IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STEVE SHIELDS

Plaintiff,

v.

ALERE HOME MONITORING, INC., ALERE SAN DIEGO, INC.

Defendants.
_____/

No. C15-2580 CRB

ORDER GRANTING MOTION TO DISMISS

Plaintiff Steve Shields filed this putative class action against Defendants Alere Home Monitoring, Inc. and Alere San Diego, Inc. (collectively, "Alere"), alleging fraudulent and unfair business practices in connection with Alere's sale of INRatio PT/INR Monitoring Systems (collectively, the "INRatio Systems" or the "devices"). Alere now moves to dismiss Shields's complaint for failure to state a claim under California's Consumer Legal Remedies Act ("CLRA") and under California's Unfair Competition Law ("CUCL"). For the reasons set forth below, the Court GRANTS Alere's motion to dismiss.

I. BACKGROUND

A. The INRatio Systems

The INRatio Systems are Class II medical devices used by healthcare professionals or patients at home to monitor the anticoagulation effects of blood thinning medications. See First Amended Complaint ("FAC") (dkt. 10) ¶ 1; Request for Judicial Notice ("Request") (dkt. 22), Ex. A (FDA INRatio 501(k) Substantial Equivalence Determination Decision

Summary, § H, Intended Use) at 1–2. Patients can only obtain these devices with a prescription. See id. § B (Purpose for Submission) at 1. The devices permit patients to monitor their blood at home, rather than having to have blood drawn at a lab on a weekly or monthly basis. See id.; FAC ¶ 1. The INRatio Systems consist of an electronic monitor for interpreting test strips as well as test strips onto which patients place a blood sample. See FAC ¶ 1.

The package insert for the INRatio Systems provides instructions on its use and a number of warnings about circumstances in which the devices can yield inaccurate results. See generally Request, Ex. B (INRatio2 Self Test User Guide). For example, the INRatio2 user guide states:

> **Your current health status**
>
> Current health status may affect test results and cause inaccurate results or results that are not what you expect. It's important to take certain health factors into consideration when interpreting test results and deciding on a course of action with your health care provider. Failure to do so may lead to an incorrect interpretation of the PT monitor results.

Id. at 8; see also id. at 7–8 (listing a series of precautions and limitations on use of the device).

B. Alere's Correction Letter and the FDA's Recall of INRatio Systems

On December 4, 2014, Alere released an urgent "Medical Device Correction," (the "correction letter") in which it advised patients that, under certain circumstances, the INRatio Systems could yield inaccurate results. See Request, Ex. C (Urgent Medical Device Correction) at 1. That same day, the U.S. Food and Drug Administration ("FDA") issued a Class I recall[1] of the devices and test strips because the FDA found that they may provide a test result lower than the expected result obtained using a laboratory method. Id., Ex. E (FDA Recall Notice) at 2. In its notice, the FDA informed device users that Alere had

[1] The FDA defines the term "recall" broadly to include both "removal" and "correction" of a marketed product. See Request for Judicial Notice, Ex. D (FDA Recalls, Corrections and Removals (Devices)) at 2. A "correction" does not require the removal of a product from the market, but rather requires the "repair, modification, adjustment, relabeling, destruction, or inspection . . . of a product without its physical removal to some other location." Id.

received 18,924 complaints about the INRatio Test Strips from 2013–2014, though "not all of [the complaints] are related to the recall." See id.

Both Alere's correction letter and the FDA recall notice advised patients that incorrect results could occur if a patient had certain medical conditions such as anemia, conditions associated with elevated fibrinogen levels, or unusual bleeding or bruising. See Urgent Medical Device Correction at 1; FDA Recall Notice at 1. Specifically, Alere advised INRatio Systems users:

> **You should contact your doctor to determine if any of these medical conditions apply to you:**
>
> - Anemia (low hemoglobin or low red blood cell count). Your hematocrit should be between 30 – 50%
> - Any conditions associated with elevated fibrinogen levels (Note: fibrinogen is the protein from which a clot is formed)
>   - acute inflammatory conditions (for example viral or bacterial infections such as pneumonia or flu)
>   - chronic inflammatory conditions (for example rheumatoid arthritis, Crohn's disease, ulcerative colitis, infectious liver diseases such as hepatitis, or inflammatory kidney diseases such as diabetic nephropathy and glomerulonephritis)
>   - severe infection (for example sepsis)
>   - advanced stage cancer or end stage renal disease requiring hemodialysis
> - any bleeding or unusual bruising

See Urgent Medical Device Correction at 1 (emphasis in original). Alere and the FDA instructed patients to discuss with their doctors whether any of the above medical conditions applied to them, and if so, they recommended certain procedures. See Urgent Medical Device Correction at 1; FDA Recall Notice at 2.

