UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, et al., Plaintiffs, v. CAROLINA LIQUID CHEMISTRIES, CORP., et al., Defendants.	Case No. 13-cv-01497-JST **ORDER GRANTING MOTION TO DISMISS** Re: ECF No. 54

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Before the Court is Defendants' motion to dismiss. ECF No. 54. The Court will grant the motion.

I. BACKGROUND

A. Parties and Claims

As set forth in the operative complaint, Defendant Carolina Liquid Chemistries Corp. ("Carolina Liquid") is a "manufacturer, distributor, reseller, and service provider of in-office [urine drug test ("UDT")] analyzers and reagents." First Amended Complaint ("FAC"), ECF No. 25 ¶ 3. Defendant Patricia Shugart is the Chief Operating Officer and Vice President of Carolina Liquid. *Id.* ¶ 18. Defendant Phil Shugart is the Chief Executive Officer and President. *Id.* ¶ 19. Both Shugarts serve on Carolina Liquid's board of directors. *Id.* ¶¶ 18-19.

Relator Randy Reagan owns a chemistry supply business; Relator James Longfield is an independent consultant in the chemistry and laboratory industry. *Id.* ¶¶ 15-16.

Relators allege that Defendants violated the False Claims Act ("FCA") and various state analogues by perpetrating a widespread fraudulent scheme based on Medicare and Medicaid billing for UDT tests. Since at least March 2009, Carolina Liquid "systematically marketed" UDT machines by falsely representing that the machines could perform "high complexity 'quantitative'

drug testing." *Id.* ¶ 2. Relators contend, however, that Carolina Liquid's machines were in fact "only capable of performing basic 'qualitative' drug testing." *Id.* Critically, Medicare and Medicaid reimburse providers for high complexity and quantitative drug testing at substantially higher amounts than they do for qualitative testingf. *Id.* Physicians and pain management clinics followed Carolina Liquid's instructions to code tests performed on those machines as high complexity, and therefore submitted numerous false claims overcharging Medicare and Medicaid for the services actually performed. *Id.*

As described in Relators' complaint, qualitative drug testing is most commonly performed by in-office immunoassays and enzyme immunoassays that detect whether a drug class or panel of drug classes is present in a urine sample. *Id.* ¶¶ 42-43. These tests produce "a 'yes/no' result, but are unable to identify specific drugs within many drug classes or the amount of the drug in the urine." *Id.* ¶ 45. Because these tests are imprecise and prone to false positives, "physicians corroborate a positive result" from one of those tests by sending samples to a laboratory that performs a more complex "quantitative chromatography or mass spectrometry test for specific drugs and their quantities." *Id.* ¶ 46. Relators also allege that, "[s]eparate from whether a test is 'qualitative' or 'quantitative,' Medicare also distinguishes in reimbursement based on the complexity of a laboratory or office." *Id.* ¶ 50. Tests may be classified as either moderate or high complexity; even high complexity tests, however, are qualitative tests when performed on the UDT machines sold by Carolina Liquid or using its reagents. *Id.* ¶ 51.

Relators explain that the reimbursement scheme for UDTs, as implemented by the Centers for Medicare & Medicaid Services ("CMS"), has evolved during the period of the alleged wrongdoing. As relevant here, prior to January 2011, CMS required providers to bill qualitative tests at a rate of $20 per test. *Id.* ¶¶ 59, 64-65. CMS then changed its practices to require providers to use one of two codes: (1) G0434, for "Drug screen, other than chromatographic; any number of drug classes, by [Clinical Laboratory Improvement Amendments ("CLIA")] waived test or moderate complexity test, per patient encounter"; or (2) G0431, for "Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter." *Id.* ¶ 68 (emphasis omitted). While G0434 tests were still

reimbursed at a rate of $20, G0431 tests would be reimbursed at $100 per test. *Id.* Based on these definitions, Relators assert that "submitting any code other than a single G0434 per patient encounter for an in-office UDT is fraudulent upcoding." *Id.* ¶ 71 (emphasis omitted).

