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First Circuit Affirms Dismissal of FCA Off-Label Marketing Case for Failure to Meet 9(b) Particularity Requirement

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In *Lawton v. Takeda Pharmaceutical Co. et al.*, 842 F.3d 125 (1st Cir. 2016), the First Circuit affirmed the lower court's dismissal of a False Claims Act ("FCA") suit alleging a drug maker fraudulently marketed a product for off-label uses. The decision focused on the application of Federal Rule of Civil Procedure 9(b) in FCA cases, explaining that a relator is required to plead with particularity both the alleged false or fraudulent statements *and* their connection to the allegedly induced false claims. Here the relator alleged the defendants violated the FCA by fraudulently marketing a drug for various off-label uses. The Court held that even if the relator met his burden with respect to the specifics of the fraudulent activities, he had failed to plead the resulting false claims with the particularity required under Rule 9(b).

Background

The relator alleged that defendants Takeda Pharmaceutical Co. (a Japanese pharmaceutical company "Takeda") and Eli Lilly and Co. (a U.S. pharmaceutical company, "Eli Lilly") violated the FCA by conspiring to engage in fraudulent marketing of the drug Actos. Actos is approved by the FDA to treat Type 2 diabetes in certain types of cases. The relator, Peter Lawson, was a patent litigator at Takeda competitor GlaxoSmithKline plc and claimed he had learned certain inside information through his work in the industry, including job interviews at Takeda.

The relator offered certain details around the alleged campaign to promote Actos for off-label uses. He alleged that since the late 1990s the defendants had developed and promoted "quasi-scientific" support for using Actos off-label, including for treatment of prediabetes. Prediabetes is a condition of abnormally high blood sugar, but not high enough to qualify as type 2 diabetes. According to the relator, the defendants funded research studies advocating the use of Actos as a treatment for prediabetes. The realtor alleged that the defendants provided various inducements to study authors and others for promoting Actos, and funded continuing medical education presentations touting Actos for treating prediabetes. In conjunction with these efforts, the relator further alleged, the defendants also developed a sales force to encourage physicians to prescribe Actos for prediabetes, and directly marketed the drug to the public for the same off-label use. As a result of these efforts, the relator claimed, Takeda and Eli Lilly caused the submission of false claims.

The defendants moved to dismiss the relator's claims on multiple grounds, including failure to plead fraud with particularity under Rule 9(b). While the relator had pointed to Actos sales (which more than doubled between 2006 and 2011), records for three non-diabetic patients, and evidence that government programs paid for more than half of Actos purchases, the defendants argued that these allegations did not satisfy Rule 9(b). The district court agreed and dismissed with prejudice.

The First Circuit's Decision

The First Circuit affirmed, holding that the relator failed to plead the submission of a false claim with particularity. The Court walked through the application of Rule 9(b) in several prior FCA cases to explain why the rule barred this case. In an FCA case, Rule 9(b) requires that *both* the circumstances of the alleged fraud and the resulting claims themselves be alleged with particularity, the First Circuit explained. While the claims may be evaluated under a more flexible Rule 9(b) standard in cases such as this one where a third party is alleged to have submitted the claims, a relator still must plead some specific details as to the claims submitted. There is no defined checklist; however, the

First Circuit referenced several key holdings, including *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13 (1st Cir. 2009) and *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004), to provide examples of information concerning the claims submitted that would be sufficient to satisfy Rule 9(b). Such information may include details about the providers submitting the claims, the date, time and amounts of the claims, the federal programs to which the claims were submitted, and specifics of the bills or identification numbers for the false claims submitted.

In comparison, the First Circuit explained, it had "little trouble concluding that [the relator's] allegations do not satisfy Rule 9(b)." Here, the relator failed to identify a provider, a location, or a number of claims, offering only the vague contention that "as much as" 30% of the claims were false. While this may suggest the possibility of fraud, the First Circuit found that such statistical evidence was not sufficient to plead the submission of false or fraudulent claims with the particularity required by Rule 9(b). The relator's state claims were properly dismissed on the same grounds.

Implications of the Decision

The First Circuit's decision reinforces the potential of Rule 9(b) to bar claims that fail to plead the false claims with particularity. As is often repeated, the submission of a false claim is the *sine qua non* of an FCA case. Even if a relator provides significant detail as to the alleged fraudulent scheme, Rule 9(b) will still bar claims where the same relator fails to adequately plead the submission of the false claims that resulted. Additionally, viewed in combination with the Court's recent holding in *United States ex rel. Kelly v. Novartis Pharmaceuticals Corp.*, 827 F.3d 5 (1st Cir. 2016), it appears the First Circuit remains committed to Rule 9(b) serving as a meaningful screen for FCA complaints.

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