Fourth Circuit Denies False Claims Act Liability For Regulatory Violations Related To Pharmaceutical Manufacturing

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Last month, the United States Court of Appeals for the Fourth Circuit affirmed the district court's dismissal of a False Claims Act ("FCA") suit against Omnicare, Inc. and related entities in relation to Medicaid and Medicare reimbursement of drugs that the relator alleged were not produced in conformance with the FDA's current Good Manufacturing Practice (cGMP) guidelines. The court noted that to hold otherwise would “sanction use of the FCA as a sweeping mechanism to promote regulatory compliance.” United States ex rel. Rostholder v. Omnicare, Inc., No. 12-2431 (4th Cir. Feb. 21, 2014). Acknowledging that Omnicare did indeed disregard the FDA safety regulations, the court employed careful analysis and lasting lessons from Omnicare’s conduct. Instead, the court stated that it dismissed the case, in part because the FDA's regulatory enforcement powers, not the FCA, were the appropriate mechanism to police compliance with the manufacturing regulations.

The ruling in Omnicare is consistent with cases coming out of the Fourth Circuit, among other circuits, that have refused to impose FCA liability for violations of regulations and other ancillary requirements that are not conditions for payment by the government. See Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 790 (4th Cir. 1999) (affirming dismissal because complaint did not state “that payments were made contingent upon representations by the Defendant that it had complied with the FDA's regulations”); United States ex rel. Hobbs v. MedQuest Assocs., 711 F.3d 707 (6th Cir. 2013) (violations of participation in Medicare program do not support FCA claim); United States ex rel. Miles v. Strauss, 274 F.3d 687, 699 (2d Cir. 2001) (“[T]he False Claims Act was not designed for use as a blunt instrument to enforce compliance with state medical regulations, but rather only those regulations that are precendent to payment.”)

Background

The relator who filed the qui tam suit was a former employee of a related entity and a licensed pharmacist. His job responsibilites included overseeing repackaging, quality assurance and regulatory affairs. He resigned in 2006 due to his concerns about the facility’s quality control efforts with respect to the improper repackaging of penicillin drugs in the same facility as non-penicillin drugs. The relator notified the FDA of the improper repackaging practices, which led to an investigation and a warning letter outlining numerous violations of FDA regulations, both related and unrelated to Omnicare’s practices of handling penicillin. The warning letter explained that Omnicare’s failure to adhere to the FDA’s cGMPs caused the drugs to be “adulterated” and that Omnicare disposed of nearly $19 million worth of inventory, it did not recall or offer to reimburse the government for drugs suspected of penicillin contamination.

Regulatory Framework

The cGMPs related to the handling of penicillin drug, are that the packing of penicillin be performed in facilities separate from those used for other drug products with completely separate air handling systems. 21 C.F.R. §§ 211.42, 211.446. The regulations further state that non-penicillin drugs be tested for the presence of penicillin if a reasonable possibility exists that the non-penicillin drug may be adulterated, and that if detectable levels of penicillin are found, the non-penicillin drug may not be marketed. The Food, Drug, and Cosmetic Act (FDCA) considers drugs that do not comply with the above requirements to be “adulterated” and thus, those drugs are not permitted to enter interstate commerce. 21 U.S.C. §§ 331,351(a)(2); 21 C.F.R. 210.1 (drugs not compliant with cGMP are “adulterated”).

The relator’s claim that Omnicare fraudulently made claims for payment for “adulterated” drugs was based on provisions governing reimbursement under relevant Medicare and Medicaid statutes. The statutes define drugs that can be covered as “those approved for safety and effectiveness” under the FDA. 42 U.S.C. § 1396r-8(k)(2)(A)(ii)(Medicaid); 42 U.S.C. § 1395w-102(e) (Medicare Part D). The FDCA sets forth an approval process that requires that an application for approval describe “the methods used in, and the facilities and controls used for, the manufacture, processing, and packaging” of the drug. 21 U.S.C. § 355(b). The FDA may refuse or withdraw approval for a drug if the methods and facilities are “inadequate to preserve [the drug’s] identity, strength, quality, and purity.” Id. § 355(d). If a new drug is not approved, it may not be introduced into interstate commerce. Id. § 355(a).

Lack Of Falsity Element For Regulatory Violation

The Fourth Circuit held that the Medicare and Medicaid statutes do not expressly prohibit reimbursement for drugs that have been adulterated, nor do they require compliance with the cGMPs as a “precondition to reimbursement.” Omnicare, No. 12-2431 at *15. In order for a drug to be covered for reimbursement, the court held that a “drug merely meets the statutory criteria as defined by the FDA.” Therefore, the court concluded that 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 a regulatory violation. To constitute a false claim, the relevant statutes must have specified that reimbursement is not appropriate where an already-approved drug has been produced in violation of FDA safety regulations. In other words, because “compliance with the cGMPs is not required for payment by Medicare and Medicaid, Omnicare has not falsly stated such compliance to the government, as contemplated by the FCA.” Id. at * 16. As such, the court found that the relator had not adequately pled the element of falsity necessary for an FCA claim.

The court anchored much of the rest of its decision on its finding that the relator had failed to adequately allege that a false claim was submitted. The court held that the relator could not adequately allege that the requisite scienter because Omnicare could not have “knowingly” submitted a false claim where the Medicare and Medicaid reimbursement statutes do not prohibit such reimbursement. Similarly, the court summarily dismissed the relator’s arguments for liability under the implied certification and worthless services theories, finding “absolutely nothing in the relevant statutes that have ‘spiraled out of control.’”

Defence To Regulatory Agency Enforcement Mechanism

As part of its decision, the court discussed regulatory enforcement powers that the FDA has at its disposal to address regulatory non-compliance. The court noted that under the FDCA, the secretary of Health and Human Services may suspend or withdraw FDA approval if the packaging process is inadequate. Furthermore, the FDA took various regulatory actions against Omnicare including conducting muck investigations, and threatening seizure of products, use of injunctive disorders, and disapprovals of any new applications for the manufacturer. Battressed by the “significant remedial powers of the FDA,” the court concluded 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.” Id. at * 18.

The decision in Omnicare is a resounding victory for Omnicare and a boon to federally regulated companies concerned with FDA enforcement. The court held 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.”

Corporative Counsel Organization Highlights

In-House Bar Files Comment Letter Aimed To Reduce Excessive Costs And Burdens Of FRCP Discovery Rules

The Association of Corporate Counsel (ACC), a global bar association representing more than 33,000 in-house counsel in 85 countries, filed comments recently with the Advisory Committee on Civil Rules supporting proposed amendments to limit the scope of the Federal Rules of Civil Procedures (FRCP) discovery rules.

In its letter, ACC states that the proposed changes are "an important step towards reducing the exorbitant cost, undue delay and unnecessarily gamesmanship associated with federal court litigation today." ACC further argues that "the excessive costs and burdens of discovery rules" have a "disparate impact on corporations" whether they act as plaintiffs or defendants. As a result, many companies settle cases before considering their merit in order to avoid federal court discovery requirements that have “spiraled out of control.”

Specifically, among other portions of the Rules, ACC supports proposed Rule 37(e)(1), which would provide a uniform standard across the United States for all discoverable information. ACC argues that the change would significantly reduce the expenses and burdens of over-preservation. Despite overall support for the suggested modifications, ACC also urges the Advisory Committee to expand proposed changes related to sanctions for information loss. "It is very important for in-house counsel to be able to make decisions about preservation without the standard being perfection,” the comments state.

The Advisory Committee will likely issue a decision in the next six months. To read the ACC comment letter, visit www.acc.com/advocacy.