Relators allege that Carolina Liquid nonetheless marketed its UDT machines to customers by representing that the machines could perform tests that qualified for "test code G0431 and other high-complexity [Current Procedural Terminology ("CPT")] codes" and using reimbursement projections based on those misrepresentations. *Id.* ¶ 74. These codes included CPT codes for quantitative testing that Carolina Liquid machines were not equipped to perform. *Id.* ¶¶ 86-87. As part of this marketing, Carolina Liquid pitched its products as capable of generating reimbursement rates as high as $476.27 per test. *Id.* ¶¶ 74, 86-87. Relators contend that Carolina Liquid sales representatives distributed written brochures containing these projections, as well as a letter from Patricia Shugart. *Id.* ¶¶ 74, 82-83, 85-87. Patricia Shugart also held internal meetings in which she instructed employees to use these sales tactics. *Id.* ¶ 81.

Relators further claim that, when they became aware of these marketing practices, they "repeatedly communicated to Carolina Liquid personnel, including Carolina Liquid's Western Regional Sales Director," that the coding being promoted was improper. *Id.* ¶ 88. No corrective action was taken. Relators also point to a response from another manufacturer, Lin-Zhi International, Inc. ("LZI"), whose reagents were used in some Carolina Liquid tests. *Id.* ¶ 89. In 2012, Lin-Zhi sent a letter to its customers clarifying that its reagents could be used in qualitative and semi-quantitative assays only. *Id.* ¶ 90.

At some point, Carolina Liquid also began offering billing and coding consultant services to its customers. *Id.* ¶ 91. Relators allege that these services were specifically directed at promoting fraudulent upcoding. *Id.*

According to Relators, Carolina Liquid has more than 300 customers across 23 states. *Id.* ¶ 92. Relators posit that these customers, using a variety of the UDT analyzers sold by Carolina Liquid, submitted Medicare and Medicaid claims pursuant to Carolina Liquid's instructions. *Id.* ¶¶ 101-103.

B. Procedural History

On April 3, 2013, Relators filed this FCA *qui tam* action under seal, as directed by 31 U.S.C. § 3730(b). ECF No. 1. In addition to their federal FCA claims, Relators asserted claims under state false claim act analogues on behalf of the states of California, Texas, New York, Michigan, and North Carolina. *Id.*

On September 13, 2013, a different relator, Delbert Salyer, filed another *qui tam* action in the Central District of California, asserting similar FCA claims on behalf of the United States and a larger collection of states. *United States ex rel. Salyer v. Carolina Liquid Chemistries Corp.*, No. 13-cv-05976-JST, ECF No. 1. That case was subsequently transferred to this district and related to the current action. *Id.*, ECF Nos. 13, 15.[1]

The cases remained under seal pursuant to a series of extensions while the United States determined whether to intervene. Ultimately, the United States elected not to intervene, and the cases were unsealed on October 23, 2018. ECF No. 27.

On October 18, 2018, shortly before the cases were unsealed, Reagan and Longfield filed the operative FAC in this action. The affected States likewise elected not to intervene, and on November 27, 2018, the Court issued an order reflecting those decisions and dismissing without prejudice all claims asserted on behalf of the State of Maryland in the Salyer action. ECF No. 33.

On March 19, 2019, Defendants filed this motion to dismiss. ECF No. 54.

II. JURISDICTION

The Court has jurisdiction over Relators' FCA claims pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a). The Court exercises supplemental jurisdiction over the state-law claims under 28 U.S.C. § 1367 and 31 U.S.C. § 3732(b).

III. LEGAL STANDARD

A. False Claims Act

Congress enacted the FCA to address "widespread fraud by government contractors who were submitting inflated invoices and shipping faulty goods to the government." *Hooper v.*

[1] All further ECF citations are to No. 13-cv-01497-JST unless otherwise indicated.

Lockheed Martin Corp., 688 F.3d 1037, 1047 (9th Cir. 2012) (quoting *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1265 (9th Cir. 1996)). As relevant here, a person who "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," is liable to the United States for civil penalties and treble damages. 31 U.S.C. § 3729(a)(1). The Act contains a *qui tam* provision permitting private individuals to bring enforcement actions on behalf of the government. *Id.* § 3730(b)(1).

To establish an FCA claim, the government or a relator must show "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017) (quoting *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006)). "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 (quoting 31 U.S.C. § 3729(b)(2)). The FCA's scienter requirement encompasses "actual knowledge," "deliberate ignorance," or "reckless disregard," and requires no showing of a "specific intent to defraud." 31 U.S.C. § 3729(b)(1).

B. Motion to Dismiss: Federal Rules of Civil Procedure 8(a) and 9(b)

Because "[t]he FCA is an anti-fraud statute," a complaint alleging FCA claims is subject to the heightened pleading standards of Federal Rule of Civil Procedure 9(b). *Bly-Magee v. California*, 236 F.3d 1014, 1018 (9th Cir. 2001). Rule 9(b) requires a party to "state with particularity the circumstances constituting fraud or mistake," Fed. R. Civ. P. 9(b), often summarized as "the who, what, when, where, and how of the misconduct charged," *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1180 (9th Cir. 2016) (quoting *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010)). "When an entire complaint, or an entire claim within a complaint, is grounded in fraud and its allegations fail to satisfy the heightened pleading requirements of Rule 9(b), a district court may dismiss the complaint or claim." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1107 (9th Cir. 2003). Such a dismissal "is the functional

equivalent of a motion to dismiss under Rule 12(b)(6) for failure to state a claim." *Id.*

In evaluating whether a plaintiff has satisfied Rule 9(b), the Court considers the "two principal purposes" identified by the Ninth Circuit. *United Healthcare Ins. Co.*, 848 F.3d 1161, 1180. First, the heightened pleading standard requires that "allegations of fraud must be specific 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 and not just deny that they have done anything wrong." *Id.* (internal quotation marks omitted) (quoting *Bly-Magee*, 236 F.3d at 1019). Second, "the rule serves 'to deter the filing of complaints as a pretext for the discovery of unknown wrongs, to protect defendants from the harm that comes from being subject to fraud charges, and to prohibit plaintiffs from unilaterally imposing upon the court, the parties and society enormous social and economic costs absent some factual basis.'" *Id.* (quoting *Bly-Magee*, 236 F.3d at 1018).

In addition to complying with Rule 9(b), an FCA complaint must "also plead plausible allegations" sufficient to satisfy Rule 8(a). *Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011). Put differently, the complaint must allege "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the misconduct alleged]." *Id.* (alteration in original) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

IV. REQUESTS FOR JUDICIAL NOTICE

Before turning to the merits, the Court addresses the parties' requests for judicial notice. "Generally, district courts may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018). Judicial notice provides an exception to this rule. *Id.*

Pursuant to Federal Rule of Evidence 201(b), "[t]he court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." If a fact is not subject to reasonable dispute, the court "must take judicial notice if a party requests it and the court is supplied with the necessary

information." Fed. R. Evid. 201(c)(2). The Ninth Circuit has cautioned, however, that courts must be wary that the "use of extrinsic documents to resolve competing theories against the complaint risks premature dismissals of plausible claims that may turn out to be valid after discovery." *Khoja*, 899 F.3d at 998. Accordingly, "a court cannot take judicial notice of disputed facts contained in . . . public records," when, for instance, "there is a reasonable dispute as to what the [record] establishes." *Id.* at 999, 1001.

Defendants' first request for judicial notice, which is unopposed, seeks judicial notice of Department of Human and Health Services regulations. ECF No. 53 at 2. Although arguably unnecessary for published federal regulations, the Court grants this request. *Navajo Nation v. Dep't of the Interior*, 876 F.3d 1144, 1153 n.3 (9th Cir. 2017) ("The Court may take judicial notice of compacts, statutes, and regulations not included in the plaintiff's complaint.").

The remainder of Defendants' first request asks the Court to judicially notice various documents published by the Food and Drug Administration ("FDA") or CMS and available on those agencies' websites. ECF No. 53 at 2-3. These records themselves are judicially noticeable as a general matter. *See Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998-99 (9th Cir. 2010) (taking judicial notice of information "made publicly available by government entities" online, where "neither party disputes the authenticity of the web sites or the accuracy of the information displayed therein"). But, as addressed in greater detail below, Defendants rely on those records "to argue a fact that is in dispute," namely, the range of permissible reimbursement codes for Carolina Liquid's machines. *Rollins v. Dignity Health*, 338 F. Supp. 3d 1025, 1034 (N.D. Cal. 2018). Because "there is a reasonable dispute as to what [these records] establish[]," *Khoja*, 899 F.3d at 1001, the Court will not take judicial notice for this purpose. Subject to these limitations, the Court grants the request.

