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Recent Appellate Decisions Suggest Significant Limits on the Use Of the False Claims Act to Police Alleged Violations of FDA Regulations



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It goes without saying that increased enforcement under state and federal False Claims Acts has necessitated a change in thinking among industry personnel. Starting with the seminal *Parke-Davis* case in 2004[1], a clear picture emerged that industry controls over sales, marketing, and medical education practices needed to be revisited in order to defend against not only traditional Food and Drug Administration (FDA) scrutiny, but also claims that non-compliance could lead to the alleged inducement of false or fraudulent claims for reimbursement. Despite the extraordinary damages provisions of the False Claims Act (FCA), many companies were willing to take the litigation risk of fighting claims brought by relators based on relatively untested theories. However, intervention by the government in such cases brought with it the threat of exclusion, additional financial penalties, and the risk of protracted litigation. Many companies have been caught in this web and are under corporate integrity agreements, or have proactively attempted to improve their compliance programs in order to avoid these adverse consequences.

Nonetheless, the impact on areas such as product manufacturing and safety reporting has largely gone unnoticed. Industry professionals tasked with ensuring compliance with FDA regulations governing product safety reporting and compliance with current Good Manufacturing Practices (cGMPs) developed a reasonable expectation that instances of non-compliance or misconduct could be worked out through well-established FDA processes. Given the technical nature

[1] A former Parke-Davis Medical Science Liaison, David Franklin, filed a qui tam complaint under the False Claims Act against his former company, alleging the company knowingly had engaged in unlawful promotional practices that caused false claims to be submitted to federal healthcare programs for the seizure drug Neurontin (gabapentin). Parke-Davis, a division of Warner-Lambert, and their parent company, Pfizer, were subsequently the subject of a far-reaching criminal and civil investigation. See DOJ Press Release, Warner-Lambert to Pay $430 Million to Resolve Criminal and Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), available at http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm. The government initially did not intervene in Dr. Franklin's case, and the Pfizer defendants moved to dismiss. The government filed a Statement of Interest in 2003, setting forth its view, inter alia, that Dr. Franklin's allegations were supported in precedent and were consistent with the government's enforcement philosophy. Judge Saris issued three key opinions in the case. A core holding of Judge Saris' first opinion, was her view that though the FCA was not intended to be used as a general tool to fight regulatory violations, it was reasonably foreseeable that promotion in violation of the FDCA by Parke-Davis employees could induce doctors to prescribe Neurontin off-label, and in turn could lead to the submission of false claims to Medicaid programs, which would make them potentially actionable under the FCA. See United States ex rel. Franklin v. Parke-Davis, 147 F.Supp.2d 39, 51-53 (D. Mass. 2001).

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of these company processes, manufacturers work to resolve instances of suspected noncompliance via corrective and preventative actions, commitments to the agency, and use of outside consulting resources. Companies that willfully obstructed FDA inspections or were grossly or persistently deficient in their internal controls were always subject to consent agreements, civil and criminal penalties and/or other FDA action. Individuals were similarly exposed to the threat of personal civil and criminal liability, including under the *Park* Doctrine, which imposes strict misdemeanor criminal liability on corporate officers.

However, two high-profile investigations into cGMP violations at GSK (2010) and Ranbaxy facilities (2013) resolved with significant civil settlements,[2] raising concern that a flood of cGMP FCA cases would result. Indeed, both defendants entered into settlement agreements with state and federal authorities resolving allegations that cGMP violations had led government healthcare programs to pay for drug products that were rendered ineligible for reimbursement. Fortunately for those who remain concerned about the oversized role that relators' lawyers and US Attorney's Offices have been playing in policing Food, Drug and Cosmetic Act (FDCA) violations, two recent appellate court decisions suggest that there are legal limits to using the FCA to combat cGMP and safety reporting violations.

