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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SANDRA SEEGERT, individually and on behalf of all others similarly situated,

Plaintiff,

v.

REXALL SUNDOWN, INC.,

Defendant.

Case No.: '17CV1243 JAH JMA

CLASS ACTION COMPLAINT

CLASS ACTION

JURY TRIAL DEMANDED

Plaintiff Sandra Seegert ("Plaintiff") brings this class action complaint against Defendant Rexall Sundown, Inc. ("Defendant"), individually and on behalf of all others similarly situated, and allege upon personal knowledge as to her acts and experiences, and, as to all other matters, upon information and belief, including investigation conducted by Plaintiff's attorneys.

NATURE OF THE ACTION

1. This is a consumer protection class action arising out of Defendant's false and misleading advertising of its glucosamine products.

2. Defendant markets, sells and distributes a line of joint health dietary supplements under the "Osteo Bi-Flex" brand name, and Defendant represents that these products are beneficial to the joints of the consumers who use them.

3. Each of the Osteo Bi-Flex products at issue in Defendant's joint health product line, through their labeling and packaging, and through Defendant's other advertising and marketing materials, communicate the same substantive message to consumers: that Osteo Bi-Flex provides meaningful joint health benefits.

4. These representations are designed to induce consumers to believe that Defendant's Osteo Bi-Flex joint health products are capable of actually providing meaningful joint benefits, and consumers purchase Defendant's Osteo Bi-Flex joint health products solely for the purpose of enjoying these purported joint health benefits.

5. Defendant's Osteo Bi-Flex products, however, are incapable of supporting or benefiting the health of human joints because the main ingredients in each of Defendant's Osteo Bi-Flex products at issue, either alone or in combination with other ingredients, cannot support or benefit joint health. Accordingly, Defendant's joint health representations are false, misleading and deceptive, and its Osteo Bi-Flex joint health products are worthless.

6. Plaintiff brings this action individually and on behalf of all other

similarly situated consumers to halt the dissemination of Defendant's false and misleading representations, correct the false and misleading perception Defendant's representations have created in the minds of consumers, and to obtain redress for those who have purchased Defendant's Osteo Bi-Flex products at issue.

JURISDICTION AND VENUE

7. The Court has original jurisdiction under to 28 U.S.C. § 1332(d)(2) because the matter in controversy, exclusive of interest and costs, exceeds the sum or value of $5,000,000 and is a class action in which there are in excess of 100 class members, and some of the members of the class are citizens of states different from Defendant.

8. This Court has personal jurisdiction over Defendant because Defendant conducts business in California. Defendant has marketed, promoted, distributed, and sold the Osteo Bi-Flex products at issue in California, rendering exercise of jurisdiction by California courts permissible.

9. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(a) and (b) because a substantial part of the events and omissions giving rise to Plaintiff's claims occurred in this district. Venue also is proper under 18 U.S.C. §1965(a) because Defendant transacts substantial business in this district.

PARTIES

10. Plaintiff Sandra Seegert is a citizen of the State of California, and, at all times relevant to this action, resided in San Diego County, California.

11. On February 20, 2017, Plaintiff saw Defendant's Osteo Bi-Flex Triple Strength product at a Walgreens retail store.

12. In reliance on the Osteo Bi-Flex product's joint health representations, Plaintiff purchased Defendant's Osteo Biflex Triple Strength product for approximately $31.99. By purchasing the falsely advertised product, Plaintiff suffered injury-in-fact and lost money.

13. The Osteo Bi-Flex product Plaintiff purchased, like all of Defendant's

Osteo Bi-Flex products at issue, cannot provide the promised benefits. Had Plaintiff known the truth about Defendant's misrepresentations and omissions at the time of purchase, Plaintiff would not have purchased Defendant's Osteo Bi-Flex product.

14. Rexall Sundown, Inc. is a Florida Corporation with its principal place of business located at 2100 Smithtown Avenue, Ronkonkoma, New York.

15. Defendant manufactures, advertises, markets, distributes, and/or sells the Osteo Bi-Flex products to tens of thousands of consumers in California and throughout the United States.

FACTUAL ALLEGATIONS

I. *Defendant's Glucosamine Products*

16. Defendant sells the glucosamine products at issue through its website, wwww.osteobiflex.com, and through various retail stores, including Walgreens, Walmart, and Costco.

