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4	UNITED STATES DISTRICT COURT		
5	NORTHERN DISTRICT OF CALIFORNIA		
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7	UNITED STATES OF AMERICA, et al.,	Case No. <u>16-cv-02043-TSH</u>	
8	Plaintiffs,		
9	v.	ORDER RE: MOTION TO DISMISS	
10	CRESCENDO BIOSCIENCE, INC., et al.,	Re: Dkt. No. 49	
11	Defendants.		
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13	I. INTRODUCTION		
14	Plaintiff-Realtor STF, LLC brings this qui tam action on behalf of the United States and		
15	the State of California against Defendants Crescendo Bioscience, Inc. and Myriad Genetics, Inc.,		
16	under the Federal False Claims Act, California False Claims Act, and California Insurance Frauds		
17	Prevention Act. Before the Court is Defendants' Motion to Dismiss STF's First Amended		
18	Complaint ("MTD"), ECF No. 49, which seeks dismissal of STF's claims pursuant to Federal		
19	Rules of Civil Procedure 9(b) and 12(b)(6). The	Court finds this matter suitable for disposition	
20	without oral argument and VACATES the May 28, 2020 hearing. <i>See</i> Civ. L.R. 7-1(b). Having		
21	considered the parties' positions, relevant legal authority, and the record in this case, the Court		
22	DENIES Defendants' motion for the following reasons.		
23	II. BACKGROUND		
24	A. Factual Background and Procedural History		

STF is a limited liability company whose members are involved in the healthcare industry.

First Amended Complaint ("FAC") ¶ 10. Crescendo Bioscience is a Delaware corporation with a

principal place of business in South San Francisco, California. Id. ¶ 11. It was purchased by

Myriad Genetics in February 2014. Id. ¶ 12. Myriad is a Delaware corporation with a principal

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place of business in Salt Lake City, Utah. *Id.* Crescendo conducts testing for auto-immune and inflammatory diseases for rheumatologists. *Id.* ¶ 33. Its main test, known as the "VectraDA," is described by the company as the "first and only multi-biomarker blood test validated to measure RA [rheumatoid arthritis] disease activity. [It] integrates the concentrations of 12 serum proteins associated with RA disease activity into a single objective score to help physicians make more informed treatment decisions." *Id.* ¶ 34. It performs testing at its Clinical Laboratory Improvement Amendments certified laboratory in South San Francisco. *Id.* ¶¶ 33-34.

STF filed its original Complaint under seal on April 19, 2016, ECF No. 1, and filed its First Amended Complaint on September 6, 2017, ECF No. 9. On January 22, 2020, the United States filed a Notice of Election to Decline Intervention. ECF No. 23. On January 27, 2020, California filed its Notice, declining to intervene. ECF No. 24. The Court subsequently unsealed the case on January 30, 2020. ECF No. 27.

The FAC asserts seven causes of action: (1) a violation of the "false presentment" provision of the Federal False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1)(A), on behalf of the United States; and on behalf of California (2) a violation of the same provision of the California False Claims Act ("CFCA"), California Government Code § 12650(a)(1)(A); (3) a violation of the California Insurance Frauds Prevention Act ("IFPA"), California Insurance Code § 1871.7(a) for employing runners, cappers, steerers, or other persons to procure patients; (4) civil liability under California Insurance Code § 1871.7(b) for presenting a false or fraudulent insurance claim in violation of California Penal Code § 550(a)(1); (5) civil liability under § 1871.7(b) for knowingly preparing or making a writing in support of a false or fraudulent insurance claim in violation of California Penal Code § 550(a)(5); (6) civil liability under § 1871.7(b) for knowingly making or causing to be made a false or fraudulent claim for payment of a health benefit in violation of California Penal Code § 550(a)(6); and (7) civil liability under § 1871.7(b) for a violation of California Penal Code § 550(a)(6); and (7) civil liability under § 1871.7(b) for a violation of California Penal Code § 549.

STF alleges that Crescendo and Myriad are engaged in two kickback schemes designed to
defraud Medicare and Medicaid and private insurers. FAC ¶ 1. The first scheme involves
Defendants paying physicians unlawful, above market "processing" fees to physicians who

1 perform blood draws to induce them to ship the samples to Crescendo's California lab for 2 processing. Id. ¶ 2-3. This, STF alleges, induces doctors and clinics to refer highly profitable 3 Medicare and Medicaid laboratory business to Crescendo. Id. $\P 2$. The second scheme involves Defendants agreeing to cap at \$25 co-pay and deductible fees for those physicians' patients and 4 5 agreeing to not send the patients to collections if and when they do not pay the fees. Id. $\P 4$. According to STF, this encourages doctors to refer patients for unnecessary testing, to refer 6 7 additional patients to Crescendo, and allows doctors to promise patients they will not be charged 8 more than \$25 or sent to collections, in exchange for which Crescendo expects doctors to refer 9 additional patients, especially government-pay business. Id. ¶ 5.

The Processing Fees Scheme

STF alleges that Crescendo enters into contractual agreements with doctors who have 11 patients who might be eligible for its testing services. Id. ¶ 37. According to STF, the contracts 12 13 provide that the doctor or a member of her staff will conduct the blood draw at their office into 14 serum separator tubes ("SST") which Crescendo provides to the doctor. Id. Once the draw is 15 done, the doctor applies a barcode label provided by Crescendo as part of a specimen kit and ships 16 the SSTs to Crescendo's lab for analysis. Id. In addition to the specimen kits, Crescendo provides all materials needed for packaging and shipping samples and pays for shipping through pre-printed 17 18 shipping labels provided along with the specimen kits. Id. ¶ 38. Crescendo's contracts provide 19 that it is responsible for "delivering to the [physician] the Specimen Collection Kits and any other 20additional information, data, supplies or equipment (if any) necessary for the [physician] to 21 perform the Processing Services in accordance with the" contracts. Id.

