UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 11-12131-RWZ

UNITED STATES OF AMERICA
and THE STATE OF CALIFORNIA,
ex rel. KIMBERLEY HERMAN, *et al.*

v.

COLOPLAST CORP, *et al.*

OPINION and ORDER

August 24, 2016

ZOBEL, J.

In its July 29, 2016 Opinion and Order (Docker # 162), the court allowed CCS Medical, Inc.'s motion to dismiss relators' False Claims Act (FCA), 31 U.S.C. §§ 3129 et seq. (2012), allegations predicated on violations of the federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b) (2012). Relators have moved for reconsideration (Docket # 166), and the United States—which, although it has not intervened in relators' claims against CCS, remains a real party in interest to those claims—has filed a statement of interest generally supportive of relators' arguments (Docket # 170). Both relators' motion and the United States' statement of interest argue persuasively that the Opinion misconstrued the AKS, and relators' motion is thus allowed.

I. Background

Relators' Third Amended Complaint (Docket # 121) alleges that CCS, a Medicare-licensed DMEPOS[1] supplier, accepted kickbacks from Coloplast Corp., a manufacturer of continence care products, in exchange for performing various services designed to boost Coloplast's market share. According to the complaint, CCS agreed to promote Coloplast products at the expense of that company's competitors, both by encouraging new patients to purchase from Coloplast and by converting existing patients from competitors' products to Coloplast's.

CCS moved to dismiss these allegations (Docket # 139), arguing that the discount scheme described in that complaint fell within the safe harbors to the AKS. This court allowed that motion, and relators now urge the court to reconsider.

II. Standard

Motions for reconsideration permit courts to correct "manifest errors of law or fact." Standard Qumica de Venez. V. Cent. Hispano Int'l, Inc., 189 F.R.D. 202, 205 (D.P.R. 1999). On reconsideration, however, the court will not consider any argument already rejected, or any theory that could—and should—have been raised earlier. See Nat'l Metal Finishing Co., Inc. v. Barclaysamerican/Commercial, Inc., 899 F.2d 119, 123 (1st Cir. 1990).

III. Discussion

A. The Anti-Kickback Statute

Relators have identified an error sufficient to warrant reconsideration. The Opinion held that relators had effectively pleaded an affirmative defense for CCS: that

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[1] Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.

its arrangement with Coloplast satisfied the AKS's statutory and regulatory discount safe harbors, 42 U.S.C. § 1320a-7b(b)(1)(B) and 42 C.F.R. § 1001.952(h) (2016).[2] Each safe harbor, however, imposes two requirements, and relators' complaint is only consistent with CCS's having met the first of each—that the discount be fixed in writing in advance of the sale. The complaint, however, contains no allegations suggesting that CCS has met the second element of either safe harbor: that the discounts be "appropriately reflected in the costs claimed or charges made" to a federal healthcare program,[3] or that CCS has provided certain information concerning the discounts to a governmental agency pursuant to its request.[4] The dismissal of relators' claims against CCS for failure to state a violation of the AKS was thus a mistake that this order corrects.

B. CCS's Motion to Dismiss

Because the Opinion resolved CCS's motion to dismiss entirely through the question of the AKS, the court turns now to the other argument raised in that motion: that relators have failed to allege an FCA violation against CCS with sufficient particularity. Because relators' complaint alleges a fraudulent scheme, it "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). This "heightened pleading requirement[]" applies to each of relators' three counts: the submission of false claims, the making or using of false record or statements material to false claims, and an FCA conspiracy. See United States ex rel. Gagne v. City of

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2 The Opinion did not hold that relators bore the burden of pleading around the safe harbors. Both are affirmative defenses on which CCS would bear the burden of proof at trial, and it does not fall on realtors to plead that an affirmative defense does not apply.

3 42 U.S.C. § 1320a-7b(b)(1)(B).

4 42 C.F.R. § 1001.952(h)(1)(iii)(B).

Worcester, 565 F.3d 40, 45 (1st Cir. 2009). All reasonable inferences will be drawn, as they must, in relators' favor. Aldridge v. A.T. Cross Corp., 284 F.3d 72, 78 (1st Cir. 2002).

1. Count I: 31 U.S.C § 3729(a)(1)(A)

As to relators' first count against CCS, the FCA prohibits the "knowing present[ation of] . . . a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Relators have alleged that CCS directly submitted false claims to the government; Rule 9(b) thus requires that they "provide details identifying particular false claims submitted, including who filed the claims, the content of the claims, when the claims were submitted, where such claims were submitted, and how much [the claims] sought in payment." United States ex rel. Nowak v. Medtronic, Inc., 806 F. Supp. 2d 310, 352 (D. Mass. 2011).

