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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

Josette Ruhnke, an individual; Cindy Verity, an individual; on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

Allergan Sales, LLC, a Delaware Corporation (as Successor-In-Interest to SkinMedica, Inc. and doing business as "SkinMedica"), and Allergan, Inc., a Delaware Corporation;

Defendants.

No. SACV14-00420 DOC (RNBx)

CLASS ACTION (FRCP 23)

THIRD AMENDED CLASS ACTION COMPLAINT

Demand for Jury Trial

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Plaintiffs Josette Ruhnke and Cindy Verity ("Plaintiffs") bring this action on behalf of themselves and all others similarly situated against Allergan Sales, LLC ("Allergan Sales"), as successor-in-interest to SkinMedica, Inc. and doing business as SkinMedica,[1] and Allergan, Inc. (collectively with Allergan Sales, "Allergan" or "Defendants"). Plaintiffs' allegations against Defendants are based upon information and belief and upon investigation of Plaintiffs' counsel, except for allegations specifically pertaining to each Plaintiff, which are based upon each Plaintiff's personal knowledge.

I. OVERVIEW

1. As a matter of law and public interest, health care companies should identify and disclose any safety issues associated with their products before marketing or selling those products to consumers. If a company markets or sells drug products that have not been approved by the relevant government agencies when approval was required, particularly drug products that may raise safety concerns, the company should disclose the failure to conduct controlled safety studies and the illegality of product sales. Moreover, drug and cosmetic manufacturers should provide full disclosure as to the nature, type, and amount of any biological ingredients in, or components of, their products.

2. SkinMedica is or was a pharmaceutical company that markets and sells a line of so-called "cosmeceutical" skin care products under the brand name "TNS®" (hereafter, "TNS Products"). Allergan Sales LLC engages in manufacturing and wholesale of drugs and pharmaceutical products. Allergan continues to market and sell the SkinMedica TNS Product line.

[1] On December 31, 2014, SkinMedica, Inc. ("SkinMedica") was merged with and into Allergan Sales, LLC. Since the merger, Allergan Sales appears to be doing business as SkinMedica.

3. TNS Products contain a proprietary mix of "human growth factors" and other biological materials (formerly trademarked as "NouriCel-MD ®" and currently referred to as "TNS®" or "Human Fibroblast Conditioned Media"). This growth factor mix is believed to be a byproduct of artificial skin that was originally derived from human foreskin tissue.

4. Human growth factors are proteins intended to mobilize, stimulate, decrease or otherwise alter the production of cells in vivo. Importantly, they have the ability to initiate mitosis (cell division).

5. The human growth factors contained in TNS Products pose significant health risks, including but not limited to the risk of cancer. Indeed, growth factors are believed to contribute to the growth of tumor cells or other abnormalities.

6. In the course of marketing and selling TNS Products, Defendants do not disclose the particular growth factors in TNS®. Furthermore, there are other undisclosed biological ingredients in this so-called "Human Fibroblast Conditioned Media" branded as TNS®, including *bovine albumin* from cow blood, which may pose additional health risks. Bovine albumin is known to bind with hormones. Allergan, however, does not disclose whether TNS® contains hormones or how it affects hormones in the human body. TNS® also includes cytokines, matrix proteins, and soluble collagen, and TNS® may contain other undisclosed biological ingredients and/or pathogens as well.

7. TNS Products qualify as drugs (and cosmetics) under both federal laws and parallel state laws governing food, drugs, and cosmetics. Neither the U.S. Food and Drug Administration ("FDA") nor the California Department of Public Health ("DPH") has determined that TNS Products are safe, and neither has approved TNS Products for sale. Rather, TNS Products are misbranded under both federal laws and parallel state laws.

8. In marketing and selling TNS Products, Allergan materially omits and does not adequately disclose the safety concerns associated with human growth factors or any other undisclosed biological materials contained in the "TNS®" in each TNS Product. Moreover, Allergan does not disclose to consumers the lack of controlled safety studies for TNS Product sales or the fact that TNS Product sales are illegal in California and the United States. In addition, Allergan does not adequately disclose to consumers the type and amount of ingredients in TNS®, *i.e.*, the composition of TNS®.

9. As discussed more fully herein, Allergan's conduct violates California's Sherman Food, Drug, and Cosmetics Law ("Sherman FD&C") (California's Health & Safety Code §§ 109875 *et. seq.*) and the following consumer protection statutes: (i) California's Business & Professions Code §§ 17200, *et seq.* (the Unfair Competition Laws or "UCL"); (ii) California Civil Code §§ 1750, *et seq.* (the Consumers Legal Remedies Act or "CLRA"); (iii) California's Business & Professions Code §§ 17500, *et seq.* (the False Advertising Laws or "FAL"); and (iv) California Civil Code §§ 1709-1710 (Deceit). Plaintiffs bring this action to vindicate state law rights on behalf of themselves and other class members.

II. PARTIES

10. Plaintiff Josette Ruhnke is and was at all relevant times a citizen of the State of California, residing in the City of Mission Viejo, California. Plaintiff has purchased and used a SkinMedica TNS Product for personal, family, or household purposes, namely TNS Essential Serum, which she purchased from the office of Dr. Lorrie Klein at 30201 Golden Lantern, Laguna Niguel, California within the past four years.

11. Plaintiff Cindy Verity is and was at all relevant times a citizen of the State of California, residing in the City of San Diego, California. Plaintiff has purchased and used SkinMedica TNS Products for personal, family, or household

purposes. In or about mid-2010, Plaintiff Verity made initial purchases of TNS Essential Serum through the office of her dermatologist and then SkinMedica-approved physician, Dr. Mitchel Goldman, on her physician's recommendation. Since then, she made online purchases through SkinMedica of TNS Essential Serum, TNS Illuminating Eye Cream, TNS Eye Repair, and TNS Line Refine, which she purchased within the past four years. Plaintiff Verity is informed and believes that Allergan maintains the details of purchases she made through the SkinMedica website.

12. Plaintiffs looked at the product packaging and labeling. If Defendants had properly disclosed the true facts about their TNS Products, Plaintiffs either would not have purchased those products and/or they would have paid less for them.

13. Defendant Allergan Sales, LLC is a pharmaceutical company headquartered in Irvine, California, and incorporated in Delaware. Allergan Sales, LLC is a subsidiary of Defendant Allergan, Inc. Defendant Allergan Sales, LLC is liable as SkinMedica, Inc.'s successor-in-interest for the conduct challenged herein.

14. Defendant Allergan, Inc. is a healthcare company headquartered in Irvine, California, and incorporated in Delaware. Allergan, Inc. commercializes pharmaceuticals and other healthcare products. On information and belief, on or about December 19, 2012, Plaintiffs allege that Allergan, Inc. acquired SkinMedica, Inc. along with the assets, liabilities, rights, and responsibilities associated with the SkinMedica TNS Product line and merged SkinMedica with and into Allergan Sales, LLC. Allergan, Inc. is jointly liable for marketing TNS Products with its subsidiary Allergan Sales, LLC (d.b.a. SkinMedica).

15. SkinMedica TNS Products are also promoted as Allergan products. For example, the "Allergan Brand Box" is an online website describing Allergan's product brands. The website identifies *SkinMedica* products as one of the *Allergan* brands, and the website provides a direct link to the SkinMedica website. As a

further example, Allergan publishes "a list of *Allergan products*" for which it claims that "all safety concerns regarding *our products* are described on the package inserts that accompany them." [2]

III. JURISDICTION AND VENUE

16. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because the amount in controversy for the Class (defined in Part V below) exceeds $5,000,000, and the Class includes members who are citizens of a different state than Defendants.

