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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

APRIL KRUEGER,

Plaintiff,

v.

WYETH, INC., *et al.*,

Defendants.

Civil No. 03cv2496 JAH (MDD)

**ORDER ON SUPPLEMENTAL BRIEFS**  
**[Doc. # 278; Doc. # 279]**

**INTRODUCTION**

Before the Court are the parties’ supplemental briefs on modification of the class definition. After a careful consideration of the briefs and relevant exhibits submitted by the parties, the Court sets forth its decision below.

**BACKGROUND**

**1. Factual Background**

Defendants manufacture the hormone replacement therapy (“HRT”) drugs Premarin, Prempro, and Premphase. See Doc. # 61-6 at 2. **Premarin**, an estrogen, is a prescription drug first approved by the Food and Drug Administration (“FDA”) in 1942 and used to prevent postmenopausal osteoporosis, treat moderate to severe vasomotor symptoms associated with menopause (e.g., hot flashes, night sweats), and treat vulvar and vaginal atrophy. See Doc. # 85 at 10-11; Doc. # 20-10 at 4. **Prempro**, a combination of estrogen and progestin, is a prescription drug approved by the FDA in 1994 “for limited use as a continuous, short-term regimen” to treat and prevent the same symptoms

1 addressed by Premarin. See Doc. # 61-6 at 2; Doc. # 85 at 10. **Premphase**, a one tablet cyclic  
2 regimen of estrogen and progestin, is an alternative form of hormone therapy also used to treat and  
3 prevent the same symptoms addressed by the other two drugs. See Doc. # 61-5 at 5; Doc. # 85 at 11.

4 Plaintiff alleges that since the 1990s, defendants used “branded” and “unbranded” campaigns  
5 to market their HRT drugs to women over 45 years old and to physicians for on- and off-label drug  
6 uses. See Doc. # 61-6 at 4-5, 9-11; Doc. # 22. Branded campaigns marketed the drugs for FDA-  
7 approved, on-label uses, while unbranded campaigns marketed the drugs for non-approved, off-label  
8 uses, including the prevention of cardiovascular disease, dementia, and Alzheimer’s disease. See Doc.  
9 # 61-6 at 4-5, 9-11. Specifically, defendants used the unbranded campaign to inform women that  
10 estrogen loss increased their risk of serious ailments, especially cardiovascular disease, dementia, and  
11 Alzheimer’s disease, with HRT effectively reducing these risks. Id. at 6-7, 9. Defendants then used  
12 the branded campaign to introduce women to the HRT drugs and the purported benefits provided by  
13 these drugs, while also emphasizing that HRT did not cause breast cancer. Id.

14 In 2002, however, the Women’s Health Initiative (“WHI”), sponsored by the National  
15 Institutes of Health (“NIH”), released a study reporting that Prempro increased a woman’s risk of  
16 stroke, heart attack, cardiovascular disease, breast cancer, dementia, and Alzheimers disease. See  
17 Doc. # 61-6 at 2-3; Doc. # 20-1. Following the study, the FDA revised the labeling of defendants’  
18 HRT drugs to reflect these health risks. See Doc. # 20-5 at 2. Thereafter, defendants began to warn  
19 consumers that Premarin, Prempro, and Premphase “should not be used to prevent coronary heart  
20 disease,” and in light of the “potential increased risks of cardiovascular events, breast cancer, and  
21 venous thromboembolic events,” their use “should be limited to the shortest duration consistent with  
22 treatment goals and risks for the individual woman, and should be periodically reevaluated.” Id.; see  
23 also Doc. # 61-6 at 3.

24 Plaintiff brings the instant action against defendants for falsely advertising and deceptively  
25 marketing the HRT drugs in violation of California’s Consumer Legal Remedies Act (“CLRA”), Cal.  
26 Civ. Code §§ 1750 et. seq., and California’s Unfair Competition Law (“UCL”), Cal. Bus. & Prof.  
27 Code §§ 17200 et. seq. See Doc. # 16.

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1 **2. Procedural History**

2 On December 12, 2003, plaintiff initiated a products liability action against defendants and  
3 Does 1-100, inclusive, in the U.S. District Court, Southern District of California. See Doc. # 1. The  
4 Judicial Panel on Multidistrict Litigation transferred the case to the Eastern District of Arkansas for  
5 coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407, which merged plaintiff's complaint  
6 with those of other class action complaints as part of In re Prempro Prods. Liab. Litig., 230 F.R.D. 555  
7 (E.D. Ark. 2005) (MDL-1507). See Doc. # 6; Doc. # 7. Thereafter, plaintiff's case was remanded  
8 back to this district after the Arkansas court declined to certify a multi-state class of consumers  
9 alleging consumer fraud and seeking medical monitoring for any future injuries that arise from their  
10 use of Prempro. See Doc. # 8; Doc. # 9.

11 On May 14, 2007, plaintiff filed a motion to certify a consumer fraud class of California  
12 women who purchased defendants' HRT drugs, which the Honorable Janis L. Sammartino ("Judge  
13 Sammartino") denied without prejudice upon a finding that plaintiff could not satisfy the "adequacy"  
14 requirement of Rule 23(a)(4) of the Federal Rules of Civil Procedure ("FRCP"). See Doc. # 15; Doc.  
15 # 16; Doc. # 44. Judge Sammartino noted, however, that plaintiff "may be able to satisfy the adequacy  
16 requirement by redefining the class," with plaintiff subsequently filing a motion before this Court for  
17 certification of a damages class pursuant to Rule 23(b)(3). Doc. # 44 at 6, n. 3; Doc. # 61 at 2. This  
18 Court granted in part and denied in part plaintiff's motion on March 30, 2011. See Doc. # 108.  
19 Defendants then filed a motion for reconsideration, which this Court denied on July 13, 2011. See  
20 Doc. # 110; Doc. # 122. Defendants subsequently filed a petition with the Ninth Circuit requesting  
21 permission to appeal this Court's class certification order. See Doc. # 123. The Ninth Circuit denied  
22 defendants' petition on October 18, 2011. See Doc. # 124. As it stands, therefore, the certified class  
23 in this case includes:

24 All California consumers who purchased Wyeth's Hormone Replacement Therapy  
25 products, Premarin, Prempro, and/or Premphase, for personal consumption between  
26 January 1995 and January 2003, and were exposed to a representation from Wyeth, or  
27 health care providers, or read in literature in which Wyeth advertised or provided to  
28 third parties to be disseminated under its brand or the third parties' brand, that  
Premarin, Prempro, and/or Premphase lowered cardiovascular, Alzheimers and/or  
dementia risk, or did not increase breast cancer risk, and do not seek personal injury  
damages resulting therefrom.

1 On September 10, 2012, defendants filed a motion for summary judgment, a motion to exclude  
2 testimony, and a motion for decertification, which the parties fully briefed. See Docs. # 206, 208, 209,  
3 220, 223, 224, 232-234, 266, 267, 270-73. Following a hearing on the motions, the Court denied  
4 defendants' motions as moot, without prejudice, because completion of discovery raised various  
5 disputed issues, thus prompting the Court to invite the parties to submit supplemental briefs addressing  
6 modification of the class definition. See Doc. # 274. The parties filed briefs in response to the Court's  
7 invitation. See Docs. # 278, 279, 280, 281. The Court now addresses the parties' arguments in their  
8 supplemental briefs.

## 9 DISCUSSION

### 10 **1. Legal Standard**

11 Whether to grant class certification is within the discretion of a court. Montgomery v.  
12 Rumsfeld, 572 F.2d 250, 255 (9th Cir. 1978). A cause of action may proceed as a class action if a  
13 plaintiff satisfies the threshold requirements of Rule 23(a) of the FRCP: numerosity, commonality,  
14 typicality, and adequacy of representation. See Fed.R.Civ.P. 23(a); Mazza v. Am. Honda Motor Co.,  
15 666 F.3d 581, 588 (9th Cir. 2012).

16 Courts have also implied an additional requirement under Rule 23(a): ascertainability. See  
17 Herskowitz v. Apple, Inc., No. 12-CV-02131-LHK, 2014 WL 3919900, at \*4 (N.D. Cal. Aug. 7,  
18 2014). A class is ascertainable if it is administratively feasible to determine whether a particular  
19 individual is a class member with a potential right to recover. See Parkinson v. Hyundai Motor Am.,  
20 258 F.R.D. 580, 593-94 (C.D. Cal. 2008); Wolph v. Acer Am. Cor., No. C 09-01314 JSW, 2012 WL  
21 993531, at \*1 (N.D. Cal. Mar. 23, 2012). However, ascertainability does not require "every potential  
22 class member... [to] be identified at the commencement of the action." O'Connor v. Boeing N. Am.,  
23 Inc., 184 F.R.D. 311, 319 (C.D. Cal. 1998); see also Knutson v. Schwan's Home Serv., Inc., No. 3:12-  
24 CV-0964-GPC-DHB, 2013 WL 3746118, at \*5 (S.D. Cal. Jul. 15, 2013) ("Class certification hinges  
25 on whether the identity of the putative class members can be objectively ascertained; the ascertaining  
26 of their actual identities is not required.").

27 Moreover, a plaintiff seeking class certification must meet one of the three criteria listed in  
28 Rule 23(b). See Fed.R.Civ.P. 23(b)(1)-(3); Wal-Mart Stores, Inc. v. Dukes, 131 S.Ct. 2541, 2548-48

1 (2011). Courts certify a Rule 23(b)(1) class when a party shows there would be a risk of substantial  
2 prejudice or inconsistent adjudications if separate adjudications were held. Fed.R.Civ.P. 23(b)(1).  
3 Courts certify a Rule 23(b)(2) class if “the party opposing the class has acted or refused to act on  
4 grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory  
5 relief is appropriate respecting the class as a whole.” Fed.R.Civ.P. 23(b)(2). Lastly, courts certify a  
6 Rule 23(b)(3) class if “questions of law or fact common to class members predominate over any  
7 questions affecting only individual members, and that a class action is superior to other available  
8 methods for fairly and efficiently adjudicating the controversy.” Fed.R.Civ.P. 23(b)(3).

9 Courts should certify a class only if they are “satisfied, after a rigorous analysis,” that Rule 23  
10 prerequisites have been met. Marlo v. U.P.S., 639 F.3d 942, 947 (9th Cir. 2011) (citation omitted).  
11 “Rigorous analysis” frequently entails “some overlap with the merits of... plaintiff’s underlying  
12 claim,” which “cannot be helped.” Wal-Mart, 131 S.Ct. at 2551. However, Rule 23 “does not  
13 authorize a preliminary inquiry into the merits of the suit for purposes other than determining whether  
14 certification [is] proper.” Ellis v. Costco Wholesale Corp., 657 F.3d 970, 983 n.8 (9th Cir. 2011)  
15 (citation omitted). In the event courts find that Rule 23’s prerequisites have been satisfied, then  
16 certification should be granted. See Gen. Tel. Co. of Sw. v. Falcon, 457 U.S. 147, 161 (1982).  
17 However, courts retain discretion to revisit class certification throughout the legal proceedings, and  
18 may rescind, modify, or amend the class definition in light of subsequent developments in the  
19 litigation. See Fed. R. Civ. Proc. 23(c)(1)(C); Falcon, 457 U.S. at 160; Dukes v. Wal-Mart, Inc., 509  
20 F.3d 1168, 1176 (9th Cir. 2007).

## 21 **2. Analysis<sup>1</sup>**

22 Defendants contend the class is not ascertainable and no common issues of fact or law  
23 predominate, thereby requiring decertification of the class. See Doc. # 278; Doc. # 281. Plaintiff  
24 opposes defendants’ assertions, and asks the Court to modify the current class definition to account  
25 for recent developments in this action. See Doc. # 279; Doc. # 280.

### 26 **a. Ascertainability**

27 Defendants contend the class should be decertified because it is not ascertainable under Carrera

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28 <sup>1</sup> The Court will not restate all of its previous findings and limits its discussion to only those issues and arguments presented by the parties in their supplemental briefs.

1 v. Bayer Corp., 727 F.3d 300, 307-08 (3d Cir. 2013). See Doc. # 278 at 5, 7, 14. Defendants explain  
2 that, in Carrera, the Third Circuit reversed a certification for consumer fraud claims because the court  
3 found there was insufficient evidence to show that retailer records could be used to identify class  
4 members. Id. According to defendants, the Third Circuit found that: (1) the need for individualized  
5 fact finding made it impossible for class members to accurately identify whether they were part of the  
6 class for purposes of opting out; (2) it was unfair to class action defendants, who possess a “due  
7 process right” to challenge class membership, to ensure all class members were similarly situated and  
8 could prove their claims through class-wide evidence; and (3) the need for individualized  
9 determinations regarding class membership undermined the class action’s basic function of “litigating  
10 claims in an economical fashion.” Id. at 7-8.

11 Like Carrera, defendants contend that these “three... problems plague” the class definition in  
12 this case. See Doc. # 278 at 8. In support, defendants first contend that identifying the HRT users  
13 who were exposed to defendants’ representations regarding the drugs in relation to risks of breast  
14 cancer, heart disease, or Alzheimer’s disease would “require” an examination of “what” each HRT  
15 user “saw or heard” about the drugs, and a determination of whether “those statements constitute  
16 claims about the drugs’ effect on the relevant conditions.” Id. at 8. Defendants next contend that,  
17 contrary to plaintiff’s earlier submissions on the issue, discovery has revealed that existing documents,  
18 such as pharmacy/medical records, sales call notes, and advertising records, cannot establish which  
19 HRT users were actually exposed to defendants’ representations. Id. at 9-10. Given such, potential  
20 class members would be unable to establish class membership, thereby forcing the Court to conduct  
21 “countless individualized mini-trials” to examine statements and documents, and to appropriately  
22 identify class members, which undermines any efficiency afforded by a class action. Id. at 8-10.  
23 Defendants further submit that if the Court “simply assum[es]” all HRT users were exposed to  
24 misrepresentations about the drugs or relies on “self-serving affidavits” to establish class membership,  
25 without “further indicia of reliability,” the Court would violate defendants’ due process right to “test  
26 the reliability of the evidence submitted to prove class membership.” Id. at 6, 8-9 (citing Carrera, 727  
27 F.3d at 307; Marcus v. BMW of N. Am., LLC, 687 F.3d 583, 592-93 (3d Cir. 2012)).

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1 Plaintiff, in response, argues the class is objectively ascertainable and defendants' reliance on  
2 Carrera is misplaced. See Doc. # 280 at 7-8. Plaintiff explains that, in Carrera, the Third Circuit faced  
3 the ascertainability issue of whether each class member purchased defendant's product in Florida, with  
4 the court finding no reliable or administratively feasible way to make this determination due to the  
5 absence of records identifying persons who purchased defendant's product during the class period.  
6 Id. at 8-10. In other words, per plaintiff, the Third Circuit's holding in Carrera was based on the lack  
7 of objective evidence establishing which individuals did (or did not) "purchase" defendant's product  
8 and not, as defendants argue, the lack of objective evidence establishing who was (or was not)  
9 "exposed" to defendant's representations. Id. at 10. Plaintiff also points out that the Third Circuit did  
10 not foreclose reliance on retail records as an acceptable method of proving class membership. Id. at  
11 9. Plaintiff further points out that defendants erroneously rely on Marcus, which purportedly "had  
12 nothing to do with individualized proof of exposure" to defendant's representations, but involved the  
13 "lack of proof-of-purchase (and proof-of-replacement) records" for defendant's products. Id. at 11.  
14 Plaintiff then points out that defendants "completely ignore[...]" this Court's prior holding on the  
15 ascertainability issue requiring each individual to produce documentation establishing class  
16 membership and to demonstrate exposure to defendants' representations, with a view to allowing  
17 defendants the opportunity to challenge an individual's membership. Id. at 4-5, 10-11 (citing Doc.  
18 # 122). Plaintiff adds that defendants mistakenly assert the individual class members are required to  
19 produce additional evidence, such as advertising records or sales call notes, to establish class  
20 membership when this Court only referred to such materials in the context of defendants "having the  
21 ability to verify... individual answers using [defendants'] own records." Id. at 5 (citing Doc. # 122).  
22 Relatedly, per plaintiff, defendants err in asserting that each class member must individually verify  
23 membership "now" rather than "during post-trial proceedings," especially since this is not required  
24 by existing California law. Id. at 6. Plaintiff therefore submits that this Court was correct in finding  
25 the class ascertainable and identifiable "without the need for extensive, individualized fact-finding or  
26 mini-trials." Id. at 10-11.

27 This Court declines to apply Carrera and notes that while Carrera may be the law in the Third  
28 Circuit, it is not the law of this circuit. See In re ConAgra Foods, Inc., 302 F.R.D. 537, 566 (C.D. Cal.

1 2014) (“It appears that pursuant to Carrera in any case where the consumer does not have a verifiable  
2 record of its purchase, such as a receipt, and the manufacturer or seller does not keep a record of  
3 buyers, Carrera prohibits certification of a class. While this may now be the law in the Third Circuit,  
4 it is not currently the law in the Ninth Circuit.”) (citing McCrary v. Elations Co., LLC, No. EDCV 13-  
5 00242 JGB OP, 2014 WL 1779243, at \*8 (C.D. Cal. Jan. 13, 2014)). Under the law of this circuit, it  
6 is enough that the class definition describes “a set of common characteristics sufficient to allow” an  
7 individual to determine whether she is a class member with a potential right to recover. Id. A class  
8 definition describing the allegedly offending product and eligible dates of purchase, as here, is  
9 “sufficient.” See id. To the extent defendants may have individualized defenses, defendants are free  
10 to employ those defenses against each claimant. See Johns v. Bayer Corp., 280 F.R.D. 551, 560 (S.D.  
11 Cal. 2012).

12 Notwithstanding, defendants contend that identifying HRT users who were exposed to  
13 defendants’ representations would require “countless individualized mini-trials,” thereby undermining  
14 any efficiency afforded by a class action. However, there is no such concern in this case where  
15 plaintiff has asserted, and this Court has found, that defendants’ widespread advertising campaign  
16 promoted the alleged representations. Plaintiff has further asserted that there are only three products  
17 at issue in this case, all purporting to treat the same symptoms and to offer the same health benefits,  
18 with the product’s packaging containing defendants’ representations. Moreover, defendants’ senior  
19 executives acknowledged that all information contained in breast cancer risk warnings, disseminated  
20 prior to 2002, applied to all estrogen products, i.e., Premarin, and all estrogen and progestin  
21 combination products, i.e., Prempro and Premphase.<sup>2</sup> See Doc. # 224-10 at 13 (¶ 29). Consequently,  
22 this Court need not “simply assum[e]” that class members were exposed to defendants’ representations  
23 regarding the drugs.

24 Defendants also contend that discovery has revealed the existing documents—such as  
25 pharmacy/medical records, sales call notes, and advertising records—cannot fully establish which HRT  
26 users were actually exposed to defendants’ representations. However, as plaintiff rightly points out,  
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28 <sup>2</sup> The Court notes that defendants have acknowledged the Premphase labels and product inserts were consistent with the Prempro labels and product inserts throughout the class period. See Doc. # 281 at 7, n. 2.



1 this Court referred to such materials in the context of defendants, not individual class members, using  
2 such records to the extent possible to verify individual's claims of class membership.

3 Defendants then contend that if the Court relies on affidavits to establish class members'  
4 exposure to the representations, this Court would violate defendants' due process right to "test the  
5 reliability of the evidence submitted to prove class membership." However, defendants have no due  
6 process interest in the question of class membership because: (1) any liability is determined in the  
7 aggregate, with total sales measuring damages regardless of class size, and defendants have no claim  
8 to residual damages; (2) even assuming fraudulent or inaccurate claims result in a pro rata reduction  
9 of **class members'** (not defendants') relief, no case law suggests such dilution would undermine this  
10 Court's ability to issue a final judgment binding all class members; and (3) should manageability  
11 problems arise during the damages phase, this Court retains the flexibility to address such problems  
12 as they arise, including the ability to decertify. See Forcellati v. Hyland's, Inc., No. CV 12-1983-  
13 GHK MRWX, 2014 WL 1410264, at \*6-7 (C.D. Cal. Apr. 9, 2014).

14 Further, courts in this circuit have found proposed classes ascertainable even when the **only**  
15 **way** to determine class membership is with self-identification through affidavits. See e.g., Ries v.  
16 AriZona Beverages LLC, 287 F.R.D. 523, 535 (N.D. Cal. 2012). Defendants have the option to  
17 respond to such affidavits by, among others, testing an individual's claim that she is a class member  
18 through a comparison of information regarding that individual's purchase with defendants' retail  
19 information during the class period, along with other similar information. See Galvan v. KDI  
20 Distribution, Inc., SACV 08-0999-JVS (ANx), 2011 WL 5116585, \*4 (C.D. Cal. Oct. 25, 2011).

21 Consequently defendants fail to present any law or arguments establishing that an inability to  
22 absolutely confirm class members' identities would independently bar class certification in this circuit.  
23 See O'Connor, 184 F.R.D. at 319 (ascertainability does not require "every potential class member...  
24 [to] be identified at the commencement of the action."). Indeed, "[i]f class actions could be defeated  
25 because membership was difficult to ascertain at the class certification stage, there would be no such  
26 thing as a consumer class action." Thurston v. Bear Naked, Inc., No. 3:11-CV-02890-H BGS, 2013  
27 WL 5664985, at \*3 (S.D. Cal. Jul. 30, 2013) (citing Ries, 287 F.R.D. at 536). Accordingly, the Court  
28 finds that the current class is sufficiently ascertainable.

1           **b.       Predominance**

2           Plaintiff seeks to remove the “exposure criteria” for class membership from the existing class  
3 definition,<sup>3</sup> and proposes the following modified definition:

4           All California consumers who purchased Wyeth’s Hormone Replacement Therapy  
5 products, Premarin, Prempro, and/or Premphase, for personal consumption between  
6 January 1995 and January 2003, and who do not seek personal injury damages  
7 resulting therefrom.

8           See Doc. # 279 at 3.

9           Plaintiff asserts that this Court included the exposure criteria “out of an abundance of caution,”  
10 pursuant to McAdams v. Monier, Inc., 182 Cal. App. 4th 174 (2010),<sup>4</sup> to ensure: (1) the class was  
11 sufficiently cohesive to warrant adjudication by representation, and (2) all class members were  
12 exposed to defendants’ unfair practices. See Doc. # 279 at 6-7 (citing Doc. # 108). According to  
13 plaintiff, however, the Court can still achieve these goals without adding an exposure criteria to the  
14 class definition. Id. at 7. In support, plaintiff argues that unlike McAdams, in which the class  
15 definition properly contained exposure criteria to account for the different sources from which  
16 customers purchased defendant’s roof tiles, “every” California woman in this case who purchased  
17 HRT drugs received a product label that “came solely” from defendants, with each label containing  
18 “misstatements... and omissions... about breast cancer risks.”<sup>5</sup> See Doc. # 279 at 8 (citing, among  
19 others, Kwikset Corp. v. Superior Court, 51 Cal. 4th 310 (2011) (label misrepresentations satisfy the  
20 standing requirement for class representatives)). Plaintiff also argues that defendants were the “sole  
21 source” of “Dear Doctor letters” sent to “every” prescribing physician in California, with the letters  
22 initially denying breast cancer risks from HRT use and, later, downplaying these risks once articles

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23           <sup>3</sup> The existing class definition is as follows, with the exposure criteria in bold: All California consumers who  
24 purchased Wyeth’s Hormone Replacement Therapy products, Premarin, Prempro, and/or Premphase, for personal  
25 consumption between January 1995 and January 2003, **and were exposed to a representation from Wyeth, or health  
26 care providers, or read in literature in which Wyeth advertised or provided to third parties to be disseminated  
27 under its brand or the third parties’ brand, that Premarin, Prempro, and/or Premphase lowered cardiovascular,  
28 Alzheimers and/or dementia risk, or did not increase breast cancer risk**, and do not seek personal injury damages  
resulting therefrom.

<sup>4</sup> In McAdams, the California Court of Appeal, Third District, added exposure criteria to the class definition and held that common issues of nondisclosure of material facts by defendant predominated over issues regarding what defendant and its sales agents may have affirmatively represented to purchasers of defendant’s product. 182 Cal. App. 4th at 174.

<sup>5</sup> Plaintiff points out that defendants concede every user who purchased their HRT products received a product label. See Doc. # 279 at 8 (citing Doc. # 233 at 4).

1 were published on the subject. Id. at 10. Plaintiff then points out that although the labels and letters  
 2 were “only” two components of defendants’ “systematic, standardized, and broadly disseminated  
 3 advertising campaign,” both components show that HRT purchasers and prescribing physicians were  
 4 “uniformly” exposed to defendants’ “misrepresentations and omissions” during the class period,  
 5 thereby distinguishing the facts of this case from McAdams. Id. at 11.

6 In further support, plaintiff points to decisions by the Ninth Circuit and California district  
 7 courts holding that when defendants’ representations are “material” and disseminated through “a  
 8 massive Tobacco II-style advertising campaign,”<sup>6</sup> it is not necessary for the class definition to include  
 9 exposure criteria. See Doc. # 280 at 14; Doc. # 279 at 12-14 (citing Mazza,<sup>7</sup> Stearns v. Ticketmaster,  
 10 655 F.3d 1013, 1022 (9th Cir. 2011),<sup>8</sup> Johnson v. General Mills, Inc., 276 F.R.D. 519, 522 (C.D. Cal.  
 11 2011);<sup>9</sup> In re Brazilian Blowout Litig., No. CV 10-8452-JFW MANX, 2011 U.S. Dist. Lexis 40158  
 12 (C.D. Cal. Apr. 12, 2011)<sup>10</sup>). Because this Court already found that defendants launched a massive  
 13 Tobacco II-style advertising campaign to inform users and prescribing physicians about the purported  
 14 benefits of HRT drugs, plaintiff argues that, pursuant to Mazza, this Court should remove the existing  
 15 class definition’s exposure criteria. See Doc. # 280 at 14; Doc. # 279 at 12-14. Plaintiff additionally  
 16 submits that modifying the class definition would not trigger new expert discovery or delay trial in  
 17 this case. See Doc. # 279 at 15. Finally, plaintiff submits that the cases cited by defendants do not  
 18 involve Tobacco II-style advertising campaigns and, thus, are inapplicable to the instant case. See  
 19 Doc. # 280 at 14-16.

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21 \_\_\_\_\_  
 22 <sup>6</sup> The complaint, in In re Tobacco II Cases, 46 Cal. 4th 298 (2009), alleged that the tobacco industry defendants  
 23 violated the UCL by conducting a decades-long campaign of deceptive advertising and misleading statements regarding  
 the addictive nature of nicotine and the relationship between tobacco use and disease.

24 <sup>7</sup> In Mazza, 666 F.3d 581, the Ninth Circuit vacated the district court’s certification order because many class  
 25 members were likely never exposed to defendant’s representations, especially in the absence of a massive Tobacco II-style  
 advertising campaign.

26 <sup>8</sup> The Ninth Circuit, in Stearns, held that causation can be established on a class-wide basis by showing that a  
 defendant made “material” representations to the entire class. 655 F.3d at 1022.

27 <sup>9</sup> The district court, in Johnson, noted that “California law permits a court to try, and a class to establish  
 28 causation/reliance as a common issue by inference.” 276 F.R.D. at 522 (citing Stearns, 655 F.3d at 1022).

<sup>10</sup> In Brazilian Blowout, the district court found that although plaintiffs must prove actual reliance for their  
 misrepresentation claims, reliance may be presumed class-wide if defendant’s misrepresentations are “material.” 2011 U.S.  
 Dist. Lexis 40158, at \*20, 24-26.

1 Defendants, in opposition, contend that plaintiff's proposed class definition is "not viable"  
2 because the Court "already considered and correctly rejected" that definition, and required plaintiff  
3 to demonstrate class-wide exposure to defendants' representations in order to satisfy Rule 23(b)(3)'s  
4 "predominance" requirement. See Doc. # 278 at 6, 11. Defendants add that plaintiff's reliance on  
5 cases like Mazza to resurrect plaintiff's old argument—i.e., that class-wide exposure exists because  
6 class members were purportedly exposed to defendants' massive advertising campaign—is "unhelpful"  
7 to plaintiff's cause because this argument was already rejected by the Court. See Doc. # 281 at 17.  
8 Defendants next turn to case law in which class certification of CLRA and UCL claims were denied  
9 because plaintiff, like those plaintiffs in the cases cited, fails to provide evidence demonstrating class-  
10 wide exposure to defendants' representations, and fails to show that class members relied on  
11 defendants' representations to make purchasing decisions. Id. at 12-13 (citing Minkler v. Kramer  
12 Laboratories, Inc., 2013 U.S. Dist. LEXIS 90651 (C.D. Cal. Mar. 1, 2013); Davis-Miller v. Auto. Club  
13 of S. Cal., 201 Cal. App. 4th 106 (2011); Faulk v. Sears Roebuck & Co., No. 11-CV-02159 YGR,  
14 2013 U.S. Dist. LEXIS 57430 (N.D. Cal. Apr. 19, 2013)).

15 To illustrate, defendants contend that plaintiff's reliance on drug labels fails to establish class-  
16 wide exposure because the labels "varied" by product and "changed throughout the class period." See  
17 Doc. # 281 at 7-9. Defendants also contend that plaintiff's reliance on two "Dear Doctor letters" fails  
18 to demonstrate class-wide exposure because the class period spans eight years (1995-2003), making  
19 it "inevitable" that a "significant number" of doctors prescribing drugs later in the class period would  
20 not have received the letters and would not have been in practice in 1995. Id. at 9-10. Defendants add  
21 that one of the letters was not even sent until February 2000, "five full years after the class period  
22 began." Id. at 9. Defendants then contend that even if the same labels and letters were sent to every  
23 HRT user's doctor, that doctor's "mere receipt" does not equal "exposure." Id. at 10 (citing, among  
24 others, Campion v. Old Republic Home Prot. Co., 272 F.R.D. 517 (S.D. Cal. 2011)).<sup>11</sup> According to  
25 defendants, moreover, plaintiff improperly relies on advertisements that contain different information,  
26 risks, and benefits, and improperly relies on sales call notes that indicate, among others, "different

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28 <sup>11</sup> In Campion, the district court denied certification due to the varying ways proposed class members acquired their home warranty plans, reasoning that members "may have seen some, all or none" of defendant's representations prior to purchase. 272 F.R.D. at 517.

1 discussions” between “different sales representatives... [and] doctors,” with some notes even failing  
2 to document any discussions. See Doc. # 278 at 13-14; Doc. # 281 at 15. But even if it is proper for  
3 the Court to presume all class members were universally exposed to defendants’ representations,  
4 defendants contend class certification would still be inappropriate because defendants are entitled to  
5 present “substantial individualized evidence” contained in the record to rebut that presumption. See  
6 Doc. # 281 at 18. Defendants further contend that plaintiff improperly uses one theory to obtain class  
7 certification and a different theory to prove her claims at trial. See Doc. # 281 at 11. Defendants  
8 explain that while plaintiff relies only on drug labels and Dear Doctor letters for class certification,  
9 plaintiff plans to introduce other types of evidence during trial,<sup>12</sup> which violates the U.S. Supreme  
10 Court’s ruling that “the theory advanced to justify class certification defines and limits what will be  
11 relevant at trial.” Id. at 12 (citing Comcast Corp. v. Behrend, 133 S. Ct. 1426 (2013)).<sup>13</sup> Defendants  
12 concede that while the materials cited by plaintiff go to liability rather than damages, plaintiff’s  
13 reliance on such “individualized evidence” would narrow the scope of trial “considerably” and render  
14 irrelevant the discovery plaintiff has provided to defendants in this case. Id. at 13. Thus, defendants  
15 submit that no viable class definition exists that would satisfy Rule 23(b)(3)’s requirement of  
16 predominance, and ask the Court to decertify the class. See Doc. # 278 at 14; Doc. # 281 at 19.

17 The central inquiry under Rule 23(b)(3) is whether the proposed class is “sufficiently  
18 cohesive” to permit “adjudication by representation.” Amchem Products, Inc. v. Windsor, 521 U.S.  
19 591, 594 (1997). If common questions “present a significant aspect of the case and they can be  
20 resolved for all members of the class in a single adjudication,” then a “clear justification” exists for  
21 “handling the dispute on a representative rather than on an individual basis,” and the predominance  
22 test is satisfied. Hanlon v. Chrysler Corp., 150 F.3d 1011, 1022 (9th Cir. 1998). However, “if the  
23 main issues in a case require the separate adjudication of each class member’s individual claim or  
24 defense, a Rule 23(b)(3) action would be inappropriate.” Zinser v. Accufix Research Institute, Inc.,

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26 <sup>12</sup> Defendants point to plaintiff’s opening brief in which plaintiff notes the “prodigious” evidence of brochures,  
27 tear sheets, advertising, magazines, articles, sales call notes, and programs establishing defendants’ “systematic,  
standardized and broadly disseminated advertising campaign.” See Doc. # 281 at 12 (citing Doc. # 279 at 11).

28 <sup>13</sup> In Comcast, the U.S. Supreme Court reversed a grant of class certification because questions of individual  
damage calculations overwhelmed questions common to the class. 133 S. Ct. at 1426. The Court’s holding, uncontested  
by the parties, required damages to be measurable based on a common methodology applicable to the entire class in  
antitrust cases. Id.

1 253 F.3d 1180, 1190 (9th Cir. 2001) (citation omitted).

2 This Court disagrees with defendants' assertion that plaintiff fails to satisfy the  
3 "predominance" requirement. As a preliminary matter, the central issue raised in this action is the  
4 allegedly overriding, material misrepresentation that defendants' HRT products lower a woman's risk  
5 of cardiovascular disease, dementia, and Alzheimers disease, without increasing breast cancer risk.  
6 Plaintiff has alleged and submitted evidence showing that this misrepresentation was communicated  
7 by the drugs' packaging and by doctors under the influence of, among others, defendants' "Dear  
8 Doctor" letters and sales representatives. Plaintiff has also alleged and submitted evidence showing  
9 that this misrepresentation was further amplified by defendants' massive marketing campaign through,  
10 among others, television, radio, newspaper, and magazine advertisements. Plaintiff has additionally  
11 alleged and submitted evidence showing that, as part of defendants' massive marketing campaign,  
12 defendants hired, among others, physicians to author or sign off on articles generally dispelling  
13 negative perceptions about defendants' HRT drugs and specifically refuting medical studies finding  
14 increased health risks associated with HRT use. At this stage of the lawsuit, plaintiff has made a  
15 sufficient showing that the issues of whether defendants' representation was material, and whether  
16 defendants' representation would have deceived reasonable consumers, **can** be litigated on a class-  
17 wide basis.

18 The Court also disagrees with defendants' assertion that common issues do not predominate  
19 because: (1) HRT product labels "varied" and "changed"; (2) the content of advertisements and sales  
20 call notes "varied"; (3) the dispatch date of "Dear Doctor" letters varied; and (4) prescribing doctors'  
21 exposure to the "Dear Doctor" letters likely varied. The Court finds that the allegedly false and  
22 deceptive packaging and marketing of the HRT drugs need not be absolutely uniform or "consist of...  
23 specifically-worded false statement[s] repeated to each and every [member] of the plaintiff class."  
24 In re First Alliance Mortg. Co., 471 F.3d 977, 992 (9th Cir. 2013). Indeed, "[t]he class action  
25 mechanism would be impotent if a defendant could escape much of his potential liability for fraud by  
26 simply altering the wording or format of his misrepresentations across the class of victims." Id.

27 This Court also finds that plaintiff has presented substantial evidence showing that HRT users  
28 were exposed to defendants' overriding and material misrepresentations of the HRT drugs. For

1 example, plaintiff has presented evidence showing that the FDA, through correspondences and various  
2 meetings, admonished defendants for misrepresenting their products, with the FDA ultimately  
3 directing defendants to cease all off-label drug promotions. *Id.* at 10 (¶ 25-26). Defendants, in  
4 response, published an insert addressing the risks of breast cancer and benefits of HRT use in the  
5 annual Physician’s Desk Reference (“PDR”). *Id.* at 12-13 (¶ 28). In its insert, defendants modified  
6 the FDA’s requested language addressing breast cancer risk by including additional language  
7 nullifying these risks, with the insert remaining unchanged from 1995 to 2002. *Id.* Defendants’ sales  
8 executives have also acknowledged that their sales representatives were trained in a standardized  
9 manner using a series of nationwide manuals and training programs to communicate the following  
10 messages: (1) that Prempro was safe for long term use; (2) that doctors should prescribe combination  
11 hormone therapy to all menopausal women even though only a minority of women suffered from  
12 significant menopausal symptoms to justify hormone treatment; (3) that Premarin and Prempro had  
13 equivalent risk/safety profiles; and (4) that Prempro did not have any significant breast cancer risks  
14 and could reduce the risk of contracting breast cancer. *Id.* at 11 (¶ 26).

15 In addition, contrary to defendants’ assertion that limiting information was provided to health  
16 care professionals, plaintiff has presented evidence showing that prescribing doctors, along with the  
17 obstetrics and gynecology community at-large, were bombarded with HRT information during the  
18 class period, and received “Dear Doctor” letters that promoted defendants’ HRT products in 1989,  
19 1995, 1998, 2000 and 2001.<sup>14</sup> *See* Doc. # 224-10 at 27-29. Indeed, from 1994 onwards, defendants  
20 strategically countered research and publications that found HRT use significantly increased breast  
21 cancer risk and related deaths. In response to one such publication in 1995, defendants circulated  
22 “Dear Doctor” letters containing language drafted by defendants’ marketing group that downplayed  
23 the research, and initiated a strategy to create “Letters to the Editor” and “Op-ed” submissions that  
24 would be presented by paid “authors.” *Id.* at 14. In 1996, the WHI’s ten-year study, sponsored by the  
25 NIH, revealed that Prempro increased, among others, breast cancer risk, to which defendants  
26 responded by adopting a “Dismiss/Distract” policy to divert attention away from this finding by

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28 <sup>14</sup> The Court notes that the 2001 letter was sent to all members of the American Congress of Obstetricians and Gynecologists. *See* Doc. # 224-10 at 29.

1 forming a “Breast Cancer Working Group” that would counter the study, and instructing defendants’  
2 public relations group to keep research results confidential and to refrain from discussing these results  
3 outside the group. Id. at 15. In 1997, after an international research group published a review  
4 showing an increased risk of breast cancer with Prempro use, defendants responded by launching a  
5 \$12 million “Myths and Misperceptions” campaign to counteract the negative publicity, and by  
6 directing their sales force to refrain from raising the issue and to focus sales presentations on HRT  
7 benefits. Id. at 16. In 1998, after another article found that “postmenopausal hormones cause breast  
8 cancer,” defendants funded a newsletter intended for obstetricians and gynecologists entitled, “Ob Gyn  
9 Rounds,” which served as an extension of the “Myths and Misperceptions” campaign. Id. Relatedly,  
10 defendants sponsored and influenced the content of reference materials and textbooks for obstetricians  
11 and gynecologists, and funded a textbook program whereby defendants purchased “reference texts”  
12 and circulated them to internal medicine and family practice residents. Id. at 34. In 1999, another  
13 article concluded that a review of existing literature revealed that almost all patients treated with  
14 Premarin had an increase in breast cancer. Id. at 16-17. Defendants decided not to respond to this  
15 article. Id. Then in early 2000, two articles were published that found increased breast cancer risk  
16 with use of combination hormone therapy. Id. at 17. Defendants questioned these findings in “Dear  
17 Doctor” letters sent to prescribing physicians. Id. These letters included breast cancer data charts that  
18 contained “misleading” information. Id. Following these publications, the FDA again asked  
19 defendants to update their breast cancer warnings, but defendants failed to do so. Id. at 24. Then in  
20 2002, the NIH discontinued the WHI clinical trial involving trial participants due to an increased risk  
21 of invasive breast cancer, increased cognitive decline, and no heart benefits. Id. at 25. WHI’s lead  
22 investigator concluded that Prempro use generated an additional 200,000 breast cancers in the United  
23 States. Id.

24         Based on the evidence provided, the Court finds that HRT users and prescribing physicians  
25 were systematically exposed to defendants’ material misrepresentations during the class period  
26 through defendants’ massive advertising campaign, which included, among others: (1) sales calls  
27 designed to mislead and/or omit crucial health risk information; (2) funding of various media  
28 advertisements and press releases; (3) funding and publication of newsletters, brochures, medical



1 studies, and other written media that downplayed, among others, breast cancer risks and promoted  
2 fictitious health benefits; (4) funding and creation of physician and patient outreach and informational  
3 programs; and (5) funding, publication, and dissemination of “Dear Doctor” letters. The Court also  
4 agrees with plaintiff that every California woman who purchased HRT drugs during the class period  
5 was exposed to defendants’ material misrepresentations through defendants’ drug labels originating  
6 from defendants.<sup>15</sup>

7 Contrary to defendants’ assertion, moreover, individualized proof of deception and reliance  
8 are not necessary under California law for plaintiff to prevail on class claims. See McAdams, 182 Cal.  
9 App. 4th at 174, 191-92; see also In re Steroid Hormone Prod. Cases, 181 Cal. App. 4th 145, 157 (2d  
10 Dist. 2010). In California, it is enough for a court to reasonably assume that no rational class member  
11 would have purchased the product had the individual known of the alleged misrepresentation. See  
12 Negrete v. Allianz Life Ins. Co. of N. Am., 238 F.R.D. 482, 491-92 (C.D. Cal. 2006). As already  
13 discussed, the common issue that predominates in this case is whether defendants’ packaging and  
14 marketing communicated a persistent and material message that HRT drugs lower a woman’s risk of  
15 cardiovascular disease, dementia, and Alzheimers disease, without increasing breast cancer risk. At  
16 minimum, everyone who purchased HRT drugs would have been exposed to defendants’  
17 representations that appeared on every package during the class period, rendering defendants’ reliance  
18 on Campion<sup>16</sup> as misplaced for the proposition that class members may have seen, at worst, **none** of  
19 defendant’s representations prior to purchase.

20 Importantly, this Court has already found that defendants launched a massive Tobacco II-style  
21 advertising campaign to inform users and prescribing physicians about the purported benefits of HRT  
22 drugs.<sup>17</sup> Given their exposure to defendants’ advertising campaign, class members need not plead  
23 specific reliance on any individual misrepresentations. See Tobacco II, 46 Cal. 4th at 328 (Plaintiff

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24  
25 <sup>15</sup> The Court has considered and finds instructive a decision by the Supreme Court of Nevada, which also found  
26 the same product labels misleading. See Wyeth v. Rowatt, 244 P.3d 765, 780 (Nev. 2010). See also supra text  
accompanying note 5.

27 <sup>16</sup> See supra text accompanying note 11.

28 <sup>17</sup> The Court adopts by reference its discussion of defendants’ massive Tobacco II-style advertising campaign  
from its earlier decision. See Doc. # 108 at 18.

1 is “not required to necessarily plead and prove individualized reliance on specific misrepresentations  
2 or false statements where, as here, those misrepresentations and false statements were part of an  
3 extensive and long-term advertising campaign.”). Given defendants’ advertising campaign, moreover,  
4 it is fair to assume that almost all, if not all, class members had been exposed to defendants’  
5 purportedly false and misleading statements and, by extension, were likely deceived by these  
6 representations.

7 The Court further agrees with plaintiff that cases cited by defendants are inapposite to this  
8 case. Unlike this case, in Davis-Miller the court found that different class members were exposed to  
9 different information by different contractors who made different representations, and plaintiff failed  
10 to present evidence showing that advertising and marketing of the subject battery service program was  
11 seen by the entire class. 201 Cal. App. 106. In Faulk, plaintiff failed to identify advertisements or to  
12 establish that class members were exposed to, and relied upon, such advertisements in purchasing the  
13 product at issue. 2013 U.S. Dist. LEXIS 57430. In Minkler, the UCL and CLRA claims were never  
14 certified because plaintiff failed to show class members’ exposure to the alleged misrepresentation.  
15 2013 U.S. Dist. LEXIS 90651. In this case, by contrast, plaintiff has identified drug labels,  
16 advertisements, and marketing materials that comprised defendants’ massive marketing campaign.  
17 Plaintiff has also presented evidence establishing that HRT users were exposed to the same product  
18 misrepresentations through defendants’ massive marketing campaign on a class-wide basis. Plaintiff  
19 has additionally presented evidence showing that product representations were generated and/or  
20 overseen solely by defendants.

21 Meanwhile, this Court disagrees with defendants’ assertion that plaintiff, under Comcast,  
22 improperly uses one theory to obtain class certification and a different theory to prove damages at  
23 trial. Even assuming Comcast is applicable to mass tort actions in some way, it is merely dicta and  
24 does not bind this Court. See Comcast, 133 S.Ct. at 1436 (Ginsburg and Breyer, JJ., dissenting)  
25 (“[T]he decision should not be read to require, as a prerequisite to certification, that damages  
26 attributable to a class-wide injury be measurable on a class-wide basis.”). Nevertheless, Comcast does  
27 not dictate a contrary result even if applied to the instant case. Unlike the situation in Comcast, there  
28 is no possibility in this case that damages could be attributed to defendants’ acts that are **not**

1 challenged on a class-wide basis because all members of the current class attribute their damages to  
2 the HRT drugs. Defendants also wrongly assume it was the existence of multiple theories in Comcast  
3 that precluded class certification. Rather, it was plaintiffs' failure to base all of the damages sought  
4 on plaintiffs' **injury**, i.e., the antitrust impact. See Doyle v. Chrysler Grp. LLC, No. SACV 13-00620  
5 JVS, 2014 WL 7690155, at \*8 (C.D. Cal. (Oct. 9, 2014) ("The Seventh Circuit has explained... that  
6 a damages suit cannot be certified to proceed as a class action unless the damages sought are the result  
7 of the class-wide injury that the suit alleges."). In this case, by contrast, HRT users were injured by  
8 purchasing drugs that did not meet those qualities represented by defendants. To the extent damages  
9 would require an individual inquiry, the Ninth Circuit has held that "[t]he amount of damages is  
10 invariably an individual question and does not defeat class action treatment." Leyva v. Medline Indus.  
11 Inc., 716 F.3d 510, 514 (9th Cir. 2013) (citation omitted).

12 This Court further notes that the question of false advertising and deceptive marketing of  
13 defendants' HRT drugs and their purported health benefits is a common issue particularly well-suited  
14 to class-wide resolution because it will turn on complex evidence and expensive expert testimony.  
15 Litigating this issue in individual cases would not only be extraordinarily duplicative and wasteful,  
16 it would increase the likelihood that courts and juries reach inconsistent decisions. Thus, the Court  
17 concludes that the predominance requirement has been satisfied in this case.

18 Lastly, turning to the question of whether to modify the current class definition, the Court finds  
19 that a modification removing the exposure requirement is appropriate in light of the discussion above,  
20 which involves consideration of new evidence, pleadings, and arguments submitted by the parties after  
21 the Court entered its previous order (doc. # 108)<sup>18</sup> addressing defendants' massive marketing  
22 campaign. The Court finds that, unlike in McAdams,<sup>19</sup> in which class members received different  
23 product representations from four separate and independent sources, defendants here directed and  
24 exercised full control over the messages and representations made by all company personnel and third  
25 parties in promoting defendants' HRT drugs as part of defendants' massive advertising campaign.<sup>20</sup>

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27 <sup>18</sup> The Court's order, doc. # 108, was entered on the record on March 30, 2011.

28 <sup>19</sup> See supra text accompanying note 4.

<sup>20</sup> The Court's previous discussion and conclusions relating to the class definition's exposure requirement (doc. # 108) are amended as expressed herein.

1 Thus, the Court adopts plaintiff's suggested class definition. The certified class in this case now  
2 includes:

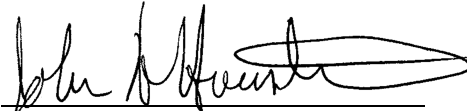
3 All California consumers who purchased Wyeth's Hormone Replacement Therapy  
4 products, Premarin, Prempro, and/or Premphase, for personal consumption between  
5 January 1995 and January 2003, and who do not seek personal injury damages  
6 resulting therefrom.

6 **CONCLUSION AND ORDER**

7 Accordingly, IT IS HEREBY ORDERED that:

- 8 1. Plaintiff satisfies the ascertainability and predominance requirements, and has met all  
9 other requirements for class certification;
- 10 2. Defendants' request to decertify the class is **DENIED**;
- 11 3. Plaintiff's request to modify the class definition is **GRANTED**; and
- 12 4. The class definition is **MODIFIED** as described herein.

13 Dated: October 7, 2015

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16 JOHN A. HOUSTON  
17 United States District Judge  
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