Neither Alere's correction letter nor the FDA's recall notice directed all patients to cease use of the devices. See Urgent Medical Device Correction at 1–2; FDA Recall Notice at 1–2. Only those patients with the conditions "detailed in the correction letter" were advised to stop using the INRatio Systems. See FDA Recall Notice at 2. The FDA has not mandated removal of the INRatio Systems from the medical device field—the devices remain on the market. See Guerdan Decl. (dkt. 21-1) ¶¶ 4, 8. See generally FDA Recall Notice. Alere, with FDA oversight, currently is working to upgrade the INRatio Systems software to reduce the potential for inaccurate test results. See Guerdan Decl. ¶ 6.

C. Shields's First Amended Complaint

Shields seeks to represent a national class of persons who paid for the INRatio Systems as well as a national subclass of persons who bought the device for "personal use," as defined by the California Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750, et seq. See FAC ¶¶ 24–25.

Shields asserts that he purchased an INRatio device "[o]n or about [] 2012" to monitor his blood. See FAC ¶ 21. After purchasing the device, Shields purchased "numerous $20 'test strips.'" Id. Shields states that he decided to purchase the device "based on promotional materials he saw on the internet." See id. According to Shields, Alere engaged in an "aggressive marketing campaign" that was directed at consumers and physicians. See id. ¶ 13. Throughout the class period, Shields states, Alere's "website, product manual, and promotional materials" promoted the INRatio Systems's "simplicity, accuracy, and convenience." See id. Shields explains that he was "told and relied upon the statements" that the device was "accurate and reliable" and a "convenient alternative to traditional lab tests." See id. ¶ 21.

Shields alleges that shortly after the INRatio Systems hit the market, Alere "began receiving reports" that the Systems were not providing accurate readings. See id. ¶ 14. According to Shields, an FDA inspection of Alere's San Jose manufacturing facility revealed that by October 2005, Alere knew their Systems were producing erroneous results. See id. The FDA's October 4, 2005 Warning Letter stated that "[The FDA's] review indicates that your firm had information indicating that INRatio devices were generating clinically significant erroneous values." See id. ¶ 15. Shields alleges that this statement by the FDA implies that Alere was "trying to conceal" the devices' problems from the FDA. See id.

Shields alleges that he recently learned that his INRatio device "was not reliable and was not a convenient alternative to traditional lab tests." See id. ¶ 22. Shields argues that he is now the owner of an INRatio device that is "essentially worthless." Id. Shields thus brings two causes of action. First, Shields alleges that Alere employed unfair or deceptive business practices intended to result in the sale of the INRatio Systems in violation of the

CLRA. See FAC ¶¶ 1, 13, 37. Shields argues that Alere's acts and practices violated, and continue to violate, the CLRA in three respects: (1) Alere represents that the INRatio Systems have characteristics, uses, or benefits that they do not have; (2) Alere represents that the INRatio Systems "are of a particular standard, quality, or grade when they are of another"; and (3) Alere advertises goods with the intent not to sell them as advertised. See id. ¶ 37.

Second, Shields alleges that, under the CUCL, Alere "knew their INRatio system was unreliable, inaccurate, and not suitable substitute [sic] for traditional laboratory tests." See id. ¶ 43. Shields further alleges that Alere "knowingly misrepresented the reliability of" the INRatio Systems. See id. ¶ 45. Finally, Shields alleges that Alere knowingly sold and continues to sell the INRatio Systems "while concealing and suppressing the nature and scope of the problems" with these devices. See id. ¶ 44.

Shields now seeks the following remedies from this Court: (1) compensatory damages to be determined at trial; (2) a civil penalty against Alere pursuant to California Civil Code § 1794; (3) restitution of funds "unlawfully acquired" by Alere by means of any acts or practices in violation of the CUCL; (4) an injunction to prohibit Alere from engaging in the unfair business practices described in the complaint; (5) punitive damages; (6) attorneys' fees; (7) costs and expenses; and (8) any other relief deemed just and proper by this Court. See FAC, Prayer for Relief ¶¶ 1–8.