According to STF, when physicians sign an agreement with Crescendo, they receive a "Welcome Letter" from Crescendo's Director of Customer Service, Sharon Dwyer, which states:

To help you with the invoice process Crescendo will email you a statement each month listing all the samples our lab has received from you during the prior month. To expedite payment simply reply back to the email indicating agreement with the information I've provided and I will submit the statement on your behalf to Account Payable.

27 *Id.* ¶ 39 (emphasis added in original). Crescendo pays physicians "processing" fees of \$15 per

28 SST, regardless of how many tubes are included in any given shipment from a physician or the

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number of patients from whom blood is drawn. Id. ¶ 40. At the end of each month during which a physician sends any sample to Crescendo, Crescendo sends the physician a "Lab Test Receipt," which is effectively an invoice. Id. ¶ 41. The receipt includes the number of patients for which samples were sent and "scored," the date Crescendo received the sample, a "TRFID" number, and the "Per Test Lab Fee" of \$15. Id. Crescendo ordinarily emails these invoices to the doctor from an email account named "Sample Processing Agreement <spa@crescendobio.com>." Id. ¶ 42. Crescendo informs the doctor that it will submit the invoice to Myriad on behalf of the doctor. Id. Myriad then sends the check to the doctor, along with an "Invoice Number," a date, and a "description" which indicates the month the payment covers. Id. \P 43.

STF alleges that because Defendants know the payments are illegal, their contracts go to great lengths to describe the processing fee as "fair market value." *Id.* ¶ 44. STF contends that a fee of \$15 "for the draw, processing, packaging or handling [of a sample] is <u>not</u> fair market value." *Id.* "In reality," it contends, "\$15 is well above the market value of the time, effort or materials required for the blood draw." *Id.* ¶ 45. STF asserts that standard industry practice, standard valuation of blood draw fees and costs, and Medicare reimburse rules make clear that this is true. *Id.* ¶ 46. It supports this contention with reference to the fee of \$3 that Medicare reimburses to medical providers for drawing a blood sample through venipuncture. *Id.* ¶¶ 46-48 (citing Medicare Claims Processing Manual, Chapter 16, Laboratory Services § 60.1; Healthcare Common Procedure Coding System Code 36415). Since the amount Defendants pay is five times the Medicare venipuncture reimbursement amount, STF alleges, Defendants' fee is an illegal payment designed to induce physicians to use Crescendo's test and refer patients to Crescendo. *Id.* ¶ 49. STF alleges that Crescendo then presents to Medicare claims for reimbursement of lab tests which are ordered by physicians in exchange for these payments. *Id.* ¶ 51. Each of these claims, STF asserts, constitutes a false claim in violation of the FCA.

The Waiving of Co-Pay and Deductibles Scheme

When a physician's non-Medicare patient is covered by private insurance, and the patient has not met their deductible with their insurance carrier, the patient is responsible for paying the cost of a service. *Id.* ¶ 54. STF alleges that the VectraDA test offered by Crescendo has a list

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price of \$989, and that the government pays 574.77 of that amount. Id.¹ Thus, according to STF, 2 when a patient has not met their deductible, they will owe between \$500 and \$989 toward the cost 3 of the VectraDA test. Id. Additionally, even when a patient has met their deductible, most private insurance plans require a patient ordering a lab test to make a co-payment of approximately 20% 4 5 of allowable charges. Id. ¶ 55. STF alleges that in the case of the VectraDA test the co-pay often exceeds \$100. Id. It alleges that Crescendo caps co-pay and deductible charges at \$25 regardless 6 7 of a patient's responsibility and agrees not to send patients to collections, and that it does so in 8 order to induce physicians to refer additional patients, especially government-pay patients. Id. \P 9 56. Crescendo tells doctors this so that they can reassure their patients that they will not be responsible for more than \$25 in fees. Id. Thus, the caps are of value to both physicians and their 10 patients. Id.

12 STF asserts that Crescendo knows this scheme is illegal because it provides significant 13 benefit to referring physicians. Id. \P 58. In an effort to conceal the scheme and avoid liability, 14 Crescendo informs its salespeople not to include information on the capping and waiving of fees 15 in emails. Id. ¶ 58. Instead, STF alleges, the information is communicated in other ways. Id. As 16 an example, STF alleges a series of communications to and from Kerri Jacobson, a former Crescendo salesperson who has since been promoted to a training position. Id. ¶ 59. Jacobson 17 18 "was asked in April 2016[:] 'From a pricing and billing point of view, can you remind me what 19 the charge (co-pay) is for patients with PPO insurance and what the options are if they feel they 20can't pay?" Id. (The FAC does not explicitly say who asked Jacobson about fees, though it was evidently a physician. See FAC ¶ 61 ("Ms. Jacobson also informed the physician")). 21 22 According to STF, on April 11, 2016, Jacobson responded via text message and email. Id. ¶ 60. 23 The text message explained: "I can't put in email our max out of pocket for our test on Email [sic] but wanted to let you know it is \$25." Id. The first of two emails from Jacobson stated: "We have 24 25 a max out of pocket for PPO, Cash, and IPA patients. And medicare [sic] patients do not have a co-pay for up to 2 tests per year." Id. The second email read, "Glad you got my text." Id. 26

¹ It is not clear from the FAC under what system STF alleges the government pays this amount.

Jacobson allegedly informed the physician that Crescendo "would not go after patients for unpaid 2 balances or send them to collections." Id. ¶ 61. On April 14, 2016, Jacobson wrote: "No we do not currently send patients to collections. However[,] if a patient gets a check from their insurance company and does not send it to us then we will bill for that amount of what they from insurance. But haven't sent them to collections." Id. STF alleges that the agreements with physicians to cap fees and not collect from patients violate the FCA. Id. ¶ 62. 6

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III. LEGAL STANDARD

Defendants move for dismissal pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6). A complaint 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). To survive a Rule 12(b)(6) motion to dismiss for "failure to state a claim upon which relief can be granted," Fed. R. Civ. P. 12(b)(6), a complaint must plead "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)). Plausibility does not mean probability, but it requires "more than a sheer possibility that a defendant has acted unlawfully." Iqbal, 556 U.S. at 687. In considering a motion to dismiss, the court accepts factual allegations in the complaint as true and construes the pleadings in the light most favorable to the nonmoving party. Manzarek v. St. Paul Fire & Marine Ins. Co., 519 F.3d 1025, 1031 (9th Cir. 2008); Erickson v. Pardus, 551 U.S. 89, 93-94 (2007). However, "the tenet that a court must accept a complaint's allegations as true is inapplicable to threadbare recitals of a cause of action's elements, supported by mere conclusory statements." Iqbal, 556 U.S. at 678.

22 "A plaintiff alleging fraud must overcome a heightened pleading standard under Rule 23 9(b)," ESG Capital Partners, LP v. Stratos, 828 F.3d 1023, 1031 (9th Cir. 2016), which provides, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting 24 25 fraud or mistake," Fed. R. Civ. P. 9(b). The rule "serves not only to give notice to defendants of the specific fraudulent conduct against which they must defend, but also to deter the filing of 26 complaints as a pretext for the discovery of unknown wrongs, to protect defendants from the harm 27 28 that comes from being subject to fraud charges, and to prohibit plaintiffs from unilaterally

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imposing upon the court, the parties and society enormous social and economic costs absent some 2 factual basis." Bly-Magee v. California, 236 F.3d 1014, 1018 (9th Cir. 2001) (applying Rule 9(b) 3 to claims brought under the FCA) (citations and internal quotations omitted). "[D]efendants accused of defrauding the federal government have the same protections as defendants sued for 4 fraud in other contexts." Id. Accordingly, in order to survive a motion to dismiss for failure to 5 plead fraud with the particularity required by Rule 9(b), "[a]verments of fraud must be 6 7 accompanied by "the who, what, when, where, and how" of the misconduct charged."" Kearns v. 8 Ford Motor Co., 567 F.3d 1120, 1124 (9th Cir. 2009) (quoting Vess v. Ciba-Geigy Corp. USA, 9 317 F.3d 1097, 1106 (9th Cir. 2003)).

IV. DISCUSSION

STF's Capacity to Sue A.

Before getting to STF's allegations, Defendants argue that STF lacks capacity to sue. They argue that STF, which is an LLC, was in "suspended" status with the California Secretary of State. According to them, STF's suspended status provides grounds for dismissal. MTD at 6 (citing Hullinger v. Anand, 2015 U.S. Dist. LEXIS 187188 (C.D. Cal. Dec. 22, 2015) ("it is a bedrock principle of corporate law that a properly cancelled LLC lacks capacity to sue")). STF counters that at the time of filing this action, it was in good standing with the Secretary of State. It asserts that after this case was unsealed, it realized that its status was suspended, and it has since "corrected the ministerial error" and is now in "active" status. Opp'n at 9. A California Business Search from April 27, 2020 shows that STF is now "active" status.² Defendants do not address this issue in their Reply. The Court considers it mooted by STF's change in status.³

²⁴ ² The Court grants both Parties' requests for judicial notice, as they are all documents produced by the California Secretary State and are matters of public record. See Fed. R. Evid. R. 201(b) (a 25 court may take judicial notice of facts that are "not subject to reasonable dispute" when they "can be accurately and readily determined from sources whose accuracy cannot reasonably be 26 questioned"); Mack v. South Bay Beer Distribs., 798 F.2d 1279, 1282 (9th Cir. 1986) (a court may

grant judicial notice of matters of public record). 27

Defendants' discussion of STF's "possible motivation" for filing this suit, see MTD at 6-7, is irrelevant. Whether Chris Riedel, STF's manager, is a professional relator or not, STF can pursue 28 this action if it carries its burden at each stage of the litigation.

B. **Relevant Statutes**

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1. The Anti-Kickback Statute

The Anti-Kickback Statute ("AKS") prohibits:

knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program

42 U.S.C. § 1320a-7b(b)(2)(A); see also United States ex rel. Reidel v. Bos. Heart Diagnostics Corp., 332 F. Supp. 3d 48, 57 (D.D.C. 2018). In other words, the statute "makes it illegal to offer, pay, solicit or receive anything of value as an inducement to generate business payable by Medicare or Medicaid." Publication of OIG Special Fraud Alerts (Dec. 19, 1994) ("1994 OIG Special Fraud Alert"), 59 FR 65,372, 65,375. The statute is violated if one purpose of a payment is to induce future referrals, even if the payment is also intended to compensate for professional services. United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989) (quoting United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985)).