17. Defendant's glucosamine products it issue are sold under the "Osteo Bi-Flex" brand name (collectively the "Osteo Bi-Flex Products"):

- Osteo Bi-Flex One Per Day;
- Osteo Bi-Flex Triple Strength;
- Osteo Bi-Flex Triple Strength MSM; and
- Osteo Bi-Flex Triple Strength with Vitamin D.

18. The main ingredient of each Osteo Bi-Flex Product is glucosamine hydrochloride.

19. Glucosamine hydrochloride is a combination of glucosamine (an amino sugar that is produced by the body and that can be isolated from shellfish) and hydrochloric acid.

20. Sometimes called degenerative joint disease or degenerative arthritis, osteoarthritis is the most common chronic condition of the joints, affecting approximately 27 million Americans. Osteoarthritis can affect any joint, but it

occurs most often in knees, hips, hands, and spine. According to the Arthritis Foundation, one in two adults will develop symptoms of osteoarthritis symptoms during their lives, and one in four adults will develop symptoms of hip osteoarthritis.

21. According to the Mayo Clinic, the signs and symptoms of osteoarthritis include joint pain, joint tenderness, joint stiffness, and the inability to move your joint through its full range of motion.[1]

II. *Defendant's False and Deceptive Advertising*

22. Defendant, through its advertisements, including on the Osteo Bi-Flex Products' packaging and labeling, has consistently conveyed to consumers throughout the United States that its Osteo Bi-Flex Products support and promote joint health.

23. For instance, on the front label of each of the Osteo Bi-Flex Products, prominently and in all caps, Defendant claims "JOINT HEALTH."

24. To reinforce the overall joint health benefits message, the front label of the Osteo Bi-Flex One Per Day, Osteo Bi-Flex Triple Strength, and Osteo Bi-Flex Triple Strength with Vitamin D products states "**JOINT SHIELD**" and that it "Shows Improved Joint Comfort within **7 Days!**" Similarly, the front label of the Osteo Bi-Flex Triple Strength MSM product states that it "Supports Cartilage Health" and "Helps Strengthen Your Joints."

25. Throughout the Osteo Bi-Flex Products' labeling, Defendant repeats similar joint health benefit claims, including "Range Of Motion," "supports joint comfort," and "helps strengthen joints while helping to maintain joint cartilage essential for comfortable joint movement".

26. To add credibility and provide consumers with a "reason to believe" the joint health message, Defendant also labels the Osteo Bi-Flex Products as the

[1] http://www.mayoclinic.com/health/osteoarthritis/DS00019/DSECTION=symptoms (last visited March 15, 2013).

"**#1** Pharmacist Recommended Brand." These claims are deceitfully likely to induce a placebo effect on consumers, irrespective of any health effect from the Osteo Bi-Flex Products' ingredients.

27. Based on these representations, it is clear that the Osteo Bi-Flex Products are intended to induce a common belief in consumers that the Osteo Bi-Flex Products are capable of providing meaningful joint health benefits.

III. *Scientific Studies Confirm That The Osteo Bi-Flex Products Are Not Effective And Defendant's Joint Health Representations Are False, Deceptive And Misleading*

28. Despite Defendant's representations, the ingredients in the Osteo Bi-Flex Products are *not* effective at supporting or benefiting joint health.

Randomized Clinical Trials

29. Randomized clinical trials ("RCTs") are "the gold standard for determining the relationship of an agent to a health outcome." Federal Judicial Center, *Reference Manual on Scientific Evidence*, 555 (3d ed. 2011). "Double-blinded" RCTs, where neither the trial participants nor the researchers know which participants received the active ingredient is considered the optimal strategy.

30. The main ingredients in the Osteo Bi-Flex Products have been extensively studied, and the well-conducted RCTs demonstrate that the ingredients, alone or in combination, are not effective at producing joint health benefits.

31. The leading series of studies testing glucosamine and chondroitin are known as the "GAIT" studies. The GAIT studies were independently conducted, and funded by the National Institutes of Health. The primary GAIT study cost over $12.5 million.

32. In 2006, results from the primary GAIT study – a 1,583-patient, 24-month, multi-center RCT – were published in the New England Journal of Medicine (the "2006 GAIT Study"). Authors of the 2006 GAIT Study concluded:

"[t]he analysis of the primary outcome measure did not show that either [glucosamine or chondroitin], alone or in combination, was efficacious . . . ." Clegg, D., *et al.*, *Glucosamine, Chondroitin Sulfate, and the Two in Combination for Painful Knee Osteoarthritis*, 354 New England J. of Med. 795, 806 (2006).

