A Bad Fit: *Qui Tam* Actions and Off-Label Use Allegations

by John R. Fleder

Many Food and Drug Administration (FDA)-regulated businesses are concerned about what some may call the corporate economic equivalent of terrorism, namely whistleblowers. These disgruntled former and current employees have a variety of legal tools to obtain redress when they believe they have been wronged.

One powerful weapon they have used is the *qui tam* provision of the federal False Claims Act (FCA).[1] An individual who brings an action in the name of the United States (a "relator") is entitled to share in any recovery obtained against a defendant who has allegedly submitted a false claim to the federal government or caused such a claim to be submitted. The United States can take over the case from the relator, or can decline to do so and allow the relator to continue the case. In rare instances the government will move to dismiss *qui tam* actions.

Any *qui tam* action filed against a company puts it in a perilous situation. The action is filed under seal, meaning that the defendant is not initially told about the action or served with the complaint. Instead, the United States Attorney where the case is filed, and the Civil Division of the Department of Justice (DOJ) in Washington are provided with copies of the case that is otherwise not known to the public. The DOJ frequently undertakes a criminal and/or civil investigation of the defendant, based on the relator's allegations. Indeed, often the first time the defendant will hear about the matter is when it is served with a government subpoena or document request, although the government will not advise the defendant of the pending case.

Given what many view is the wide breadth of the FCA, many relators have alleged in court cases that FDA-regulated companies have violated the FCA by causing false claims to be submitted to the federal government when the government was asked to reimburse for transactions based on the defendant's "off-label" marketing and promotional practices. In other words, the relator alleges that the defendant engaged in fraud by causing pharmacies and/or others to seek reimbursement under Medicare or some other federal program for a product prescribed for uses other than the FDA-approved use of the product.

A 2001 court ruling in Massachusetts has provided much of the impetus for what has been a splurge of FCA off-label use cases.[2] The court ruled that a relator had alleged the elements of an FCA action. However, that decision flies in the face of subsequently decided precedent from many courts, and is now considered to have had little or no precedential value.[3]

Over the last few years, there has been a growing trend of the courts to dismiss FCA off-label use cases on a number of grounds. In particular, the courts have concluded that the *sine qua non* of such an action is that a complaint filed by a relator must specifically identify some, if not all, of the allegedly false claims that were submitted to the government for reimbursement. Because *qui tam* actions are based on purported fraud, the relator must plead the fraud with specificity.[4]

These courts have rejected complaints even when the relator, who is often a current or former employee in the defendant's sales or marketing departments, presents detailed allegation of the purported off-label use scheme. Because such a relator had no personal involvement in the claims process, that person usually has no knowledge of how claims were submitted. Of course, that burden is made even more difficult when (as is almost always the case) claims are submitted by a third party such as a pharmacy.

United States ex rel. Rost v. Pfizer, Inc.

The relator alleged that the defendants had engaged in illegal, off-label marketing of the drug Genotropin, and thereby knowingly caused the submission of false claims to both federal and state health insurance programs.[5] The court dismissed the *qui tam* complaint because the relator failed to identify with any particularity the submission of any false claim to the Government:

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"Plaintiff's complaint fails to satisfy the strict pleading requirements of Rule 9(b). Plaintiff's complaint alleges, in great detail, the framework of Defendants' illegal marketing, promotion, and distribution of Genotropin. Plaintiff's complaint discusses bribes, kickbacks, and other financial incentives given from Defendants to various drug distributors and physicians. Plaintiff's complaint, furthermore, alleges very serious violations of federal regulations regarding the marketing, distribution, and sale of pharmaceuticals. Liability under the FCA, however, does not rest on violations of federal law or regulations. Instead, FCA liability flows solely from the existence of a false claim for payment that has been submitted to the government. To satisfy the pleading requirements of Rule 9(b), therefore, Plaintiff must identify actual false claims submitted to the government."[6]

Because the complaint merely "speculate[d] that Defendants' marketing activities must have caused physicians to prescribe Genotropin for off-label uses and that some of these prescriptions were inevitably reimbursed by federal and state government health care programs,"[7] the court ruled that "[n]o matter how likely the existence of false claims, this court cannot speculate that such claims inevitably flowed from Defendants' activities."[8]

On appeal, the First Circuit agreed that the complaint failed to satisfy Rule 9(b), concluding that the complaint:

