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9	UNITED STATES DISTRICT COURT	
10	CENTRAL DISTRICT OF CALIFORNIA	
11	UNITED STATES OF AMERICA, et al.,	Case No.: 2:19-cv-10960-MEMF-SKx
12	Plaintiffs,	ORDER GRANTING IN PART MOTION TO
13		DISMISS [ECF NO. 68]
14	V.	
15	MEDTRONIC PLC, et al.,	
16	Defendants.	
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21	Before the Court is the Motion to Dismiss filed by Defendants Covidien PLC, Medtronic	
22	Inc., and Medtronic PLC. ECF No. 68. For the reasons stated herein, the Court hereby GRANTS IN	
23	PART the Motion to Dismiss.	
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BACKGROUND

I. <u>Factual Background¹</u>

The Court set out in detail the facts alleged by Relators John Birkle and Michael Bates on behalf of the United States of America and the several States² ("Relators") in its prior Order Granting Motion to Dismiss. ECF No. 51 ("MTD Order"). To briefly summarize, this *qui tam* action concerns two medical devices manufactured by Defendant Covidien PLC ("Covidien")³: (1) the Puritan Bennett 980 Series Ventilator System ("PB 980") and (2) the Vital Sync Informatics Manager & Virtual Patient Monitoring Platform ("Vital Sync," and collectively, the "Subject Devices"). Although Covidien received clearance from the Food and Drug Administration ("FDA") for the devices in 2014, Relators allege they are defective and unreliable, and further allege that Defendants gave kickbacks to hospitals to purchase these devices at government expense.

II. Procedural History

On December 30, 2019, Relators filed the instant *qui tam* action against Defendants. *See generally* ECF No. 1. On April 28, 2021, Relators filed a First Amended Complaint under seal, alleging forty-six (46) causes of action: (1) violation of the federal False Claims Act, 31 U.S.C. § 3729, *et seq.* (Counts 1 through 7); (2) violations of various state fraud statutes (Counts 8 through 38); (3) breach of contract (Count 39); (4) breach of implied covenant (Count 40); (5) retaliation (Count 41); (6) violation of California Labor Code § 1102.5 (Count 42); (7) constructive discharge in violation of public policy (Count 43); (8) defamation (Count 44); (9) retaliation, failure to promote/transfer, and constructive discharge in violation of the Fair Employment and Housing Act (Count 45); and (10) Fair Employment and Housing Act – disparate impact (Count 46). ECF No. 16.

¹ Unless otherwise indicated, the following factual background is derived from the Second Amended Complaint. ECF No. 62 ("SAC"). For the purposes of the Motion to Dismiss, the Court treats these factual allegations as true, but at this stage of the litigation, the Court makes no finding on the truth of these allegations and is therefore not—at this stage—finding that they are true.

² The "several States" in this action refers to the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, and the District of Columbia.

³ Covidien was purchased by Defendant Medtronic, Inc. on January 26, 2015, and the combined company is Defendant Medtronic PLC (collectively, "Defendants"). SAC ¶ 4.

On March 14, 2023, Defendants moved to Dismiss the First Amended Complaint. ECF No. 49. After briefing and argument from the parties, the Court issued an order granting Defendants' Motion to Dismiss with leave to amend. MTD Order.

On July 17, 2023, Relators filed the operative Second Amended Complaint, re-alleging the same causes of action. *See generally* SAC. On August 18, 2023, Defendants filed this instant Motion to Dismiss and Request for Judicial Notice. ECF Nos. 69 ("Motion"), 70 ("RJN"). On September 19, 2023, Relators filed their opposition to the Motion. ECF No. 72 ("Opposition"). On October 3, 2023, Defendants filed their reply. ECF No. 73 ("Reply"). On December 14, 2023, the Court heard oral argument on the Motion.

REQUEST FOR JUDICIAL NOTICE

I. Applicable Law

A court may take judicial notice of facts not subject to reasonable dispute where the facts "(1) [are] 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." Fed. R. Evid. 201(b). Under this standard, courts may take judicial notice of "undisputed matters of public record," but generally may not take judicial notice of "disputed facts stated in public records." Lee v. City of Los Angeles, 250 F.3d 668, 690 (9th Cir. 2001), overruled on other grounds by Galbraith v. County of Santa Clara, 307 F.3d 1119, 1125–26 (9th Cir. 2002). Moreover, even when documents are not physically attached to the complaint, courts may nonetheless consider such documents if: "(1) the complaint refers to the document; (2) the document is central to the plaintiff's claim; and (3) no party questions the authenticity of the document." United States v. Corinthian Colleges, 655 F.3d 984, 999 (9th Cir. 2011); Lee, 250 F.3d at 688.

