Court Limits Use of False Claims Act *Qui Tam* Suits Regarding Product Safety Issues

Relators bringing safety-based False Claims Act (FCA) *qui tam* suits continue to face skepticism from the courts. In *US ex rel. Ge v. Takeda Pharmaceutical Co.*, No. 10-11043, 2012 US Dist. LEXIS 156752 (D. Mass. Nov. 1, 2012), Judge Saylor dismissed a relator's *qui tam* complaints alleging that the pharmaceutical manufacturer's failure to submit post-marketing adverse events, as required by the Food, Drug and Cosmetic Act (FDCA), resulted in the submission of false claims for reimbursement in violation of the FCA. The court found that the relator's complaint failed to state a claim under Rule 12(b)(6) because compliance with post-marketing adverse event reporting requirements is not a material precondition to payment for drugs by government healthcare programs.

The Decision

A former medical reviewer in Takeda's pharmacovigilance division filed two *qui tam* complaints alleging that Takeda's failure to report to the FDA a number of post-marketing adverse events for four of the company's drugs resulted in the submission of false claims to government healthcare programs in violation of the FCA. According to the relator, had Takeda properly reported these adverse events, then the government would have paid for fewer prescriptions of these drugs either because doctors would have written fewer prescriptions in light of the additional safety information, or because the FDA would have withdrawn approval for the drugs. Takeda moved to dismiss the *qui tam* complaints for failure to state a claim under Rule 12(b)(6) and for failure to plead fraud with particularity under Rule 9(b).

Judge Saylor held that the relator failed to state a claim under Rule 12(b)(6) because the complaint failed adequately to allege that the claims submitted to the government for reimbursement were false or fraudulent. The relator relied on an implied certification theory arguing that claims submitted for government reimbursement contain an implied representation that the manufacturer has complied with adverse event reporting requirements. As the district court noted, the First Circuit and others have recognized the implied certification theory in other contexts (e.g., claims submitted for government reimbursement have been found to contain an implied representation that the prescription was not induced by a kickback). But in the under-reporting context, the court found that the relator did not—and could not—demonstrate that compliance with the reporting requirements was a material precondition to payment, which is the linchpin of the implied certification theory of liability. The court found materiality lacking because although regulations *permit* the FDA to withdraw drug approval, the regulations do not *require* withdrawal for under-reporting adverse events and instead provide the FDA with alternatives, such as issuing an injunctive order, imposing monetary fines, or imprisoning individual defendants. Judge Saylor also found that the relator failed to satisfy Rule 9(b)'s heightened pleading standard because, although the relator had alleged facts demonstrating the intentional under-reporting of adverse events, she failed to allege the specific details, such as date, place or amount, for any of the claims that were allegedly rendered false as a result of the under-reporting.

Conclusion

Judge Saylor's decision reinforces a recent trend among the courts not to recognize FCA *qui tam* suits premised on the concealment of safety data. Earlier this year, in *US ex rel. Simpson v. Bayer Healthcare Pharmaceuticals*, No. 08-5758, 2012 WL 5358333 (D. Minn. July 19, 2012), the court granted Bayer's motion to dismiss FCA allegations that claims for Baycol prescriptions were false because Bayer concealed risks from the government and health care providers. Holding that the relator's complaint failed to meet Rule 9(b), the court found that the relator failed to link the government's payment decision to pay Baycol claims to any alleged fraud regarding risk concealment, noting that such claims could not be false or fraudulent for patients whose cholesterol was in fact lowered. Reinforcing the view that the FCA is an inappropriate remedy for product safety issues, Judge Saylor in *Takeda* stated that the relator should have petitioned the FDA to bring action against Takeda for not properly reporting adverse events, rather than file an FCA *qui tam.*

Although recent district court decisions demonstrate the difficulty that relators face in pursuing FCA *qui tam* suits against pharmaceutical manufacturers premised on the alleged concealment of safety information, observers should take note of legal actions taken by the Department of Justice pursuant to the FCA and by state attorneys general pursuant to their state FCA statutes or consumer protection statutes against pharmaceutical manufacturers for concealing or minimizing drug safety issues. For instance, GlaxoSmithKline's (GSK) recent $3 billion dollar settlement resolved, among other misconduct, allegations that GSK had made misleading statements to health care providers about the safety profile for Avandia. And a number of state court verdicts against Johnson & Johnson resulted from findings that the company downplayed the risks of Risperdal.

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