Fourth Circuit Dismissal of U.S. ex rel. Rostholder v. Omnicare and DOJ's Statement of Interest

In February 2014, the Fourth Circuit affirmed a lower court's dismissal of a *qui tam* action brought against Omnicare premised on a theory that Omnicare caused the submission of false claims by failing to adequately comply with FDA cGMP requirements.[3] Relator Rostholder, a former quality and regulatory compliance officer with Heartland Repack Services, LLC (a company owned by Omnicare) asserted that Omnicare caused the submission of false claims for penicillin products repackaged in violation of cGMPs. According to Rostholder, these claims were ineligible for Medicaid or Medicare reimbursement because the cGMP violations rendered the drugs in question ''adulterated'' under the FDCA, and therefore outside of compliance with new drug approval requirements referenced in the Medicare and Medicaid statutes. Relator Rostholder alleged he had advised the defendant of the regulatory risks of repackaging Heartland non-penicillin products in a facility that also repackaged Omnicare penicillin drugs, had recommended ways in which Heartland could repackage penicillin in compliance with FDA regulations, and that his recommendations were ignored.

Relator Rostholder subsequently resigned in 2006, and alerted FDA to the non-compliance. FDA inspected the facility and was allegedly assured by Heartland employees that no repackaging of penicillin was occurring in the facility. FDA inspectors left and later interviewed Relator Rostholder, who provided specific details about the alleged penicillin exposure at the facility. Following FDA's reinspection of the facility and discovery that penicillin was indeed being repackaged there and that penicillin contamination in fact was occurring throughout the facility FDA issued a Warning Letter to Omnicare citing numerous cGMP violations and noting that the non-compliance had rendered the drugs at issue adulterated under the FDCA. Omnicare reportedly destroyed $19 million worth of drug product. According to Relator Rostholder, Omnicare did not recall any contaminated product, nor did it reimburse payors for contaminated product.

In May 2007, Relator Rostholder filed a *qui tam* complaint in the District of Maryland. Following the government's decision not to intervene, Relator Rostholder filed a second amended complaint in 2010. The District Court granted Omnicare's motion to dismiss under F.R.C.P. Rule 12(b)(6), holding that Relator Rostholder had failed to state an actionable claim that Omnicare had made false statements or engaged in fraudulent conduct. Nor, according to the District Court, had Rostholder properly alleged the details of any false claims. Because the relator had amended his complaint twice, the District Court further denied Relator Rostholder leave to amend a third time. The Fourth Circuit affirmed the District Court's judgment, however noting that Relator Rostholder was an appropriate original source for the information in his complaints, as required by the FCA.

As it often does in declined qui tam cases, the United States filed a Statement of Interest in response to Omnicare's Motion to Dismiss the complaint. [4] According to the United States, the critical issue was not whether government payment was conditioned on compliance with the regulations but ''whether the deficiencies in the drug resulting in the cGMP violations may impact the government's decision to pay a claim for the drug.''[5] The United States further suggested that violations of cGMP regulations may be relevant in the FCA context if the violations are ''significant, substantial, and give rise to actual discrepancies in the composition or functioning of the product.''[6] The United States did ''readily'' acknowledge, however, that ''not every violation of the Food, Drug and Cosmetic Act is a *per se* violation of the FCA because not every regulatory violation has a nexus to payment.''[7]

The Fourth Circuit disagreed with Relator Rostholder's argument that Omnicare's failure to comply with cGMPs rendered the drugs adulterated and thus not ''covered outpatient drugs'' reimbursable under Medi-

[2] Both the GSK and Ranbaxy cases also included criminal pleas to charges of introduction of adulterated drugs. See U.S. Department of Justice, Press Releases October 26, 2010 , May 13, 2013 http://www.justice.gov/opa/pr/2010/October/10-civ-1205.html (08 PLIR 1363, 10/29/10), and http://www.justice.gov/opa/pr/2013/May/13-civ-542.html (11 PLIR 626, 5/17/13).

In addition to paying significant criminal and civil fines and penalties, most of Ranbaxy's manufacturing facilities were enjoined from producing drugs for the US market or placed under ''import alerts,'' at the time of this article.

[3] *United States ex rel. Rostholder v. Omnicare*, No. 12-2431, slip. op. (4th Cir. Feb. 21, 2014) (Keenan, J.), available at http://www.ca4.uscourts.gov/Opinions/Published/122431.P.pdf. (hereinafter ''Omnicare Opinion'') (12 PLIR 266, 2/28/14)

[4] United States' Statement of Interest as to Defendants' Motion to Dismiss, *United States ex rel. Rostholder v. Omnicare, Inc.*, Civ. No. 1:07-cv-1283-CCB, at 5 (D. Md. filed Nov. 18, 2011) (hereinafter ''Statement of Interest'').

[5] *Id.* at 3.

[6] *Id.* at 4.

[7] *Id.* at 5.

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care and Medicaid. Rather, the Court found that a drug must merely be approved by the FDA to qualify as a ''covered outpatient drug'' even if it had been produced or packaged in violation of FDA regulations.[8] Accordingly, the Court determined ''once a new drug has been approved by the FDA and thus qualifies for reimbursement under the Medicare and Medicaid statutes, 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.''[9]

In addressing Relator Rostholder's assertion that compliance with cGMPs was material to the government's decision to pay for regulated drugs, the court noted that an FCA claim requires both materiality and a false statement or fraudulent course of conduct. As compliance with cGMP regulations was not a requirement for payment by Medicare and Medicaid, Omnicare had not falsely stated such compliance and thus Rostholder's allegations of regulatory violations did not support FCA liability. Because the Medicare and Medicaid statutes do not prohibit reimbursement of drugs packaged in violation of cGMPs, the court further found relator could not plausibly plead the requisite FCA scienter as Omnicare could not have knowingly submitted false claims for such drugs. Finally, the court expressed its disapproval of the FCA as a mechanism to promote regulatory compliance noting, ''When an agency has broad powers to enforce its own regulations, as the FDA does in this case, allowing FCA liability could 'short-circuit the very remedial process the Government has established to address non-compliance with those regulations.' '' (citing *United States ex rel. Wilkins v United Health Group, Inc.*, 659 F.3d 295, 310 (3rd Cir. 2011)).

The Fourth Circuit's Opinion in *Omnicare* is helpful, in that it recognizes that payment for a drug that is technically adulterated may still continue while a manufacturer works with FDA to bring the relevant production process into compliance. Further, the Opinion is a win for our litigation-weary industry, where many seasoned in-house regulatory and compliance counsel live in a state of constant paranoia that otherwise reasonable legal risk-taking will be second guessed at every turn by either relators or the government. The Fourth Circuit Opinion sets precedent that makes it harder for plaintiffs and the government (at least in that Circuit) to prevail on the theory that presentation of a claim for reimbursement for a non-cGMP-compliant drug constitutes a false certification under Medicare and Medicaid.[10] More generally, it is an example of one court taking a balanced view of the interests of plaintiffs and the government to combat fraud using the FCA and those of parties regulated under FDA's hypertechnical regulatory regime.

First Circuit Dismissal of U.S. ex rel. Ge v. Takeda and DOJ's Amicus Brief

In December 2013, the First Circuit affirmed a lower court's dismissal of a *qui tam* action brought against Takeda premised on a theory that Takeda caused the submission of false claims by failing to adequately comply with FDA's safety reporting regulations.[11] The relator in that case (a former Takeda safety officer) asserted that a failure to comply with FDA's adverse event reporting regulations, followed by submissions of claims for reimbursement, constituted an actionable false certification to government payors. The argument is premised on the fact that, according to the relator, payors explicitly or implicitly premise payment for drug claims on compliance with federal healthcare law requirements, including FDA's adverse event reporting regulations. The District Court (Judge Saris) dismissed Relator Ge's Second Amended Complaint for failing to state a claim under F.R.C.P. Rule 12(b)(6) and failing to properly plead a claim under F.R.C.P. Rule 9(b). Judge Saris' 12(b) (6) dismissal held that Relator Ge had not established that compliance with Adverse Event reporting requirements was a material pre-condition to payment, as required under a well-pleaded false certification-based FCA complaint. The First Circuit affirmed the dismissal on December 6 of last year on Rule 9(b) grounds without reaching the 12(b) (6) issue.[12]

Significantly, prior to the First Circuit's dismissal, the government (through DOJ) filed an *amicus* brief ''in support of neither party'' to clarify what it saw as the District Court's error in ''suggest[ing] there existed a bright line rule that failure to report adverse events can never serve as a basis for [FCA] liability.''[13] DOJ unequivocally noted that ''[c]ompliance with the adverse event reporting requirements is not, in itself, a material precondition of payment under Medicare or Medicaid; reimbursement for prescription drugs is not conditioned on a pharmaceutical company's compliance with these requirements.''[14] DOJ went on to state that ''while it would be a rare circumstance where the nondisclosure of adverse events would be material to CMS's payment decisions, a per se bar to FCA liability [as implied by the District Court] is inappropriate.''[15] Underscoring the rare set of facts where safety reporting violations

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[8] Omnicare Opinion at 15.