II. Discussion

Defendants ask the Court to take judicial notice of two documents: (1) a 501(k) Summary of Substantial Equivalence for the PB 980 (ECF No. 71-1 ("Ex. A")); and (2) a 501(k) Summary of Effectiveness for Vital Sync (ECF No. 71-2 ("Ex. B")). Relators do not appear to object to

Defendants' RJN.⁴ Defendants assert that the exhibits were issued by the FDA and therefore public records of administrative bodies widely recognized as proper subjects of judicial notice. *See, e.g.*, *United States v. 14.02 Acres of Land More or Less in Fresno Cnty.*, 547 F.3d 943, 955 (9th Cir. 2008) ("Judicial notice is appropriate for records and 'reports of administrative bodies." (quoting *Interstate Nat. Gas Co. v. S. Cal. Gas Co.*, 209 F.2d 380, 385 (9th Cir. 1954))). The Court therefore GRANTS the Request for Judicial Notice and takes judicial notice of Exhibits A and B.⁵

MOTION TO DISMISS

I. Applicable Law

A. Motions to Dismiss for Failure to State a Claim

Under Federal Rule of Civil Procedure Rule 12(b)(6), a party may file a motion to dismiss for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). The purpose of Rule 12(b)(6) is to "enable defendants to challenge the legal sufficiency of claims asserted in a complaint." *Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 738 (9th Cir. 1987). A district court may properly dismiss a claim under Rule 12(b)(6) if the complaint fails to allege sufficient facts to support a cognizable legal theory. *Caltex Plastics, Inc. v. Lockheed Martin Corp.*, 824 F.3d 1156, 1159 (9th Cir. 2016).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter . . . to 'state a claim for 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)). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* While a complaint does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than "threadbare recitals of the elements of a cause of action." *Id.* "Determining whether a complaint states a plausible claim for relief is 'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Ebner v. Fresh, Inc.*, 838 F.3d 958, 963 (9th Cir. 2016) (quoting *Iqbal*, 556 U.S. at 679).

⁴ Accordingly, the Court presumes there is no objection as to the authenticity of the exhibits.

⁵ However, the Court notes that these documents appear to relate to claims that Relators have abandoned.

When evaluating a complaint under Rule 12(b)(6), the court "must accept all well-pleaded material facts as true and draw all reasonable inferences in favor of the plaintiff." *Caltex*, 824 F.3d at 1159; *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008) ("We accept factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party."). This tenet, however, is "inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678.

Moreover, Federal Rule of Civil Procedure 9(b) states that an allegation of "fraud or mistake must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Specifically, the "circumstances" required by Rule 9(b) are the "who, what, when, where, and how" of the fraudulent activity. *Vess v. Ciba—Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003); *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir. 1993) ("[Rule 9(b) requires] the times, dates, places, benefits received, and other details of the alleged fraudulent activity."). Additionally, the allegation "must set forth what is false or misleading about a statement, and why it is false." *Vess*, 317 F.3d at 1106 (quoting *In re Glenfed, Inc. Secs. Litig.*, 42 F.3d 1541, 1548 (9th Cir. 1994)). Rule 9(b)'s heightened pleading standard applies not only to federal claims, but also to state law claims brought in federal court. *Id.* at 1103.

A district court should generally grant leave to amend freely. *Cervantes v. Countrywide Home Loans, Inc.*, 656 F.3d 1034, 1041 (9th Cir. 2011). However, "a district court may dismiss without leave where a plaintiff's proposed amendments would fail to cure the pleading deficiencies and amendment would be futile." *Id.*

B. False Claims Act & Anti-Kickback Statute

The False Claims Act ("FCA") prohibits the submission of false or fraudulent claims to the federal government and imposes liability on an individual who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or who knowingly makes a "false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B). A claim under the False Claims Act requires a showing of:

(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 Sci., Inc., 862 F.3d 890, 899 (9th Cir. 2017) (quoting United States ex rel. Hendow v. Univ. of Phx., 461 F.3d 1166, 1174 (9th Cir. 2006)).

