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# The Fourth Circuit Limits FCA Liability in cGMP Cases

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The Court of Appeals for the Fourth Circuit has put a limit on the expansive scope of liability sought by private plaintiffs (relators) and the U.S. Department of Justice under the False Claims Act (''FCA'' or ''Act''), at least as to claims premised on alleged violations of the U.S. Food and Drug Administration's (''FDA'') current Good Manufacturing Practices (''cGMPs''). In *United States ex rel. Barry Rostholder v. Omnicare, Inc.*, — F.3d —, 2014 WL 661351 (4th Cir. Feb. 21, 2014), the Fourth Circuit held that a claim cannot be ''false'' under the Act unless compliance with the regulation allegedly violated is a condition of reimbursement, and that compliance with cGMP regulations is not *per se* a precondition of Medicare or Medicaid reimbursement. The Fourth Circuit held that FCA liability, therefore, did not follow from an alleged violation of cGMPs.

In a significant victory for the pharmaceutical industry, the Fourth Circuit recognized that there must be some restriction on liability under the Act. The government in recent years has recovered billions of dollars from companies doing business with the government and, in particular, pharmaceutical companies. The Department of Justice has used aggressively expansive theories under the FCA to recover these extraordinary penalties, but a number of courts—including most recently the Fourth Circuit—have begun to impose limits, recognizing that FCA liability cannot automatically extend to any and all circumstances of noncompliance, because to do so would interfere with an administrative agency's exercise of discretion over its own statutes and regulations. In *Rostholder*, the Fourth Circuit understood that imposing liability would allow relators to effectively substitute their own judgment for the experience and expertise of the FDA.

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## The False Claims Act: A Growing Area of Federal Enforcement

The FCA's key provision imposes liability on one who knowingly presents, or causes to be presented, ''a false or fraudulent claim for payment or approval'' to the government. 31 U.S.C. § 3729(a)(1). To state a claim under the FCA, a plaintiff must allege that (1) ''there was a false statement or fraudulent course of conduct''; (2) ''made or carried out with the requisite scienter''; (3) ''that was material''; and (4) ''that caused the government to pay out money or to forfeit money due (i.e., that involved a 'claim').'' *Rostholder*, 2014 WL 661351, *4 (internal quotation marks omitted).

In the early years of the modern enforcement era, FCA liability was imposed for ''factually false'' claims for payment. This meant that the ''false claim'' must include ''an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.'' *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001). For example, an FCA violation would lie where the claim for payment to the government was for 100 pills of a drug when only 50 pills were provided. The government and courts have pushed the boundaries of liability further, adding a broader ''legally false'' theory to the factually false theory. Under the legally false theory, the factual truth of the claim itself became irrelevant and, instead, what

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mattered was whether there was ''a false representation of compliance'' with a statutory, regulatory, or contractual obligation. *Id.* at 696.

Courts have wrestled with various forms of the ''legally false'' theory, allowing claims premised on an ''express false certification'' theory as well as, in some instances, an ''implied false certification'' theory. Under the express false certification theory, one who submits a claim for payment containing a false affirmative certification of compliance with a statutory, regulatory, or contractual obligation may be liable. Christopher L. Martin, Jr., Comment, *Reining in Lincoln's Law: A Call to Limit the Implied Certification Theory of Liability Under the False Claims Act*, 101 Cal. L. Rev. 227, 239 (2013); *see Straus*, 274 F.3d at 698. The implied certification theory, which has been adopted by the majority of appellate courts,[1] is even broader, imposing liability simply for ''the act of submitting a claim for reimbursement itself'' because the submission of a claim for payment ''implies compliance'' with statutes, regulations, and contract provisions. *Straus*, 274 F.3d at 699.

