Counsel's Advisory

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CIRCUIT COURT AFFIRMS HIGH PLEADING STANDARD FOR "INDUCED" FALSE CLAIMS *QUI TAM* ACTIONS

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In December 2013, the U.S. Court of Appeals for the First Circuit affirmed the dismissal of a closely-watched *qui tam* suit alleging that a pharmaceutical manufacturer violated the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, by misreporting adverse events the Food & Drug Administration ("FDA") relating to four of its drugs. *United States ex rel. Ge v. Takeda Pharmaceutical Co.*, 737 F.3d 116 (1st Cir. 2013). The appellate court punted on the key issue that drew so much attention to the case, declining to opine on the district court's holding that a violation of FDA's adverse-event reporting rules could never be the basis for FCA liability. The First Circuit instead resolved the case under Rule 9(b), holding that the relator failed to allege sufficiently that the manufacturer's supposed regulatory violation caused false claims to be submitted. In so holding, the First Circuit reemphasized the key principle that a *qui tam* relator who files an FCA suit on the theory that a defendant's regulatory violation caused third parties to submit false claims must plead those claims with particularity, and cannot rely on a mere inference that the violation caused them.

Relator alleged that but for the manufacturer's misreporting, FDA might have altered the approved labeling for the affected drugs or withdrawn approval altogether, and that physicians might have stopped prescribing the drugs. Relator thus claimed that the manufacturer's fraud rendered all claims for the drugs false.

The district court dismissed relator's complaint under Rule 12(b)(6), holding that compliance with FDA's adverse-event reporting rules is not a "material precondition" to federal reimbursement because FDA has discretion and exclusive authority to punish violations of those rules in multiple ways, just one of which is the withdrawal of drug approval that would lead to non-reimbursement. *United States ex rel. Ge v. Takeda Pharmaceutical Co.*, Nos. 10-11043, 11-10343, 2012 WL 5398564, *6 (D. Mass. Nov. 1, 2012). The manufacturer argued that allowing a FCA suit based on such a regulatory violation would undermine FDA's exclusive authority to enforce the adverse-event reporting rules. The district court agreed, noting that FDA's enforcement procedures enable citizens to petition the agency to bring actions against violators of its rules, and that relator should have presented her allegations through "that mechanism, rather than an FCA lawsuit." *Id*.

The United States declined to intervene in the case, but filed an *amicus* brief disputing this portion of the district court's decision and arguing that a violation of FDA's adverse-event reporting rules can, at least in some circumstances, trigger FCA liability, even though compliance with those rules is not a precondition to federal reimbursement.

The First Circuit left this issue unresolved, relying exclusively on Rule 9(b) to decide the case. Even accepting relator's allegation that the manufacturer defrauded FDA, the Court held that relator failed to adequately allege that such fraud caused health care providers to submit false claims. The court refused to infer that false claims "necessarily follow[ed]" from the fraud, and emphasized that relator was required to provide "factual or statistical evidence to strengthen the inference of fraud beyond possibility." *Id.* at 124. Relator failed to do so because she did not "identify specific entities who submitted claims . . ., much less times, amounts, and circumstances." *Id.*

The First Circuit's decision reaffirms Rule 9(b) as a significant hurdle for relators who contend that a defendant's regulatory violation caused third parties to submit false claims. In addition, although the court did not decide whether the FCA is an appropriate tool to enforce compliance with FDA's adverse-event reporting rules, it left the district court's reasoning undisturbed, creating the possibility that an appellate court may embrace that limitation on FCA liability in the future.

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