Fourth Circuit Holds cGMP Violations Do Not Create False Claims Under Medicare and Medicaid

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In the first appellate decision of its kind, the U.S. Court of Appeals for the Fourth Circuit held on Friday, February 21, that because compliance with the Food and Drug Administration's (FDA) Current Good Manufacturing Practices (cGMP) regulations is not a precondition for reimbursement under Medicare and Medicaid, violations of the cGMP regulations by themselves cannot form the basis for False Claims Act (FCA) claims under those programs. The opinion can be found here.

The Fourth Circuit's decision, in *United States ex rel. Rostholder v. Omnicare, Inc.*, No. 12-2431,[1] comes on the heels of what appears to be an increased effort by the Department of Justice to enforce the cGMP regulations, through both criminal and civil sanctions. Early last year, for example, Deputy Assistant Attorney General Maame Ewusi-Mensah Frimpong warned that drug manufacturers who disregard cGMP do so "at their peril" and that the government would "be taking an especially hard look whenever patients are placed at an unacceptably high risk of harm by . . . violations of current good manufacturing practices."[2] Soon thereafter, generic drug manufacturer Ranbaxy pleaded guilty to seven felonies related to cGMP violations at its Indian facilities and agreed to settle pending criminal and civil claims for a total of $500 million.[3]

The Decision

The *Rostholder* decision arises out of a *qui tam* lawsuit filed by a pharmacist/operations manager against Omnicare, the parent company of his former employer, Heartland Repack Services. The relator alleged that Heartland and Omnicare (the nation's largest nursing home pharmacy) operated a facility in Toledo, Ohio that packaged both penicillin and non-penicillin products in the same building, with inadequate separation and controls to prevent cross-contamination.[4] After resigning from Heartland, the relator alerted the FDA to his concerns. According to the relator's allegations, the FDA investigated, found that the facility violated cGMP, and issued a warning letter to Omnicare.[5] In response to the warning letter, Omnicare allegedly disposed of $19 million worth of inventory, but did not recall any of its drugs or otherwise reimburse the government for any drugs previously purchased.[6]

The relator alleged that, in violation of the FCA, Omnicare had submitted for reimbursement to Medicare and Medicaid claims for drugs that were not packaged in conformance with cGMP "and

therefore [were] adulterated and misbranded, . . . not in their FDA-approved form, and thus ineligible for coverage under government programs."[7] The government declined to intervene and, in late 2012, Judge Blake of the U.S. District Court for the District of Maryland granted Omnicare's motion to dismiss.[8]

The Fourth Circuit affirmed the dismissal. It acknowledged that drugs not packaged in conformance with cGMP are "adulterated" within the meaning of the Food, Drug and Cosmetic Act (FDCA).[9] In an FCA case, however, the court reasoned, the question is not whether the drugs were "adulterated," but whether they were reimbursable under Medicare and Medicaid.[10] Under Medicare and Medicaid the government will only reimburse "covered outpatient drugs," which are defined by statute as drugs "approved for safety and effectiveness under the Food, Drug, and Cosmetic Act."[11] The court found nothing to suggest that approved drugs, even if "adulterated," somehow lose their approved status.[12]

Because the court concluded that "adulterated drugs are subject to reimbursement by Medicare and Medicaid," it held that there was simply no "false statement or fraudulent course of conduct as required for an FCA claim."[13] Stressing that falsity of claims and materiality to the government's decision to pay are distinct elements of FCA claims, the court further held that, there being no "falsity," it did not matter whether cGMP compliance was material to the government's decision to reimburse Omnicare for the allegedly adulterated drugs.[14] Without any "false statement or other fraudulent misrepresentation," the court held, there could be no FCA liability.[15] For the same reason, the court, in a one-sentence footnote, rejected any effort to re-characterize the relator's claims under an "implied certification" or "worthless services" theory.[16] In explaining its rationale, the court reiterated that the FCA is a statute meant to protect the government from fraud rather than "a sweeping mechanism to promote regulatory compliance."[17]

Implications

1. The *Rostholder* decision gives strength to an important defense in FCA cases based on cGMP violations, particularly in those circuits-which include the Fifth and Seventh as well as the Fourth-that have not adopted the implied certification theory of liability.

2. How influential the decision will prove to be in the large number of circuits that have embraced *implied* certification liability remains to be seen. In those circuits, relators and the government will likely argue that although cGMP compliance is not an express condition for reimbursement under Medicare and Medicaid, it should be treated as an implicit one.

3. Other defendants may try to extend the Fourth Circuit's reasoning in *Rostholder* to other kinds of FDCA violations or to violations of other statutes and implementing regulations concerning FDA approval, such as those governing medical devices. On the other hand, the government and relators may look for other provisions in the Medicare and Medicaid statutes, such as the requirement that items and services be "reasonable and necessary" for their reimbursed use, as an alternative basis on which to allege the falsity of claims for reimbursement of drugs manufactured in violation of cGMP regulations.

