KAYE | SCHOLER

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Litigation Alert

Fourth Circuit Finds Violations of FDA Safety Regulations Do Not Support False Claims Act Liability

Relators bringing False Claims Act (FCA) *qui tam* suits based on FDA regulatory violations concerning product safety continue to face skepticism from the courts. In *U.S. ex rel. Rostholder v. Omnicare, Inc.*, No. 12-2431, 2014 WL 661351 (4th Cir. Feb. 21, 2014), the Fourth Circuit affirmed the dismissal of relator's *qui tam* complaint alleging that the defendant repackager of drugs failed to comply with FDA regulations requiring separate facilities for packaging penicillin and non-penicillin drugs. Relator claimed that this regulatory breach resulted in the submission of false claims for reimbursement in violation of the FCA because the improperly repackaged drugs were not eligible for reimbursement. The court disagreed, holding that the relator failed to state a claim because the Medicare and Medicaid reimbursement statutes did not require compliance with the packaging regulations "or any other FDA safety regulations" as a precondition for reimbursement by the government. In dismissing, the Fourth Circuit cautioned against the FCA's broad use as a "regulatory-compliance mechanism" in light of FDA's own "significant remedial powers."

The Decision

Relator was a licensed pharmacist and former quality-assurance employee at a non-penicillin drug-repackaging company owned by defendant Omnicare. The repackaging company shared a building with another Omnicare-owned company that processed penicillin. Relator resigned over concerns that the non-penicillin repackaging company failed to comply with FDA regulations embodied in the Current Good Manufacturing Processes (CGMPs), requiring that penicillin and non-penicillin drugs be packaged in complete isolation from each other. Relator

then notified FDA, which was told by defendant's employees that penicillin was not being repackaged. FDA subsequently learned that was not true, and issued a warning letter charging defendant with violating CGMPs and causing drugs to be "adulterated."

Relator filed an FCA *qui tam* action in the District of Maryland alleging that Omnicare's regulatory noncompliance caused its repackaged drugs to be presumptively unsafe, and therefore ineligible for reimbursement by Medicare and Medicaid. Consequently, any claim for reimbursement for these drugs under government programs was false or fraudulent within the meaning of the FCA according to the relator. The government declined to intervene in relator's case. The district court dismissed, holding that relator failed to allege that Omnicare made a false statement to the government or engaged in fraudulent conduct.

The Fourth Circuit affirmed, holding that relator's allegations of regulatory violations failed to support FCA liability because the Medicare and Medicaid reimbursement statutes did not require compliance with the CGMPs, and therefore Omnicare's reimbursement requests were not "false" under the FCA. Accepting relator's contention that the repackaging caused the drugs to be "adulterated," the Fourth Circuit found that Medicare and Medicaid reimbursement statutes do not "expressly prohibit" reimbursement for adulterated drugs and "do not require compliance with the CGMPs or any other FDA safety regulations as a precondition to reimbursement." Therefore, once FDA has approved a drug "the submission of a reimbursement request for that drug cannot constitute a 'false' claim under the FCA on the sole basis that the drug has been adulterated as a result of having been processed in violation of FDA safety regulations."

The Court explained that the False Claims Act is not a "sweeping mechanism to promote regulatory compliance," noting that FDA has its own "broad powers" to enforce safety regulations, including conducting site inspections, issuing warning letters, seizing noncompliant products, using injunctive remedies and recommending disapproval of new drug applications manufactured at the offending site. The Court also held that Relator could not plausibly allege scienter for the same reasons. Although the Fourth Circuit emphasized that it did not condone Omnicare's disregard of FDA safety regulations, the Court remained "convinced" that Omnicare's submission of claims for reimbursement for drugs produced in violation of the CGMPs had not constituted fraud on the government.

Analysis

The Fourth Circuit's decision appears to set forth an absolute rule that violations of FDA regulations regarding the manufacture and processing of drugs cannot support an FCA case on

their own. Because the Medicare and Medicaid statutes do not condition the reimbursement of drugs on whether they have been made or processed in accordance with FDA safety regulations, which are extensive, the Court refused to find that such failures adversely affect the government's funds or property. The government, however, does not take such an absolute view, arguing in its statement of interest to the district court in the *Rostholder* case that "the violation of CGMP regulations may be relevant in FCA cases where the violations are significant, substantial, and give rise to actual discrepancies in the composition or functioning of the product." In that statement, the government further opined that some deficiencies may render a drug "essentially worthless" giving rise to potential FCA liability.

Nevertheless, the *Rostholder* decision continues a trend of cases largely rejecting relator attempts to press FCA claims based on noncompliance with safety regulations. *See U.S. ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 737 F.3d 116, 119 (1st Cir. 2013) (affirming dismissal on 9(b) grounds relator's claim that defendant failed to report promptly and accurately to the FDA post-approval adverse events associated with the four subject drugs because relator failed to allege with particularity that defendant's alleged misconduct resulted in the submission of false claims for government payment); *U.S. ex rel. Simpson v. Bayer Healthcare Pharm. (In re Baycol Prods. Litig.)*, 732 F.3d 869, 878-80 (8th Cir. 2013) (affirming the dismissal of relator's claim that a manufacturer's downplaying of drug risk led to the submission of false claims to government health care programs because the relator failed to identify any representative examples of actual false claims that were submitted because of the risk minimization marketing scheme or show "how such reimbursement claims were false in and of themselves"); *U.S. ex rel. Tessitore v. Infomedics, Inc.*, 847 F. Supp. 2d 256, 264-66 (D. Mass. 2012) (dismissing on 9(b) grounds relator's claims that defendant's failure to report approximately 7,000 adverse drug events resulted in the submission of false claims because relator failed to provide any details regarding the alleged false certifications the company submitted to FDA or any factual support that submitting the adverse reports would have hastened FDA's decision to require warnings and that such warnings would have resulted in doctors writing fewer prescriptions for the drug).

Although these recent decisions call into question the vitality of FCA cases based on alleged violations of FDA safety regulations, such suits are unlikely to disappear. The government's position is that safety issues can, in certain cases, give rise to FCA claims — for instance, where CGMP violations are "significant, substantial and give rise to actual discrepancies" in a product's composition or functioning, or renders the drug "essentially worthless." Moreover, the government has taken the position that faulty adverse event reporting, which was at issue in the *Takeda* case, could trigger FCA liability in the "rare" circumstances where the concealed adverse events "are so serious that FDA would have

withdrawn a drug's approval for all indications had these events been properly reported." Brief for the United States of America as Amicus Curiae in Support of Neither Party at 11, *U.S. ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 737 F.3d 116, 118 (1st Cir. 2013) (No. 13-1088). Thus, plaintiffs will likely continue to bring FCA cases based on safety regulations, attempting to squeeze through the openings suggested in the government's positions.

Contact Us

Manvin Mayell
+1 212 836 7031
manvin.mayell@kayescholer.com

Ari B. Fontecchio
+1 212 836 8004
ari.fontecchio@kayescholer.com