Relators' unopposed request for judicial notice and Defendants' second unopposed request for judicial notice concern the indictment, government's trial brief, and judgment in a federal criminal proceeding in the District of Massachusetts purportedly involving one of Carolina Liquid's customers. ECF No. 56-1 at 2; ECF No. 58 at 2. Defendants also seek judicial notice of the underlying complaint in a case cited by Relators. ECF No. 58 at 2. The Court "may take

judicial notice of court filings and other matters of public record" for purposes such as determining what issues were litigated in other proceedings. *Reyn's Pasta Bella, LLC v. Visa USA, Inc.*, 442 F.3d 741, 746 n.6 (9th Cir. 2006). Accordingly, the Court takes judicial notice that those documents were filed, that they contain certain allegations, and that Fathalla Mashali pleaded guilty to various offenses. *See* ECF No. 56-1 at 30. But the Court does not take judicial notice of the truth of the underlying facts alleged in these filings. The Court grants the request under these terms.

V. DISCUSSION

Relators' theory is that Defendants violated the FCA by knowingly causing Carolina Liquid customers to submit Medicare and Medicaid reimbursement claims that were "factually false." *United States ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 675 (9th Cir. 2018) (quoting *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001), *abrogated on other grounds by Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989 (2016)). In other words, because customers improperly coded tests, their reimbursement claims were based on "an incorrect description of goods or services provided or . . . goods or services never provided." *Id.* (quoting *Mikes*, 274 F.3d at 697).[2]

At the outset of its analysis, the Court notes that Relators' 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B) claims appear to rest on this same factual theory. Moreover, the parties do not distinguish between the two FCA claims and do not mention the state-law claims at all. Consistent with this approach, the Court treats Relators' single FCA theory as dispositive of the complaint as a whole.

A. False Claims

According to Defendants, Relators have inadequately pleaded that Defendants caused the

[2] Defendants' argument that Relators fail to allege a violation of "any applicable rule, guidance or regulation," ECF No. 54 at 17, appears at least partly directed to an express or implied certification theory, which Relators have not raised. *See Ebeid*, 616 F.3d at 998 (explaining that both types of certification theories turn on whether an entity, expressly or implicitly, falsely represents its "compliance with a law, rule or regulation" as part of its claim for payment). Here, Relators' theory of why claims were false is straightforward: Carolina Liquid customers overcharged the government for their services.

submission of false claims in two respects. First, Defendants dispute whether claims submitted using the codes Relators describe would necessarily be false. Second, Defendants assert that, even assuming that Relators' theory of improper upcoding is viable, Relators have not identified any false claims that Defendants actually caused to be submitted.

1. Falsity

The Court takes as true the complaint's allegations that Carolina Liquid customers submitted claims using G0431 codes and CPT quantitative testing codes, charging as much as $476 for a single test. FAC ¶¶ 74, 86-87. The complaint alleges that the G0431 code was improper because Carolina Liquid analyzers do not perform high complexity tests. *Id.* ¶¶ 68, 73. Relators similarly assert that the CPT quantitative codes were improper because Carolina Liquid analyzers run immunoassays that do not produce quantitative results. *Id.* ¶¶ 74, 87. To the extent Defendants' argument invokes Rule 9(b), the Court finds that these allegations describe with sufficient particularity why the use of those codes would produce false claims. *See United Healthcare Ins. Co.*, 848 F.3d at 1181-82.

The main thrust of Defendants' argument, though, seems to be that Relators' theory is not plausible under Rule 8(a). *See Cafasso*, 637 F.3d at 1055. The argument is not persuasive. Defendants first fault Relators' complaint for failing to provide "any supporting scientific or regulatory authority" to show that "particular billing codes apply to particular tests." ECF No. 54 at 17. But the complaint sets forth the definitions for the contested codes, FAC ¶¶ 59, 63, 68, and plausibly describes why Carolina Liquid machines are incapable of meeting those standards. Relators need not prove their case at this stage. *See Rhoades v. Avon Prod., Inc.*, 504 F.3d 1151, 1160 (9th Cir. 2007) ("[T]he question presented is whether [the] FAC is, on its face, sufficient to survive a motion to dismiss, not whether the alleged facts will ultimately prove accurate.").