D. Summary of Alere's Arguments Presented in the Motion to Dismiss

Alere contends that Shields's FAC should be dismissed for two reasons: First, Shields lacks Article III standing to bring his claims because (1) Shields has not alleged an injury in fact and (2) nothing suggests that Shields was using an INRatio Systems device at the time that Alere's correction letter was issued. See Mot. to Dismiss (dkt. 21) at 4–8. Thus, Alere asserts, Shields's complaint should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1). See id. Second, Alere argues that Shields fails to state a claim upon which relief can be granted because (1) Shields has not alleged facts to support a CLRA violation based on affirmative misrepresentation and (2) Shields has failed to satisfy the "unlawful,"

"unfair," and "fraudulent" prongs of the CUCL. See id. at 8–13. Accordingly, Alere asserts that Shields's complaint should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6). See id.

II. LEGAL STANDARD

A. Federal Rule of Civil Procedure 12(b)(1)

A plaintiff must "have 'standing' to challenge the action sought to be adjudicated in the lawsuit." Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc., 454 U.S. 464, 471 (1982). To establish Article III standing, a plaintiff must satisfy three "irreducible constitutional minimum" requirements: (1) he suffered an "injury in fact," meaning a concrete and particularized injury that is actual or imminent; (2) the injury must be causally related to the defendant's challenged actions; and (3) it must be "likely" that the injury will be "redressed by a favorable court decision." Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992). The plaintiff, as the party invoking federal jurisdiction, has the burden of establishing these elements. Id. at 561.

Article III standing implicates the court's subject matter jurisdiction, and is thus subject to challenge under Federal Rule of Civil Procedure 12(b)(1). See Maya v. Centex Corp., 658 F.3d 1060, 1067 (9th Cir. 2011). Rule 12(b)(1) attacks can be either facial, confining the inquiry to allegations in the complaint, or factual, permitting the court to look beyond that complaint. White v. Lee, 227 F.3d 1214, 1242 (9th Cir. 2000). Once the moving party has converted the motion to dismiss into a factual motion by presenting evidence demonstrating a lack of subject matter jurisdiction, the opposing party must furnish evidence necessary to satisfy its burden of establishing that the court, in fact, possesses subject matter jurisdiction. Savage v. Glendale Union High Sch., Dist. No. 205, Maricopa Cty., 343 F.3d 1036, 1039 n.2 (9th Cir. 2003) (considering affidavits furnished by both parties in evaluating Rule 12(b)(1) motion to dismiss); St. Clair v. City of Chico, 880 F.2d 199, 201 (9th Cir. 1989) ("Unlike a Rule 12(b)(6) motion, a Rule 12(b)(1) motion can attack the substance of a complaint's jurisdictional allegations despite their formal sufficiency, and in so doing rely on affidavits or any other evidence properly before the court.").

B. Federal Rule of Civil Procedure 12(b)(6)

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) tests whether the complaint "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). When deciding a Rule 12(b)(6) motion, the court must accept the facts pleaded in the complaint as true, and construe them in the light most favorable to the plaintiff. Falkner v. ADT Sec. Servs. Inc., 706 F.3d 1017, 1019 (9th Cir. 2013); Cousins v. Lockyer, 568 F.3d 1063, 1067–68 (9th Cir. 2009). The court, however, is not required to accept "legal conclusions . . . cast in the form of factual allegations." W. Mining Council v. Watt, 643 F.2d 618, 624 (9th Cir. 1981); see Iqbal, 556 U.S. at 678; Twombly, 550 U.S. at 555.

After accepting all non-conclusory allegations as true and drawing all reasonable inferences in favor of the plaintiff, the court must determine whether the complaint alleges a plausible claim to relief. See Iqbal, 556 U.S. at 679–80. A claim is plausible on its face when the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. at 678.

C. Federal Rule of Civil Procedure 9(b)

Allegations of fraud and allegations that "sound in fraud" must be pleaded with particularity. Fed. R. Civ. P. 9(b); Vess v. Ciba-Geigy Corp. U.S.A., 317 F.3d 1097, 1103–05 (9th Cir. 2003). Conclusory allegations of fraud are insufficient. Moore v. Kayport Package Express, Inc., 885 F.2d 531, 540 (9th Cir. 1989). A pleading satisfies Rule 9(b) when it is "specific enough to give defendants notice of the particular misconduct . . . so that they can defend against the charge and not just deny that they have done anything wrong." Vess, 317 F.3d at 1106. Consequently, a plaintiff must plead "the who, what, when, where, and how" of the alleged fraud. Id. A plaintiff must therefore "state the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986). Further, if the plaintiff claims that a statement is false or misleading, "[t]he

plaintiff must set forth what is false or misleading about a statement, and why it is false." In re GlenFed, Inc. Sec. Litig., 42 F.3d 1541, 1548 (9th Cir. 1994) (emphasis added).[2]

III. DISCUSSION

A. Shields Lacks Article III Standing

Alere moves to dismiss the FAC for lack of Article III standing, offering the following two arguments: (1) Shields has not alleged an injury in fact and (2) Shields did not use the INRatio Systems during the relevant time period, which is required to sufficiently allege injury in fact. See Mot. to Dismiss at 4–8. Shields responds that his injuries are "purely economic" and that he is entitled to relief because his device is "worthless" given that it does not reliably provide accurate results. See Opp. at 7.

