

## First Circuit Affirms Dismissal of FCA Whistleblower Suit Against Takeda Pharmaceuticals

The First Circuit recently affirmed the dismissal of *U.S. ex rel. Ge v. Takeda Pharmaceuticals*, a whistleblower suit alleging that defendant's failure to disclose certain risks relating to four drugs and to report adverse events under the Food & Drug Administration's regulations resulted in False Claims Act ("FCA") violations. The court affirmed the district court's dismissal for failure to plead with sufficient particularity under Federal Rule of Civil Procedure 9(b). The court held without reservation that Rule 9(b) requires relators to plead with specificity that false claims were actually submitted, and that pleading circumstances that allegedly give rise to the inference that false claims were filed is not enough. The court declined to address substantively or to rule on the district court's second basis for dismissal: failure to state a claim under Rule 12(b)(6). A copy of the court's decision can be found [here](#).

### Procedural History

Relator, Dr. Helen Ge, worked as a contractor for defendant Takeda, performing medical review of adverse event reports for four drugs. This appeal resulted from the dismissal of two consolidated complaints alleging that Takeda violated adverse event reporting requirements by instructing doctors to modify their findings and by failing to make public information about adverse side effects of the drugs. The district court dismissed both complaints for failure to plead fraud with particularity under Federal Rule of Civil Procedure 9(b) and for failure to state a claim under Rule 12(b)(6).

On appeal, relator challenged both of the district court's holdings with respect to FCA liability. First, she argued dismissal under Rule 9(b) was inappropriate because a *qui tam* relator alleging that a defendant caused a third party to submit a false claim need only provide factual or statistical evidence to strengthen the inference of fraud; she argued a relator need not provide detail as to the false claims that were allegedly submitted. Relator argued that she met this standard by providing aggregate expenditure data in her motion for reconsideration before the district court. Second, relator maintained that the district court erred in dismissing her claims under Rule 12(b)(6) because it improperly narrowed the FCA's materiality standard. The district court held that defendant's violations could not be material because the FDA had the discretion—but, critically, not the obligation—to remove drugs from the market for violations of reporting requirements.

### The First Circuit Affirmed on Rule 9(b) Grounds

In affirming the dismissal under Rule 9(b), the Court found that relator's twice-amended complaints failed to satisfy the heightened pleading standards for fraud. Rule 9(b) requires relators to state with particularity the "who, what, when, where, and how" of the alleged FCA violation. The court highlighted relator's failure to allege facts showing that any false *claims* were actually submitted as a result of defendant's alleged regulatory violations. The court flatly rejected relator's proposed *per se* rule that if sufficient allegations of misconduct are pled, it must follow that false claims were submitted. As the court noted, "[w]hat is missing are any supporting allegations upon which her conclusion rests and any particulars." Relator made no attempt to identify some subset of claims submitted for government payment which were false, and the court was even less convinced that *all* claims submitted for these four drugs during the relevant time period were false. Though relator attempted to add aggregate expenditure data and declarations from patients in her motion for reconsideration, the court found that the additional facts were added too late and, in any event, were still insufficient to satisfy Rule 9(b).

Relator attempted to allege three new theories on appeal, which the court deemed waived as a result of her failure to introduce the arguments at the district court level. Notably, the court expressed doubt that such theories would have survived the Rule 9(b) analysis, citing with approval the Fourth Circuit's Rule 9(b) analysis in *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*<sup>1</sup>

## The Government's Amicus Position and Future Implications of *Ge*

Though the government did not intervene in relator's FCA complaints, the U.S. Department of Justice filed an *amicus curiae* brief during the course of this appeal, challenging the district court's legal grounds for the Rule 12(b)(6) dismissal. First, the government addressed its view of the materiality standard for false statements regarding compliance with rules and regulations that are a precondition to payment. It stated that a false statement or omission (like failing to report adverse effects of a drug to the FDA) is material if, in light of the statement, the agency was *permitted* to deny payment, regardless of whether it actually did so or was required to deny payment. Second, the government asserted that the availability of alternative administrative remedies does not preclude FCA claims. Rather, the government argued, the FCA allows for multiple enforcement mechanisms that both the government and whistleblowers may use. Third, the government argued against a *per se* rule barring FCA liability for failure to comply with FDA adverse event reporting requirements, though it conceded that liability in such circumstances would be rare.

By affirming the district court on Rule 9(b) grounds alone, the First Circuit left these critical issues regarding the use of the FCA to police regulatory compliance for another day. It also left intact the line of district court cases that have held that violations of adverse event reporting requirements are *not* automatically grounds for FCA liability. We will continue to monitor developments in this evolving area of FCA jurisprudence. If you have further questions about the implications of the *Ge* decision, please consult your usual Ropes & Gray advisor or an attorney in our [False Claims Act](#) practice.

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<sup>1</sup> The relator-appellant in *Nathan* has filed a pending petition for certiorari with the United States Supreme Court to appeal the Fourth Circuit's ruling requiring relators to "allege with particularity that specific false claims actually were presented to the government for payment" where a defendant's actions "could have led, but *need not necessarily* have led, to the submission of false claims."