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ALERT

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Seventh Circuit Grants Interlocutory Appeal in Rx Discount Program Qui Tam Suit to Answer Several Important Questions

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In *United States ex rel. Garbe v. Kmart Co.*, 824 F.3d 632 (7th Cir. 2016), the Seventh Circuit granted interlocutory appeal following numerous motions for partial summary judgment to consider four questions: (1) whether the amendments to 31 U.S.C. § 3729(a)(2) (now 31 U.S.C § 3729(a)(1)(B) in the Fraud Enforcement and Recovery Act ("FERA")) apply to all *cases* "pending on or after June 7, 2008," or just all *claims* as of that date; (2) whether private-entity Part D reimbursement intermediaries are "officers or employees of the United States" under the FCA; (3) whether Relator's claims satisfied the FCA's materiality requirement; and (4) whether the district court identified the correct "usual and customary" price in its decision.

Background

Beginning in 2004, Kmart Corporation ("Kmart") introduced a prescription discount program that offered certain generic drugs to its pharmacy customers at a discounted rate of $15 for a 90-day prescription. In connection with the Medicare Part D prescription benefit added in 2006, the federal Centers for Medicare and Medicaid Services ("CMS") required that retail pharmacies charge Part D beneficiaries their "usual and customary" price for each prescription. In late 2005, before the Part D rollout, Kmart had revamped its discount program to offer low prices to discount-program cash-paying customers, while treating the higher prices paid by non-program cash-paying customers as the "usual and customary" prices for purposes of Part D reimbursements. However, Relator's complaint alleged that Kmart pharmacists routinely overrode official program pricing to match competitor prices, Kmart charged nearly all of its cash-paying customers the discount program prices, and "the barriers to joining the Kmart 'programs' were almost nonexistent, to the extent they were enforced at all." *Kmart*, 824 F.3d at 643.

Relator James Garbe, a pharmacist, began working at a Kmart pharmacy in Ohio in 2007. One day he picked up a personal prescription at a competitor pharmacy and noticed that his Part D insurer was charged far less than Kmart would ordinarily charge for the same prescription. Upon some investigation, Garbe discovered that Kmart routinely charged its insured customers higher prices than its cash-paying customers. Additionally, Garbe noted that cash-paying customers in Kmart's discount programs paid much less than other cash-paying customers. Nevertheless, the discount program prices were ignored when Kmart calculated its "usual and customary" generic drug prices for purposes of Part D reimbursements. On July 12, 2008, Garbe filed a complaint in the United States District Court for the Southern District of Illinois alleging that Kmart had violated the FCA by manipulating its "usual and customary" prices to reap inflated Part D reimbursements. The United States did not intervene.

At the close of discovery, following numerous cross-motions for partial summary judgment, the district court denied Kmart's motions and granted partial summary judgment in favor of Garbe on some issues.

Seventh Circuit Affirms in Large Part

On appeal, the Seventh Circuit first analyzed whether Garbe's claims should be analyzed under the 1994 or the 2009 version of the FCA; the 1994 version had included requirements that claims be directly presented to an "officer or employee of the United States government" for payment or approval, whereas the 2009 version removed this presentment requirement. 824 F.3d at 638 ("as amended, the FCA contains no presentment requirement"). When the

FCA was amended by FERA in 2009, the amendments were made effective as if they had been enacted on June 7, 2008, and applied "to all claims under the False Claims Act that are pending on or after that date." Relator filed his case shortly after the effective date, but it was based on claims for reimbursement that occurred almost entirely before the effective date. Reaffirming existing precedent and consistent with the law in many other circuits, the Seventh Circuit found that the "all claims" language in the 2009 statute referred to all FCA *cases* rather than demands for payment, and that the 2009 version of the FCA therefore applied.

What is more notable about the decision, however, is the Seventh Circuit's subsequent analysis of whether § 3729(a)(1)(A) and its removal of the presentment requirement applies retroactively to transactions occurring before the statute became effective. Concluding that there was no ambiguity that the 1994 version of the statute contained a presentment requirement and that the 2009 amendment was a substantive change in law, as opposed to a "clarification," the court held it was not retroactively applicable. *Id.* at 642. The Seventh Circuit next addressed whether contractors implementing a government program should be considered "the government." Here the Seventh Circuit held that the district court's finding that Pharmacy Benefit Managers and Plan Sponsors were officers or employees of the United States was in error. Relators could not show presentment for any claims for payment at issue in the case made prior to June 7, 2008. *Id.* at 645.[1]

Finally, the court addressed whether Kmart's discount program cash customers should be considered part of the "general public" for purposes of determining Kmart's "usual and customary" pricing, which is ordinarily defined as the cash price offered to the general public. The Seventh Circuit found "no reason to think that there was any meaningful selectivity for the people who joined Kmart's programs," and that such people therefore could not "be distinguished in any way from the 'general public.'" *Kmart*, 824 F.3d at 643. The court noted that the discount programs themselves were offered to the general public and that there were no meaningful barriers to joining the programs. Additionally, Garbe's expert indicated that most of Kmart's cash-paying customers received the "discount" prices. The court found that the "usual and customary" price is meant to ensure that Medicare Part D receives the lowest price at which a particular drug is widely and consistently available to a pharmacy's cash-paying customers, and that "[a]llowing Kmart to insulate high 'usual and customary' prices by artificially dividing its customer base would undermine a central purpose of the statutory and regulatory structure." *Kmart*, 824 F.3d at 645. For those reasons, the Seventh Circuit held that Kmart's widely and consistently available discounted prices, which were offered to the general public, represented its "usual and customary" charges for the drugs.

A rehearing and rehearing *en banc* were denied in July 2016, and Kmart filed a petition for a writ of certiorari on September 23, 2016. That petition was denied in January 2017.

Implications

Although growing less important with the passage of time, the Seventh Circuit's retroactivity analysis provides a unique defense to FCA defendants that do not present claims directly to the government for payment. The decision also provides some very specific guidance to the many pharmacies concerning determination of their "usual and customary" prices for purposes of Medicare Part D reimbursement.

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[1] Less clear is the significance of the court's holding regarding materiality. In this case, decided before the Supreme Court's decision in *Escobar*, the Seventh Circuit concluded that the post-FERA materiality standard required nothing more than that the "misstatements had to be capable of influencing the decisionmaking body to which they were addressed." *Id.* at 639 The court concluded the claims at issue met that lower standard. However, in the wake of *Escobar*, FCA defendants in the Seventh Circuit will need to await further development of the law.