1. Shields has not alleged an injury to himself

Shields does not claim that he has suffered or imminently will suffer from relying on an inaccurate INRatio test result. Shields fails to even allege that he has received an inaccurate test result himself or that he imminently will receive one. If Shields had alleged that he suffered from one of the medical conditions detailed in Alere's correction letter, his imminent risk of receiving an inaccurate and detrimental test result might have been cognizable. Shields fails to include those allegations in the FAC. Instead, he sweepingly argues that because the INRatio Systems may produce inaccurate results in some situations, those possible inaccuracies render the entire device unreliable and inaccurate. See FAC ¶ 22; Opp. at 4.

Shields thus fails to allege that he personally suffered a concrete and particularized injury. See Lujan, 504 U.S. at 561 n.1 ("By particularized, we mean that the injury must affect the plaintiff in a personal and individual way."); Warth v. Seldin, 422 U.S. 490, 501 ("[T]he plaintiff still must allege a distinct and palpable injury to himself, even if it is an

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[2] A motion to dismiss a claim or complaint "grounded in fraud" under Rule 9(b) for failure to plead with particularity is the "functional equivalent" of motion to dismiss under Rule 12(b)(6) for failure to state a claim. Vess, 317 F.3d at 1107. "If insufficiently pled averments of fraud are disregarded, as they must be, in a complaint or claim grounded in fraud, there is effectively nothing left in the complaint." Id. Given that dismissal of a complaint or claim has the same consequences under both Rule 9(b) and Rule 12(b)(6), dismissals under the two rules are treated in the same manner. Id.

injury shared by a large class of other possible litigants.") (emphasis added). At most, Shields pleads a potential risk of inaccurate test results that could affect other, unidentified INRatio Systems users who disregard Alere's warnings and use the devices even though they suffer from one of the few at-risk medical conditions detailed in Alere's correction letter. Shields's claim thus fails because he has not alleged a sufficient injury "to himself" and therefore lacks standing. See Seldin, 422 U.S. at 501; Cal. Bus. & Prof. Code §§ 17203–17204 (authorizing representative CUCL claims on behalf of others only if the claimant meets standing requirements, including injury in fact).

2. Shields's injury is hypothetical and alleged economic harm here does not constitute injury in fact

Shields responds that his alleged injury—possessing a "worthless" device—is not hypothetical because "there have been more than 18,000 complaints that the device does not provide accurate results." See FAC ¶ 17; Opp. at 6. Shields reasons that these complaints prove the INRatio Systems do not provide accurate results, are unreliable, and are "essentially worthless for all purchasers." See FAC ¶ 19; Opp. at 6. Shields further argues that the FDA recall notice supports his "core allegation that the monitor does not work as intended." See Opp. at 6. Shields reasons that his injury is not hypothetical because he "in fact . . . purchased a home monitoring device that is now completely useless." See Opp. at 7. Shields alleges that owning a worthless medical device that "he paid hundreds of dollars for" constitutes an actual, non-hypothetical injury. See id.

Furthermore, Shields claims that the INRatio Systems's inherent potential to produce inaccurate test results for some individuals with certain medical conditions has reduced the value of his device. See FAC ¶ 19; Opp. at 6. Specifically, Shields argues that because the INRatio Systems might produce inaccurate results for a subset of users, the devices are "worthless," and "[paying] hundreds of dollars" for a "worthless product" amounts to injury in fact under Article III. See Opp. at 6–7.

The Court concludes, however, that Shields has failed to allege anything more than the possibility that he could have suffered harm; his arguments about economic injury fail under Ninth Circuit case law. In Birdsong v. Apple, Inc., a case in which the plaintiffs

alleged economic harm given that a product defect had allegedly lowered the value of their iPods, the Ninth Circuit held that the plaintiffs' alleged economic injury was not an injury in fact. 590 F.3d 955 (9th Cir. 2009). In that case, plaintiffs failed to claim that they used their iPods in a way that exposed them to the alleged injury, hearing loss. Id. at 960. At most, the plaintiffs alleged a potential risk of hearing loss not to themselves, but to other unidentified iPod users who might choose to use their iPods in an unsafe manner. Id. (emphasis in original). The court therefore concluded that the alleged loss in value of the iPods did not constitute "distinct and palpable injury that is actual or imminent" because it rested on the "hypothetical risk" of injury to other consumers "who may or may not choose to use" their products in a risky manner. Id. at 961.

