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Court of Appeals Affirms Dismissal of Off-Label Marketing Case

By John R. Fleder –

On December 4, 2009, the United States Court of Appeals for the Eleventh Circuit in Atlanta issued a 24-page Opinion in James Hopper v. Solvay Pharmaceuticals, Inc., No. 08-15810. The Court affirmed the District Court's dismissal of a False Claims Act (FCA), (31 U.S.C. 3729 et. seq.) lawsuit that two former sales representatives (Relators) of Solvay Pharmaceuticals, Inc. filed in 2004, in the United States District Court for the Middle District of Florida. The Court of Appeals ruled that the Relators' complaint was legally deficient under Rule 9(b) of the Federal Rules of Civil Procedure because the alleged fraud was not pleaded with the necessary specificity. The Relators had alleged that the defendants had violated the FCA by engaging in an allegedly unlawful off-label marketing scheme that had caused the federal government to pay "false" claims through federal programs for the drug Marinol.

This is an important ruling in the context of FCA litigation generally, but more specifically with regard to off-label use cases. There has been a plethora of FCA litigation over the past decade involving allegations that companies have violated the FCA by causing the submission of false claims based on off-label marketing campaigns. This litigation has resulted in huge monetary payments by a number of companies in lawsuits brought by the Department of Justice. However, in addition to the Justice Department's right to commence litigation under FCA, individuals who are often referred to as Relators or whistleblowers can initiate an FCA action. This case is that type of case, because the Justice Department declined to intervene in, and take over, the case after the Relators filed it.

The Eleventh Circuit's ruling is the first decision by a United States Court of Appeals that a FCA action should be dismissed when, as here, the Relators are unable to present any evidence that the defendant company actually caused false claims to be submitted based on an alleged off-label marketing campaign. Many off-label FCA actions have been initiated by company sales representatives who claim first-hand knowledge about an alleged off-label sales program. However, many company sales representatives do not have first-hand knowledge about the reimbursement practices of the company, because those functions are handled by others in the company. Thus, where as here, the Relators have no knowledge that their former employer actually caused false claims to be submitted to the federal government, their alleged knowledge of an off-label marketing campaign, without more, is legally insufficient to initiate an FCA action.

In this case, the District Court dismissed the case because the Relators had not identified any specific false claims that the defendants caused to be submitted to the federal government. The Relators appealed to the Eleventh Circuit arguing that they were not required to allege specific false claims because they had alleged an off-label marketing campaign, and showed that there was a marked increase in prescriptions for Marinol and an increase in federal government payments for the drug during the period that the defendants allegedly engaged in an off-label marketing campaign. As a result, the Relators claimed that they had adequately pleaded an FCA case because they pleaded "factual allegations which reliably indicated" that false claims were submitted to the government. Opinion at 7.

The Court of Appeals correctly concluded that the Relators' Complaint did not identify even a single alleged false claim or that the Defendants intended that the government rely on any alleged false statements or records in deciding whether to pay claims that were submitted with regard to the drug. The Defendants argued (and the District Court earlier agreed) that there could not be a viable FCA action in the absence of the Relators identifying specific (alleged) false claims.

The Court relied on three earlier rulings by that same court which had dismissed FCA cases that did not involve off-label marketing allegations. The Court found that regardless of the specificity of the Relators' allegations concerning off-label activities, more is required. Here, the Court found that Relators did "not allege the existence of a single actual false claim. In fact, we are unable to discern from the complaint a specific person or entity that is alleged to have presented a

claim of any kind, let alone a false or fraudulent claim." Opinion at 12. Nor did Relators "identify a single physician who wrote a prescription with such knowledge [that the federal government would reimburse], does not identify a single pharmacist who filled such a prescription, and does not identify a single healthcare program that submitted a claim for reimbursement to the federal government." Opinion at 13. Instead, to bring an FCA case, a Relator's complaint "requires that actual presentment of a claim be plead with particularity," Opinion at 14, or that the defendants intended that their alleged false statements influenced the government's decision to pay a false claim and that the Relator presented proof that the government actually paid a false claim. Opinion at 16, 17.

It is too soon to know whether this decision will end this litigation. The Relators could ask the Court of Appeals to revisit this ruling. Alternatively, the Relators could ask the United States Supreme Court to hear the case.

The defendants are represented in this case by Jack E. Fernandez and Marcos E. Hasbun of the law firm of Zuckerman Spaeder LLP, as well as Hyman, Phelps & McNamara P.C. (John R. Fleder and Douglas B. Farquhar). The Defendants' appellate brief in the case can be found here. Also, Richard Samp of the Washington Legal Foundation submitted a brief, urging affirmance of the District Court's dismissal of the case.

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