"A claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for the purposes of [the federal False Claims Act]." 42 U.S.C. § 1320a-7b(g); see also United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 96 (3d Cir. 2018) (confirming that the purpose of amendment to the Anti-Kickback Statute is to "strengthen[] whistleblower actions based on medical care kickbacks" and "to ensure that all claims resulting from illegal kickbacks are considered false claims" (quoting 155 Cong. Rec. § 10852-54 (daily ed. Oct. 28, 2009) (statement of Rep. Kaufman))); United States v. Medtronic PLC, 2022 WL 541604, at * 4 (C.D. Cal. Feb. 23, 2022) ("When the procurement of medical supplies is tainted by a knowing violation of the Anti-Kickback Statute and the violator knows those supplies are subject to reimbursement by a federal health care program, the submission to the government of a reimbursement claim for those supplies turns the Anti-Kickback Statute violator into a False Claims Act violator as well.").

Rule 9(b)'s heightened pleading standard applies to the False Claims Act. *Ebeid v. ex rel U.S. v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010). However, a relator need not identify representative examples of false claims to support every allegation. *Id.* Rather, "use of representative examples is simply one means of meeting the pleading obligation." *Id.* 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." *Id.* at 998–99 (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). However, even under this "relaxed standard," a relator "must provide enough detail 'to give [defendants] notice of the particular misconduct which is alleged to constitute the fraud charged so that [they] can defend against the charge." *Id.* at 999 (quoting *U.S. ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1051–52 (9th Cir. 2001)).

II. Discussion

Defendants contend that the Court should grant its Motion to Dismiss because: (1) Relators fail to adequately allege violations of the federal FCA, (2) Relators' state law claims fail as they parallel the federal FCA claim, and (3) Relators fail to adequately allege Birkle's employment-related claims. For the reasons discussed below, the Court finds that (1) Relators fail to allege federal FCA violations based on false certification, but adequately allege violations based on kickbacks, (2) their parallel state law claims are adequately alleged only as to certain states, and (3) Relators have abandoned the majority of their employment-related claims, but Birkle's retaliation claims survive.

A. Relators sufficiently plead claims for violations of the federal FCA based on kickbacks (Counts 1–2, 4–5), but not false certification (Counts 3, 6)

i. Relators fail to plead fraud based on false certification (Counts 3, 6).

In their opposition on the initial motion to dismiss, Relators specifically sought "leave to file a Second Amended Complaint to further detail Medtronic's express and implied false certifications of compliance with contractual, statutory, and regulatory requirements." ECF No. 54 at 2. The Court therefore granted Relators leave to amend their complaint to allege their false certification theory of liability under the FCA. MTD Order at 14. Despite having amended their complaint for a second time, Relators have abandoned their fraud based on false certification theory entirely in the face of Defendants' Motion. Opposition at 1 ("Relators do not oppose the dismissal of claims under the first theory."). Relators only explicitly concede as to Counts 3 and 6 on this point, and argue that the remaining federal FCA causes of action are viable under their kickback theory. *See* Opposition at n.1 (referencing Counts 3 and 6 only). Defendants argue that this concession should extend to Counts 1, 2, and 5 as well, but the Court finds that the SAC adequately pleads these counts based on false claims that can be satisfied by a violation of the Anti-Kickback Statute. SAC ¶ 258, 262, 276.

As Relators' concession comes after being given an opportunity to amend their allegations, the Court GRANTS the Motion as to Counts 3 and 6 without leave to amend. *See Chodos v. West Publishing Co.*, 292 F.3d 992, 1003 (9th Cir. 2002) (explaining that although leave to amend is liberally granted, a district court's discretion in allowing subsequent leave to amend is "particularly broad" when it has "already granted a plaintiff leave to amend").

ii. Relators sufficiently plead fraud based on kickbacks (Counts 1–2, 4–5).

A violation of the Anti-Kickback Statute occurs when the defendant: (1) knowingly and willfully (2) offers or pays remuneration (3) to induce the payee to purchase or recommend for purchase (4) any good or service that is reimbursable under a federal healthcare program. 42 U.S.C. § 1320a-7b(b)(2)(B); see also United States v. Miles, 360 F.3d 472, 479–80 (5th Cir. 2004). With regards to the AKS violation, the parties dispute the elements of remuneration and inducement. As explained below, the Court finds that Relators have sufficiently alleged these elements. To find a violation of the FCA, the Court must also find that any alleged kickback was material to the government's payment of an actual claim, and that there was scienter on the part of the Defendants. See Campie, 862 F.3d at 899. The Court finds that Relators have adequately alleged these elements at this stage.

