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ALERT

False Claims Act

September 30, 2016

First Circuit Affirms Stringent Rule 9(b) Particularity Requirement in False Claims Act Cases

Attorneys
Kirsten Mayer
John P. Bueker
Alexandra Roth

On June 17, 2016, the First Circuit issued an opinion addressing, among other things, the particularity requirement that applies in False Claims Act ("FCA") cases where the defendants are not alleged to have directly submitted false claims for payment, but rather where they are alleged to have caused a third party to submit false or fraudulent claims. In *United States ex rel. Kelly v. Novartis Pharmaceuticals Corp.*, 827 F.3d 5, 13 (1st Cir. 2016), the court provided important clarification of what is required to provide "factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim," the "more flexible" Rule 9(b) standard articulated seven years ago by the First Circuit for such cases in *U.S. ex rel Duxbury v. Ortho Biotech.* In *Kelly*, the Court emphasized that Rule 9(b) requires significant particularity in pleading – in *Duxbury*-type cases – and that complaints that don't adequately plead the nexus between the alleged fraudulent conduct and resulting false claims will be dismissed.

Background

Relators Frank Garcia and Allison Kelly jointly filed a *qui tam* complaint in 2006, alleging that defendants Novartis, Genentech, Inc. and Roche Holdings had marketed Xolair, an asthma medication, unlawfully by illegally promoting it for off-label uses, paying kickbacks to doctors, and encouraging sales representatives improperly to complete and influence the completion of Statement of Medical Necessity forms. In 2010, another relator, Stephen Fauci, filed a complaint that lodged similar allegations against Novartis and Genentech. In 2011, after the United States declined to intervene in both actions, Kelly asked to be dismissed as a relator in the pending 2006 action and that her name remain under seal. She then filed a new complaint in June 2012, which, all parties agreed, largely built upon the allegations in the 2006 complaint.

Shortly after Kelly filed her complaint in 2012, Garcia and Fauci moved to consolidate and amend their pending actions with the new action. The court did not initially rule on that motion, and in 2013 unsealed the 2012 complaint. The court later, on a motion from the United States, lifted the seal on the 2006 and 2010 complaints, on the grounds that, because the 2012 complaint was largely based on these earlier allegations, it may have been subject to the first-to-file bar.

After litigation regarding relators' requests to refile their pending motion to consolidate and amend, the district court denied the motion, and defendants then filed a motion to dismiss the 2006 and 2012 complaints. The district court granted the motion in full, holding that the complaints failed to plead fraud with particularity as required by Rule 9(b), and that amendment would be futile. The court also dismissed relators' state-law claims with prejudice.

The First Circuit's Holding

A unanimous panel of the First Circuit agreed with the district court's decision to dismiss the complaints. To reach this conclusion, however, the panel held that the district court should have dismissed the 2012 complaint under the first-to-file bar, in light of the fact that all parties agreed that both the 2012 and the earlier 2006 and 2010 actions involved the same general facts and issues. To avoid waste and delay, however, the First Circuit declined to simply remand the matter for the district court to dismiss the 2012 complaint without prejudice, and instead addressed the district court's particularity rulings as to both complaints.

With respect to 9(b), the panel squarely rejected relators' argument that the complaint sufficiently pled "factual or statistical evidence that strengthened the inference of fraud beyond mere possibility." First, the panel noted in elaborating what is required that the particular details pled in the *Duxbury* case were "barely adequate." *Kelly* at *15. This is the second time in recent years that the First Circuit has repeated and reaffirmed its statement from *Duxbury* that the details pled there set a real floor for what needs to be pled to survive a motion to dismiss. Next, the panel emphasized that here – in this FCA case based on claims resulting from alleged violations of the anti-kickback statute – it was not enough to identify doctors, enrolled in federal health care programs, who received incentives from the defendant, and prescribed the product at issue. Relators must also "tie these independently unexceptional allegations together into particular charges about specific fraudulent claims for payment." *Id.* at *15. Finally – in case it wasn't already clear enough – the First Circuit specifically noted that, while "it may not be irrational to infer that given [the allegations,] some false claims for [the drug's] reimbursement were submitted to the government" that is not enough to satisfy Rule 9(b). *Id*. Under this standard, the First Circuit held that the relators' 2012 pleadings were not sufficient to survive a motion to dismiss.

Implications of the Court's Decision

The First Circuit's rejection of the *Kelly* relators' attempt to establish a weaker Rule 9(b) particularity requirement is notable. In particular, the requirement that the nexus between the allegedly fraudulent conduct and resulting false claims for payment be pled with specificity shows that the First Circuit is committed to retaining Rule 9(b) as an important screen for FCA complaints.

If you have any questions or would like to discuss the foregoing or any related matter, please contact the Ropes & Gray attorney with whom you regularly work, or an attorney in our False Claims Act practice.