[9] *Id*.

[10] In the parlance of FCA case law, express or implied certification would establish ''legal falsity'' in cases where there was compelling evidence of non-compliance with cGMPs. Although the Omnicare Court refused to address relator's arguments of FCA liability premised on implied certification or worthless goods theories because it found adulterated drugs subject to reimbursement by Medicare and Medicaid, there may be circumstances involving express certification of cGMP compliance as part of government contracts in which a court would reach a different conclusion. For example, the government views the ''worthless goods'' theory in the cGMP context as viable under FCA case law. *See* Statement of Interest at 4. The *Omnicare* case also is unlikely to affect cases based on ''factual falsity.'' Such theories could be raised where relators or the government have compelling evidence of overt fraud—e.g., intentional misrepresentation of cGMP compliance status of a product on which a payor relies in making a coverage decision. *Cf. United States ex rel. Connor v. Salina Regional Health Center, Inc.* 543 F.3d 1211 (10th Cir. 2008) (noting that FCA cases are analyzed by courts are under two rubrics: legal falsity and factual falsity).

[11] *United States ex rel. Ge v. Takeda*, Civ. No. 13-1088; 13-1089, 737 F. 3d. 116 (1st Cir. 2013) (11 PLIR 1480, 12/13/13).

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[12] *Id.*

[13] *See* Brief for the United States as Amicus Curiae, *United States ex rel. Ge v. Takeda*, Civ. No. 13-1088; 13-1089, 19-20 (1st Cir. filed Aug. 1, 2013).

[14] *Id.* at 20.

[15] *Id*. at 22-23.

could give rise to false claims, DOJ further stated: ''However, where the concealed adverse events are so serious and unexpected that FDA, would have, for example, withdrawn its approval of the drug for all indications had it known about the concealed information, claims for reimbursement for that drug would be [in DOJ's estimation] ineligible for payment.''[16]

Conclusion

DOJ's statements in its *amicus* brief in *Takeda* and its Statement of Interest in *Omnicare*, taken together with the courts' appellate rulings, suggest that there are significant limits to the appropriateness of the FCA as a remedy to police FDA violations. Readers will recall that the extent of Ranbaxy's publicly reported problems were so extreme that FDA eventually prohibited importation as well as pending and future applications from the facilities which had the repeated (and eventually criminal) cGMP violations. Based on the public filings, the Ranbaxy case appears to have met the test DOJ set forth in its Statement of Interest in *Omnicare*—the FDCA violations were so significant, substantial and gave rise to actual discrepancies in the composition or functioning of the product—or in its amicus brief in *Takeda* —the FDCA violations were so egregious that the affected products could not stay on the market for any use. Conceptualizing the government's enforcement policy in this way helps explain why the enforcement against Ranbaxy was so aggressive, and why the government was not interested pursuing similar false claims theories against Takeda or Omnicare.

At the same time, the authors do not expect that these two cases will stop relators from continuing to test the waters on the nexus between the FCA and the FDCA. In anticipation of this trend, some companies have already increased their focus on pharmacoviligance and quality functions in their corporate compliance monitoring and internal audit plans. While FDA regulations require continuous review and auditing in these areas, the additional investment of trained professionals (and, where necessary, outside audit and ''inspection readiness'' experts) can help foster quality and pharmacovigilance systems which allow for rapid identification and resolution of issues. Such proactive steps can better position companies to defend against the inevitability that relators' counsel will become more sophisticated, just as they have in the marketing context, and develop theories that will survive motions to dismiss.

[16] *Id.* at 20-21.

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