1. Relators sufficiently allege remuneration under the AKS.

Defendants first challenge Relators' allegations supporting that Defendants offered or paid anything that could constitute remuneration under the AKS. Defendants specifically make arguments as to whether the provision of the following categories of goods or services can constitute remuneration: EVQs, filters, cleaning services, warranties, FlexTech, rentals, and trade-ins. The Court addresses each in turn, and finds that the majority of these properly support remuneration.

EVQs. The Court previously found that the provision of free EVQs was not remuneration because (1) it was not specifically pleaded whether the replacements were for defective products (which would not be remuneration) or for non-defective products (which may be remuneration) and (2) the EVQs had not been alleged to have been sold separately with individual and inherent value. MTD Order at 18–19. Relators have now alleged affirmatively that Defendants provided free EVQs "not to replace defective units," but because hospital staff members would often damage them during cleaning and installation. SAC ¶ 169. The Court acknowledges that it could be interpreted

⁶ The Court notes that the Opposition does not make any arguments as to the FlexTech program, rentals, and trade-ins specifically. At the hearing, Defendants requested that the Court find that Relators have waived arguments as to these categories of services, which the Relators objected to. At this stage, the Court declines to limit the scope of any claim. While the Court addresses all the categories raised by Defendants, the Court finds that this element is satisfied if even one category of goods and services can constitute remuneration at the motion to dismiss stage.

from the allegations that the defect with the PB 980 itself was how susceptible it was to damage in conjunction with how much it had to be cleaned. *Id.* ¶¶ 101, 102. Nevertheless, drawing all inferences in favor of the complainant, the Court finds that the allegations sufficiently support the inference that EVQs were freely provided to hospitals to replace damaged (and not inherently defective) products, and that otherwise the hospitals would have had to separately spend around \$900 to replace the EVQs themselves. SAC ¶ 169. Given the broad scope of the AKS,⁷ the Court finds that Relators have adequately pleaded remuneration in the form of provision of free EVQs.

Filters. For the same reasons as with the EVQs, the Court finds that Relators have adequately pleaded facts that would support that the provision of free DAR and Berriobac filters as remuneration. Specifically, Relators have alleged that Defendants provided "thousands of dollars worth of DAR filters as 'free samples." SAC ¶¶ 179–181. The fact that they were given to address an "alarm problem" with the PB 980 does not necessarily mean that they were given to replace defective products—rather, Relators allege that the issue was that there was a lack of alarm if hospitals used their own filters. *Id.* Therefore, a supported interpretation is that the PB 980s were properly used with Defendants' filters, and while hospitals may have preferred to use their own brands of filters, this does not necessarily equate to a defect with either the PB 980 or Defendants' filters. Therefore, the Court finds that the provision of free filters can qualify as remuneration.

Cleaning Services. Again, to the extent that the inference is drawn that the PB 980s being difficult to clean were not in it of itself a defect, the provision of free cleaning services would constitute remuneration. SAC ¶ 170.

Warranties. Relators have alleged that hospitals were provided with a "highly valuable extended warranty, including a maintenance agreement at no charge." SAC ¶¶ 183–187. The Court finds that this sufficiently supports the inference that the warranties had an independent value, and therefore constitute remuneration.

FlexTech. The FlexTech sales program was allegedly used to allow hospitals to receive a PB 840 ventilator, and then upgrade to the PB 980 after a year. SAC ¶ 182. Relators have alleged that

⁷ See Hanleser Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995) (recognizing Congress's intent to broaden the reach of the AKS).

hospitals would keep the PB 840 much longer than this period. *Id.* It appears that the value stems from the hospitals "getting an extra two and a half years of extra use out of these new ventilators at no charge, before receiving new PB 980s." *Id.* However, it is unclear how this is an additional value, as it is not clear that the PB 840s are somehow worth less than the PB 980s, which are the newer product. Based on the allegations, what is clear is that no hospital had more than one ventilator at a time under the program—if they kept the PB 840, they would not receive the PB 980. Therefore, the Court finds that the allegations regarding the FlexTech program have not been adequately pleaded to constitute a remuneration.

Rentals. Relators have pleaded that on two occasions, a hospital required Defendants to rent it ventilators because "it did not have faith in the PB 980 ventilators." SAC ¶ 188. While the Court finds that it is plausible that the hospital did not have faith because there were actually defects with their PB 980s, drawing the inference in favor of complainants, the hospitals could have also just wanted to use a different product. The Court finds this adequately supports remuneration, as these rentals had a specific value. *Id*.

Trade-Ins. The Court previously found that the allegations of allowing hospitals to keep trade-in ventilators for an extended period of time satisfied remuneration, and does not find it necessary to revisit the analysis here. MTD Order at 19–21.

