surely invite every other delayed claimant into the courts, converting the agency process into a hybrid process involving judicial action."

"There is no evidence that Congress ever entertained such an idea," the judge added. WJ

Attorneys:
Appellant: Kathryn F. Taylor, K&L Gates, Morrisville, NC

Appellee: Joshua M. Salzman, U.S. Department of Justice, Washington, DC

Related Court Document:
Opinion: 2016 WL 860334

Facing suit over Oregon Obamacare exchange, Oracle demands feds investigate

By Michael Scott Leonard, Senior Legal Writer, Westlaw Journals

Oracle America has filed a lawsuit demanding the federal government investigate crippling problems with Oregon's Affordable Care Act health insurance exchange, which the state blamed on the software giant in a separate complaint in January.

Oracle America Inc. v. Burwell, No. 16-cv-451, complaint filed (D.D.C. Mar. 8, 2016).

In a suit filed March 8 in the U.S. District Court for the District of Columbia, Oracle accuses the state of filing its own earlier claims in bad faith as part of a multipronged political effort to discredit the company and saddle it with undeserved liability for the debacle. *Rosenblum v. Oracle Am.*, No. S063817, *complaint filed* (Or. Cir. Ct., Marion Cty. Jan. 14, 2016).

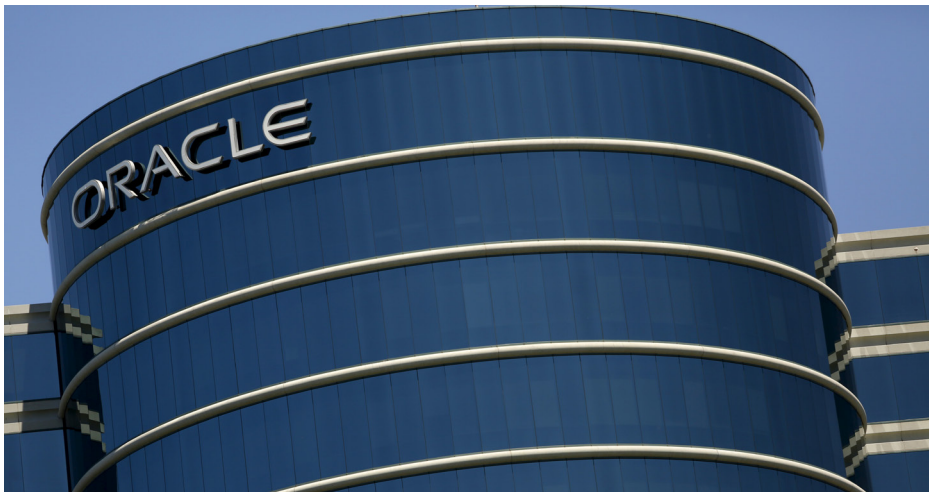
As part of that campaign, the suit says, "political operatives" working for then-Gov. John Kitzhaber in 2014 took over the state's Obamacare health insurance exchange, or HIX, from Cover Oregon, the public corporation the state had established to run it.

They then "embarked on a public relations campaign to blame Oracle" for the exchange's failure, the complaint claims, even though the governor's own administration had shut down the HIX "for partisan political purposes" as he was gearing up to run for re-election.

Kitzhaber won re-election that fall but resigned the following March amid allegations of influence-peddling involving his fiancée.

"Emails made public last year reveal that the governor, embroiled in a contested re-election fight, directed the political operatives advising his campaign to shore up his re-election efforts by quelling the HIX controversy," the suit says. "With the governor's full support, these operatives orchestrated a scheme to shut down the HIX, to claim falsely that it was an unsalvageable technological failure and to blame Oracle for its demise."

According to the complaint for a writ of mandamus, Oregon's state court lawsuit interferes with the federal government's authority to oversee federal funds expenditures — a responsibility that Health and Human Services Secretary Sylvia M. Burwell has a legal duty to perform under Obamacare.



REUTERS/Robert Galbraith

A "writ of mandamus" is a relatively rare type of court order compelling a government official or agency to do its job.