Relators contend that they have met this burden with Exhibit 6 to their Third Amended Complaint. This exhibit contains a host of information concerning thirty-one claims submitted to Medicare: it lists the submission and processing date for the claim, the amount paid by the government, the submitting provider's National Provider Identifier (NPI) code, and generic codes and descriptions concerning the billed-for products. As a general matter, such an abundance of information amply satisfies Rule 9(b)'s particularity requirements. See United States ex rel. Ge v. Takeda Pharm. Co. Ltd., 737 F.3d 116, 123 (1st Cir. 2013). Relators, however, face a problem: none of the three NPI codes listed in Exhibit 6 belongs to CCS. Querying these NPI codes against the Centers for Medicare and Medicaid Services' (CMS) NPI database[5] yields two

[5] Available at https://npiregistry.cms.hhs.gov/.

different providers: one NPI code belongs to MP Totalcare Medical, Inc., one to a Florida address of DEGC Enterprises (U.S.), Inc., and one to a California address DEGC. Neither company is a defendant in this case, and nothing in the operative complaint—or any exhibit thereto—links them to CCS. Relators urge the court simply to ignore this, and argue that the source of Exhibit 6—CMS, acting through the United States Attorney's Office—undoes whatever troubles plague that exhibit's data. The court declines this invitation: while the FCA bestows upon the federal government unique powers given its unique role within that statute,[6] relators may not, by suggestion of the government's imprimatur, negate facts that ostensibly contradict their theory of liability. Their allegations, however, are saved by the public record, of which the court may take judicial notice. In re Colonial Mortg. Bankers Corp., 324 F.3d 12, 16 (1st Cir. 2003). Although the record of this case fails to tie CCS to either MP Totalcare or to DEGC, the public record does so amply. See, e.g., Press Release, Warburg Pincus, CCS Medical and MP TotalCare Merge (Oct. 3, 2005);[7] Degc Enterprises Us Inc. Company Profile, Bloomberg.[8]

CCS further argues, unavailingly, that Exhibit 6 suffers from two additional deficiencies. First, the company notes that while Exhibit 6 lists product codes for each of the claims submitted, that code does not identify the product's manufacturer. This is a gap in relators' pleading readily filled by the sort of reasonable inference to which they

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6 E.g., 31 U.S.C. § 3730(e)(4)(A) (2012) (court may not dismiss any action pursuant to the public disclosure bar if opposed by the government).

7 Available at http://www.prnewswire.com/news-releases/ccs-medical-and-mp-totalcare-merge-54879527.html.

8 Available at http://www.bloomberg.com/profiles/companies/3340017Z:US-degc-enterprises-us-inc.

are entitled at this stage of the litigation, as the codes listed are consistent with Coloplast products. Second, CCS contends that Exhibit 6 is insufficiently particular given its failure to indicate whether the claims stemmed from CCS's inducement or conversion of patients to buy Coloplast. This misapprehends the interplay between the AKS, the FCA, and Rule 9(b). Relators have alleged that CCS purchased from Coloplast pursuant to an agreement that violates the AKS: lower prices for promotional services. Such an agreement taints all claims for payment submitted by CCS to federal healthcare programs for Coloplast products while in effect. Relators, therefore, need not plead that any individual claim resulted from the performance of those promotional services to plead their FCA claim with the requisite particularity: the fact of the agreement, not CCS's performance, renders the company's claims for payment false.

2. Count II: 31 U.S.C § 3729(a)(1)(B)

Relators' second count against CCS alleges that that the company "knowingly ma[de] . . . a false record or statement material to a false or fraudulent claim" in violation of 31 U.S.C. § 3729(a)(1)(B). For such allegations to satisfy Rule 9(b), they must allege particular false statements made by CCS material to the government's decision to pay. See United States ex rel. Worsfold v. Pfizer Inc., No. 09-cv-11522, 2013 WL 6195790, *8–9 (D. Mass. Nov. 22, 2013).

The aforementioned difficulties concerning Exhibit 6 likewise affect this count, though the public record again rehabilitates it. As a matter of law, Rule 9(b) does not require relators to point to any particular claim for payment to adequately plead a violation of Section (a)(1)(B)—it merely requires them to identify a particular false statement made by the defendant. See id. In this case, however, relators have based their Section (a)(1)(B) allegations entirely on false statements of compliance made by

CCS on the claim forms themselves, but have only provided evidence of such forms submitted by MP Totalcare and DEGC—not CCS. As discussed above, however, the public record links both providers to CCS; this grounds the reasonable inference that statements made on the claim form are attributable to CCS.

3. Count III: 31 U.S.C § 3729(a)(1)(C)

For their final count against CCS, relators allege a conspiracy to violate the FCA by way of a kickback scheme with Coloplast. The FCA explicitly prohibits conspiracies to violate any of its provisions. 37 U.S.C. § 3729(a)(1)(C). To adequately plead an FCA conspiracy under Rule 9(b), a relator must plead, first, the existence of a conspiracy between the defendant and another person, and second, an act to effect the conspiracy's purpose by at least one of the purported conspirators. See United States v. President & Fellows of Harvard Coll., 323 F. Supp. 2d 151, 196 (D. Mass. 2004).

Relators' Third Amended Complaint, and the attachments thereto, adequately plead both elements of an FCA conspiracy. At Exhibit 5, relators have provided emails between Coloplast and CCS executives negotiating the discounts at the heart of their allegations. These emails ground the reasonable inference of an agreement between the two companies. Such an agreement, on its face, runs afoul of the AKS. The complaint further notes that CCS had enrolled in Medicare as a DMEPOS supplier. Taken together, this supports the conclusion that CCS and Coloplast had agreed to a kickback scheme that would taint each claim CCS submitted for Coloplast products, and that CCS would submit at least some of these claims to Medicare. Submitting kickback-tainted claims to Medicare violates the FCA. Relators have likewise identified acts in furtherance of this conspiracy in the form of the aforementioned Exhibit 6, which

identifies claims actually submitted to Medicare while the agreement between CCS and Coloplast was in effect.

IV. Conclusion

Relators' Motion for Reconsideration (Docket # 166) is ALLOWED, and CCS's Motion to Dismiss (Docket # 139) is, on reconsideration, DENIED.

August 24, 2016
DATE

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