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9	UNITED STATES DISTRICT COURT	
10	SOUTHERN DISTRICT OF CALIFORNIA	
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12	UNITED STATES OF AMERICA, et	Case No.: 3:20-cv-286-W (AGS)
13	al.; ex rel. EVEREST PRINCIPALS, LLC,	ORDER GRANTING IN PART AND
14	Plaintiffs and Relator	DENYING IN PART DEFENDANTS'
15	V.	MOTION TO DISMISS RELATOR'S FIRST AMENDED COMPLAINT
16	ABBOTT LABORATORIES, INC.	WITH LEAVE TO AMEND [DOC.
17	a/k/a ABBOTT LABORATORIES,	45]
18	ABBOTT CARDIOVASCULAR SYSTEMS INC., and ABBOTT	
19	VASCULAR INC.,	
20	Defendants	5.
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22	Pending before the Court is Defendants Abbott Laboratories, Inc. a/k/a Abbott	
23	Laboratories, Abbott Cardiovascular Systems Inc., and Abbott Vascular Inc.'s	
24	(collectively, "Abbott" or "Defendants") Motion to Dismiss Plaintiff and Relator Everest	
25	Principals, LLC's <sup>1</sup> ("Plaintiff" or "Relator") First Amended Complaint for failure to state	
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27	e e	ed States of America, the District of Columbia, and the

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<sup>28 ||</sup> following 27 states: California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New

a claim under Federal Rule of Civil Procedure 12(b)(6). (*Mot.* [Doc. 45].) Relator opposes the Motion. (*Opp'n* [Doc. 48].) The Court decides the matter on the papers submitted and without oral argument. See Civ. L.R. 7.1(d)(1).

For the reasons stated below, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' Motion to Dismiss **WITH LEAVE TO AMEND**. [Doc. 45]. Specifically, the Court **DENIES** Defendants' Motion to Dismiss as to Relator's Federal False Claims Act Claims (Counts 1-3) and **GRANTS** Defendants' Motion to Dismiss as to Relator's State False Claims Act claims (Counts 4-31) **WITH LEAVE TO AMEND**.

# I. <u>BACKGROUND</u>

Plaintiff and Relator Everest Principals, LLC is a "single member Delaware
limited liability corporation whose sole member was employed by Abbott from August
2015 to April 2017 as a Therapy Development Specialist in its Structural Heart
Division." (*First Amended Compl.* ("*FAC*") [Doc. 35] ¶ 5.) Defendant Abbott
Laboratories is a publicly traded, global healthcare company that owns the patent for
MitraClip (or "MC Device")—a medical device used on certain cardiac patients. (*Id.* ¶¶
2, 6.) Defendant Abbott Laboratories, Inc. is allegedly the parent company of Defendants
Abbott Cardiovascular Systems Inc., and Abbott Vascular Inc. (*Id.* ¶¶ 6-9.)

Relator brings this action against Abbott pursuant to the *qui tam* provisions of the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, and applicable analogue state laws. (FAC ¶ 1.) Relator alleges that "Abbott devised and conducted illicit schemes whereby it paid kickbacks in the form of cash, and cash equivalents, including patient referrals, lavish meals, free marketing and patient practice-building support to healthcare providers, including physicians and hospitals, with the specific intent of inducing these healthcare providers to

Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Washington. The federal government and these 27 states declined to intervene in this case. (*Mot.* at 2; Doc. 8.)

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perform the [Transcatheter Mitral Valve Repair, or "TMVR"] procedure using Abbott's
[MitraClip] on their cardiac patients covered by Government Healthcare Programs." (*Id.*¶ 57.) According to Relator, through these alleged illicit schemes, "Abbott has caused the submission of thousands of false claims to Medicare, Medicaid, TRICARE, the Veterans Administration healthcare program, and other state and federally funded healthcare programs in violation of the AKS, the FCA, and analogous state laws." (*Id.*)

7 Relator alleges that the "central aspect" of Abbott's kickback scheme "involves 8 remuneration to implanting physicians and hospitals in the form of patient referrals and 9 patient practice building." (FAC  $\P$  66.) Abbott allegedly targets physicians who are not certified to implant MitraClip ("non-implanting physicians") and "induces them through 10 11 free luncheons, cocktail parties, and dinner conferences to refer their cardiac patients to Abbott's targeted implanting physicians and hospitals for the TMVR procedure using 12 13 Abbott's [MitraClip] device." (Id.) Abbott also allegedly "targets implanting physicians" 14 and hospitals and provides them with illegal remuneration through, *inter alia*, patient 15 referrals, sham speaker program honoraria, free patient marketing and practice building 16 and promises to participate in future clinical trials, to induce them to use Abbott's [MitraClip] Device for their cardiac patients." (Id.) 17