17. This Court has personal jurisdiction over Plaintiff Josette Ruhnke because she resides in Mission Viejo, California and she submits to the Court's jurisdiction. This Court has personal jurisdiction over Plaintiff Cindy Verity because she resides in San Diego, California and she submits to the Court's jurisdiction.

18. This Court has personal jurisdiction over Defendant Allergan, Inc. because it is headquartered in this Central District of California and it conducts substantial business in this district and throughout the State of California.

19. This Court has personal jurisdiction over Defendant Allergan Sales because it is headquartered in this Central District of California, it is a subsidiary of Allergan and it conducts substantial business in this district and throughout the State of California.

20. Venue is proper in this Court under 28 U.S.C. § 1391(b) because one or more of the Defendants resides in this district, both Defendants reside in this State, Defendants have marketed and sold TNS Products within this district, and a substantial number of the acts and omissions alleged in this Complaint occurred within this district.

[2] Emphasis added. Plaintiffs allege that Allergan, Inc. is liable for cross-marketing TNS® Products.

IV. FACTUAL ALLEGATIONS

A. The Marketing and Sale of TNS Products.

21. Allergan's human growth factor mix was originally developed by a company called Advanced Tissue Sciences ("ATS"). On March 21, 2003, SkinMedica, Inc. acquired the "NouriCel" product line and all of the related assets from ATS. SkinMedica, Inc. began selling NouriCel in 2003 as its "TNS Recovery Complex" skin care product. At present, Allergan Sales markets several TNS Products, all of which contain substantially the same proprietary mix of human growth factors—*i.e.*, each TNS Product contains this same growth factor mix in one concentration or another.

22. Allergan develops, markets, distributes, and sells TNS Products through doctors' offices and retailers in California and nationwide.

23. TNS Products (current and former) include the following: (i) TNS Essential Serum®; (ii) TNS Recovery Complex®; (iii) TNS Ultimate Daily Moisturizer™; (iv) TNS Body Lotion™; (v) TNS Ceramide Treatment Cream™; (vi) TNS Eye Repair®; (vii) TNS Lip Plump System®; (viii) TNS Line Refine®; (ix) TNS Illuminating Eye Cream®; (x) TNS Body Mist®; (xi) TNS Hydrating Masque®; (xii) TNS Hydrafacial™ Serum®; and (xiii) TNS Recovery Complex Body Lotion®.

24. For purposes of the claims asserted in this action, each TNS Product is substantially similar to each of the other TNS Products insofar as: (a) each TNS Product is a topical skin care product that is developed, marketed, and sold by Allergan; (b) each TNS Product contains the same proprietary human growth factor mix called "TNS®" or "Human Fibroblast Conditioned Media" (formerly called NouriCel-MD®); (c) the labeling and packaging of each TNS Product omits the same material facts about TNS® and the human growth factors or other biological ingredients contained therein; and (d) Plaintiffs allege the same misbranding and

nondisclosures about TNS® and the human growth factors or other biological ingredients contained therein, under the same federal law and parallel state law requirements, for the same reasons with respect to each TNS Product.

25. Allergan promotes TNS Products as "cosmeceuticals" containing a mix of endogenous "growth factors" for skin rejuvenation. The term "cosmeceutical" conveys that a product is both a cosmetic and pharmaceutical. In SkinMedica, Inc.'s 2004 IPO summary listed on NASDAQ, the company publicized:

> We are a specialty pharmaceutical company focused on developing, acquiring and commercializing products that treat dermatologic conditions and diseases and improve the appearance of skin. Through our own sales force, we market and sell primarily to dermatologists both prescription pharmaceutical products and physician-dispensed, non-prescription skin care products, which we refer to as cosmeceuticals for marketing purposes.
>
> * * *
>
> Our cosmeceutical products are physician-dispensed, non-prescription products designed to enhance skin appearance, reduce signs of aging and provide other skin care benefits. Our leading cosmeceutical product line is Tissue Nutrient Solution, or TNS, which contains a biotechnology-derived, naturally occurring mix of growth factors and other key ingredients that, when applied topically, may improve the appearance of skin.

26. Each TNS Product lists "Human Fibroblast Conditioned Media" as an active ingredient, and each TNS Product contains the same human growth factor mix—TNS® (formerly known as NouriCel-MD). The labeling and packaging of

each TNS Product, however, omits the same material facts about TNS® (as discussed more fully below). Each TNS Product fails to identify the growth factors or other biological ingredients (such as bovine albumin from cow blood) contained in the so-called Human Fibroblast Conditioned Media (TNS®). Each TNS Product also fails to identify the relative amount of each growth factor or other biological ingredient in the so-called Human Fibroblast Conditioned Media (or TNS®).

27. The SkinMedica Product Guide described TNS Products as "skin rejuvenation" products vital to the anti-aging process that works with the skin's "natural cellular restructuring process." SkinMedica described growth factors in the Product Guide as proteins that "regulate cellular growth and the activity of skin cells." SkinMedica further described TNS®, a Tissue Nutrient Solution, as "a combination of growth factors and other naturally occurring elements that are crucial to the regeneration of healthy skin." A snapshot of a relevant portion of the SkinMedica 2011 Product Guide follows:

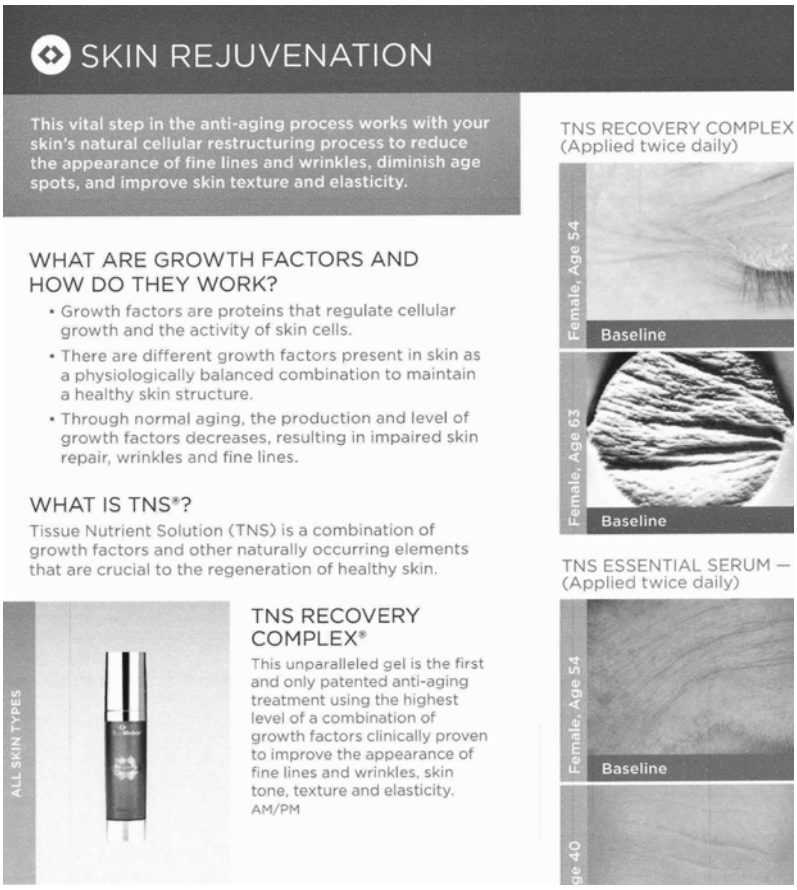

Figure 1

28. In the same Product Guide, SkinMedica also described the flagship TNS Recovery Complex® product as the first and only patented anti-aging treatment using a combination of "growth factors clinically proven to improve the appearance of fine lines and wrinkles, skin tone, texture, and elasticity."