"amply describes illegal practices in which Pfizer allegedly engaged. But those practices, while illegal, are not a sufficient basis for an FCA action because they do not involve claims for government reimbursement. As presently pled, the complaint does not sufficiently establish that false claims were submitted for government payment in a way that satisfies the particularity requirement."[9]

The First Circuit rejected the relator's argument that the "primary purpose of pleading fraud with particularity is to give notice to [a defendant] of the false claims, and that his complaint accomplishe[d]" that objective:

"The argument fails on two grounds: First, the complaint does not give notice to Pfizer of false claims submitted by others for federal reimbursement of off-label uses, only of illegal practices in promotion of the drug. Second, notice is not the only reason for the requirement of Rule 9(b). It is a serious matter to accuse a person or company of committing fraud, and the mere accusation often causes harm. Further, the rule discourages plaintiffs from filing allegations of fraud merely in the hopes of conducting embarrassing discovery and forcing settlement."[10]

The court ruled that while it may well have been true that doctors prescribed the drug for off-label uses as a result of the defendant's illegal marketing of the drug, those same doctors and their patients may never have sought reimbursement.[11]

United States ex rel. McDermott v. Genentech, Inc.

The relator alleged a scheme to market the drug Rituxan off-label to treat individuals with rheumatoid arthritis.[12] In particular, the complaint alleged that the defendants' off-label marketing campaign included training sales representatives in methods of avoiding the detection of their off-label promotional activities. Between 2000 and 2005, the defendants' annual sales of Rituxan increased from $424 million to $1.8 billion. According to the relator, such annual sales could have occurred only if a governmental medical reimbursement system reimburses claims for widespread off-label use of that drug. The complaint alleged, however, that given the:

"secret and confidential nature of the reimbursement claims the disclosure of which is prohibited by law, no one (including Defendants, the Government and Relator) knows which specific Rituxan reimbursement claims among the thousands submitted to the Government were false or fraudulent . . . and it would be impossible for anyone to identify them without formal discovery and court assistance."[13]

Nevertheless, the court dismissed the complaint pursuant to Rule 9(b).

United States ex rel. Hess v. Sanofi-Synthelabo, Inc.

The relator, a former sales representative, alleged that the defendant submitted false claims in connection with the off-label marketing of two drugs, Eloxatin and Elitek.[14] With respect to Eloxatin, the relator alleged that the defendant trained the relator and other sales representatives on Eloxatin's off-label uses, and also trained them on how to obtain Medicare reimbursement for such off-label uses. With regard to Elitek, the relator alleged the defendant trained the relator and other sales representatives on Elitek's off-label uses and encouraged off-label sales of the drug.

In connection with the claim relating to Elitek, the court concluded the relator failed to allege "the who, what, when, where and how regarding Defendant's sales representatives allegedly promoting" Elitek's off-label use.[15] Moreover, the relator did "not allege the nature or content of claims made which were allegedly fraudulent."[16] Finally, the relator failed to "allege that doctors to whom Plaintiff promoted off-label use of Elitek actually submitted false claims to the Government for off-label uses of this prescription drug. …"[17]

United States ex rel. West v. Ortho-McNeil Pharm., Inc.

The relator was a quintessential insider, a sales representative who interacted on a daily basis with Ortho-McNeil's customers, hospital employees and physicians, the very individuals whom, he contended, engaged in unlawful conduct.[18] The relator alleged the defendants caused false claims to be submitted by having Ortho-McNeil sales representatives instruct physicians that a drug should be used to treat prostatitis, a non-FDA approved use for the drug. The court held that West's allegations did not meet the heightened pleading standard set forth in Rule 9(b).

United States ex. rel. Hopper v. Solvay Pharmaceuticals, Inc.

In September 2008, a court in Tampa dismissed this *qui tam* FCA case (and also some state FCA claims) by adopting a Magistrate Judge's report and recommendation.[19] The relators, former company sales representatives, alleged that the defendants had used illegal off-label marketing practices for the drug Marinol. The court noted that the relators had conceded that they had no evidence of a false claim. As a result, the court followed three binding Eleventh Circuit decisions that held that a *qui tam* action fails to comply with Rule 9(b) unless it alleges the particular false claims that were submitted to the government. This is true, the court found, even if the relator describes in detail a defendant's alleged scheme to defraud the government, because liability under the FCA depends on the submission of a false claim, not the alleged disregard of government regulations. The court ruled that speculation that a false claim must have been submitted to the federal government was not enough to pass the Rule 9(b) mandate.

United States ex rel. Kennedy v. Aventis Pharmaceuticals, Inc.