Here, as in Birdsong, Shields's allegation of suffering a "purely economic" injury, see Opp. at 7, rests entirely on a risk of harm to other consumers, and even then, a harm that might only occur if those consumers fall within the at-risk category and ignore the instructions of Alere's correction letter. See 590 F.3d at 961; Urgent Medical Device Correction at 1. Shields's FAC establishes only a "hypothetical" risk of harm that is insufficient to establish injury in fact as required by Article III. See id.; Lujan, 504 U.S. at 561 n.1. The Court thus concludes that the FAC should be dismissed. See Fed. R. Civ. P. 12(b)(1).

B. The FAC Fails Generally Under Rule 9(b)

Shields alleges that Alere fraudulently misrepresented information about the INRatio Systems and concealed knowledge of product defects. See FAC ¶¶ 1, 2, 37–38, 40, 43–46. A plaintiff alleging fraudulent conduct must satisfy Rule 9(b)'s heightened pleading standard, which requires the plaintiff to plead the circumstances constituting fraud with particularity. Kearns v. Ford Motor Co., 567 F.3d 1120, 1126 (9th Cir. 2009).

Shields generally pleads that he relied upon Alere's statements that the devices were accurate and reliable. See FAC ¶ 21 ("The reason [Shields] decided to purchase the System was based on promotional materials he saw on the internet. Specifically, Plaintiff was told and relied upon the statements that the System was accurate and reliable. . . ."). Rule 9(b)'s

particularity requirement can be satisfied by "identifying or attaching the representative samples" if the alleged misrepresentations occur in printed form. See, e.g., Von Koeing v. Snapple Beverage Corp., 713 F. Supp. 2d 1066, 1078 (E.D. Cal. 2010) (dismissing plaintiff's claims to the extent that they were "based upon other advertisements and marketing or based upon other labels not submitted to the court."); Ries v. Hornell Brewing Co., Inc., 2011 WL 1299286 at *4 (N.D. Cal. April 4, 2011) (same).

Shields fails to adequately identify or attach representative samples here. In Kearns v. Ford Motor Co., a case in which the plaintiff's complaint failed to identify what advertisements or sales materials he had relied upon when purchasing a product, the Ninth Circuit affirmed the dismissal of the plaintiff's complaint under Rule 9(b). See 567 F.3d at 1126. The court held the plaintiff's allegations insufficient, where the plaintiff failed to specify "what the television advertisements or sales material stated [or] when he was exposed to them or which ones he found material." Id. at 1125–26. Shields, like the plaintiff in Kearns, fails to indicate what particular statements (in advertisements or otherwise) he relied upon when purchasing his INRatio device. See 567 F.3d at 1125–26. Shields does not allege who specifically stated that the INRatio Systems were "accurate and reliable," nor does he state where or when he saw or heard that representation. See Minkler v. Apple, Inc., 65 F. Supp. 3d 810, 821 (N.D. Cal. 2014) (holding insufficient allegations "that Apple made specific representations that [its] Maps [application] would be accurate and improve over time" because plaintiff failed to identify "any specific statement by Apple that expressly indicates that Apple Maps would always work flawlessly and without error"). As a result, Shields's claims fail under Rule 9(b). See Kearns, 567 F.3d at 1125–26.

C. Shields Fails to Adequately Plead a CLRA Claim

The CLRA prohibits "unfair methods of competition and unfair or deceptive acts or practices" in consumer sales. Cal. Civ. Code § 1770; Berger v. Home Depot USA, Inc., 741 F.3d 1061, 1069 (9th Cir. 2014). A consumer may bring an action under the CLRA pursuant to § 1780(a), which provides that "[any] consumer who suffers any damage as a result of the

use or employment by any person of a method, act, or practice declared to be unlawful by Section 1770 may bring an action against that person . . .” Cal. Civ. Code § 1780(a).

Shields argues that Alere violated the CLRA by: (1) representing that the INRatio Systems have “characteristics, uses or benefits they do not have”; (2) representing that the devices “are of a particular standard, quality or grade when they are of another”; and (3) advertising the devices with intent not to sell them as advertised. See FAC ¶ 37.