18 Relator contends that these kickback schemes encompass Abbott's "entire 19 marketing strategy and were developed by management and ratified by the highest levels 20 of the company." (Id. ¶ 67.) Indeed, according to Relator, "Abbott employees are 21 evaluated and rewarded based on the number of referrals they successfully secure for 22 their targeted physicians and the number of [MitraClip] procedures performed by those 23 physicians." (Id.) Relator also alleges that its old manager, Michael Meadors, "constantly pressured" Abbott's sales team to host events with physicians to drive up 24 25 MitraClip implants, and "met with physicians to make Abbott's expectations in exchange 26 for remuneration clear." (Id. ¶ 68.) These events included educational speaker programs 27 and "meals that were primarily social in nature to referring physicians with no legitimate business purpose" and were allegedly organized by Abbott to help build the participating 28

physicians' practices. (Id. ¶ 84, 88, 94.) Abbott allegedly instructed Relator to emphasize to its targeted implanting physicians that "they have an ideal opportunity to build their patient base from Abbott's referral physicians." (Id. ¶ 88.)

#### Allegations Concerning Dr. M.P. Α.

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One of the key physicians Relator was responsible for building a partnership with was Dr. M.P., a "San Diego interventional cardiologist who specializes in structural heart procedures." (Id. ¶ 88.) Relator was allegedly expected to build a partnership with Dr. M.P. through meal events and speaker programs. (Id.) In fact, Relator hosted more than ten "primarily social" meal events for Dr. M.P. and his/her referring physicians from October 2015 to June 2016. (Id. ¶¶ 84, 88.) The alleged goal of these meal events was to help grow Dr. M.P.'s practice area and solicit patient referrals. (Id. ¶ 88.)

For example, in February 2016, Relator hosted a dinner event for Dr. M.P. at 12 13 Fleming's Prime Steakhouse and Wine Bar in Palm Desert, California, with local 14 referring physicians because Dr. M.P. was allegedly interested in growing his practice in 15 that area. (Id.) Likewise, on March 10, 2016, Relator hosted a marketing dinner for Dr. 16 M.P. and Dr. M.M., a patient referring physician. (Id. ¶ 84.) The alleged goal of this meal event was to "funnel" Dr. M.M.'s patients with Mitral Regurgitation ("MR") to Dr. 17 M.P. for the MC Device. (Id.) According to Relator, "this practice building social event 18 19 exceeded Abbott's per person meal spend limit." (Id.) Similarly, on May 24, 2016, 20 Relator arranged a dinner for Dr. M.P. in Temecula, California because Dr. M.P. allegedly wanted to solicit patient referrals in that area. (Id.  $\P$  88.) And on June 6, 2016, Relator arranged a lunch for Dr. M.P. with the Cardiology Specialists Medical Group (CSM), "whom Dr. M.P. specifically requested that Abbott target to refer patients to him." (*Id.*) 24

25 Relator also arranged speaking programs for Dr. M.P. where Abbott allegedly paid 26 Dr. M.P. "generous speaker honorarium" fees and offered him free marketing and 27 advertising to potential referring physicians to help build his patient practice. (*Id.*) 28 Relator's manager, Mr. Meadors, told Dr. M.P. on August 3, 2016, that the doctor's

MitraClip "continues to steadily improve," that "getting to advocacy requires an urgency
 to treat on your part and an urgency to refer from the non-MitraClip implanting
 physicians," and that he looked forward to partnering more closely with him. (*Id.* ¶ 89.)
 According to Relator, Dr. M.P. received approximately \$179,000 in Medicare payments
 for the TMVR procedure from 2016 to 2018.<sup>2</sup> (*Id.* Ex. A.)

