

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

United States of America <i>ex</i>)	
<i>rel.</i> Crystal Derrick,)	
)	
Plaintiff-Relator,)	
)	
v.)	No. 1:14-cv-04601
)	
Roche Diagnostics Corp., <i>et</i>)	
<i>al.</i> ,)	
)	
Defendants.)	

Memorandum Opinion and Order

In this *qui tam* action, plaintiff-relator Crystal Derrick ("relator") sues her former employer Roche Diagnostics Corporation, and its affiliate Roche Diabetics Care, Inc., (collectively "Roche" or the "Roche defendants"),¹ along with Humana, Inc., and Humana Pharmacy, Inc., (collectively "Humana" or the "Humana defendants"), alleging that they violated the False Claims Act ("FCA" or "the Act"), 31 U.S.C. §§ 3729-3733, by engaging in a business scheme in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and by retaliating against her for raising concerns about the lawfulness of that scheme. Roche and Humana have each filed a

¹ The complaint also names Roche Holding AG, but that entity does not appear to have been served with process, and no attorney has made an appearance on its behalf.

motion to dismiss the complaint, and relator has moved to strike certain documents that Roche filed in support of its motion. For the reasons that follow, defendants' motions are denied except that Count IV of the complaint is dismissed against Humana, and relator's motion to strike is denied as unnecessary.

I.

The following summary is drawn from the second amended complaint ("SAC" or "the complaint"), whose factual allegations I accept as true for present purposes. See *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir. 2011). The Roche defendants manufacture and market blood glucose monitoring products used by individuals with diabetes. SAC ¶¶ 5-7, 49. Humana is an insurance company that offers health insurance plans nationwide, including Medicare Advantage plans, which Humana provides pursuant to contracts with the federal government. *Id.* ¶¶ 8, 47-48, 72. Humana maintains formularies on which it lists products covered by its Medicare Advantage and other federally funded plans. *Id.* ¶¶ 42-49. Humana Pharmacy operates a mail-order pharmacy called RightSource, which primarily disburses to members covered by government insurance programs. *Id.* ¶ 48.

The Medicare Advantage Program, otherwise known as Medicare Part C, contracts with private insurance companies called Medicare Advantage Organizations ("MAOs"), of which Humana is one. The Centers for Medicare & Medicaid Services ("CMS")

compensates MAOs at a capitated rate for the delivery of benefits. To participate in the Medicare Advantage program, MAOs must submit bids to CMS every year in which they offer to provide services for a specified amount per member, per month. Each participating MAO must then enter into a contract with CMS, the terms of which require the MAO to comply with certain laws, including the AKS and the FCA. 42 C.F.R. § 422.503(a), § 422.504(h). To receive payment for services provided under the Medicare Advantage program, MAOs must submit monthly payment requests to CMS along with monthly reports certifying that "all information submitted to CMS in this report is accurate, complete, and truthful." SAC ¶¶ 72, 74-77.

Prior to the events giving rise to the complaint, Roche contracted with Humana to make its glucose monitoring products available on Humana's Medicare Advantage and RightSource formularies. Relator was a national accounts manager for Roche from October 2012 to December 2013 and was involved in overseeing Roche's account with Humana. *Id.* ¶¶ 4, 48-51. According to the complaint, Humana notified Roche in March of 2013 that it would be terminating an agreement under which Roche's products were available on Humana's RightSource formularies. *Id.* ¶ 50. Relator describes this news as a "significant blow" to Roche's business. *Id.*

In May of 2013, relator discovered that Humana had not complied with certain terms of its formulary agreements with Roche. *Id.* ¶ 51. As a result of Humana's noncompliance, Roche had paid rebates to Humana that were not actually owed. *Id.* Relator met with Bethany Stein, a contract strategist at Humana, to discuss Roche's rebate overpayments. *Id.* ¶ 52. Stein acknowledged the overpayments and agreed "that it would be appropriate for Roche to quantify" the amount it had overpaid. *Id.* In a subsequent conversation, Stein indicated that "due to the potentially large size of the reimbursement" it owed Roche, Humana had decided to have an auditor perform a formal calculation. *Id.* ¶ 54.