1. Injury

The CLRA allows recovery when a consumer “suffers any damage as a result of” the unlawful practice. Cal. Civ. Code § 1780(a). This provision “requires that plaintiffs in a CLRA action show not only that a defendant’s conduct was deceptive but that the deception caused them harm.” In re Vioxx Class Cases, 180 Cal. App. 4th 116, 129 (Ct. App. 2009); see also Berger, 741 F.3d at 169 (“[T]he CLRA demands that each potential class member have both an actual injury and show that the injury was caused by the challenged practice.”). The meaning of “any damage” is not defined in the CLRA. In enacting the CLRA, the legislature “set a low but nonetheless palpable threshold of damage.” Meyer v. Sprint Spectrum L.P., 45 Cal. App. 4th 634, 646 (Ct. App. 2009). California courts have thus recognized that “damage” under the CLRA is not synonymous with “actual damages,” and may encompass “harms other than pecuniary damages.” In re Steroid Hormone Prod. Cases, 181 Cal. App. 4th 145, 156 (Ct. App. 2010). A consumer may allege harm from having purchased an item that he would not have bought but for defendant’s deceptive marketing practices. Id.

Here, Shields has failed to adequately plead that he has suffered damages as a result of any representation made by Alere. As discussed above, Shields has not alleged that he has received an inaccurate result from his INRatio device. See Birdsong, 590 F.3d at 961 (holding that a hypothetical risk of harm is insufficient to establish injury in fact); Seldin, 422 U.S. at 501 (requiring a plaintiff to allege a distinct and palpable injury to himself) (emphasis added). Moreover, Shields has failed to sufficiently allege that Alere’s conduct was deceptive. Shields claims that Alere’s materials were deceptive because they

stated that the INRatio Systems were "accurate and reliable," when they were not. See FAC ¶¶ 13–14. Yet, Shields provides no description of these materials upon which he allegedly relied, nor does he point to any specific material for the Court to evaluate for deceptiveness. See Vess, 317 F.3d at 1106 (requiring a plaintiff to plead "the who, what, when, where, and how" of the alleged fraud); In re Sony Gaming Networks & Customer Data Sec. Breach Litig., 996 F. Supp. 2d 942, 989 (S.D. Cal. 2014) (explaining that the determination of deceptive or misleading conduct is "fact intensive"). The only material Shields points to with sufficiency is Alere's correction letter, which provides transparent, non-deceptive caveats regarding the accuracy and reliability of the INRatio Systems. See Urgent Medical Device Correction at 1 (advising patients that, under certain circumstances, the INRatio Systems could yield inaccurate results).

2. Particularity

Alere contends that Shields's CLRA claim is based upon misrepresentations and fraudulent omissions and thus must meet the heightened pleading requirements applicable to fraud-based claims. See Mot. to Dismiss at 9. Federal Rule of Civil Procedure 9(b) applies to claims brought under the CLRA and CUCL where a "unified course of fraudulent conduct" is alleged as the basis of such a claim. Kearns, 567 F.3d at 1125. Here, Shields alleges that Alere violated the CLRA by misrepresenting the reliability and accuracy of its INRatio Systems. See FAC ¶ 37. Given that Shields's CLRA claim relies on a course of allegedly deceptive conduct by Alere, the requirements of Rule 9(b) apply. See Kearns, 567 F.3d at 1125.

Shields has not adequately pled—under Rule 9(b)—that Alere misrepresented the reliability and accuracy of the INRatio Systems. In Doe 1 v. AOL LLC, a case in which the plaintiffs specified misleading statements made by AOL in its privacy policy and other statements posted on AOL's website, the court held that the plaintiffs had alleged sufficient facts to satisfy Rule 9(b)'s heightened pleading requirements. 719 F. Supp. 2d 1102, 1112 (N.D. Cal. 2010). In that case, AOL represented to its consumers that AOL would endeavor to maintain the privacy and security of their personal information. Id. The plaintiffs alleged,

however, that AOL later made confidential data pertaining to 658,000 AOL members available to the public. Id. The court found that such allegations were sufficient to satisfy the purpose of Rule 9(b), which "is to ensure that defendants accused of the conduct specified have adequate notice of what they are alleged to have done, so that they may defend against the accusations." Id.; Concha v. London, 62 F.3d 1493, 1502 (9th Cir. 1995).