OREGON HIRES ORACLE

The case concerns the high-profile failure of the health insurance exchange Oregon tried to set up under the Affordable Care Act, which requires that states either run their own exchanges or opt in to the federal HealthCare.gov marketplace.

Oregon was one of 17 states that chose to operate their own exchanges. The state established Cover Oregon — a "freestanding quasi-governmental agency," according to the complaint — and charged it with getting the HIX up and running.

Cover Oregon retained Oracle as a consultant to help design and build the exchange.

But the suit says the agency "grossly mismanaged" the program, destabilizing the HIX by taking on multiple large projects at once without engaging a "systems integrator," the information technology equivalent of an architect, to oversee the whole endeavor.

"For reasons of its own, Oregon chose not to hire a systems integrator," the complaint says. "Instead, it elected to assume that role itself, installing *policy* advisors, rather than experienced IT professionals, to lead a complex *technology* project.

"Oregon's competence ... simply did not match the state's ambitions," the suit adds. "Acting as their own project managers, [Oregon] and Cover Oregon compromised the project by constantly changing and redefining the requirements that dictated how contractors, including Oracle, needed to configure the HIX's technology."

'POLITICS GOT IN THE WAY'

According to suit, despite years of bureaucratic mismanagement and related setbacks, Oracle was nevertheless ready to roll out a version of the health exchange in early 2014, as Kitzhaber, a Republican, was preparing to run for re-election that fall.

But the company claims Kitzhaber's campaign team decided scrapping the health exchange entirely and scapegoating Oracle for its failure would play better with voters than drawing attention to the program's many overruns by finally rolling it out at a politically inopportune moment.

"With assurances from both Cover Oregon and Gov. Kitzhaber, Oracle anticipated a successful launch," the suit says. "Then politics got in the way.

"Political operatives advising the governor's campaign determined that the only way to staunch the bleeding was to abandon the HIX and blame Oracle for its purported 'failure,'" the complaint adds. "The governor embraced the plan."

Around that time the governor's political team also took over Cover Oregon, which the state Legislature set up as an independent agency, so that they could "engineer the decision to shut down the HIX" and opt in to HealthCare.gov instead, Oracle says. The agency voted to shut down the HIX in late April 2014.

Those same advisers also concocted a "scheme" to sue Oracle and deflect blame away from Kitzhaber, the company says.

"The evidence establishes, in short, that the governor, driven by political instincts and guided by political operatives, induced legal action blaming Oracle for the state's own failures as part of an orchestrated plan to shore up his re-election efforts," the suit says.

CONFLICT OF INTEREST

According to Oracle, the state's lawsuit would "impermissibly usurp federal authority" by interfering with Burwell's "non-discretionary obligation" under the Affordable Care Act, 42 U.S.C.A. § 18033(a)(5), to account for federal funds spent on Obamacare exchanges.

The state squandered hundreds of millions of federal dollars in its failed bid to set up the HIX, and the federal government, not Oregon, has the sole authority to determine who misspent all those appropriations, the company argues.

"The ACA imposes a mandatory duty on the secretary to monitor the integrity of state grantees and state health insurance exchanges, and Oregon's suit ... undoubtedly implicate[s] Oregon's integrity," the suit says. "Oregon's entire lawsuit is unauthorized, unlawful, invalid, and ultra vires because it seeks to recover federally granted funds using Oregon law."

Moreover, the complaint says, with its concerted effort to "go after" Oracle, the state has shown it cannot be trusted to adjudicate the controversy.

"Oregon's conflicts of interest and unclean hands amplify and highlight the overriding federal interest in requiring an impartial federal agency to resolve claims concerning the HIX," the suit says. WJ

Attorneys:
Plaintiff: Seth A. Rosenthal, John F. Cooney, Brian L. Schwalb and Mitchell Y. Mirviss, Venable LLP, Washington, DC; Jamie Gorelick and Edward N. Siskel, Wilmer Cutler Pickering Hale & Dorr, Washington, DC; Robert P. Reznick, Karen G. Johnson-McKewan, Robert S. Shwarts and Erin M. Connell, Orrick Herrington & Sutcliffe, Washington, DC

Related Court Document:
Complaint: 2016 WL 888116

Horizon Pharma hid drug price inflation from investors, suit says

By Nicole Banas, Senior Content Writer, Westlaw Daily Briefing

Horizon Pharma Plc failed to tell investors that its mail-order prescription drug program improperly inflated drug prices, according to a class-action lawsuit filed in Manhattan federal court.

Schaffer v. Horizon Pharma PLC et al., No. 16-cv-1763, complaint filed (S.D.N.Y. Mar. 8, 2016).

The suit says Horizon's share price has declined in recent months on news that the Ireland-based company's "prescriptions made easy" program used specialty pharmacies to ensure that less expensive generic equivalents are not used as substitutes for its drugs.

Investors were further damaged when Horizon revealed Feb. 29 that it was subpoenaed by government investigators late last year, according to the suit filed in the U.S. District for the Southern District of New York.

Horizon allegedly violated federal securities law by failing to disclose that the PME program created "unsustainable" sales revenue and subjected the company to increased regulatory risks.

The suit also names as defendants Horizon chairman and CEO Timothy Walbert, CFO Paul Hoelscher and former CFO Robert De Vaere.

Horizon develops drugs to treat arthritis, pain and inflammatory diseases, the suit says. The company's stock trades on Nasdaq.

MAIL-ORDER DRUG PROGRAM

The suit says Horizon disclosed in its March 2014 annual report to the Securities and Exchange Commission that the PME program contracts with three "partner pharmacies" to ship prescribed medications directly to patients.

The company said it developed the program to "address the impact of pharmacies switching from branded products prescribed by doctors to substitute products."

Horizon disclosed in an SEC filing Feb. 27, 2015, that its ability to gain market share depended on physicians' continued adoption of the PME program, according to the suit.

The complaint says Horizon reported operating losses in 2013 and 2014, but reported net income of nearly $32 million in second-quarter results released Aug. 7.

In a statement announcing those results, the company said its sales revenue had increased 161 percent, in part due to increased use of the PME program.

'CAPTIVE' PHARMACIES?

The suit says the truth about Horizon started to emerge Oct. 19 when The New York Times reported that certain drugmakers, including Horizon, worked with specialty pharmacies to ensure that patients received their products instead of less expensive equivalents.

Horizon's share price dropped nearly 20 percent on the news, closing at $15.26 on Oct. 20, according to the suit.

It tumbled again when pharmacy benefits manager Express Scripts Holding Co. announced Nov. 10 that it had removed specialty pharmacy Linden Care LLC from its network because it primarily dispensed Horizon drugs.

Express Scripts also said it had filed a $140 million suit against Horizon over Linden's alleged failure to fulfill its contractual obligations, according to the complaint.

In a statement that day, Horizon denied that Linden was a "captive pharmacy" and said it worked with a "diverse group" of pharmacies.

INVESTIGATION REVEALED

The complaint alleges those assurances came into question Feb. 29 when Horizon revealed in an SEC filing that it had received an investigative subpoena in November for documents related to the company's marketing and commercialization activities.

Horizon also disclosed that its PME program, now renamed "HorizonCares," might implicate state laws related to fraud, excessive fees for services and tortious interference with patient contracts, the suit says.

Horizon's share price declined 13 percent on the news, according to the complaint.

SECURITIES FRAUD CLAIMS

Horizon allegedly kept investors in the dark about the PME program's effect on the company's business and prospects.

The defendants' false and misleading statements violated the anti-fraud and control-person provisions in Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C.A. §§ 78j(b) and 78t(a), the suit says.

The suit seeks compensation for investors who bought Horizon securities during a 23-month period ending Feb. 26. WJ

Related Court Document:
Complaint: 2016 WL 889602

Omnicare standard doesn't revive Sanofi fraud suit, 2nd Circuit says

By Jason Seashore, J.D., Senior Content Writer, Westlaw Daily Briefing

A 2nd U.S. Circuit Court of Appeals appeals panel has upheld the dismissal of a 2013 shareholder fraud suit that accused drugmaker Sanofi SA of failing to disclose a snag in regulatory approval for a new product, saying the U.S. Supreme Court's 2015 *Omnicare* ruling would not have changed the result.

Tongue et al. v. Sanofi et al., No. 15-588, 2016 WL 851797 (2d Cir. Mar. 4, 2106).

In a January 2015 decision, U.S. District Judge Paul A. Engelmayer of the Southern District of New York ruled that Sanofi's alleged misleading statements did not rise to the level of fraud because they were either immaterial or were "genuinely held" statements of opinion. *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510 (S.D.N.Y. Jan. 28, 2015).

While an appeal to the 2nd Circuit was pending, the Supreme Court in another case, *Omnicare Inc. v. Laborers District Council Construction Industry Pension Fund*, 135 S. Ct. 1318 (2015), said that a "statement of opinion" that allegedly omits facts must be assessed in light of what a reasonable investor would expect to be disclosed.

In appeals papers, Sanofi shareholders argued that the intervening *Omnicare* standard ought to save their suit because the company's opinion about the likelihood of Food and Drug Administration approval for the drug omitted key information that the agency had taken a view undercutting the company's optimism.

The 2nd Circuit panel March 4 affirmed Judge Engelmayer's decision, saying that even in light of the new *Omnicare* standard, the plaintiffs still failed to allege any materially misleading statements of opinion.

PAYMENTS TIED TO FDA APPROVAL

The suit stemmed from a delay in FDA approval of Lemtrada, a multiple sclerosis drug that Paris-based Sanofi acquired from its developer, Genzyme Corp., in February 2011 for more than $20 billion. The deal included "contingent value rights" shares issued to Genzyme investors.

The CVR shares provided for a series of milestone payments tied to FDA approval of and sales marks for Lemtrada.

According to the complaint, the defendants failed to disclose the FDA repeatedly criticized the use of a "single-blind" trial for Lemtrada and informed Sanofi it would carry a heavier burden of proof than had it used a "double-blind" approach.

Investors allegedly learned in November 2013 through an FDA briefing report that Lemtrada was "critically flawed" and would not be approved. The regulator formally rejected Lemtrada the next month, although it eventually approved the drug in November 2014.

Lead plaintiff Glenn Tongue, the general partner of hedge fund Deerhaven Capital Management, sought compensation for investors who acquired Sanofi CVR shares during a 20-month period ending Nov. 7, 2013.

In addition to Sanofi and senior executives, the suit named Genzyme's CEO as a defendant.

INTERVENING *OMNICARE* STANDARD

The 2nd Circuit panel found no significant conflict between the FDA's "interim, albeit repeated, concerns" about Sanofi's clinical trial methodology and the defendants' optimism about the likelihood of the agency's approval for Lemtrada.

The FDA has "long made public its preference for double blind trials," and the defendants admitted they were relying on single-blind trials, so the agency's concern would not have come as a surprise to investors, the panel said.

That is especially true in the case of sophisticated investors buying a complex financial instrument whose value is tied to FDA approval, the panel said. Such investors "may be expected to keep themselves apprised of the FDA's public positions on testing methodology," it said.

"Reasonable investors understand that dialogue with the FDA is an integral part of the drug approval process, and no sophisticated investor familiar with standard FDA practice would expect that every view of the data taken by defendants was shared by the FDA," the panel said. WJ

Related Court Document:
Complaint: 2016 WL 851797

2nd Circuit to issuers: Don't worry about *Omnicare*

By Alison Frankel

(Reuters) – It's been just about a year since the U.S. Supreme Court said in *Omnicare v. Laborers District Council Construction Industry,* 135 S. Ct. 1318 (2015), that securities issuers can be liable to investors even if their misstatements are couched as opinions.

But in a ruling March 4 in the *In re Sanofi*, case, the 2nd U.S. Circuit Court of Appeals held that despite *Omnicare*, issuers don't have to tell investors about important information that may contradict the opinions they are expressing. *Tongue v. Sanofi et al.*, No. 15-588, 2016 WL 851797 (2d Cir. Mar. 4, 2016).

If the Supreme Court opened the door in *Omnicare* to class actions based on issuers' dubious opinions, the 2nd Circuit — the busiest appellate court for securities class actions — mostly closed it again in the *Sanofi/Tongue* decision. "The circuit has clearly stated that things aren't going to change much under *Omnicare*," said Robert Fumerton of Skadden Arps Slate Meagher & Flom, who was not directly involved in the case. (Weil Gotshal & Manges won it for Sanofi.) "It's going to be very difficult for plaintiffs in this circuit to establish liability," Fumerton said.

The *Sanofi* case involved the company's representations about the multiple sclerosis drug Lemtrada, which Sanofi picked up when it acquired Genzyme in 2011. At the time, Lemtrada was considered a potential blockbuster but had not been approved by the Food and Drug Administration. To account for the uncertainty, Genzyme shareholders received specialized financial instruments called "contingent value rights" as part of the Sanofi deal. The CVRs, as the securities are known, entitled Genzyme shareholders to cash payments of up to $2 per share if Lemtrada met target dates for FDA approval and global sales. After the merger between Genzyme and Sanofi, the CVRs traded independently as securities.

In a class action and separate multiplaintiff case against Sanofi, CVR purchasers claimed the company deceived them by repeatedly expressing optimism about Lemtrada's FDA approval without acknowledging the FDA's longstanding concern that the drug was only being tested in single-blind clinical studies, not double-blind tests. When the FDA issued its initial rejection of Lemtrada in December 2013, the value of the CVRs fell to 32 cents per share. By the time the drug was ultimately approved the following November, CVR holders had already missed out on their first cash payment because the approval came after the agreed-upon target date.

The trial judge, U.S. District Judge Paul Engelmayer, had dismissed CVR holders' claims in January 2015, citing the 2nd Circuit's 2011 decision in *Fait v. Regions Financial Corp.*, 655 F.3d 105 (2011), which held that issuers are not liable for opinions unless they did not actually believe what they said at the time they made the statement. *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510 (S.D.N.Y. Jan. 28, 2015)

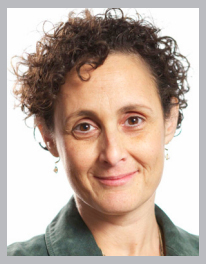
Two months, later, the Supreme Court issued its *Omnicare* decision, implicitly rejecting the 2nd Circuit's *Fait* precedent.

So the key question for the 2nd Circuit panel in the *Sanofi* case was whether *Omnicare* created potential liability for Sanofi because the company did not warn CVR investors about the FDA's objections to its testing protocols. The class, represented by the Weiser Law Firm, and individual plaintiffs represented by Ross Orenstein & Baudry argued that Sanofi's opinions were actionable because the omitted information conflicted with what "reasonable investors" would assume from Sanofi's stated opinions.

The 2nd Circuit panel — Judges Barrington Parker, Raymond Lohier and Susan Carney — said in an opinion by Judge Parker that reasonable investors would have been interested in what the FDA was telling the company and might even have changed their mind about buying CVRs based on that information. Nevertheless, the court said, "*Omnicare* does not impose liability merely because an issuer failed to disclose information that ran counter to an opinion expressed."

The Supreme Court itself cautioned against an expansive reading of *Omnicare* the 2nd Circuit said, acknowledging that "reasonable investors" should not expect issuers to disclose every fact conflicting with the opinion it is expressing. Context counts, according to the appellate panel, and in this case, reasonable investors in these complex securities should have realized the FDA and Sanofi were engaged in give-and-take over the testing regimen for Lemtrada.

"Plaintiffs' case essentially boils down to an allegation that the statements were misleading for failure to include a fact that would have potentially undermined defendants' optimistic projections," the 2nd Circuit said. "But *Omnicare* imposes no such disclosure requirements on issuers.



Alison Frankel updates her blog, "On the Case," multiple times throughout each day on WestlawNext Practitioner Insights. A founding editor of Litigation Daily, she has covered big-ticket litigation for more than 20 years. Frankel's work has appeared in The New York Times, Newsday, The American Lawyer and several other national publications. She is also the author of "Double Eagle: The Epic Story of the World's Most Valuable Coin."

Defendants need not have disclosed the FDA feedback merely because it tended to cut against their projections."

John Neuwirth of Weil, who argued for Sanofi at the 2nd Circuit, said in an email statement that the company believes the appeals court made "the right decision."

If there's any salvation for investors in the 2nd Circuit's opinion, it is in the panel's repeated references to the sophistication of CVR investors, who trade in highly specialized securities. Though the plaintiffs' lawyers who argued the case, Christopher Nelson of Weiser and John Orenstein of Ross Orenstein, did not respond to my email requests for comment, I can certainly see ordinary shareholders arguing that Sanofi doesn't apply to their claims because they're presumably not as sophisticated as CVR investors.

One final word about the *Sanofi* ruling: The claims at issue in the 2nd Circuit appeals involved both Section 11 allegations under the Securities Act of 1933 and 10b-5 allegations under the Securities and Exchange Act of 1934. The Supreme Court's *Omnicare* decision addressed just '33 Act claims and there has been some question whether *Omnicare* applies also to '34 Act allegations. The 2nd Circuit suggested, albeit without specifically discussing *Omnicare*'s breadth, that the Supreme Court decision extends to 10b-5 claims as well as claims under Section 11. WJ

NEWS IN BRIEF

NEW JERSEY DOCTOR GETS 3-YEAR PRISON SENTENCE FOR BILLING FRAUD

A physician from Bergen County, New Jersey, was sentenced to 37 months in prison March 15 for defrauding Medicare, Medicaid and private insurance companies out of $280,000 by billing for nonexistent office visits. Albert Ades, 61, of Englewood, previously pleaded guilty to one count of health care fraud in the U.S. District Court for the District of New Jersey. According to the U.S. attorney's office for the District of New Jersey, from 2005 through June 2014, Ades wrote prescriptions and performed other medical services for patients he never saw. Ades also admitted that he altered medical charts by adding fake blood pressure readings and other clinical notes to make it appear his patients had come into the office. In addition to the prison term, U.S. District Judge Esther Salas sentenced Ades to three years of supervised release and ordered him to forfeit $280,000.

United States v. Ades, No. 15-cr-95, defendant sentenced (D.N.J. Mar. 15, 2016).

AMBULANCE DRIVER SENTENCED TO 37 MONTHS IN PRISON FOR FRAUD

Fritzroy Brown, 39, of Philadelphia was sentenced March 10 to a 37-month prison term for fraudulently billing federally insured health care programs while employed by Brotherly Love Ambulance Inc. The U.S. attorney's office for the Eastern District of Pennsylvania said Brown transported patients who were able to ride in other vehicles or could walk and were therefore ineligible for ambulance transportation under Medicare requirements. Brown also allegedly paid kickbacks to patients to ensure they would use Brotherly Love transport when not medically necessary. In addition to the prison term, Judge Gerald J. Pappert of the U.S. District Court for the Eastern District of Pennsylvania ordered Brown to serve three years of supervised release and pay restitution of over $2 million to Medicare. Brown also allegedly collected unemployment compensation while working for the ambulance service and will repay $14,150 to the state.

United States v. Brown, No. 14-cr-596, defendant sentenced (E.D. Pa. Mar. 10, 2016).