The U.S. Department of Health and Human Services, Office of Inspector General ("OIG") 16 "has made clear that 'disguising remuneration for Federal referrals through offers or payments of 17 18 inflated amounts for non-Federal business or simply by offering or paying remuneration for non-19 Federal referrals to "pull through" the Federal business' 'may violate the Anti-Kickback Statute."" 20Bos. Heart, 332 F. Supp. 3d at 58 (quoting OIG, Advisory Opinion No. 00-8: Spectrum Housing, d/b/a Housing Referrals of Maine at 5 (2000) ("In other words, the [AKS] prohibits payments 22 made purposefully to induce referrals of business for which payment may be made by a Federal 23 health care program."). In a 2005 Advisory Opinion, the OIG stated that an arrangement, "by 24 which [a] [1] ab would provide referring physicians with free blood drawing supplies and payments 25 for blood drawing services that may exceed what the [1]ab receives for such services and supplies from Medicare, would clearly implicate the antikickback statute." Advisory Opinion No. 05-08 at 26 4 (2005) ("2005 OIG Advisory Opinion"). Under such an arrangement, the Opinion advised, "an 28 inference arises that the compensation is paid as an inducement to the physician to refer patients to United States District Court Northern District of California 1

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the laboratory, particularly in the circumstances presented here." *Id.* Similarly, in a 2014 Special
Fraud Alert, the OIG advised that an arrangement "under which clinical laboratories are providing
remuneration to physicians to collect, process, and package patients' [blood] specimens" may
indicate the AKS where, among other things, the payment to physician "exceeds fair market value
for services actually rendered" and "[p]ayment is for services for which payment is also made by a
third party, such as Medicare." OIG, Special Fraud Alert: Laboratory Payments to Referring
Physicians at 3-5 (2014) ("2014 OIG Special Fraud Alert").

Additionally, in its 1994 Special Fraud Alert, the OID advised that "a provider, practitioner or supplier who routinely waives Medicare copayments or deductibles also could be held liable under the Medicare and Medicaid anti-kickback statute." 59 FR at 65375. Among indicators of potentially unlawful waivers was "[f]ailure to collect copayments or deductibles for a specific group of Medicare patients for reasons unrelated to indigency (e.g., a supplier waives coinsurance or deductible for all patients from a particular hospital, in order to get referrals)." *Id*.

2. False Claims Acts

"The False Claims Act makes liable anyone who 'knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,' or 'knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."" *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 898-99 (9th Cir. 2017) (quoting 31 U.S.C. § 3729(a)(1)(A), (B)). "A 'claim' includes direct requests for government payment as well as reimbursement requests made to the recipients of federal funds under a federal benefits program." *Campie*, 862 F.3d at 899 (citing 31 U.S.C. § 3729(b)(2)(A)). A claim under the FCA "can be false where a party [] falsely certifies compliance with a statute or regulation as a condition to government payment," *United States v. Univ. of Phoenix*, 461 F.3d 1166, 1171 (9th Cir. 2006), what is known as the "false certification theory." But "[a]nother approach to finding [FCA] liability in the absence of an explicitly false claim is the 'promissory fraud' or 'fraud-inthe-inducement' theory." *Id.* at 1173. This theory is somewhat broader: "rather than specifically requiring a false statement of compliance with government regulations," "[i]t holds that liability will attach to each claim submitted to the government under a contract, when the [contract or]

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extension of government benefit was originally obtained through false statements or fraudulent conduct." *Id.* (citing *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787 (4th Cir. 1999). In other words, the "subsequent claims are false because of an original fraud (whether a certification or otherwise)." *Univ. of Phoenix*, 461 F.3d at 1173. The Ninth Circuit has held that under either of these theories, "the essential elements of False Claims Act liability remain the same: (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." *Id.* at 1174.

"Claims that result from unlawful kickbacks are false claims for purposes of the False Claims Act." *Mauss v. NuVasive, Inc.*, 2015 U.S. Dist. LEXIS 178117, at *28-29 (S.D. Cal. Aug. 28, 2015) (citing 42 U.S.C. § 1320a-7b(g) ("In addition to the penalties provided for in this section or [42 USCS § 1320a-7a], a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA].")). Violations of the AKS can be pursued under the FCA "since they would influence the government's decision of whether to reimburse Medicare Claims." *Bos. Heart*, 332 F. Supp. 3d at 59 (quoting *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008)).

STF brings its CFCA claim pursuant to California Government Code § 12651(a)(1), which 17 18 prohibits "[k]nowingly present[ing] or caus[ing] to be presented a false or fraudulent claim for 19 payment or approval." Where, as is the case here, "the statutory provisions of the federal FCA and 20 California FCA are the same, courts apply the same analysis to federal and California FCA claims." United States v. Safran Grp., S.A., 2017 U.S. Dist. LEXIS 8408, at *13 (N.D. Cal. Jan. 21 19, 2017) (citing Fassberg Const. Co. v. Hous. Auth. of City of L.A., 152 Cal. App. 4th 720, 735 22 23 (2007) (as modified) (holding that federal case law is used to interpret the CFCA because "the 24 California False Claims Act is patterned after the federal False Claims Act")).

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3. California Insurance Frauds Prevention Act

"[T]aken as a whole, section 1871 et seq. is specifically tailored toward preventing and
punishing the making of fraudulent claims to insurance companies." *State of California ex rel. Metz v. CCC Information Services, Inc.*, 149 Cal. App. 4th 402, 413 (2007) (citation omitted).

Subdivision (a) of section 1871.7 makes it "unlawful to knowingly employ runners, cappers, steerers, or other persons to procure clients or patients to perform or obtain services or benefits or to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer." Cal. Ins. Code § 1871.7(a). The Act allows for an "interested person" to bring a qui tam action "for the person and for the State of California" and "in the name of the State." Id. § 1871.7(e)(1). It applies to fraudulent conduct, including kickbacks, used to procure patients or obtain services or benefits covered by insurance. See California v. AbbVie Inc., 390 F. Supp. 3d 1176, 1178-79 (N.D. Cal. 2019) (case involving two schemes, including a kickback scheme, used by defendant to inflate sales of its drug); United States v. CardioDx, Inc., 2019 WL 2163002, at *8 (N.D. Cal. May 17, 2019) ("Absent case law to the contrary, I find that the IFPA applies to the kickback conduct alleged against [the defendant].").