Here—unlike in Doe 1, where plaintiffs alleged that AOL represented to its customers that their information would remain private but subsequently made the information available to the public—Shields has not adequately alleged that Alere misrepresented the reliability and accuracy of the INRatio Systems. See 719 F. Supp. 2d at 1112. Shields simply asserts that Alere received 18,924 complaints "related to the [INRatio] System[s]." See FAC ¶ 2. Shields does not allege that these complaints stated that the INRatio Systems produced inaccurate or unreliable results, nor does Shields allege that he himself received inaccurate or unreliable results from his INRatio device. Further, Shields fails to adequately identify the alleged deceptive materials. See Vess, 317 F.3d at 1106 (requiring a plaintiff to "state the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations"). Shields merely claims that the deceptive materials consisted of "Alere's website, product manual, and promotional materials," as well as "promotional materials he saw on the internet." See FAC ¶¶ 13, 21. The Court thus concludes that Shields's CLRA claim fails under Rule 9(b)'s particularity requirement. See Doe 1, 719 F. Supp. 2d at 1112.

3. Causation

Under the CLRA, a claim may be brought by a consumer who has suffered injury "as a result of the use or employment of a proscribed method, act, or practice." Cal. Civ. Code § 1780(a) (emphasis added). For purposes of the CLRA, causation is sufficiently alleged where the complaint plausibly suggests that the defendant's misrepresentation "played a substantial part, and so has been a substantial factor" in influencing the plaintiff's actions, which, in turn, led to his harm. Hale v. Sharp Healthcare, 183 Cal. App. 4th 1373, 1386–87 (Ct. App. 2010). For example, allegations that the plaintiff entered into an agreement

expecting that "regular" rates would be charged instead of the excessive rates actually charged have been sufficient to plead causation under the CLRA and CUCL. See id.

In Doe 1, where plaintiffs alleged that AOL misrepresented that it would protect members' private information from public disclosure, the court held that plaintiffs adequately demonstrated a link between their reliance on AOL's misrepresentations and their injury. 719 F. Supp. 2d at 1113. The court explained that a reasonable consumer would have serious reservations about disclosing sensitive, personal data if she or he were aware that AOL, contrary to its privacy policy, would make such information readily available to the public without consumers' knowledge or consent. Id. For this reason the court found that plaintiffs had adequately alleged causation for purposes of stating a claim under the CLRA. Here, unlike in Doe 1, Shields cannot establish the requisite link between Alere's alleged misrepresentations and his injury because he has not established an injury in the first place. See Birdsong, 590 F.3d at 961; Lujan, 504 U.S. at 561 n.1. The Court therefore concludes that Shields has failed to satisfy the CLRA's causation requirement. See Cal. Civ. Code § 1780(a).

D. Shields Fails to Adequately Plead a CUCL Claim

The CUCL prohibits unfair competition, which it broadly defines as including "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200; Kearns, 567 F.3d at 1126. Each prong of the CUCL is a separate and distinct theory of liability. Kearns, 567 F.3d at 1126. Under the CUCL, a private enforcement action can only be brought by "a person who has suffered injury in fact and has lost money or property as a result of the unfair competition." § 17204; Kwikset v. Superior Court, 51 Cal. 4th 310, 321–22 (Cal. 2011); In re Tobacco II Cases, 46 Cal. 4th 298, 324–25 (Cal. 2009). Moreover, if a CUCL claim is said to be grounded in fraud, "the pleading of that claim as a whole must satisfy the particularity requirement of [FRCP] Rule 9(b)." Kearns, 567 F.3d at 1126 (quoting Vess, 317 F.3d at 1103–04).

1. The "unlawful" prong of the CUCL

The CUCL prohibits "unlawful" practices. Saunders v. Superior Court, 27 Cal. App. 4th 832, 838 (Ct. App. 1994). The statute "borrows" violations of other laws and treats them as actionable. Cel-Tech Commc'ns v. Los Angeles Cellular Tel. Co., 20 Cal. 4th 163, 180 (Ct. App. 1999).

In his FAC, Shields makes only a cursory suggestion that Alere engaged in "unlawful" practices. See FAC ¶ 47 ("Defendants' unlawful and unfair business practices present a continuing and ongoing threat to the public in that Defendants continue to mislead and deceive the public regarding the quality and nature of the INRatio Systems."). Shields does not identify any specific statute or law that Alere allegedly violated. In his opposition, Shields argues that the FAC establishes "unlawful" conduct by citing the Federal Food, Drug, & Cosmetic Act ("FDCA"), which requires medical device manufacturers to provide adequate warnings and refrain from falsely advertising the benefits of their devices. See 21 U.S.C. § 352(a); Opp. at 11. Shields also alleges a violation of the CLRA. See Opp. at 11.