In or around June of 2013, Roche's finance department determined that the company had overpaid Humana by \$45 million. *Id.* ¶ 55. Recognizing "an opportunity to be placed back on Humana's formularies," Roche's general manager, Mark Gibley, directed the company's vice president of finance, David Barnes, to "do whatever it would take" to preserve the relationship with Roche, and Barnes instructed relator to emphasize "Roche's continuation of the Humana contracts in its anticipated negotiations with Humana concerning the overpayment." *Id.* ¶ 56. Barnes further instructed relator to discuss the negotiations only with him, and to refrain from speaking about them with anyone else. *Id.*

Negotiations ensued. Although Humana originally indicated that it would involve auditors and seek advice from in-house counsel to determine an appropriate reimbursement amount, defendants ultimately did neither. *Id.* ¶¶ 57, 60, 62. Roche offered to settle the overpayment debt for \$27.6 million notwithstanding its \$45 million estimate, as it "did not want to jeopardize" its relationship with Humana" by requesting the full amount. *Id.* ¶ 59. Barnes later sent Stein an email formally requesting repayment of the rebates, which Stein viewed as "pretty harsh" and "not reflective of" defendants' discussions. *Id.* ¶ 63. Humana responded that it would pay no more than \$20 million. *Id.* ¶ 64.

Negotiations continued over the course of the next several months. In early December of 2013, defendants signed a contract to place Roche products back on Humana's formularies and to exclude competing brand products from Humana's formularies. *Id.* ¶ 69. The same week, Humana paid Roche a sum that, according to the complaint, did not exceed \$11 million to cover its overpayment debt. *Id.* ¶ 70. Relator alleges that Roche reserved the right to recover the full amount owed if Humana did not satisfactorily perform its obligations under the parties' new agreement. *Id.*

Relator alleges that she was concerned that defendants' arrangement ran afoul of the AKS and repeatedly expressed her

concerns to Barnes and to other Roche executives. *Id.* ¶¶ 67-68, 79. Although she had originally been praised for her discovery of Roche's overpayment to Humana, she was terminated shortly after the parties executed the December 2013 agreement. The putative reason for relator's termination was a mistake Roche claimed she had made two months earlier, when she provided a client with pricing information that the company had not approved. *Id.* ¶¶ 69-70, 80-84, 87-88, 90. In relator's view, the real reason she was fired was her effort to blow the whistle on defendants' unlawful kickback scheme.

Relator asserts four claims under the FCA. In Count I, she alleges that Humana presented, and Roche caused to be presented, false claims to CMS in violation of § 3729(a)(1)(A). In Count II, she claims that Humana made material false statements, and that Roche caused material false statements to be made, in conjunction with claims Humana submitted to CMS in violation of § 3729(a)(1)(B). In Count III, she alleges that defendants violated § 3729(a)(1)(C) by engaging in a conspiracy to commit the violations asserted in Counts I and II. And in Count IV, relator asserts that defendants retaliated against her because of her efforts to stop the aforementioned FCA violations.

Defendants move for dismissal on the ground that the complaint fails the particularity and plausibility standards of Rule 9(b) and Rule (8). They argue that dismissal is appropriate

for the additional reason that the conduct relator attributes to them in the complaint falls within the AKS's safe harbor provisions and is consistent with Congress's intent in establishing a "managed care" exception to the statute.

II.

The False Claims Act is the government's "primary litigative tool for combatting fraud against the federal government." *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 745 (9th Cir. 1993) (internal quotations omitted). It empowers the Attorney General and private persons, known as relators, to bring civil actions in federal court to enforce the Act's anti-fraud provisions on behalf of the government. *Id.*; *Fanslow v. Chicago Mfg. Ctr., Inc.*, 384 F.3d 469, 479 (7th Cir. 2004) (citing 31 U.S.C. § 3730(b)). The Act imposes civil liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," 31 U.S.C. § 3729(a)(1)(B); or conspires to present a false claim or make a false statement, 31 U.S.C. § 3729(a)(1)(C). See *United States ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 740-41 (7th Cir. 2007), *overruled in part on other grounds by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009). It also prohibits retaliation against

any employee, contractor, or agent who takes lawful steps to stop FCA violations, including but not limited to reporting suspected fraud to a supervisor or filing a *qui tam* action in federal court. 31 U.S.C. § 3730(h)(1).

