UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DINA ANDREN, SIDNEY BLUDMAN, VIRGINIA CIOFFI, BERNARD FALK, JEANETTE KERZNER-GREEN, CAROL MONTALBANO, and DONALD RIGOT, individually, and on behalf of other members of the general public similarly situated,

Plaintiff,

v.

ALERE, INC., a Delaware corporation, ALERE HOME MONITORING, INC., a Delaware corporation, ALERE SAN DIEGO, INC., a Delaware corporation,,

Defendant.

Case No.: 16cv1255-GPC(AGS)

ORDER DENYING PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

[REDACTED-ORIGINAL FILED UNDER SEAL]

[Dkt. No. 75.]

Before the Court is Plaintiffs' motion for class certification. (Dkt. No. 75.) Defendants filed an opposition, and Plaintiffs filed a reply. (Dkt. Nos. 100, 102.) With Court approval, Defendants filed a sur-reply on September 15, 2017.[1] (Dkt. No. 121.) A

[1] Finding good cause, the Court granted Defendants' ex parte request to file a sur-reply. (Dkt. Nos. 106, 117.)

hearing was held on September 22, 2017. (Dkt. No. 122.) After the hearing, the Court directed supplemental briefing on the issue of claim splitting. (Dkt. No. 125.) Plaintiffs filed a supplemental brief on October 13, 2017, and Defendants filed their supplemental brief on October 20, 2017. (Dkt. Nos. 128-29.) After careful review of the parties' briefs, supplemental briefs, the record, and the applicable law, the Court DENIES Plaintiffs' motion for class certification.

Procedural Background

On May 26, 2016, Plaintiffs Dina Andren and Sidney Bludman filed a purported class action complaint alleging that Defendants Alere, Inc., Alere Home Monitoring, Inc., ("AHM"), and Alere San Diego, Inc. ("Alere SD") (collectively "Defendants" or "Alere") unlawfully, deceptively and misleadingly engaged in the manufacturing, marketing and sale of the INRatio products which include "INRatio PT/INR Monitors," "INRatio PT/INR Test Strips," "INRatio2 PT/INR Monitors" and "INRatio2 PT/INR Test Strips" (collectively, "INRatio Products"). (Dkt. No. 1, Compl.) After the Court granted Defendants' motion to dismiss with leave to amend, (Dkt. No. 19), on October 3, 2016, Plaintiffs Dina Andren ("Andren"), Sidney Bludman ("Bludman"), Virginia Cioffi ("Cioffi"), Bernard Falk ("Falk"), Jeanette Kerzner-Green ("Kerzner-Green"), Carol Montalbano ("Montalbano") and Donald Rigot ("Rigot") filed a purported first amended class action complaint against Defendants for unlawfully, deceptively and misleadingly engaging in the advertising, marketing and sale of the INRatio Products. (Dkt. No. 21, FAC.) The FAC alleges sixteen causes of action for violations of (1) California's Consumer Legal Remedies Act, ("CLRA"), Cal. Civil Code §§ 1750 et seq.; (2) California's Unfair Competition Law, ("UCL"), Cal. Bus. & Prof. Code §§ 17200 et seq.; (3) fraud; (4) unjust enrichment; (5) Colorado Consumer Protection Act, Colo. Rev. Stat. §§ 6-1-101 et seq.; (6) breach of the implied warranty of merchantability, Colo. Rev. Stat. § 4-2-314; (7) Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201, et seq.; (8) breach of the implied warranty of merchantability, Fla. Stat. §§ 672.314, et seq.; (9) Georgia Fair Business Practices Act, Ga. Code Ann. §§ 10-1-390, et

seq.; (10) Georgia Uniform Deceptive Trade Practices Act, Ga. Code Ann. §§ 10-1-370, et seq.; (11) Maryland Consumer Protection Act, Md. Code Com. Law §§ 13-101, et seq.; (12) breach of the implied warranty of merchantability under Md. Code Com. Law § 2-314; (13) New York General Business Law, N.Y. Gen. Bus. Law § 349; (14) New York General Business Law, N.Y. Gen. Bus. Law § 350; (15) Pennsylvania Unfair Trade Practices and Consumer Protection Law, Pa. Stat. Ann. §§ 201-1, et seq.; and (16) breach of the implied warranty of merchantability, 13 Pa. Stat. Ann. § 2314.[2] (Id.)

Factual Background

In the late 1990's Defendants' predecessor, HemoSense, Inc.[3], developed and manufactured the INRatio Products which are electronic testing devices designed to assist patients who have been prescribed blood-thinners, such as warfarin, to monitor their blood clotting times at home. (Dkt. No. 21, FAC ¶¶ 19, 25.) The INRatio monitor, paired with the INRatio test strips are known as the "INRatio System." (Dkt. No. 100-8, Guerdan Decl. ¶ 5.) The FDA approved the INRatio System as a Class II prescription medical device in 2002[4], and in 2007, the FDA approved the INRatio 2 System. (Id. ¶¶ 3-4.) INRatio went through design changes over time, leading to additional 510(k) clearances in 2007, 2010 and 2012. (Id. ¶ 6; Dkt. No. 100-2, Alt Decl., Ex. 3, San George Decl. ¶ 14.)

Warfarin is the most commonly prescribed anti-coagulant medication. (Dkt. No. 100-2, Alt Decl., Ex. 1, White Decl. ¶ 6.) The International Normalized Ratio ("INR") is

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[2] On January 17, 2017, the Court granted Defendants' motion to strike paragraph 74 of the FAC and denied Defendants' request to strike the remaining paragraphs of 75-80. (Dkt. No. 41.)

[3] In August 2007, Alere, Inc., then known as Inverness Medical Innovations, Inc., purchased HemoSense, Inc. (Dkt. No. 21, FAC ¶ 19.) In 2008, HemoSense, Inc. transferred its operations to Alere, Inc's facility in San Diego, California. (Id.) In 2013, HemoSense, Inc.'s operations were merged into the Alere San Diego corporate entity. (Id.)

[4] On May 6, 2002, CDRH (Center for Devices and Radiological Health) cleared the initial INRatio System for professional use and on October 24, 2002, CDRH cleared the INRatio System for self-test. (Dkt. No. 100-8, Guerdan Decl. ¶ 3.)

a standardized test used to determine the relative speed at which blood clots in a patient's body and helps doctors in prescribing warfarin dosages. (Dkt. No. 21, FAC ¶ 22; Dkt. No. 100-2, Alt Decl., Ex. 1, White Decl. ¶¶ 9, 12, 13.)

In May 2005, the FDA sent a warning letter to HemoSense, Inc., Alere's predecessor, informing that it failed to submit a Medical Device Report ("MDR") as set forth in 21 C.F.R. § 803.50(a)(1) which requires "device manufacturers to report within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a device that they marketed (1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and that device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." (Dkt. No. 75-3, Pifko Decl., Ex. 12.) The letter noted, "[o]ur review indicates that your firm had information indicating that INRatio devices were generating clinically significant erroneous values." (Id.) In November 2006, FDA sent HemoSense, Inc. another warning letter concerning, inter alia, violations noted during an inspection of its company and failure to investigate complaints involving discrepant results. (Id., Ex. 13.)

On April 16, 2014, Alere SD issued a recall notice, entitled, "Urgent: Medical Device Recall" to healthcare professionals solely for the INRatio2 test strips, citing the disparity between INR results when re-testing was performed by an independent laboratory. (Dkt. No. 75-3, Pifko Decl., Ex. 6 at 12.) The recall noted Alere had received nine serious adverse event reports and the INRatio2 test strips results were reported as lower than the laboratory results. (Id.) Alere did not know the root cause of the issue but was concerned that the "INRatio2 PT/INR Professional test strips may report an inaccurately low INR result." (Id.) The recall directed healthcare professionals to inform patients to immediately stop using the INRatio2 test strip and use an alternative method, such as the INRatio test strip. (Id.)

In October 2014, Alere SD informed the FDA that the INRatio System, in certain circumstances, could produce falsely low results in patients who had extended clotting

times (INR ≥6), and presented data to the FDA regarding its investigation. (Dkt. No. 100-8, Guerdan Decl. ¶ 7.) It also told the FDA that it was working on a software improvement to help mitigate the risk of such occurrences. (Id.)

On December 5, 2014, with the FDA's knowledge and input concerning the content of the notice, Alere issued an Urgent Medical Device Correction ("Correction") to consumers. (Dkt. No. 75-3, Pifko Decl., Ex. 7; Dkt. No. 100-8, Guerdan Decl. ¶ 8.) It informed consumers that the INRatio monitor, the INRatio2 monitor and the INRatio test strips may provide an INR result that is "significantly lower" than a result obtained in a laboratory. (Dkt. No. 75-3 Pifko Decl., Ex. 7.) It noted that the issue arises if the patient has certain medical conditions, and directed that the System should not be used by them, and for those without those medical conditions, they should contact their doctor about performing a hematocrit measurement to determine if they should continue using the system, and conduct periodic laboratory INR testing for a comparison. (Id.)

After the December 5, 2014 Correction, Alere attempted to address the "potential, in certain cases of the system to deliver a result that differs from that of another measurement method." (Dkt. No. 75-3, Pifko Decl., Ex. 9.) For example, in May 2015, Alere provided the FDA with a Pre-Submission that described their validation strategy for the software modifications to be submitted through a 510(k) premarket notification. (Dkt. No. 100-8, Guerdan Decl. ¶ 9.) In December 2015, Alere submitted a 501(k) pre-market notification for the software modification which it had fully anticipated would be cleared by the FDA. (Id.) In late February 2016, the FDA sought additional information, Alere had a meeting with the FDA in March 2016, and subsequently submitted additional evidence to address the FDA's concerns. (Id. ¶¶ 9, 10, 11.) Nonetheless, the FDA ultimately concluded that Alere should withdraw the device from the market. (Id. ¶ 11.)

[redacted] (Dkt. No. 111-12, Pifko Decl., Ex. 11 at 2 (UNDER SEAL); Dkt. No. 100-8, Guerdan Decl. ¶

11.) [redacted] (Dkt. No. 111-12, Pifko Decl., Ex. 11 at 2 (UNDER SEAL).) [redacted] (Id. at 3 (UNDER SEAL).) [redacted] (Id. (UNDER SEAL).) [redacted] (Id. (UNDER SEAL).)

On July 11, 2016, Alere, Inc. issued a nationwide voluntary recall of the INRatio products, including the INRatio and INRatio2 PT/INR Monitoring System. (Dkt. No. 75-3, Pifko Decl., Ex. 9.) To carry out the market withdrawal, Alere engaged Stericycle Corp. to obtain customer information from Independent Diagnostic Testing Facilities ("IDTF") and third party distributors to distribute customer notification letters, and collect and dispose of returned monitors. (Dkt. No. 100-8, Guerdan Decl. ¶ 12.)

