United States District Court
District of Massachusetts

United States of America, ex rel. Michael Mullen,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 19-12488-NMG**
Cardinal Health, Inc. et al.,	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

Michael Mullen ("Relator"), a former executive of Cardinal Health, Inc. ("Cardinal Health"), brought this action pursuant to the qui tam provisions of the federal False Claims Act, 31 U.S.C. § 3729 et seq. ("the FCA") with two other Cardinal Health executives on behalf of the United States and certain states against Cardinal Health and several physician practices.

Five of those physician practices, Birmingham Hematology and Oncology Associates, LLC; Oncology Specialties, PC; Dayton Physicians, LLC; Northwest Medical Specialties, PLLC and Health First Medical Group, LLC (collectively, "the practice defendants") now seek to dismiss this action for failure to state a claim upon which relief can be granted. For the following reasons, their motions to dismiss will be allowed.

I. Background

Plaintiff-Relator Mullen was employed by Cardinal Health, a drug wholesaler and medical supplier, from 2014 to 2018. Mullen was Senior Vice President and General Manager of the Cardinal Health Specialty Solutions Group ("CHSS"), a subsidiary of Cardinal Health, and the CHSS Group Provider Solutions Business Unit. In that role, he oversaw the operations of Cardinal Health's Specialty Pharmaceutical Distribution ("SPD") and VitalSource GPO, through which Cardinal sold and distributed specialty pharmaceuticals.

Cardinal Health sold and distributed those specialty pharmaceuticals to the practice defendants which are community oncology and urology physician practices (i.e. individual physicians associated with each other and organized for the purpose of practicing medicine). Relator alleges, based on his first-hand knowledge, that Cardinal Health offered, and the practice defendants accepted, "kickbacks" in the form of upfront payments in advance of any drug purchases to induce the practice defendants to enter into exclusive distribution deals with Cardinal Health. Relator contends that the practice defendants accepted millions of dollars in illegal kickbacks and billed over one billion dollars in kickback-tainted claims to government health care programs, including Medicare and

Medicaid. According to Mullen, the scheme enabled Cardinal Health to increase its sales of specialty pharmaceuticals from less than $400 million to nearly four billion dollars between 2012 and 2018.

In October, 2018, Omni Healthcare, Inc., a community oncology practice in Florida, filed a qui tam FCA suit in this Court against Cardinal Health, Inc., Cardinal Health 108, LLC and Cardinal Health 118, LLC d/b/a VitalSource GPO. See Complaint, U.S. ex rel. Omni Healthcare v. Cardinal Health, Inc., No. 18-cv-12039 (D. Mass. Oct. 2, 2018) ("the Omni complaint"). Omni alleged it was offered an upfront payment by Cardinal Health to enter into an exclusive supply agreement in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("the AKS") and the FCA, and that Omni accepted the payment and contracted with Cardinal Health.

One year later, in December, 2019, Mullen and his two co-relators filed a qui tam complaint, this action, alleging the same fraudulent scheme. In January, 2022, the United States ("the government") elected to intervene in both actions for settlement purposes as to Cardinal Health only.

Following the government's intervention, it settled the upfront payment claims with Cardinal Health for over 13 million dollars ("the Settlement"). Omni Healthcare, as first-filed

relator, received a relator's share of $2,467,500. In turn, Omni Healthcare agreed to pay an undisclosed amount to Mullen and his two co-relators. After the Settlement, Omni Healthcare and the two co-relators dismissed their remaining claims against all defendants with prejudice.

Mullen subsequently filed an amended complaint in July, 2022 in which he maintained only the claims alleging that the practice defendants solicited or accepted kickbacks. Several named practice defendants reached settlements with the federal and relevant state governments. Five practice defendants, however, moved to dismiss the amended complaint.

II. Motion to Dismiss

A. Legal Standard

To survive a motion under Fed. R. Civ. P. 12(b)(6), the subject pleading must contain sufficient factual matter to state a claim for relief that is actionable as a matter of law and "plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible if, after accepting as true all non-conclusory factual allegations, the court can draw the reasonable inference that the defendant is liable for the misconduct alleged. Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 12 (1st Cir. 2011).

