Recent Developments in FCA Litigation

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As the federal government continues to expand its use of the False Claims Act (FCA) to recover billions in alleged false claims, the federal courts are increasingly being asked to limit the scope and reach of the FCA through motions to dismiss under the Federal Rules of Civil Procedure. Courts have examined whether the heightened pleading requirements of Rule 9(b)[1] require complainants to identify the *specific* false claims that were presented to the government, or whether the mere allegation of underlying fraudulent activity is sufficient. The courts have also considered whether, in order for a claim to qualify as false under the FCA and survive a motion to dismiss under Rule 12(b)(6)[2], the claim must have misrepresented that it complied with a *material precondition of the payment*. Several recent cases, including a Supreme Court request for the Government's views in a pending petition for certiorari from the Fourth Circuit, have further highlighted these issues.

On October 29, 2013, the United States District Court for the Southern District of Georgia granted the Defendants' Motion to Dismiss for failing to satisfy the specificity requirements of Federal Rule of Civil Procedure 9(b) as to the Corporate Defendants, but denied the Motion to Dismiss for failure to state a claim under Rule 12(b)(6). On November 7, 2013, the United States Court of Appeals for the First Circuit heard arguments in a relator's appeal of the district court's dismissal of her *qui tam* suit under both Rules 9(b) and 12(b)(6). Tellingly, while the Government had declined to intervene in the original lawsuit, the Government filed and argued an *amicus* brief challenging the district court's 12(b)(6) dismissal. Even before these developments, however, in early October, the Supreme Court signaled that it may be preparing to take up the issue of the impact of Rule 9(b) requirements on allegations of FCA violations.

In *United States ex rel. Reid Lawson v. Aegis Therapies, et al.*, CV. 210-72, (S.D.GA.), the relator filed a *qui tam* complaint against Aegis Therapies, Inc., asserting that Aegis had submitted false claims for physical therapy services under the FCA, false claims under the Georgia statute, and false claims as part of a conspiracy under both the FCA and the Georgia statute. On January 2, 2013, the United States intervened on the first count and declined to intervene on the other two. Subsequently, the Government filed an amended complaint adding six defendants, including four claims against each defendant. The defendants moved to dismiss for failure to satisfy Rule 9(b) and failure to state a claim under Rule 12(b).

The six new defendants argued that the Complaint failed under Rule 9(b) because the Government had failed "to identify a single time, place and substance of any alleged fraud, but only generally aver[ed] that these companies either own and operate skilled nursing facilities ('SNFs') or are related to other separate companies that own and operate [SNFs]." Apparently agreeing that it had not sufficiently alleged facts against the companies "with particularity," the Government argued instead that the defendants were liable under a veil-piercing or alter-ego theory, and asked the court to decline to rule on the motion and to allow the Government to develop the relevant facts through discovery. Alternatively, the defendants requested the court to dismiss the complaint without prejudice in order to allow the Government to develop sufficient facts to support a veil-piercing theory, and then to amend the complaint accordingly.

1 Rule 9(b) stiplutes that, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."

2 Rule 12(b)(6) provides for dismissal of a claim "for failure to state a claim upon which relief can be granted."

The court found that the government had failed to plead facts with particularity as to the defendants: "Specifically, there are no allegations about how, when, and where Corporate Defendants were involved in the alleged fraudulent activity, who at the companies was involved, and what statements were made." The court similarly found that the complaint failed to allege sufficient facts to support the veil-piercing theory. While the court declined to delay ruling on the motion in order to allow the Government to obtain the benefit of discovery, it granted the Government's request for dismissal without prejudice.

The court declined to find, however, that the complaint failed to state a claim that the defendants had provided unnecessary speech therapy, concluding that the Government had presented "facts that plausibly create a claim for relief under the FCA."

On November 7, 2013, the First Circuit heard arguments in *United States ex rel. Helen Ge, M.D. v. Takeda Pharmaceutical Company, Ltd.*, Nos. 13-1088 and 13-1089. The United States District Court for the District of Massachusetts dismissed the relator's two complaints against Takeda under both Rule 9(b) and Rule 12(b)(6). The relator argued that Takeda had intentionally under-reported adverse events involving the drugs Actos, Uloric, Kapidex/ Dexilant, and Prevacid. Had Takeda properly reported these events, the complaint alleged, the FDA might have required additional warnings – which might have caused physicians to prescribe the drugs less often, resulting in fewer reimbursement claims. Alternatively, according to the complaint, the FDA might never have approved the drugs or might have withdrawn the approvals for the subject drugs.

The district court found that, "although relator has alleged facts that would demonstrate a "fraud-on-the-FDA with respect to intentional under-reporting of adverse events, she has failed to allege the specific details of any claims that were allegedly rendered 'false' as a result." Instead of providing details of the alleged false claims, the relator argued, in effect, that all of the claims were false because of Takeda's failure to report adverse events. Noting that withdrawal of drug approval is not mandatory for the type of reporting violations the relator alleged, however, the court found that she had failed to provide the specific factual allegations to support the claim that the FDA would have withdrawn the drugs if the adverse events had been reported, and, thus, failed to plead the allegations with the requisite specificity under Rule 9(b).

Because the FDA can pursue different remedies for reporting violations, of which withdrawal is only one, the court found compliance with the reporting procedures was not a material precondition for payment of the claims, and that the complaint did not state a claim for relief under Rule 12(b)(6).

The relator appealed and the Government entered as *amicus*. While the Government took no position on the district court's fact-based dismissal under Rule 9(b), it took issue directly with the district court's interpretation of the FCA and its dismissal of the case under Rule 12(b)(6). The Government argued that, where a defendant misrepresents its compliance with a legal requirement that includes authorization to deny payment, that statement is material, even if there were other alternatives to denying payment. The Government also disagreed with the district court's opinion that the failure to report adverse events could never be a basis for liability under the FCA, noting that "[a]lthough rare, there are circumstances where such failures could trigger liability under the Act."

More broadly, with respect to the alleged failure to report adverse events, the Government argued that the FCA also covers *material omissions*, and that the underlying false statement need not be made directly to the paying agency for there to be liability under the FCA.

On October 7, 2013, in another case involving Takeda on a petition for certiorari, the Supreme Court invited the Solicitor General to file a brief expressing the Government's views regarding the level of specificity required for allegations under the FCA. The relator's complaint alleged that Takeda's marketing of the drug Kapidex had caused false claims to be submitted to the Government. In *United States ex rel. Nathan v. Takeda Pharmaceuticals*, 707 F.3d 451 (4th Cir. 2013), the Fourth Circuit affirmed the district court's dismissal of the complaint for failure to state a claim with particularity under Rule 9(b). The Court of Appeals rejected the relator's argument that he needed only to allege a fraudulent scheme as the underlying basis for an FCA claim, ruling instead that he was required to allege the specific false claims that were presented to the government.

As reported, the issue before the Court and on which the Government has been invited to comment is: "Whether Rule 9(b) of the Federal Rules of Civil Procedure requires that a complaint under the False Claims Act "allege with particularity that specific false claims actually were presented to the government for payment," as required by the Fourth, Sixth, Eighth, and Eleventh Circuits, or whether it is instead sufficient to allege the "particular details of" the "scheme to submit false claims" together with sufficient indicia that false claims were submitted, as held by the First, Fifth, Seventh, and Ninth Circuits."

The Court's invitation to the Solicitor General, as well as the existence of a substantial split involving eight of the Circuits, strongly suggests that the Court will take up the question of Rule 9(b)'s role in defining the extent or limits of potential claims under the FCA. A decision on this issue will significantly impact FCA litigation in general and the healthcare industry in particular.

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