# **B.** Allegations Concerning Dr. D.S.

Relator was also responsible for developing a relationship with Dr. D.S., an implanting cardiologist in La Mesa, California. (*Id.* ¶ 109.) Relator alleges that its goal was to help Dr. D.S. build his patient practice by providing free marketing and advertising services. (*Id.*) For instance, on September 30, 2016, Relator (on Abbott's behalf) prepared a sushi cocktail party for Dr. D.S. (*Id.* ¶ 109-110.) According to Relator, "24 of the 70 invitees appear to have been personal guests," of Dr. D.S. in violation of Abbott's Office of Ethics and Compliance ("OEC") guidelines, which prohibit a physician's personal guests from attending these types of events. (*Id.* ¶ 110.) Dr. D.S. also told Relator which physicians to invite. (*Id.*) When Relator informed Meadors that it was having difficulty arranging the event, particularly due to the excessive sushi costs, Meadors allegedly instructed Relator to "manipulate the final receipts by attributing the excessive meal costs to items that were unrelated to food such as equipment rental and set up charges." (*Id.*)

# C. Allegations Concerning Dr. H.N.

Relator also alleges it was responsible for assisting Dr. H.N. (an implanting cardiologist in Arizona) in building his/her patient practice. (*Id.*  $\P$  92.) For example, on January 12, 2016, Relator put together a "lavish dinner event with alcohol" for Dr. H.N. and potential referring physicians at Fleming's Prime Steakhouse and Wine Bar in Chandler, Arizona. (*Id.*  $\P\P$  84, 92.) According to Relator, following this event, Dr, H.N. performed at least eight TMVR procedures in roughly two and a half months. (*Id.*  $\P$  92.)

<sup>&</sup>lt;sup>2</sup> Approximately \$52,000 in 2016; \$54,000 in 2017; and \$72,000 in 2018. (*FAC*, Ex. A.)

In addition, Relator alleges that it arranged a lunch event for Dr. H.N. on March 8, 2016. (*Id.* ¶ 124.) However, Dr. H.N. allegedly told Relator and Abbott that while Abbott may 3 cater the event, he/she does not want Abbott at the actual meeting. (Id.) Instead, Relator 4 only dropped the food off but was not present for the presentation. (Id.) According to Relator, this "dine and dash" program violates the AdvaMed Code of Ethics, which states 6 that a company may not provide meal or refreshments if a company representative is not present during the program. (*Id.*) Relator alleges that Dr. H.N. received approximately \$11,000 in Medicare payments for the TMVR procedure in 2016, \$20,000 in 2017, and \$23,000 in 2018. (FAC, Ex. A.)

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#### The January 2017 TMVR Summit D.

11 Meadors also allegedly instructed Relator to organize Abbott's first Transcatheter Mitral Valve Repair ("TMVR") Summit in January 2017, secure a specific five-star 12 13 luxury resort for the venue, and "characterize any of the costs exceeding the \$125.00 per person limit as a "room charge," as that would not be included in the per person spend 14 calculation and, thus, would not have to be reported by Abbott to CMS [the Centers for 15 Medicare and Medicaid Services]." (Id. ¶ 120.) Because of the excessive costs, Meadors 16 allegedly directed Relator to obtain assistance from a colleague named Oh "who had 17 18 experience with organizing these events and with hiding event excessive spend charges." 19 (*Id.*) Oh, however, told Relator that the invoice numbers were so high, "the overspending so egregious," that Oh "did not have a viable solution to hide it." (Id. ¶ 121.) Oh 20 21 allegedly told Relator that the \$267.63 cost per person was the highest she has ever seen 22 with any hotel. (Id.) So Meadors allegedly told Relator to use its "Abbott credit card to 23 pay the outstanding balance so the payment would not be associated with the event and, 24 thus, would not have to be reported by [Abbott]." (Id.)

25 Further, Relator alleges that Abbott hired several physicians to put on educational 26 presentations for the TMVR Summit. (Id. ¶ 125.) The physicians were allowed to create 27 their own slide decks for the presentations but these slides allegedly "did not go through 28 Abbott's formal vetting process and, thus, were not guaranteed to be of significant

education value nor assigned an approval number." (Id.) Relator alleges that when it 2 sought to get the speaker payment checks approved, Abbott management instructed 3 Relator "in a February 15, 2017 email to simply use a phony Accounts Payable ("AP") number for the slide decks so the speakers could get paid." (Id.) One of these physicians 4 was Dr. R.G., whose presentation allegedly only included "a few, non-educational, and 5 6 non-substantive slides that he prepared himself." (Id.) According to Relator, Dr. R.G. 7 was paid \$2,500 for the presentation "even though his slide deck was marked with a phony AP number." (*Id.*) 8

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The Court must dismiss a cause of action for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of the complaint. Parks Sch. of Bus., Inc. v. Symington, 51 F.3d 1480, 1484 (9th Cir. 1995). A complaint may be dismissed as a matter of law either for lack of a cognizable legal theory or for insufficient facts under a cognizable theory. Balistreri v. Pacifica Police Dep't., 901 F.2d 696, 699 (9th Cir. 1988). In ruling on the motion, a court must "accept all material allegations of fact as true and construe the complaint in a light most favorable to the non-moving party." Vasquez v. L.A. Cnty., 487 F.3d 1246, 1249 (9th Cir. 2007).

Complaints must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The Supreme Court has interpreted this rule to mean that "[f]actual allegations must be enough to rise above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. 554, 555 (2007). The allegations in the complaint must "contain 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) (citing Twombly, 550 U.S. at 570).

Well-pleaded allegations in the complaint are assumed true, but a court is not 27 28 required to accept legal conclusions couched as facts, unwarranted deductions, or

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unreasonable inferences. <u>Papasan v. Allain</u>, 478 U.S. 265, 286 (1986); <u>Sprewell v.</u>
 <u>Golden State Warriors</u>, 266 F.3d 979, 988 (9th Cir. 2001). Leave to amend should be
 freely granted when justice so requires. <u>See Fed. R. Civ. P. 15(a)</u>. However, denial of
 leave to amend is appropriate when such leave would be futile. <u>See Cahill v. Liberty</u>
 <u>Mut. Ins. Co.</u>, 80 F.3d 336, 339 (9th Cir. 1996); <u>Plumeau v. Sch. Dist. No. 40 Cnty. of</u>
 <u>Yamhill</u>, 130 F.3d 432, 439 (9th Cir. 1997).

The Parties agree that the heightened pleading requirements of Rule 9(b) apply to claims brought under the False Claims Act. (*Mot.* at 6; *Opp 'n* at 6.) Rule 9(b) requires that in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. <u>United States ex rel. Solis v. Millennium Pharm.</u>, Inc., 445 F.Supp.3d 786, 794–95 (E.D. Cal. 2020) (citation and quotations omitted). Relators must allege the "who, what, when, where, and how of the misconduct charged." <u>Id.</u> (citation and quotations omitted).

# III. **DISCUSSION**

### A. False Claims Act (FCA) and the Anti-Kickback Statute (AKS)

"The FCA was enacted during the Civil War with the purpose of forfending widespread fraud by government contractors who were submitting inflated invoices and shipping faulty goods to the government." <u>Ebeid ex rel. U.S. v. Lungwitz</u>, 616 F.3d 993, 995 (9th Cir. 2010) (quoting <u>United States ex rel. Hopper v. Anton</u>, 91 F.3d 1261, 1265–66 (9th Cir.1996)). "To encourage insiders to disclose fraud and thereby bolster enforcement, the FCA contains a *qui tam* provision that permits private persons (known as "relators") to bring civil actions on behalf of the United States and claim a portion of any award." <u>Ebeid</u>, 616 F.3d at 995. The FCA imposes liability on anyone who, among other things: "(A) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraphs (A), (B) . . . " 31 U.S.C. § 3729(a)(1).

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To state an FCA claim, a relator must allege with particularity: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." <u>U.S. ex rel.</u> <u>Hendow v. Univ. of Phx.</u>, 461 F.3d 1166, 1174 (9th Cir. 2006).

A claim "resulting from" a violation of the federal Anti-Kickback Statute ("AKS") is a false claim for purposes of the FCA. 42 U.S.C. § 1320a-7b(g). To proceed on such a theory, the relator "must establish a connection between the alleged kickback scheme and actual false claims submitted to the government." <u>U.S. ex rel. Gough v. Eastwestproto, Inc.</u>, 2018 WL 6929332, at \*5 (C.D. Cal. Oct. 24, 2018). Stating an AKS violation, in turn, requires pleading that the defendant (1) "knowingly and willfully" (2) offered or paid remuneration, (3) "to induce" the purchase or ordering of products or items for which payment may be made under a Federal healthcare program. 42 U.S.C. § 1320a-7b(b)(2)(B). The term "remuneration" has been broadly defined by the Courts to mean "anything of value." <u>United States v. Chang</u>, 2017 WL10544289, at \*7 (C.D. Cal. July 25, 2017). Claims resulting from kickbacks are "false." <u>U.S. ex rel. Brown v. Celgene Corp.</u>, 2014 WL 3605896, at \*7 (C.D. Cal. July 10, 2014). "Because the government would not knowingly reimburse kickback-tainted claims, any claims resulting from [Defendant's] alleged kickbacks constitute false claims." Id. at \*8.

# 1. Presentment of a False Claim

First, Abbott moves to dismiss Relator's FCA claims on grounds that Relator fails to allege the presentment of a false claim. (*Mot.* at 6.)

"[T]he [FCA] holds a defendant liable if it pursues a scheme that ultimately results in the submission of a false claim, even if the defendant does not participate in the actual submission of the claim." <u>United States ex rel. Kuzma v. N. Arizona Healthcare Corp.</u>, ("Kuzma II"), 2021 WL 120901, at \*5 (D. Ariz. Jan. 13, 2021) (citing 31 U.S.C. § 3729(a)(1)(A)-(B); <u>United States v. Mackby</u>, 261 F.3d 821, 827 (9th Cir. 2001)). "[I]n accord with general pleading requirements under Rule 9(b), [] it is sufficient to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." <u>Ebeid</u>, 616 F.3d at 998-99 (quotations and citation omitted). "Likewise, a plaintiff may, but need not, provide representative examples to establish the payment element of the prima facie case. The Rule 9(b) standard may be satisfied by pleading with particularity a reasonable basis to infer that the government either paid money or forfeited moneys due." <u>Id.</u> at 999, n.4.

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For example, in <u>United States v. Orthopedic All., LLC</u>, the relator identified specific doctors involved in the kickback scheme who had performed many hip and knee surgeries on Medicare eligible patients." 2020 WL 8173025, at \*7 (C.D. Cal. Nov. 19, 2020). The relator also alleged that 75% of the surgeries performed using Defendant's hardware were billed to Medicare. <u>Id.</u> Thus, the Court found that the relator's allegations rose to the level of "reliable indicia that lead to a strong inference that claims were actually submitted." <u>Id.</u> (quoting <u>Ebeid</u>, 616 F.3d at 998).

Similarly, here, Relator's allegations rise to the level of reliable indicia that lead to a strong inference that claims were actually submitted to the federal government. The median age for the MitraClip procedure is 76, which indicates that at least a majority of the patients are covered by Medicare. (*Opp 'n* at 19.) Relator alleges that Dr. M.P. was a participant in Abbott's kickback scheme through at least 2015-2016. (*Id.*) Relator allegedly hosted at least ten meal events for Dr. M.P. and his/her referring physicians from October 2015 to June 2016. (*FAC* ¶¶ 84, 88.) The alleged goal of these meal events was to help grow Dr. M.P.'s practice areas in the locations where the meals were held. (*Id.* ¶ 88.)

For example, in February 2016, Relator hosted a dinner event for Dr. M.P. in Palm Desert, California, with local referring physicians because Dr. M.P. was allegedly interested in growing his practice in that area. (*Id.*) And on June 6, 2016, Relator arranged a lunch for Dr. M.P. with the Cardiology Specialists Medical Group (CSM), "whom Dr. M.P. specifically requested that Abbott target to refer patients to him." (*Id.*) The First Amended Complaint identifies 25 instances in which Dr. M.P. implanted the MC Device during this 2015-2016 period. (*Id.* ¶ 96.) And Dr. M.P. allegedly received approximately \$179,000 in Medicare payments for the TMVR procedure from 2016 to 2018. (*Id.* Ex. A.)

Relator was also allegedly responsible for assisting Dr. H.N. in building up his/her patient practice. (*Id.* ¶ 92.) Relator put together a social dinner for Dr. H.N. in January 2016 and following this event, Dr. H.N. allegedly performed at least eight TMVR procedures in roughly two and a half months. (*Id.*) Relator also arranged a "dine and dash" program for Dr. H.N. on March 8, 2016. Dr. H.N. received approximately \$50,000 in Medicare payments for the TMVR procedure from 2016 to 2018. (*Id.* Ex. A.)

Taking these allegations together and assuming the truth thereof, Relator has sufficiently pled reliable indicia that lead to a strong inference that false claims were actually submitted.

### 2. Inducement of a False Claim

Second, Abbott argues that Relator fails to allege that Abbott induced any false claim. (*Mot.* at 10.) According to Abbott, the First Amended Complaint provides no details linking its alleged kickback scheme to any claim submitted to a federal healthcare program. (*Id.*) Moreover, Abbott argues that Relator fails to particularly allege that Abbott's alleged AKS violations "actually resulted" in false claims. (*Id.*)

At the pleading stage, relators need not demonstrate that every procedure by a doctor was done in exchange for a kickback. See U.S. ex rel. Bilotta v. Novartis Pharm. <u>Corp.</u>, 50 F.Supp.3d 497, 523 (S.D.N.Y. 2014); <u>United States v. TEVA Pharm. USA</u>, <u>Inc.</u>, ("<u>TEVA I</u>") 2016 WL 750720, at \*17 (S.D.N.Y. Feb. 22, 2016). "This is because the focus of the AKS is not the success of the bribe, but the bribe itself." <u>TEVA I</u>, 2016 WL 750720, at \*17. Relators "need only prove that 'one purpose' of remuneration is to induce a person to use a service for which payment is made under a federal healthcare program." <u>Id.</u> (citations and internal quotations omitted); <u>U.S. v. Kats</u>, 871 F.2d 105, 108 (9th Cir. 1989). To establish this "one purpose," relators need only establish a "link" between the kickback and the claim for reimbursement. <u>United States v. TEVA Pharm.</u> <u>USA, Inc.</u>, ("<u>TEVA II</u>") 2019 WL 1245656, at \*24 (S.D.N.Y. Feb. 27, 2019). [A] claim is false if it seeks reimbursement for a prescription that was not provided in compliance with the Anti-Kickback Statute, regardless of whether the claim was the result of a *quid-pro-quo* exchange or would have been submitted even absent the kickback. *See Greenfield*, 880 F.3d at 96. Relators need not show that a *quid pro quo* exchange occurred, or that the physicians would not have prescribed Defendant's medication but for the kickbacks. It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, even if the physician would have prescribed those drugs absent the kickback.

Id. (citations omitted).

As discussed above, Relator alleges that Abbott assisted Dr. M.P. with "practice building" meal events and free marketing and advertising assistance for the purpose of inducing MC Device usage. (*FAC* ¶ 88; *Opp 'n* at 22-23.) One of these practice building meal events took place in February 2016, and according to Relator, Dr. M.P. performed the MC Device procedure nine times between February 2016 and April 2016. (*FAC* ¶ 96.) Abbott argues that "[I]t defies common sense to conclude that a meal for a doctor as part of a business meeting—a routine industry practice—would be anything more than a "token gesture" of goodwill, much less that the meal constitutes criminal conduct." (*Mot.* at 10.) According to Abbott, "the far more plausible explanation is that Abbott hosted meetings that included meals to educate doctors." (*Id.* at 12.)

However, taking Relator's allegations as true, these meal events with Dr. M.P. cannot be characterized as routine educational events or simply "token gestures" of goodwill. Relator alleges that it hosted at least ten primarily social meal events for Dr. M.P. and his/her referring physicians from 2015-2016; Dr. M.P. directed Relator who to invite to at least four of these meal events; and Dr. M.P. allegedly told Relator to host at least four of these events in various locations in California to solicit patient referrals in those areas. (*FAC* ¶¶ 84, 88.) Therefore, it is equally plausible that Abbott hosted these meal events for Dr. M.P. to help grow his/her practice area; not simply as a token of goodwill or to educate certain doctors. As noted above, remuneration is defined broadly and means "anything of value." See Chang, 2017 WL10544289, at \*7. This free

advertising and marketing to help Dr. M.P. grow his/her medical practice can be
considered something of value. Thus, Relator sufficiently establishes the link between
the kickback and the claim for reimbursement.

## 3. Causation

Abbott next argues that Relator fails to properly plead that Abbott's alleged misconduct actually caused to be presented a false claim for payment. (*Mot.* at 13.) Indeed, Relator alleged in its original Complaint that Abbott's MC Device is the only FDA-approved TMVr device. (*Compl.* [Doc. 1] ¶ 41.) Thus, according to Abbott, "[w]ith no other FDA-approved options for this breakthrough technique, it is far more plausible that physicians' usage of, or referrals for, MitraClip reflects their independent medical judgment regarding the best treatment for their patients." (*Mot.* at 13.) In addition, Abbott argues that several independent actors, like hospitals, referring doctors, and implanting doctors, must approve of the MC Device's use, which further breaks the chain of causation between Abbott's alleged fraud and the doctors' decision to use the MC Device. (*Id.* at 14.)

However, there are two issues with Abbott's arguments. First, according to Relator, the MC Device is not the only procedure for treating Mitral Regurgitation. (*FAC* ¶¶ 58-59; *Opp'n* at 24.) Second, a government reimbursement claim is a false claim under the FCA if it is tainted by an AKS violation. <u>See Brown</u>, 2014 WL 3605896, at \*8 ("Because the government would not knowingly reimburse kickback-tainted claims, any claims resulting from [Defendant's] alleged kickbacks constitutes false claims."). According to <u>United States ex rel. Greenfield v. Medco Health Solutions, Inc.</u>, the "broad statutory text" of the FCA and AKS does not require "a plaintiff to show that a kickback directly influenced a patient's decision to use a particular medical provider." 880 F.3d 89, 97 (3rd Cir. 2018); <u>but see U.S. ex rel, Cairns v. D.S. Medical LLC, et al.</u>, No. 20-2445 (8th Cir. July 26, 2022) (imposing a "but-for" causal requirement between an AKS violation and the "items or services" included in the claim).

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Regardless of this apparent split of authority between the Third and Eighth Circuits (and the 9th Circuit's silence as to this "but-for" cause issue), the Court finds that Relator adequately establishes a "link" between the kickback and the claim for reimbursement. 3 Relator alleges that Abbott assisted Dr. M.P. with "practice building" meal events and 4 free marketing and advertising assistance for the purpose of inducing MC Device usage. 6 (FAC ¶¶ 84, 88; Opp 'n at 22-23.) This is enough to establish a "link" at this stage of the proceedings. See Strom ex re. U.S. v. Scios, Inc., 676 F.Supp.2d 884, 894 (N.D. Cal. 2009) ("While there may ... be factual disputes as to which claims, if any, were the result of Defendants' fraudulent activity, it is not Plaintiff's burden to prove such causation at the pleading stage."); see also Brown, 2014 WL 3605896, at \*8. 10

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#### **Illegal Kickbacks** 4.

Abbott argues that Relator fails to adequately allege improper kickbacks, and specifically, that Relator's "practice building" allegations are too vague to satisfy Rule 9(b). (*Mot.* at 16.) According to Abbott, its hosting of programs for doctors to discuss the benefits of the MC Device show nothing more than routine educational activity. (Id. at 16-17.) But as discussed above, Relator sufficiently alleges the details of these allegedly fraudulent practice-building events.

For example, Relator alleges that its old manager, Michael Meadors, "constantly pressured" Abbott's sales team to host events with physicians to drive up MitraClip implants, and "met with physicians to make Abbott's expectations in exchange for remuneration clear." (FAC  $\P$  68.) These events included educational speaker programs and "meals that were primarily social in nature to referring physicians with no legitimate business purpose" and were allegedly organized by Abbott to help build the participating physicians' practices. (Id. ¶¶ 84, 88, 94.) Abbott allegedly instructed Relator to emphasize to its targeted implanting physicians that "they have an ideal opportunity to build their patient base from Abbott's referral physicians." (Id. ¶ 88.)

27 More specifically, Relator alleges that it put together at least ten social meal events 28 for Dr. M.P. and his/her referring physicians between October 2015 and June 2016 to

help grow Dr. M.P.'s practice area and solicit patient referrals in the areas where the
meals took place. (*Id.* ¶¶ 84, 88.) The repeat nature of these events at Dr. M.P.'s
direction and the fact that Dr. M.P. was able to request who would attend these events
lead to a plausible inference that these events were not simply "routine educational
activities."

Similarly, Relator hosted a social meal event for Dr. H.N. and potential referring physicians in January 2016 and arranged a dine and dash program for Dr. H.N. in March 2016. (*Id.* ¶ 92.) While one inference is that these were routine educational events, an equally strong inference is that Abbott arranged these meals to provide free advertising and marketing assistance to Dr. H.N. to help grow his/her patient practice.

These allegations identify the dates of the alleged practice building meal events, who was there, the alleged purpose, and how they were put together. That is enough to satisfy Rule 9(b)'s specificity standards because it gives fair notice to Abbott and enables it to defend itself effectively. <u>See Starr v. Baca</u>, 652 F.3d 1202, 1216 (9th Cir. 2011); <u>see</u> <u>also Strom</u>, 676 F.Supp.2d at 894.

### 5. Scienter Under the FCA and AKS

Abbott argues that Relator fails to adequately allege scienter under the FCA and AKS. (*Mot.* at 22.)

The FCA requires that a defendant act "knowingly," defined as acting either with actual knowledge, in deliberate ignorance of the truth or falsity of the information, or in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1)(A). The AKS requires that a defendant act "knowingly and willfully," 42 U.S.C. § 1320a-7b(2)(B), but "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [it]," <u>id.</u> § 1320a-7b(h). "Although Rule 9(b) allows plaintiffs to allege scienter generally, scienter must still be pled with plausibility under Rule 8(a)." <u>Adomitis ex rel. U.S. v. San Bernardino Mountains Cmty. Hosp. Dist.</u>, 816 F. App'x 64, 66 (9th Cir. 2020) (citation omitted).

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Relator has sufficiently pled scienter under the FCA and AKS. Relator alleges based on personal knowledge that Abbott instructed Relator to put together noneducational "practice building" events for certain implanting doctors and their referring physicians. (FAC ¶¶ 84, 88, 92; Opp 'n at 15.) Under the guidance of Abbott, Relator allegedly hosted a dine and dash program for Dr. H.N., which allegedly violated certain ethical policies. (FAC ¶ 92.) Moreover, Relator (on Abbott's behalf) allegedly hosted a sushi cocktail party for Dr. D.S. where Dr. D.S. told Relator which physicians to invite. (*Id.* ¶ 110.) Twenty-four of the seventy invitees were allegedly personal guests of Dr. D.S., which violated Abbott's OEC guidelines. (Id.) And when Relator told Meadors it was having trouble arranging the event because of the excessive food costs, Meadors allegedly instructed Relator to "manipulate the final receipts by attributing the excessive meal costs to items that were unrelated to food such as equipment rental and set up charges." (Id.) Lastly, during the TMVR Summit, Abbott allegedly paid Dr. R.G. \$2,500 for a "non-educational" presentation. (Id. ¶125.) This presentation did not go through Abbott's formal vetting process and was not assigned an approval number. (Id.) Relator alleges that when it sought to get this speaker payment check approved, Abbott management instructed Relator to simply use a phony accounts payable number so Dr. R.G. could be paid. (Id.) Taking Relator's non-conclusory allegations as true, Relator has sufficiently established scienter under the FCA and AKS at this stage of the proceedings.

# B. State Law FCA Claims

Finally, Abbott argues that Relator's State FCA claims should be dismissed under Rule 9(b) because it fails to allege facts with specificity with respect to each asserted state. (*Mot.* at 25); <u>U.S. ex rel. Nowak v. Medtronic, Inc.</u>, 806 F.Supp.2d 310, 357 (D. Mass. 2011) ("[Relator] must allege some specificity with respect to each asserted state and cannot rely upon generalized pleadings."). Relator has not alleged with particularity how any false claims were submitted to each state identified in the FAC. In addition,

Relator's Massachusetts claim appears deficient because an artificial entity cannot bring a qui tam action on behalf of that State. See Phone Recovery Servs., LLC v. Verizon of New England, 480 Mass. 224, 228-230 (2018). Thus, Abbott's Motion to Dismiss as to Relator's State Law FCA claims is **GRANTED WITH LEAVE TO AMEND**. 

# IV.

# **CONCLUSION AND ORDER**

For the foregoing reasons, the Court GRANTS IN PART AND DENIES IN **PART** Defendants' Motion to Dismiss. [Doc. 45]. Specifically, the Court **DENIES** Defendants' Motion to Dismiss as to Relator's Federal False Claims Act Claims (Counts 1-3) AND **GRANTS** Defendants' Motion to Dismiss as to Relator's State False Claims Act claims (Counts 4-31) WITH LEAVE TO AMEND. Relator has until September 22, 2022, to file a second amended complaint addressing the deficiencies noted above. See Civ. L.R. 15.1.

**IT IS SO ORDERED.** 

Dated: August 18, 2022

omas J. Whelan United States District Judge