One way courts have restricted the almost limitless liability imposed under the ''legally false'' theory is to require that certification with a certain statute, regulation, or contractual term be ***an express condition of the federal payment.*** *See, e.g., United States ex rel. Steury v. Cardinal Health Inc.*, 625 F.3d 262, 268-70 (5th Cir. 2010). Even those courts that recognize the implied certification theory have limited liability by adopting an express condition of payment requirement. *See United States ex rel. Steury v. Cardinal Health Inc.*, 735 F.3d 202, 207 n.3 (5th Cir. 2013) (' '[M]ost of the courts that have accepted the implied false certification theory have done so only where the government expressly conditioned payment on compliance with the underlying statute or regulation.' '' (quoting John T. Boese, 1 Civil False Claims and Qui Tam Actions § 2.02(B)(3) (4th ed. 2012))); *e.g.*, *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 307-11 (3d Cir. 2011); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011); *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1218 (10th Cir. 2008); *see generally* Martin, *supra*, at 243-46. This condition of payment requirement ''recognizes that unless the Government conditions payment on a certification of compliance, a contractor's mere request for payment does not fairly imply such certification.'' *Steury*, 625 F.3d at 268.

Other circuits, however, have rejected a condition of payment requirement and recognized a theory of implied certification virtually without limit. *See, e.g.*, *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 386-88 (1st Cir. 2011) (''[T]he rule . . . that only express statements in statutes and regulations can establish preconditions of payment is not set forth in the text of the FCA.''); *United States v. Sci. Apps. Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010) (''[T]o establish the existence of a 'false or fraudulent' claim on the basis of implied certification of a contractual condition, the FCA plaintiff—here the government—must show that the contractor withheld information about its noncompliance with material contractual requirements. The existence of express contractual language specifically linking compliance to eligibility for payment may well constitute dispositive evidence of materiality, but it is not . . . a necessary condition.''); *Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429, 434 (1994) (''The payment vouchers represented an implied certification by Ab-Tech of its continuing adherence to the requirements for participation in the 8(a) program. Therefore, by deliberately withholding from SBA knowledge of the prohibited contract arrangement with Pyramid, Ab-Tech not only dishonored the terms of its agreement with that agency but, more importantly, caused the Government to pay out funds in the mistaken belief that it was furthering the aims of the 8(a) program.''); *see generally* Martin, *supra*, at 246-48. The D.C. Circuit, for example, has held that a violation of a contractual obligation that was ''material'' to the Government's obligation to pay a claim can support FCA liability, regardless of whether there is ''express contractual language specifically linking compliance to eligibility for payment.'' *Sci. Apps. Int'l Corp.*, 626 F.3d at 1269-71.[2]

The courts have struggled to find the boundary separating noncompliance that rises to the level of fraud and that supports FCA liability from noncompliance that is simply a regulatory matter. On the one hand, as the First Circuit reasoned in *United States ex rel. Jones v. Brigham & Women's Hospital*, 678 F.3d 72, 85 (1st Cir. 2012), courts have ''rejected rigid divisions between factual and legal falsity, and express and implied certification,'' and decided to ''take a broad view of what may constitute a false or fraudulent statement to avoid 'foreclos[ing] FCA liability in situations that Congress intended to fall within the Act's scope.' '' On the other, courts have recognized that FCA liability must have some limitation because ''[c]orrecting regulatory problems may be a laudable goal, but one not actionable under the FCA in the absence of actual fraudulent conduct.'' *Mann v.Heckler & Koch Def., Inc.*, 630 F.3d 338, 346 (4th Cir. 2010) (internal quotation marks omitted).

[1] The Fourth, Fifth, Seventh, and Eighth Circuits have not recognized the implied certification theory. *See United States ex rel. Badr v. Triple Canopy, Inc.*, 950 F. Supp. 2d 888, 899-900 (E.D. Va. June 19, 2013); *United States ex rel. Steury v. Cardinal Health Inc.*, 735 F.3d 202, 205-06 (5th Cir. Aug. 30, 2013); *United States ex rel. Yarberry v. Sears Holding Co.*, No. 09-cv-00588, 2013 WL 1287058, *3 (S.D. Ill. Mar. 28, 2013); *United States ex rel. Stone v. OmniCare, Inc.*, No. 09 c 4319, 2012 WL 5877544, *1 (N.D. III. Nov. 20, 2012); *United States ex rel. Miller v. Weston Educ., Inc.*, No. 4:11-CV-00112, 2012 WL 6190307, *8 (W.D. Miss. Dec. 12, 2012); Martin, *supra*, at 242 tbl.1.