2. Relators sufficiently allege inducement under the AKS.

Although not explicit in its moving papers, Defendants also challenge the inducement element of the AKS. *See* Reply at 4. At the hearing, Defendants explained that their argument on the inducement element in its moving papers was "married" with their 9(b) argument that "a causal connection between alleged kickbacks and any alleged false claims paid" must be specifically pleaded. Motion at 18. However, this marriage is exactly why Defendants' argument fails on this point.⁸ In its MTD Order, the Court previously noted the allegations in the FAC did not indicate that the kickbacks induced the hospital to submit false claims. MTD Order at 22. The Court clarifies that actual inducement is not a requirement of the AKS—that remuneration was given "to induce" is

⁸ The Court notes that this is an independent determination from whether there is sufficient causation under the FCA, which the Court does not reach here.

sufficient for a violation of the AKS. See U.S. v. TEVA Pharmaceuticals, Inc. USA, Inc., 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016) (noting that the "focus of the AKS is not the success of the bribe, but the bribe itself" and that a relator only need to show that "one purpose of remuneration is to induce a person to use a service for which payment is made under a federal healthcare program" (citing U.S. v. Katz, 871 F.2d 105, 108 (9th Cir. 1989)). Therefore, the fact that Relators have not alleged that "every single purchase of a Subject Device was induced by a kickback" is not necessary to plead inducement under the AKS. Motion at 18. Even if no Subject Devices were bought because of the inducement, it would be a violation of the AKS if Defendants gave renumeration to induce, which has been sufficiently pleaded at this time. See SAC ¶ 166 ("This equipment was given to hospitals and physicians for free in order to change the behavior of the surgeons and induce more sales of Defendants' products.").9 Accordingly, the Court finds that the inducement element has been adequately pleaded.

3. Relators sufficiently allege materiality under the FCA.

"The term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. Winter ex rel. United States v. Gardens Regional Hospital and Medical Center, Inc., 953 F.3d 1108, 1121 (9th Cir. 2020). "For a false statement to be material, a plaintiff must plausibly allege that the statutory violations are 'so central' to the claims that the government 'would not have paid these claims had it known of these violations." Id. To satisfy Rule 9(b) in the context of an FCA violation, 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," nor "identify representative examples of false claims to support every allegation." United States v. United Healthcare Insurance Company, 848 F.3d 1161, 1180 (9th Cir. 2016) ("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.").

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⁹ Defendants, for the first time on Reply, make the argument that "induce" in the AKS must mean something similar to criminal solicitation. Reply at 6–7. Regardless, the Court finds that the allegations adequately characterize that Defendants' intent in giving remuneration was to solicit unlawful acts.

Here, Relators have alleged that the government would not pay out for claims that were not accurate or truthful, or "tainted by unlawful kickbacks." SAC ¶ 196–200. As alleged, payment to providers is "conditioned upon [an] express certification that the Provider has complied with the AKS." Id. ¶ 69. This is sufficient—as the Court has found that Relators have sufficiently pleaded the underlying AKS violation at this time, the Court does not find that materiality is a high bar to meet. The Court acknowledges that not every misrepresentation is "material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." Universal Health Services, Inc. v. U.S., 579 U.S. 176, 194 (2016). However, designated compliance is nonetheless still "relevant" in evaluating materiality (id.), and courts have previously found that compliance with AKS is material to the FCA. See, e.g., U.S. ex rel. Macias v. Pacific Health Corporation, 2019 WL 2396305, at *7 (C.D. Cal. June 5, 2019) ("Several courts have found that compliance with the AKS is material for the purpose of the FCA."). The Court sees no reason to require more for materiality in this case. Interpreting the allegations in favor of Relators, Defendants provided remuneration to hospitals with the expectation that they would continue to buy and use their products. It follows that the government would not have paid for claims for ventilators that were part of this kickback scheme, if the kickbacks had been disclosed. Accordingly, this omission could be considered material to the government's payment of claims.

Defendants' main argument as to materiality is intertwined with the requirement of the FCA that any false statement (which may be satisfied by an AKS violation) actually cause the government to pay out money. Defendants argue that even accepting there was remuneration, as alleged, none of the remuneration could have led to the purchase of any new Subject Devices. *See* Reply at 7. Rather, they argue that all of the remuneration alleged has to do with servicing of existing PB 980s, which the hospitals already had. Moreover, Defendants argue that the particularity requirement of Rule 9(b) is not satisfied because rather than identify specific claims that were caused by any remuneration, Relators have merely set forth a chart of total government payment to hospitals over a seven-year time period related to all ventilator use. SAC ¶ 7.