This court *did* apply a relaxed Rule 9(b) standard to absolve relators of the requirement to identify a false claim with particularity because it found that specific facts regarding particular claims were not likely within relators' reach.[20] However, this ruling is unlikely to represent a dent in the defense armor discussed above. *Kennedy* failed to discuss a Seventh Circuit decision which ruled that an FCA complaint failed to comply with Rule 9(b) because the relators were required, but failed, to plead the particulars of an alleged false claim at an individualized transaction level demonstrating that the defendant had violated the FCA.[21]

"Original Source" Requirement

There is a second large hurdle that *qui tam* relators have to overcome. A court does not have jurisdiction over an FCA action where the allegations are based on the public disclosure of allegations from an "investigation, … unless the person bringing the action is an original source of the information."[22] A public disclosure can occur, for instance, during a government investigation, when the defendant produces documents to the government. A recent Supreme Court decision[23] sets a high bar for relators to overcome to establish that they were the original source of the *qui tam* case allegations. A relator must show that it was the original source of the allegations that result in the recovery of money in the case. Thus, even if a relator brings a matter to the government's attention through the filing of a *qui tam* case, a court will have to closely scrutinize the particular matters raised in that case and compare those allegations to the court's findings that a violation has occurred. If, for instance, a relator discloses to the government that a company has engaged in a fraud in several respects, the relator will not be deemed an original source if the court rules that the defendant engaged in a fraud only in some other respect, even if the government would have probably never investigated that other "respect" but for the relator's complaint.

1 *See* 31 U.S.C. §§ 3729-3733. Many states have their own state False Claims Acts patterned after the federal statute.
2 *See* United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39 (D. Mass. 2001).
3 *See* United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220 (1st Cir. 2004). Indeed, another judge in Boston has ruled that Parke-Davis conflicts with the First Circuit's heightened pleading requirements. United States ex rel. Rost v. Pfizer, Inc., 446 F. Supp. 2d 6, 27 (D. Mass. 2006), *aff'd*, 507 F.3d 720 (1st Cir. 2007).
4 Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake"). In United States ex rel. Radcliff v. Purdue Pharma L.P. No. 1:05CV00089, 2008 involved allegations that the defendants made misrepresentations to physicians reguarding the potency of defendants products, allegedly resulting in federal and state agencies overpaying for drugs.
5 United States ex rel. Rost v. Pfizer, Inc., 446 F. Supp. 2d 6 (D. Mass. 2006), *aff'd*, 507 F.3d 720 (1st Cir. 2007). On remand, another district court judge dismissed part of the complaint, ruling that off-label claims that were approved by a state Utilization Review Board are not false. However, the district court ruled that the relator's amended complaint did satisfy Rule 9(b) because the relator had identified more than 200 false claims that had been submitted to Medicaid and had identified very specific information about those claims. 2008 WL 4293642 (D. Mass., Sept. 18, 2008).
6 *Id.* at 27.
7 *Id.* at 27-28
8 *Id.* at 28.
9 *Rost*, 507 F.3d. at 733
10 *Id.*
11 *Id.*
12 United States ex rel. McDermott v. Genentech, Inc., No. 05-147-P-C, 2006 WL 34741920 (D. Me., Dec. 14, 2006).
13 *Id.* at *10.
14 United States ex rel. Hess v. Sanofi-Synthelabo, Inc., No. 4:05CV570(MLM), 2006 WL 1064127 (E.D. Mo., Apr. 21, 2006).
15 *Id.* at *6
16 *Id.*
17 *Id.*
18 United States ex rel. West v. Ortho-McNeil Pharm., Inc., No. 03-C-8239, 2007 WL 2091185 (N.D. Ill. July 20, 2007).
19 United States ex. rel. Hopper v. Solvay Pharmaceuticals, Inc., No. 8:04-CV-02356-T-23TGW, 2008 WL 4177927 (M.D. Fla. Sept. 8, 2008) appeal docketed, No. 08-15810 (11th Cir. Oct. 8, 2008). The author is one of the counsel of record for the defendants in that case.
20 United States ex rel. Kennedy v. Aventis Pharmaceuticals, Inc., 512 F. Supp. 2d 1158 N.D. Ill. (2007).
21 United States ex rel. Fowler v. Caremark Rx, LLC, 496 F.3d 730, 741-742 (7th Cir. 2007).
22 31 U.S.C. § 3730(e)(4)(A).
23 Rockwell Intern. Corp. v. United States, 127 S. Ct. 1397, 1410 (2007).