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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. RELIANCE MEDICAL SYSTEMS,LLC; APEX MEDICAL TECHNOLOGIES, LLC; KRONOS SPINAL TECHNOLOGIES, LLC; BRET BERRY; JOHN HOFFMAN; ADAM PIKE; and ARIA O. SABIT, M.D. , Defendants.	Case No. CV 14-06979 DDP (PJWx) **ORDER DENYING DEFENDANTS' MOTION TO DISMISS CASE** [DKT. NO. 12]

Presently before the Court is Defendants' motion to dismiss the action (the "Motion"). (Docket No. 12.) For the reasons stated in this order, the Motion is DENIED.

I. Background

Plaintiff United States of America ("Plaintiff") brings this action against Reliance Medical Systems, LLC ("Reliance"); Apex Medical Technologies, LLC ("Apex"); Kronos Spinal Technologies, LLC ("Kronos"); Bret Barry ("Barry"); John Hoffman ("Hoffman"); Adam Pike ("Pike"); and Aria O. Sabit, M.D. ("Dr. Sabit") (collectively,

"Defendants") to recover damages and civil penalties under the False Claims Act ("FCA") and related common law claims. (See Complaint, Docket No. 1, ¶ 1.) Plaintiff alleges that Defendants were part of a scheme to knowingly submit fraudulent claims to Medicare. (Id.)

Reliance is a company that sells spinal implants, which are medical devices surgically inserted into patients by doctors during spinal fusion surgeries to help stabilize the spine.[1] (Id. ¶¶ 2, 44.) Reliance operated and controlled multiple distributor companies for their spinal implant products, including Apex and Kronos, that had financial relationships with physician-investors. (Id. ¶¶ 9-13.)

Defendants Berry and Pike are founders and owners of Reliance, and each is an investor in approximately twenty companies that distribute Reliance spinal implants, including Apex and Kronos. (Id. ¶¶ 14, 16.) Defendant Hoffman is a distributor for Reliance and an investor in approximately five companies that distribute Reliance spinal implants, including Apex and Kronos. (Id. ¶ 15.) Defendant Dr. Sabit was an Apex physician-investor from 2010 to 2012. (Id. ¶ 17.)

Plaintiff alleges, essentially, that Berry and Pike offered investment opportunities in Kronos and Apex to physicians who agreed to use Reliance implants in their spinal surgeries. (Id. ¶ 98.) Plaintiff alleges that this arrangement was improper and violated the Anti-Kickback Statute ("AKS"). (Id. ¶ 303.) Plaintiff

[1]Paragraphs 49-58 of the Complaint describe certain types of spinal implant devices and the amount that Reliance charged for those devices.

alleges that physicians who were asked to invest often actually invested very little or no capital and were subject to a "trial period," during which time Apex or Kronos would determine whether the physician was using a high volume of Reliance implants. (Id. ¶¶ 138-155.) If the physician was using a sufficient volume of Reliance implants, the physician was asked to become an "investor" and would be paid a substantial amount in comparison to that physician's smaller capital contribution. (Id. ¶¶ 108-110, 115-119, 223-242.) Plaintiff alleges that this "investment" scheme was really a scheme to pay the physicians for their use of Reliance devices in their surgeries. (Id. ¶¶ 112, 120.) In some instances, physician-investors were pushed out, or their shares "bought out," by Apex or Kronos (or by another physician-investor), allegedly when the original physician was not using a high enough volume of Reliance products. (Id. ¶¶ 156-169.) Plaintiff includes substantial specific factual allegations that illustrate this arrangement and that support its allegation that Berry, Pike, and Hoffman expected physician-investors to meet this "requirement" that they use a high volume of Reliance products.

Plaintiff alleges that Defendants violated the False Claims Act through this scheme, by which they knew that the physician-investors and hospitals would submit false or fraudulent Medicare claims for surgeries performed by the physician-investors. Plaintiff alleges that the Medicare claims were false or fraudulent because the claims were tainted by the kickbacks that the physician-investors received in exchange for their use of Reliance implants. Further, Plaintiff alleges that some of the surgeries performed were not medically necessary or were more extensive than

necessary as result of this scheme, as physician-investors allegedly performed such surgeries to increase their usage of Reliance products (and thereby increase the amount of kickbacks received). Plaintiff alleges that some of the Medicare claims were false or fraudulent for this additional reason. Plaintiff also alleges a conspiracy claim under the False Claims Act, unjust enrichment claims against Berry, Hoffman, Pike, and Dr. Sabit, and a payment by mistake claim against Dr. Sabit. Defendants, with the exception of Dr. Sabit,[2] now move to dismiss all claims. (Docket No. 12.)