33. In 2008, additional GAIT study findings were published. *See* Sawitzke, A.D., *et al.*, *The Effect of Glucosamine and/or Chondroitin Sulfate on the Progression of Knee Osteoarthritis: A GAIT Report*, 58(10) J. Arthritis Rheum. 3183–91 (Oct. 2008). The 2008 GAIT publication explored the effects of glucosamine and chondroitin on progressive loss of joint space width. The researchers found "no significant differences in mean [joint space width] loss over 2 years between the treatment groups and the placebo group…" In other words, glucosamine and chondroitin, alone or in combination do not work and do not impact joint space width loss or otherwise rebuild cartilage.

34. In 2010, the NIH released a third set of results from the GAIT studies. *See* Sawitzke, A.D., *Clinical Efficacy And Safety Of Glucosamine, Chondroitin Sulphate, Their Combination, Celecoxib Or Placebo Taken To Treat Osteoarthritis Of The Knee: 2-Year Results From GAIT*, 69(8) Ann Rhem. Dis. 1459-64 (Aug. 2010). Authors of the 2010 GAIT report concluded that glucosamine and chondroitin do not provide pain, function, stiffness or mobility benefits. The authors also determined glucosamine and chondroitin do not benefit those with moderate-to-severe knee pain – a *post-hac*, secondary analysis which the original GAIT publication found inconclusive.

35. In addition to the GAIT studies, four other RCTs have examined a combination of glucosamine and chondroitin sulfate versus placebo. Each of these studies found glucosamine and chondroitin do not work.

36. In 2007, Messier *et al.*, published results from their 12-month, double-blind RCT examining 89 subjects in the United States. Messier SP *et al.*, *Glucosamine/chondroitin combined with exercise for the treatment of knee*

osteoarthritis: a preliminary study. Osteoarthritis and Cartilage, 15:1256-1266 (2007). Messier and co-authors concluded that daily consumption of a combination of glucosamine hydrochloride and chondroitin sulfate (the same ingredients in the Move Free Products) does not provide joint pain, function, stiffness or mobility benefits.

37. In 2011, Notarnicola *et al.*, published results from their RCT examining 60 subjects who consumed a daily combination of methylsulfonylmethane (MSM) and boswellic acid or placebo. Notarnicola *et al.*, *The "MESACA" Study: Methysulfonylmethane and Boswellic Acids in the Treatment of Gonarthrosis*, Adv Ther, 28(10):894-906 (2011). The primary endpoint of this study was to assess the efficacy of MSM and boswellic acid in terms of reducing pain and improving joint function. The researchers found that daily consumption of MSM and boswellic acid did not reduce pain or improve joint function.

38. Fransen *et al.* (2014) examined 605 subjects over a 2-year period. Fransen M *et al.*, *Glucosamine and chondroitin for knee osteoarthritis: a double-blind randomized placebo-controlled clinical trial evaluating single and combination regimens*, Ann Rheum Disease 74(5):851-858 (2014). Fransen concluded that glucosamine and chondroitin, alone or in combination, are no better than placebo for reducing pain or improving physical function:

> For the main symptomatic outcome … no significant effect on maximum knee pain over year 1 … was demonstrated for the three treatment allocations, compared with placebo. Over year 2 … there were no differences between the four allocations … and there was no significant difference in knee pain reduction between any of the treatment groups and placebo after adjusting for baseline values. Among the subgroup of 221 (37%) participants with severe knee pain … at baseline, there were no significant differences with respect to

their maximum knee pain or global assessment and score across different treatment groups.

Id. at 3-4; *see also id.* at 5-6 ("there were no significant reductions in knee pain detected for glucosamine or chondroitin alone, or in combination, over the 2-year follow-up period versus placebo") and *id.* at 4 ("[t]here were no significant differences" for any secondary measures, including WOMAC pain or function).

39. Yang *et al.* (2015) analyzed 1,625 participants to estimate the effectiveness of the combination of glucosamine and chondroitin in relieving knee symptoms and slowing disease progression among patients with knee osteoarthritis. Yang, *et al.*, entitled *Effects of glucosamine and chondroitin on treating knee osteoarthritis: an analysis with marginal structural models*, Arthritis & Rheumatology, Vol. 63, No. 3, 714-23 (March 2015). The researchers found that glucosamine and chondroitin combinations provided no clinically significant benefits in terms of reducing pain or stiffness, improving physical function or mobility, or delay the progression of joint space narrowing or osteoarthritis.

