

Appeals Court Dismisses Off-Label False Claims Act Complaint; Adds to Growing List of Successful Challenges to FCA Actions Against Drug and Device Companies

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In an important ruling for pharmaceutical and medical technology companies, the 11th Circuit Court of Appeals affirmed a lower court's dismissal of a False Claims Act (FCA) suit against Solvay Pharmaceuticals on December 4, 2009. *United States ex rel. Hopper v. Solvay Pharms., Inc.*, No. 04-02356-CV-T-23-TGW (11th Cir. Dec. 4, 2009). Two former sales representatives had filed a *qui tam* complaint against the company for allegedly causing the government to pay or approve payments relating to off-label prescriptions of the drug Marinol. The court, for the first time at the federal appellate level, affirmed an off-label FCA dismissal because the plaintiffs failed to identify any false claims Solvay allegedly caused to be made to the government.

Background

Solvay and its subsidiary, Unimed Pharmaceuticals, manufactured and marketed a synthetic form of THC known as Marinol. James Hopper and Colin Hutto, ex-Solvay sales representatives, sued their former employer in 2004 under the whistleblower provision of the federal FCA and parallel state statutes. The FCA imposes liability on anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." The whistleblowers' complaint alleged that Solvay executed a sophisticated marketing plan for the purpose of inducing physicians to prescribe Marinol for uses not approved by the FDA, including appetite loss and nausea. The company's conduct, according to the complaint, "caused submission for reimbursement by Government Healthcare Programs of millions of dollars worth of prescriptions which were ineligible for such reimbursement." After reviewing the allegations, the U.S. Justice Department decided not to intervene in the action, and the whistleblowers proceeded on their own.

Insufficient particularity

The 11th Circuit affirmed the lower court's dismissal of the case because the whistleblowers were unable to point to any specific instances in which the alleged off-label marketing caused false claims to be paid or approved by the government. Therefore, the court found that the whistleblowers had failed to plead their case with "particularity," as required by Rule 9(b) of the Federal Rules of Civil Procedure in FCA cases.

Although the whistleblowers alleged conduct regarding an off-label marketing scheme, this did not satisfy their pleading requirements. They also needed to allege that the purported improper scheme caused the payment or approval of false claims by the government. On this count, they fell short. The whistleblowers were unable to identify the existence of a single allegedly false claim, nor a claim of any other kind, according to the court. The whistleblowers pointed to an increase in Marinol prescriptions and reimbursements as indirect evidence that false claims were paid, but the court was unmoved. Because of their inability to plead facts that served to describe the alleged FCA violation with particularity, the court dismissed the complaint.

A common evidentiary shortcoming for whistleblowers in off-label cases

The *Solvay* decision underscores a pleading deficit commonly seen in whistleblower-initiated off-label FCA cases. In *Solvay*, as in a number of other off-label FCA cases, the whistleblowers were former sales representatives. Due to their position in the sales organization, they are able to make general allegations regarding a purported improper marketing scheme, but do not have knowledge of any actual claims submitted to the government in connection with such schemes. *Solvay* establishes that merely alleging off-label marketing is insufficient to mount an FCA case. The whistleblower (or government, if it has intervened) must show the connection between the off-label promotion and government payment or approval of a false claim.

Recent cases demonstrate availability of defenses in FCA cases

The recent proliferation of *qui tam* filings has proven to be a serious challenge for many pharmaceutical and device manufacturers. Historically, companies have settled such actions through civil penalties and Corporate Integrity Agreements. But in a few recent cases, including *Solvay*, courts have confirmed the viability of defenses for companies facing an FCA claim. The outlook remains challenging, but it has become increasingly clear that defenses are available in a variety of situations.

Insufficient factual allegations tying off-label promotion to false claims. Confirming the usefulness of the *Solvay* pleading defense are three similar district court cases in which the court dismissed FCA claims based, at least in part, on plaintiffs' failure to plead fraud with particularity. In *United States ex rel. Polansky v. Pfizer, Inc.*, the court found that the whistleblower had not identified with specificity any false claims or physicians who were induced to write a prescription for an off-label use. No. 04-cv-0704 (ERK), 2009 U.S. Dist. LEXIS 43438 (E.D.N.Y. May 22, 2009). In *United States ex rel. Poteet v. Lenke, M.D.*, one of the court's grounds for dismissal was that the whistleblower's complaint was "devoid of specific allegations linking the distributor defendants to ... the filing of false claims with the government" and that plaintiffs had failed to specify details including which distributors were involved in the alleged scheme, how they were allegedly involved, whether the alleged gift recipients purchased Medtronic products, whether the alleged gift recipients filed a claim for Medicare benefits, or whether the gifts caused a false filing with Medicare. No. 07-10237-RGS, 2009 U.S. Dist. LEXIS 24342 (D. Mass. Mar. 20, 2009). Finally, in *United States ex rel. Stephens v. Tissue Science Laboratories, Inc.*, a complaint alleging that off-label device promotion caused the submission of false claims to Department of Defense and Veterans Administration facilities failed to meet the Rule 9(b) pleading requirements because it did not identify who purchased the product, in which surgeries the product was used, or why physicians decided to use the product.

Alleged off-label promotion was immaterial to government's payment decision. Another recent ground for off-label FCA dismissal has been the finding that alleged off-label marketing, even if the basis for a false claim, had no effect on government payment and was therefore immaterial. In *Stephens*, discussed above, plaintiffs also alleged that off-label promotion of a device had led to its use in procedures reimbursed by Medicare and Medicaid. No. 1:07-CV-2357-ODE (N.D. Ga. Aug. 13, 2009). But the court noted that reimbursements take place at a predetermined amount based on the patient's Diagnosis Related Group (DRG); therefore, the court found that the alleged unlawful promotion was immaterial to the government's payment. Analyzing the facts under FCA provisions prior to enactment of the Fraud Enforcement and Recovery Act of 2009 (FERA), which added an explicit materiality requirement to the FCA, the court concluded that when a claim is submitted based on a patient's DRG, the materiality requirement of the FCA cannot be met. Likewise, the court in *United States v. Aventis Pharms., Inc.*, operating under pre-FERA law, found that a drug company's

alleged off-label promotion was immaterial because in-patient hospital services, including prescriptions of the drug at issue, were reimbursed at the fixed DRG rate. No. 03-CV-02750 (N.D. Ill. Dec. 10, 2008). (After that adverse order, however, the *Aventis* plaintiffs submitted an amended complaint alleging with particularity that off-label marketing led to outlier claims on hospital cost reports that included off-label prescriptions of the defendant's drug. This, the court said, was a valid claim.)

The whistleblower suit was based on a public disclosure. A second basis for the dismissal in *Poteet* was that the claim was held to be based on a public disclosure. This is impermissible in a *qui tam* suit unless the whistleblower is an original source of the information underlying the action. The majority rule, followed in *Poteet*, says that an action is considered “based upon” a public disclosure “when the supporting allegations are similar to or the same as those that have been publicly disclosed ... regardless of where the [whistleblower] obtained his information.”

Helpful in a range of off-label FCA cases

The 11th Circuit's decision in *Solvay* should be helpful to pharmaceutical and medical technology defendants in many, though not all, FCA cases. The decision is particularly useful in defending against whistleblower actions brought by field-based sales personnel, personnel at competitor companies, or others who have little or no knowledge regarding claims submitted to the government. Also, the decision may assist manufacturers in handling a broader range of actions via its affirmation that mere allegations of an off-label scheme, even if detailed, are insufficient to establish an FCA violation. As many courts have observed, identification of an actual false claim is the *sine qua non* of an FCA case.