First Circuit's Oral Argument in *Rost* Revisits Prior Case Law Expanding False Claims Act Liability

On May 8, 2012, the United States Court of Appeals for the First Circuit heard oral arguments in *United States ex rel. Rost v. Pfizer, Inc.* (10-2215). The central issues in the case are (1) whether compliance with the federal Anti-Kickback Statute constitutes a precondition of payment for certain government benefits (in this case, Medicaid reimbursement), (2) whether the claims presented to the government falsely represented compliance with a precondition of payment, (3) whether the alleged kickback was material to the government's decision to pay, and (4) whether the party who allegedly offered the kickback had the requisite knowledge that a resulting claim would be rendered ineligible for payment. This marks the Court's first opportunity to revisit two prior decisions that expanded the scope of False Claims Act ("FCA") liability and created a split among the circuits: *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377 (1st Cir. 2011) and *New York v. Amgen, Inc.*, 652 F.3d 103 (1st Cir. 2011). It also marks the first time that the Court will address *at the summary judgment stage* the issues raised in those two cases.

In *Rost*, a relator sued Pharmacia Corp. (later acquired by Pfizer), alleging that it illegally gave kickbacks to physicians with respect to a drug called Genotropin in violation of the Anti-Kickback Statute ("AKS"). The relator claimed that these physicians prescribed Genotropin to patients and the pharmacies who filled these prescriptions later submitted Medicaid reimbursement claims, thereby violating the False Claims Act. Applying the analytic framework that was in wide use before the First Circuit's decisions last year, the district court granted the defendant's motion for summary judgment. The relator appealed.

Both the relator and the government (as amicus) argued that summary judgment was inappropriate based on a relatively straightforward application of *Hutcheson* and *Amgen*, the former of which held that FCA liability could exist even though the actual claim in question was submitted by an innocent third-party. The defendants, however, countered that *Hutcheson* and *Amgen* were distinguishable because the relator had not come forward with evidence that the pharmacies that actually submitted the Medicaid claims had represented, in provider agreements or otherwise, that the underlying transaction complied with the AKS. As a result, the relator failed to raise a genuine question whether the pharmacies made false representations in submitting their claims.

Argument Focuses on Procedural Posture of *Rost*

During oral argument, both the Court and the attorneys highlighted the important differences between summary judgment and a motion to dismiss. Pharmacia emphasized that, unlike in *Hutcheson* and *Amgen*, *Rost* was decided at the summary judgment stage with a fully developed factual record, instead of accepting as true allegations in the relator's complaint. The panel commented on this distinction and questioned what implications the different procedural posture might have with respect to the FCA's knowledge requirement. In particular, the panel asked what evidence there was indicating that Pharmacia knew that the purported "kickbacks" it provided pharmacists, such as paying for physicians' attendance at conferences or to participate in research studies, rose to such a level that they would constitute kickbacks that would taint the Medicaid claims and render them ineligible for payment. The panel described this as "the real question coming from *Hutcheson*."

Panel Identifies Questions Left Unanswered in *Hutcheson* and *Amgen*

Pharmacia argued that, because the relator submitted no evidence regarding the pharmacies that allegedly submitted Medicaid claims or the representations they made in the claims they submitted, there was no evidence of a false claim. Pharmacia argued that in *Hutcheson* the plaintiff's claims survived only because

plaintiff alleged that provider agreements were in place specifically acknowledging that AKS violations would preclude reimbursement, which gave rise to an implied representation that a transaction for which reimbursement was sought was not tainted by any kickback. Pharmacia further noted that in *Amgen*, likewise, state law required the providers who submitted their claims to represent that they complied with the law. Because there was no such evidence here, Pharmacia contended, the relator's claims failed.

The panel's questions at argument suggested, however, that the court was uncertain whether those features of *Hutcheson* and *Amgen*, which made those cases "easier" to decide, were essential to making out a claim under the FCA. The panel's questions indicated that it did not regard First Circuit precedent as settling the question whether anything more was needed to establish falsity when the claim at issue was tainted by an AKS violation.

Panel Probes Whether Plaintiff Must Show that Prescriptions were Medically Improper

During oral argument, the panel pressed counsel on whether, in order to establish a false claim, it was necessary to prove that, even if the prescribing physicians received kickbacks, the prescription was not medically appropriate to treat the patients to whom it was given. The panel's question advanced with respect to the falsity element of the FCA its earlier reference to the "embedded" question of materiality, which required an inquiry into whether the alleged kickback was "material" to the presented claim for payment.

Relator's counsel argued that a case-by-case analysis was unnecessary because the payment of any kickback categorically violates the AKS.

Defendant Argues Alternative Grounds Exist

Pharmacia offered additional grounds for affirmance that would allow the First Circuit to side-step some of these thornier doctrinal issues. While the district court did not fully address the issue, Pharmacia argued on appeal that the Court could find that none of Pharmacia's allegedly unlawful conduct actually amounted to a kickback. Pharmacia also argued that there was insufficient evidence that its supposed kickbacks actually caused any increase in the number of Genotropin prescriptions written, another issue the district court did not address.

We will continue to monitor this case and its potential impact on our clients, and report on the First Circuit's decision. If you would like further information, please contact the Ropes & Gray attorney who usually advises you.