Defendants also contend that Relators' allegations are "demonstrably false." ECF No. 54 at 18; *see also id.* at 19-20. In determining whether Relators' theory of falsity is plausibly alleged, the Court "need not . . . accept as true allegations that contradict matters properly subject to judicial notice or by exhibit." *Gonzalez v. Planned Parenthood of L.A.*, 759 F.3d 1112, 1115 (9th Cir. 2014) (alteration in original) (quoting *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988

(9th Cir. 2001). Nonetheless, judicial notice is not a vehicle "to resolve competing theories" or other factual disputes at the pleading stage. *Khoja*, 899 F.3d at 998. Accordingly, the facts Defendants seek to establish by judicial notice must be both beyond "reasonable dispute," Fed. R. Evid. 201(b), and plainly inconsistent with the allegations necessary to support Relators' claims.

Defendants' records do not meet this high bar. To support their argument that Carolina Liquid machines are capable of semi-quantitative and quantitative testing, Defendants cite two documents related to FDA approval under Section 510(k) of the Food, Drug and Cosmetic Act, 21 U.S.C. § 360(k). The documents apply to two different individual assays produced by third-party manufacturer Lin-Zhi and appear to reflect that one assay was approved for qualitative and semi-quantitative analysis, ECF No. 53-3 at 3, and the other approved for quantitative analysis, ECF No. 53-4 at 2. These records, which lack context within the larger allegations of this case, at most raise factual disputes that the Court cannot resolve in Defendants' favor in this posture. The parties have not adequately addressed whether semi-quantitative tests are appropriately billed as qualitative or quantitative. It is likewise unclear whether the assay approved for quantitative analysis is encompassed by the Lin-Zhi letter referenced in the complaint, which Relators argue disclaims quantitative testing uses. FAC ¶ 90. More generally, there is no indication of the relationship between these two products and the numerous Carolina Liquid machines at issue, or how broadly any conclusions drawn from these records would apply. In short, these two records are not sufficient to render implausible Relators' allegations regarding the inability of Carolina Liquid machines to perform quantitative testing.

Defendants also assert that Carolina Liquid "machines are capable of highly complex testing that appropriately may be billed under G0431." ECF No. 54 at 20. Defendants point to the applicable regulations, which provides that "[n]otices will be published in the Federal Register which list each specific test system, assay, and examination categorized by complexity." 42 C.F.R. § 493.17(a). Further, "[i]f a laboratory test system, assay or examination does not appear on the lists of tests in the Federal Register notices, it is considered to be a test of high complexity." *Id.* § 493.17(c)(4). Defendants then reason that Carolina Liquid tests are by default high complexity because they do not appear in the FDA's database of waived and moderate complexity

tests, ECF No. 54 at 20, of which Defendants ask the Court to take judicial notice.

Here, Defendants' assertion cannot "be accurately and readily determined" from the entire FDA database to which they direct the Court. Fed. R. Evid. 201(b)(2).[3] Moreover, settling this particular dispute in Defendants' favor would not foreclose Relators' claims based on quantitative CPT codes. FAC ¶¶ 71, 86-87.[4]

The Court therefore finds that Relators have adequately pleaded falsity.

2. Fraudulent Conduct

The Court next turns to whether Relators have sufficiently alleged that Defendants caused such claims to be submitted. Defendants assert that, "[a]t a minimum, Relators must specifically identify the false or fraudulent claims that were presented to the government." ECF No. 54 at 16.

As a threshold matter, Defendants' assertion does not accurately reflect the law of this Circuit. The Ninth Circuit has directly rejected a requirement that a relator must "identify representative examples of false claims to support every allegation." *Ebeid*, 616 F.3d at 998; *see also Silingo*, 904 F.3d at 678-79 ("We do not require the complaint to identify representative examples of actual false claims, though that is one way to satisfy the heightened pleading requirement."); *United Healthcare Ins. Co.*, 848 F.3d at 1180 (same). Rather, "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.'" *Ebeid*, 616 F.3d at 998-99 (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). As another district court in this Circuit has noted, this approach makes particular sense "where, as here, the

[3] An initial search of the database using "Carolina Liquid" as "Test System/Manufacturer" reveals 359 entries listing various tests using Carolina Liquid analyzers and/or reagents as "moderate complexity," with effective dates ranging from November 16, 2010 to February 22, 2019. *See generally* Food & Drug Administration, *CLIA – Clinical Laboratory Improvement Amendments*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm (last visited July 15, 2019). The Court's unguided and unconstrained research through this morass of data is unlikely to produce readily determinable facts beyond reasonable dispute.

[4] The Court notes that it is unclear from the complaint whether these two disputes (high versus moderate complexity and quantitative versus qualitative) apply to reimbursement claims submitted during the same period of time or under different coding regimes. *See* FAC ¶¶ 59-71. Nonetheless, this ambiguity impacts the period for which Defendants are plausibly liable, but does not dictate dismissal of Relators' claims in either scenario.

defendant is alleged to have induced third parties to submit false claims." *United States ex rel. Brown v. Celgene Corp.*, No. CV 10-3165-GHK SSX, 2014 WL 3605896, at *9 (C.D. Cal. July 10, 2014). In that case, "the relator cannot reasonably be expected to allege details about the individual claims that were submitted." *Id.*

Here, assuming that Carolina Liquid engaged in the widespread fraudulent marketing that Relators alleged, a court could easily infer for the purposes of a motion to dismiss that Carolina Liquid's customers then actually submitted claims using that improper upcoding. In that scenario, "[i]t would stretch the imagination to infer the inverse," *Silingo*, 904 F.3d at 679 (alteration in original) (citation omitted), namely, that providers all ignored the more profitable billing practices pitched by Carolina Liquid.

But Relators must describe the misconduct – here, the marketing of Carolina Liquid products – with the particularity required by Rule 9(b). Relators have described the reason that the alleged marketing was fraudulent, identifying the specific codes that should not have been charged, and the precise amounts that the government would have overpaid as a result. FAC ¶¶ 71, 74, 86-87. Yet Relators' complaint is otherwise devoid of the details of Carolina Liquid's marketing. Relators generally allege that Patricia Shugart chaired internal meetings instructing sales representatives in these practices, *id.* ¶ 81, but do not specify any details of these meetings or when they took place. Similarly, Relators quote from alleged Carolina Liquid documents, *id.* ¶¶ 82, 84-87, but do not identify any specific customers who were presented with these documents or the circumstances of any discussions. In short, Relators' description of this fraudulent marketing scheme, on which their FCA claim hinges, falls short of providing the "who, what, when, where and how of the alleged fraud." *United Healthcare Ins. Co.*, 848 F.3d at 1181.

A particularized theory of a fraudulent scheme, absent sufficient details to show that it took place, is insufficient to satisfy Rule 9(b). Relator's "allegations may be sufficient to 'give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge,' but they are insufficient to show the allegations against these defendants have a 'factual basis.'" *Id.* at 1182 (quoting *Bly-Magee*, 236 F.3d at 1018-19). The district court's decision in *Brown*, on which Relators rely, primarily illustrates what the

complaint lacks here. In *Brown*, the relator was a sales representative for defendants and therefore "a direct participant in [their] off-label promotion." 2014 WL 3605896, at *9. As the complaint in that case indicates, Brown described in granular detail specific meetings at which she was trained to market defendants' drug off-label and particular instances in which she in fact did so. *See, e.g.*, ECF No. 58-2 ¶¶ 136-150.[5] Other cases from this district likewise finding Rule 9(b) satisfied have relied on similar details. *See United States v. N. Am. Health Care, Inc.*, No. 14-CV-02401-WHO, 2015 WL 6871781, at *6 (N.D. Cal. Nov. 9, 2015) (citing "first-hand information" from a particular videoconference where defendant directed employees (including relator) to engage in fraudulent conduct, paired with "specific examples of kickbacks"); *Strom ex rel. United States v. Scios, Inc.*, 676 F. Supp. 2d 884, 888-89, 894 (N.D. Cal. 2009) (describing "particular marketing efforts" and "a series of examples" where defendants paid health-care professionals to promote off-label use of a drug).