II. Legal Standard

A complaint will survive a motion to dismiss when it contains "sufficient factual matter, accepted as true, to state a claim to relief that is 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)). When considering a Rule 12(b)(6) motion, a court must "accept as true all allegations of material fact and must construe those facts in the light most favorable to the plaintiff." Resnick v. Hayes, 213 F.3d 443, 447 (9th Cir. 2000). Although a complaint need not include "detailed factual allegations," it must offer "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Iqbal, 556 U.S. at 678. Conclusory allegations or allegations that are no more than a statement of a legal conclusion "are not entitled to the assumption of truth." Id. at 679. In other words, a pleading that merely offers "labels and conclusions," a "formulaic recitation of the elements," or "naked assertions" will

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[2]Dr. Sabit has not appeared in the action and has not joined the Motion.

not be sufficient to state a claim upon which relief can be granted. Id. at 678 (citations and internal quotation marks omitted).

"When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement of relief." Id. at 679. Plaintiffs must allege "plausible grounds to infer" that their claims rise "above the speculative level." Twombly, 550 U.S. at 555. "Determining whether a complaint states a plausible claim for relief" is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Iqbal, 556 U.S. at 679.

III. Discussion

There appear to be two reasons that Plaintiff contends that the claims submitted for Medicare reimbursement as part of the alleged scheme were false: (1) all of the claims involved unlawful kickbacks, and (2) some of the claims were for procedures or devices that were not medically necessary or were more extensive than necessary.

A. Kickbacks

As to the unlawful kickbacks, Defendants do not directly challenge the sufficiency of these allegations, though they certainly disagree as to what the underlying facts will show after discovery. However, one theme of Defendants' papers is that the overall allegations in Plaintiff's complaint are implausible. As a result, a brief discussion of the law surrounding whether the claims at issue represent "false" claims under the FCA as a result of a violation of the AKS is warranted.

The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits "knowingly and willfully solicit[ing] or receiv[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, ... in cash or in kind" in exchange for referring, or inducing another to refer, an individual to particular goods or services "for which payment may be made in whole or in part under a Federal health care program." Under the False Claims Act, "any person who ... knowingly presents, or causes to be presented, a false or fraudulent claim for payment ... is liable to the United States Government." 31 U.S.C. § 3729(a)(1). Essentially, Plaintiff's claim in this action is that the scheme at issue constituted a violation of the AKS; as a result, the claims for Medicare reimbursement for the medical procedures and equipment resulting from the kickback scheme were "false" claims because the submission of such claims for reimbursement implies compliance with applicable laws, where such compliance is required for payment. See Hanlester Network v. Shalala, 51 F.3d 1390, 1399 (9th Cir. 1995); see also U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 313-14 (3d Cir. 2011); U.S. ex rel. Hutcheson v. Blackstone Medical, Inc., 647 F.3d 377, 389 (1st Cir. 2011).

Under Hanlester, the Ninth Circuit has found a claim of this nature to be viable where it was implied to investors that "eligibility to purchase shares depended on an agreement to refer program-related business;" where prospective investors were told that "the number of shares they would be permitted to purchase ... would depend on the volume of business they referred;" and where "partners who did not refer business would be pressured to leave the partnerships." Hanlester, 51 F.3d at 1399. However, mere

"encourage[ment]" of physician-investors to refer business, along with telling the investors that the "success of the limited partnerships depended on referrals from the limited partners," is not enough to establish a FCA claim under these circumstances. Id. A high volume of referrals, or a large return on investment, similarly are not enough. Id. Further, in order to prove a violation of the AKS, the conduct must have been knowing and willful. Id.

Plaintiff's allegations in this case are sufficient to support a plausible inference that the scheme at issue here crosses the line articulated in Hanlester. Plaintiff does not merely allege that Defendants "encouraged" the physician-investors to use Reliance products in their surgeries, but also includes facts that strongly suggest that Apex and Kronos would not even consider offering a physician an interest in the company until the company could verify that the physician performed substantial surgeries using Reliance products. Further, Plaintiff alleges that some of the physicians invested almost no capital. There are also facts suggesting that physician-investors who continued to use a high volume of Reliance products began receiving higher payments from Apex and Kronos, while physician-investors who performed fewer surgeries or did not otherwise meet the "expectations" of Reliance were bought out of their investment. It is also plausible to infer from the alleged facts that Berry, Pike, and Hoffman knew that, as a result of their inducements of the physician-investors, false claims would be submitted; indeed, the complaint includes facts suggesting that Defendants ignored legal advice that specifically informed them that such a scheme would be a problem under existing

law. (Complaint ¶¶ 179-202.) Therefore, as a general matter, Plaintiff has alleged sufficient facts to survive the Motion.

Defendants bring up two specific arguments regarding the alleged violations of the AKS. First, Defendants argue that none of the claims submitted prior to March 23, 2010 may be deemed to be false under the Ninth Circuit law prior to that date. Second, Defendants argue that all claims submitted on or after that date may only be found to be false as to the hospital bills, which include payments for medical devices, but not on the physician bills, which presumably bill only for physician labor or services.

