UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 07-12153-RWZ

UNITED STATES OF AMERICA, *ex rel.*
JAMES BANIGAN and RICHARD TEMPLIN, *et al.*

v.

ORGANON USA INC., *et al.*

ORDER

August 23, 2016

ZOBEL, J.

Before the court are two motions for summary judgment filed by Omnicare, Inc., a long-term care pharmacy. The first (Docket # 414) concerns Omnicare itself and the second (Docket # 417) concerns a group of pharmacies—American Pharmaceutical Services, Inc. (APS), SunScript Pharmacy Corporation, NeighborCare Inc., and NCS Healthcare, Inc.—acquired by Omnicare in the early 2000s (collectively, the Acquired Pharmacies). Relators contend that Omnicare and the Acquired Pharmacies violated the federal False Claims Act (FCA), 31 U.S.C. §§ 3729 et seq. (2006),[1] by submitting to Medicaid claims for payment tainted by violations of the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b) (2012). The alleged kickbacks came to Omnicare in the form of

[1] Relators' claims predate the Fraud Enforcement and Recovery Act of 2009, which substantively amended the FCA.

discounts offered by drugmaker Organon[2] on two formulations of its antidepressant Remeron: the Tablet and SolTab (collectively, Remeron). Relators have also filed a motion to supplement the summary judgment record (Docket # 470), which Omnicare partially opposes.

Omnicare's motion concerning its own conduct is denied, and its motion concerning the Acquired Pharmacies is allowed in part and denied in part. Relators' motion is allowed in its entirety.

I. Background

Previous opinions have set forth the facts underlying this case in detail, see United States ex rel. Banigan v. Organon USA Inc., 883 F. Supp. 2d 277, 283–85 (D. Mass. 2012), leaving only a brief recitation necessary here.

Relators allege that Omnicare both solicited and received kickbacks from Organon from 1999 through 2005 as part of that company's efforts to protect and expand its profits from Remeron. From 1999 until October 2001, Omnicare purchased Remeron through its membership in several group purchasing organizations (GPOs).[3] Each agreement between Organon and a GPO hews to the same general framework: Organon offers a GPO volume-based discounts on Remeron, and the GPO agrees, in effect, to promote the potential benefits of the agreement to its member pharmacies. These agreements clearly delineate the Remeron discount schedule, typically in an appendix or an attachment. Each GPO earns discounts on Remeron based on that

[2] "Organon" refers to Organon Biosciences N.V., Organon USA, Inc., Organon Pharmaceuticals USA, Inc., Organon International, Inc., Schering Plough Corp., and Merck & Co., Inc. Organon is no longer a defendant in this case. See Docket # 173.

[3] GPOs aggregate their members' purchasing power to secure better prices from pharmaceutical organizations. Because these organizations negotiate on behalf of their members, Omnicare had no involvement in the negotiation of any GPO agreement with Organon.

drug's market share—as measured against a collection of comparable antidepressants—within a specified group of pharmacies. This discount gives each GPO an incentive to promote Remeron among its members, and the agreements enshrine this incentive as an obligation: the GPOs agree to publicize the agreement to member pharmacies, and to make them aware of the financial benefits that could result from an uptick in Remeron's market share. The agreements likewise provide that they cannot be modified or amended without a writing signed by both parties. Omnicare's direct purchasing agreements with Organon, in effect from October 2001 through 2005, follow the same pattern: the pharmacy accepts a volume-based discount for Remeron in exchange for a promise to promote the agreement's potential financial benefits to its clients.

During this time, Omnicare moved to expand its business through a series of four mergers and acquisitions. On December 5, 2001, it purchased certain assets of APS, free and clear of liabilities, pursuant to a bankruptcy proceeding; the bankruptcy court approved that transaction on December 17 of that year. In December 2002, Omnicare merged with NCS. On July 13, 2003, it purchased certain SunScript assets during the latter's post-bankruptcy reorganization. The agreement consummating that transaction explicitly states that Omnicare had not agreed to acquire any of SunScript's liabilities save a few exceptions pertaining to SunScript's continuing operation. And in July 2005, Omnicare and NeighborCare merged. Although none of these Acquired Pharmacies had dealt directly with Organon, each purchased Remeron through GPOs on the terms described above.

Relators filed their complaint on September 13, 2007, alleging that Omnicare and its Acquired Pharmacies had violated the FCA by soliciting and/or receiving kickbacks for Remeron prescriptions and submitting kickback tainted claims to Medicaid. The operative complaint (Docket # 105) asserts these claims on behalf of the United States and twenty-eight states,[4] none of whom have intervened. These counts survived a motion to dismiss given that relators' complaint alleged "that the full terms and amounts of the [Remeron] discount were . . . concealed in various sham collateral contracts." Banigan, 883 F. Supp. 2d at 296. Such allegations adequately stated an FCA claim predicated on violations of the AKS, as the arrangement described by the complaint—a public-facing discount contract modified through hidden side agreements, with discounts not reflected in charges made to Medicaid—falls well outside that statute's safe harbor for discounts. See id. With this case lurching towards trial, Omnicare has moved for summary judgment, arguing both that relators have furnished insufficient proof to proceed and that it has met its burden of proof as to two affirmative defenses.

II. Standard

Summary judgment is granted when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Genuine" disputes are those that a jury might resolve in favor of the nonmoving party, and "material" facts are those "that might affect the outcome of the suit under the governing law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). If the nonmoving party bears the ultimate burden of persuasion, that

[4] California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Maryland, Michigan, Minnesota, Montana, New Hampshire, New Jersey, New Mexico, New York, Nevada, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin.

party must present "definite, competent evidence" that demonstrates such a genuine dispute. United States v. One Parcel of Real Property, 960 F.2d 200, 204 (1st Cir. 1992). Should the moving party bear that burden, "that party must support its motion with credible evidence . . . that would entitle it to a directed verdict if not controverted at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 331 (1986) (Brennan, J., dissenting); see also Liberty Lobby, 477 U.S. at 251 ("[S]ummary judgment should be granted where the evidence is such that it would require a directed verdict for the moving party.") (quotation omitted). In either case, the court views the record in the light most favorable to the nonmoving party, and draws reasonable inferences in that party's favor. Griggs-Ryan v. Smith, 904 F.2d 112, 115 (1st Cir. 1990).

III. Discussion

Relators allege that the discount agreements entered into or participated in by Omnicare and the Acquired Pharmacies violate the AKS, and that this violation renders false the claims for payment submitted by pharmacies to the federal government. However, the terms on which Omnicare acquired APS and SunScript unambiguously resolve the question of successor liability in Omnicare's favor. As to them, summary judgment is therefore allowed.

The AKS sweepingly prohibits any person from "knowingly and willfully solicit[ing] or receiv[ing] any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind" in exchange for recommending any product or service that may be paid for "in whole or in part under a Federal health care program." 42 U.S.C § 1320a-7b(b)(1)(B). Its next section, however, bars the statute's application against "any discount or other reduction in price . . . if the reduction in price is properly disclosed and appropriately reflected in the . . . charges made by the provider or entity under a Federal health care

program." Id. § 1320a-7b(b)(3)(A). Regulations interpreting that statute provide an independent[5] safe harbor for discounts offered to charge-based providers[6] if: (1) they are "made at the time of the sale," and "fixed and disclosed in writing . . . at the time of the initial sale" and (2) the provider furnishes, "upon request by the Secretary or a State agency," documentation both of the discount and that provider's awareness of its obligation to report it. 42 C.F.R. §§ 1001.952(h)(1)(iii). Claims for payment that result from a prohibited kickback violate the FCA. See, e.g., United States ex rel. Lisitza v. Johnson & Johnson, 765 F. Supp. 2d 112, 127–28 (D. Mass. 2011) (collecting cases).[7]

Omnicare contends, first, that its solicitation of discounts could not have "knowingly and willfully" violated the AKS given the company's conduct and ambiguities in the regulatory landscape; second, that those discounts are in any event protected by the statute's statutory and regulatory safe harbors; and finally, that it has not run afoul of the FCA in any event. These arguments are unavailing.

A. Scienter Under the AKS

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[5] Congress, directing the Secretary of Health and Human Services to promulgate regulations "specifying payment practices that shall not be treated as a criminal offense" under the AKS, provided that "[a]ny practices specified in regulations . . . shall be in addition" to those exempted by the AKS itself. Pub. L. No. 100-93, § 14(a), 101 Stat. 680, 697 (1987). See also 64 Fed. Reg. 63,518, 63,528 (Nov. 19, 1999) ("In sum, the regulatory [discount] safe harbor both incorporates and enlarges upon the statutory [discount] exception.")

[6] Different regulations apply to health maintenance organizations and competitive medical plans acting in accordance with risk contracts and to cost-based providers. See 42 C.F.R. §§ 1001.952(h)(1)(i), (ii) (2016). Omnicare is a charge-based provider.

[7] The Patient Protection and Affordable Care Act (PPACA), passed in 2010, amended the AKS to clarify that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). This case, filed in 2007, arises under the pre-PPACA FCA, though as Lisitza and the cases cited therein demonstrate, the PPACA amendment simply fixes in the statute the overwhelming majority view of the federal courts concerning the interplay between the AKS and the FCA.

The AKS applies only to "knowing[] and willful[]" solicitation or receipt of remuneration, "directly or indirectly."[8] 42 U.S.C § 1320a-7b(b)(1). To act knowingly, a defendant must "do something voluntarily . . . do it deliberately . . . not do something by mistake or accident or even negligently," and to act willfully, a defendant must "do something purposely, with the intent to violate the law . . . do something purposely that law forbids." United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 33 (1st Cir. 1989).

Relators bear the burden of proving this issue at trial and must thus demonstrate that a genuine dispute exists to defeat Omnicare's motions. They have done so. Although Omnicare has offered some evidence that favors its position—particularly, that discounts were an industry custom in which other pharmacies openly participated, both on their own and through GPOs—relators have furnished evidence sufficient to put the question of scienter before a jury. This evidence includes a June 2001 Omnicare report flagging the pharmacy's relationship with Organon—characterized as "quid pro quo"—as a potential problem and an Omnicare compliance policy that evinces ample familiarity with the AKS and related guidance. That guidance notably includes the Department of Health and Human Services' 1994 publication of an OIG Special Fraud Alert that explicitly maligns the sort of product conversion campaign in which Omnicare and Organon participated. 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994). This evidence either predates or overlaps with both the GPO agreements—in effect from 1999 through 2001—and the direct purchasing agreements—in effect until 2005—making summary

[8] Because the AKS prohibits even the indirect receipt of prohibited remuneration, it plainly encompasses the GPO agreements in which Omnicare, NCS, and NeighborCare participated. Whether those pharmacies negotiated, or participated in the negotiation of, those agreements has no effect on that broad statutory proscription.

judgment in Omnicare's favor inappropriate as to both. This conclusion applies with equal force to both NeighborCare and NCS, given that each company's 10-K demonstrated a substantial awareness of the 1994 Special Fraud Alert.

Omnicare further argues that neither it nor any of the Acquired Pharmacies could be found to have have willfully violated the law given its reasonable behavior in the face of regulatory ambivalence concerning discounts. The pharmacy is correct that a "not objectively unreasonable" navigation of a regulatory thicket surrounding the AKS would negate the necessary scienter. See Safeco Ins. co. of Am. v. Burr, 551 U.S. 47, 67 (2007). On the record before the court, however, whether or not Omnicare's behavior was "objectively unreasonable" remains an open question. To suggest the reasonableness of its behavior, the company leans heavily on a 1998 OIG Advisory Opinion stating that a volume-based discount arrangement conditioned on "certain promotional support" would not run afoul of the AKS, OIG Advisory Opinion 98-2 (Apr. 8, 1998). Federal regulations, however, prohibit Omnicare from offering this document as a defense to AKS allegations. See 42 C.F.R. § 1008.55(b) (2016) ("An advisory opinion may not be introduced into evidence by a person or entity that was not the requestor of the advisory opinion to prove that the person or entity did not violate . . . any . . . law."). Removing that opinion from consideration, the regulatory terrain includes the aforementioned Special Fraud Alert prohibiting conversion campaigns[9] and a regulatory clarification noting that the regulatory discount safe harbor might permit tiered rebates "[i]n some"—entirely unspecified—"circumstances."[10] Against this backdrop, a

[9] 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994).

[10] 64 Fed. Reg. 63,518, 63,529 (Nov. 19, 1999).

jury could plausibly find that the solicitation of tiered discounts predicated on a conversion campaign—or participation in a GPO agreement embodying the same—was objectively unreasonable.

B. The AKS's Safe Harbors

Omnicare further argues that its discount agreements fall within one or both of the two discount safe harbors of the AKS. The statutory safe harbor protects any discount that meets two requirements: the discount is (1) "properly disclosed," and (2) "appropriately reflected in the costs claimed or charges made . . . to a Federal health care program." 42 U.S.C. § 1320a-7b(b)(3)(A). The regulatory safe harbor likewise has two elements and protects discounts: (1) that are "made at the time of the sale," and "fixed and disclosed in writing . . . at the time of the initial sale" and (2) for which the provider furnishes, "upon request by the Secretary or a State agency," documentation both of the discount and that provider's awareness of its obligation to report it. 42 C.F.R. § 1001.952(h)(1)(iii).

Both the statutory and regulatory safe harbors are affirmative defenses on which Omnicare bears the burden of proof. See United States ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39, 80 (D. Mass. 2011). The pharmacy must therefore furnish evidence that, if not genuinely controverted, would suffice for a directed verdict in its favor. Omnicare has not met this standard for either of the safe harbors. Omnicare has shown, by the contracts themselves, that both the GPO and direct purchase agreements contained and disclosed the entire terms of the agreement between it and Organon. While this clears the first element of each safe harbor, however, the pharmacy offers no evidence whatsoever as to the second element of either. As to the statutory safe harbor, Omnicare has offered not an iota of evidence that the discounts were

reflected at all, much less "appropriately," in its charges to Medicaid. As to the regulatory safe harbor, Omnicare has not shown, nor can show, that it made the relevant disclosures pursuant to a governmental investigation, as the parties agree that no such investigation took place during the relevant period. Although an Omnicare executive has testified that the company would have provided the requisite information had a governmental agency requested it, this single statement, untested by either cross-examination or by a jury's determinations as to its credibility, is not such that it "would require a directed verdict for" Omnicare on this issue, Liberty Lobby, 477 U.S. at 251. This does not take Omnicare to task for either its own good luck or regulatory laxity: as discussed above, the statutory and regulatory safe harbors are independent affirmative defenses, and government action a necessary condition only of the latter. As Omnicare has likewise offered no evidence whatsoever as to the second element of either affirmative defense for either NeighborCare or NCS, summary judgment is inappropriate as to each set of claims.

C. False Claims Act Liability

Finally, Omnicare argues that it faces no False Claims Act consequences—whatever its liability under the AKS—by challenging relators' proof as to the FCA's materiality and scienter requirements. The pharmacy likewise argues that claims for payment submitted before September 13, 2001—six years before this case's filing date—fall outside the FCA's statute of limitations.

Relators bear the ultimate burden of persuasion on both materiality and scienter and must thus establish that a jury might reasonably find in its favor as to each. Falsity immaterial to the government's decision to pay is not actionable, and falsity is not material unless "it has a natural tendency to influence, or is capable of influencing, the

decision of the decisionmaking body to which it was addressed." United States ex rel. Loughren v. Unum Corp., 613 F.3d 300, 307 (1st Cir. 2010). Omnicare contends that relators have not established and cannot establish that any—let alone each—of the twenty-eight state Medicaid programs at issue might hesitate to pay kickback-tainted claims.

Relators, however, have pointed to healthcare regulatory regimes and/or provider agreements for all states concerned, and each state either prohibits kickbacks directly through its own laws, e.g., Cal. Welf. & Ins. Code § 14107.2 (West 2016), or indirectly by incorporating the federal AKS, e.g., Conn. Dep't of Soc. Servs., Provider Enrollment Agreement ¶ 27 (requiring Medicaid providers "[t]o comply with state and federal law, including . . . [the federal Anti-Kickback Statute]"). See Docket # 454-1. By enshrining their distaste for kickbacks in statutes and provider agreements, these states have made plain their unwillingness to pay kick-back tainted claims.

Omnicare likewise argues that the record cannot establish scienter. The FCA imposes liability only on those defendants who have "knowingly" submitted false claims, and defines "knowingly" as "actual knowledge" or "deliberate ignorance . . . or . . . reckless disregard of . . . truth or falsity." 31 U.S.C. § 3129(b) (2006). Courts within the First Circuit require at least one individual within a corporate entity to have acted knowingly, although the First Circuit itself has not yet spoken on this isusue. E.g., United States ex rel. Dyer v. Raytheon Co., No. 08-cv-10341, 2013 WL 5348571, *26 (D. Mass. Sept. 23, 2013).

Relators have furnished evidence sufficient to create a genuine dispute as to this issue. A June 2001 report from Kevin Duffy, Omnicare's Senior Vice President of Global

marketing and Business Development, mentions concerns over the pharmacy's relationship with Organon, with a sales representative describing it as "quid pro quo." This report, sent by a senior executive, coupled with the robust awareness of the AKS evinced by Omnicare's lengthy compliance policy, would permit a reasonable jury to conclude that an individual within the company knew of potential AKS violations and thus the falsity of Omnicare's Medicaid claims. This is equally true of both NeighborCare and NCS: each company's 10-Ks contained referenced a 1994 Special Fraud Alert concerning conversion campaigns and explicitly identified the possibility of enforcement actions predicated on those campaigns. Despite this, both pharmacies participated in GPO agreements with marked parallels to those frowned upon by that Special Fraud Alert. These facts amply suffice to ground a genuine dispute as to whether a single individual within each pharmacy possessed the requisite scienter under the FCA.

The statute of limitations likewise poses no barrier to any of relators' claims. An FCA case must be brought before the latter of: (1) six years past the date of an FCA violation; or (2) three years after the date upon which the relevant federal official knew or should have known of the facts material to the cause of action, but never more than ten years after the FCA violation itself. 31 U.S.C. § 3731(b) (2012). Omnicare argues that the former provision constrains relators given that the federal government has declined to intervene; this, however, is not the position taken by courts within the First Circuit. See United States ex rel. Ven-A-Care v. Actavis Mid Atl. LLC, 659 F. Supp. 2d 262, 273–74 (D. Mass. 2009). In non-intervened cases, the FCA leaves relators with "the right to conduct the action," 31 U.S.C. § 3730(c)(3) (2006), and this right encompasses the tolling provision of the FCA's statute of limitations. United States ex

rel. Eisenstein v. City of New York, 556 U.S. 928 (2009), does not affect this conclusion: Eisenstein holds simply that, in non-intervened FCA cases, although the federal government is a real party in interest, it is not a "party" for purposes of the Federal Rules of Appellate Procedure. Id. at 937. This does not dislodge Ven-A-Care, which holds simply that the FCA endows relators with certain procedural rights created by the statute itself—not that relators enjoy the same rights as the federal government for every federal statute and rule.

IV. Conclusion

Omnicare's Motion for Summary Judgment concerning its own conduct (Docket # 414) is DENIED; its Motion for Summary Judgment concerning the Acquired Pharmacies (Dockeet # 417) is ALLOWED as to SunScript and APS, but is otherwise DENIED. Relators' Motion to Supplement Summary Judgment Record (Docket # 470) is ALLOWED.

August 23, 2016
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE