CASE NO. 08-1409

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

UNITED STATES OF AMERICA *ex rel.* MARK E. DUXBURY and DEAN MCCLELLAN, *Plaintiffs-Appellants*,

v.

ORTHO BIOTECH PRODUCTS, LP, *Defendant-Appellee*

APPEAL FROM THE UNITED STATES DISTRICT COURT,
DISTRICT OF MASSACHUSETTS
Case no. 03-12189-RWZ
HONORABLE RYA W. ZOBEL

BRIEF *AMICUS CURIAE* OF TAXPAYERS AGAINST FRAUD EDUCATION FUND IN SUPPORT OF APPELLANT AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Taxpayers Against Fraud Education Fund states that it is a corporation organized under § 501(c)(3) of the Internal Revenue Code. It has no parent corporation and no stock owned by a publicly owned company. TAFEF represents no parties in this matter and has no pecuniary interest in its outcome. However, TAFEF has an institutional interest in the effectiveness and correct interpretation of the Medicare Act and the federal False Claims Act.

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

Taxpayers Against Fraud Education Fund is a nonprofit public interest organization dedicated to combating fraud against the Federal Government through the promotion of the *qui tam* provisions of the False Claims Act. It has a profound interest in ensuring that the Act is appropriately utilized. The issue here is the correct application of Federal Rule of Civil Procedure 9(b) to False Claims Act *qui tam* suits. The decision below gravely undermines the efficacy of the Act in policing fraud on the federal government, because it derails meritorious suits by incorrectly demanding evidentiary proof of actual claims at the pleading stage of litigation.

STATEMENT OF THE ISSUE

Whether the district court erred in dismissing the relator's False Claims Act *qui tam* suit against a pharmaceutical company on the grounds that the relator did not possess actual claims evidence at the pleading stage of litigation.

ARGUMENT

I. THE DISTRICT COURT ERRED WHEN IT HELD THAT FEDERAL RULE OF CIVIL PROCEDURE 9(B) REQUIRES FALSE CLAIMS ACT RELATORS TO IDENTIFY PARTICULAR FALSE CLAIMS

The False Claims Act is subject to the pleadings requirements of Federal Rule of Civil Procedure 9(b), which states that "the circumstances constituting fraud . . . shall be stated with particularity." *See e.g., U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 (1st Cir. 2007); *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 227-228 (1st Cir. 2004); *U.S. ex rel. Walsh v. Eastman Kodak Corp.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000). However, Rule 9(b) does not require that plaintiffs identify actual false claims at the pleading stage of litigation in order to maintain actions under the False Claims Act.

This Court seemingly recognized that fact when it decided *Karvelas*, which relied heavily on the Eleventh Circuit's rationale in *U.S. ex rel. Clausen v. Laboratory Corp. of Am., Inc.*, 290 F.3d 1301 (11th Cir. 2002). In *Clausen*, the Eleventh Circuit did not hold that plaintiffs must identify specific false claims in order to satisfy Rule 9(b). Rather, as

was referenced in *Karvelas*, the Eleventh Circuit held that in order to satisfy Rule 9(b), "some indicia of reliability must be given in the complaint to support the allegation of an actual false claim for payment being made to the Government." *Klausen*, 360 F.3d at 234, *quoting Clausen*, 290 F.3d at 1311 (emphasis omitted). Moreover, the Eleventh Circuit's reasoning is in accord with that of the United States government attorneys who prosecute actions under the False Claims Act. In fact, the United States Solicitor General, in a brief to the U.S. Supreme Court, stated that "[i]n the view of the United States, it is possible for a relator (or the government) in a FCA action to describe the alleged fraudulent scheme with sufficient specificity to satisfy Rule 9(b)'s particularity requirement even without identifying specific false claims. That is particularly so in light of the flexibility provided by Rule 11(b)(3), which allows pleadings based on evidence reasonably anticipated after further investigation or discovery." Brief for the United States, *Rockwell Int'l Corp. v. United States*, No. 05-1272, 2006 WL 3381295 *28 (U.S. Nov. 20, 2006) (internal citations omitted).

Here, the U.S. District Court for the District of Massachusetts failed to consider whether the complaint at issue included any "indicia of reliability" that would support the relators' allegation that false claims were submitted to the Government. Instead, the district court dismissed the relators' complaint, in part, because it "fail[ed] to identify a single false claim." *U.S. ex rel. Duxbury v. Orth Biotec Prods., L.P.*, 551 F. Supp. 2d 100, 115 (D. Mass. 2008). In support of its disposition, the court stated that "this is

precisely the point of requiring relators to identify particular claims, for under *Karvelas* and *Rost* the court is not permitted to surmise that false claims 'must have' occurred as a result of defendant's conduct." *Id.* at 116. Moreover, contrary to the district court's implication, neither *Karvelas* nor *Rost* requires relators to identify particular claims in their FCA complaints. As this Court articulated in *Rost*, "*Karvelas* recognized that Rule 9(b) may be satisfied where, although some questions remain unanswered, the complaint as a while is sufficiently particular to pass muster under the FCA." *Rost*, 507 F.3d 720, 732 (referencing *Karvelas*, 360 F.3d at 233 n.17). Thus, the district court's holding that Rule 9(b) required the complaint at issue to identify particular false claims was erroneous, and overstates this Court's rulings in *Karvelas* and *Rost*. Consequently, this action should be remanded to the district court and the district court's January 28, 2008 Order should be vacated.

In addition, it does not appear that the district court applied the appropriate standard when dismissing the relators' complaint. The U.S. Supreme Court has repeatedly stressed that, when a court is assessing the sufficiency of a complaint at the pleading stage, the pleadings may be "based on evidence reasonably anticipated after further investigation or discovery." *Rotella* v. *Wood*, 528 U.S. 549, 560 (2000). In turn, when deciding whether to dismiss a complaint, the district court should resolve all reasonable inferences in favor of the plaintiff. *See, e.g.*, *Cook v. Gates*, 528 F.3d 42, 48 (1st Cir. 2008) ("We review a district court's grant of a motion to dismiss *de novo*,

accepting the complaint's well-pleaded facts as true and indulging all reasonable inferences in the plaintiff's favor."); *Wholey v. Tyrell*, No. 07-11927, 2008 WL 2879668, at *3 (D. Mass. July 28, 2008); *Talentburst, Inc. v. Collabera, Inc.*, No. 08-10940, 2008 WL 2854496, at *5 (D. Mass. July 25, 2008). For instance, in *U.S. ex rel. Franklin v. Parke-Davis, Division of Warner-Lambert Co.*, 147 F. Supp. 2d 39 (D. Mass. 2001), the district court denied the defendant's motion to dismiss a complaint alleging a scheme of off-label marketing and Medicaid fraud, even though the relator did not identify any specific false claims. The court did not speculate as to whether or not false claims were actually submitted, but still held that the relator's complaint could be maintained, because "when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud." *Franklin*, 147 F. Supp. 2d at 52-53. It does not appear that the district court engaged in a similar analysis in this case. If, in this case, after conducting a *de novo* review of the district court's decision, the Court determines that the district court did not properly draw all reasonable inferences in favor of the relators, then the district court's January 28, 2008 Order should be vacated.

II. THE DISTRICT COURT ERRED WHEN IT FAILED TO CONSIDER WHETHER A RELAXED PLEADING STANDARD UNDER FEDERAL RULE OF CIVIL PROCEDURE 9(B) SHOULD APPLY

In some circumstances, a strict application of Rule 9(b) should not apply, in favor of a more relaxed standard. The district court, relying on well-settled law in jurisdictions around the country, has observed that it is sometimes appropriate to relax Rule 9(b)'s pleading standard, since "an alleged scheme of fraud may involve numerous transactions that occur over a long period of time, and pleading the precise specifics with regard to every instance of fraudulent conduct may be impractical." *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d 164, 172 (D. Mass. 2007). Due to the volume of false claims alleged in *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, the district court relaxed the Rule 9(b) standard and held that Rule 9(b) would be satisfied as long as "the complaint alleges the basic framework, procedures, and the nature of fraudulent scheme." Yet, it appears that the district court failed to consider its earlier holding in *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, since it apparently did not even investigate whether or not the Rule 9(b) pleading standard should be relaxed in this case, even though the relators alleged a fraud "scheme to give kickbacks to providers and hospitals to induce them to prescribe Procrit" and the court was aware that the "[r]elators allege that the kickbacks caused providers and hospitals to submit false claims for payment to Medicare. They claim that the time period of the false claims is from 'December 1992 to the present.'" 551 F. Supp. 2d 100, 104. The district

court's failure to even consider whether the Rule 9(b) pleading standard should have been relaxed was reversible error and consequently, the district court's January 28, 2008 Order should be vacated.

Furthermore, the district court seemingly failed to consider its reasoning in a different opinion, in the *In re Pharmaceutical Indus. Average Wholesale Price Litig.* matter, in which it opined that, pursuant to First Circuit jurisprudence, the pleading standard under Rule 9(b) largely depends on whether or not the defendant is alleged to have submitted false claims to the Government or whether the defendant caused some third party to do so. The district court recently stated that

> The First Circuit has recognized that the specific requirements to satisfy 9(b) will depend on the circumstances of the case. In *Karvelas*, which involved a defendant who submitted claims directly to government programs, the First Circuit held that a relator 'must provide details that identify particular false claims for payment that were submitted to the government.' However, in *Rost*, where the alleged false claims were submitted not by the defendant, but by a third party instead, the First Circuit explained that the relator need not allege details of particular claims, so long as 'the complaint as a whole is sufficiently particular to pass muster under the FCA.

In re Pharmaceutical Indus. Average Wholesale Price Litig., 538 F. Supp. 2d 367, 390 (D. Mass. 2008) (internal citations omitted). As noted above, the relators in the present case alleged that "the kickbacks caused providers and hospitals" – not the defendant – "to submit false claims for payment to Medicare," yet the district court did not undertake an

inquiry into whether or not the pleading standard should be relaxed, such that the relators did not need to allege details of specific false claims. This failure by the district court also constitutes reversible error and, as a result, the district court's January 28, 2008 Order should be vacated.

Finally, the district court acknowledged that the relators in this case argued that they could not "identify all the false claims submitted to the government because the claims 'were submitted by Providers with most of whom Relator has had no dealings, and the records of the false claims are not within Relator's control." 551 F. Supp. 2d 100, 116. Notwithstanding that fact, the district court failed to consider whether or not it was appropriate to relax the pleading standard in this case, in contravention of its decision in the *Franklin* case discussed above. In *Franklin*, the district court recognized that "while a Relator must allege the circumstances of the fraud, he is not required to plead all of the evidence or facts supporting it. In addition, strict application of requirements of Rule 9(b) may be relaxed in certain circumstances. For instance, where facts underlying the fraud are 'peculiarly within defendants' control,' a plaintiff may be excused from pleading the circumstances of the fraud with a high degree of precision." *Franklin*, 147 F. Supp. 2d at 47-48 (citing *Boston & Me. Corp. v. Hampton*, 987 F.2d 855, 866 (1st Cir. 1993)). Certainly here, where the relators have alleged that the facts underlying the alleged fraud are within the control of third parties, it was necessary for the district court to conduct an inquiry into whether or not Rule 9(b) should be strictly applied. There is

no evidence to suggest that the district court engaged in such an inquiry. If the district court failed to do so, then its failure should be deemed reversible error and its January 28, 2008 Order should be vacated.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be vacated and remanded to the district court.

Respectfully submitted,

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August 11, 2008

CERTIFICATE OF COMPLIANCE

In accord with Fed. R. App. P. 32(a)(7)(C), the undersigned certifies that this brief complies with the type-volume limitation set forth in the Rule. Excluding the portions exempted by Rule 32(a)(7)(B)(iii), the brief contains 2,011 words as reported by the word count function of Microsoft Word. The brief was prepared in Microsoft Word in Times New Roman font, 14-point type for both text and footnotes.

August 11, 2008

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CERTIFICATE OF SERVICE

I hereby certify that copies of this Brief *Amicus Curiae* of Taxpayers Against Fraud Education Fund were served by first-class mail, postage prepaid this 11th day of August, 2008, upon:

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The Brief *Amicus Curiae* of Taxpayers Against Fraud was filed with the clerk on August 11, 2008, pursuant to Fed. R. App. P. 25(a)(2)(B) by first-class United States Mail.

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