On March 23, 2010, Congress amended the AKS to include the following: "in addition to the penalties provided under [the AKS], a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). Defendants argue that until this amendment was made, if a hospital submitted claims that it had no reason to believe were false, those claims cannot be considered to be "false claims" under the FCA. Plaintiff contends that the amendment was merely a clarification of the existing law such that the amendment has retroactive effect. The question, then, is whether, prior to the March 23, 2010 amendment, a hospital submitting a Medicare claim that resulted from a violation of the AKS would have to know about the kickbacks in order for the claim to constitute a violation of the FCA.

Prior to this amendment, other circuits were already following the approach announced by the amendment. The Ninth Circuit joined these other circuits in recognizing the viability of an "implied false certification" theory, whereby the submission of a claim

impliedly certifies that the claim complies with all express requirements for payment under the applicable federal law. See Ebeid ex rel. U.S. v. Lungwitz, 616 F.3d 993, 996-97 (9th Cir. 2010). In Ebeid, the Ninth Circuit cited the standard articulated by the Second Circuit in Mikes v. Straus, whereby "a claim under the [FCA] is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment." 274 F.3d 687, 697 (2d Cir. 2001). Further, Mikes holds that "[l]iability under the [FCA] may properly be found therefore when a defendant submits a claim for reimbursement while knowing ... that payment expressly is precluded because of some noncompliance by the defendant." Id. However, it does not appear that this logic is inconsistent with allowing Plaintiff's claims to proceed here. Though the hospital did not have knowledge that the claims were false when it submitted them, Plaintiff's theory is that Defendants *caused* the hospital to submit false claims that the Defendants *knew* were false because of violations of the AKS.

Defendants further argue that even after March 23, 2010, the only bills that may be considered violations of the FCA are hospital bills, which include billing for surgical devices, but not the physicians' bills for services. This argument is unavailing. The use of a particular device, and the need for reimbursement for the cost of the device itself, does not occur in a vacuum. A physician must perform a surgery during which the device is implanted in a patient. The AKS plainly states that "a claim that includes items *or services* resulting from a violation ... constitutes a false or fraudulent claim." 42 U.S.C. § 1320a-7b(g) (emphasis added). This makes sense; without a qualified physician

willing and able to perform the surgery to implant a Reliance device, there is no need for the device. Thus, the physician's services are themselves an integral part of the alleged scheme at issue here, and claims for reimbursement for physician services stemming from the scheme constitute false claims to the same extent that claims for reimbursement for the implants do. Therefore, the Court DENIES the Motion as to Plaintiff's claims based on violations of the AKS.

B. Medically Unnecessary Procedures

Defendants also argue that Plaintiff has not sufficiently alleged FCA claims based on the performance of medically unnecessary (or more extensive than necessary) surgeries using Reliance devices. As Plaintiff points out in its opposition, this is an alternative basis for establishing the fraudulent nature of a subset of the claims at issue in this case. Plaintiff alleges that all claims submitted as part of the alleged scheme were false due to the kickbacks, but that some of the claims are false for the additional reason that the procedures for which reimbursement was sought were not medically necessary.

Plaintiff includes sufficient details regarding five specific procedures to plausibly establish that some of the medical procedures performed as part of the alleged scheme were medically unnecessary. (See Complaint, ¶¶ 251-301.) As to Dr. Sabit, who allegedly performed three of the five "example" procedures, it is clear that Plaintiff has stated a claim, since it would be highly plausible that Dr. Sabit, as a medical professional, would have known that the procedures were unnecessary (or more extensive than necessary) and therefore known that false claims would be submitted

regarding those surgeries. Whether the surgeries were in fact medically unnecessary is not an issue that may be resolved at this time.

As to the moving Defendants (those other than Dr. Sabit), the requisite knowledge is less clear, but the Court finds that the pleadings plausibly establish that Berry, Pike, and Hoffman may have known that their scheme would induce physicians to perform more surgeries than necessary in order to satisfy the quotas expected of them. (See Complaint ¶ 173.) Generally, a defendant may be held liable for causing another to submit a false claim where the submission of such claim was "reasonably foreseeable." See U.S. ex rel. Cantekin v. Univ. of Pittsburgh, 192 F.3d 402, 415-16 (3d Cir. 1999). If Plaintiff is successful in proving that the physician-investors received unlawful kickbacks for their use of Reliance devices, it is plausible to infer that Defendants knew that the physicians would do whatever it took to continue receiving such large kickbacks, including performing unnecessary or more extensive than necessary surgeries. Therefore, the Court DENIES the Motion as to this alternative theory of liability.

IV. Conclusion

For the foregoing reasons, the Motion is DENIED.

IT IS SO ORDERED.

Dated: November 5, 2014

DEAN D. PREGERSON
United States District Judge