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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

DANIKA GISVOLD,

Plaintiff,

vs.

MERCK & CO., INC. *et al.*,

Defendants.

Case No. 14cv1371 DMS (JLB)

**ORDER GRANTING
MOTION TO DISMISS**

Pending before the Court in this putative consumer class action is Defendants’ Merck & Co., Inc., MSD Consumer Care Inc., and Merck Sharp & Dohme Corp.’s (collectively “Merck Defendants” or “Merck”) motion to dismiss the First Amended Complaint (“FAC”). Plaintiff Danika Gisvold filed an opposition and Defendants replied. The motion came on for hearing on November 4, 2014. James Patterson appeared on Plaintiff’s behalf; David Stanley appeared on behalf of Defendants. Upon consideration of the briefing and oral argument, and for the reasons set forth below, Defendants’ motion to dismiss is granted.

Plaintiff alleges the Merck Defendants are manufacturers, distributors and marketers of Coppertone over-the-counter (“OTC”) sunscreen products, including products labeled with Sun Protection Factor (“SPF”) 50 and above. (FAC ¶ 1.) Plaintiff claims she purchased Coppertone SPORT SPF 100+ sunscreen lotion at Wal-Mart for

1 a premium price (\$1.00 or more than the same size SPF 50 product) after “reading
2 [Merck’s] Coppertone SPORT SPF 100+ Sunscreen Lotion label.” (FAC ¶ 12.)

3 Plaintiff alleges that consumers have learned to associate higher SPF values with
4 greater sun protection; consumers assume a product with an SPF of 100+ provides twice
5 the protection against sunburn caused by ultraviolet B (“UVB”) of a sunscreen product
6 with an SPF of 50, when in fact products with SPF values of over 50 do not provide any
7 increase in clinical benefit over SPF 50 sunscreen products. (FAC ¶ 3.) Plaintiff
8 alleges that Merck’s SPF 55, 70+, 80 and 100+ representations on its sunscreen
9 products are therefore false, misleading, and reasonably likely to deceive the public.
10 (FAC ¶ 3.) Plaintiff filed this action alleging violations of the Unfair Competition Law,
11 Cal. Bus. & Prof. Code § 17200 *et seq.* (“UCL”) and the Consumer Legal Remedies
12 Act, Cal. Civ. Code § 1750 *et seq.* (“CLRA”), and breach of express warranty under
13 California common law. She seeks damages and injunctive relief for herself and a class
14 of similarly situated individuals. Specifically, Plaintiff requests an order that
15 Defendants charge the same price for SPF 50+ products as SPF 50 products, and/or that
16 they include “a disclaimer on the label or packaging that a SPF value above 50 does not
17 provide proportional clinical benefits.” (*Id.* at 10-11 & 16.) Plaintiff further seeks an
18 order requiring that Merck “engage in a corrective advertising campaign.” (FAC,
19 Prayer for Relief, ¶ E.) The Court has subject matter jurisdiction pursuant to 28 U.S.C.
20 §1332(d).

21 Defendants filed their motion to dismiss under Rule 12(b)(6), which tests the
22 sufficiency of the complaint. *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001).
23 Dismissal is warranted where the complaint lacks a cognizable legal theory. *Shroyer*
24 *v. New Cingular Wireless Serv., Inc.*, 622 F.3d 1035, 1041 (9th Cir. 2010) (internal
25 quotation marks and citation omitted). Alternatively, a complaint may be dismissed
26 where it presents a cognizable legal theory, yet fails to plead essential facts under that
27 theory. *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 534 (9th Cir. 1984); *see*
28 *also Shroyer*, 622 F.3d at 1041. In reviewing a Rule 12(b)(6) motion, the Court must

1 assume the truth of all factual allegations and construe them most favorably to the
2 nonmoving party. *Huynh v. Chase Manhattan Bank*, 465 F.3d 992, 997 (9th Cir. 2006).
3 However, legal conclusions need not be taken as true merely because they are couched
4 as factual allegations. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Similarly,
5 "conclusory allegations of law and unwarranted inferences are not sufficient to defeat
6 a motion to dismiss." *Pareto v. Fed. Deposit Ins. Corp.*, 139 F.3d 696, 699 (9th Cir.
7 1998).

8 Defendants argue Plaintiff's action is pre-empted by the Food, Drug, and
9 Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). "In pre-emption cases, the question
10 is whether state law is pre-empted by a federal statute, or in some instances, a federal
11 agency action." *Pom Wonderful LLC v. The Coca-Cola Co.*, ___ U.S. ___, 134 S.Ct.
12 2228, 2236 (2014). Although it is presumed that Congress does not intend to displace
13 state law,

14 State action may nonetheless be foreclosed by express language in a
15 congressional enactment, by implication from the depth and breadth of a
16 congressional scheme that occupies the legislative field, or by implication
because of a conflict with a congressional enactment.

17 *Holmes v. Merck & Co., Inc.*, 697 F.3d 1080, 1085 (9th Cir. 2012) (internal quotation
18 marks and citations omitted); *see also Arizona v. United States*, 567 U.S. ___, 132 S.Ct.
19 2492, 2500-01 (2012). "Regardless of the type of preemption involved – express, field,
20 or conflict – 'the purpose of Congress is the ultimate touchstone of pre-emption
21 analysis.'" *Gilstrap v. United Air Lines, Inc.*, 709 F.3d 995, 1003 (2013), quoting
22 *Cipollone v. Liggett Group., Inc.*, 505 U.S. 504, 516 (1992) (brackets omitted). The
23 "task is to 'identify the domain expressly pre-empted by that language.' That task must
24 'in the first instance focus on the plain wording of the clause, which necessarily
25 contains the best evidence of Congress' pre-emptive intent.' We may find preemption
26 only where it is the 'clear and manifest purpose of Congress.'" *Do Sung Uhm v.*
27 *Humana, Inc.*, 620 F.3d 1134, 1148 (9th Cir. 2010), quoting *Medtronic, Inc. v. Lohr*,

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1 518 U.S. 470, 484 (1996); *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)
2 & *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

3 The FDCA, which includes an express pre-emption statute, is unambiguous and
4 broad in scope:

5 no State ... may establish or continue in effect any requirement [¶] that
6 relates to regulation of [OTC drugs]; and [¶] that is different from or *in*
7 *addition to, or that is otherwise not identical with* a requirement under [the
8 FTCA].

9 21 U.S.C. § 379r (emphasis added).

10 The current regulations establish labeling requirements, provide for effectiveness
11 testing upon which the labeling relies, and identify false and misleading claims that
12 render a product misbranded. 76 Fed. Reg. 35620-21 (Jun. 17, 2011) (*Labeling and*
13 *Effectiveness Testing: Sunscreen Drug Products for Over-the-Counter Human Use*)
14 (“Final Rule”). The Final Rule requires compliance with the regulation’s labeling
15 requirements, and embodies the Food and Drug Administration’s (“FDA”) “current
16 determination on appropriate regulation on these aspects of sunscreens.” *Id.* at 35620
& 35621.

17 Significantly, the regulations promulgated by the Final Rule *mandate* that OTC
18 sunscreen labels state the SPF value resulting from the detailed testing procedure
19 described in the regulation. 21 C.F.R. § 201.327(a)(1) & (I) (describing testing
20 procedure to arrive at appropriate SPF values and providing labels “shall” state the SPF
21 value). Merck argues its labeling simply complies with the FDA’s mandate; it does no
22 more than state the SPF value. In her opposition, Plaintiff argues her claim is not that
23 SPF values above 50 are *per se* misleading, but that Merck “markets” its sunscreen
24 products in a way that misleads consumers into believing that SPF values above 50
25 provide proportionally superior sun protection. (Opp’n at 10, citing FAC ¶¶ 6, 18 &
26 22.) Plaintiff argues the SPF values (55-100+) placed on Merck’s sunscreen products,
27 combined with premium pricing – a dollar or more for SPF 100+ than the same size
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1 SPF 50 product – misleads consumers into believing they are purchasing proportionally
2 superior sun protection, when they are not. (FAC ¶¶ 6 & 18.)

3 The problem with Plaintiff’s argument, however, is that it expands the claim she
4 has actually alleged. The essence of Plaintiff’s claim is that “Merck’s SPF 55, 70+, 80
5 or 100+ representations (the ‘superior UVB protection claims’) *on its Coppertone SPF*
6 *55-100+ collection* are false, misleading, and reasonably likely to deceive the public.”
7 (FAC ¶ 4) (emphasis added). There are no allegations that Plaintiff was exposed to
8 anything other than Merck’s sunscreen label on its products, that Merck was involved
9 in any way in setting price or staging product at retail outlets, that Merck made any
10 affirmative claims of proportionally greater UVB protection for SPF 50+ sunscreen
11 products, or that Merck used misleading labels, such as “sunblock” or “waterproof.”

12 Plaintiff argues she is not seeking “to disrupt existing federal regulations, but
13 rather to provide greater consumer protections that are consistent with FDA
14 regulations.” (Opp’n at 15-16.) But in seeking to provide greater consumer
15 protections, Plaintiff targets Merck’s sunscreen label (which complies with current FDA
16 regulations),¹ and proposes a disclaimer regarding the level of sunscreen effectiveness
17 beyond SPF 50. Because the proposed disclaimer plainly adds to and is not identical
18 with the FDA’s requirements, Plaintiff’s action is expressly pre-empted under 21 U.S.C.
19 § 379r.²

20 Plaintiff’s reliance on *Corra v. Energizer Holdings, Inc.*, 962 F. Supp. 2d 1207
21 (E.D. Cal. 2013) and *Lombardo v. Johnson & Johnson Consumer Companies*, case no.

23 ¹ Although Plaintiff specifically alleged Merck’s sunscreen labeling (“SPF 55-
24 100+”) is false and misleading, (FAC ¶ 4), she has retreated from that assertion and now
25 concedes that Merck’s sunscreen labeling is not, standing alone, false or misleading.
See Opp’n at 10 (Plaintiff does not claim that Merck’s “SPF values on [its] Coppertone
50-100+ [sic] Products are themselves per se false or misleading.”)

26 ² Plaintiff also requests that the Merck Defendants be barred from charging a
27 premium for sunscreens with SPF values above 50. As noted, the Merck Defendants
28 are not retailers. And the FAC is devoid of any allegation that Merck sets the price
charged by retailers, such as Wal-Mart, or that Merck dictates how its products are
staged by retailers. Assuming such allegations, however, Plaintiff’s requested relief
would be precluded by the doctrine of primary jurisdiction, discussed below.

1 13-60536-Civ-Scola (S.D. Fla. Dec. 19, 2013 & Sep. 10, 2014), is unpersuasive.
2 *Lombardo* is distinguishable, in part, as it involved labeling (“Waterproof Sunblock”)
3 that is squarely proscribed by the FDA. Moreover, neither *Corra* nor *Lombardo*
4 considered whether a disclaimer regarding clinical benefits, as proposed by Plaintiff in
5 the present case, would add to or be identical with the FDA’s labeling requirements.
6 See *Corra*, 962 F. Supp. 2d at 1215 (“If Plaintiff were to prevail under the UCL and
7 CLRA, Defendants’ SPF labeling duties would remain unchanged.”); *Lombardo*, 13-
8 60536-Civ-Scola, docket no. 47, at 6 (“labeling requirements would remain
9 unchanged”) & docket no. 75, at 5 (“*Lombardo* is not attempting to enforce any sort of
10 state labeling requirement in addition to the Final Rule”).

11 The Court also rejects Plaintiff’s argument that 21 C.F.R. § 201.327(g) expressly
12 permits actions alleging false or misleading labeling claims. The regulation is not as
13 broadly worded as Plaintiff assumes. It provides:

14 False and misleading claims. There are claims that would be false and/or
15 misleading on sunscreen products. These claims include but are not
16 limited to the following: “Sunblock,” “sweatproof,” and “waterproof.”
These or similar claims will cause the product to be misbranded under
section 502 of the FD & C Act (21 U.S.C. § 352).

17 Although the regulation does not purport to provide an exclusive list of false and/or
18 misleading claims, its scope is limited to claims *similar* to those listed. Plaintiff does
19 not argue, nor could she, that premium pricing or the lack of a disclaimer regarding
20 proportional clinical benefits of SPF 50+ products are similar to the claims precluded
21 by the regulation. Defendants’ motion to dismiss based on express pre-emption under
22 the FDCA is therefore granted.

23 Defendant’s motion is also granted on primary jurisdiction grounds. Primary
24 jurisdiction is a prudential doctrine, which, under appropriate circumstances, provides
25 that “the initial decisionmaking responsibility should be performed by the relevant
26 agency rather than the courts.” *GCB Communications, Inc. v. U.S. South*
27 *Communications, Inc.*, 650 F.3d 1257, 1263 (9th Cir.2011). The courts must defer to
28 an administrative agency “where (1) the issue is not within the conventional experiences

1 of judges, (2) the issue involves technical or policy considerations within the agency's
2 particular field of expertise, (3) the issue is particularly within the agency's discretion,
3 or (4) there exists a substantial danger of inconsistent rulings.” *Maronyan v. Toyota*
4 *Motor Sales, U.S.A., Inc.*, 658 F.3d 1038, 1048–49 (9th Cir. 2011) (internal quotation
5 marks and citation omitted). “[T]he doctrine is not designed to secure expert advice
6 from agencies every time a court is presented with an issue conceivably within the
7 agency's ambit[, but] is to be used only if a claim requires resolution of an issue of first
8 impression, or a particularly complicated issue that Congress has committed to a
9 regulatory agency.” *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114-15. (9th
10 Cir.2008) (internal quotation marks and citation omitted).

11 Underlying all of Plaintiff’s claims is the allegation that sunscreen products
12 labeled above SPF 50 are clinically no more effective than SPF 50 products, and thus,
13 labeling such products with values of 55-100+ is inherently misleading. The issue of
14 any additional clinical benefit of sunscreen products with values above SPF 50 has been
15 *pending* before the FDA since June 2011, when the FDA issued a proposed rule seeking
16 comment and submission of data on this very issue. 76 Fed. Reg. 35672 (Jun. 17, 2011)
17 (*Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter*
18 *Human Use*) (“Proposed Rule”). While the FDA may be moving glacially, and
19 ultimately, may come out the way Plaintiff urges in this action, that determination is
20 underway and yet to be made. Through this action, Plaintiff invites the Court to weigh
21 in, find in her favor, and take action by requiring Merck to make a disclaimer and
22 engage in corrective advertising.

23 Exercising such jurisdiction over Plaintiff’s claims presents substantial risk of
24 inconsistent rulings on issues presently pending before the FDA.³ The investigation of
25 clinical benefits of drugs is particularly within the FDA’s initial decisionmaking
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28 ³ The timing of the Merck Defendants’ marketing or labeling does not affect the
potential for inconsistent findings on the clinical benefit issue. Accordingly, Plaintiff’s
oral request at the hearing to limit the time frame of her claim is denied.

1 domain, and is therefore not appropriate for adjudication before completion of the
2 FDA's own decisionmaking process. The FDA regulations support this conclusion:

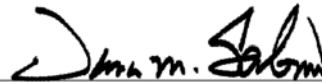
3 FDA has primary jurisdiction to make initial determination on issues
4 within its statutory mandate, and will request a court to dismiss, or to hold
5 in abeyance its determination of or refer to the agency for administrative
6 determination, any issue which has not previously been determined by the
7 agency or which, if previously determined, the agency concluded should
8 be reconsidered and subject to a new administrative determination.

9 21 C.F.R. §10.25. Plaintiff's reliance on *Corra* and *Lombardo* is unpersuasive because
10 those courts did not consider the effect of 21 C.F.R. § 10.25 and did not analyze
11 primary jurisdiction in the context of the FDA's pending decisionmaking process
12 regarding the clinical benefit of SPF 50+ sunscreen products.

13 For the foregoing reasons, Defendants' motion to dismiss is granted. This action
14 is dismissed without prejudice.

15 **IT IS SO ORDERED.**

16 DATED: November 25, 2014



17 HON. DANA M. SABRAW
18 United States District Judge