Subdivision (b) of section 1871.7 "authorizes an action on behalf of the state against 'every person' who violates Penal Code sections 549 and 550." *Metz*, 149 Cal. App. 4th at 414 (citation and internal quotation marks omitted). STF asserts violations of section 550(a), subdivisions (1), (5), and (6), as well as section 549. Those subdivisions of section 550(a) make it unlawful to: "(1) knowingly present or cause to be presented any false or fraudulent claim for the payment of a loss or injury, including payment . . . under a contract of insurance." [¶] "(5) knowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim." [¶] or "(6) knowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit." Section 549 makes it unlawful to solicit, accept, or refer any business "with the knowledge that, or with reckless disregard for whether, the individual or entity for or from whom the solicitation or referral is made, or the individual or entity who is solicited or referred, intends to violate Section 550 ….." Cal. Pen. Code § 549.

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C. Analysis

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The Processing Fees Scheme

a. Rule 12(b)(6)

Defendants argue that STF's processing fee theory fails because STF fails to adequately allege a specific intent to reduce referrals. But STF alleges that "Defendants pay physicians over five times what is considered to be fair market value . . . and five times the Medicare reimbursement rate" for "processing" fees, and it alleges that the payment "is designed to induce physicians to order the VectraDA test . . . and to induce the referral of patients." FAC ¶ 49 (emphasis added). In the next paragraph it alleges that the fees "have the effect of incentivizing physicians to order more tests," with the inference being that physicians would order more VectraDA tests. *Id.* ¶ 50. These allegations sufficiently allege an intent to induce referrals.

Defendants contend that STF's "processing" fee theory is based on a faulty assumption 12 13 that any payment greater than \$3 exceeds the fair market value for the services that physician 14 offices provide to Defendants. In essence, Defendants argue that because STF has not plausibly 15 alleged that Defendants paid physicians processing fees in excess of the fair market value, it has 16 not alleged an improper inducement in violation of the AKS. According to Defendants, STF's reliance on the 2005 OIG Advisory Opinion is in error. That opinion stated that "Medicare pays 17 18 \$3 per patient encounter for specimen collection fees . . . for the service and supplies [physicians] 19 use in collecting blood samples." Defendants argue that since the opinion said nothing about 20"processing, packaging or handling" fees, it is not an apt reference here, where STF has alleged 21 that Defendants made payments not only for specimen draws but also for those services. The 22 2014 OIG Special Fraud Alert confirms a distinction between a "a nominal specimen collection 23 fee in certain circumstances, including times when the person draws a blood sample through 24 venipuncture (i.e., inserting into a vein a needle with syringe or vacuum tube to draw the 25 specimen)," and a fee "for processing and packaging specimens for transport to a clinical laboratory 26 through a bundled payment," each of which is billed to Medicare with a separate Current Procedural Technology ("CPT") code. See 2014 OIG Special Fraud Alert at 3, 4. The latter is "intended to 27 28 reflect the work involved to prepare a specimen prior to sending it to a laboratory, including

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1 centrifuging a specimen, separating serum, labeling tubes, packing the specimens for transport, 2 filling out laboratory forms, and supplying necessary insurance information and other 3 documentation." Id. at 4. Defendants contend that a relator cannot allege inducement if the relator fails to allege at least some facts that could give rise to an inference that a fee paid is above 4 fair market value. Id. They contend that since STF has failed to allege "any facts demonstrating 5 that [the] alleged \$15 payments exceeded market value," they have not alleged inducement. MTD 6 7 at 11. The Court disagrees.

The 2014 OIF Special Fraud Alert notes that the AKS can be implicated whenever a clinical laboratory pays a physician for services, even if payment doesn't exceed fair market value for the service: 10

> Whether an actual violation of the statute occurs depends on the intent of the parties-the anti-kickback statute prohibits the knowing and willful payment of such amounts if even one purpose of the payment is to induce or reward referrals of Federal health care program business. This is true regardless of whether the payment is fair market value for services rendered.

15 Fraud Alert at 4 (emphasis added)⁴; see also OIG Supplemental Compliance Program Guidance for Hospitals, 70 FR 4858, 4864 ("[U]nder the anti-kickback statute, neither a legitimate business 16 purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is 17 18 also an illegal purpose (i.e., inducing Federal health care program business.).") (emphasis added). 19 The Fraud Alert suggests other characteristics of a specimen processing arrangement which may 20also be evidence of unlawful purpose, including "[p]ayment is for services for which payment is also made [to the physician] by a third party, such as Medicare," "[p]ayment is made directly to 21 22 the ordering physician rather than to the ordering physician's group practice, which may bear the 23 cost of collecting and processing the specimen," and "payment is made on a per-specimen basis 24 for more than one specimen collected during a single patient encounter or on a per-test, perpatient, or other basis that takes into account the volume or value of referrals." Fraud Alert at 3-4. 25 26

⁴ The Fraud Alert does provide, however, that "[t]he probability that a payment is for an illegitimate purpose is increased [] if a payment exceeds fair market value or if it is for a service 28 for which the physician is paid by a third party, including Medicare."

It also advises:

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the laboratory should consider whether payment is appropriate at all; if the services for which the laboratory intends to compensate the physician are paid for by a third party through other means, such as payments intended to reimburse the physician for overhead expenses, any payment by the laboratory to the physician may constitute double payment for the physician's services and, consequently, provide evidence of unlawful intent.

Here, STF alleges that Crescendo pays physicians a "processing" fee of \$15 per SST, regardless of 6 how many tubes a physician includes in a shipment or the number of patients from whom blood is 7 8 drawn. FAC ¶ 40. This allegation, if true, suggests that Crescendo's arrangement might implicate 9 the FCA for multiple reasons, whether or not its payments were at fair market value. See also 2005 OIG Advisory Opinion at 3 ("The Proposed Arrangement would not fit in the [42 C.F.R. § 10 1001.952(d)] safe harbor because the physicians will be paid on a per-patient basis, and, thus, the 12 compensation would not be set in advance."); id. at 4 ("Because the physicians would receive a 13 portion of the Lab's reimbursement for blood tests resulting from the physicians' referrals, the 14 physicians have a strong incentive to order more blood tests."); id. ("[A]ny specimen collection 15 claims submitted by the Lab to Medicare for blood draws performed by the referring physicians 16 would be improper claims and would implicate the [FCA] . . . Medicare rules would prohibit the Lab from billing Medicare for blood collection services rendered by the referring physicians."). 17 18 But more importantly, STF's fair-market-fee allegation does not stand alone. STF has also alleged 19 with significant detail how Crescendo was capping patients' co-pays and deductibles at \$25 and 20declining to send patients to collections, and that at least one salesperson was reluctant to discuss these issues through email. See FAC ¶¶ 56-61. If those allegations are true, which the Court must 22 assume at this stage, they are other indicia of an intent to induce referrals. See section IV(B)(2)(a)below. Those allegations together with the allegation that Crescendo was paying physicians' blood draw and processing fees are sufficient to create a reasonable inference that the payments were being made to induce referrals, whether or not the payments exceeded fair market value. Thus, STF has plausibly alleged improper inducements under the AKS. 26

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Rule 9(b)

b.

Defendants argue that even if STF is able to allege an AKS violation well enough to satisfy

Rule 12(b)(6), it nevertheless fails to satisfy the heightened pleading requirements of Rule 9(b). According to Defendants, STF fails to allege the who, what, when, where, and how of the allege "processing" fee scheme. They contend that "[STF] does not allege a single specific payment amount, any physician who received such a payment, a Crescendo or Myriad representative involved in making such payment, details of any agreement between either of the Defendants and any physician, or the date on which any such payment was allegedly made." MTD at 13.

Although a plaintiff alleging fraud must plead the who, what, when, where, and how of the alleged misconduct, the Ninth Circuit has specified that "[b]ecause [the Rule 9(b)] standard 'does not require absolute particularity or a recital of the evidence,'" *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1180 (9th Cir. 2016) (quoting 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1298 (3d ed. 2016)), "a complaint need not allege 'a precise time frame,' 'describe in detail a single specific transaction' or identify the 'precise method' used to carry out the fraud," *United Healthcare*, 848 F.3d at 1180 (quoting *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997)). "The complaint also need not 'identify representative examples of false claims to support every allegation." *United Healthcare*, 848 F.3d at 1180 (quoting *Ebeid v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010)). "[I]t 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." *Ebeid*, 616 F.3d at 998-99 (quotoing *United States ex rel. Grubbs v. Ravikumar Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)).

STF alleges numerous details concerning the alleged processing fee scheme. It alleges that Crescendo entered into contracts with physicians, and it alleged the basic contours of those agreements—that physicians would draw blood into SSTs provided by Crescendo, apply barcode labels provided by STF as part of "Specimen Kits," and return the samples to Crescendo for analysis; that in addition to the Specimen Kits, Crescendo provided "all materials" needed for shipping the samples and paid for shipping; and, of course, that Crescendo would pay physicians a processing fee of "\$15 per SST." FAC ¶¶ 37-38, 40 (emphasis in original). It alleged that Sharon Dwyer, Crescendo's Director of Customer Service, would send physicians a "Welcome Letter," and it quoted specific language from the letter. See id. ¶ 39. According to the FAC, the Welcome

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Letter informed physicians that Crescendo would send out a monthly statement of all samples 1 2 received and directed them to reply back to the email "indicating agreement," and informed them 3 that Dwyer would submit the statements on their behalf to accounts payable. Id. STF alleges that each month Crescendo would send physicians a "Lab Test Receipt," which was "effectively an 4 invoice" that included the number of patients for which samples were sent, and that Crescendo 5 would send these invoices from an email account named "Sample Processing Agreement 6 7 <spa@crescendobio.com>." Id. ¶¶ 41-42. It alleges Myriad would then send checks to 8 physicians, and the checks would include an "Invoice Number" with a date and "description" that 9 noted the month the payment covered. Id. ¶ 43. Also, according to STF Crescendo and Myriad knew such payments were illegal, and "the contract[s] go[] to great lengths to describe [the] fees 10 as 'fair market value' for the physician's work." Id. ¶ 44. 11

Contrary to Defendants' assertion, STF has alleged great detail concerning the alleged processing fees scheme. True, it hasn't alleged any particular transaction or named a particular physician who sent samples to Crescendo, but it doesn't need to allege a precise time frame or describe in detail a specific transaction, as long as it alleges details of the scheme sufficient enough to "give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge" *United Healthcare*, 848 F.3d at 1180 (quoting *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001) (discussing Rule 9(b) in the context of an FCA claim)). It has done that.

c. Scienter

Defendants argue that STF failed to allege the necessary scienter to support a claim under the FCA. They argue that STF "does not make a single allegation suggesting that Defendants knew or had reason to know that the alleged conduct violated the AKS." Mem. at 15. The Court disagrees.

Rule 9(b) provides that while "a party must state with particularity the circumstances
constituting fraud or mistake," "[m]alice, intent, knowledge, and other conditions of a person's
mind may be alleged generally." The Ninth Circuit has interpreted Rule 9(b) to mean "plaintiffs
may aver scienter generally, just as the rule states - that is, simply by saying that scienter existed."

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Decker v. GlenFed, Inc. (In re GlenFed, Inc. Sec. Litig.), 42 F.3d 1541, 1547 (9th Cir. 1994). STF alleges, among other things, that, "[b]ecause Crescendo and Myriad know such payments are *illegal*, the contract goes to great lengths to describe this ["processing"] fee as 'fair market value.' for the physician's work." FAC ¶ 44 (emphasis added). Defendants counter that "[i]nstead of establishing the Defendants 'knowingly' submitted false claims, this allegation shows [their] diligence and good faith belief that payments made to doctors were paid at fair market value." Mem. at 15-16. That's one way to read that allegation. But another plausible inference to draw from that allegation is as STF describes: "Defendants knew their practice was prohibited renumeration and were trying to stay one step ahead of the string of successful cases holding other laboratories responsible for the same conduct." Opp'n at 13. And on a motion to dismiss the Court is required to "read the complaint in the light most favorable to the non-moving party." Odom v. Microsoft Corp., 486 F.3d 541, 545 (9th Cir. 2007).

13 Defendants also point out that the Ninth Circuit has written that in pleading the knowledge 14 element of the FCA, a complaint "must set out sufficient factual matter from which a defendant's 15 knowledge of a fraud might reasonably be inferred." United States ex rel. Silingo v. Wellpoint, 16 Inc., 904 F.3d 667, 679-80 (9th Cir. 2018). More recently the Ninth Circuit specified that "[a] complaint needs only to allege facts supporting a plausible inference of scienter." Winter ex rel. 17 18 United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc., 953 F.3d 1108, 1122 (9th Cir. 2020) 19 (citing United States ex rel. Lee v. Corinthian Colls., 655 F.3d 984, 997 (9th Cir. 2011)). That is 20 the case here. Proving the scienter element under the FCA requires "no proof of specific intent to defraud[,]" 31 U.S.C. § 3729(b)(1)(B), and the facts alleged in the FAC support a plausible 22 inference that Defendants were paying processing fees to physicians in order to induce them to 23 refer patients. Doing so can be the basis for a violation of the FCA, whether or not a party 24 specifically intended to defraud the government. Furthermore, the FAC alleges facts creating an 25 inference that at least one of Crescendos' salespeople knew that she was not supposed to discuss the waiving of patient co-pay fees in an email. Even though the alleged processing fees scheme is 26 distinct from the allege scheme of waiving co-pays and not collecting from patients, STF's 27 28 allegations concerning Jacobson's texts and emails create a reasonable inference that Defendants

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knew that their conduct might be unlawful and were taking steps in response.

2.

The Alleged Patient Co-Pay and Deductible Scheme

a. Rule 12(b)(6)

Defendants argue that STF's co-pay and deductible capping allegations fail because STF does not allege facts supporting a connection between the alleged fraudulent practice (capping fees and not sending patients to collections) and inducement of physicians to send Crescendo government-pay business. They also argue that STF does not address how a physician benefitted from the alleged capping of co-pays. But STF alleges both. It alleges: In order to induce the referral of additional business, especially government pay business, Crescendo does not charge patients any

government pay business, Crescendo does not charge patients any amount in excess of \$25 . . . and agrees not to send any patients to collections, even if the \$25 is never paid. Crescendo tells doctors this so that they can reassure their patients that they will not be responsible for more than \$25, regardless of the amount they owe. These caps are a value to both physicians and their patients.

13 FAC ¶ 56. A reasonable reading of that allegation is that Crescendo "does not charge patients any amount in excess of \$25," something of "value to both physicians and their patients," "in order to 14 15 induce the referral of additional business." Defendants make much of the fact that STF does not 16 explicitly draw the line from Crescendo waiving co-pays or deductibles to physicians referring patients. "[STF] presupposes a link," they argue, "and in doing so, asks the Court to fill the gap." 17 18 Mem. at 18. But the gap is not a large one to fill: no patient likes additional costs; if a lab waives 19 patients' fees and commits to not referring patients to collections, thus allowing physicians to 20"reassure their patients that they will not be responsible for more than \$25," that is something of 21 value to physicians and they might be induced to send more patients to that lab (especially when 22 the lab is paying \$15 per sample to boot). See Bos. Heart, 332 F. Supp. 3d at 66 (allegation 23 sufficiently alleged how "purported waiver practice provided value to physicians; namely, by 24 saving their time not spent on explaining co-payment and deductible charges to patients and 25 providing them an opportunity to market free laboratory testing"). In any event, STF referenced 26 the 1994 Special Fraud Alert, see FAC ¶ 53, which advised that "[i]n certain cases, a provider, 27 practitioner or supplier who routinely waives Medicare copayments or deductibles also could be 28 held liable under the Medicare and Medicaid anti-kickback statute," 59 FR at 65374-75; see also

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id. at 65377 ("Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business."); 2014 OIG Special Fraud Alert (advising the same). Thus, whether or not STF alleged why routine waivers of co-pays or deductibles might run afoul of the AKS, STF managed to raise an inference that they do.

b. **Rule 9(b)**

Like with the processing fee scheme, Defendants argue that even if STF successfully pled the fee-waiving scheme, it has nevertheless failed to meet the heightened pleading standards of Rule 9(b). They argue that the FAC is devoid of "any details of any agreement requiring Defendants to limit co-pays or not pursue patient collections in exchange for referrals." MTD at 19. But the FAC alleges that "Crescendo does not charges any patients any amount in excess of \$25 ... and agrees not to send any patients to collections " FAC ¶ 56 (emphasis). Then later it alleges "[t]he agreement not to collect from patients and the cap on the amount of money ... both violate the [FCA]." Id. ¶ 62 (emphasis added). And the issue of an express agreement aside, STF's theory here is that these schemes "encouraged" physicians to refer patients (i.e., inducement), and that STF "expected" doctors to refer patients in return for processing fees and patient fee waivers, not that physicians were *required to* by contract. See FAC ¶ 5 ("[The schemes] encourage[] doctors to refer patients . . . In exchange [for capping patient fees and not collecting from patients] Crescendo expects doctors will refer additional patients, especially government pay business. This scheme is no more legal than if Defendants simply handed doctors envelopes with money in exchange for . . . referrals."); id. ¶ 56 ("In order to induce the referral of additional business . . . Crescendo does not charge patients any amount in excess of \$25).