The complaint's lack of detail is particularly problematic given that Relators purport to have "direct inside knowledge of Carolina Liquid's marketing practices." FAC ¶ 88. Courts have permitted "the traditional pleading standards for fraud under Rule 9(b) [to] be relaxed" for certain cases "where the evidence is within a defendant's exclusive possession." *Ebeid*, 616 F.3d at 999 (citation omitted). But the Ninth Circuit has declined to expand this exception to the FCA, which "is geared primarily to encourage insiders to disclose information necessary to prevent fraud on the government." *Id.* Consistent with the FCA's focus on this inside information, relators have met their pleading burden without identifying representative claims where they instead provided details based on their "first-hand experience of the scheme unfolding." *Silingo*, 904 F.3d at 679 (citation omitted); *see also Grubbs*, 565 F.3d at 191 ("The complaint sets out the particular workings of a scheme that was communicated directly to the relator by those perpetrating the fraud."); *Brown*, 2014 WL 3605896, at *9 (same). Given Relators' claim of direct knowledge, pleading the details of their personal experience should not be overly burdensome.

In sum, Relators' allegations do not describe Carolina Liquid's fraudulent marketing with

[5] As noted above, the Court takes judicial notice of the complaint not for the truth of the allegations therein, but for the level of detail considered and found adequate by the *Celgene* court.

the particularity required by Rule 9(b). Because this is the essential link in Relator's FCA theory, the Court cannot infer from the complaint that Carolina Liquid caused false claims to be submitted.

Given that Relators have not adequately alleged that Carolina Liquid caused false claims to be submitted, Relators' claims that Phil and Patricia Shugart did so in their capacities as Carolina Liquid executives fail as well. The Court also notes that, to the extent that the Shugarts did not have "the exact same role in [the alleged] fraud," the complaint provides minimal details of Patricia Shugart's role and contains no allegations regarding Phil Shugart's individual actions. *Silingo*, 904 F.3d at 677.

Accordingly, the Court dismisses the FCA claims against all Defendants.

B. Scienter

In order to pursue their claims further, Relators must amend their allegations regarding Defendants' marketing practices. Therefore, it would be premature to evaluate whether those allegations are sufficient "to support an inference or render plausible that" Defendants had actual knowledge of, were deliberately indifferent to, or recklessly disregarded the possibility that the billing practices they promoted were illegal. *United States v. Corinthian Colleges*, 655 F.3d 984, 997 (9th Cir. 2011); *see also* 31 U.S.C. § 3729(b)(1). The Court therefore does not reach this issue.

C. Statute of Limitations

Finally, Defendants argue that the claims against Phil and Patricia Shugart must be dismissed to the extent because they allege violations only prior to October 18, 2012,[6] six years before Relators' amended their complaint to name the Shugarts individually. ECF No. 54 at 22; *see also* 31 U.S.C. § 3731(b). Relators respond that the claims should not be dismissed wholesale, given that the FAC alleges ongoing misconduct after that date. ECF No. 56 at 20. In addition, they assert, the claims against the Shugarts relate back under Federal Rule of Civil Procedure 15(c)(1)(C). *Id.* at 20-12. Defendants do not respond to these arguments on reply.

[6] Although Defendants identify November 18, 2012, as the relevant date, the FAC was filed on October 18, 2018.

Particularly given Defendants' seeming abandonment of this argument, the Court finds it sufficient to agree that Relators have alleged FCA violations after October 18, 2012.[7] The statute of limitations therefore does not require the Court to dismiss these claims with prejudice.

D. Leave to Amend

Even though Relators' opposition does not expressly request leave to amend, "[l]eave to amend can and should generally be given, even in the absence of such a request by the party." *Hoang v. Bank of Am., N.A.*, 910 F.3d 1096, 1102 (9th Cir. 2018). Defendants do not argue, and the Court does not find, that Relators' complaint "could not possibly be cured by the allegation of other facts." *Yagman v. Garcetti*, 852 F.3d 859, 863 (9th Cir. 2017) (citation omitted). Accordingly, the Court will grant leave to amend.[8]

CONCLUSION

For the foregoing reasons, the Court grants Defendants' motion to dismiss without prejudice. Relators may file an amended complaint within 21 days.

IT IS SO ORDERED.

Dated: July 16, 2019

JON S. TIGAR
United States District Judge

[7] The Court expresses no view at this time whether Relators' claims against the Shugarts relate back to the date of their original complaint.

[8] The United States filed a statement of interest requesting that, even if the Court dismisses Relators' claims with prejudice, such dismissal be without prejudice to the United States. ECF No. 59. Because the Court grants leave to amend, it need not reach the issue.