[2] The Ninth and Eleventh Circuits have apparently recognized the implied certification theory, but have not expressed a view on the ''condition-of-payment'' requirement. Martin, *supra,* at 248-49. The Ninth Circuit ''has taken a number of positions on th[e] issue,'' including at one point ''disavow[ing] the *Mikes* express condition-of-payment requirement.'' *Id.*; *see also Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 n.3 (9th Cir. 2010) (''We need not decide whether to adopt the Second Circuit's requirement in the Medicare context that 'the underlying statute ''expressly'' condition payment on compliance,' as Ebeid's position fails regardless.''). The Eleventh Circuit ''has recognized the implied certification theory without using the label.'' Martin, *supra*, at 249; *see also United States ex rel. Freedman v. Suarez-Hoyos*, 781 F. Supp. 2d 1270, 1278-79 (M.D. Fla. 2011) (citing *McNutt v.Haleyville Med. Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005)). The Eleventh Circuit has apparently not ruled on the ''express condition-of-payment requirement.'' Martin, *supra*, at 249.

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## The Government Targets Health Care Fraud Through the FCA

The expansive use of the False Claims Act in the pharmaceutical industry has been a lucrative enterprise for the government. The FCA has become ''the government's primary civil remedy to redress false claims'' for payments made to government programs such as Medicaid, Medicare, and other government programs administered by the Department of State, the U.S. Agency for International Development, and other agencies. Since 1986, the government has recovered approximately $34 billion under the FCA. In Fiscal Year 2013 alone, the government recovered $3.8 billion in settlements and judgments. *See* Press Release, Dept. of Justice (Dec. 20, 2013), http://www.justice.gov/opa/pr/2013/December/13-civ-1352.html (''FY2013 Press Release'').

The FCA has been used, in particular, to recover significant amounts from alleged health care fraud. Of the $3.8 billion recovered in FY2013, the government recovered $2.6 billion in health care fraud recoveries. This is due at least in part to the ''high priority'' given by the Obama Administration to prosecuting health care fraud. Of this $2.6 billion, $1.8 billion was recovered from ''alleged false claims for drugs and medical devices under federally insured health programs,'' such as Medicare and Medicaid. Many of these settlements involved ''off-label'' marketing allegations, that is, claims that the pharmaceutical manufacturer ''improperly promoted [its] drug[] for [a] use[] not approved by the [FDA].'' *See* FY2013 Press Release, *supra*. In July 2012, for example, GlaxoSmithKline resolved criminal and civil claims relating, in part, to its off-label promotion of certain drugs for $3 billion, $2 billion of which settled FCA allegations. *See* Justice News (July 2, 2012), http://www.justice.gov/opa/pr/2012/July/12-civ-842.html.

The $1.8 billion also included recoveries for drugs manufactured in facilities that failed to comply with cGMPs - in other words, that the pharmaceutical company submitted false claims to the government by selling ''adulterated'' drugs not manufactured and distributed in accordance with federal regulations. The drugs themselves may not be ''adulterated'' as that word is generally understood; they may actually be safe and effective, yet be considered ''adulterated'' because they were manufactured in cGMP non-compliant facilities. Generic drug manufacturer Ranbaxy Laboratories Ltd. and its subsidiaries paid $350 million to settle a civil FCA qui tam complaint alleging, among other things that Ranbaxy drugs distributed in the United States were manufactured in non-GMP compliant facilities in India. Ranbaxy USA Inc. also pleaded guilty to a criminal information as part of the overall settlement, and paid $150 million in fines and forfeitures. *See* FY2013 Press Release, *supra*.

The extension of FCA liability from the typical off-label marketing case into manufacturing quality through violation of cGMPs was perhaps not surprising. The Department of Justice announced in early 2013 that it would be taking ''an especially hard look'' at cGMP violations in the context of FCA liability.[3] Justice News, Deputy Assistant General Maame Ewusi-Mensah Frimpong Speaks at the 2013 CBI Pharmaceutical Compliance Congress (Jan. 29, 2013), *available at* http://www.justice.gov/iso/opa/civil/speeches/2013/civ-speech-130129.html.

## United States ex rel. Barry Rostholder v. Omnicare, Inc.

The legitimacy of DOJ's ''hard look'' was exactly the issue tested recently by the Fourth Circuit in *United States ex rel. Barry Rostholder v. Omnicare, Inc.* The Fourth Circuit recognized the express condition of payment requirement as a limit to FCA liability, holding that noncompliance with cGMPs does not give rise to FCA liability because such compliance is not a condition of payment under Medicare and Medicaid.

In *Rostholder*, the relator filed a qui tam action under the FCA against his former employer and its affiliated companies, alleging that they violated FDA cGMP safety regulations that require penicillin and non-penicillin drugs to be packaged separately from each other. The relator alleged that by failing to comply with cGMPs, Omnicare's drugs were ''adulterated'' under the Act, prohibited from interstate commerce, and not eligible for reimbursement by Medicare or Medicaid. Under the relator's theory, any claim made to government payors was false or fraudulent under the FCA due to this regulatory noncompliance in manufacturing.

The government declined to intervene in the case, and the district court later granted Omnicare's motion to dismiss the second amended complaint. The district court held that the relator had not alleged a false statement or fraudulent conduct and had not adequately alleged the details of a false claim that had been submitted for reimbursement to the government. The district court denied further leave to amend the complaint.

On appeal, the Fourth Circuit affirmed, holding that the complaint failed to allege that Omnicare made a false statement or engaged in a fraudulent course of conduct. The court looked to FDA's cGMP regulations and the statutes governing reimbursement under Medicare and Medicaid. 2014 WL 6611351, at *4-5. The statutes governing reimbursement define ''covered outpatient drug[s]'' as those drugs ''approved for safety and effectiveness'' under the Food, Drug, and Cosmetic Act (''FDCA''). 42 U.S.C. § § 1396r-8(k)(2)(A)(i); 1395w-102(e). Under the FDA's new drug approval process, an application for approval must describe ''the methods used in, and the facilities and controls used for, the manufacture, processing, and packing'' of the drug. 21 U.S.C. § 355(b). The FDA may refuse such an application if the methods or facilities ''are inadequate to preserve [the drug's] identity, strength, quality, and purity.'' *Id.* § 355(d), (e). Unless there is an approved application in effect, a new drug may not be introduced into interstate commerce. *Id.* § 355(a).

The Fourth Circuit explained that the statutes ''do not expressly prohibit reimbursement for drugs that have been adulterated,'' nor do they ''require compliance with the CGMPs or any other FDA safety regulations as a precondition to reimbursement''; they only refer to

[3] In 2010, a subsidiary of GlaxoSmithKline, PLC, SB Pharmco Puerto Rico Inc., entered into a civil FCA and criminal resolution ''relating to the manufacture and distribution of certain adulterated drugs.'' The Company paid a criminal fine and forfeiture of $150 million and a civil settlement of $600 million. *See* Justice News (Oct. 26, 2010), http://www.justice.gov/opa/pr/2010/October/10-civ-1205.html.

the FDCA's requirements for new drug approval and marketing. *Rostholder*, 2014 WL 6611351, at *5. To qualify as a ''covered outpatient drug,'' a drug only need be approved by the FDA, as distinguished from manufactured and distributed in accordance with cGMP regulations. Therefore, once a new drug has been approved and qualifies as a ''covered outpatient drug'' for reimbursement under Medicare and Medicaid, the submission of a claim for reimbursement for a drug that is allegedly ''adulterated'' because the drug was manufactured through processes that did not comply with cGMP violations cannot be a ''false claim'' under the FCA.

In reaching its conclusion that the relator had failed to allege a false statement or fraudulent course of conduct, the Fourth Circuit emphasized that the FCA is not concerned with ''the correction of regulatory problems'' and is not ''a sweeping mechanism to promote regulatory compliance''; rather, it is ''aimed at protecting the financial resources of the government from the consequences of fraudulent conduct.'' *Id.* at *5-6. Federal agencies, such as FDA, the court noted, are charged with enforcing regulatory compliance and policing noncompliance. In *Rostholder*, the FDA had taken ''numerous regulatory actions'' against the Company, including inspections and issuance of a Warning Letter, and threatened seizure of drug products, injunctive relief, and other actions. In short, the Court held that the False Claims Act did not provide the authority to the relator or to the Court to displace the FDA in its role as the regulator. FCA liability cannot automatically extend to any and all circumstances of noncompliance, because to do so would interfere with a government agency's exercise of discretion over its own statutes and regulations.

Furthermore, the term ''express condition'' must mean something—in other words, if the government agency would have discretion to accept or reject a claim if it knew of the alleged violation, then payment is not ''expressly conditioned'' on compliance. *See Salina Reg'l Med. Ctr., Inc.*, 459 F. Supp. 2d at 1086-88 (D. Kan. 2006); *United States ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1222 (E.D. Cal. 2002) (''To allow FCA suits to proceed where government payment of Medicare claims is not conditioned on perfect regulatory compliance . . . would improperly permit qui tam plaintiffs to supplant [an agency's regulatory discretion].'').

As much as *Rostholder* constitutes a blow to FCA liability based on manufacturer non-compliance with cGMPs, it may not significantly impact FCA recoveries for off-label marketing. The FDA approves drugs and devices for specific intended uses, which are usually reflected in the labeling of the drug or device. Drug and device manufacturers in most cases are prohibited from promoting their drugs and devices for those uses not approved by the FDA (or ''off-label'' uses), though physicians can prescribe the drugs or devices for such off-label uses. But federal health care programs may not pay for the off-label uses. The Medicaid statute permits states ''to exclude or otherwise restrict coverage of a covered outpatient drug'' if it is prescribed for a use that has not been approved by the FDA or which is not supported by citations in the American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, or the DRUGDEX Information System compendia. 42 U.S.C. §§ 1396r-8(d)(1)(B)(ii), (k)(6), (g)(1)(B)(i). Medicare Part D likewise limits ''covered drugs'' to those prescribed for FDA approved indications or those uses supported by any of the three compendia. *Id.* §§ 1395w102(e)(1), 1395x(t)(2)(B)(ii); Laura Laemmle-Weidenfeld, Esq., ''The False Claims Act and Good Manufacturing Practices: The Next Frontier?,'' at 6, *available at* http://www.healthlawyers.org/Members/PracticeGroups/LS/Documents/Laemmle_paper.pdf. Because prescribing drugs for their approved indications appears to be a condition of payment, unlike compliance with cGMPs, *Rostholder* may not have a chilling effect on the Department of Justice and the relators' bar, which have been tremendously successful in recent years pursuing off-label promotion FCA claims.

## Conclusion

Time and additional cases will reveal whether the *Rostholder* decision is limited to cGMP cases in the pharmaceutical industry, or whether it signals the beginning of a more general retrenchment in FCA liability. Some circuits have adopted the condition of payment requirement, though not in the pharmaceutical industry context like *Rostholder*. In other circuits, however, that do not require that the alleged regulatory, statutory, or contractual violation be a condition of payment, *Rostholder* may be of very limited use. Likewise, there is reason to believe that *Rostholder* may have limited effect on FCA cases pursued under an off-label marketing theory. Despite these observations, courts—including now the Fourth Circuit in *Rostholder*—are beginning to recognize and impose limits to the extraordinary reach of the False Claims Act.

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