Alere, Inc. is a Delaware corporation with its headquarters in Waltham, Massachusetts which is the parent company of Alere SD and AHM. (Dkt. No. 21, FAC ¶ 16.) Alere SD is headquartered in San Diego. (Dkt. No. 21, FAC ¶ 18.) Alere SD did not sell INRatio to end users, but sold them to authorized medical device distributors for sale to physicians, or to IDTFs for use with patient self-testers. (Dkt. No. 100-6, Blundell Decl. ¶ 2.) INRatio monitors and test strips are Class II medical devices that require a prescription by a licensed healthcare professional. (Id. ¶ 3.) From 2009 on, more than half of the INRatio products were designed, labeled and packaged for use by healthcare professionals while the remaining would have been designed, labeled and packaged for use by patient self-testers who were prescribed their devices by their healthcare provider

and under the supervision of the IDTF. (Id.) The IDTF provides monitoring services to patients, and include training, providing all necessary equipment and supplies, collecting and relaying test results to the individual patient's healthcare provider. (Id.) Alere SD has not sold INRatio directly to patients or to healthcare professionals; instead, it relies on authorized distributors of medical products to sell monitor kits and test strip supplies to health care professional and relied on IDTFs to provide the products to their patients. (Id. ¶ 4.) For the few individual parties who directly buy monitors kits, an IDTF will usually refer them to one of Alere SD's authorized distributor to buy the product. (Id.) Alere SD has not engaged in any consumer advertising except for some brochures that doctors could give to patients in their offices in 2010. (Id. ¶ 7.) Otherwise no promotional aids focused on patients. (Id.)

Alere Home Monitoring, Inc is headquartered in Livermore, California. (Dkt. No. 21, FAC ¶ 17.) AHM is an IDTF and has provided INR monitoring services to patients on warfarin therapy. (Dkt. No. 100-10, Owlet Decl. ¶ 2.) The Center for Medicare and Medicaid Services ("CMS") created a benefit that would allow persons on warfarin to obtain the use of a Point of Care ("POC") monitor and the terms of the benefits are "physician must prescribe the service; the patient must receive face to face training; the patient must demonstrate proficiency in testing; the patient must adhere to his or her testing regimen; and the patient may not test more frequently than once a week." (Id. ¶ 4.) AHM aids patients in availing themselves of this benefit and provides all training and material that a patient needs to conduct home INR testing. (Id. ¶ 5.) AHM receives all the INR test results and relays them to the patients' doctors. (Id.)

CMS pays AHM for providing the services, i.e., the number of tests performed, and not for the materials provided. (Id. ¶ 6.) AHM retains ownership over the monitors and materials associated with the service and they are regarded as overhead. (Id.) Most insurance companies provide the same type of benefits as CMS although the amounts they pay for the services vary. (Id. ¶ 7.) Also, a few insurers provide that patients should

actually own their own devices and buy strips, and are provided the device for ownership per this contract. (Id.)

AHM's advertising and promotional activity focused on informing patients and doctors of the availability and benefits of IDTF service and not on the use or feature of any specific testing device. (Id. ¶ 3.) AHM provided services using three different types of point of care ("POC") devices and its advertising did not endorse one type of device or another. (Id.) AHM's advertising focused almost exclusively on the benefits of patient self-testing. (Id. ¶ 10.) The Alere website as well as the joint website of Alere and AHM contain information about INRatio Products. (Dkt. No. 100-6, Blundell Decl. ¶ 8.)

Plaintiffs are residents of states outside of California. Dina Andren is a resident of the State of New York. (Dkt. No. 21, FAC ¶ 84.) On April 30, 2015, she purchased the INRatio2 PT/INR testing kit for $375.00 and purchased numerous boxes of replacement INRatio2 test strips which ranged in price from $240-285. (Dkt. No. 75-3, Alt Decl., Ex. 15, Andren Decl. ¶ 2.) She alleges she bought the System from a pharmacy. (Dkt. No. 21, FAC ¶ 86.) She claims she never received a prescription for the INRatio Products and was not required to show proof of any prescription when she purchased it. (Id. ¶ 87.)

Plaintiff Sidney Bludman is a resident of the State of Maryland[5] and was prescribed the INRatio2 product. (Dkt. No. 21 FAC ¶¶ 98, 104; Dkt. No. 75-3, Alt Decl., Ex. 16, Bludman Decl. ¶ 1.) He was a customer of AHM. (Id. ¶ 3.) He began using the INRatio2 PT/INR System in 2013 and was required to purchase boxes of replacement INRatio2 test strips that cost about $120 per box in order to continue his INR testing. (Dkt. No. 21, FAC ¶ 102.) He paid several hundred dollars for the INRatio products. (Dkt. No. 75-3, Alt Decl., Ex. 16, Bludman Decl. ¶ 3.)

Plaintiff Virgina Cioffi is a resident of the State of Florida and purchased the INRatio2 PT/INR System for $3,519.00 and paid several hundred dollars for the test

[5] The FAC alleges that Bludman was born in New York. (Dkt. No. 21, FAC ¶ 98.)

strips. (Dkt. No. 75-3, Alt Decl., Ex. 17, Cioffi Decl. ¶¶ 1, 2.) She is a customer of AHM. (Id. ¶ 4.) In the FAC, she alleges she was never prescribed the INRatio products and was not required to show any proof at the time of purchase. (Dkt. No. 21, FAC ¶ 112.) The FAC alleges that her decision to purchase the product was based, in part, on a video advertisement that she viewed on Defendants' website in February 2013. (Id. ¶ 113.)

Plaintiff Bernard Falk is a resident of the State of Pennsylvania and he paid about $2,558.47 for the INRatio System between January 1, 2012 to the present and he was a customer of AHM. (Dkt. No. 75-3, Alt Decl., Ex. 18, Falk Decl. ¶¶ 1, 2, 3.) After viewing an advertisement for the INRatio2 PT/INR System in a heart journal, he contacted his caregiver, and received a prescription. (Dkt. No. 21, FAC ¶¶ 119, 120.)

Plaintiff Jenette Kerzner-Green is a resident of the State of Georgia and from January 1, 2009 to the present, she paid several hundred dollars for INRatio Products and is a customer of AHM. (Dkt. No. 75-3, Alt Decl., Ex. 19, Kerzner-Green Decl. ¶¶ 1, 2, 3.)

Plaintiff Carol Montalbano is a resident of the State of New York and between January 1, 2014 until the present, she paid several hundred dollars for the INRatio products and was a customer of AHM. (Dkt. No. 75-3, Alt Decl., Ex. 20, Montalbano Decl. ¶¶ 1, 2, 3.) She was prescribed the INRatio2 Product in 2014. (Dkt. No. 21, FAC ¶ 134.) Since September 2015, Montalbano rented an INRatio2 PT/INR monitor and purchased numerous replacement boxes of the INRatio2 PT/INR test strips. (Id. ¶ 135)

Plaintiff Donald Rigot is a resident of the States of Colorado and in October 2012, he paid about $1,200 for the INRatio PT/INR System and paid hundreds of dollars for the replacement strips. (Dkt. No. 75-3, Alt Decl., Ex. 21, Rigot Decl. ¶¶ 1, 2.) He was also a customer of AHM during this time. (Id. ¶ 3.) He was prescribed the product. (Dkt. No. 21, FAC ¶ 141.)

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Discussion

A. Legal Standard on Class Certification

"The class action is an exception to the usual rule that litigation is conducted by and on behalf of individual named parties only. In order to justify a departure from that rule, a class representative must be a part of the class and possess the same interest and suffer the same injury as the class members." Wal-Mart Stores, Inc. v. Dukes, 131 S. Ct. 2541, 2550 (2011) (internal quotation marks and citations omitted). A plaintiff seeking class certification must affirmatively show the class meets the requirements of Rule 23. Comcast Corp. v. Behrend, 133 S. Ct. 1426, 1432 (2013) (citing Dukes, 131 S. Ct. at 2551-52). To obtain certification, a plaintiff bears the burden of proving that the class meets all four requirements of Rule 23(a)--numerosity, commonality, typicality, and adequacy. Ellis v. Costco Wholesale Corp., 657 F.3d 970 979-80 (9th Cir. 2011). If these prerequisites are met, the court must then decide whether the class action is maintainable under Rule 23(b). United Steel, Paper & Forestry, Rubber, Mfg. Energy, Allied Indus. & Serv. Workers Int'l Union AFL–CIO, CLC v. ConocoPhillips Co., 593 F.3d 802, 806 (9th Cir. 2010). This case involves Rule 23(b)(3), which authorizes certification when "questions of law or fact common to class members predominate over any questions affecting only individual class members," and "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). The Court exercises discretion in granting or denying a motion for class certification. Staton v. Boeing Co., 327 F.3d 938, 953 (9th Cir. 2003).

The Court is required to perform a "rigorous analysis," which may require it "to probe behind the pleadings before coming to rest on the certification question." Dukes, 131 S. Ct. at 2551. "'[T]he merits of the class members' substantive claims are often highly relevant when determining whether to certify a class. More importantly, it is not correct to say a district court may consider the merits to the extent that they overlap with class certification issues; rather, a district court must consider the merits if they overlap with Rule 23(a) requirements." Ellis, 657 F.3d.at 981. Nonetheless, the district court

does not conduct a mini-trial to determine if the class "could actually prevail on the merits of their claims." Id. at 983 n.8; ConocoPhillips Co., 593 F.3d at 808 (citation omitted) (court may inquire into substance of case to apply the Rule 23 factors, however, "[t]he court may not go so far . . . as to judge the validity of these claims.").

Here, Plaintiffs seek to certify a Nationwide Class to include,

> **Nationwide Class**
> All residents of the United States of America who, during the period January 1, 2009 through the present, purchased, rented or otherwise paid for the use of the INRatio products manufactured, marketed, sold or distributed by Defendants.

Plaintiffs also seek to certify six sub-classes from States represented by them: a Colorado, Florida, Georgia, Maryland, New York and Pennsylvania Sub-Class to include, "All residents of [each Plaintiffs' respective home State] who, during the period January 1, 2009 through the present, purchased, rented or otherwise paid for the use of the INRatio products manufactured, marketed, sold or distributed by Defendants."

B. Federal Rule of Civil Procedure 23(a)

1. Numerosity and Commonality

Defendants do not challenge Plaintiffs' argument that the putative class is sufficiently numerous or that issues of law or fact are common to the class.

To establish numerosity, a plaintiff must show that the represented class is "so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1); Bates v. United Parcel Serv., 204 F.R.D. 440, 444 (N.D. Cal. 2001). A court may reasonably infer based on the facts of each particular case to determine if numerosity is satisfied. Ikonen v. Hartz Mtn. Corp., 122 F.R.D. 258, 262 (S.D. Cal. 1988). [redacted] (See Dkt. No. 111-23, Pifko Decl., Ex. 22 at 8 (UNDER SEAL).) The Court agrees that the numerosity element has been met. See Ikonen, 122 F.R.D. at 262 ("As a general rule, classes of 20 are too small, classes of 20–40 may or may not be big enough depending on the circumstances of each case, and classes of 40 or more are numerous enough.").

As to commonality, Rule 23(a)(2) require Plaintiffs to show "there are questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). Commonality requires the plaintiff to demonstrate that the class members 'have suffered the same injury.'" Dukes, 131 S. Ct. at 2551. "That common contention . . . must be of such a nature that it is capable of classwide resolution – which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." Id. "'What matters to class certification . . . is not the raising of common 'questions' . . . but, rather the capacity of a classwide proceeding to generate common answers apt to drive the resolution of the litigation. Dissimilarities within the proposed class are what have the potential to impede the generation of common answers.'" Id. (emphasis in original) (citation omitted). The commonality requirement demands only that "class members' 'situations share a common issue of law or fact and are sufficiently parallel to insure a vigorous and full presentation of all claims for relief.'" Wolin v. Jaguar Land Rover N. Am., LLC, 617 F.3d 1168, 1172 (9th Cir. 2010) (quoting Cal. Rural Legal Assistance, Inc. v. Legal Servs. Corp., 917 F.2d 1171, 1175 (9th Cir. 1990)).

Here, Plaintiffs assert that the significant common question is "whether Alere knowingly omitted material information – specifically, that the INRatio Products contained a defect that produced false and erroneous results – from its marketing materials, labels and warnings." (Dkt. No. 75-1 at 21-22.) "[C]ommonality only requires a single significant question of law or fact." Mazza v. American Honda Motor Co., Inc., 666 F.3d 581, 589 (9th Cir. 2012) (commonality not disputed as to whether Honda "had a duty to disclose or whether the allegedly omitted facts were material and misleading to the public."). Plaintiffs also propose that another common question is "whether Alere included material misrepresentations in its packing by referring to the INRatio Products as 'monitors' when they were anything but." (Id. at 22.) Lastly, other common questions of law and fact proposed by Plaintiffs include "(1) whether Alere's omissions and misrepresentations concerning the INRatio Products' functionality are likely to deceive a reasonable consumer in Alere's target audience; (2) whether Alere's omissions and

misrepresentations concerning the INRatio Products' functionality were material to class members' decision to pay for the INRatio Products; and (3) whether, and to what extent, class members were economically damaged by paying for the INRatio Products." (Id.) Defendants do not dispute Plaintiffs' common issues of law and fact, and the Court concludes that these common issues apply to the entire class and satisfy the less rigorous commonality requirement. See Hanlon v. Chrysler Corp., 150 F.3d 1011, 1019 (9th Cir. 1998) (recognizing that commonality under Rule 23(a)(2) to be "less rigorous" than the predominance companion requirement under Rule 23(b)(3)); Mazza, 666 F.3d at 589 (referring to Rule 23(a)(2) commonality requirement as a "limited burden").

2. Adequacy

As to adequacy, Rule 23(a)(4) provides that class representatives must "fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). In analyzing whether Rule 23(a)(4) has been met, the Court must ask two questions: "(1) do the named plaintiffs and their counsel have any conflicts of interest with other class members and (2) will the named plaintiffs and their counsel prosecute the action vigorously on behalf of the class?" Evon v. Law Offices of Sidney Mickell, 688 F.3d 1015, 1031 (9th Cir. 2012) (quoting Hanlon, 150 F.3d at 1020).

Defendants argue that Plaintiffs are not typical or adequate representatives because they are claim splitting by seeking only economic damages and disclaiming personal injury damages. As a result, Defendants claim that Plaintiffs are jeopardizing the interests of the putative class and have interests different than its members. Not only do Plaintiffs allege that thousands of absent class members have sustained physical injuries or were at risk of such injuries, but Plaintiffs Andren and Bludman also claim to have sustained personal injuries and their interests are not aligned with the putative economic injury class. In reply, Plaintiffs argue that claim splitting applies only when a plaintiff abandons a panoply of relief available to putative class members and here, they have not abandoned any relief for personal injuries as their causes of action are not premised on

personal injury and they do not allege any facts that would entitle class members to personal injury damages; therefore, they have not split any claims.

a. Claim Splitting

The general principles of res judicata apply to class actions where a prior judgment in a class action is binding on class members in any subsequent litigation. Cooper v. Fed. Reserve Bank of Richmond, 467 U.S. 867, 874 (1984); see also Matsushita Elec. Indus. Co. v. Epstein, 516 U.S. 367, 377-79 (1996). "A judgment in favor of either side is conclusive in a subsequent action between them on any issue actually litigated and determined, if its determination was essential to that judgment." Cooper, 467 U.S. at 874. Therefore, "[c]laim splitting is generally prohibited by the doctrine of res judicata . . . [and] class certification should be denied on the basis that class representatives are inadequate when they opt to pursue certain claims on a class-wide basis while jeopardizing the class members' ability to subsequently pursue other claims." In re Conseco Life Ins. Co. Life Trend Ins. Sales and Marketing Litig., 270 F.R.D. 521, 531 (N.D. Cal. 2010) (quoting In re Universal Serv. Fund Tel. Billing Prac. Litig., 219 F.R.D. 661, 668 (D. Kan. 2004)); Kruger v. Wyeth, Inc., No. 03cv2496-JLS(AJB), 2008 WL 481956, at *3 (S.D. Cal. Feb. 19, 2008) ("Other courts agree that the existence of claim splitting constitutes a compelling reason to deny class certification.").

In the Ninth Circuit, "the general rule is that a class action suit [brought under Fed R. Civ. P. 23(b)(2)] seeking only declaratory and injunctive relief does not bar subsequent individual damages claims by class members, even if based on the same events." Hiser v. Franklin, 94 F.3d 1287, 1291 (9th Cir. 1996). However, the Ninth Circuit has not ruled on whether Plaintiffs' certification under Rule 23(b)(3) seeking damages would bar subsequent individual suits for another type of damages.

The Fifth Circuit has recently addressed claim splitting in a class action case and provides factors for courts to consider when "deciding whether a class representative's decision to forego certain claims defeats adequacy." See Slade v. Progressive Sec. Ins. Co., 856 F.3d 408, 413 (5th Cir. 2017). Courts should inquire about "(1) the risk that

unnamed class members will forfeit their right to pursue the waived claim in future litigation, (2) the value of the waived claim, and (3) the strategic value of the waiver, which can include the value of proceeding as a class (if the waiver is key to certification)." Id.

i. Risk that Unnamed Class Members Will be Barred to Pursue Waived Claims in Future

The Court looks first at whether there is a risk that unnamed class members may be barred from pursuing personal injury claims in future litigation. See id.

"The preclusive effect of a federal-court judgment is determined by federal common law." Taylor v. Sturgell, 553 U.S. 880, 891 (2008). Under federal common law, where a federal court judgment is based on diversity, a court looks to the rules of preclusion of the state where the Court rendered the judgment sat. Semtek Int'l Inc. v. Lockheed Martin Corp., 531 U.S. 497, 508-09 (2001); Taylor, 553 U.S. at 891 n. 4. Since this Court sits in California, its preclusion law would apply.

Despite California's law on claim preclusion, a Court cannot predetermine whether its case will be subject to preclusion. See Fed. R. Civ. P. 23(c)(3) advisory committee notes (1966 amendment) ("[s]ubdivision (c)(3) does not disturb the recognized principle that the court conducting the action cannot predetermine the res judicata effect of the judgment; this can be tested only in a subsequent action."); Matsushita Elec. Indus. Co. v. Epstein, 516 U.S. 367, 396 (1996) (Ginsberg, J., concurring in part and dissenting in part) (a "court conducting an action cannot predetermine the res judicata effect of the judgment; that effect can be tested only in a subsequent action."); see also Gates, 265 F.R.D. at 218 (court cannot prejudge res judicata effect of a decision). The Fifth Circuit recognized that a court cannot predetermine the res judicata effect of its judgment because courts have not consistently applied claim preclusion to class actions. Slade, 657 F.3d at 413 (citing cases).

However, courts have noted that any risk of preclusion can be mitigated through the opt-out provisions under Rule 23(b)(3), see Slade, 856 F.3d at 414 (court noting that

the preclusion risk is smaller under a certification under Rule 23(b)(3) due to the opportunity to opt out); In re Amla Litig., --F. Supp. 3d – 2017 WL 4792256, at *3 (S.D.N.Y. 2017) (adequacy met even though plaintiff only sought refund of $50 in statutory damages concerning misrepresentations made by the defendants and those with more serious injuries will have the opportunity to opt out), or by amending the class definition to exclude personal injury individuals, see Gates v. Rohm and Haas Co., 265 F.R.D. 208, 218 (E.D. Pa. 2010) (any potential conflict removed by amending class definition to exclude personal injury individuals who presently have any physical injury due to the defendants' conduct and an opt-out may be available for those class members with present personal injuries).

Courts can also expressly reserve the plaintiff's right to maintain a second action. See Restatement (Second) of Judgment § 26(1)(b) (court can "expressly reserve[ ] the plaintiff's right to maintain the second action"); 18 Wright & Miller, et al. Fed. Prac. & Proc. § 4413 (3d ed.) ("A judgment that expressly leaves open the opportunity to bring a second action on specified parts of the claim or cause of action that was advanced in the first action should be effective to forestall preclusion."); but see Thompson v. American Tobacco Co., Inc., 189 F.R.D. 544, 550-51 (D. Minn. 1999) ("even if the Court permits the reservation of issues in this case, whether a subsequent court would honor such a reservation is, at best, undeterminable at this time" and concluding that possible prejudice to class members is too great to conclude that named plaintiffs' interests are aligned with those of the class).

Therefore the risk that absent class members may be barred from pursuing personal injury claims is low due to mechanisms that will mitigate the risk.

Plaintiffs, relying on the Supreme Court's decision in Cooper, argue that issue preclusion does not apply here because the issues that will be litigated in the consumer protection claim are distinct from those presented in a personal injury action. Specifically, the consumer protection claim is premised on Defendants' alleged misrepresentations and material omissions when the class members purchased the

INRatio products. Meanwhile, a personal injury action depends on erroneous readings from the INRatio products which allegedly caused individual plaintiffs to improperly adjust their warfarin dosages. As a result, the issues litigated by an economic injury class are distinct from the issues decided in a personal injury class action, and class members will not be barred from bringing future claim based on personal injury. Defendants disagree arguing that the facts underlying the economic injury and personal injury claims are the same.

In Cooper, the Supreme Court held that "[a] judgment in favor of either side is conclusive in a subsequent action between them on any issue actually litigated and determined, if its determination was essential to that judgment." Cooper, 467 U.S. at 874. The Court held that the class action claim, certified under Rule 23(b)(2) and (3), which determined that the employer did not engage in a general pattern or practice of racial discrimination against certified class of employees, did not bar class members from filing subsequent civil rights actions for individual claims of racial discrimination against the employer during same time period. Id. The Court observed that the class claim that the employer followed "policies and practices" of discrimination as well as individual claims of the four intervening plaintiffs had been decided, but the Court explained that there is a "crucial difference" between a class action alleging a general pattern or practice of discrimination and an individual's claim of discrimination. Id. at 875-76 (a reason for a particular employment decision is distinct from a pattern of discriminatory decision making and noting difference in the legal analysis).

In this case, Plaintiffs seek to certify an economic injury class for the cost of the INRatio Products in which Plaintiffs relied on misrepresentations made by Defendants under the CLRA, fraud, unjust enrichment, numerous state consumer protection laws, and breach of the implied warranty of merchantability under four state laws. In contrast, a plaintiff seeking to file an action based on personal injuries suffered seeks relief under the products liability laws. For example, Plaintiff Andren, currently has a pending state court action seeking personal injury damages based on products liability under strict liability

and negligence. (See Dkt. No. 129-2, Alt Decl., Ex. E.) Therefore, because the issues that will actually be litigated in the consumer protection claim are distinct from those in products liability action, under Cooper, an absent class member may file another lawsuit seeking relief on personal injury claims based on different legal theories that were not adjudicated in this case.

