Fourth Circuit Affirms Dismissal of False Claims Act Suit Against Pharmaceutical Company, Rejects Theory of Liability Premised Solely on Alleged Regulatory Violations

Last week, the United States Court of Appeals for the Fourth Circuit issued its opinion in *United States ex rel. Rostholder, et al. v. Omnicare, Inc., et al.* (No. 12-2431), affirming the district court's dismissal of the relator's False Claims Act ("FCA") suit. The relator had alleged that certain pharmaceutical drug repackaging operations at an Omnicare, Inc. subsidiary violated Food and Drug Administration ("FDA") regulations, thereby rendering Medicare and Medicaid reimbursement requests fraudulent under the FCA. The Fourth Circuit soundly rejected this broad theory of liability, emphasizing that the FCA is not "a sweeping mechanism to promote regulatory compliance" but instead a statutory regime "aimed at protecting the financial resources of the government from the consequences of fraudulent conduct." The Fourth Circuit's opinion confirms that regulatory violations do not, in and of themselves, render requests for payment fraudulent under the FCA.

Facts and Procedural History

Relator Barry Rostholder worked at an Omnicare subsidiary's facility that housed both a pharmacy and pharmaceutical drug repackaging operations. Rostholder oversaw repackaging quality to ensure compliance with FDA Current Good Manufacturing Practice regulations ("cGMPs"). Rostholder grew concerned about perceived deficiencies with respect to the processing of penicillin, so he resigned and notified the FDA about his concerns. The FDA inspected the facilities and eventually issued a warning letter to Omnicare, stating that its failure to adhere to cGMP caused the drugs to become "adulterated."

In May 2007, Rostholder filed a *qui tam* action under the FCA. He alleged that Omnicare's drugs were ineligible for reimbursement under government programs because they had been manufactured under conditions that violated cGMP, and therefore that Medicare and Medicaid reimbursement requests for those drugs were false or fraudulent under the FCA. Omnicare moved to dismiss relator's complaint on several grounds. The district court granted Omnicare's motion, concluding that relator failed to allege that Omnicare had made a false statement to the government or engaged in fraudulent conduct. The district court also denied relator leave to amend his complaint for a third time. Relator then appealed to the Fourth Circuit.

The Fourth Circuit's Opinion

The unanimous Fourth Circuit panel affirmed the district court's dismissal. The arguments on appeal centered on whether a violation of cGMP requirements renders a claim for payment false or fraudulent.

Relator asserted that Omnicare's failure to comply with cGMP rendered the drugs ineligible for reimbursement under Medicare and Medicaid, and any reimbursement requests that Omnicare submitted to the government for the drugs were therefore false and fraudulent. The Fourth Circuit disagreed. While the FDA approval process for new drugs requires an applicant to describe controls for processing and packaging, the Medicare and Medicaid statutes do not require compliance with the cGMPs, or any other FDA regulations, as a precondition to payment. Said otherwise, nothing in the Medicare or Medicaid statutes prevents the U.S. government from paying for an already approved drug that has been produced or packaged in violation of FDA regulations. While "the correction of regulatory problems is a worthy goal," the court emphasized that such a theory is "not actionable under the FCA in the absence of *actual fraudulent conduct*."

Based on this reasoning, the Fourth Circuit further explained that relator also did not adequately plead the knowledge element of a valid FCA claim: "Because the Medicare and Medicaid statutes do not prohibit reimbursement for drugs packaged in violation of the cGMPs, Omnicare could not have *knowingly* submitted a false claim for such drugs." The court thus concluded that the district court's dismissal under Federal Rule of Civil Procedure 12(b)(6) was appropriate. The court additionally held that the district court did not abuse its discretion in denying relator leave to amend his complaint, thereby affirming the judgment of the district court in full.

Significance of the Court's Decision

The Fourth Circuit's opinion advances a clear interpretation of the FCA. Contrary to relator's assertion, the court reaffirmed that "Congress did not intend that the FCA be used as a regulatory-compliance mechanism in the absence of a false statement or fraudulent conduct directed at the federal government." Instead, agencies like the FDA can and do ensure compliance with regulations like the cGMPs.

The Fourth Circuit's opinion nips in the bud an effort to expand the reach of the FCA. This case represents a victory for life sciences companies facing novel attacks by increasingly aggressive relators, as the Fourth Circuit's reasoning points to the preconditions of payment outlined in the Medicare and Medicaid statutes to assess the reach of the FCA. But the opinion's effects may be even broader. In other regulated industries, future FCA claims should also continue to turn on a close examination of the preconditions of payment under governing law, not the overall regulatory landscape.

Ropes & Gray will continue to monitor developments in this area. 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 any other attorney in our false claims act practice.