When rendering that determination, a court may not look beyond the facts alleged in the complaint, documents incorporated by reference therein and facts susceptible to judicial notice. Haley v. City of Boston, 657 F.3d 39, 46 (1st Cir. 2011). A court also may not disregard properly pled factual allegations even if actual proof of those facts is improbable. Ocasio-Hernandez, 640 F.3d at 12. Rather, the relevant inquiry focuses on the reasonableness of the inference of liability that the plaintiff is asking the court to draw. Id. at 13.

A claim sounding in fraud, such as a violation of the False Claims Act, as alleged here, must also comply with Fed. R. Civ. P. 9(b) which requires a party to state "with particularity the circumstances constituting fraud". Fed. R. Civ. P. 9(b); U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 228 (1st Cir. 2004) ("Rule 9(b) applies to claims under the FCA."). To meet those requirements, a plaintiff

> must specify the time, place, and content of an alleged false representation sufficiently to put defendants on notice and enable them to prepare meaningful responses.

OrbusNeich Med. Co. v. Boston Sci. Corp., 694 F. Supp. 2d 106, 118 (D. Mass. 2010). That standard is satisfied when a plaintiff avers with particularity the "who, what, where and when of the allegedly false or fraudulent representation" but

other elements, such as intent and knowledge may be pled in general terms. Rodi v. S. New England Sch. Of L., 389 F.3d 5, 15 (1st Cir. 2004).

B. Application

The practice defendants move to dismiss Relator's amended complaint on the grounds that the amended complaint: 1) violates the "first-to-file" and "government action" prohibitions on qui tam suits under the FCA, 2) fails to plead that any of the practice defendants had the requisite scienter to violate the AKS, 3) fails plausibly to allege that any defendant had an obligation to make repayment to the government that would constitute a "reverse false claim" and 4) fails to plead facts supporting a conspiracy.

Because the Court finds that Relator's amended complaint violates the FCA's first-to-file bar, it will not address defendants' other arguments.

The FCA first-to-file rule prevents any "person other than the Government" from "bring[ing] a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The First Circuit has interpreted 31 U.S.C. § 3730(b)(5) to bar

> a later-filed related action, that alleges "all the essential facts" or "the same elements of a fraud described" in an earlier-filed complaint while that complaint is still pending.

U.S. ex. rel. Kelly v. Novartis Pharms. Corp., 827 F.3d 5, 11 (1st Cir. 2016) (quoting U.S. ex rel. Wilson v. Bristol-Myers Squibb, Inc., 750 F.3d 111, 117 (1st Cir. 2014)). This judicially created test adopted by the First Circuit is known as the "essential facts" or "material elements" test. Wilson, 750 F.3d at 117. The goal of the first-to-file rule is

> [to] provide incentives to relators to promptly alert the government to the essential facts of a fraudulent scheme.

Id. (quoting U.S. ex rel. Duxbury v. Ortho Biotech Prod., L.P., 579 F.3d 13, 24 (1st Cir. 2009)).

As an initial matter, Relator filed his complaint ("the Mullen complaint") in December, 2019 while the Omni Healthcare case was still pending. The Omni complaint was filed in October, 2018 and amended in August, 2020. The Settlement was entered into January, 2022, and the case was dismissed five months later. Because the Omni complaint alleging the same fraudulent scheme was still pending when Mullen filed his complaint, Mullen's complaint is barred by the first-to-file rule. See Kelly, 827 F.3d at 11; U.S. ex rel. Heineman-Guta v. Guidant Corp., 718 F.3d 28, 35–36 (1st Cir. 2013) ("A later-filed complaint that mirrors the essential facts as the pending earlier-filed complaint does nothing to help reduce fraud of which the government is already aware.").

Turning to the crux of the "essential facts" test, an earlier-filed complaint need only provide "the essential facts to give the government sufficient notice to initiate an investigation into allegedly fraudulent practices." Heineman-Guta, 718 F.3d at 36–37. Of significant importance is the fact that, although the relevant statute, 31 U.S.C. § 3730(b)(5), bars later related actions based on the same underlying facts:

> it does not require that the actions be identical for the rule to come into play.