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 $^{^{10}}$ Defendants' main arguments at the hearing on the Motion related to this point, which the Court addresses here.

The Court first finds that the SAC plausibly alleges that the remuneration could have led to further purchases of the Subject Devices, or other related claims to be submitted. For example, Relators have alleged that in one instance, Defendants left trade-in equipment at UCLA despite giving the hospital the trade-in discount applied to the purchase of a new PB 980. SAC ¶ 173. Drawing all inferences in favor of the complainant, it is plausible that the hospital was induced to purchase the new PB 980 from Defendants because the hospital was getting not only a trade-in discount, but were actually getting to keep the old device. The SAC also pleads that regarding warranties, some customers "demanded an even further extended warranty before purchase." SAC ¶ 183. While the Court acknowledges that other forms of remuneration may not obviously appear related to a specific claim, the Court does not find that Relators must specifically identify each and every claim submitted that they are alleging were induced by the remuneration at issue at this stage.

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To the extent that Defendants gave remuneration to the hospitals during the time period identified by Relators (2014 to 2021) and these hospitals submitted government claims for purchases from Defendants, it is plausible that all of the purchases from Medtronic were induced by kickbacks. SAC ¶ 7. This is how kickbacks work—a company gives a hospital something of value, so that the hospital will continue to use their services and products. The branching consequence of every remuneration identified by Relators is appropriately resolved through the discovery process—the Court finds it sufficient at this point that Relators have specifically alleged that Defendants gave kickbacks to the hospitals, and that the hospitals then made claims to the government for purchases from Defendants without disclosing these kickbacks. See Ebeid, 616 F.3d at 998 (concluding that it is sufficient under Rule 9(b) to allege the "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted"); see also U.S. ex rel. Everest Principals, LLC v. Abbott Lab., 622 F. Supp. 3d 920, 933 (S.D. Cal. Aug. 18, 2022) (holding that "[r]egardless of [the] apparent split of authority between the Third and Eighth Circuits (and the 9th Circuit's silence as to [the] 'but for' cause issue)," the relators adequately established a link simply by pleading that the defendant gave remuneration "for the purpose of inducing" usage of a medical device); Strom ex rel. U.S. v. Scios, Inc., 676 F. Supp. 2d 884, 894 (N.D. Cal. 2009) ("While there may indeed 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").

Similarly, to the extent that Defendants gave remuneration to the hospitals during the time period identified by Relators (2014 to 2021) and these hospitals submitted government claims for use of the Defendants' ventilators in treatment, it is plausible that all of this use was induced by kickbacks. SAC ¶ 7. And the Relators explicitly allege that the kickbacks led the hospitals to continue using these ventilators in treatment and file claims for their usage. SAC ¶¶ 6, 7, 10, 12. Furthermore, the Relators plausibly allege the connection between the usage claims and the purchases by alleging that the government "funded these equipment purchases after the fact by providing reimbursement for the use of Defendants' devices." *Id.* ¶ 10. Given the allegations cited above regarding new purchases, the Court need not determine at this stage whether claims for usage of ventilators purchased as part of the kickback scheme would be sufficiently linked to the AKS violation as to constitute false claims. The Relators can attempt to develop this theory during discovery and either party may seek to prevail on their respective positions at summary judgment or trial.

Here, the details in the Complaint sufficiently give Defendants notice of the misconduct alleged so that they may properly defend against the allegations, which satisfies the purpose of Rule 9(b). *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir. 1993) ("This court has interpreted Rule 9(b) to require that 'allegations of fraud are 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 . . .").

Accordingly, the Court finds Relators have sufficiently pleaded materiality.

4. Relators sufficiently allege scienter under the FCA.

Rule 9(b) allows plaintiffs to allege scienter "generally," although it must still be plausible. *Winter*, 953 F.3d at 1122. Moreover, "a plaintiff need not prove a 'specific intent to defraud' under the FCA—the Act imposes liability on any person acting 'knowingly,' which includes acting with 'actual knowledge, as well as acting 'in deliberate ignorance,' or 'in reckless disregard of the truth or falsity of the information." *Id.* Here, the Court finds this standard met, as there are plausible

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allegations regarding Defendants' knowledge that they were giving kickbacks, and that hospitals it gave kickbacks to would make claims and receive government money for its purchases of the Subject Devices. SAC ¶¶ 189, 193–106, 203 (alleging knowledge of Defendants' conduct).