40. A 2016 randomized, double-blind, placebo-controlled clinical trial by Roman-Blas, *et al.*, entitled *Combined Treatment With Chondroitin Sulfate and Glucosamine Sulfate Shows No Superiority Over Placebo for Reduction of Joint Pain and Functional Impairment in Patients With Knee Osteoarthritis*, Arthritis & Rheumatology, Vol 69, No. 1, 77-85 (Jan. 2017), concluded that a combination of glucosamine and chondroitin was not superior to a placebo pill in terms of reducing joint pain and functional impairment in patients with symptomatic knee osteoarthritis over a six month period.

41. In 2016, Lugo *et al.*, also published the results from a study comparing a combination of glucosamine and chondroitin versus placebo. Lugo JP *et al.*, *Efficacy and tolerability of an undenatured type II collagen supplement in modulating knee osteoarthritis symptoms: a multicenter randomized, double-blind, placebo-controlled study*, Nutrition Journal (2016). Lugo was a multicenter,

double-blind RCT examining 190 subjects over 180 days. Lugo and co-authors found that a combination of glucosamine hydrochloride and chondroitin sulfate (the same ingredient combination in the Move Free Products) was no better than placebo in terms of joint pain, stiffness, mobility or physical function.

42. The results from GAIT and these other clinical studies testing glucosamine and chondroitin combinations versus placebo, are also consistent with the reported results of prior and subsequent studies.

43. For example, a 1999 study involving 100 subjects by Houpt *et al.*, entitled *Effect of glucosamine hydrochloride in the treatment of pain of osteoarthritis of the knee*, 26(11) J. Rheumatol. 2423-30 (1999), found that glucosamine hydrochloride performed no better than placebo at reducing pain at the conclusion of the eight week trial.

44. Likewise, a 2004 study by McAlindon, *et al.*, entitled *Effectiveness of Glucosamine For Symptoms of Knee Osteoarthritis: Results From and Internet-Based Randomized Double-Blind Controlled Trial*, 117(9) Am. J. Med. 649-9 (Nov. 2004), concluded that "glucosamine was no more effective than placebo in treating symptoms of knee osteoarthritis," meaning glucosamine is ineffective. *Id.* at 646 ("[W]e found no difference between the glucosamine and placebo groups in any of the outcome measures, at any of the assessment time points.").

45. Many studies have also confirmed there is a significant "placebo" effect with respect to consumption of Move Free Products represented to be effective in providing joint health benefits such as Defendant's Move Free Products.

46. Indeed, more than 30% of persons who took placebos in these studies believed that they were experiencing joint health benefits when all they were taking was a placebo.

47. A 2004 study by Cibere, *et al.*, entitled *Randomized, Double-Blind, Placebo-Controlled Glucosamine Discontinuation Trial In Knee Osteoarthritis*,

51(5) Arthritis Care & Research 738-45 (Oct. 15, 2004), studied users of glucosamine who claimed to have experienced at least moderate improvement after starting glucosamine. These patients were divided into two groups – one group that was given glucosamine and another group that was given a placebo. For six months, the primary outcome observed was the proportion of disease flares in the glucosamine and placebo groups. A secondary outcome was the time to disease flare. The study results reflected that there were no differences in either the primary or secondary outcomes for glucosamine and placebo. The authors concluded that the study provided no evidence of symptomatic benefit from continued use of glucosamine – in other words, any prior perceived benefits were due to the placebo effect and ***not*** glucosamine. *Id.* at 743 ("In this study, we found that knee OA disease flare occurred as frequently, as quickly, and as severely in patients who were randomized to continue receiving glucosamine compared with those who received placebo. As a result, the efficacy of glucosamine as a symptom-modifying drug in knee OA is not supported by our study.").

48. A 2008 study by Rozendaal, *et al.*, entitled *Effect of Glucosamine Sulfate on Hip Osteoarthritis*, 148 Ann. of Intern. Med. 268-77 (2008), assessed the effectiveness of glucosamine on the symptoms and structural progression of hip osteoarthritis during two years of treatment. Rozendaal and co-authors examined 222 subjects and concluded that glucosamine was no better than placebo in reducing pain, improving physical function, or impacting the structural progression of osteoarthritis.