Wilson, 750 F.3d at 118.

The Omni and Mullen complaints proffer very similar underlying facts alleging the same fraudulent scheme. See id. Both complaints state that Cardinal Health controlled a small portion of the specialty pharmaceutical distribution market for physician practices which it sought to penetrate. The complaints suggest that Cardinal Health devised the "pre-bate" scheme to penetrate that market. Both complaints explain that Cardinal Health paid the physician practices before the drugs were purchased and that Cardinal Health required the practices to purchase all (or nearly all) of their pharmaceutical products from Cardinal Health for a specified time, often three years.

Although the Mullen complaint provides additional detail based on his experience supervising the Cardinal Health division that was implicated in the original qui tam suit, both

complaints describe the same fraudulent scheme. The Omni complaint provided the government with the "essential facts" it needed to investigate the allegations against Cardinal Health. See Heineman-Guta, 718 F.3d at 36-37.

Relator asserts that the Omni complaint did not, however, contain all the "essential facts" of the alleged fraudulent scheme. In particular, he avers that the identity of a defendant is a material element of a fraud claim and emphasizes that because the Omni complaint did not name the specific physician practices as defendants, his complaint is not barred by the first-to-file rule.

The Court is underwhelmed by Relator's argument. The First Circuit has held that

> [u]nder this "essential facts" standard, § 3730(b)(5) can still bar a later claim even if that claim incorporates somewhat different details.

U.S. ex rel. Duxbury v. Ortho Biotech Prod., L.P., 579 F.3d 13, 32 (1st Cir. 2009); see also U.S. ex rel. Poteet v. Medtronic, Inc., 552 F.3d 503, 517 (6th Cir. 2009), abrogated on other grounds by U.S. ex rel. Rahimi v. Rite Aid Corp., 3 F.4th 813 (6th Cir. 2021) ("[B]ecause the purpose of the FCA's first-to-file provision is to prevent the filing of more qui tam suits once the government already has been made aware of the potential fraud perpetrated against it, the fact that the later action

names different or additional defendants is not dispositive as long as the two complaints identify the same general fraudulent scheme.").

Moreover, the goal of 31 U.S.C. § 3730(b) is to

> ensure the federal government receives the information it needs to launch a meaningful investigation into fraudulent conduct.

U.S. ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Baxter Healthcare Corp., 772 F.3d 932, 937 (1st Cir. 2014). Here, the Omni complaint provided the government with the necessary information to investigate Cardinal Health's upfront payment scheme. Although the Omni complaint did not name the specific practice defendants in the Settlement, the government listed 38 physician practices that had contracts with Cardinal Health. All five of the practice defendants at issue here were listed in that Settlement. Thus, the Omni complaint contained "genuinely valuable information of sufficiently notice-supplying quality" to enable the government's investigation. Id.

In short, the First Circuit does not read 31 U.S.C. § 3730(b) to allow

> later-filing relators [to] sue merely because they offer additional information that might also help the government carry out its investigation.

Id. That statutory provision prevents Mullen's action from proceeding. His complaint offers only "additional facts and

details about the same scheme" pled in Omni Healthcare's earlier-filed complaint, Heineman-Guta, 718 F.3d at 36, which already provided the government with the "essential facts" of that same scheme. See Ven-A-Care of the Fla. Keys, Inc., 772 F.3d at 944. Therefore, the motions of the practice defendants to dismiss will be allowed.

ORDER

For the foregoing reasons, the motions to dismiss of defendants Health First Medical Group, LLC (Docket No. 122), Birmingham Hematology and Oncology Associates, LLC (Docket No. 126), Northwest Medical Specialties, PLLC (Docket No. 128), Oncology Specialists, PC (Docket No. 130) and Dayton Physicians, LLC (Docket No. 133) are **ALLOWED**. The Practice Defendants' duplicative joint motion to dismiss (Docket No. 125) is also **ALLOWED**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated: September 7, 2023