FLORIDA MAN SENTENCED TO 14 YEARS IN PRISON FOR HEALTH CARE FRAUD

David Brock Lovelace, 45, of Land O'Lakes, Florida, has been sentenced to 174 months in prison for his role in a multimillion-dollar health care fraud scheme. In December of last year, a jury found the defendant guilty of conspiracy to commit health care fraud and wire fraud; conspiracy to commit money laundering, and aggravated identity theft, according to a March 7 Justice Department statement. From about June 2010 to May 2014, Lovelace and his co-conspirators used Cornerstone Health Specialists, Summit Health Specialists and Coastal Health Specialists to submit over $12 million in false claims for radiology, audiology, cardiology and neurology services, the U.S. attorney's office for the Middle District of Florida said. Lovelace and his co-conspirators also allegedly paid illegal kickbacks to patients, used forged documents and billed Medicare for services that had not been provided. They also disbursed the $2.8 million paid by Medicare among themselves through shell companies and cash withdrawals, the Justice Department added. Judge Steven D. Merryday of the U.S. District Court for the Middle District of Florida also ordered the defendant to pay more than $2.5 million in restitution.

United States v. Lovelace, No. 14-cr-164, defendant sentenced (M.D. Fla. Mar. 8, 2016).

Medicaid ruling

CONTINUED FROM PAGE 1

and were referred to another Arbour staff member, who allegedly represented herself as a doctor, court documents say.

The parents say they later discovered she was a nurse, and they allege their daughter's treatment and mental health suffered as a result of substandard care.

They claim the nurse prescribed Trileptal, an anti-epilepsy drug, but Rivera stopped taking the drug after a few days because of its side effects. The nurse allegedly had not told Rivera that abruptly stopping the drug can cause seizures, according to the government.

In October 2009, Rivera died from a seizure while home alone, the government's brief says.

Her parents filed a qui tam suit in 2011 in the U.S. District Court for the District of Massachusetts, asserting violations of the False Claims Act, 21 U.S.C.A. § 3729. Under the FCA, private citizens may bring qui tam suits on behalf of the government and share in any recovery.

The parents alleged the owner of the Arbour facility, Universal Health Services, submitted false bills for payment to Medicaid because the employees who provided counseling and medication to their daughter were not properly qualified or supervised, in violation of the regulations of the Massachusetts Medicaid agency, MassHealth. Medicaid is a joint federal and state-funded program.

LOWER COURT PROCEEDINGS

The District Court granted Universal Health's motion to dismiss the suit for failure to state a claim. The court concluded that any alleged violation of supervisory standards could not form the basis for an FCA claim because the standards were "conditions of participation," not "conditions of payment." *United States ex rel. Escobar v. Universal Health Servs.*, No. 11-11170, 2014 WL 1271757 (D. Mass. Mar. 26, 2014).

On appeal, the 1st Circuit overturned the decision after finding that the staffing must meet all the requirements of the state. Since the plaintiffs - had alleged noncompliance with Massachusetts regulations pertaining to supervision, their suit should have survived a motion to dismiss, the appeals court ruled. *United States ex rel. Escobar v. Universal Health Servs.*, 780 F.3d 504 (1st Cir. 2015).

CERTIORARI PETITION

Universal Health has asked the Supreme Court to review the 1st Circuit decision, arguing that the MassHealth policies and procedures did not expressly require compliance with staffing regulations as a condition of payment.

In its respondent's brief, the United States says Universal Health "knowingly hired unlicensed, unqualified, and unsupervised 'counselors' to provide sensitive mental health services in clear violation of several express requirements" of the state's Medicaid program.

The government argues Universal Health implied its staff met state requirements and that such "implied certification" is critical to the purpose of the FCA.

> Universal Health's approach would immunize providers from False Claims Act liability simply because a requirement was not labeled a "condition of payment," the U.S. says.

"Many if not most government requirements are obviously material conditions of payment because they affect the nature or quality of the goods or services delivered," the brief says.

Universal Health's approach would immunize providers from FCA liability simply because a requirement was not labeled a "condition of payment," according to the brief.

The FCA was implemented to reach the numerous ways that health care providers or contractors can steal from the public fisc, and the appellate court ruling should be affirmed, the government says. WJ

Related Court Documents:
Petitioner's brief: 2016 WL 322599
Respondent's brief: 2016 WL 750226

See Document Section A (P. 23) for the respondent's brief.

CASE AND DOCUMENT INDEX