Accordingly, the Court finds Relators have sufficiently pleaded scienter.

* * *

The Court therefore DENIES the Motion to Dismiss with respect to the claims of FCA violation based on kickbacks (Counts 1–2, 4–5). The Court GRANTS the Motion to Dismiss with respect to the claims of FCA violation based on false certification (Counts 3, 6) without leave to amend.

B. Relators' sufficiently allege California, Hawaii, and Nevada state law claims (Counts 8, 9, 16, 27) but do not sufficiently allege state law claims as to other states (Counts 10–15, 17–26, 28–38)

The parties appear to be in agreement that Relators' state law claims parallel the FCA claims, and therefore rise and fall with the federal FCA claims. Motion at 19–20; Opposition at 2. As the Court finds FCA claims based on a kickback theory adequately alleged at this stage, the Court also finds the equivalent state law claims adequate. Nevertheless, the Court notes that the SAC alleges remuneration mostly being given to California hospitals, (see, e.g., SAC ¶ 170 (discussing Kaiser Baldwin Park), 171 (Torrance Memorial Medical Center), 173 (UCLA Ronald Regan Medical Center)). The SAC also shows a chart of hospitals that purchased PB 980 ventilators, with one Hawaii hospital and the rest in California. SAC ¶ 7. At one point, the SAC alleges that Birkle stated that Defendants should not do business with "13 different California and Nevada hospitals" which all received government reimbursement. SAC ¶ 241. Accordingly, the Court finds that there are sufficient allegations tying Defendants' actions to hospitals in California, Hawaii, and Nevada, as the Court infers that these hospitals would likely submit similar false claims in their respective states. However, there is a lack of allegations from which the Court can infer false claims were submitted to any other state government. See U.S. ex rel. Everest Principals, LLC v. Abbott Laboratories, Inc., 622 F. Supp. 3d 920, 935 (S.D. Cal. Aug. 18, 2022) (dismissing state claims where the relator did not allege "with particularity how any false claims were submitted to each state identified").

The Court therefore DENIES the Motion as to Counts 8, 9, 16, and 27—which bring causes of action for violation of California, Hawaii, and Nevada law—but GRANTS the Motion with leave to amend for the remaining states (Counts 10–15, 17–26, 28–38).

C. Birkle adequately pleads his retaliation causes of action (Counts 7, 41) but has abandoned his remaining employment-related claims (Counts 39–40, 42–46)

Defendants move to dismiss the various employment-related claims asserted by Birkle: retaliation under the federal FCA and its California analogue (Counts 7, 41); violation of California's whistleblower statute (Count 42); constructive discharge (Count 43); breach of contract (Count 39); implied covenant of good faith and fair dealing (Count 40); defamation (Count 44); and age-based discrimination claims under FEHA (Counts 45–46). Relators have only opposed Defendants' arguments with respect to retaliation claims in their Opposition. The Court therefore only addresses the retaliation claims here and finds the rest of the claims abandoned. *See Jenkins v. County of Riverside*, 398 F.3d 1093, 1096 n.4 (9th Cir. 2005) (noting that the plaintiff "abandoned her other [] claims by not raising them in opposition").

A relator alleging an FCA retaliation claim must demonstrate that: (1) he engaged in protected activity; (2) his employer knew that conduct was protected; and (3) he suffered an adverse employment action causally linked to that protected conduct. *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1103 (9th Cir. 2008). The Court previously found that Birkle had not adequately alleged the first two elements. MTD Order at 28. Birkle has now alleged that he had multiple conversations with Medtronic Vice President Blake Tatum, where Birkle "expressed that it was unethical and an obvious violation of their Compliance Wire training that Defendants were providing customer hospital accounts with free equipment . . ." and that he complained quarterly to Vice President of Sales Kevin Hardage that Birkle "was concerned about the unethical nature of Defendants providing" certain goods and services. SAC ¶¶ 232–233.

Defendants' arguments on this issue appear to focus on allegations that Birkle raised concerns about customer complaints and allegedly defective products. Motion at 21; Reply at 13.

¹¹ Nevertheless, as there is no dispute that California's False Claims Act ("CFCA") has a parallel standard, the Court interprets Relators to have opposed Defendants' arguments as to retaliation under CFCA, even if not explicitly stated. *McVeigh v. Recology S.F.*, 213 Cal. App. 4th 443, 445 (2013).

