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10 UNITED STATES DISTRICT COURT
11 CENTRAL DISTRICT OF CALIFORNIA
12 SOUTHERN DIVISION

13 Josette Ruhnke, an individual, *et al.*; on
behalf of herself and all others similarly
14 situated,

15 Plaintiff,

16 vs.

17 SkinMedica, Inc., a Delaware
Corporation, and Allergan, Inc., a
18 Delaware Corporation,

19 Defendants.
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27
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Case No. 8:14-cv-00420 DOC (JPRx)

**DEFENDANTS' NOTICE OF
MOTION AND MOTION TO
DISMISS PLAINTIFF'S FIRST
AMENDED CLASS ACTION
COMPLAINT UNDER FEDERAL
RULE OF CIVIL PROCEDURE
12(b)(6)**

*[MEMORANDUM OF POINTS AND
AUTHORITIES AND PROPOSED
ORDER FILED CONCURRENTLY
HEREWITH; REQUEST FOR
JUDICIAL NOTICE AND EXHIBITS
FILED SEPARATELY]*

Date: August 4, 2014
Time: 8:30 a.m.
Ctm: 9D
Judge: Hon. David O. Carter

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT on August 4, 2014, at 8:30 a.m. or as soon thereafter as may be heard, before the Honorable David O. Carter in Courtroom 9D of the United States District Court for the Central District of California, located at 411 West Fourth Street, Santa Ana, California 92701, Defendants SkinMedica, Inc. and Allergan, Inc. will and hereby do move the Court for an order to dismiss the First Amended Class Action Complaint in the above-titled action for failing to state a claim upon which relief can be granted.

This Motion is based on this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, Defendants' Request for Judicial Notice in Support of this Motion, the Declaration of Steven N. Feldman in support thereof, the exhibits to the Request for Judicial Notice, the pleadings and papers on file herein, such arguments and evidence as may be presented in supplemental memoranda or as may be presented at the hearing, and any other matters of which the Court may take notice.

This motion is made following the conference of counsel pursuant to Local Rule 7-3, which took place on June 16, 2014.

Dated: June 23, 2014

IRELL & MANELLA LLP

By: /s/ John C. Hueston

John C. Hueston

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TABLE OF CONTENTS

		<u>Page</u>
1		
2		
3	I. PRELIMINARY STATEMENT	1
4	II. BACKGROUND	2
5	A. Plaintiff's Safety-Related Omission Theory	3
6	B. Plaintiff's Regulatory-Approval Omission Theory	6
7	III. ARGUMENT	8
8	A. Plaintiff's FAC Must Satisfy The Rule 8(a) And Rule 9(b)	
9	Pleading Requirements	8
10	B. Plaintiff's FAC Fails To Satisfy Rule 8(a) And Rule 9(b)	
11	Because It Fails To Adequately Allege Why The	
12	Allegedly Omitted "Facts" About The Safety And	
13	Regulatory Approval Of TNS® Products Are True	10
14	1. Plaintiff fails to sufficiently and plausibly allege	
15	why TNS® products pose "serious safety concerns"	10
16	2. Plaintiff fails to sufficiently and plausibly allege that	
17	TNS® products are "drugs," not cosmetics.....	17
18	3. Plaintiff also fails to sufficiently plead a duty to	
19	disclose and scienter	19
20	C. Plaintiff's Failure To Differentiate Between Allergan And	
21	SkinMedica Also Runs Afoul Of Rule 9(b).....	20
22	D. Plaintiff's Claims Against Allergan Must Be Dismissed	
23	Because Plaintiff Fails To Sufficiently Allege That	
24	SkinMedica Was Allergan's Agent	21
25	E. Plaintiff's Requests For Punitive Damages And Injunctive	
26	Relief Should Be Dismissed	23
27	1. Plaintiff did not properly plead punitive damages	23
28	2. Plaintiff does not have standing to seek injunctive	
	relief	23
	IV. CONCLUSION	25

TABLE OF AUTHORITIES**Page(s)****Cases**

<i>Altman v. PNC Mortgage</i> , 850 F. Sup. 2d 1057 (E.D. Cal. 2012).....	20
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009)	9
<i>Bates v. United Parcel Serv., Inc.</i> , 511 F.3d 974 (9th Cir. 2007).....	23, 24
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007)	9
<i>Biotics Res. Corp. v. Heckler</i> , 710 F.2d 1375 (9th Cir. 1983).....	19
<i>Bly-Magee v. California</i> , 236 F.3d 1014 (9th Cir. 2001).....	16
<i>Bowoto v. Chevron Texaco Corp.</i> , 312 F. Supp. 2d 1229 (N.D. Cal. 2004).	22
<i>Brazil v. Dole Food Co.</i> , 935 F. Supp. 2d 947 (N.D. Cal. 2013)	18
<i>Bronson v. Johnson & Johnson, Inc.</i> , No. C12-4184-CB, 2013 U.S. Dist. LEXIS 54029 (N.D. Cal. Apr. 2013).....	15
<i>Campion v. Old Republic Home Protection Co., Inc.</i> , 861 F. Supp. 2d 1139 (S.D. Cal. 2012)	24
<i>Cattie v. Wal-Mart Stores, Inc.</i> , 504 F. Supp. 2d 939 (S.D. Cal. 2007)	24
<i>Corral v. Carter's Inc.</i> , No. 13-0262, 2014 U.S. Dist. LEXIS 5880 (E.D. Cal. Jan. 16, 2014).....	passim
<i>D'Lil v. Best Western Encina Lodge & Suites</i> , 538 F.3d 1031 (9th Cir. 2008).....	23
<i>Daimler Chrysler Corp. v. Cuno</i> , 547 U.S. 332 (2006)	23
<i>Eckler v. Wal-Mart Stores, Inc.</i> , No. 12-CV-727-LAB-MDD, 2012 U.S. Dist. LEXIS 157132 (S.D. Cal. Nov. 1, 2012).....	13, 15, 16
<i>Hahn v. Mirda</i> , 147 Cal. App. 4th 740 (2007).....	20

	<u>Page(s)</u>
1	
2	
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4	417 F. Supp. 30 (D. Minn. 1976) 17
5	<i>Holt v. Kormann</i> ,
6	No. SACV 11-1047-DOC (MLGx), 2012 U.S. Dist. LEXIS 5198
7	(C.D. Cal. Jan. 12, 2012) 22
8	<i>In re Action Performance Cos. Secs. Litig.</i> ,
9	No. 05-2512-PHX-DGC, 2007 U.S. Dist. LEXIS 10236 (D. Ariz.
10	Feb. 13, 2007) 9, 12
11	<i>In re GlenFed, Inc. Sec. Litig.</i> ,
12	42 F.3d 1541 (9th Cir. 1994) 9
13	<i>In re Worlds of Wonder Sec. Litig.</i> ,
14	694 F. Supp. 1427 (N.D. Cal. 1988) 21
15	<i>Kearns v. Ford Motor Co.</i> ,
16	567 F.3d 1120 (9th Cir. 2009) 9, 10
17	<i>Lent v. JP Morgan Chase Bank, N.A.</i> ,
18	No. SACV 11-345 DOC RNBX, 2011 U.S. Dist. LEXIS 137553
19	(C.D. Cal. Nov. 29, 2011) 22
20	<i>McCormick v. Fund Am. Cos.</i> ,
21	26 F.3d 869 (9th Cir. 1994) 10
22	<i>Nat'l Council Against Health Fraud v. King Bio Pharm., Inc.</i> ,
23	107 Cal. App. 4th 1336 (2003) 15
24	<i>Otto v. Abbott Laboratories, Inc.</i> ,
25	CV 12-1411-SVW (DTB), 2013 U.S. Dist. LEXIS 53287 (C.D.
26	Cal. Mar. 15, 2013) 13, 14, 15
27	<i>Park v. Welch Foods, Inc.</i> ,
28	No. 12-cv-6449-PSF, 2013 U.S. Dist. LEXIS 139715 (N.D. Cal.
	Sept. 26, 2013) 18
	<i>Pegasus Holdings v. Veterinary Centers of Am., Inc.</i> ,
	38 F. Supp. 2d 1158 (C.D. Cal. 1998) 20
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	Case No. 11cv862-IEG(BLM), 2012 U.S. Dist. LEXIS 47895
	(S.D. Cal. Apr. 3, 2012) 15
	<i>Swartz v. KPMG LLP</i> ,
	476 F.3d 756 (9th Cir. 2007) 20
	<i>Taddeo v. Taddeo</i> ,
	No. 08-CV-01463-KJD-RJJ, 2011 U.S. Dist. LEXIS 103649 (D.
	Nev. Sept. 13, 2011) 12

	<u>Page(s)</u>
1	
2	
3	<i>United States v. An Article . . . Consistent of 216 Cartoned Bottles,</i>
4	<i>More or Less . . . Sudden Change,</i>
	409 F.2d 734 (2d Cir. 1969) 17
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	524 U.S. 51 (2003) 22
6	<i>United States v. Kasz Enters., Inc.,</i>
7	855 F. Supp. 534 (D.R.I. 1994) 7, 17
8	<i>United States v. Storage Spaces Designated Nos. “8” & “49”,</i>
	777 F.2d 1363 (9th Cir. 1985) 7, 17
9	<i>Vess v. Ciba-Geigy Corp. USA,</i>
10	317 F.3d 1097 (9th Cir. 2003) 9
11	<i>Wang v. OCZ Tech. Grp., Inc.,</i>
	276 F.R.D. 618 (N.D. Cal. 2011) 24
12	<i>White v. Ultramar, Inc.,</i>
13	21 Cal. 4th 563 (1999) 23
14	<u>Statutes</u>
15	21 U.S.C. § 301 6
16	21 U.S.C. § 321 17
17	CAL. BUS. & PROF. CODE § 17200 2
18	CAL. BUS. & PROF. CODE § 17500 2
19	CAL. CIV. CODE § 1750 2
20	CAL. CIV. CODE § 3294 23
21	CAL. HEALTH & SAFETY CODE § 109875 6
22	<u>Rules</u>
23	FED. R. CIV. P. 12(b)(6) 8
24	FED. R. CIV. P. 8 1, 10, 20
25	FED. R. CIV. P. 9 passim
26	
27	
28	

1 **I. PRELIMINARY STATEMENT**

2 This case concerns a cosmetic skin care line sold by SkinMedica, Inc.
 3 (“SkinMedica”) under the brand name “TNS®” (the “TNS® products”). The TNS®
 4 line is comprised of thirteen unique skin care products – ranging from body lotion to
 5 eye cream. For over a decade, SkinMedica has safely sold these products to
 6 thousands of consumers across the country. Although Plaintiff Josette Ruhnke
 7 (“Plaintiff”) does not allege that she or anyone else has suffered any physical harm
 8 from using TNS® products, she nevertheless brings suit, alleging that SkinMedica
 9 and its parent company, Allergan, Inc. (“Allergan”), deceived consumers by
 10 concealing (1) purported safety concerns with TNS® products, as well as (2) the
 11 alleged “fact” that those products qualify as “drugs” under federal and state laws
 12 and are therefore misbranded. Notably, despite the fact that SkinMedica has
 13 publicly sold TNS® products as cosmetics – not drugs – since 2003, Plaintiff does
 14 not allege that the Food and Drug Administration (“FDA”), the California
 15 Department of Public Health (“DPH”), or anyone else has said – or even suggested
 16 – that TNS® products are “drugs,” or otherwise accused SkinMedica of unlawfully
 17 selling TNS® products.

18 Because Plaintiff’s First Amended Class Action Complaint (“FAC”) sounds
 19 in fraud, it must satisfy both Federal Rule of Civil Procedure 8(a) and 9(b)’s
 20 pleading requirements. Plaintiff’s FAC fails to satisfy these basic pleading
 21 standards for several reasons and must therefore be dismissed.

22 *First*, Plaintiff’s entire FAC should be dismissed because it fails to allege
 23 sufficiently plausible or particular facts demonstrating that the allegedly omitted
 24 information about the safety and regulatory approval of TNS® products is true.
 25 Indeed, as discussed below, a close examination of the few facts Plaintiff does
 26 allege reveals that there is absolutely no basis for her claims.

27 *Second*, Plaintiff’s entire FAC should be dismissed because it fails to
 28 differentiate between SkinMedica and Allergan, and thus fails to inform each

1 Defendant separately of the allegations surrounding its alleged participation in the
2 fraud.

3 *Third*, Plaintiff's claims against Allergan must be dismissed because Plaintiff
4 fails to sufficiently allege, under this Court's precedent, that SkinMedica was acting
5 as Allergan's agent.

6 *Fourth*, Plaintiff's request for punitive damages should be dismissed because
7 she does not, as she must, allege that any officers, directors, or managing agents for
8 SkinMedica or Allergan consciously disregarded, authorized, or ratified any acts of
9 oppression, fraud, or malice.

10 *Finally*, Plaintiff's request for injunctive relief should be dismissed because
11 she does not have standing to pursue that relief, given that her claim is based solely
12 on her past purchases of TNS® products.

13 **II. BACKGROUND**

14 Plaintiff's FAC is premised entirely on vague allegations that the labeling and
15 packaging of thirteen different TNS® products¹ omit material information regarding
16 safety and regulatory approval. Based on these allegations, Plaintiff asserts claims
17 for deceit and for violations of California's Unfair Competition Law, Cal. Bus. &
18 Prof. Code §§ 17200, *et seq.*; California's False Advertising Law, Cal. Bus. & Prof.
19 Code §§ 17500, *et seq.*; and California's Consumers Legal Remedies Act, Cal. Civ.
20 Code §§ 1750, *et seq.* (FAC ¶¶ 91-131.)

21 Plaintiff identifies only one TNS® product that she has purchased, TNS®
22 Essential Serum, and she does not specify when she bought it. (FAC ¶ 9.)
23 Nevertheless, she claims that before making that purchase from her doctor, she
24 looked at the product packaging and labeling, and "[h]ad she known about the safety
25

26 ¹ The thirteen products are: (1) TNS® Essential Serum; (2) TNS® Recovery
27 Complex; (3) TNS® Ultimate Daily Moisturizer; (4) TNS® Body Lotion; (5) TNS®
28 Ceramide Treatment Cream; (6) TNS® Eye Repair; (7) TNS® Lip Plump System;
(8) TNS® Line Refine; (9) TNS® Illuminating Eye Cream; (10) TNS® Body Mist;
(11) TNS® Hydrating Masque; (12) TNS® Hydrafacial Serum; and (13) TNS®
Recovery Complex Body Lotion. (FAC ¶ 21.)

1 concerns associated with TNS Products (including but not limited to an increased
2 risk of cancer), or that the products were misbranded, lacked required safety studies,
3 and were legally unsaleable,” she would “either” not have purchased the product or
4 “paid less.” (FAC ¶¶ 10, 98.)

5 Plaintiff’s safety and regulatory-approval omissions theories are described
6 below.

7 **A. Plaintiff’s Safety-Related Omission Theory**

8 SkinMedica’s TNS® products each contain, at different concentration levels,
9 a proprietary and physiologically balanced mixture of over 110 different human
10 growth factors, together with other ingredients typically found in skin care
11 cosmetics. (FAC ¶¶ 19, 23, 25, 51.) The growth factors in TNS® products are
12 naturally occurring elements in human skin. (FAC ¶¶ 23, 25.) The crux of
13 Plaintiff’s safety-related omission theory is that Defendants failed to disclose that
14 these “growth factors contained in TNS products pose significant health risks,
15 including but not limited to the risk of cancer.” (FAC ¶ 5.) Critically, though,
16 Plaintiff stops short of actually alleging that any TNS® product (each with its own,
17 unique concentration level of the balanced mixture of growth factors) *itself* poses
18 health risks or causes cancer. Plaintiff also makes no allegation that she or anybody
19 else suffered any physical harm from using TNS® products; in fact, she
20 affirmatively pleads that she “does not assert any personal injury claim in this action
21 as a result of using Defendants’ TNS Products.” (FAC ¶ 81.) This is notable
22 because, as Plaintiff admits, SkinMedica has sold TNS® products for over ten years
23 to thousands of consumers, yet Plaintiff fails to identify even a *single* specific
24 incident of an adverse reaction or cancer, or any consumer complaint, related to
25 TNS® products. (FAC ¶¶ 19, 82.)

26 Rather, according to Plaintiff, Defendants concealed material facts about the
27 safety of TNS® products because those products’ packaging and labels do not
28 disclose “serious safety concerns” that have been observed in “scientific literature”

1 regarding unspecified growth factors, including concerns about “the risk of cancer,”
 2 “tumor growth,” and “adverse reactions (such as allergic reactions, eye issues, and
 3 rashes).” (FAC ¶¶ 48, 50, 63.) Yet despite this lofty pronouncement, Plaintiff is
 4 able to cite just *one* inapposite scientific article from 2006 (FAC ¶ 51 n.5 (citing
 5 Journal of the National Cancer Institute, Vol. 98, No. 12, 2006)) (the “Finch
 6 article”), which discusses the use of just *one* of the over 110 growth factors
 7 balanced in TNS® products (a growth factor known as “KGF-1”), in a dramatically
 8 different setting inapplicable to cosmetics consumers. According to Plaintiff, this
 9 single article constitutes “substantial scientific evidence” that this one growth factor
 10 “contributes to the growth of a number of cancers (e.g., breast cancer).” (FAC
 11 ¶ 51.)

12 Tellingly, though, Plaintiff fails to quote or cite a single conclusion from the
 13 Finch article to support her claim. This is not surprising because the article actually
 14 reaches *the exact opposite conclusion* from the one Plaintiff alleges. Specifically,
 15 after summarizing the relevant scientific research, the article concludes that “*there is*
 16 *little evidence* that KGF promotes tumorigenesis” – *i.e.*, the production or formation
 17 of tumors. (RJN, Ex. 1 at 819 (emphasis added).²) Among the article’s other
 18 conclusions (which Plaintiff also conspicuously fails to mention) are that (1) “it is
 19 unlikely that . . . exposure from pharmacologic doses of KGF would have much
 20 impact on tumor growth,” (2) “KGF might reduce the number of cells that have
 21 mutations and, consequently, limit the likelihood of subsequent cancers,” and (3)
 22 “[i]t is possible that KGF could facilitate the development of more effective
 23 chemoradiotherapy” (*Id.* at 819-20.) If anything, that Plaintiff can cite *only*
 24 *one* specific article, concerning *only one* specific growth factor, for a proposition
 25

26 ² *In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1405 n.4 (9th Cir. 1996)
 27 (“Documents whose contents are alleged in a complaint and whose authenticity no
 28 party questions, but which are not physically attached to the pleading, may be
 considered in ruling on a Rule 12(b)(6) motion to dismiss.” (quotation marks
 omitted)).

1 that the article does not actually support, betrays her inability to allege specific facts
2 supporting her conclusory claim that TNS® products pose undisclosed safety risks.

3 What is more, these conclusions are not the only omitted details from the
4 Finch article that demonstrate the article provides no support for Plaintiff's claims.
5 Indeed, Plaintiff also omits that the article concerned and studied the use of KGF in
6 an entirely different circumstance to its use in TNS® products. Specifically, the
7 article concerned using KGF to treat patients with solid tumors, *not* to improve the
8 appearance of skin by applying it as part of a topical, balanced mixture of growth
9 factors and other ingredients. (FAC ¶ 51; RJN, Ex. 1.) Plaintiff also fails to
10 mention that all of the experiments discussed in the article were done in "cell lines"
11 (*i.e.*, cell cultures), excised tissues, and transgenic animals (*i.e.*, genetically altered
12 animals). (RJN, Ex. 1.) In other words, *none* of the experiments came even close to
13 mimicking or modeling the situation in which the small quantities of KGF in TNS®
14 products are used by TNS® consumers. Thus, even if these experiments were
15 "substantial scientific evidence" that KGF plays a role in the growth of tumor cells
16 in cell lines, excised tissues, and genetically altered animals (they clearly are not),
17 they still would not be sufficient to show or suggest that the use of the small
18 quantity of KGF (in combination with many other growth factors) in TNS®
19 products contributes to the growth of cancer when applied topically to intact human
20 skin. As to the other *109-plus growth factors* that make up the vast majority of the
21 TNS® products' physiologically balanced mixture, Plaintiff's FAC is silent.

22 Relatedly, Plaintiff vaguely suggests that – despite a long history of safe
23 public use (which she does not dispute) – there is supposedly insufficient research
24 regarding the safety of growth factors in TNS® and similar cosmetic products.
25 (FAC ¶¶ 52-53.) In support of this allegation, she cherry-picks a single, innocuous
26 sentence from a roughly seven-year-old³ report by Dr. Richard Fitzpatrick –

27 _____
28 ³ The FAC states that Dr. Fitzpatrick's report was published in 2008. (FAC
¶ 53.) This appears to be a typographical error because the citation provided in
footnote 7 is to a report published by Dr. Fitzpatrick in 2007.

1 SkinMedica’s founder and the doctor credited with creating the human growth
2 factor component of TNS® products. (FAC ¶ 53.) Specifically, Plaintiff alleges
3 that Dr. Fitzpatrick “acknowledged” in his report that: “More double-blind and
4 controlled studies are needed to confirm the preliminary clinical effects of growth
5 factor products, and more controls on product quality and stability need to be
6 established.” (FAC ¶ 53.) Dr. Fitzpatrick’s full statement, however, of which this
7 Court may take judicial notice, reveals that this comment in no way suggested that
8 more studies were needed to confirm the *safety* of growth factors in cosmetic skin
9 care products. To the contrary, it simply stated his opinion that – as of seven years
10 ago – more studies were needed to confirm certain *clinical effects* of growth factors,
11 such as their effect in “reduc[ing] the signs and symptoms of skin aging, including
12 statically significant reduction in fine lines and wrinkles and increase in dermal
13 collagen synthesis.” (RJN, Ex. 2 at 350.) In short, this and Plaintiff’s other
14 allegations provide no support for her conclusory claim that TNS® products “raise
15 serious safety concerns.”

16 **B. Plaintiff’s Regulatory-Approval Omission Theory**

17 Plaintiff’s other omission theory alleges that Defendants deceived consumers
18 by selling TNS® products for use as cosmetics because, according to Plaintiff,
19 TNS® products “qualify as drugs” both under the Federal Food, Drug, and
20 Cosmetics Act (“FDCA”) (21 U.S.C. §§ 301, *et seq.*) and California’s parallel
21 Sherman Food, Drug, and Cosmetics Law (“Sherman FD&C Law”) (Cal. Health &
22 Safety Code §§ 109875, *et seq.*). (FAC ¶¶ 27, 40.) Because TNS® products are not
23 approved or labeled as “drugs,” Plaintiff also alleges that they are “misbranded” and
24 unlawfully sold under the Sherman FD&C Law. (FAC ¶¶ 42-43.)

25 Notably, though, Plaintiff does *not allege* that in the 10-plus years TNS®
26 products have been sold to consumers across the country, the FDA, the DPH, or
27 anyone else has said – or even suggested – that TNS® products are “drugs,” or
28 otherwise accused SkinMedica of unlawfully selling TNS® products. (They have

1 not.) Rather, Plaintiff's FAC simply recites the FDCA and Sherman FD&C Law's
2 definitions of drugs, (FAC ¶ 27), and then – in one paragraph – vaguely explains her
3 belief that TNS® products meet those definitions because they allegedly “use
4 human growth factors . . . to affect cell biology” and are allegedly “designed to
5 affect the skin's structure and function by inducing cell division and replication and
6 stimulating skin cell production.” (FAC ¶ 40.) Plaintiff's FAC conveniently fails to
7 mention, however, how the FDA or DPH regularly apply the relevant statutory
8 definitions to determine whether a product is a drug, or the criteria or types of
9 evidence they consider and examine in making that determination. Nor does
10 Plaintiff make any effort to apply those standards or criteria to TNS® products.
11 Indeed, Plaintiff wholly omits that “[i]n establishing whether or not a product is a
12 drug, for purposes of the FDCA, . . . it is the *vendor's intent*, as determined or
13 inferred from labeling, promotional material, advertising, or any other relevant
14 source, which controls, and not the actual physical effect on the human body.”
15 *United States v. Kasz Enters., Inc.*, 855 F. Supp. 534, 539 (D.R.I. 1994) (emphasis
16 added); *see also id.* (“The intended use of a product is determined by the vendor's
17 *objective* intent in promoting, distributing, and selling the product.”); *United States*
18 *v. Storage Spaces Designated Nos. “8” & “49”*, 777 F.2d 1363, 1366 (9th Cir.
19 1985) (“The vendor's intent is the key element in th[e] statutory definition [of a
20 drug]. . . . This intent may be derived or inferred from labeling, promotional
21 material, or any other relevant source.” (citation omitted)).

22 Critically, the FAC makes no allegations about SkinMedica's objective intent
23 in promoting, distributing, and selling TNS® products that could support a
24 determination that those products are drugs under this standard. For example,
25 Plaintiff does not identify any specific claims in the labeling, promotional material,
26 or advertising of TNS® products that she contends evinces SkinMedica's objective
27 intent that TNS® products be used as drugs, not cosmetics. To the contrary,
28 Plaintiff alleges that “SkinMedica maintains that most of its products (*including*

1 **TNS Products**) are intended to meet the FDA’s definition of cosmetic products but
2 are not intended to be drug products.” (FAC ¶ 46 (emphasis added).)

3 Plaintiff also alleges that she “knows of *two*” products that contain human
4 growth factors that the FDA regulates as drugs – “REGRANEX® Gel” and
5 “Kepivance.” (FAC ¶¶ 55-58 (emphasis added).) However, neither of these
6 products are topical skin creams, neither are used in a manner similar to TNS®
7 products (that is, neither are applied topically to intact skin), and neither contain a
8 similar balanced mixture or concentration of growth factors as TNS® products.
9 Rather, Regranex Gel is intended to treat diabetic foot ulcers (open wounds), which
10 Plaintiff admits is a “severe medical condition[.]” (FAC ¶¶ 55-57.) Regranex Gel
11 also contains a pharmacologic dose of just a single growth factor (becaplermin), not
12 a physiologically balanced mixture of multiple growth factors, like TNS® products.
13 (FAC ¶ 55-56.) Kepivance is similarly intended to treat “severe oral mucositis”
14 (severe ulceration in the mouth), and is applied “*intravenous[ly]*,” not topically.
15 (FAC ¶ 58 (emphasis added).) It also contains a pharmacologic dose of only one
16 growth factor (palifermin). Simply put, aside from the fact that these products also
17 contain growth factors (albeit ones dramatically different from the proprietary and
18 physiologically balanced mixture in TNS® products), Plaintiff fails to explain how
19 they relate in any way to TNS® skin care products, or why the regulatory status of
20 these other products as “drugs” has anything to do with the regulatory status of
21 TNS® products. They do not.

22 Lastly, Plaintiff does not allege that TNS® products are the only skin care
23 products that contain growth factors (other products do), and her FAC is silent about
24 the regulatory status of other, similar skin care products containing growth factors.

25 **III. ARGUMENT**

26 **A. Plaintiff’s FAC Must Satisfy The Rule 8(a) And Rule 9(b) Pleading** 27 **Requirements**

28 A complaint must be dismissed under Federal Rule of Civil Procedure

1 12(b)(6) if it does not contain “enough facts to state a claim to relief that is plausible
2 on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A plaintiff must
3 therefore identify specific facts. “[L]abels and conclusions” or “a formulaic
4 recitation of the elements of the cause of action will not do.” *Ashcroft v. Iqbal*, 556
5 U.S. 662, 678 (2009) (quotation marks omitted).

6 This basic requirement is expanded by Rule 9(b), which requires that a
7 plaintiff alleging fraud “state with particularity the circumstances constituting
8 fraud.” FED. R. CIV. P. 9(b). To meet Rule 9(b)’s heightened standard, a plaintiff
9 must specifically identify the “who, what, when, where, and how” of the allegedly
10 fraudulent conduct. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124, 1126 (9th Cir.
11 2009). Simply alleging that fraud occurred is insufficient. *Id.* Importantly, a
12 plaintiff must also “set forth an explanation as to why the statement or omission
13 complained of was false and misleading.” *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d
14 1541, 1548 (9th Cir. 1994); *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106
15 (9th Cir. 2003) (“The plaintiff must set forth what is false or misleading about a
16 statement, and why it is false.” (quotation marks omitted)).

17 Where, as here, a complaint is “[c]ast in the context of fraud by omission,
18 application of the same rule requires that the complaint adequately allege why the
19 omitted fact is true.” *Corral v. Carter’s Inc.*, No. 13-0262, 2014 U.S. Dist. LEXIS
20 5880, at *13-14 (E.D. Cal. Jan. 16, 2014); *see also In re Action Performance Cos.*
21 *Secs. Litig.*, No. 05-2512-PHX-DGC, 2007 U.S. Dist. LEXIS 10236, at *9 (D. Ariz.
22 Feb. 13, 2007) (a complaint must “state[] with particularity the facts on which [a]
23 [p]laintiff bases its belief that the alleged omission is true”).

24 When allegations rely on a “unified course of fraudulent conduct,” the
25 pleading is “‘grounded in fraud’ . . . [and] as a whole must satisfy the particularity
26 requirement of Rule 9(b).” *Vess*, 317 F.3d at 1103-04. Here, each of Plaintiff’s
27 claims relies on a single allegedly fraudulent course of conduct – namely, that
28 Defendants allegedly deceived consumers by omitting material facts about the safety

1 and regulatory approval of TNS® products. Since these claims sound in fraud,
2 Plaintiff's entire FAC must meet the heightened pleading requirements of Rule 9(b).
3 *Kearns*, 567 F.3d at 1125 (applying Rule 9(b) to UCL and CLRA claims where
4 plaintiff alleges that the defendant engaged in a fraudulent course of conduct). As
5 explained below, the FAC fails to meet both Rule 8(a) and Rule 9(b)'s standards.

6 **B. Plaintiff's FAC Fails To Satisfy Rule 8(a) And Rule 9(b) Because It**
7 **Fails To Adequately Allege Why The Allegedly Omitted "Facts"**
8 **About The Safety And Regulatory Approval Of TNS® Products**
9 **Are True**

10 Plaintiff's FAC must be dismissed because, as explained below, it does not
11 contain sufficiently plausible or particular allegations that the allegedly omitted
12 "facts" about the safety and regulatory approval of TNS® products are "true."
13 *Corral*, 2014 U.S. Dist. LEXIS 5880, at *13-14 (Rule 9(b) requires "the complaint
14 adequately allege why the *omitted* fact is true"); *see also McCormick v. Fund Am.*
15 *Cos.*, 26 F.3d 869, 879 (9th Cir. 1994) (a defendant "can hardly be faulted for
omitting to say something that was not true").

16 1. *Plaintiff fails to sufficiently and plausibly allege why TNS®*
17 *products pose "serious safety concerns"*

18 Plaintiff's safety-related allegations fall far short of plausibly or sufficiently
19 alleging that the physiologically balanced mixture of human growth factors in
20 TNS® products actually "raise serious safety concerns," including the risk of
21 cancer. This is because, on its face, the FAC fails to identify a single fact or shred
22 of evidence that ***actually connects*** TNS® products to any safety issues. Plaintiff's
23 claims must therefore be dismissed for failing to satisfy Rule 8(a) and Rule 9(b)'s
24 standards.

25 A complaint alleging an omission must be dismissed under Rule 9(b) if it
26 does not "adequately allege why the *omitted* fact is true." *Corral*, 2014 U.S. Dist.
27 LEXIS 5880, at *13-14. For example, in *Corral*, the court dismissed an analogous
28 consumer fraud action premised on a defendant's alleged failure to disclose that its

1 infant “crib bumpers” posed “a significant risk of injury or death to infants,”
2 because the plaintiff failed to allege sufficient facts demonstrating that the
3 defendant’s product actually increased the risk of infant harm. *Id.* at *3, *12. While
4 the plaintiff had identified a study that “linked crib bumpers as a class of products to
5 27 accidental deaths,” the study did “not specify the type of crib bumpers in
6 question – whether [they were] of the same or different design as Defendant’s – or
7 to what extent the fatalities noted could be attributed to faulty installation of the
8 product or the extent to which a product failure contributed to the accidental injury
9 or death.” *Id.* at *12. Though the plaintiff also alleged that “a number of
10 professional and infant safety advocacy groups . . . recommended against the use of
11 bumper pads in cribs,” the court properly held that the recommendations of those
12 groups did “not constitute proof of the [f]act” that the defendant’s bumper pads
13 substantially increased the risk of infant death. *Id.* at *13.

14 In short, because neither the study, the advocacy group recommendations, nor
15 any of the other “evidence alleged by [the] [p]laintiff . . . connect[ed] any crib
16 bumper made by [the] [d]efendant to any infant harm,” the plaintiff “failed to allege
17 evidence sufficient to establish the existence of the [f]act that [the] [d]efendant
18 [wa]s accused of concealing” – namely, the risk of injury or death associated with
19 the defendant’s products. *Id.* at *14-15. The court thus dismissed plaintiff’s false
20 advertising claims for failure to satisfy Rule 9(b)’s requirements and pointedly
21 noted: “If Plaintiff wishes to enlist the court’s authority to force Defendant to
22 affirmatively warn consumers of a significant risk of harm to infants from the use of
23 its product, Plaintiff will be required to draw a more direct link between actual harm
24 to infants and *Defendant’s* product.” *Id.* at *15.

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1 Plaintiff's safety-related allegations here are just like those that the *Corral*
2 court found to be fatally deficient.⁴ The gravamen of Plaintiff's claim is that
3 Defendants failed to disclose that the "growth factors contained in TNS products
4 pose significant health risks, including but not limited to the risk of cancer." (FAC
5 ¶ 5.) But just as in *Corral*, Plaintiff fails to allege sufficient facts or evidence to
6 plausibly establish – let alone with the particularity required by Rule 9(b) – that this
7 omitted "fact" is true, for a number of reasons:

8 *First*, Plaintiff does not allege that she or anybody else actually suffered any
9 physical harm or cancer from using TNS® products. Nor does she identify a *single*
10 specific incident of any adverse reaction or any consumer complaint associated with
11 TNS® products. This is especially notable given that SkinMedica has sold TNS®
12 products for over a decade to thousands of consumers.

13 *Second*, while Plaintiff vaguely cites "scientific literature" that purportedly
14 observed a connection between unspecified growth factors and "the risk of cancer"
15 and "adverse reactions," just as in *Corral*, Plaintiff fails to allege a sufficient
16 connection between this literature and TNS® products. (FAC ¶¶ 48, 50.) Indeed,
17 Plaintiff specifically cites only one inapposite article. As to the other unidentified
18 "literature," Plaintiff fails to allege the context in which any research was
19 performed, including what experiments were performed, what growth factors were
20 examined, or how or in what concentration levels those growth factors were used.
21 For example, Plaintiff does not allege that any research (a) studied either the same
22 or a sufficiently similar naturally occurring, physiologically balanced mixture of
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24 ⁴ Other courts have also routinely dismissed complaints under similar
25 circumstances. See *Taddeo v. Taddeo*, No. 08-CV-01463-KJD-RJJ, 2011 U.S. Dist.
26 LEXIS 103649, at *20 n.3 (D. Nev. Sept. 13, 2011) (noting that "[p]laintiff must set
27 forth facts showing that the allegedly omitted facts were *true*" and dismissing
28 complaint because it "has no such facts"); *In re Action Performance Cos.*, 2007 U.S.
Dist. LEXIS 10236, at *15-16 (dismissing claim that defendants "should have
disclosed that [they] would have to pay extra to ship products by air" where "the
Complaint provide[d] no particularized allegations that [the defendants] actually
paid extra for air shipping").

1 growth factors as that used in TNS® products, (b) used those growth factors in the
2 same or a similar way growth factors are used in TNS® products, or (c) applied or
3 used a similar concentration of growth factors to that found in any TNS® product.
4 To the contrary, Plaintiff *concedes* that this research “has looked primarily at the
5 issue of wound healing” – an entirely different use of growth factors from TNS®
6 products. (FAC ¶ 52.) Consequently, the FAC fails to allege that any unidentified
7 “literature” actually connects any safety concerns to TNS® products.

8 *Third*, the one and only research paper that Plaintiff actually cites – the Finch
9 article – is eight years old and concerned only KGF, *just one* of the over 110 growth
10 factors that are found in TNS® products. (FAC ¶ 51.) This fact alone renders the
11 article insufficient to give rise to a plausible claim regarding the safety of TNS®
12 products. For example, in *Otto v. Abbott Laboratories, Inc.*, CV 12-1411-SVW
13 (DTB), 2013 U.S. Dist. LEXIS 53287 (C.D. Cal. Mar. 15, 2013), the court
14 dismissed a similar consumer fraud action in which the plaintiff alleged that
15 scientific articles proved the defendant’s products did not provide certain claimed
16 benefits, because “none of the articles [we]re apposite as they fail[ed] to test the
17 precise combination of ingredients in the [defendant’s] [p]roducts.” *Id.* at *24.
18 “Even construing the[] articles in the light most favorable to [p]laintiff,” the court
19 “conclude[d] that the well-pleaded facts d[id] not support a plausible claim.” *Id.* So
20 too here, where Plaintiff relies on the Finch article’s discussion of research that did
21 not involve any TNS® products, or anything close to their precise combination of
22 ingredients. *See also Eckler v. Wal-Mart Stores, Inc.*, No. 12-CV-727-LAB-MDD,
23 2012 U.S. Dist. LEXIS 157132, at *24-27 (S.D. Cal. Nov. 1, 2012) (scientific
24 studies did not lend “facial plausibility” to plaintiff’s consumer fraud claims when
25 none of the studies addressed the specific product at issue, which consisted of a
26 combination of at least ten ingredients); *Corral*, 2014 U.S. Dist. LEXIS 5880, at *12
27 (“no studies cited in Plaintiff’s FAC link the use of *Defendant’s* product according
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1 to the instructions provided with increase in the frequency of infant death”). The
2 Finch article therefore cannot support a plausible claim.

3 Moreover, even if the Finch article were relevant to the safety of TNS®
4 products (it is not), it still fails to support Plaintiff’s claims because it actually
5 concludes (though Plaintiff conspicuously fails to mention it) that “*there is little*
6 *evidence* that KGF promotes tumorigenesis” – *i.e.*, the production or formation of
7 tumors.⁵ (See RJN, Ex. 1 at 819 (emphasis added).) Nevertheless, Plaintiff
8 curiously alleges that the Finch article constitutes “[s]ubstantial scientific evidence”
9 that “KGF-1 contributes to the growth of a number of cancers.” (FAC ¶ 51.)
10 Fortunately, this Court does not need to take Plaintiff’s word for the contents of the
11 article, since it is properly subject to judicial notice. For instance, in *Abbott*
12 *Laboratories*, the plaintiff cited an “isolated statement” from a study and claimed
13 that it supported his allegations that the defendant’s product was ineffective. 2013
14 U.S. Dist. LEXIS 53287, at *11. The court noted that, like the Finch article, the
15 study was subject to judicial notice. *Id.* at *9, *14-16. The court therefore
16 “scrutiniz[ed]” the study and other facts that the plaintiff “omit[ted] to mention.” *Id.*
17 The court then concluded that, “at face value,” the study did not actually support the
18 plaintiff’s contention and thus could not “give rise to a plausible claim that the
19 [defendant’s] representation [wa]s misleading.” *Id.* at *15 n.8. It therefore
20 dismissed the plaintiff’s claims. *Id.* at *24. This Court should do the same.⁶

21 _____
22 ⁵ The following additional conclusions in the article also seriously undermine
23 Plaintiff’s allegations: (1) “it is unlikely that . . . exposure from pharmacologic
24 doses of KGF would have much impact on tumor growth,” (2) “KGF might reduce
the number of cells that have mutations and, consequently, limit the likelihood of
subsequent cancers,” and (3) “[i]t is possible that KGF could facilitate the
development of more effective chemoradiotherapy” (RJN, Ex. 1 at 819-20.)

25 ⁶ As noted, *supra*, Plaintiff omits other critical details about the Finch article
26 that further demonstrate that it in no way supports her claims. For example, she
27 omits that the article concerned the use of KGF to treat patients with solid tumors,
not to improve the appearance of skin as part of a topical skin care application. She
also fails to mention that the experiments the article discussed were performed in
cell lines, excised tissues, and transgenic animals. (RJN, Ex. 1.) In other words, no
experiment came close to modeling the situation in which KGF is used by the
TNS® consumer.

1 *Finally*, to the extent Plaintiff’s claims rest on allegations that TNS® Products
2 “are not adequately substantiated for safety,” (FAC ¶ 54), her claims are not
3 actionable. Indeed, to Defendants’ knowledge, every court that has decided the
4 issue has held that “[c]laims that rest on a lack of substantiation, instead of a
5 provable falsehood, are not cognizable under the California consumer protection
6 laws,” because under California’s consumer protection regime, “[c]hallenges based
7 on a lack of substantiation are left to the Attorney General and other prosecuting
8 authorities.” *Bronson v. Johnson & Johnson, Inc.*, No. C12-4184-CB, 2013 U.S.
9 Dist. LEXIS 54029, at *22 (N.D. Cal. Apr. 16, 2013).⁷ “[P]rivate plaintiffs, in
10 contrast, have the burden of proving that advertising is actually false or misleading.”
11 *Id.* In short, Plaintiff’s “lack of substantiation” theory is simply not cognizable.

12 Furthermore, even if a claim for lack of substantiation were cognizable
13 (again, it is not), Plaintiff fails to plausibly allege that, despite over a decade of safe
14 public use, the safety of TNS® products has not been substantiated. To support her
15 “lack of substantiation” theory, Plaintiff does little more than make insufficient,
16 boilerplate allegations about an alleged “lack of controlled safety studies” for TNS®
17 products. (FAC ¶ 7.) Plaintiff also cites a single sentence – taken entirely out of
18 context – from a report that Dr. Fitzpatrick, the founder of SkinMedica, wrote
19 roughly seven years ago, and suggests that the statement somehow
20 “acknowledge[s]” a lack of evidence regarding the safety of growth factor products.
21 (*Id.* ¶ 53.) Specifically, Plaintiff quotes the following statement from Dr.
22 Fitzpatrick’s report: “More double-blind and controlled studies are needed to
23 confirm the preliminary clinical effects of growth factor products, and more controls
24 on product quality and stability need to be established.” (*Id.*) The full context of

25 ⁷ See, e.g., *Nat’l Council Against Health Fraud v. King Bio Pharm., Inc.*, 107
26 Cal. App. 4th 1336, 1344-45 (2003) (“private plaintiffs are not authorized to
27 demand substantiation for advertising claims”); *Otto*, 2013 U.S. Dist. LEXIS 53287,
28 at *16 n.10 (“claims for lack of substantiation do not give rise to a private cause of
action under the California consumer statutes”); *Eckler*, 2012 U.S. Dist. LEXIS
157132, at *3 (same); *Stanley v. Bayer Healthcare LLC*, Case No. 11cv862-
IEG(BLM), 2012 U.S. Dist. LEXIS 47895, at *18 (S.D. Cal. Apr. 3, 2012) (same).

1 Dr. Fitzpatrick's statement, however, makes crystal clear that it had absolutely
2 nothing to do with the safety of growth factor products. (RJN, Ex. 2.) Rather, Dr.
3 Fitzpatrick simply stated, in 2007, that more studies were needed to confirm that the
4 "[t]opical application of human growth factors . . . reduce[s] the signs and symptoms
5 of skin aging, including statically significant reduction in fine lines and wrinkles and
6 increase in dermal collagen synthesis." (*Id.* at 350.) Accordingly, his statement has
7 no applicability to Plaintiff's claims, and Plaintiff has not otherwise plausibly or
8 adequately alleged that the safety of TNS® products has not been substantiated. *See*
9 *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *28 ("When false advertising claims do
10 survive a motion to dismiss . . . there is not this kind of mismatch between the
11 representations at issue and the evidence that allegedly debunks them.").

12 Beyond the allegations discussed above, which upon examination do not
13 actually support her case, Plaintiff alleges no facts that could plausibly establish her
14 conclusory assertion that TNS® products pose undisclosed safety concerns. In the
15 end, Plaintiff's claims are doomed by her failure to cite a single fact or shred of
16 evidence that actually connects TNS® products to any "serious safety concerns."
17 Rule 9(b) requires much more to give Defendants sufficient "notice of the particular
18 misconduct which is alleged to constitute the fraud charged so that they can defend
19 against the charge and not just deny that they have done anything wrong." *Bly-*
20 *Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001). This Court should also
21 require more before allowing Plaintiff "to enlist the [C]ourt's authority to force
22 [d]efendant[s] to affirmatively warn consumers of a significant risk of harm . . .
23 from the use of [TNS®] product[s]." *Corral*, 2014 U.S. Dist. LEXIS 5880, at *15.

24 For these reasons, Plaintiff's safety-related claims must be dismissed.
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2. *Plaintiff fails to sufficiently and plausibly allege that TNS® products are “drugs,” not cosmetics*

Plaintiff also fails to plead sufficient facts to plausibly establish that TNS® products are “drugs,” not cosmetics. Her regulatory approval claims must therefore also be dismissed.

Under the FDCA, the determination of whether a product is a drug depends on its “intended use.” 21 U.S.C. § 321(g)(1)(B) & (C). Specifically, the FDCA defines “drug” as any article “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” or “intended to affect the structure or any function of the body of man.” *Id.* “Whether or not a product is a drug, for purposes of the FDCA, therefore depends not on the physical properties of the product or what effect the product has on humans but rather on the *intended* uses or effects of the product.” *Kasz Enters.*, 855 F. Supp. at 539; *see also United States v. An Article . . . Consistent of 216 Cartoned Bottles, More or Less . . . Sudden Change*, 409 F.2d 734, 739 (2d Cir. 1969) (“Congress has made a judgment that a product is subject to regulation as a drug if certain promotional claims are made for it.”).

In establishing the intended use of a product, “it is the vendor’s intent, as determined or inferred from labeling, promotional material, advertising, or any other relevant source, which controls, and not the actual physical effect on the human body.” *Kasz. Enters.*, 855 F. Supp. at 539; *see also Storage Spaces*, 777 F.2d at 1366 (same). In other words, objective intent is “demonstrated by, among other things, ‘labeling’ claims, advertising material, oral and written statements, and evidence that the vendor is aware that his product is being offered or used by others for a purpose for which it is neither labeled.” *Kasz Enters.*, 855 F. Supp. at 539; *Hanson v. United States*, 417 F. Supp. 30, 34-35 (D. Minn. 1976) (“Countless court decisions emphasize that it is the *intended use* of an article which determines whether or not it is a ‘drug,’ It is also well established that the ‘intended use’ of a product, within the meaning of the Act, is determined from its label,

1 accompanying label, promotional claims, advertising, and any other relevant public
2 source.”).

3 Here, Plaintiff’s FAC fails in several ways to allege sufficient facts or
4 evidence that could support a determination that TNS® products are “drugs” under
5 this standard.

6 *First and foremost*, Plaintiff’s FAC contains little more than a description of
7 the regulatory definitions of a “drug” alongside a formulaic recitation that those
8 definitions apply to TNS® products. (*See* FAC ¶ 40 (“TNS Products are articles
9 (other than food) used and intended to affect the structure or any function of the
10 human body, namely the skin.”)) This conclusory allegation leaves Defendants
11 guessing as to the “how” and “why” of Plaintiff’s alleged fraud theory, and is
12 plainly insufficient under well-established case law.

13 For example, in *Brazil v. Dole Food Co.*, 935 F. Supp. 2d 947 (N.D. Cal.
14 2013), the court granted dismissal of similar California consumer protection claims
15 based on alleged violations of the FDCA, because the complaint “provide[d] little
16 more than a long summary of the FDCA and its food labeling regulations, a
17 formulaic recitation of how the[] regulations appl[ied] to [the] [d]efendants’
18 products, and conclusory allegations regarding [the] [d]efendants’ ‘unlawfulness.’”
19 *Id.* at 964. Similarly, in *Park v. Welch Foods, Inc.*, No. 12-cv-6449-PSF, 2013 U.S.
20 Dist. LEXIS 139715 (N.D. Cal. Sept. 26, 2013), the court granted dismissal of
21 California consumer protection claims based on FDCA and Sherman FD&C Law
22 violations because the complaint was “filled with vague assertions that, despite
23 general references to multiple categories of state and federal regulations, le[ft]
24 unclear the precise nature of any alleged violation.” *Id.* at *14 (quotation marks
25 omitted). Plaintiff’s allegations here are similarly deficient and her FAC must
26 therefore be dismissed for the same reasons.

27 *Second*, Plaintiff’s comparisons to Regranex Gel and Kepivance – the only
28 two FDA-approved products she “knows of” that contain growth factors – are red

1 herrings because neither of those products are topical skin care products, neither are
2 used in a manner similar to TNS® products, and neither are alleged to have a similar
3 mixture or concentration of growth factors as TNS® products. (FAC ¶¶ 55-58.) It
4 is therefore entirely unclear what the regulatory status of those products has to do, if
5 anything, with the regulatory status of TNS® products.

6 *Third*, Plaintiff does not (because she cannot) allege that TNS® products are
7 the only skin care products that contain human growth factors, and her complaint is
8 noticeably silent about the regulatory status of other similar skin care products
9 containing growth factors. It is likewise telling that Plaintiff does not allege that the
10 FDA – which has primary jurisdiction to determine whether a product is a “drug” –
11 has ever said, or even suggested, that TNS® products (which have been sold for
12 over a decade) are “drugs” or otherwise unlawfully sold. *Biotics Res. Corp. v.*
13 *Heckler*, 710 F.2d 1375, 1377 (9th Cir. 1983) (“the FDA has primary jurisdiction to
14 determine the status of a product”).

15 *Fourth*, Plaintiff does not allege that any specific promotional material or
16 labeling claims for TNS® products demonstrate SkinMedica’s objective intent that
17 the products be used as drugs. To the contrary, she *affirmatively alleges the*
18 *opposite* – conceding that “SkinMedica maintains that most of its products
19 (*including TNS Products*) are intended to meet the FDA’s definition of cosmetic
20 products but are not intended to be drug products.” (FAC ¶ 46 (emphasis added).)

21 At bottom, Plaintiff’s pleading (or lack thereof) fails to plausibly establish –
22 let alone with the particularity required by Rule 9(b) – that TNS® products should
23 be classified as “drugs,” rather than cosmetics, and that Defendants therefore made
24 actionable omissions by failing to disclose that purported “fact.” Plaintiff’s
25 regulatory-approval claims should therefore be dismissed.

26 3. *Plaintiff also fails to sufficiently plead a duty to disclose and*
27 *scienter*

28 Plaintiff’s failure to plausibly and sufficiently plead that any of the “facts”

1 that Defendants allegedly omitted are “true” also destroys any allegation that
2 Defendants were under a duty to disclose those “facts,” or that they acted “with the
3 intent to defraud” by not disclosing those “facts.”⁸ Put differently, since Plaintiff
4 has failed to plausibly and sufficiently allege that any safety concerns or regulatory
5 approval issues even exist, she has necessarily failed to allege that Defendants had a
6 duty to make any additional disclosures.

7 Because neither of the fraud theories on which Plaintiff rests her claims
8 satisfy Rule 8(a) – let alone the heightened pleading requirements of Rule 9(b) – her
9 FAC must be dismissed.

10 **C. Plaintiff’s Failure To Differentiate Between Allergan And**
11 **SkinMedica Also Runs Afoul Of Rule 9(b)**

12 Plaintiff’s FAC must also be dismissed for failure to satisfy Rule 9(b) because
13 it fails to differentiate between Allergan and SkinMedica. As a consequence, the
14 FAC fails to inform – as it must – each Defendant separately of the allegations
15 surrounding its alleged participation in the fraud.

16 Rule 9(b) “does not allow a complaint to merely lump multiple defendants
17 together but ‘require[s] plaintiffs to differentiate their allegations when suing more
18 than one defendant . . . and inform each defendant separately of the allegations
19 surrounding his alleged participation in the fraud.’” *Altman v. PNC Mortgage*, 850
20 F. Sup. 2d 1057, 1070 (E.D. Cal. 2012) (quoting *Swartz v. KPMG LLP*, 476 F.3d
21 756, 764-65 (9th Cir. 2007)). Plaintiffs “must provide each and every defendant
22 with enough information to enable them to ‘know what misrepresentations are
23 attributable to them and what fraudulent conduct they are charged with.’” *Pegasus*

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25 ⁸ See *Hahn v. Mirda*, 147 Cal. App. 4th 740, 745 (2007) (“[T]he elements of
26 an action for fraud and deceit based on concealment are: (1) the defendant must
27 have concealed or suppressed a material fact, (2) the defendant must have been
28 under a duty to disclose the fact to the plaintiff, (3) the defendant must have
intentionally concealed or suppressed the fact with the intent to defraud the plaintiff,
(4) the plaintiff must have been unaware of the fact and would not have acted as he
did if he had known of the concealed or suppressed fact, and (5) as a result of the
concealment or suppression of the fact, the plaintiff must have sustained damage.”).

1 *Holdings v. Veterinary Centers of Am., Inc.*, 38 F. Supp. 2d 1158, 1163 (C.D. Cal.
2 1998) (quoting *In re Worlds of Wonder Sec. Litig.*, 694 F. Supp. 1427, 1433 (N.D.
3 Cal. 1988)). Plaintiff's FAC does not meet these pleading requirements.

4 Indeed, Plaintiff makes few, if any, individualized allegations against
5 SkinMedica and Allergan. Rather, the FAC simply refers to SkinMedica and
6 Allergan collectively as "Defendants" and alleges that "Defendants" engaged in
7 various forms of wrongdoing. (*See, e.g.*, FAC ¶ 64 ("Defendants actively concealed
8 the safety concerns, lack of controlled safety studies, and illegality associated with
9 TNS Product sales.")). The FAC similarly fails to inform any of the "Defendants"
10 *how* they are individually alleged to have participated in the wrongdoings alleged.
11 This is especially problematic because Allergan did not even acquire SkinMedica
12 until well over two years into the putative class period. (FAC ¶ 12.) In short,
13 Plaintiff's allegations are plainly insufficient. All of her claims should be dismissed
14 for failing to plead specific facts against Allergan and SkinMedica.

15 **D. Plaintiff's Claims Against Allergan Must Be Dismissed Because**
16 **Plaintiff Fails To Sufficiently Allege That SkinMedica Was**
Allergan's Agent

17 Given that Plaintiff acknowledges that TNS® products are SkinMedica
18 products – not Allergan products – her claims against Allergan appear to be based
19 entirely on her theory that SkinMedica was Allergan's agent.⁹ (FAC ¶¶ 3, 13.)
20 Under this Court's clear standards for pleading agency, Plaintiff has failed to
21 sufficiently allege an agency relationship, and her claims against Allergan must
22 therefore be dismissed. (FAC ¶ 13.)

23 "It is a general principle of corporate law deeply ingrained in our economic
24 and legal systems that a parent corporation . . . is not liable for the acts of its
25

26 ⁹ Plaintiff vaguely alleges, in one paragraph, that "[a]t present, SkinMedica
27 TNS Products are also promoted as Allergan products," but her FAC otherwise
28 contains no facts to support this conclusory assertion. (FAC ¶ 12.) Regardless, this
sentence is certainly not sufficient to state an independent claim against Allergan for
products that Plaintiff acknowledges belong to SkinMedica.

1 subsidiaries.” *United States v. Bestfoods*, 524 U.S. 51, 61 (2003) (quotation marks
2 omitted). One exception to this general principle, which Plaintiff incorrectly alleges
3 applies here, is when a subsidiary acts as an agent to its parent corporation. *See*
4 *Bowoto v. Chevron Texaco Corp.*, 312 F. Supp. 2d 1229, 1238 (N.D. Cal. 2004).

5 This Court has held that, in cases sounding in fraud, Rule 9(b) requires a
6 plaintiff “to plead this relationship with particularity.” *Holt v. Kormann*, No. SACV
7 11-1047-DOC (MLGx), 2012 U.S. Dist. LEXIS 5198, at *9 (C.D. Cal. Jan. 12,
8 2012) (Carter, J.). A complaint proceeding on an agency theory must therefore be
9 dismissed if it does not set forth specific facts showing: (1) the agent holds power to
10 alter legal relations between the principal and a third person and between the
11 principal and himself; (2) the agent is a fiduciary with respect to matters within the
12 scope of the agency; and (3) the principal has right to control the conduct of the
13 agent with respect to matters entrusted to him. *Id.* at *9-10. For example, in *Holt*,
14 this Court dismissed agency claims because the complaint failed to plead facts to
15 establish the elements of an agency relationship. *Id.* at *10 (“the FAC fails to raise
16 allegations supporting . . . a[n] [agency] theory, let alone plead them with
17 particularity”). Instead, the complaint rested entirely on an improper “legal
18 conclusion” about the existence of such a relationship, which this Court deemed
19 insufficient. *Id.* at *9; *see also Lent v. JP Morgan Chase Bank, N.A.*, No. SACV 11-
20 345 DOC RNBx, 2011 U.S. Dist. LEXIS 137553, at *7 (C.D. Cal. Nov. 29, 2011)
21 (Carter, J.) (“If Plaintiff wishes to rely on an agency theory, she must allege facts in
22 support thereof; legal conclusions are insufficient.”).

23 Likewise, here, Plaintiff does not plead any facts to establish the elements of
24 an agency relationship; rather, her agency claim rests entirely on the allegation that
25 “after December 19, 2012, SkinMedica, Inc. was and is an agent of Allergan, Inc.”
26 (FAC ¶ 13.) As in *Holt*, this is nothing more than a legal conclusion, and is
27 insufficient to plead agency. 2012 U.S. Dist. LEXIS 5198, at *9 (“Asserting that
28 Guerchon is a principal or officer of KRR is a legal conclusion.”).

1 Plaintiff's claims against Allergan must therefore be dismissed.

2 **E. Plaintiff's Requests For Punitive Damages And Injunctive Relief**
3 **Should Be Dismissed**

4 1. *Plaintiff did not properly plead punitive damages*

5 Plaintiff's FAC requests that Plaintiff and the class be awarded punitive
6 damages. (FAC ¶ 111.) But to state a claim for punitive damages, Plaintiff must
7 allege that an "officer, director, or managing agent" for each Defendant
8 "conscious[ly] disregarded, authorize[d], or ratif[ied]" each act of "oppression,
9 fraud, or malice" that each defendant allegedly committed. CAL. CIV. CODE
10 § 3294(a)-(b); *see also White v. Ultramar, Inc.*, 21 Cal. 4th 563, 572 (1999) ("For
11 corporate punitive damages liability, [Civil Code] section 3294, subdivision (b),
12 requires that the wrongful act giving rise to the exemplary damages be committed
13 by an 'officer, directors, or managing agent.'").

14 Plaintiff's FAC does not contain any allegations that officers, directors, or
15 managing agents for Allergan or SkinMedica consciously disregarded, authorized,
16 or ratified any acts of oppression, fraud, or malice. The request for punitive
17 damages must therefore be dismissed.

18 2. *Plaintiff does not have standing to seek injunctive relief*

19 Plaintiff bears the burden of showing that she has Article III standing to
20 pursue claims for injunctive relief. *Daimler Chrysler Corp. v. Cuno*, 547 U.S. 332,
21 352 (2006) ("[A] plaintiff must demonstrate standing separately for each form of
22 relief sought."); *D'Lil v. Best Western Encina Lodge & Suites*, 538 F.3d 1031, 1036
23 (9th Cir. 2008). Plaintiff has not carried this burden.

24 To have standing to seek prospective injunctive relief, Plaintiff must
25 "demonstrate that [she has] suffered or [is] threatened with a concrete and
26 particularized legal harm" and that there is "a sufficient likelihood that [she] will
27 again be wronged in a similar way." *Bates v. United Parcel Serv., Inc.*, 511 F.3d
28 974, 985 (9th Cir. 2007) (citations and quotation marks omitted). To satisfy the

1 “sufficient likelihood” inquiry, Plaintiff must “establish a real and immediate threat
2 of repeated injury.” *Id.* (quotation marks omitted). It is well-established that past
3 wrongs are not sufficient to create a “real and immediate threat of injury necessary
4 to make out a case or controversy.” *Id.*

5 Here, Plaintiff does not have standing to seek injunctive relief because her
6 claim is premised entirely on her past purchases of TNS® products. Importantly,
7 Plaintiff has not alleged that there is a “sufficient likelihood” that she will purchase
8 TNS® products in the future. *Id.* Nor can she plausibly allege future purchases
9 given the allegations in the FAC. For example, Plaintiff alleges that the human
10 growth factors “in TNS Products pose[] significant health risks, including but not
11 limited to the risk of cancer from unintended cell growth or other abnormalities.”
12 (FAC ¶ 48.) Given this allegation, it is hard to fathom that Plaintiff would purchase
13 TNS® products again in the future. And even if Plaintiff were tempted to purchase
14 TNS® products in the future, she will admittedly already know about the purported
15 safety concerns associated with them. Thus, Plaintiff cannot show that there is a
16 “sufficient likelihood” that she will be harmed by Defendants’ allegedly false
17 advertising in the future. This likewise dooms her ability to seek injunctive relief on
18 behalf of the class. *Wang v. OCZ Tech. Grp., Inc.*, 276 F.R.D. 618, 626 (N.D. Cal.
19 2011) (“Allegations that a defendant’s continuing conduct subjects unnamed class
20 members to the alleged harm is insufficient if the named plaintiffs are themselves
21 unable to demonstrate a likelihood of future injury.”).

22 For these reasons, Plaintiff’s request for injunctive relief should be dismissed.
23 *Campion v. Old Republic Home Protection Co., Inc.*, 861 F. Supp. 2d 1139, 1147-51
24 (S.D. Cal. 2012) (dismissing plaintiff’s request for injunctive relief for lack of
25 standing because the plaintiff did not show that there was “an actual and immediate
26 threat” that he would be “wronged again in the same way” by the defendant); *Cattie*
27 *v. Wal-Mart Stores, Inc.*, 504 F. Supp. 2d 939, 951 (S.D. Cal. 2007) (same).
28

1 **IV. CONCLUSION**

2 For the reasons discussed above, Plaintiff's FAC should be dismissed.

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4 Dated: June 23, 2014

IRELL & MANELLA LLP

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By: /s/ John C. Hueston

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John C. Hueston

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Attorneys for Defendants SkinMedica,
Inc. and Allergan, Inc.

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9

10 UNITED STATES DISTRICT COURT
11 CENTRAL DISTRICT OF CALIFORNIA
12 SOUTHERN DIVISION

13 Josette Ruhnke, an individual, *et al.*; on
behalf of herself and all others similarly
14 situated,

15 Plaintiff,

16 vs.

17 SkinMedica, Inc., a Delaware
Corporation, and Allergan, Inc., a
18 Delaware Corporation,

19 Defendants.
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Case No. 8:14-cv-00420 DOC (JPRx)

**[PROPOSED] ORDER GRANTING
DEFENDANTS' MOTION TO
DISMISS PLAINTIFF'S FIRST
AMENDED CLASS ACTION
COMPLAINT UNDER FEDERAL
RULE OF CIVIL PROCEDURE
12(b)(6)**

*[NOTICE OF MOTION AND MOTION,
AND MEMORANDUM OF POINTS
AND AUTHORITIES FILED
CONCURRENTLY HEREWITH]*

Date: August 4, 2014
Time: 8:30 a.m.
Ctrm: 9D
Judge: Hon. David O. Carter

1 The Court, having considered Defendants SkinMedica, Inc. and Allergan,
2 Inc.'s Motion to Dismiss Plaintiff's First Amended Class Action Complaint
3 ("FAC") Under Federal Rule of Civil Procedure 12(b)(6), all papers in support and
4 in opposition, and the argument of counsel, and good cause appearing therefore;

5 **IT IS HEREBY ORDERED** that Defendants' Motion to Dismiss is granted.
6 Plaintiff's FAC is hereby dismissed.

7 **IT IS SO ORDERED.**

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9 Dated: _____

10 Hon. David O. Carter
11 Judge, United States District Court
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