B. Federal and California Food, Drug, and Cosmetics Laws.

29. The federal Food, Drug, and Cosmetics Act ("FDCA") (21 U.S.C. §§ 301 *et. seq.*) defines drugs to mean, in relevant part [C]: "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [21 § U.S.C. 321(g)(1)(C)]. Likewise, California's Sherman FD&C (California's Health & Safety Code §§ 109875 *et. seq.*) provides in pertinent part that "'Drug' means any of the following: . . .(c) Any article other than food, that is used or

intended to affect the structure or any function of the body of human beings or any other animal." [Cal. Health & Safety Code § 109925(c)]

30. Notably, there is no separate category for "cosmeceuticals" under the FDCA or Sherman FD&C. Products that qualify both as drugs and cosmetics must comply with regulations both for drugs and cosmetics.

31. The regulatory scheme for drugs (including drug products marketed as cosmeceuticals) varies based on whether the product is a prescription only product or an Over-The-Counter ("OTC") product. Under the federal scheme, drug manufacturers generally must file NDAs (New Drug Applications) with the FDA in order to start the regulatory process.

32. When a drug product qualifies as a "biologic" under FDA regulations, the manufacturer (or other responsible party) must file a Biologics License Application ("BLA") to start the process of obtaining FDA approval. Biologics are regulated like prescription drugs. The BLA is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce. BLA requirements include, among other things, pre-clinical studies, clinical studies, and labeling requirements.[3]

33. Under the FDCA, non-biologic OTC drug products that conform to "monographs" for particular drug categories could be marketed under federal law without an NDA, but they still would need to conform to the monographs in the Code of Federal Regulations, and the FDA has stringent labeling requirements for such drugs. In addition to providing specific and mandated information about the contents of OTC drugs, the FDCA requires labeling disclosures about dosages, warnings, and allergic reaction alerts (among other required disclosures).

[3] "Biologics" may include proteins derived from human sources and isolated through biotechnology methods.

34. The introduction or delivery of "misbranded" drug products in interstate commerce is prohibited under the FDCA, as is the misbranding of any drug product. [21 U.S.C. § 331] Under the FDCA, a drug product will be deemed "misbranded" for the following reasons (among others): if its labeling is false or misleading in any particular (such as by failing to disclose material facts about the drug product to consumers); if any required wording is not prominently displayed and clearly stated on the label; if the labeling does not bear adequate warnings against unsafe dosage, or methods, or duration of administration or application; if it is dangerous to health when used in the dosage or manner or with the frequency or duration prescribed, recommended or suggested in the labeling; or if there is a failure or refusal to comply with any requirement prescribed under the FDCA. [21 U.S.C. § 352]

35. California's Sherman FD&C parallels the FDCA in material part and adopts all nonprescription drug regulations and NDA regulations pursuant to the federal FDCA as state regulations.

36. Under California's Sherman FD&C laws, no one may sell any new drug unless it has an approved NDA or BLA under federal law or unless the California DPH has approved a new drug application. In addition, no person shall manufacture any drug in California unless he or she has a valid license from the California DPH.

37. The Sherman FD&C further provides that any drug that, because of the potentiality for harmful effect is not safe for use except under the supervision of a licensed practitioner requires a prescription and a product label warning that sale requires a prescription.

38. Furthermore, the drug product labeling and packaging must conform to specific state regulations and the labeling must bear adequate warnings against unsafe dosage or methods or duration of administration or application. All advertising materials must include a summary of side effects and contraindications.

39. Under the Sherman FD&C, much like under the federal FDCA, it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug that is misbranded, or to misbrand any drug. [Cal. Health & Safety Code §§ 111440, 111445] A drug is "misbranded" under the Sherman FD&C Law if it fails to comply with any of the above-described regulations or if its labeling is otherwise false or misleading in any particular (such as by failing to disclose material facts about the drug product to consumers). [Cal. Health & Safety Code §§ 111290, 111330, 111335]

40. Under the FDCA, a "cosmetic" product will be deemed "misbranded" if its labeling is false or misleading in any particular. [21 U.S.C. § 362] Under the governing regulations, the label of a cosmetic product must bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product. [21 C.F.R. § 740.1] Each ingredient used in a cosmetic product and each finished cosmetic product must be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded under the FDCA unless it contains the following conspicuous statement on the principal display panel: "WARNING—THE SAFETY OF THIS PRODUCT HAS NOT BEEN DETERMINED." [21 C.F.R. § 740.10]

41. Likewise, under the California Sherman FD&C, a "cosmetic" product is "misbranded" when its labeling is false or misleading in any particular (such as failing to disclose material facts about the cosmetic product to consumers). [Cal. Health & Safety Code §§ 110290, 111730] Failing to provide a warning of possible health concerns that may be associated with a cosmetic product, or failing to adequately substantiate the safety of each cosmetic ingredient prior to marketing (absent a suitable warning), constitutes misbranding under the Sherman FD&C.

42. A product that claims to enhance the appearance through physiological activity or by affecting the structure of the skin is a cosmetic *and* a drug product. The product categories "drug" and "cosmetic" are not mutually exclusive.

43. Notably, the FDA's Center for Drug Evaluation and Research (CDER) explicitly states that it regulates certain "categories of biological products mostly produced by biotechnology methods, including: … *growth factors* (proteins that affect the growth of a cell)." (emphasis added)[4]

C. TNS Products Qualify as Drug Products and Require Approval and Controlled Safety Studies Before Marketing.

44. TNS Products are articles (other than food) used and intended to affect the structure or any function of the human body, namely the skin. "Growth factors are proteins that regulate cellular growth, proliferation and differentiation under controlled conditions" and they affect "skin structure and function."[5] Indeed, TNS Products are designed to affect the skin's structure and function by inducing cell division and replication and stimulating skin cell production.[6] TNS Products do not strictly mask, cleanse, or moisturize the skin (as do plain cosmetics)—TNS Products use human growth factors to affect cell biology. Furthermore, the TNS® in TNS Products is designed to promote the formation of collagen and/or elastic fibers in the skin. More generally, TNS Products are marketed as regenerating healthy skin, reducing wrinkles, diminishing age spots, and improving skin texture and elasticity.

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[4] U.S. Food and Drug Administration, FDA 101: BIOLOGICAL PRODUCTS, at 2 (2008), *available at*: http://www.fda.gov/forconsumers/consumerupdates/-ucm048341.htm.

[5] *See* Role of Growth Factors in Skin Creams, Facts About the Skin from DermNet New Zealand Trust, *available at*: http://www.dermnetnz.org/-treatments/growth-factor-creams.html).

[6] Skin care products that are designed to regenerate skin cells have been recognized as drug products by the FDA. *See, e.g.*: http://www.fda.gov/Cosmetics/-GuidanceComplianceRegulatoryInformation/ucm074201.htm.

For each of these reasons, TNS Products qualify as drugs both under the FDCA and the Sherman FD&C, and regulations thereunder. As such, SkinMedica required FDA approval and/or California DPH approval before it could lawfully make, market, and sell TNS Products.

45. TNS Products could also be "biologics" insofar as they contain proteins (human growth factors) derived from human foreskin tissue and isolated through biotechnology methods.

46. Allergan's manufacture, marketing, and sale of TNS Products violate California's Sherman FD&C (Health & Safety Code §§ 109875 *et. seq.*) and constitutes misbranding thereunder (and corresponding provisions of federal law). The labeling and packaging fail to disclose important and mandatory information about use of TNS Products (and the human growth factors contained therein). Without limitation, TNS Products are misbranded and sold unlawfully as follows: (i) under § 111330, because the product labeling is misleading insofar as it fails to disclose all significant safety concerns and/or fails to disclose that safety has not been determined; (ii) under § 111335, because the product labeling and packaging do not conform to the requirements of Chapter 4 (commencing with § 110290); (iii) under § 111355 because the product labeling does not bear the established name and quantity of each active ingredient; (iv) under § 111360, because Allergan fails to include in all advertising materials a summary of all side effects and contraindications; (v) under § 111375, because the product labeling does not bear adequate warnings as to unsafe dosages or methods or duration of administration or application; and/or (vi) under § 111400, because it may be dangerous to health when used in the suggested frequency, duration, or dosage.

47. Moreover, Allergan's manufacture, marketing, and sale of TNS Products are unlawful under the Sherman FD&C because the products are sold

without an approved new drug application or BLA [California's Health & Safety Code § 111550].

D. TNS Products Are Not Approved by either the FDA or California DPH, and the Product Labeling Does Not Provide Adequate Safety Warnings.

48. Although TNS Products qualify as drugs under federal and state laws alike, they are not approved either by the FDA or California DPH.

49. Allergan markets TNS Products as if they satisfied government safety requirements when they have not.

50. On its website, SkinMedica maintains that most of its products (including TNS Products) are intended to meet the FDA's definition of cosmetic products but are not intended to be drug products.[7] Importantly, however, TNS Products are intended to use human growth factors (a byproduct originally derived from human foreskin tissue) to affect the structure and function of the skin through cell division, multiplication, and regeneration of skin tissue. Consequently, TNS Products meet the definition of "drugs" under both federal laws and parallel state laws.

51. Allergan wrongly pronounces that TNS Products do not require FDA approval (and implicitly the safety requirements that go with it). Because TNS Products are drug products being sold without FDA approval, and because Allergan does not provide mandatory and important product labeling information (as required by the FDA and California DPH for such products), they are misbranded under both the federal FDCA and parallel provisions of California's Sherman FD&C.

52. In particular, TNS Products require—but do not provide—disclosures of significant health risks associated with human growth factors. That is to say, Allergan markets and sells TNS Products without warning consumers that the TNS®

[7] Allergan Sales' own website, for example, has included such a representation at the bottom of the home page. *See* http://www.skinmedica.com.

in TNS Products may pose significant health risks, including but not limited to the risk of cancer from unintended cell growth or other abnormalities.

53. According to Allergan, all safety concerns associated with SkinMedica TNS Products are described on package inserts that accompany the products.[8]

54. In reality, the labeling and package inserts that accompany TNS Products do not describe the safety concerns at issue. The available scientific literature regarding human growth factors indicates that growth factors (including those in TNS) raise serious safety concerns, including tumor growth and adverse reactions (such as allergic reactions, eye issues, and rashes). Growth factors have known carcinogenic potential because they literally cause cells to grow, and every growth factor has certain tumor types that secrete the specific growth factor. TNS Products, however, do not describe these safety concerns.

55. For example, TNS Products contain a formula that purportedly blends over 110 growth factors, including KGF-1. Substantial scientific evidence shows that KGF-1 contributes to the growth of a number of cancers (*e.g.*, breast cancer).[9] The labeling and package inserts that accompany TNS Products do not identify any cancer risks due to the human growth factors contained in the products.

56. "Most of the research on human growth factors for skin has looked primarily at the issue of wound healing, and at short-term use. Much remains unknown at this time, especially in terms of long-term risk or stability, when growth factors are used in cosmetics and applied to skin. Well-controlled clinical studies are

[8] *See, e.g.*, Letter from Sulaiman Hamidi, Allergan Manager of Health & Safety, to Allergan Customers, May 2014 (emphasis added), *available on Allergan, Inc.'s website at*: http://www.allergan.com/assets/pdf/msds/ehs-material_safety_data_sheet_letter.pdf.

[9] *See* Journal of the National Cancer Institute, Vol. 98, No. 12, 2006.

lacking."[10] Wound healing treatments using human growth factors have a black box warning and are approved by the FDA. The dearth of well-controlled clinical studies is particularly dangerous in this context, since skin care products get used repeatedly and often over extended periods of time.

57. Dr. Fitzpatrick is a doctor credited with researching and developing TNS®, the key component of TNS Products. In a 2008 report written by Dr. Fitzpatrick, he acknowledged: "More double-blind and controlled studies are needed to confirm the preliminary clinical effects of growth factor products, and more controls on product quality and stability need to be established."[11] No such double-blind and controlled studies—particularly no controlled safety studies—have been reported and do not appear to be recognized by the FDA or California DPH.

58. TNS Products are misbranded even when evaluated as cosmetics. Namely, TNS Product labeling omits important safety information. Despite the facts that growth factors have been linked to cancer and have caused other adverse reactions, TNS product labeling does not warn of any increased health risk (whether cancer-related or otherwise). Moreover, TNS Products (and the growth factors and other biological ingredients contained therein) are not adequately substantiated for safety. Yet, TNS Product labeling does not warn of this fact.

E. Two Growth Factor Products with FDA Approval (Not TNS Products).

59. Plaintiffs know of two FDA-approved drug products available to the public that contain human growth factors—both products provide prominent safety warnings on their labels addressing significant health risks. *See* **Figures 2, 3,** and **4**

[10] *See* Role of Growth Factors in Skin Creams, Facts About the Skin from DermNet New Zealand Trust (*available at*: http://www.dermnetnz.org/-treatments/growth-factor-creams.html).

[11] *See* http://www.ncbi.nlm.nih.gov/pubmed/18045360.

below. Both products are authorized only for the treatment of specific and limited severe medical conditions.

WARNING: INCREASED RATE OF MORTALITY SECONDARY TO MALIGNANCY

An increased rate of mortality secondary to malignancy was observed in patients treated with 3 or more tubes of REGRANEX Gel in a postmarketing retrospective cohort study. REGRANEX Gel should only be used when the benefits can be expected to outweigh the risks. REGRANEX Gel should be used with caution in patients with known malignancy. (5.1)

Figure 2

5 WARNINGS AND PRECAUTIONS

5.1 Cancer and Cancer Mortality

REGRANEX Gel contains becaplermin, a recombinant human platelet-derived growth factor, which promotes cellular proliferation and angiogenesis. [*see Clinical Pharmacology (12.1)*] The benefits and risks of becaplermin treatment should be carefully evaluated before prescribing. Becaplermin should be used with caution in patients with a known malignancy.

Malignancies distant from the site of application have occurred in becaplermin users in both a clinical study and postmarketing use, and an increased rate of death from systemic malignancies was seen in patients who have received 3 or more tubes of REGRANEX Gel.

In a follow-up study, 491 (75%) of 651 subjects from two randomized, controlled trials of becaplermin gel 0.01% were followed for a median of approximately 20 months to identify malignancies diagnosed after the end of the trials. Eight of 291 subjects (3%) from the becaplermin group and two of 200 subjects (1%) from the vehicle/standard of care group were diagnosed with cancers during the follow-up period, a relative risk of 2.7 (95% confidence interval 0.6–12.8). The types of cancers varied and all were remote from the treatment site.

In a retrospective study of a medical claims database, cancer rates and overall cancer mortality were compared between 1,622 patients who used REGRANEX Gel and 2,809 matched comparators. Estimates of the incidence rates reported below may be under-reported due to limited follow-up for each individual.

- The incidence rate for all cancers was 10.2 per 1,000 person years for patients treated with REGRANEX Gel and 9.1 per 1,000 person years for the comparators. Adjusted for several possible confounders, the rate ratio was 1.2 (95% confidence interval 0.7–1.9). Types of cancers varied and were remote from the site of treatment.
- The incidence rate for mortality from all cancers was 1.6 per 1,000 person years for those who received REGRANEX Gel and 0.9 per 1,000 person years for the comparators. The adjusted rate ratio was 1.8 (95% confidence interval 0.7–4.9).
- The incidence rate for mortality from all cancers among patients who received 3 or more tubes of REGRANEX Gel was 3.9 per 1,000 person years and 0.9 per 1,000 person years in the comparators. The adjusted rate ratio for cancer mortality among those who received 3 or more tubes relative to those who received none was 5.2 (95% confidence interval 1.6–17.6). [*see Boxed Warning*]

5.2 Application Site Reactions

If application site reactions occur, the possibility of sensitization or irritation caused by parabens or m-cresol should be considered. Consider interruption or discontinuation and further evaluation (e.g. patch testing) as dictated by clinical circumstances.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In a follow-up study from two randomized, controlled trials, an increased rate of cancer remote from the becaplermin treatment site was observed in subjects treated with REGRANEX Gel. [*see Warnings and Precautions (5.1)*]

In clinical trials, erythematous rashes occurred in 2% of patients treated with REGRANEX Gel (and good ulcer care) or placebo (and good ulcer care), and none in patients receiving good ulcer care alone. Patients treated with REGRANEX Gel did not develop neutralizing antibodies against becaplermin.

6.2 Postmarketing Experience

An increased rate of mortality secondary to malignancy was observed in patients treated with 3 or more tubes of REGRANEX Gel in a postmarketing retrospective cohort study. [*see Boxed Warning and Warnings and Precautions (5.1)*]

Burning sensation at the site of application and erythema have been reported during post-approval use of REGRANEX Gel. Because post approval adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the drug.

Figure 3

5 WARNINGS AND PRECAUTIONS

5.1 Potential for Stimulation of Tumor Growth

The safety and efficacy of Kepivance have not been established in patients with non-hematologic malignancies. The effects of Kepivance on stimulation of KGF receptor-expressing, non-hematopoietic tumors in patients are not known. Kepivance has been shown to enhance the growth of human epithelial tumor cell lines *in vitro* and to increase the rate of tumor cell line growth in a human carcinoma xenograft model *[see Clinical Pharmacology (12.1)]*.

6 ADVERSE REACTIONS

The most common adverse reactions attributed to Kepivance were skin toxicities (rash, erythema, edema, pruritus), oral toxicities (dysesthesia, tongue discoloration, tongue thickening, alteration of taste), pain, arthralgias, and dysesthesia. The median time to onset of cutaneous toxicity was 6 days following the first of 3 consecutive daily doses of Kepivance, with a median duration of 5 days. In patients receiving Kepivance, dysesthesia (including hyperesthesia, hypoesthesia, and paresthesia) was usually localized to the perioral region, whereas in patients receiving placebo dysesthesias were more likely to occur in extremities.

Figure 4

60. There is one FDA-approved topical formula containing human growth factors: REGRANEX® Gel (Becaplermin). Regranex was approved by the FDA under a BLA, because Regranex contains a recombinant human platelet-derived growth factor (rhPDGF-BB) for topical administration. Accordingly, growth factors derived from human cells have been recognized by the FDA as biologics.

61. Regranex, which is used for diabetic foot ulcers, includes a black box warning that describes a fivefold increase in deaths from cancer when three or more tubes are used. The Regranex label warns that the product contains "a recombinant human platelet-derived growth factor, which promotes cellular proliferation and angiogenesis," and further warns that the benefits and risks of the growth factor treatment should be carefully evaluated (**Figure 3** at 5.1). By contrast, the labeling and package inserts that accompany TNS Products do not provide similar safety warnings.

62. There is one FDA-approved intravenous drug containing growth factors: Kepivance, which was approved for treatment of severe oral mucositis. According to its label, "Kepivance has been shown to enhance the growth of human epithelial tumor cell lines in vitro" and poses other risks such as skin toxicities (**Figure 4**). By contrast, the labeling and packaging of TNS Products do not provide similar safety warnings.

F. Defendants Had a Duty to Disclose Safety Concerns about TNS Products and the True Nature of TNS Product Sales.

63. Defendants had a duty to disclose: (a) safety concerns posed by the human growth factor mix in TNS Products; (b) the lack of government controlled safety studies and the lack of other studies substantiating the safety of the TNS® or growth factors in TNS products; (c) the illegality of TNS Product sales; and (d) the type and amount of the ingredients in TNS® -- *i.e.*, the composition of TNS®.

64. At all relevant times, Defendants had superior and exclusive knowledge of material facts about the health risks and related safety concerns posed by the human growth factor mix in TNS Products, and about the lack of controlled safety studies and illegality of TNS Product sales. Such facts were not known or reasonably accessible to Plaintiffs. Plaintiffs are informed and believe that Defendants had superior and exclusive knowledge of these material facts through its product testing and internal legal reviews (and Allergan's due diligence review in connection with the acquisition of SkinMedica, Inc.) that would have revealed the safety concerns associated with TNS Products, the lack of controlled safety studies, the illegality of TNS Product sales, and the composition of TNS®.

65. Plaintiffs are further informed and believe that Defendants were aware of consumer complaints and scholarly research about safety concerns and adverse reactions associated with TNS® or the human growth factors or other biological ingredients contained therein, which information was reasonably known to Defendants at all relevant times.

66. Defendants were familiar with the requisite federal and state regulatory scheme having sought approval for a variety of drug products other than TNS Products. Plaintiffs are informed and believe that, through consumer complaints, competitors, and/or market research, Defendants were aware that they were marketing and selling TNS Products without proper government approvals and without controlled safety studies, but Defendants continued to market and sell such products anyway.

67. Defendants actively concealed material facts from Plaintiffs and members of the Class about safety concerns associated with TNS Products, the lack of controlled safety studies for TNS Products, the illegality of TNS Product sales, and the composition of TNS®. Defendants also ignored reports of adverse reactions from human growth factors.

68. At the same time, Defendants were intimately aware of the true nature of the TNS® in TNS Products, including that it was designed to affect the structure and/or function of the skin, and thus knew or reasonably should have known that TNS Products were drug products within the governing federal and state law definitions. Nonetheless, Defendants represented to consumers that TNS Products were strictly considered cosmetics (rather than drugs). Defendants also wrongly informed consumers that TNS Product packaging disclosed all relevant safety information. In this manner, Defendants actively concealed the safety concerns, lack of controlled safety studies, illegality associated with TNS Product sales, and composition of TNS®.

69. By marketing and selling TNS Products, Defendants effectively represented that the products were recognized as safe by the FDA and California DPH, and that they were legally saleable, when they were not. Such representations were misleading absent full disclosure of material facts about safety concerns, failure to determine the safety of growth factors in TNS Products, illegality of TNS Product sales, and composition of TNS®.

70. Reasonable consumers would consider the omitted facts to be important in determining whether or not to purchase TNS Products, namely the omitted facts regarding: safety concerns, the lack of controlled safety studies, illegality of sales, and the composition of TNS®. To be sure, nondisclosures about such facts are generally recognized to be material omissions.

G. Plaintiffs and Members of the Class Suffered Injury as a Result of Defendants' Misconduct.

71. Allergan's conduct violates California's UCL, CLRA, FAL, and civil laws against deceit. In particular, this class action seeks to remedy Allergan's unlawful, unfair, and deceptive marketing and sale of misbranded drug products without full and adequate disclosure of: (a) significant safety concerns, (b) the lack

of controlled safety studies, (c) the illegality of product sales, and (d) the composition of TNS®. Allergan's conduct violates California's consumer protection laws and injures consumers in California and nationwide.

72. At all relevant times, Allergan has been under a duty to Plaintiffs and other similarly situated consumers to identify and disclose the true health risks and related safety concerns associated with human growth factors contained in TNS Products. At the same time, Allergan has been under a duty to disclose to consumers the lack of controlled safety studies, the illegality of TNS Product sales, and the type and amount of ingredients in TNS®.

73. Since at least March 31, 2004, SkinMedica (now Allergan) has failed to disclose the significant safety concerns associated with TNS Products, the lack of controlled safety studies, the illegality of TNS Product sales, and the composition of TNS®. Plaintiffs are informed and believe that Defendants have not conducted adequate safety studies on TNS Products.

74. Upon information and belief, at least thousands of consumers have been victims of Defendants' unlawful, unfair, and deceptive marketing and sale of TNS Products. Defendants know or reasonably should know that the marketing and sale of TNS Products was and is unlawful, unfair, and deceptive.

75. The true facts about safety concerns, lack of controlled safety studies, illegality of TNS Product sales, and the composition of TNS® would be material to a reasonable consumer. Therefore, consumer reliance upon Defendants' material omissions can and should be presumed as a matter of law.

76. Plaintiffs purchased TNS Products while unaware of significant safety concerns, the lack of controlled safety studies, the illegality of product sales, or the composition of TNS®.

77. Plaintiffs and members of the Class lost money as a result of Defendants' material omissions regarding the health risks, legal status of TNS Products, and composition of TNS®.

78. Based on the material omissions described herein, Plaintiffs and members of the Class were induced to and did purchase TNS Products instead of saving their money or purchasing competing skin care products.

79. Plaintiffs and members of the Class altered their position to their detriment and suffered injuries that include payment of the purchase price for TNS Products and/or payment of price premiums for such products.

80. At the time Plaintiffs purchased TNS Products, Plaintiffs relied upon Defendants' material omissions of fact regarding significant safety concerns, the lack of controlled safety studies, the illegality of product sales, and the composition of TNS®. Plaintiffs and other similarly situated consumers were likely to be misled, and they reasonably and justifiably relied to their detriment on Defendants' omissions of material facts.

81. If Allergan had disclosed the truth about significant safety concerns, the lack of controlled safety studies, the illegality of product sales, and the composition of TNS®, Plaintiffs would not have purchased TNS Products or paid as much for them.

82. As a result of the alleged misconduct, Allergan has generated substantial revenues from the sale of TNS Products.

83. Plaintiffs, individually and on behalf of all others similarly situated, seek damages, restitution and injunctive relief to put an end to Defendants' unfair business practices.

V. CLASS ACTION ALLEGATIONS

84. Plaintiffs seek certification of a Class defined as follows:

> All consumers nationwide who: (i) purchased any TNS Product (ii) for personal, family, or household purposes

> (iii) at any time from March 31, 2004 to the date of class certification ("The Class"). Excluded from the Class are Defendants; the officers, directors or employees of Defendants; any entity in which Defendants have a controlling interest; and any affiliate, legal representative, heir or assign of Defendants. Also, excluded from the Class are any federal, state or local governmental entities, any judicial officer presiding over this action and the members of his/her immediate family and judicial staff, and any juror assigned to this action.

85. Plaintiffs do not assert any personal injury claim in this action as a result of using Defendants' TNS Products.

86. Plaintiffs do not know the exact number of Class members at the present time. However, due to the nature of the trade and commerce involved, there appear to be thousands of Class members such that joinder of all Class members is impracticable.

87. The Class is ascertainable and notice can be provided through techniques similar to those customarily used in other consumer fraud cases and complex class actions, and through Allergan's business records.

88. There are questions of law and fact common to the Class. Defendants' unlawful omissions similarly impact Class members, all of who purchased one or more TNS Products.

89. Plaintiffs assert claims that are typical of the Class. Plaintiffs and all Class members have been subjected to the same wrongful conduct because they all have purchased Defendants' misbranded TNS Products that contained TNS®, that lacked regulatory approval from the FDA and California DHS and thus bypassed controlled safety studies, that failed to provide adequate warnings of health risks and the fact that safety of the products has not been determined, and that failed to disclose the composition of TNS®. As a result, and like other members of the Class, Plaintiffs purchased and paid an amount for TNS Products which they otherwise would not have paid.

90. Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs are represented by counsel competent and experienced in both consumer protection and class action litigation.

91. Class certification is appropriate because Defendants have acted on grounds that apply generally to the Class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the Class as a whole.

92. Class certification is also appropriate because common questions of law and fact substantially predominate over any questions that may affect only individual members of the Class, including, *inter alia*, the following:

a. Whether TNS Products qualify as drug products under federal and parallel state laws governing food, drugs, and cosmetics;

b. Whether TNS Products are misbranded under federal and parallel state laws governing food, drugs, and cosmetics;

c. Whether the manufacture, marketing, or sale of TNS Products are unlawful under federal and parallel state laws governing food, drugs, and cosmetics;

d. Whether Defendants had a duty to disclose material facts regarding safety concerns associated with TNS Products, or the lack of controlled safety studies, or the illegality of TNS Product sales, or the composition of TNS®;

e. Whether Defendants failed to disclose material facts regarding safety concerns associated with TNS Products, such as the potential for uncontrolled cell growth or other adverse reactions;

f. Whether Defendants failed to disclose material facts regarding the lack of controlled safety studies for TNS Products;

g. Whether Defendants failed to disclose material facts regarding the illegality of TNS Product sales;

h. Whether Defendants failed to disclose material facts regarding the type and/or amount of ingredients in TNS®;

i. Whether Defendants' nondisclosures would be material to a reasonable consumer;

j. Whether Defendants' nondisclosures constitute an unlawful business practice in violation of the UCL;

k. Whether Defendants' nondisclosures constitute an unfair business practice in violation of the UCL;

l. Whether Defendants' nondisclosures were likely to deceive a reasonable consumer in violation of the UCL, CLRA, or FAL;

m. Whether Defendants knowingly or willfully failed to disclose significant safety concerns associated with TNS Products;

n. Whether Defendants knowingly or willfully failed to disclose material facts regarding the lack of controlled safety studies of TNS Products;

o. Whether Defendants knowingly or willfully failed to disclose material facts regarding the illegality of TNS Product sales;

p. Whether Defendants knowingly or willfully failed to disclose material facts regarding the composition of TNS®;

q. Whether the challenged practices harmed Plaintiffs and members of the Class; and

r. Whether Plaintiffs and members of the Class are entitled to damages, restitution, equitable relief, and/or injunctive relief.

93. A class action is superior to other available methods for the fair and efficient adjudication of this controversy, since joinder of all the individual Class members is impracticable. Furthermore, because the restitution and/or damages suffered, and continue to be suffered, by each individual Class member may be relatively small, the expense and burden of individual litigation would make it very difficult or impossible for individual Class members to redress the wrongs done to each of them individually and the burden imposed on the judicial system would be enormous.

94. The prosecution of separate actions by the individual Class members would create a risk of inconsistent or varying adjudications, which would establish incompatible standards of conduct for Defendants. In contrast, the conduct of this

action as a class action presents far fewer management difficulties, conserves judicial resources and the parties' resources, and protects the rights of each Class member.

VI. CAUSES OF ACTION

FIRST CAUSE OF ACTION

VIOLATION OF THE CALIFORNIA UNFAIR COMPETITION LAW (CAL. BUS. & PROF. CODE § 17200, *et seq.*)

95. Plaintiffs reallege and incorporate by reference all paragraphs alleged herein.

96. Cal. Bus. & Prof. Code § 17200 prohibits any "unlawful, unfair, or fraudulent business act or practice." Defendants have engaged in unlawful, and unfair, and fraudulent business acts and practices in violation of the UCL.

97. Defendants have violated the unlawful prong by virtue of their violations of the Sherman Food Drug & Cosmetics Laws, California's Health & Safety Code §§ 109875 *et seq.*, and selling misbranded drug and cosmetic products thereunder.

98. In addition, Defendants have violated the unlawful prong by virtue of their violations of the CLRA, the FAL, and Cal. Civil Code §§ 1709-1710.

99. Defendants have violated the unfair prong of section 17200 because the acts and practices set forth in the Complaint—including the omission of product safety concerns—offend established public policy. The challenged conduct is substantially injurious to consumers. The harm that these acts and practices cause to consumers greatly outweighs any benefits associated with them. Reasonable consumers are not in a position to know and understand the safety concerns posed by the TNS Products being made, marketed, and/or sold by Defendants or the lack of controlled safety studies for such products.

100. Defendants' conduct also impairs competition within the market for skin care products, and stops Plaintiffs and Class members from making fully

informed decisions about the kind of skin care products to purchase or the price to pay for such products.

101. Defendants have violated the fraudulent prong of section 17200 because their material omissions about safety concerns associated with TNS Products were likely to deceive a reasonable consumer and the true facts would be material to a reasonable consumer. Moreover, Defendants material omissions about the lack of controlled safety studies of TNS Products, the illegality of TNS product sales, and/or the composition of TNS® were likely to deceive a reasonable consumer, and the true facts would be material to a reasonable consumer.

102. Plaintiffs have suffered injury in fact, including the loss of money, as a result of Defendants' unlawful, unfair, and/or deceptive practices. As set forth more fully above, in purchasing TNS Products, Plaintiffs relied on Defendants to make complete disclosures of all material information about her purchase. Had they known about the safety concerns associated with TNS Products (including but not limited to an increased risk of cancer), or that the products were misbranded, lacked required safety studies, and were legally unsaleable, or that the TNS® contained biological ingredients such as bovine albumin from cows blood, they would not have purchased those TNS Products or they would have paid less for them.

103. All of the wrongful conduct alleged herein occurred, and continues to occur, in the conduct of SkinMedica's business. Defendants' wrongful conduct is part of a general practice that is still being perpetuated and repeated throughout the State of California and nationwide.

104. Plaintiffs request that this Court enter such orders or judgments as may be necessary to enjoin Defendants from continuing its unlawful, unfair, and deceptive business practices, to restore to Plaintiffs and members of the Class any money that Defendants acquired by unfair competition (as provided in Cal. Bus. & Prof. Code § 17203), and to provide such other relief as set forth below.

SECOND CAUSE OF ACTION

VIOLATIONS OF THE CONSUMERS LEGAL REMEDIES ACT (CAL. CIV. CODE § 1750, *et seq.*)

105. Plaintiffs reallege and incorporate by reference all paragraphs alleged herein.

106. Defendants are "persons" under Cal. Civ. Code § 1761(c).

107. Plaintiffs are "consumers," as defined by Cal. Civ. Code § 1761(d), who purchased TNS Products, which are goods that were made, marketed, and/or sold by Defendants.

108. Cal. Civ. Code § 1770(a)(2) prohibits "[m]isrepresenting the source, sponsorship, approval, or certification of goods or services." Defendants violated this provision by marketing and selling misbranded drug and cosmetic products, which required controlled safety studies prior to sale, but which did not have it. The sale of each TNS Product was a misrepresentation to consumers that the product was recognized as safe by the FDA and/or California DPH.

109. Cal. Civ. Code § 1770(a)(5) prohibits "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have…." Defendants violated this provision by marketing and selling misbranded drug and cosmetic products that posed safety concerns. The sale of each TNS Product misrepresented that the product was free of undisclosed safety concerns. In addition, the sale of each TNS Product misrepresented that the product had been determined to be safe (*i.e.*, through controlled safety studies) and was otherwise legally offered for sale. Furthermore, the sale of each TNS Product misrepresented the type and amount of ingredients.

110. Cal. Civ. Code § 1770(a)(7) prohibits "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another." Defendants violated this provision by marketing and selling misbranded drug products that posed safety concerns. The

sale of each TNS Product misrepresented that the product was free of undisclosed safety concerns. In addition, the sale of each TNS Product misrepresented that the product had been determined to be safe (*i.e.*, through controlled safety studies) and was otherwise legally offered for sale. Furthermore, the sale of each TNS Product misrepresented the composition of the product.

111. The CLRA (including §§ 1770(a) (2), (5), (7)) supports claims for omissions of material fact that Defendants were obligated to disclose. In this case, Defendants were obligated to disclose—but failed to disclose—the known safety concerns associated with human growth factors or other undisclosed biological ingredients contained in TNS Products, the lack of controlled safety studies for TNS Products, the illegality of TNS Product sales, and the composition of TNS®.

112. Plaintiffs and the Class lost money and were damaged as a result of Defendants' violations of the CLRA because: (a) they purchased TNS Products due to the material omissions about the products' safety status, saleability, and composition; and (b) they would not have purchased TNS Products on the same terms if the true facts had been known. Absent these material omissions, Plaintiffs and the Class would not have purchased TNS Products at all or they would have paid less for them.

113. As a result of these violations, Defendants have caused and continue to cause damage to Plaintiffs and members of the Class and, if not stopped, will continue to harm them.

114. In accordance with Cal. Civ. Code § 1780(a), Plaintiffs and members of the Class seek injunctive and equitable relief for Defendants' violations of the CLRA.

115. In addition, having mailed appropriate notice and demand in accordance with Cal. Civil Code § 1782(a) & (d), Plaintiffs hereby amend the original Complaint to include a request for damages. In particular, pursuant to and in accordance with

§1782, Plaintiff Ruhnke sent written notice to Defendants via certified mail on March 19, 2014, addressing the alleged violations under CLRA §1770 as detailed in the original Complaint (based on the unfair, unlawful, and deceptive marketing and sale of TNS Products without adequate safety disclosures), demanding that Defendants reimburse Plaintiff and class members for the alleged violations of §1770. Within 30 days of receiving Plaintiff's notice, which was extended until May 19, 2014, Defendants failed to make the appropriate reimbursements or other remedies requested by Plaintiff Ruhnke, and Defendants failed to agree to give the requested remedies within a reasonable time. Furthermore, Defendants failed to identify similarly-situated consumers who purchased TNS Products; Defendants failed to notify such consumers that upon their request Defendants shall make the appropriate reimbursement or other remedy; Defendants did not give the reimbursements requested on behalf of such consumers, and Defendants did not offer to do so in a reasonable time. Further, Defendants did not cease from engaging in the alleged CLRA violations, and Defendants did not agree to do so in a reasonable time. Accordingly, Plaintiffs now amend their Complaint to include a request for damages under the CLRA, and Plaintiffs seek all relief authorized under Civil Code § 1780, including compensatory and punitive damages, and attorneys' fees and costs, as requested more fully in the Prayer for Relief.

116. Plaintiffs include an affidavit with this Complaint reflecting that venue in this District is proper, to the extent such an affidavit is required by Cal. Civ. Code § 1780(d) in federal court.

THIRD CAUSE OF ACTION

VIOLATIONS OF THE FALSE ADVERTSING LAW (CAL. BUS. & PROF CODE §§ 17500, *et seq.*)

117. Plaintiffs reallege and incorporate by reference all paragraphs alleged herein.

118. California Business & Professions Code §§ 17500, *et seq.* (the "FAL") broadly proscribes deceptive advertising in this State. Section 17500 makes it unlawful for any corporation intending to sell products or perform services to make any statement in advertising those products or services concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading, or not to sell those products or services as advertised at the price stated therein, or as so advertised.

119. When the seller has a duty to disclose material facts about a product, the sale of the product to consumers without disclosure of such material facts runs afoul of the FAL.

120. Allergan markets and sells the TNS Product line as if the products are free of significant safety concerns, when in fact, they are not. Allergan effectively misrepresents the health risks posed by certain human growth factors or other biological ingredients found in TNS®, and the failure to conduct adequate safety evaluations thereof.

121. Allergan also markets and sells the TNS Product line as if the safety of such products has been determined and the products are legally offered for sale, when in fact, product safety has not been substantiated, such as through controlled safety studies, the products actually are misbranded and sold illegally, and the composition of TNS® has been concealed from consumers.

122. Section 17535 effectively provides that the Court may enjoin any corporation or other person who violates the FAL, and may make such orders or judgments as may be necessary to prevent the use of such practices, or which may be necessary to restore to any person in interest any money or property which may have been acquired by means of such practices. An FAL claim may be prosecuted by any person who has suffered injury in fact and has lost money or property as a result of a violation of the FAL. The action may be prosecuted on a representative basis when it meets the traditional class action requirements.

123. Plaintiffs and the Class have suffered injury in fact and lost money or property as a result of Defendants' violations of the FAL because: (a) they purchased TNS Products due to the material omissions about safety concerns, the lack of controlled safety studies, the illegality of product sales, and the composition of TNS®; and (b) they would not have purchased TNS Products on the same terms if the true facts had been known. Absent the material omissions, Plaintiffs and the Class would not have purchased TNS Products at all or they would have paid less for them.

124. As a result of these violations, Defendants have caused and continue to cause damage to Plaintiffs and members of the Class and, if not stopped, will continue to harm them.

125. Plaintiffs and members of the Class request that this Court enjoin Defendants from continuing to market and sell TNS Products without required safety studies, disclosure of known safety concerns, and disclosure of the composition of TNS®.

126. In addition, Plaintiffs and members of the Class request that this Court enter such orders or judgments as may be necessary to restore to any person in interest any money which may have been acquired by means of such material omissions and deceptive marketing and selling of TNS Products to consumers.

FOURTH CAUSE OF ACTION

DECEIT (CAL CIV. CODE §§ 1709-1710)

127. Plaintiffs reallege and incorporate by reference all paragraphs alleged herein.

128. Under California Civil Code § 1709: "One who willfully deceives another with intent to induce him to alter his position to his injury or risk, is liable for any damage which he thereby suffers."

129. Under California Civil Code § 1710, Deceit includes (among other things): "[i] The suggestion, as a fact, of that which is not true, by one who does not believe it to be true; or [ii] the suppression of a fact, by one who is bound to disclose it, or who gives information of other facts which are likely to mislead for want of communication of that fact."

130. By marketing and selling TNS Products, Defendants willfully suggest that they have completed adequate safety studies for TNS Products, and are lawfully offered for sale. The suggested facts are not true, and Plaintiffs are informed and believe that Defendants do not believe them to be true.

131. Plaintiffs are informed and believe that Defendants willfully suppressed and omitted the material facts concerning safety concerns, the lack of controlled safety studies, illegality of TNS Product sales, and the composition of TNS®.

132. Defendants had a duty to disclose these material facts. The duty to disclose arises from: (a) their superior and exclusive knowledge of these material facts, which were not known or reasonably accessible to Plaintiffs; (b) their active concealment of these material facts, and/or (c) their marketing and sale of TNS Products strictly as skin rejuvenating cosmetics, which is likely to mislead consumers absent full disclosure of the material facts at issue. In any event, product sellers should also disclose safety concerns associated with the sale of consumer

goods (particularly drug products) or the fact that safety has not been adequately determined for such products.

133. Defendants suppressed and omitted these material facts concerning the safety concerns, lack of controlled safety studies, illegality of TNS Product sales, and composition of TNS® with the intent to induce Plaintiffs and members of the Class to purchase TNS Products.

134. Plaintiffs and the Class were unaware of these suppressed and omitted material facts at the time of their purchases of TNS Products. If they had known of such material facts at the time of their purchases, Plaintiffs and the Class would not have purchased the TNS Products, and/or they would have paid less for them.

135. As a result of Defendants' suppression and omission of material facts, Plaintiffs and the Class sustained economic damages to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, respectfully request that this Court enter a judgment against Defendants and in favor of Plaintiffs, and grant the following relief:

A. Determine that this action may be maintained as a Class action with respect to the Class identified herein and certify it as such under Rules 23(b)(2) and/or 23(b)(3), or alternatively certify all issues and claims that are appropriately certified, and designate and appoint Plaintiffs as Class Representatives and their counsel as Class Counsel;

B. Declare, adjudge and decree the conduct of the Defendants as alleged herein to be unlawful, unfair and/or deceptive;

C. Enjoin Defendants from continuing the unlawful, unfair and/or deceptive marketing and sale of TNS Products without full disclosure of safety concerns, the lack of controlled safety studies, the regulatory status of such products, and the composition of TNS®;

D. Award Plaintiffs and the Class restitution of all monies paid to Defendants as a result of the unlawful, unfair, and/or deceptive business practices;

E. Award Plaintiffs and the Class actual, compensatory damages, as proven at trial;

F. Award Plaintiffs and the Class exemplary damages in such amount as proven at trial;

G. Award Plaintiffs and the Class reasonable attorneys' fees, costs, and pre- and post-judgment interest; and

H. Award Plaintiffs and the Class such other further and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

JURY TRIAL DEMAND

Plaintiffs, by counsel, request a trial by jury on their legal claims, as set forth herein.

DATED: February 19, 2015

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