The Anti-Kickback Statute, to which relator's FCA fraud claims are tethered, is a criminal fraud statute aimed at protecting federal healthcare programs from "increased costs and abusive practices resulting from provider decisions that are based on self-interest rather than cost, quality of care or necessity of services." *United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015). It proscribes the knowing and willful solicitation, receipt, payment, or offer of any form of remuneration in return for the purchase, lease, or order of any good or service for which payment may be made under a Federal health care program. 42 U.S.C. § 1320a-7b(b)(1)-(2). The statute is violated when something of value is given or paid "purposefully to induce or reward referrals of items or services payable by a Federal health care program." Dep't of Health & Human Servs. Office of Inspector Gen. Advisory Op. No. 12-05, at *3 (April 24, 2012). A payee (or payor) of illicit remuneration violates the AKS by: (1) knowingly and willfully (2) receiving (or offering) remuneration (3) in exchange for purchasing (or inducing the purchase) of any federally-reimbursed items or services. 42 U.S.C. § 1320a-7b(b)(1)-(2). Pursuant to § 1320a-

7b(g) of the AKS, claims for payment that include "items or services resulting from a violation of [the AKS]" are false or fraudulent for purposes of the FCA.

Relator articulates two theories of FCA liability: first, that Humana's claims to CMS for payment of Roche products it placed on its formularies pursuant to defendants' December 2013 agreement are *per se* false or fraudulent because Humana purchased those items in violation of the AKS; and second, that Humana's monthly payment requests impliedly certified to CMS that it was in compliance with the AKS when that was not true. Defendants attack both theories on the ground that relator does not plead an AKS violation, or any false claim, with the requisite particularity.

Humana argues that relator's allegations of a kickback scheme do not identify any specific claim that was actually presented for payment and that included items or services resulting from an AKS violation. But as a Roche employee, relator would not be expected to have access to information about Humana's claims submissions. Where a relator "lacks access to all facts necessary to detail [her] claim," it is enough that her allegations support an inference that Humana necessarily submitted claims covering items or services resulting from an AKS violation. *Corley v. Rosewood Care Ctr., Inc.*, 142 F.3d 1041, 1045 (7th Cir. 1998); see also *United States ex rel.*

Presser v. Acacia Mental Health Clinic, LLC, 836 F.3d 770, 778 (7th Cir. 2016). Here, relator alleges that Humana placed Roche's products on its RightSource and Medicare Advantage formularies pursuant to its debt forgiveness agreement with Roche, and that Humana's contracts with the Medicare Advantage program required it to submit monthly claims for payment covering those products. SAC ¶¶ 27-34, 72-77. These allegations necessarily lead to the conclusion that Humana presented claims to CMS that were tainted by the alleged fraud. See *Presser*, 836 F.3d at 777-78 ("a plaintiff does not need to present, or even include allegations about, a specific document or bill that the defendants submitted to the Government," so long as "the alleged facts necessarily [lead] one to the conclusion" that the defendants presented such claims).²

Defendants also insist that relator has not pled the scienter required for an AKS violation. The statute's willfulness requirement indeed means that relator must allege that defendants had at least some "bad purpose ... to do

² Humana's reply suggests that because Humana is not *exclusively* in possession of its claim information, since the government also has that information, relator must plead the particulars of individual claims Humana allegedly presented. But the case Humana cites for this argument, *Peterson v. Cmty. Gen. Hosp.*, No. 01-C-50356, 2003 WL 262515, at *2 (N.D. Ill. Feb. 7, 2003), predates *Presser* and in any event does not stand for the proposition that a relator must identify specific claim information unless that information is in exclusive possession of the defendant.

something that the law forbids." *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 675 (N.D. Ill. 2006). But willful conduct can be proven circumstantially, *id.* at 676, and relator's allegations raise a plausible inference that defendants knew that the debt forgiveness arrangement—and thus Humana's claims covering items Humana purchased from Roche as part of that arrangement—were unlawful. For example, she alleges that Humana considered, but decided against, seeking actuarial and legal counsel in negotiating defendants' debt forgiveness arrangement, and that her supervisor at Roche instructed her to discuss the arrangement with no one but himself. Contrary to Roche's insistence that the complaint lacks "any allegations evidencing consciousness of illegality or wrongdoing," these allegations plausibly suggest that individuals acting on defendants' behalf were aware that they were doing "something the law forbids." *Id.* Discovery may ultimately reveal a benign motive behind these individuals' alleged conduct, but the complaint need not "exclude all possibility of honesty in order to give the particulars of fraud." *Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009).

Roche characterizes the arrangement relator calls "debt forgiveness" as simply a routine, arms-length compromise involving a disputed contractual obligation and argues that it does not amount to "remuneration" under the AKS. This argument

is unavailing because the AKS defines "remuneration" broadly to include "anything of value." *United States v. Omnicare, Inc.*, No. 07 C 05777, 2013 WL 3819671, at *15-17 (N.D. Ill. July 23, 2013); *Klaczak*, 458 F. Supp. 2d at 678. It includes things of value such as rebates, payments disguised as rent or consulting fees, facility time, or waived insurance deductibles. See, e.g., *United States v. Adam*, 70 F.3d 776, 778 (4th Cir. 1995) (rent); *United States v. Ruttenberg*, 625 F.2d 173, 174 (7th Cir. 1980) (consulting fees); *United States ex rel. Fry v. Health Alliance of Greater Cincinnati*, No. 1:03-cv-00167, 2008 WL 5282139, at *7 (S.D. Ohio Dec. 18, 2008) (physician time); 61 Fed. Reg. 2122, 2124 (Jan. 25, 1996) (insurance deductibles and copayments). Even assuming the transfer of value had a legitimate business purpose, it may nevertheless have amounted to illegal remuneration for AKS purposes if one reason for it was to "compensate[] past or induce[] future referrals." *United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011). Roche's alleged acceptance of an amount less than Humana's debt to it plausibly amounts to "remuneration" for purposes of the AKS. See *United States ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-CV-3396, 2015 WL 5178074, at *13 (S.D. Tex. Sept. 3, 2015) ("The forgiveness of debt owed for services previously rendered can constitute 'remuneration' for the purposes of the AKS."); *United States ex rel. Fontanive v. Caris Life Sciences, Inc.*, No. 3:130-cv-02237-

P, 2013 WL 11579021, at *9-11 (N.D. Tex. Oct. 23, 2013) (alleged client billing waivers were a form of remuneration); *United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, No. 2:08-CV-00114, 2012 WL 628515, at *7 (S.D. Ohio Feb. 27, 2012) (forgoing collection of outstanding client bills can constitute remuneration). That defendants had not agreed about the precise amount of Roche's overpayment before settling the debt for a lesser amount does not compel a contrary conclusion.

Finally, Humana complains that relator's fraud-based claims suffer from "group pleading" that fails to attribute adequately specific conduct to each defendant. Humana is correct that allegations of fraud that "lump[] together" multiple defendants generally do not survive Rule 9(b). *Rocha v. Rudd*, 826 F.3d 905, 911 (7th Cir. 2016). But "a plaintiff need not individualize the role of multiple defendants when the necessary information is 'uniquely within the defendant's knowledge.'" *Levine v. Prudential Bache Properties, Inc.*, 855 F. Supp. 924, 930 (N.D. Ill. 1994) (quoting *Vicom, Inc. v. Harbridge Merch. Servs. Inc.*, 20 F.3d 771, 778, n. 5 (7th Cir. 1994)). As noted above, relator would not be expected to know the particulars of Humana's internal operations.³ The critical question is whether her

³ Relator was presumably better positioned to know which of the Roche entities was responsible for which aspects of the scheme she alleges, but the Roche defendants do not complain that they

allegations are sufficient to "inform each defendant of the nature of his alleged participation in the fraud." *Clay Fin. LLC v. Mandell*, No. 16 C 11571, 2017 WL 3581142, at *7 (N.D. Ill. Aug. 18, 2017) (quoting *Vicom*, 20 F.3d at 777-78). Here, relator identifies by name the individuals she claims participated in the allegedly unlawful agreement, and she describes the role of each. Humana needs no more to understand the nature of its alleged participation in the scheme.

Nor am I persuaded that dismissal of relator's fraud-based claims is appropriate on the ground that defendants' conduct falls within the AKS's managed care safe harbor at 42 C.F.R. § 1001.952(t)(1)(i). "Safe-harbor provisions are an affirmative defense that must be proven by the Defendant." *United States v. George*, 171 F. Supp. 3d 810, 818 (N.D. Ill. 2016). Roche attaches to its motion agreements that, in its view, establish as a matter of law that the requirements for application of the safe harbor are satisfied. These materials are not appropriately considered at this juncture. See *Geinosky v. City of Chicago*, 675 F.3d 743, 745 n.1 (7th Cir. 2012). While the attached documents may indeed be central to defendants' affirmative defense, they are not "critical" to relator's claims. *Id.* Accordingly, the general rule obtains: if a party seeking

lack notice of which entity allegedly engaged in the unlawful conduct she describes.

dismissal relies on materials outside of the complaint, the motion must be converted to one for summary judgment. *Id.* Because the complaint itself does not unambiguously establish all of the elements required for the safe harbor to apply, dismissal is not appropriate on that basis.⁴

Both defendants also seek dismissal of relator's retaliation claim. Although relator claims to have been employed only by Roche, the complaint alleges that "Defendants" harassed and discharged her in "retaliation for her questioning of the lawfulness" of their business dealings. SAC ¶ 107. Relator offers no response to the Humana defendants' argument for dismissal of this claim as to them, which indeed appears to be appropriate. The claim may proceed, however, against Roche.

