

## E-ALERT | Litigation

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### ROST DECISION LIMITS FALSE CLAIMS ACT LIABILITY FOR CLAIMS SUBMITTED BY THIRD PARTIES

A recent decision in the U.S. District Court for the District of Massachusetts limits the ability of the government and relators to establish a violation of the False Claims Act (“FCA”) based on kickback allegations. It also potentially limits liability in other FCA cases where the Defendant is not the party that submitted claims for payment to the government. In *United States ex rel. Rost v. Pfizer, Inc.*, No. 03, 11084-PBS (Sept. 14, 2010), Judge Patti B. Saris granted summary judgment for Pfizer and Pharmacia Corporation because, even if the relator could establish a violation of the Anti-Kickback Statute (“AKS”), he had failed as a matter of law to prove that claims submitted to the government were rendered false by the alleged kickbacks.<sup>1</sup>

This decision has important implications for pharmaceutical companies and other health care providers. The allegations in *Rost* are similar to those found in many FCA cases involving pharmaceutical companies. *Rost* alleged that Pharmacia had provided kickbacks to physicians who prescribed Genotropin (a Pharmacia product) in violation of the AKS by providing paid trips to medical conferences and by paying for data entry in a clinical study. *Rost* further alleged that these “kickbacks” caused physicians to prescribe Genotropin, and that pharmacies submitted claims for reimbursement for many of those prescriptions to state Medicaid agencies. Based on these allegations, *Rost* asserted that Pharmacia had violated the FCA.

A defendant is liable under the FCA if it “causes” the submission of a false claim. As Judge Saris recognized, a claim can either be factually false or legally false. A claim is factually false if, for example, it misstates the services provided or requests reimbursement for a service that was never provided. A claim is legally false if the claimant falsely certifies its compliance with applicable statutes and regulations. False certifications come in two forms: express and implied. An express certification occurs when the claim is accompanied by an explicit statement of compliance—for example, when the claim form has language stating: “By signing this form, I certify that I have complied with all applicable laws and regulations.” In contrast, an implied certification contains no such statement; instead, compliance with applicable laws and regulations is implied by the courts based solely on the fact that the claimant submitted a claim for payment.

*Rost* based his case on the implied certification theory. He could not establish that any claim was factually false because he had no evidence that any pharmacy ever submitted a claim with false information. Nor could he rely on an express certification theory. As Judge Saris held, “there is no evidence of any false express certification of compliance with the AKS either by the pharmacies or the prescribing physicians . . . .” Slip op. 21. Instead, he argued that the claims were legally false under the implied certification theory because, in submitting the claims, the pharmacies had impliedly certified that Pharmacia and the prescribing physicians had not violated the AKS. Although the government had declined to intervene in the case, it filed a Statement of Interest in which it agreed with *Rost*’s view of the implied certification theory.

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<sup>1</sup> As a result of this holding, the Court did not need to determine whether any of the conduct complained of by *Rost* violated the AKS. The Court did note, though, that two of the challenged programs did not “function[] as illegal kickbacks.” Slip. op. 24-25 & n.5.

The district court described the implied false certification theory as “an evolving area of the law.” *Id.* at 17. It noted that the “Supreme Court has long held that a person may be liable under the FCA for causing an innocent third party to submit a false claim to the government without knowing it is false.” *Id.* at 19. But the law also makes clear that a “claim cannot be false merely because the activity underlying the claim was illegal, [it] is the false certification of compliance which creates liability.” *Id.* at 20 (quotation marks omitted). In light of these principles, the court considered it a “difficult legal question” whether the FCA is violated when an innocent pharmacy submits a claim for reimbursement for a prescription written by a physician who had violated the AKS. *Id.* at 19.

The government argued “that when you bill Medicaid you are impliedly certifying that no kickbacks have been paid in any of the underlying transactions.” *Id.* at 22. But, as the court acknowledged, “there are no statutes, regulations, or express certifications by pharmacies cited to supported this argument.” *Id.* Accordingly, consistent with two other recent district court decisions, the court concluded that “the pharmacies that submitted the claims implicitly certified compliance with applicable statutes and regulations only with respect to themselves and those persons they control (e.g. employees).” *Id.* (emphasis added).

According to the district court, “the implied certification theory should be applied with caution only in limited circumstances.” *Id.* at 24. The court explained:

Neither the government nor the parties have cited any cases that have stretched the implied certification theory to reach back to impose FCA liability on a payer of kickbacks where the person who submitted the claim was innocent of wrongdoing and where (a) the claim itself was not factually false, (b) the claim was not legally false due to an express certification of compliance with the AKS or (c) compliance with the federal statute was not an expressly stated precondition of payment.

*Id.* Thus, the court held that Rost’s “implied certification theory fails as a matter of law.” *Id.*

Covington & Burling LLP represented Pfizer and Pharmacia in the litigation. The Covington litigation team included partners Ethan Posner and Benjamin Razi and associates Mark Mosier, Kelly Vanderzell, and Michael Maya. All are based in the firm’s Washington, DC office.

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