Defendants once again object that STF does not identify a physician who allegedly
benefitted from the capping of co-pays "or the renumeration or benefit that any physician
received." But again, STF does not need to identify a specific transaction if its allegations
otherwise satisfy Rule 9(b)—the absence of such an allegation is not fatal to the complaint. STF
has alleged that: in order to induce the referral of business, Crescendo capped patient fees at \$25,
"regardless of the patient's responsibility," and agreed not to send patients to collections, and told

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doctors this so that the doctors could reassure patients that they wouldn't be on the hook for more than \$25; that Crescendo knew this strategy was illegal and informed its salespeople not to include these facts in emails; that one of Crescendo's salespeople—whom STF identified by name—was asked on April 11, 2016 about patient co-pays and patients inability to pay fees, and that Jacobson responded in a text that she couldn't put in an email that the cap was \$25; and that Jacobson wrote on April 14, 2016 that "we do not currently send patients to collections. . . . [We] haven't sent them to collections."

Here again, STF has alleged great detail concerning the alleged patient fee-waiver scheme,
including a specific period of time. It has given Defendants fair notice of the particular
misconduct alleged. Thus, it has satisfied the pleading requirements of Rule 9(b). *See United Healthcare*, 848 F.3d at 1180 ("'[P]erhaps the most basic consideration for a federal court in
making a judgment as to the sufficiency of a pleading for purposes of Rule 9(b) is the
determination of how much detail is necessary to give adequate notice to an adverse party and
enable that party to prepare a responsive pleading."") (quoting 5A Charles Alan Wright & Arthur
R. Miller, Federal Practice and Procedure § 1298 (3d ed. 2016)).

c. Scienter

Defendants' scienter argument is again unavailing. They argue that "[t]he sum total of the 17 18 Relator's effort to plead scienter is that 'CRESCENDO knows this strategy is illegal because it 19 provides a significant benefit to a referring physician." MTD at 21 (quoting FAC ¶ 58). But 20 that's not true. STF also alleges the text messages and emails from Jacobson concerning co-pays 21 and sending patients to collections, which allegations give rise to a reasonable inference that 22 Defendants knew their alleged waiving of patient fees was improper. Defendants discount these 23 allegations, arguing that "[o]ne text message by a single sales employee does not support an 24 allegation or inference of a company-wide policy or practice and is insufficient to tag a corporate 25 entity with knowledge or endorsement of an alleged fraudulent cover-up." MTD at 21. But a logical inference from Jacobson's text message stating "I can't put in email our max out of pocket 26 for our test" is that someone higher up than Jacobson told her she shouldn't be putting that 27 28 information into email communications. And presumably there was some reason that that

someone told Jacobson to not do so. Reading the FAC in the light most favorable to STF, as the Court must do, one inference is that the reason was because Defendants knew or suspected their conduct was improper. STF has alleged facts supporting a plausible inference of scienter.

3. STF's IFPA Claims

Defendants argue that STF's IFPA claims all fail because they involved allegations of fraud and, as with its claims under the FCA, all STF's IFPA claims fail to meet the Rule 9(b) pleading standard. Much of Defendants' argument here attacks as overly broad or too generalized the allegations STF makes under each IFPA claim. But under each IFPA claim, STF expressly incorporates by reference and realleges the rest of the allegations in the FAC, as it may do. Many of the specific objections Defendants make vis-à-vis the IFPA claims, *see* MTD at 23-24, mirror objections Defendants made in relation to the FCA claims and thus are unavailing for the reasons already explained above. Similarly, Defendants' argument that STF failed to allege the scienter necessary to sustain its IFPA claims is unavailing for the reasons already discussed. Defendants' assertion that STF did not identify any private insurers that were allegedly defrauded as a result of Defendants' actions is not true. STF alleges multiple managed care companies which it alleges were damaged, along with "the plans they serve," by Defendants' conduct. *See* FAC ¶ 66-70.

Regarding Defendants' argument that the IFPA claims must be limited to insurance claims made to California payors regulated by the California Department of Insurance, that sort of limiting—even if warranted by law, as Defendants suggest—is not appropriate at this stage, where STF obviously doesn't haven't access to that type of information.

V. CONCLUSION

For the reasons stated above, the Court **DENIES** Defendants' Motion to Dismiss.
Defendants shall file their answers to STF's First Amended Complaint within 14 days of this
Order. The Court will conduct a telephonic Case Management Conference on June 25, 2020 at 10:00
a.m. This conference shall be attended by lead trial counsel. By June 18, 2020, the parties shall file a
Joint Case Management Statement containing the information in the Standing Order for All Judges in
the Northern District of California, available at: http://cand.uscourts.gov/tshorders. The Joint Case
Management Statement form may be obtained at: http://cand.uscourts.gov/civilforms. If the statement

1	is e-filed, no chambers copy is required.
2	IT IS SO ORDERED.
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4	Dated: May 23, 2020
5	TM. J.
6	THOMAS S. HIXSON United States Magistrate Judge
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