However, to the extent that Birkle raised complaints that the provision of free goods and services was "unethical," and an "obvious violation," this would plausibly allege that Birkle was concerned that Defendants were inducing false claims. 12 See Moore v. Cal. Inst. of Tech. Jet Propulsion Lab., 275 F.3d 838, 845–86 (9th Cir. 2002) (defining protected activity as where an employee in good faith and reasonably believes, "that the employer is possibly committing fraud against the government"). At the hearing, Defendants argued that the SAC merely alleges that Birkle raised complaints that Defendants were not complying with the training they provided him, which is insufficient to rise to the level of a protected activity under the FCA. However, Birkle has alleged that the training in question "specifically discussed regulatory requirements that Defendants not provide any free products or services because that could constitute [undue] influence" under the AKS and FCA. SAC ¶ 231. Therefore, Birkle's complaints that he believed Defendants to be violating what they were told in this training directly reflects that he was concerned specifically that Defendants were violating the AKS and FCA, which is actionable. U.S. ex rel. Hopper v. Anton, 91 F.3d 1261, 1269 (9th Cir. 1996) (explaining that "the plaintiff must be investigating matters which are calculated, or reasonably could lead, to a viable FCA action"). Defendants relied on *Hopper* in arguing that there, the relator's retaliation claim was dismissed even though she submitted numerous complaints. However, her "investigatory activity did not have any nexus to the FCA." Id. Here, even though Birkle may not have raised as many specific complaints as the relator in *Hopper*, his complaints, as alleged, have a clear nexus to the FCA.

Moreover, there are allegations that Birkle made complaints not tied specifically to violation of any training—for example, his complaints also expressed concern that one of Medtronic's competitors would find out about the kickbacks and complain about them to the government, and that the retention of trade-in equipment could be considered a kickback. SAC ¶ 232–233. The allegations also specifically show knowledge by senior management and leadership of Birkle's complaints, as they were directly made to Tatum and Hardage. This would constitute knowledge by

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¹² The Court draws all inferences in favor of Relators in inferring that the customer hospitals Birkle complained about were places that received government funding.

Defendants that Birkle was engaging in this protected activity.¹³ The Court finds that this is sufficient to meet the first two prongs of a retaliation claim.

Finally, the Court finds that Birkle has adequately alleged adverse conduct based on protected activity. Specifically, Birkle has alleged the adverse conduct as Defendants trying to "force" him out of the company "through a process of retaliation" in part due to his complaints. SAC ¶ 244. The Court finds this sufficient to meet the final element of the claims at this stage of the case. See Mendiondo v. Centinela Hosp. Medical Center, 521 F.3d 1097, 1101 (9th Cir. 2008) (holding that notice pleading standard, as opposed to a heightened pleading standard, applies to FCA retaliation claims). Accordingly, the Court finds that Birkle has adequately pleaded his retaliation claims under the FCA and CFCA.

* * *

The Court therefore GRANTS the Motion to Dismiss as to Counts 39–40, 42–46 without leave to amend, but DENIES the Motion to Dismiss as to Counts 7 and 41.

III. Conclusion

For the foregoing reasons, the Court hereby ORDERS as follows:

- 1. The Request for Judicial Notice is GRANTED;
- 2. The Motion to Dismiss is DENIED as to:
 - a. Relators' federal FCA claims based on a kickback theory (Counts 1 –2, 4–5);
 - b. Relators' California, Hawaii, and Nevada state law claims paralleling the federal FCA (Counts 8, 9, 16, 27);
 - c. Relators' claims for retaliation under the federal FCA and CFCA (Counts 7, 41);
- 3. The Motion to Dismiss is GRANTED with leave to amend as to:
 - a. Relators' remaining state law claims paralleling the federal FCA (Counts 10–15, 17–26, 28–38);
- 4. The Motion to Dismiss is GRANTED WITH PREJUDICE as to:

¹³ While the Court acknowledges Defendants' arguments as to the veracity of the allegations and alternative theories, the Court does not find it appropriate at this stage to make factual determinations—rather, the Court must draw all inferences in favor of Birkle, and in doing so, does not find anything in the SAC that would facially contradict the allegations it identifies here as sufficient to plead the retaliation claims.

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- a. Relators' federal FCA claims based on a false certification theory (Counts 3, 6); and
- b. Relators' remaining employment-related claims (Counts 39–40, 42–46).

IT IS SO ORDERED.

Dated: March 28, 2024

MAAME EWUSI-MENSAH FRIMPONG

United States District Judge