As Alere highlights, however, Shields's FAC never mentions a violation of the FDCA. See Mot. to Dismiss at 6. Moreover, Shields has not pled facts showing that Alere's corrective action or the FDA recall has any relevance to him; he has not alleged that he suffers from any of the medical conditions at issue in the correction and recall. Shields, given his medical condition, thus cannot claim that his INRatio device provides him readings less accurate than it was advertised to provide at the time of sale. On the contrary, Shields effectively asks this Court to adopt a rule that any time a drug or device manufacturer issues a new warning, all previous purchasers should get their money back, regardless of whether the new warning has any application to them. See Mot. to Dismiss at 6. The Court declines this invitation.

2. The "unfair" prong of the CUCL

Under California law, an act or practice is "unfair" if the consumer injury is "substantial, is not outweighed by any countervailing benefits to consumers or to competition, and is not an injury the consumers themselves could reasonably have avoided."

Daugherty v. Am. Honda Motor Co., Inc., 144 Cal. App. 4th 824, 839 (Ct. App. 2006). As discussed above, Shields has not adequately pled injury from using his INRatio device, and the Court therefore concludes that Shields has failed to satisfy the "unfair" prong of the CUCL.

3. The "fraudulent" prong of the CUCL

To satisfy the CUCL "fraudulent" prong, a plaintiff must allege that the defendant acted in a way likely to deceive a reasonable consumer. Clemens v. DaimlerChrysler Corp., 534 F.3d 1017, 1125 (9th Cir. 2008). Here, Shields fails to satisfy the CUCL's "fraudulent" prong for three reasons. First, Shields alleges that Alere deceived consumers, including Shields, into purchasing "unreliable" INRatio Systems. See FAC ¶ 44. As discussed above, however, Shields fails to identify with particularity any false or deceptive statements he personally saw or upon which he actually relied—as is required when a CUCL claim, like Shields's, is grounded in fraud. See Kearns, 567 F.3d at 1126; Minkler v. Apple, Inc., 65 F. Supp. 3d at 821; see also In re Tobacco II Cases, 46 Cal. 4th at 326 (a private person asserting a CUCL claim must demonstrate actual reliance on allegedly misleading statements); Laster v. T-Mobile USA, Inc., 407 F. Supp. 2d 1181, 1194 (S.D. Cal. 2005), aff'd, 252 F. App'x 777 (9th Cir. 2007).

Second, the alleged fraudulent statements that Shields proffers amount to nothing more than non-actionable puffery. Shields alleges that Alere promoted the INRatio Systems's "simplicity, accuracy, and convenience," and represented that the devices were "accurate and reliable" and a "convenient alternative to traditional lab tests." See FAC ¶ 21. Although "[m]isdescriptions of specific or absolute characteristics of a product are actionable," Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1145 (9th Cir. 1997) (citation omitted), "[g]eneralized, vague, and unspecified assertions, constitute 'mere puffery' upon which a reasonable consumer could not rely, and hence are not actionable," Anunziato v. eMachines, Inc., 402 F. Supp. 2d 1133, 1139 (C.D. Cal. 2005) (quoting Glen Holly Entm't, Inc. v. Tektronix Inc., 343 F.3d 1000, 1015 (9th Cir. 2003)). Here, the allegedly fraudulent terms used by Alere are general assertions that say nothing about the

specific characteristics or components of the INRatio Systems and provide nothing concrete upon which a reasonable consumer could rely. See Anunziato v. eMachines, Inc., 402 F. Supp. 2d at 1140–41 (holding that such terms as "reliable," "high quality," "high performance," and "latest technology" are non-actionable puffery); see also Shroyer v. New Cingular Wireless Servs., Inc., 622 F.3d 1035, 1042–43 (9th Cir. 2010) (holding that "advantages" is too vague); cf. Cook, Perkiss & Liehe, Inc., 911 F.2d 242, 246 (9th Cir. 1990) (holding that advertiser's statement that its lamps were "far brighter than any lamp ever before offered for home movies" was puffery; however, when the advertiser quantified numerically the alleged superior brightness with statements such as "35,000 candle power and 10-hour life," the assertions became actionable) (citation omitted)).

Third, Shields has failed to allege how any omission of relevant information has harmed him. Shields has not pled that he possesses one of the at-risk medical conditions detailed in Alere's correction letter, nor has he pled any facts suggesting that he obtained his device with a prescription and that Alere's representations deceived his prescribing doctor. Shields has thus failed to satisfy the "fraudulent" prong of the CUCL. See In re Tobacco II Cases, 46 Cal. 4th at 326.

V. CONCLUSION

For the foregoing reasons, this Court GRANTS Alere's motion to dismiss.

IT IS SO ORDERED.

Dated: November 17, 2015

CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE