

FIFTH CIRCUIT ADDRESSES PRE-SUIT DISCLOSURE AND CAUSATION REQUIREMENTS FOR FCA THEORIES OF LIABILITY

The Fifth Circuit recently addressed pre-suit disclosure and causation requirements for FCA theories of liability in *United States ex rel. King v. Solvay Pharmaceuticals Inc.*, 871 F.3d 318 (5th Cir. 2017). Two former employees ("Relators") of Solvay Pharmaceuticals, Inc. filed a *qui tam* suit claiming that Solvay induced false Medicaid claims through a variety of marketing and lobbying initiatives. Relators claimed that Solvay's marketing tactics caused physicians to prescribe drugs for off-label uses to Medicaid patients. Relators also claimed they were terminated for making internal complaints about the marketing strategy. The district court granted summary judgment in favor of Solvay and the Fifth Circuit affirmed.

ANALYSIS

Relators' action was based on a number of FCA liability theories, including the following.

1. Solvay marketed three separate drugs for off-label uses causing physician to prescribe them to Medicaid patients for those uses.
2. Solvay lobbied members of state pharmaceutical and therapeutic committees to list the three drugs on their preferred drug lists.
3. Solvay used misleading scientific literature to lobby a publisher of a drug compendium to include the off-label uses in the compendium.
4. Solvay paid doctors kickbacks to prescribe these drugs to Medicaid patients in violation of the Anti-Kickback Statute.
5. Relators were wrongfully terminated for making internal complaints about Solvay's marketing scheme.

The Fifth Circuit methodically dismissed each of the Relators' claims, starting with Relators' failure to meet the public disclosure bar on their first theory of FCA liability.

RELATORS' ALLEGATIONS OF OFF-LABEL MARKETING SCHEME

Public Disclosure Bar

Relators' first theory of FCA liability alleged that Solvay marketed three separate drugs—Luvox, Aceon and AndroGel—for off-label uses. The district court determined that it lacked jurisdiction to consider any of Relators' claims regarding AndroGel. This determination, affirmed by the Fifth Circuit, rested on the fact that Relators' AndroGel claims were based on publicly disclosed allegations from a magazine article and that Relators' pre-suit disclosure made the day before filing could not satisfy the voluntary disclosure requirement of the original source exception.

To survive the public disclosure bar, relators must show that they qualified under the original source exception. If a relator fails to meet this exception, the public disclosure bar "strips" the court of subject matter jurisdiction. In affirming the district court's decision, the Fifth Circuit relied on a Fourth Circuit case stating that where a relator's pre-suit disclosure never connected information about the alleged fraudulent conduct with the filing of a claim for reimbursement from the government, the public disclosure bar was not cleared.

The Fifth Circuit agreed with the district court that Relators failed to present any evidence indicating that their pre-suit disclosure connected the knowledge of Solvay's conduct to false claims made to the government. The Fifth Circuit highlighted this causation requirement stating, "[f]or Relators to satisfy the FCA's voluntary pre-suit disclosure requirement of disclosing information underlying their FCA action, their disclosure must—at a minimum—connect direct and independent knowledge of information about Solvay's conduct to false claims submitted to the government, i.e., suggest and FCA violation."

Off-Label Marketing to Physicians

Also at issue in Relators' first claim was that the FDA prohibits a drug from being introduced into interstate commerce unless the FDA approves the drug as safe and effective for each of the uses suggested on its labeling. Relators contended that "[b]ecause off-label prescriptions may be ineligible for Medicaid reimbursement, submitting such claims for Medicaid reimbursement may result in FCA liability."

The Fifth Circuit acknowledged, “The main issue on appeal is the sufficiency of Relators’ evidence that this alleged off-label marketing caused the filing of false Medicaid reimbursement claims.” In affirming the lower court’s decision, the Fifth Circuit stated, “At best, Relators’ circumstantial evidence suggests only the potential for a causal link between Solvay’s alleged off-label marketing and off-label prescriptions but says nothing about whether the marketing scheme *actually caused* off-label prescriptions to Medicaid patients.” Because Relators failed to show actual causation, their off-label marketing theory of FCA liability could not withstand summary judgment.

RELATORS’ ALLEGATIONS OF LOBBYING STATE P&T COMMITTEES

For this claim, Relators alleged that Solvay violated the FCA by unduly influencing pharmaceutical and therapeutic (“P&T”) committees to place Solvay’s drugs on preferred drug lists.

Like Relators’ first claim of FCA liability, this claim falls on the issue of causation. Relators’ evidence showed Solvay campaigned to get its drugs added to three state-preferred drug lists and that those states ultimately added those drugs to their preferred drug lists. However, the court noted Relators lacked evidence indicating that Solvay’s campaign *caused* these results. However, the most important role of causation in this claim was not that Solvay’s lobbying efforts caused the drugs to be added to preferred lists but that it *caused* any filing of a false claim. In affirming the district court’s decision, the Fifth Circuit stated, “[m]oreover, even assuming that the P&T committees were influenced by Solvay’s campaign, Relators have not connected this theory of liability to the filing of any false claims.” With no evidence of causation, this claim for FCA liability could not survive.

RELATORS’ ALLEGATIONS OF UTILIZING MISLEADING SCIENTIFIC LITERATURE TO INFLUENCE A DRUG COMPENDIUM

Relators accused Solvay of violating the FCA by misleading one of the leading drug compendia, DrugDex. In making this unique argument, Relators stated Solvay manufactured medical literature and engaged in deception and collusion in an effort to have DrugDex list the off-label uses of Solvay’s drugs so they might be deemed eligible for reimbursement under Medicaid or Medicare.

Once again, the Fifth Circuit noted the lack of causation in this argument. The court stated, “[b]ut Relators point to no evidence indicating that Solvay’s failure to publish studies showing negative results while also paying for lower quality studies to support Luvox’s off-label uses misled DrugDex’s publisher and caused it to list Luvox on its compendium.” As with the others, this claim fell to the Fifth Circuit’s hard stance causation.

RELATORS’ ALLEGATIONS OF ANTI-KICKBACK STATUTE VIOLATIONS

Relators claimed that Solvay violated the anti-kickback statute by paying illegal kickbacks to physicians through various marketing programs intended to induce physicians to write prescriptions for off-label uses. While on its face this is a straightforward anti-kickback claim, Relators also hinted at an FCA violation in the claim by stating the purpose of these kickbacks “would in turn cause pharmacists to submit claims for fraudulent Medicaid and Medicare Part D reimbursement.”

As with the previous claims, the Fifth Circuit highlighted Relators’ failure to show any actual causation related to this claim. The Fifth Circuit noted the payment structure did not violate the Anti-Kickback Statute and eliminated any inkling of FCA liability by stating, “Nowhere, however, do Relators cite to evidence creating a genuine issue of material fact that such compensation, or any incidental benefits, caused those physicians to prescribe to Medicaid patients.”

RELATORS’ CLAIM OF WRONGFUL TERMINATION UNDER THE FCA

Both Relators brought an FCA retaliation claim against Solvay alleging they were terminated for filing internal complaints about Solvay’s alleged off-label marketing campaign.

The Fifth Circuit applied the established *McDonnell Douglas* framework to determine if there was violation of the anti-retaliation provision of the FCA. This framework requires the employer to state a legitimate, non-retaliatory reason for termination after the employees have established their prima facie case. After the employer has done so, the burden then shifts back to the employee to demonstrate that the employer’s reason is a pretext for retaliation.

Here, Solvay claimed Relators were terminated for creating unapproved marking materials. Relators also admitted to violating Solvay’s marketing policies. Relators argued that they received strong performance reviews and were terminated three and a half months after making their complaints. The court noted, as with all of the previous claims, there exists a causation problem. The court stated, “Relators point to no evidence that Solvay raised dubious performance problems as a reason for their termination, mistreated them immediately after their protected activities, or knew of their policy violations prior to Relators’ positive performance reviews. Simply put, Relators have failed

to show that a reasonable jury could conclude that their complaints were the but-for cause of their terminations.”

PRACTICAL TAKEAWAYS

- The Fourth and Fifth Circuit agree that to clear the public disclosure bar, a relator must satisfy the pre-suit disclosure requirement. To meet this requirement, relators must *connect direct and independent knowledge* of the conduct to the filing of a false claim.
- Loose causal connections are not sufficient to demonstrate FCA liability. Rather, the Fifth Circuit seeks direct, but-for causation of the alleged misconduct to the filing of a false claim.
- Lobbying for off-label drug uses is not a *per se* violation of the FCA. Relators are required to show how those lobbying efforts directly caused a false claim to be submitted.
- A violation of the Anti-Kickback Statute may lead to FCA liability if a relator can show that the kickback was a reason for submission of a false claim.
- A wrongful termination argument under the FCA requires a but-for showing that the employee’s protected conduct was the reason for their termination.

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