In sum, the Court concludes that the potential risk that unnamed class members may be barred from pursuing personal injury claims is small, not only based on the holding in Cooper, but also the ability to mitigate the potential risk through the notice and opt-out procedures, by amending the class definition, or through an express reservation of the claim.

ii. Value of the Waived Claim

Plaintiffs assert that the total value of their class claim is over $100 million, (Dkt. No. 111-2, Ex. A, Andrien Expert Report at 7 (UNDER SEAL), which exceeds the value of potential personal injury suits even though the value of potential personal injury suits is unknown. In response, Defendants contend that Plaintiffs have failed to present any evidence to support their "value" assessment because while Plaintiffs argue that the value of the personal injury claims are unknown they also allege that INRatio "kills people" and has caused hundreds or thousands of injuries or death.

Generally, courts have held that claim splitting between personal injuries and economic injuries bars class certification if the personal injuries are large in relation to the economic injuries. See Slade, 856 F.3d at 415 ("[u]nless a district court finds that personal injuries are large in relation to statutory damages, a representative plaintiff must be allowed to forgo claims for compensatory damages in order to achieve class certification.") (quoting Murray v. GMAC Mortg. Corp., 434 F.3d 948, 953 (7th Cir. 2006)). In Murray, the plaintiff sought statutory damages under the Federal Credit Reporting Act, requiring "wilful conduct", instead of compensatory damages under negligence, an "easier" standard, in order to pursue a consumer class action. Murray v. GMAC Mortg. Corp., 434 F.3d 948, 952 (7th Cir. 2006). The compensatory damages for

individual losses would likely be small and making the determination of a million consumers individual losses would make the case unmanageable. Id. at 953. The court explained that such decisions do not justify denial of class certification because individual compensatory damages would defeat class certification. Id. at 952-53. The Seventh Circuit explained that a representative plaintiff "must be allowed to forego claims for compensatory damages in order to achieve class certification" unless the court "finds that personal injuries are large in relations to statutory damages." Id. at 953. If there are only a few class members' injuries that are substantial, they may opt out and litigate separately. Id. "Only when all or almost all of the claims are likely to be large enough to justify individual litigation is it wise to reject class treatment altogether." Id.

Similarly, in Tasion, the district court concluded that the plaintiffs were inadequate to represent the class because they only sought one type of damage which was the labor cost to replace the defective cable product and chose to forgo all other possible elements of damages. Tasion Comm'ns, Inc. v. Ubiquiti Networks, Inc., 308 F.R.D. 630, 641 (N.D. Cal. 2015). The district court noted that the waived damages were "likely to exceed by many times the direct replacement labor cost Plaintiffs now seek." Id. at 641. Because the plaintiffs were willing to abandon significant damages claims, which were highlighted extensively in the complaint, and there was evidence in the record that the abandoned damages could be significant, the Court concluded that the plaintiffs were not adequate representatives. Id. at 641, 643.

In the case of In re Light Cigarettes Mktg. Sales Practices Litig., 271 F.R.D. 402, (D. Maine 2010), the defendants argued that the representative plaintiffs were inadequate as they have waived "potentially more lucrative personal injury claims" on behalf of absent class members. Id. at 415. In concluding that the representative plaintiffs met the adequacy requirement, the court noted that the plaintiffs' unjust enrichment and statutory consumer protection claims allege economic injury without regard to whether the misrepresentations caused physical harm. Id. (noting that personal injury claims would render class certification questionable requiring individualized presentation of evidence).

However, the Court observed that the defendants did not show that any of the proposed class representatives currently have a claim for personal injury. Id. Finally, it noted that Rule 23(c)(2)'s notice requirements "softens the impact of res judicata" on these proceedings. Id.

In O'Connor v. Uber Techs., Inc., 311 F.R.D. 547, 565-66 (N.D. Cal. 2015), the plaintiff sought only vehicle-related and phone expenses and waived other damages. The court held the representative plaintiff was not inadequate and noted that the plaintiff presented some evidence that these expenses will consist of the majority of any recoverable expenses. Id. at 565 (noting that this is not a case where the plaintiff seeks to waive damages that are likely to "exceed by many times" the damages sought").

Finally, Gates is a case involving contamination of the soil and air by the defendants where the plaintiff only sought a class consisting of property loss and medical monitoring and not for any present personal injuries. Gates, 265 F.R.D. at 217. The court held that the plaintiffs were adequate representatives because it appeared that the vast majority of absent class members did not have present physical injuries. Id. at 218. The district court observed that even if absent class members had present physical injuries, they would have already sued individually, as some of their neighbors had done, and several individual suits were brought in state court, during the litigation by residents with present physical injuries. Id. The Court also found that any potential conflict could be resolved by amending the class definition and the "opt-out" procedure may be available. Id. The court concluded that the absent class members that have present personal injuries are not a "great impediment" to certification. Id.

Here, Defendants attach five state court complaints filed in California and Connecticut. One state court complaint was filed on May 1, 2015, by an individual plaintiff in Connecticut alleging claims of product liability, negligence, lack of adequate warning under Connecticut Products Liability Act, breach of express warranty, breach of implied warranty, recklessness against Alere, Inc. concerning the INRatio product for physical and mental injuries. (Dkt. No. 129-2, Alt Decl., Ex. F.) Four other state court

complaints were filed in San Diego Superior Court between February 27, 2017 to September 14, 2017. (Id., Exs. B-E.) The five state court complaints encompass 25 named plaintiffs against Defendants for, inter alia, claims of personal injury. (Id., Exs. B-F.) In fact, one of the state court complaint filed on May 22, 2017 in San Diego Superior Court was by Plaintiff Andren alleging personal injury claims under legal theories of products liability under strict liability and negligence. (Id., Ex. E.)

In this case, the putative class members most likely received notice of a nationwide recall of the INRatio Products that was issued on July 11, 2016. Defendants present five complaints filed by 25 individual plaintiffs who suffered from personal injuries due to the INRatio Products. Compared to the thousands or tens of thousands of individuals who purchased the INRatio Products,[6] 25 individual plaintiffs' claims for personal injury claims are not significant in numbers or, potentially, in damages. While the personal injury claims may be significant in these existing state court complaints, this is not a case where Plaintiffs seek to waive damages that are likely to "exceed by many times" the damages sought in this case. See O'Connor, 311 F.R.D. at 565. Plaintiffs are not jeopardizing the class members' ability to pursue far more substantial, meaningful claims while pursuing relatively insignificant claims. See In re Universal, 219 F.R.D. at 669.

As noted by the Fifth Circuit in Slade, as litigation progresses, if the number of putative class plaintiffs opting out creates a conflict that undermines the adequacy of the representative plaintiffs, the Court can decertify the class. See Slade, 856 F.3d at 414. The Court concludes that the value of the waiver is not great relative to the damages sought in this case.

iii. Strategic Value of the Waiver

Courts have recognized the strategic value of waiving claims in order to achieve class certification and look to the reasons behind a representative plaintiff's decision to

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[6] [redacted]. (Dkt. No. 111, Pls. Mot. at 20 (UNDER SEAL).)

forgo certain damages or claims and whether the plaintiff's interests align with those of the class or whether they conflict with class members who will be prejudiced. In re Conseco Life Ins. Co. LifeTrend Ins. Sales & Mktg. Litig., 270 F.R.D. at 532 (noting that the plaintiffs were not seeking to split their claims and "Plaintiffs are permitted to press a theory of contract liability that affords them the best chance of certification and of success on behalf of the class."); In re Universal Serv. Fund Tel. Billing Practices Litig., 219 F.R.D. at 669 ("This is not a case where the class representatives are pursuing relatively insignificant claims while jeopardizing the ability of class members to pursue far more substantial, meaningful claims. Rather, here the named plaintiffs simply decided to pursue certain claims while abandoning a fraud claim that probably was not certifiable."); Murray, 434 F.3d at 953 ("Refusing to certify a class because the plaintiff decides not to make the sort of person-specific arguments that render class treatment infeasible would throw away the benefits of consolidated treatment"); Benedict v. Altria Group, Inc., 241 F.R.D. 668, 675 (D. Kan. 2007) (adequacy not defeated when class representative brought claims for consumer protection and unjust enrichment, foregoing personal injury claim, "which would likely inject individual issues defeating class certification").

In Kennedy v. Jackson Nat'l Life Ins. Co., No C 07-371 CW, 2010 WL 2524360, at *5 (N.D. Cal. June 23, 2010), the plaintiff filed suit against defendant for unlawful practices in the solicitation, offering and sale of its deferred annuity products. The court concluded that the defendant's concerns about claim-splitting by not pursuing certification on multiple theories of liability asserted in the complaint did not apply. Id. at *5. The court explained that after discovery, the plaintiff learned that the theories she now asserts affords the greatest likelihood of success on behalf of the class and a claim based on what Plaintiff had abandoned could require individualized inquiry and would unravel the putative class. Id.

In this case, if Plaintiffs were to seek personal injury damages, it would require individualized inquiries and both parties recognize that these individualized inquiries

would defeat class certification. Plaintiffs should not be required to pursue a damages theory that would potentially defeat class certification in light of the fact that the risk of preclusion is low and value of the waived claim is not as great as the economic injury claim. The Court concludes that there is strategic value to the waiver of the personal injury claims.

In sum, at this stage of the proceedings, the Court concludes that the adequacy prong has been satisfied under Rule 23(a)(4).

3. Typicality

Under typicality, the Court must determine whether the claims or defenses of the representative parties are typical of the claims or defenses of the class. Fed. R. Civ. P. 23(a)(3). "Under the rule's permissive standards, representative claims are 'typical' if they are reasonably co-extensive with those of absent class members; they need not be substantially identical." Hanlon, 150 F.3d at 1020. "The purpose of the typicality requirement is to assure that the interest of the named representative aligns with the interests of the class." Hanon v. Dataproducts Corp., 976 F.2d 497, 508 (9th Cir. 1992) (internal citation omitted). "The test of typicality is whether other members have the same or similar injury, whether the action is based on conduct which is not unique to the named plaintiffs, and whether other class members have been injured by the same course of conduct." Id.

Defendants argue that class certification should be denied because Andren and Cioffi are subject to unique defenses. Plaintiffs reply that unique defenses will not subsume the litigation.

"Several courts have held that "class certification is inappropriate where a putative class representative is subject to unique defenses which threaten to become the focus of the litigation." Hanon, 976 F.2d at 508. A motion for class certification should not be granted if "there is a danger that absent class members will suffer if their representative is preoccupied with defenses unique to it." Id. (citation omitted). "Defendants need not show that these unique defenses will necessarily succeed, but rather that they will shape

the focus of litigation in a way that may harm class members and ultimately risk the class' chance of recovery." Schaefer v. Overland Express Family of Funds, 169 F.R.D. 124, 129 (S.D. Cal. 1996).

Defendants contend that Andren obtained the INRatio Products in a highly unusual manner. She did not receive a prescription, she did not buy it at an authorized dealer but bought it from a medical recycling company more than six months after Alere SD stopped selling new devices. (Dkt. No. 113, Alt Decl., Ex. 5, Andren Depo. at 68:23-69:20.) Later, when she found out about the Correction, she threw away evidence relating to her results and communications with her doctors while she was hiring counsel to represent her. She will be subject to a defense that she did not buy the device based on representations made by Defendants and that she intentionally destroyed evidence. As to Cioffi, she received her device subject to a free 30 day return policy and during this time she read her User's Guide and therefore cannot represent a class pursuing claims for breach of implied warranty. (Dkt. No. 113, Alt Decl., Ex. 7, Cioffi Depo. at 60:5-18; Dkt. No. 100-3, Alt. Decl, Ex. 12.)

Plaintiffs dispute Defendants' allegation that Andren intentionally destroyed evidence as they have relied on distorted chronology and argue that the defenses do not threaten to become the focus of the litigation as Alere has already conducted all discovery on these topics.

Defendants summarily raise a couple of defenses that they claim are not typical of the defenses of the class without explaining why these defenses would subsume the litigation. Plaintiffs' claims are all based on Alere's omission that the INRatio Products were defective. Thus, Plaintiffs' claims are "reasonably co-extensive with those of absent class members." See Hanlon, 150 F.3d at 1020; see also Plascencia v. Lending 1st Mort., 259 F.R.D. 437, 444 (N.D. Cal. 2009) (particular facts that are unique to the plaintiffs' claims, that the plaintiffs did not read the loan disclosure documents and their loan documents may be different from the other class members do not render the plaintiffs' claims atypical "in the sense that they differ from the claims of most class

members" and these fact go to Rule 23(b)(3), not Rule 23(a)(3)). The Court concludes that Plaintiffs have demonstrated typicality.

C. Federal Rule of Civil Procedure 23(b)(3)

Under Rule 23(b)(3), the plaintiff must demonstrate "that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy" and that "the questions of law or fact common to class members predominate over any questions affecting only individual members." Fed. R. Civ. P. 23(b)(3). Rule 23(b)(3) assesses whether a proposed class is "sufficiently cohesive to warrant adjudication by representation." Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 623 (1997).

1. Nationwide Class[7]

Defendants argue that Plaintiffs cannot maintain a nationwide class due to conflict of law principles. In their motion, Plaintiffs seeks to certify a nationwide class under California's CLRA, UCL, fraud and unjust enrichment causes of action. (Dkt. No. 75-1 at 26.) Plaintiffs respond that Defendants have failed to meet their burden that California law should not apply to a nationwide class.

"Choice-of-law rules determine whether California law will apply to the claims of nonresidents, and those rules in turn are circumscribed by due-process considerations." In re Charles Schwab Corp. Sec. Litig., 264 F.R.D. 531, 537 (N.D. Cal. 2009). A forum state, may apply its own substantive law to claims of a nationwide class without violating the federal due process clause if the forum state has a "'significant contact or significant aggregation of contacts' to the claims asserted by each member of the plaintiff class, contacts 'creating state interests,' in order to ensure that the choice of [the forum state's] law is not arbitrary or unfair." Phillips Petroleum, Co. v. Shutts, 472 U.S. 797, 821-22 (1985); see Wash. Mut. Bank v. Superior Court, 24 Cal. 4th 906, 921 (2001) ("Under

[7] Defendants do not address which factor under Rule 23 applies to their argument concerning choice of law for a nationwide class. However, many courts address the issue of nationwide class when discussing the predominance factor under Rule 23(b)(3).

California's choice of law rules, the class action proponent bears the initial burden to show that California has 'significant contact or significant aggregation of contacts to the claims of each class member.'").

Here, Plaintiffs assert that due process is satisfied because Alere San Diego and AHM are headquartered in California, and in reply argue, without relying on specific evidence in the record, that the offending conduct, the marketing and advertising, emanates from California. (Dkt. No. 75-1 at 26 n.9; Dkt. No. 102 at 12.) In response, Defendants assert that none of the named Plaintiffs live in California and they talked to their doctors, received medical care, learned about, obtained and used INRatio products, made payments and entered insurance contracts within their states of residence.

"[C]onduct by a defendant within a state that is related to a plaintiff's alleged injuries and is not 'slight and casual' establishes a 'significant aggregation of contacts, creating state interests.'" AT & T Mobility LLC v. AU Optronics Corp., 707 F.3d 1106, 1113 (9th Cir. 2013). District courts have held that where Defendants are headquartered and some misconduct conduct originates in Defendant's home state, that is sufficient to establish "significant contact" for due process purposes. See Forcellati v. Hyland's, Inc., 876 F. Supp. 2d 1155, 1160 (C.D. Cal. 2012) (defendants being headquartered in California was sufficient to satisfy due process); Chavez v. Blue Sky Natural Beverage Co., 268 F.R.D. 365, 379 (N.D. Cal. 2010) ("Defendants are headquartered in California and their misconduct allegedly originated in California."); In re Charles Schwab Corp. Sec. Litig., 264 F.R.D. at 538 (defendant was headquartered in the state and the challenged conduct took place in California); Keilholtz v. Lennox Hearth Prods., Inc., 268 F.R.D. 330, 339 (N.D. Cal. 2010) (19 percent of product sold to distributors, retailers or installer in California and constitute significant amount of contact between Defendants and California); In re Brazailian Blowout Litig., No. CV 10-8452-JFW(MANx), 2011 WL 10962891, at *6 (C.D. Cal. Apr. 12, 2011) (significant contact was established where the defendant is headquartered in California, maintains its principal offices in California and key marketing and advertising decisions regarding the product were made by

management from offices in California); Yamada v. Nobel Biocare Holding AG, 275 F.R.D. 573, 581 (C.D. Cal. 2011) (significant contacts existed because defendant's principal place of business is in California, the warranty program is administered in California and the products are made in California); see also Clothesrigger, Inc. v. GTE Corp., 191 Cal. App. 3d 605 (1987) (concluding application of California law was constitutionally permissible where defendant's principal offices were in California and the allegedly fraudulent misrepresentations emanated from California and a large number of plaintiffs resided in California); Wershba v. Apple Computer, Inc., 91 Cal. App. 4th 224, 242 (2001) (affirming application of California law to the claims of a nationwide class where defendant was a California corporation, with its principal place of business in California, and where the brochures promising free telephone support were prepared in California and distributed from California).

In Tidwell v. Thor Indus., Inc., Civil No. 05cv2088-L(BLM), 2007 WL 8083631, at *8 (S.D. Cal. Mar. 26, 2017), the district court concluded due process was not satisfied because there was insignificant connection to California by defendants and only a small percentage of the product at issue was sold in California. Id. One defendant was headquartered in California while its frames were manufactured in another state, and the other two defendants were foreign corporations with their headquarters and manufacturing facilities in other states. Id.

In re Hitachi Television Optical Block Cases, No. 08cv1746 DMS, 2011 WL 9403 (S.D. Cal. Jan. 3, 2011), is instructive. One defendant was a Japanese corporation with its principal place of business in Japan and another defendant was a California corporation with its principal place of business in California. The third defendant was a New York corporation with an assertion by defendants that its principal place of business was in New York. Id. at 7. According to the court, the exact location of the design and development of the products at issue was unclear. Id. The manufacturing of the product occurred in Mexico. Id. The court also noted that the defendants did not sell their product directly to consumers but instead used retailers that market and promote the

products directly to consumers; therefore the plaintiffs' argument that the defendants' marketing efforts for the products at issue originated at the headquarters in California was not persuasive. Id. It was not clear whether the distribution of the products to independent retailers throughout the country had a central location. Id. It noted that corporate presence, by itself, is not sufficient to establish a connection with the claims of the individual class members. Id. at 9. The analysis for due process "measures the forum state's contacts with the individual claims." Id.

Here, Alere, Inc. is not headquartered in California but in Waltham, Massachusetts. AHM is headquartered in California but the evidence demonstrates that AHM did not conduct any advertising or marketing of the INRatio Products. (See Dkt. No. 100-10, Owlet Decl. ¶¶ 3, 10.) Alere SD is headquartered in California. (Id.) Plaintiffs present a summary allegation that the offending marketing and advertising emanated from California but do not point to any evidence that Alere SD conducted marketing and advertising that were directed to the end users. Moreover, the evidence reveals that Defendants' marketing and advertising were directed to healthcare professionals who prescribed the medical device to Plaintiffs in their respective home states.

At the hearing, Plaintiffs asserted that communications concerning the INRatio Products with the FDA were with Alere SD. (Dkt. No. 75-3, Pifko Decl., Ex. 10, 11.) Moreover, the recalls dated April 16, 2014 and the December 5, 2014 Correction originated from Alere SD.[8] (Id., Ex. 6.)

Here, besides the fact that AHM and Alere, SD are headquartered in California, there is no supporting evidence that any marketing and advertising of the INRatio products emanated from California. Communications between the FDA and Alere SD, concerning issues with the INRatio Products do not provide an indication that the marketing and advertising to Plaintiffs came from Alere SD in San Diego.

[8] The Court notes that the July 11, 2016 nationwide recall of the product appears to have originated with Alere, Inc., which is headquartered in Waltham, MA. (Dkt. No. 75-3, Pifko Decl., Ex. 9.)

While the court in Forcellati concluded that being headquartered in the home state is sufficient to satisfy due process, most of the cases require a showing of some conduct more than just being headquartered in the forum state. After the Court's review of cases addressing the amount of contact needed to satisfy due process, the Court concludes that solely being headquartered in a forum state is not sufficient to establish "'significant contact or significant aggregation of contacts' to the claims asserted by each member." See Shutts, 472 U.S. at 821-22. Accordingly, based on the record, the Court concludes that Plaintiffs have not met their burden to demonstrate Defendants' significant contact with California sufficient to satisfy due process.

Nonetheless, even if Plaintiffs demonstrated there were significant contacts, the Court concludes that Defendants have demonstrated that the conflict of law analysis would bar the application of California law to a nationwide class.

Once due process is shown, the burden shifts to Defendants to demonstrate that the laws of another state apply. Wash. Mut. Bank, 24 Cal. 4th at 921. "A federal court sitting in diversity must look to the forum state's choice of law rules to determine the controlling substantive law." Mazza, 666 F.3d at 589 (quoting Zinser v. Accufix Research Institute, 253 F.3d 1180, 1187 (9th Cir. 2001)). Here, the parties do not dispute that California's three-step governmental interest analysis applies to the choice of law inquiry. See Wash. Mut. Bank, 24 Cal. 4th at 919.

"Under the first step of the governmental interest approach, the foreign law proponent must identify the applicable rule of law in each potentially concerned state and must show it materially differs from the law of California. The fact that two or more states are involved does not in itself indicate there is a conflict of laws problem." Wash. Mut. Bank, FA, 24 Cal. 4th at 919-20. "If . . . the trial court finds the laws are materially different, it must proceed to the second step and determine what interest, if any, each state has in having its own law applied to the case." Id. at 920. "Only if the trial court determines that the laws are materially different and that each state has an interest in having its own law applied, thus reflecting an actual conflict, must the court take the final

step and select the law of the state whose interests would be 'more impaired' if its law were not applied." Id.

a. Material Differences in State Laws

Defendants argue that there are material conflicts between California law and the laws of other states. Defendants rely on Mazza to support their argument that applying California law to non-resident citizens would not comply with California's governmental interest test. In Mazza the Ninth Circuit considered whether California law should apply to consumer protection claims brought by non-California plaintiffs for transactions that took place outside of California. Id. at 589-94. The district court certified, under Rules 23(a) and 23(b)(3), "a nationwide class of people in the United States who . . . purchased or leased new or used Acura RL vehicles equipped with the CMBS [Collision Mitigation Braking System]." Id. at 587. The Ninth Circuit reversed holding that "the district court abused its discretion in certifying a class under California law that contained class members who purchased or leased their car in different jurisdictions with materially different consumer protection laws." Id. at 590. The court explained that the defendant had demonstrated that other states' consumer protection laws materially differed from the law of California, other states had a "strong interest in applying its own consumer protection laws," and California had an "attenuated" interest in applying its law to residents of foreign states. Id. at 590-94. The court further held that "each class member's consumer protection claim should be governed by the consumer protection laws of the jurisdiction in which the transaction took place." Id. at 594. Finally, the court concluded that "[b]ecause the law of multiple jurisdictions applies here to any nationwide class of purchasers or lessees of Acuras including a CMBS system, variances in state law overwhelm common issues and preclude predominance for a single nationwide class." Id. at 597. The court noted that the defendant, in its brief, "exhaustively detailed the ways in which California law differs from the laws of the 43 other jurisdictions in which class members reside." Id. at 591.

Plaintiffs argue that Defendants fail to meet their burden to demonstrate the differences among the laws of the various states and only abstractly show that some differences exist. Defendants have also failed to address the material differences in state laws that would have a significant effect on the outcome of a trial. Plaintiffs rely on cases where districts courts granted a nationwide class because the defendants failed to bear their burden on the governmental interest test by conducting a careful analysis on the differences in the various states' consumer protection laws. See Bruno v. Eckhart Corp., 280 F.R.D. 540, 543-44 (C.D. Cal. 2012) (applying CLRA and UCL to nationwide class because Defendant failed to bear its burden explaining "Defendants provide[d] no law from any jurisdiction for the Court to consider, instead citing another court's conclusion that 'there are material conflicts between California's consumer protection laws and the consumer protection laws of the other forty-nine states.'"); Allen v. Hyland's Inc., 300 F.R.D. 643, 658 (C.D. Cal. 2014) ("this Court understands Mazza's holding to be that, under the facts in that case, with the issue fully briefed by the parties, foreign law applied under the governmental interest test. This case, however, involves different facts, and Defendants have not borne their burden of demonstrating that foreign law applies); Forcellati, 876 F. Supp. 2d at 1160 ("Defendants do not even discuss the differences between the consumer protection laws of [different states], let alone address whether these differences are material based on the facts and circumstances of this case."). District courts have rejected a wholesale reliance on Mazza to meet a defendant's burden under the governmental interest test.

The Court disagrees with Plaintiffs' assessment of Defendants' analysis and finds that Defendants do not rely solely on Mazza but conduct their own careful analysis. Defendants lay out the important and meaningful differences between the consumer protection laws of certain states as to the elements of proof of injury, need for proof of actual deception, whether scienter is required, whether reliance is required, whether relief is limited to equitable relief or damages, whether pre-filing notice is required and the varying statute of limitations. (Dkt. No. 100 at 24-25.) For example, in their opposition,

Defendants highlight the material differences of scienter noting that at least thirteen states, AL, AZ, AK, CO, KS, MS, NV, PA, SD, UT, VA,WI, and WY, require some degree of scienter, while other states, such as CA, CT, FL and GA, do not. (Dkt. No. 100 at 25.) In addition, as to reliance/causation, Defendants note that at least eight states, AZ, CA, IN, OR, PA, VA, WV, and WI, include a reliance requirement while other states, AL, CT, DE, FL, IL, MA, MT, NH, and NY, do not. (Id.) Furthermore, there are material differences in the remedies provided by each state. Some states permit recovery of damages such as AZ, AK, HI, IN, MA, NH, RI, SD and TX while other states such as California's UCL and Georgia's UDTPA and Utah limit their remedies to equitable relief. (Id.)

Defendants also attach a 50 state survey of each state's consumer protection and deceptive trade practices laws and each state's limitations on unjust enrichment, if any. (Dkt. No. 100-2, Alt Decl., Ex. 4.) The 50 state survey addresses the material elements of consumer protection laws, deceptive trade practices laws and unjust enrichment demonstrating that there are material conflicts between California law and the laws of the other states. See Holt v. Globalinx Pet LLC, No. CV 13-0041-DOC(JPRx), 2014 WL 347016 (C.D. Cal. Jan. 30, 2014) (Defendant met its burden by cataloguing a number of ways in which California's consumer protection laws differ based on the plaintiff's claims in this case).

In contrast to the cases relied on by Plaintiffs where the defendants relied primarily on other cases to demonstrate the differences in the other state laws and did not conduct their own analysis, in this case, Defendants have presented not only a chart of the differences in all fifty states in their consumer protection, deceptive trade practices laws and unjust enrichment, but also they have laid out the material differences between the laws of California and laws of other states that would "spell the difference between the success and failure of a claim." Mazza, 666 F.3d at 591. In fact, Plaintiffs do not dispute that there are material differences in the consumer protection laws among the 50 states.

As to unjust enrichment, Defendants also note that twenty states and the District of Columbia do not allow claims for unjust enrichment where the plaintiff has received the benefit of the bargain. See Mazza, 666 F.3d at 591 ("The elements necessary to establish a claim for unjust enrichment also vary materially from state to state."); Bias v. Wells Fargo & Co., 312 F.R.D. 528, 540 (N.D. Cal. 2015) (while district courts have certified nationwide unjust enrichment claims, since Mazza, the plaintiffs did not present a case to do so). Defendants also note that there are material differences among the states on a fraud cause of action. For example, some states, CA, CO, CT, FL, IL, MA, NJ and NY, require scienter to prove intentional misrepresentation, while other states, AZ, IN, MO, OH, PA and TX, do not. (Dkt. No. 100 at 26.) Moreover, some states require proof of fraud by clear and convincing evidence, such as CO, CT, FL, IL, MA, NY and PA, while other states require proof by a preponderance of the evidence such as CA, IN and TX. (Id.)

These differences going to the elements to prove these causes of action are material and other courts have also made such a finding. See Gianino v. Alacer Corp., 846 F. Supp. 2d 1096, 1102 (C.D. Cal. 2012) (citing In re Hitachi Tele. Optical Block Cases, No. 08cv1746, 2011 WL 9403 at *6 (S.D. Cal. Jan. 3, 2011) (stating that "there are material conflicts between California's consumer protection laws and the consumer protection laws of the other forty-nine states"); In re Bridgestone/Firestone, Inc., 288 F.3d 1012, 1018 (7th Cir. 2002) ("State consumer-protection laws vary considerably, and courts must respect these differences rather than apply one state's law to [activities] in other states with different rules."); In re Grand Theft Auto Video Game, 251 F.R.D. 139, 147 (S.D.N.Y. 2008) ("Most of the courts that have addressed the issue have determined that the consumer-fraud . . . laws in the fifty states differ in relevant respects."). In conclusion, the Court concludes that Defendants have met their burden demonstrating there are material differences in state laws.

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b. Other State's Interests in Applying Its Own Laws

On the second factor, Defendants, relying on the reasoning in Mazza, assert that each state has important interests in applying its own law to the case as each "state has an interest in balancing the range of products and prices offered to consumers with the legal protection afforded to them." See Mazza, 666 at 592. Plaintiffs do not dispute this factor.

Mazza emphasized the importance of the principles of federalism that "each State makes its own reasoned judgment about what conduct is permitted or proscribed within its borders." Mazza, 666 F.3d at 591 (citation omitted). In the consumer protection statutes, each state has an interest in setting the amount of liability for companies conducting business within its territory and each state has a valid interest "in shielding out-of-state businesses from what the state may consider to be excessive litigation." Id. at 592. Obtaining the optimal balance "between protecting consumers and attracting foreign business, with resulting increase in commerce and jobs" is a "decision properly to be made by the legislatures and courts of each state." Id.

The Court concludes that the other forty-nine states have an interest in applying their own consumer protection laws to injuries or transactions that takes place within their borders.

c. Which State's Interest is Most Impaired

Third, Defendants argue that each state's interests would be impaired if California law was applied nationwide because the place of the wrong occurred in the foreign states where Plaintiffs reside. In their sur-reply, Defendants argue that it is clear that the interests of the putative class members' domiciles across the country will be substantially more impaired than California's interests if California law is applied nationwide. Plaintiffs contend that Defendants fail to meet their substantial burden proving that the interests of the remaining 49 states will be more impaired than California's, not that the other states interests may be impaired.

On the final step, where the states have conflicting laws, the Court must determine which state's interest would be more impaired if its policy was subordinated to the policy of the other state. See id. at 593-94 (citation omitted). Mazza explained that the third factor is not intended to "'weigh' the conflicting governmental interests in the sense of determining which conflicting law manifested the 'better' or the 'worthier' social policy on the specific issue . . . but the test recognizes the importance of our most basic concepts of federalism." Mazza, 666 F.3d at 593; see also McCann v. Foster Wheeler LLC, 48 Cal. 4th 68, 97 (2010) (the court's task is not to determine which law is the better or worthier rule, "but rather to decide--in light of the legal question at issue and the relevant state interests at stake--which jurisdiction should be allocated the predominating lawmaking power under the circumstances of the present case.").

As noted in Mazza, with respect to regulating conduct within its borders, in California, "the place of the wrong has the predominant interest." Mazza, 666 F.3d at 593. The question is not whether California has a greater interest in apply its own laws to its own residents but "whether California has a greater interest in applying its own laws to a non-resident than the non-resident's home state." In re Yahoo Mail Litig., 308 FRD 577, 603 (N.D. Cal. 2015).

In California, the place of the wrong has the predominant interest and is the state "where the last event necessary to make the actor liable occurred." Mazza, 666 F.3d at 593 (citing McCann, 48 Cal. 4th at 94 n.12). In a case involving misrepresentations and omission of material information, such as in this case, "the place of the wrong [is] the state where the misrepresentations were communicated to the plaintiffs, not the state where the intention to misrepresent was formed or where the misrepresented acts took place." Mazza, 666 F.3d at 593-94 (citing Zinn v. Ex–Cell–O Corp., 148 Cal. App. 2d 56, 80, n. 6 (1957)).

In In re: First American Home Buyers Protection Corp. Class Action Litig., 313 F.R.D. 578, 603 (S.D. Cal. 2016), although the advertising was created in California and a call center was in California, the misrepresentations were communicated to putative

class members in their respective home states; therefore, the court concluded that their respective home states have a stronger interest in applying their laws. Id. at 603. Similarly, in Darisse v. Nest Labs, Inc., Case No. 5:14cv1363-BLF, 2016 WL 4385849, at *15 (N.D. Cal. Aug. 15, 2016), while the defendant was headquartered in California and its marketing, sales and engineering departments were located in California, its "interest in applying its laws to residents of other states who purchase and used [the product] in those other states is much more attenuated." Id. "California considers the geographic location of the omission or where the misrepresentations were communicated to the consumer as the place of the wrong. . . . For the out-of-state … buyers, the place of the wrong is not California, but the state where each . . . buyer saw [the defendant's] advertising, relied on it, and bought the [product]." Id.

In this case, the last event necessary to make Defendants liable is the state where the misrepresentations were communicated or advertised to the non-resident plaintiffs, which is the geographic location where these plaintiffs relied on the misrepresentation and where they bought the INRatio Products. It is undisputed that none of the named Plaintiffs reside in California and that the named Plaintiffs talked to their physicians, received medical care, learned about and were prescribed their INRatio Products or purchased the INRatio Products in their home states, and not in California. Therefore, according to California law, the foreign states' interest will be most impaired if the Court applied California law to a nationwide class. See Gianino, 846 F. Supp. 2d at 1102-03 (while California had an interest in applying its laws because the defendant was headquartered in California, a large number of the proposed nationwide class resides in California, almost 50% of the products were manufactured in California, the California Department of Health Services has regulated the products from California and the corporate decision regarding packaging and marketing were all made in California, the district court noted that California interest in applying its laws to residents of other states who purchased the products in other states is "much more attenuated" because California recognized that the place of the wrong has a predominant interest.").

Therefore, the Court concludes that as to the nationwide class, common questions of law do not predominate over the questions affecting individual class members under Rule 23(b)(3). Accordingly, the Court DENIES Plaintiffs' motion for class certification of a nationwide class under California law. See Mazza, 666 F.3d at 589-94 (vacating the district court's class certification order after holding that each class member's claim should be governed by the consumer protection laws of the jurisdiction in which the transaction took place); Zinser, 253 F.3d at 1186 (affirming the district court's denial of class certification because of the procedural complexity of trying a class action under the laws of multiple jurisdictions); Gianino, 846 F. Supp. 2d at 1099, 1104 (denying class certification because the application of the consumer protection laws of all 50 states prevented the lawsuit from meeting both the predominance and superiority requirements).

2. Article III Standing

Defendants also contend that predominance cannot be met because thousands of putative class members lack Article III standing because there are individuals who used the INRatio Products, got accurate results, managed their warfarin dosing effectively and never lost the use of the device. Plaintiffs reply that the putative class has Article III standing under Ninth Circuit precedent.

The plaintiff class bears the burden that Article III standing is met which requires that plaintiffs have: "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1547 (2016) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992)). In a class action, named plaintiffs must demonstrate they have Article III standing but not "other, unidentified members of the class to which they belong." Id. at 1547 n. 6. The Ninth Circuit has held that in a class action, Article III standing is satisfied if at least one named plaintiff meets the requirements. Ollier v. Sweetwater Union High Sch. Dist., 768 F.3d 843, (9th Cir. 2014 (quoting Bates v. United Parcel Serv., Inc., 511 F.3d 974, 985 (9th Cir. 2007) (en banc)).

Here, it is not disputed that at least one named Plaintiff has standing and Article III standing is satisfied. Instead, Defendants' reliance on a statement in Mazza, "no class may be certified that contains members lacking Article III standing" addresses the propriety of certification under Rule 23, not Article III subject matter jurisdiction. See Moore v. Apple Inc., 309 F.R.D. 532, 541-42 (N.D. Cal. 2015) (noting that courts have acknowledged the tension between Mazza, and prior Ninth Circuit authority holding that Article III standing is met if at least one plaintiff meets the standard). The issue is "whether or not the proposed class includes class members who have not suffered an injury" which is addressed under Rule 23. Id. at 542; see also Bruno, 280 F.R.D. at 533 ("In sum, the majority of authority militates in favor of the following rule, which this Court adopts: where the class representative has established standing and defendants argue that class certification is inappropriate because unnamed class members' claims would require individualized analysis of injury or differ too greatly from the plaintiff's, a court should analyze these arguments through Rule 23 and not by examining the Article III standing of the class representative or unnamed class members.").

The Court therefore addresses whether Plaintiffs' proposed class definition is overbroad under Rule 23 because it contains members who lack Article III standing. See Moore, 309 F.R.D. at 542 (citing Mazza, 666 F.3d at 594). The proposed class definition include, "[a]ll residents of [CO, FL, GA, MD, PA, or NY] who, during the period January 1, 2009 through the present, purchased, rented or otherwise paid for the use of the INRatio products manufactured, marketed, sold or distributed by Defendants."

Here, Plaintiffs claim that all class members suffered an economic injury because they all purchased the medical device, that was worthless, and were directed to cease using the devices, thereby losing use of them when they were recalled. See Clinton v. City of New York, 524 U.S. 417, 432-33 (1998) (noting a "sufficient likelihood of economic injury" establishes injury in fact for Article III standing). The Court concludes that the class definition is not overbroad as they include purchasers of the INRatio

Products who were all directed to discard them by the recall, and thereby, suffered economic injury. Therefore, Defendants' Article III standing argument is without merit.

3. Plaintiffs' Consumer Protection Claims

Plaintiffs seek to certify sub-classes alleging consumer protection claims under the laws of Colorado, Florida, Georgia, Maryland, New York and Pennsylvania. (Dkt. No at 29.)

a. Georgia and Colorado Consumer Protection Laws Prohibit Representative Actions for Monetary Relief

Defendants assert that two states, Colorado and Georgia, expressly prohibit class actions seeking monetary relief. See Col. Rev. Stat. § 6-113(2) ("Except in a class action . . . any person who, in a private civil action, is found to have engaged in or caused another to engage in any deceptive trade practice listed in this article shall be liable in an amount equal to the sum of . . . ."); Ga. Rev. Stat. § 10-1-399(a) ("Any person who suffers injury or damages . . . as result of consumer acts or practices in violation of this part . . . may bring an action individually, but not in a representative capacity, against the person or persons engaged in such violations . . . ."). Therefore, a class action cannot be maintained for these two state claims. Plaintiffs argue that the United States Supreme Court's decision in Shady Grove Orthopedic Assocs., P.A. v. Allstate Inc. Co., 559 U.S. 393, 399-400 (2010) allows actions to be certified as a class despite a state's consumer protection statutes that expressly bar damages in class actions.

In Shady Grove, the United States Supreme Court held that a New York law that prohibited class action suits seeking penalties or statutory minimum damages would be trumped by Federal Rule of Procedure 23 which allows class actions to be maintained as long as two conditions are met. Id. at 411. The Supreme Court held that matters may proceed as putative class actions, regardless of whether state statutes prohibit such claims, so long as the application of Rule 23 does not "abridge, enlarge or modify any substantive right." Id. at 407 (quoting 28 U.S.C. § 2072(b)).

District courts in this circuit applying Shady Grove have held that class actions may proceed despite state consumer protection statutes prohibiting such actions. See In re Hydroxycut Mktg. and Sales Practices Litig., 299 F.R.D. 648 (S.D. Cal. 2014) (permitting claims under Georgia, South Carolina and other state consumer protection statutes to proceed as class action under Rule 23 where state statutes do not allow class actions). The court in In re Hydroxycut, explained that the "different opinions of the fractured Court took contrasting approaches to determining whether a New York statute prohibiting class actions in suits seeking penalties or statutory minimum damages precluded a federal district court sitting in diversity from entertaining a class action under Rule 23." Id. at 653. After conducting an analysis of Shady Grove and pre-Shady Grove Ninth Circuit cases, the court concluded that a rule barring class action does not preclude individuals from bringing their own lawsuits; therefore, the substantive rights of these individuals are not affected but only affect "how the claims are processed." Id. at 654. Therefore state consumer protection laws that prohibit class actions are "procedural", and a class action may be certified as long as the requirements of Rule 23 are met.

As noted by a district court relying on the reasoning in In re Hydroxycut, other courts in this circuit have reached the same conclusion. Reed v, Dynamic Pet Prods., No. 15cv987-WQH-DHB, 2016 WL 3996715, at *6 (S.D. Cal. July 21, 2016) (citing In re Lithium Ion Batteries Antitrust Litig., No. 13-MD-2420 YGR, 2014 WL 4955377, at *21 (N.D. Cal. Oct. 2, 2014) (finding that the class-action bans challenged were "procedural, not substantive, and that application of Rule 23 to them would not modify any substantive right")); Los Gatos Mercantile, Inc v. E.I. DuPont De Nemours & Co., No. 13-CV-01180-BLF, 2015 WL 4755335 (N.D. Cal. Aug. 11, 2015) (similar); Johnson v. Ashley Furniture Indus., Inc., No. 13-CV-2445-BTM-DHB, 2014 WL 6892173 (S.D. Cal. Nov. 4, 2014) (similar)); but see In re Myford Touch Consumer Litig., No. 13cv3072-EMC, 2016 WL 7734558, at *27 (N.D. Cal. Sept. 14, 2016) (declining to certify class for violation of the Colorado Consumer Protection Act's limitation on class actions is intertwined with state substantive rights). This Court also finds the reasoning

in In re Hydroxycut persuasive and concludes that a representative action for monetary relief is not barred under Georgia or Colorado law.

b. Learned Intermediary

Defendants next argue that the learned intermediary doctrine applies to prescription medical devices and defeats predominance as it will require individual inquiries into the knowledge of each individual prescribing physician. They assert that the states under which Plaintiffs seek to assert claims recognize the learned intermediary doctrine.[9] They also contend that Plaintiffs have provided no evidence as to what the prescribing medical doctors knew or believed about the INRatio System. Plaintiffs oppose merely arguing it is premature to the address the issue at this stage as it should be addressed at summary judgment or at trial citing Saavedra v. Eli Lily and Co., No. 12cv9366-SVW-MAN, 2013 WL 6345442, at *6 (C.D. Cal. Feb. 26, 2013). Saavedra is not supportive of Plaintiffs' position because the district court was ruling on a motion to dismiss, and concluded that determining whether the learned intermediary doctrine applies must be determined at summary judgment or trial, not on a motion to dismiss. Id. at 3. Plaintiffs do not address whether the learned intermediary doctrine applies or not.

Restatement (Third) of Torts concerning Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices provides,

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[9] Dkt. No. 100 at 33 n. 16 (citing Florida, Georgia, Maryland, New York, Pennsylvania and Colorado cases applying learned intermediary doctrine). The Court notes that these cases apply the learned intermediary doctrine to failure to warn claims and not to consumer protection laws. Based on the Court's research, Pennsylvania and Florida have applied the learned intermediary doctrine to cases arising out of the consumer protection laws. McLaughlin v. Bayer Corp., 172 F. Supp. 3d 804, 831 (E.D. Pa. 2016); Luke v. Am. Home Prods. Corp., No. 1998-C-1977, 1998 WL 1781624, at *8 (Pa. Com. Pl. Nov. 18, 1998) Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1372 (S.D. Fla. 2007) ("[F]ederal courts in jurisdictions across the country, including Florida, have held that the learned intermediary doctrine encompasses all claims based upon a pharmaceutical manufacturer's failure to warn, including claims for fraud, misrepresentation, and violation of state consumer protection laws.").

> (d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
> (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; . . .

Restatement (Third) Torts, Prod. Liab. § 6(d)(1) (1998). A "treating physician's decision not to inform a patient of the risk of injury is an intervening cause, which severs any causal connection between the patient's injury and the manufacturer." Krasnopolsky v. Warner–Lambert Co., 799 F. Supp. 1342, 1347 (E.D.N.Y. 1992). The "learned intermediary [i.e., the doctor] breaks the chain in terms of reliance, since the patient cannot obtain [a] prescription [device] without the physician no matter what [the patient] believe[s] about [the device]." Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364, 384 (D.N.J. 2004) (applying Pennsylvania law). Thus, it is only the "prescribing physician who [can] provide[ ] the grounds for justifiable reliance" under the UTPCPL. In re Avandia Mktg., Sales Practices and Prods. Liab. Litig., No. 10-2401, 2013 WL 3486907, at *2 (E.D. Pa. July 10, 2013) (citation omitted). However, the learned intermediary doctrine is not a shield against liability where the manufacturer has not given adequate warnings to the physician. See Lance v. Wyeth, 624 Pa. 231, 270 (2014); Centocor, Inc v. Hamilton, 372 S.W.3d 140, 170 (Tx. 2012).

In this case, Defendants have raised the defense of learned intermediary arguing that the doctrine is not amenable to class wide treatment due to the predominance of individual questions. In opposition, Plaintiffs have not directly addressed Defendants' argument. It does not appear that Plaintiffs dispute that INRatio Products are prescription medical devices and that the learned intermediary doctrine applies to their case. However, it is not clear whether Plaintiffs are claiming that Defendants did not adequately warn the prescribing physicians. While Plaintiffs cite to Lance to support the proposition that prescribing physicians are not "learned" if adequate warnings from the defendant were not relayed to the physicians, Plaintiffs do not present any argument or facts to support Lance's proposition to their case. Because the INRatio Products were

prescribed medical devices, in order to determine whether the learned intermediary doctrine applies, individualized inquiries will be required to determine whether Defendants informed the prescribing physicians and whether each treating physician knew about the risks associated with the INRatio products and when they knew it.[10] As such, Plaintiffs have not demonstrated, with evidentiary proof, that the predominance factor has been met. See Comcast Corp., 569 U.S. at 33 (a plaintiff must satisfy Rule 23(b) with evidentiary proof). Therefore, the Court concludes that Plaintiffs have not demonstrated predominance under Rule 23(b)(3) concerning the consumer protection claims.

4. Breach of Implied Warranty of Merchantability

Plaintiffs further seek to certify statewide classes alleging implied warranty claims under the laws of Colorado, Florida, Maryland and Pennsylvania as these states have adopted section 2-314 of the Uniform Commercial Code ("UCC"). (Dkt. No. 75 at 29.) Section 2–314 of the U.C.C. provides a cause of action for an implied warranty of merchantability, which warrants that goods must be at least "fit for the ordinary purposes for which such goods are used." U.C.C. § 2-314; see also Pa. Stat. § 2314(a); Fla. Stat. § 672.314(2); Colo. Rev. Stat. § 4-21-314; Md. Code, Commercial Law § 2-314.

a. INRatio Products are Goods, Not Services

Defendants argue that the implied warranty of merchantability claims apply only to the sale of goods, not services. They argue that the class includes many people who did not purchase the INRatio Products but instead received an INR monitoring service which provided these materials. Defendants claims that AHM personnel have estimated that fewer than 10% of its customers actually buy strips or monitors so the class is overbroad by at least 90%. In response, Plaintiffs contend that the INRatio Products are clearly

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[10] Because Plaintiffs have not demonstrated predominance concerning the learned intermediary doctrine, the Court need not discuss Defendants' alternative argument that there was no uniform evidence of exposure to the alleged misrepresentations or omissions to Plaintiffs.

goods, and not a service. Plaintiffs and class members parted with money in exchange for the products.

Defendants' summary argument is not supported. They do not cite any evidence that only 10% of its customers actually buy strips or monitors. The facts support the contrary. Plaintiff Bludman was a customer of AHM, (Dkt. No. 75-3, Alt Decl., Ex 16, Bludman Decl. ¶ 3), but he was required to purchase boxes of replacement INRatio2 test strips to continue his INR testing. (Dkt. No. 21, FAC ¶ 102.) Plaintiff Cioffi was a customer of AHM and she purchased the INRatio2 PT/INR System for $3,519.00. (Dkt. No. 75-3, Alt Decl., Ex. 17, Cioffi Decl. ¶¶ 1, 2, 4.) Plaintiff Falk was also a customer of AHM and spent $2,558.47 for the INRatio System. (Dkt. No. 75-3, Alt Decl., Ex. 18, Falk Decl. ¶¶ 1, 2, 3.) Similarly, Plaintiffs Kerzner-Green, Montalbano and Rigot assert they were customers of AHM and purchased either the INRatio System and/or the replacement test strips. (Dkt. No. 75-3, Alt Decl., Ex. 19, Kerzner-Green Decl. ¶¶ 1, 2, 3; Dkt. No. 75-3, Alt Decl., Ex. 20, Montalbano Decl. ¶¶ 1, 2, 3; Dkt. No. 75-3, Alt Decl., Ex. 21, Rigot Decl. ¶¶ 1, 2.)

Each of the named Plaintiffs purchased a good or goods; therefore, Defendants' argument lacks merit.

b. Manifestation of a Defect and Individual Issues of Privity, Notice and Disclaimer of Warranties

Defendants next contend that manifestation of a defect is a key question requiring individual issues as to whether Plaintiffs experienced any manifestation of the alleged INRatio Product defect. Defendants further argue that issues of privity, notice and receipt of disclaimer of warranties require individualized inquiries. Plaintiffs respond that the INRatio Products were uniformly defective and valueless since the INRatio Products were recalled and destroyed by a medical waste company, and therefore, not fit for ordinary purpose for which it was used. They also argue that the cases Defendants rely on to support their argument on privity, notice and receipt of disclaimer of warranties are not applicable in this case.

The Court notes that the parties present summary arguments without citing to legal authority in the relevant state court. For example, Defendants cite to Eighth Circuit cases as well as Pennsylvania, New York, and Florida district court cases to support the issue concerning manifestation of a defect; however, the only relevant state law that they cite to is Pennsylvania and New York, and not Maryland and Colorado. In response, Plaintiffs only cite to Ninth Circuit law, which has no relevance on this issue.

As to the issue of privity, Defendants present a two sentence analysis citing to a Florida and a Georgia district court case where the only relevant case would be the Florida case. (See Dkt. No. 100 at 36-37.) As to notice, they cite to a Georgia state court case, a case with the Northern District Court of Georgia, and an Eleventh Circuit case addressing whether California and Texas law required pre-suit notice. (Id. at 37.) None of these cases address notice concerning implied breach of warranty claims under Colorado, Florida, Maryland and Pennsylvania law. Finally, as to disclaimer, Defendants provide no supporting caselaw. (Id.) Defendants' arguments do not present sufficient analysis and support for their argument that individual issues will prevail on the breach of the implied warranty claims in the laws of Colorado, Florida, Maryland and Pennsylvania, and are without merit.

5. Statute of Limitations

Defendants further argue that the statute of limitations for breach of warranty and consumer protection fraud claims will require individual questions as some of the proposed class members include persons who purchased the product as far back as 2009, more than eight years ago. In support, Defendants cite to Colorado's three year statute of limitations for breach of warranty and consumer fraud claims, and Florida's four year statute of limitations on statutory claims and Maryland's three year statute of limitations period but do not address New York, Pennsylvania, and Georgia's statute of limitations. Next, they argue that equitable tolling does not apply in some states yet only cite one Pennsylvania case. Lastly, they argue that Andren's case demonstrates that some members may have had notice of their claims long before the case was filed since she

claims to have had multiple errant readings, revealed by lab reference testing and her doctor could not explain why. However, Andren purchased her INRatio 2 PT/INR testing kit in 2015 and her claims are timely.

In response, Plaintiffs contend that the discovery rule applies in this case citing California and Ninth Circuit law but fail to address whether the courts in Colorado, Florida, Georgia, Maryland, New York and Pennsylvania have adopted the discovery rule.

Defendants raise the question of whether the statute of limitations will require individual inquiry as there will be class members who purchased the product as far back as 2009 and may be barred from being a class member. Defendants present the question in a conclusory manner, so it is unclear whether the statute of limitations will give rise to individual issues. However, Plaintiffs have failed to demonstrate that the discovery rule applies to extend the statute of limitations in Colorado, Florida, Georgia, Maryland, New York and Pennsylvania. Accordingly, because Defendants have raised a question about the statute of limitation which Plaintiffs have failed to properly address, the Court concludes that Plaintiffs have not demonstrated that the predominance factor has been met as it concerns the statute of limitations on all claims.

6. Damages

Plaintiffs seek a full-refund damages model to support their claims. They argue that because the INRatio Products could not safely and reliably monitor a user's INR, it was worthless. Defendants argue that Plaintiffs have not articulated a viable damages model that satisfies Comcast citing to California law. Plaintiffs reply that they have demonstrated damages using the full refund damages model and also cite to California law.

The United States Supreme Court held that plaintiffs must present a damages model that is consistent with their liability case, and the court "must conduct a rigorous analysis to determine whether that is so." Comcast, 133 S. Ct. at 1433 (internal quotation marks omitted). Plaintiffs "must be able to show that their damages stemmed from the

defendant's actions that created the legal liability." Leyva v. Medline Industries, Inc., 716 F.3d 510, 514 (9th Cir. 2013). While a plaintiff must present the likely method for determining class damages, "it is not necessary to show that [this] method will work with certainty at this time." Chavez, 268 F.R.D. at 379.

Here, both parties rely on California law to address Plaintiffs' full refund damages model theory. Because the Court denies Plaintiffs' motion to certify a nationwide class, as discussed above, California law is no longer applicable. Plaintiffs also seek certification of six state sub-classes but they have not addressed whether the full refund model is consistent with their theories of liability under Colorado, Florida, Georgia, Maryland, New York and Pennsylvania law. Because Plaintiffs have not demonstrated that their damages model satisfies Comcast, they have not demonstrated predominance of common issues of law or fact concerning damages.

Because Plaintiffs fail to satisfy the predominance requirement, the Court concludes that a class action would not be "superior to other methods for fairly and efficiently adjudicating the controversy." See Rule 23(b)(3); Pace v. PetSmart Inc., No. SACV 13-00500 ODC(RNBx), 2014 WL 2511297, at *12 (C.D. Cal. June 3, 2014) (no need to address superiority if predominance requirement not met).

In sum, the Court DENIES Plaintiffs' motion for class certification.

Conclusion

Based on the above, the Court DENIES Plaintiffs' motion for class certification.

IT IS SO ORDERED.

Dated: December 20, 2017

Hon. Gonzalo P. Curiel
United States District Judge