The FCA's anti-retaliation provision authorizes relief for any employee who is:

⁴ The managed care safe harbor excepts from the definition of "remuneration" in the AKS any payment between "an eligible managed care organization ["MCO"] and any first tier contractor ["FTC"] for providing or arranging for items of services," as long as three requirements are met. First, the MCO and FTC must have a written and signed agreement that spans at least a one-year term, that specifies the items and services covered, and that prohibits the FTC from claiming payment from any Federal health care programs for the items and services covered by the agreement. Second, neither party may give or receive remuneration in exchange for or to induce any other federally funded business not covered by the agreement. Finally, neither the MCO nor the FTC may shift financial burdens under the agreement to any federal health care program. 42 C.F.R. § 1001.952(t)(1)(i).

discharged...[or] harassed because of lawful acts done by the employee...in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

31 U.S.C. 3730(h)(1). Roche seeks dismissal on the ground that the allegations do not plausibly suggest that relator engaged in protected conduct. The Seventh Circuit has observed, however, that as amended in 2009, § 3730(h)(1) protects two categories of conduct: (1) acts taken "in furtherance of an [FCA] action," and (2) "other efforts to stop" FCA violations, "such as reporting suspected conduct to internal supervisors." *Halasa v. ITT Educ. Servs., Inc.*, 690 F.3d 844, 847-48 (7th Cir. 2012). Relator alleges that she engaged in the latter category of protected conduct when she told her supervisors that she was concerned that the transaction defendants were contemplating would violate AKS, and when she "repeatedly raised concerns with her contract support team" regarding "the lawfulness of Roche's seeking recovery of only a portion of Humana's debt in exchange" for a new agreement. SAC ¶¶ 67-68, 79.

Roche contends that relator's internal reports were unprotected because she could not have *reasonably* believed that Roche was committing fraud against the government, even if she *actually* believed it was. The reasonableness of relator's belief depends on the facts known to her at the time that she expressed her concerns to her supervisors. See *United States ex rel. Uhlig*

v. Fluor Corp., 839 F.3d 628, 635 (7th Cir. 2016). Relator alleges that when she disclosed her concerns about contravening the AKS, she knew that the parties were contemplating settling the rebate debt owed to Roche for a below-value sum, without involving any auditors, in exchange for securing Roche's placement on Humana's Medicare and commercial formularies. See SAC ¶¶ 57-59, 64, 67-68, 79. Because debt forgiveness can constitute illegal remuneration, see *Ruscher*, 2015 WL 5178074, at *13, and because giving remuneration in exchange for recommending purchasing of items with federal healthcare program money is prohibited, 42 U.S.C. § 1320a-7b(b)(2), relator had a reasonable basis to believe that the proposed transaction could violate the AKS when she allegedly reported her concerns. And because claims that result from AKS violations may also violate the FCA, 42 U.S.C. § 1320a-7b(g), a reasonable person in relator's position could have believed that Humana and Roche were defrauding the government with this arrangement.

Roche further argues that the FCA's retaliation protections are unavailable to relator because she never provided the employer with "specific, factual allegations of fraud being committed against the government." But neither the statute nor case law suggests that a relator is required to meet Rule 9(b)'s particularity standard when reporting suspected fraud to his or her employer. The statute protects "efforts to stop" FCA

violations, including the internal reporting of misconduct that the reporting employee reasonably and in good faith believes to have occurred. See *Uhlig*, 839 F.3d at 635. If Roche's proposed standard were correct, a relator would need to be an FCA expert to report suspected fraud internally, which clearly is not the Act's objective.

III.

For the foregoing reasons, defendants' motions to dismiss are denied, except that Humana's motion to dismiss Count IV is granted. Relator's motion to strike is denied as unnecessary.

ENTER ORDER:



Elaine E. Bucklo
United States District Judge

Dated: June 7, 2018