4. The Fourth Circuit's decision rests on the premise that once a drug has been approved by the

FDA, cGMP violations do not by themselves undermine that approved status. Relators and the government may argue that when cGMP violations are significant enough that drugs are not manufactured "according to the approved formulation," they are effectively new, unapproved drugs not eligible for reimbursement under Medicare and Medicaid. This was one of the theories upon which the government relied for the FCA claims resolved as part of the Ranbaxy settlement, and it seems to be the theory the government advanced in a statement of interest filed in the district court in *Rostholder*. The government acknowledged that not all FDCA violations, including cGMP violations, are sufficient to ground FCA claims with respect to Medicare and Medicaid.[18] But it insisted that "where the violations are significant, substantial, and give rise to actual discrepancies in the composition or functioning of the product," they should suffice to support FCA claims.[19] In the government's view:

> This may occur, for example, in cases where, as a result of the cGMP violations, the affected drug's strength materially differed from, or the purity or quality fell below, the strength, purity or quality specified in the drug's FDA-approved New Drug Application, the drug's labeling, and/or the standards set forth in an official compendium. *See* 21 U.S.C. § 351(b), (c). Moreover, in some situations, manufacturing deficiencies may affect the strength, purity and/or quality of the affected drug such that the drug is essentially "worthless" and not eligible for payment by the government. Submitting claims, or causing claims to be submitted, to federal healthcare programs for drugs that are so deficient as to be essentially worthless may give rise to liability under the FCA.[20]

The government's position in *Rostholder* parallels the position it took last year in *United States ex rel. Ge v. Takeda Pharm.*, 737 F.3d 116 (1st Cir. 2013), where it acknowledged in an amicus brief that "[s]imply alleging that a company failed to comply with FDA's adverse event reporting requirements is insufficient to state an FCA claim," but contended that "if the unreported adverse events are so serious that the FDA would have withdrawn a drug's approval for all indications had these events been properly reported, the failure to report would be material to the government's payment decisions concerning claims under the Medicare and Medicaid programs, since claims for drugs for which FDA approval has been withdrawn are ineligible for payment under these programs."[21]

5. The *Rostholder* decision affects only FCA cases. It does not affect the ability of the Justice Department to bring criminal or civil cases based on cGMP violations directly under the FDCA. While it is possible that the *Rostholder* decision will have some dampening effect on whistleblower referrals and thus on some of the government's sources of information about possible cGMP violations, it seems unlikely to diminish the government's vigor in pursuing its announced goal of increased cGMP enforcement.

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[1] *United States ex rel. Rostholder v. Omnicare, Inc.*, No. 12-2431, slip. op. (4th Cir. Feb. 21, 2014), available at http://www.ca4.uscourts.gov/Opinions/Published/122431.P.pdf.

[2] Maame Ewusi-Mensah Frimpong, Deputy Assistant Attorney General, Remarks at CBI Pharmaceutical Compliance Congress (Jan. 29, 2013), available at http://www.justice.gov/iso/opa/civil/speeches/2013/civ-speech-130129.html.

[3] Press Release, Department of Justice, Generic Drug Manufacturer Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA (May 13, 2013), available at http://www.justice.gov/opa/pr/2013/May/13-civ-542.html.

[4] *Rostholder*, slip op. at 4-5.

[5] *Id*. at 5-6.

[6] *Id*. at 6.

[7] *Id*. at 7 (quoting complaint).

[8] *United States ex rel. Rostholder v. Omnicare, Inc.*, Civ. No. CCB-07-1283, 2012 WL 3399789 (D. Md. Aug. 14, 2012).

[9] *Rostholder*, slip op. at 13-14.

[10] *Id*. at 14.

[11] *Id*.

[12] *Id*. at 14-15.

[13] *Id*. at 11, 16 n.7.

[14] *Id*. at 16-17.

[15] *Id*. at 17.

[16] *Id*. at 16 n.7.

[17] *Id*. at 17.

[18] United States' Statement of Interest as to Defendants' Motion to Dismiss at 5, *United States ex rel. Rostholder v. Omnicare, Inc.*, Civ. No. CCB-07-1283 (D. Md. Nov. 18, 2011), 2011 WL 10857612.

[19] *Id*. at 3.

[20] *Id*. at 4.

[21] Brief for the United States of America as Amicus Curiae in Support of Neither Party at 11, 26, *United States ex rel. Ge v. Takeda Pharms.*, 737 F.3d 116 (No. 13-0188), 2013 WL 4038688, at *11, *21.

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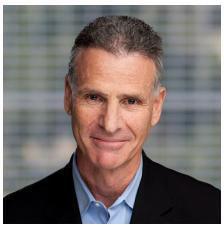

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