49. On July 7, 2010, Wilkens, *et al.*, reported that there was no difference between placebo and glucosamine for the treatment of low back pain and lumbar osteoarthritis and that neither glucosamine nor placebo were effective in reducing pain related disability. The researchers also concluded that, "Based on our results, it seems unwise to recommend glucosamine to all patients" with low back pain and lumbar osteoarthritis. Wilkens, *et al.*, *Effect of Glucosamine on Pain-Related*

Disability in Patients With Chronic Low Back Pain and Degenerative Lumbar Osteoarthritis, 304(1) JAMA 45-52 (July 7, 2010).

50. Kwoh *et al.* (2014) is a report from a randomized, placebo-controlled clinical trial measuring the effect of oral glucosamine hydrochloride on joint degradation, and secondarily, pain and function in 201 individuals. Kwoh, *et al.*, *Effect of Oral Glucosamine on Joint Structure in Individuals With Chronic Knee Pain*, Arthritis & Rheumatology, Vol 66, No. 4, 930-39 (Apr. 2014). Kwoh, which studied a mix of subjects with and without osteoarthritis, concluded that glucosamine supplementation provided no structural, pain or function benefits.

51. Runhaar *et al.* (2015) was an independently-analyzed double-blind, placebo-controlled, factorial design trial testing a diet-and-exercise program and 1500mg oral glucosamine or placebo on the incidence of knee osteoarthritis among 407 women at high-risk for knee osteoarthritis. Runhaar *et al.*, *Prevention of Knee Osteoarthritis in Overweight Females: The First Preventative Randomized Controlled Trial in Osteoarthritis*, Am J Med, 128(8):888-895 (2015). Researchers examined the impact of daily glucosamine consumption on the incidence of knee osteoarthritis, as well as on pain and physical function. After 2.5 years, no effect from glucosamine was found on subjects' overall quality of life or knee pain, physical function, or the incidence of knee osteoarthritis.

52. A 2017 study by Roman-Blas, *et al.*, entitled *The combined therapy with chondroitin sulfate plus glucosamine sulfate or chondroitin sulfate plus glucosamine hydrochloride does not improve joint damage in an experimental model of knee osteoarthritis in rabbits*, European Journal of Pharmacology, Vol. 794 8-14 (Jan. 2017), concluded that the combination of chondroitin sulfate and glucosamine sulfate and the combination of chondroitin sulfate and glucosamine hydrochloride failed to improve structural damage or ameliorate the inflammatory profile of joint tissues.

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Meta-analyses and Scientific Review Articles

53. Well-conducted meta-analyses are considered a higher level of evidence than individual clinical trials as they provide a method to evaluate the aggregated results of all relevant studies according to their pooled effects and methodological quality.

54. In a 2007 meta-analysis, Vlad, *et al.*, reviewed all studies involving glucosamine hydrochloride and concluded that "[g]lucosamine hydrochloride is not effective." *Glucosamine for Pain in Osteoarthritis*, 56:7 Arthritis Rheum. 2267-77 (2007); *see also id.* at 2275 ("[W]e believe that there is sufficient information to conclude that glucosamine hydrochloride lacks efficacy for pain in OA.").

55. A 2010 meta-analysis by Wandel, *et al.*, entitled *Effects of Glucosamine, Chondroitin, Or Placebo In Patients With Osteoarthritis Or Hip Or Knee: Network Meta- Analysis*, BMJ 341:c4675 (2010), examined prior studies involving glucosamine and chondroitin, alone or in combination, and whether they relieved the symptoms or progression of arthritis of the knee or hip. This independent research team reported that glucosamine and chondroitin, alone or in combination, did not reduce joint pain or have an impact on the narrowing of joint space: "Our findings indicate that glucosamine, chondroitin, and their combination do not result in a relevant reduction of joint pain nor affect joint space narrowing compared with placebo." *Id.* at 8. The authors further concluded "[w]e believe it unlikely that future trials will show a clinically relevant benefit of any of the evaluated preparations." *Id.*

56. In 2011, Miller and Clegg, after surveying the clinical study history of glucosamine and chondroitin, concluded that, "[t]he cost-effectiveness of these dietary supplements alone or in combination in the treatment of OA has not been demonstrated in North America." Miller, K. and Clegg, D., *Glucosamine and Chondroitin Sulfate*, Rheum. Dis. Clin. N. Am. 37 103-118 (2011).

57. In 2012, a report by Rovati, *et al.*, entitled *Crystalline glucosamine sulfate in the management of knee osteoarthritis: efficacy, safety, and pharmacokinetic properties*, Ther Adv Muskoloskel Dis 4(3) 167-180, noted that glucosamine hydrochloride "ha[s] never been shown to be effective."

58. The recent meta-analysis by Eriksen *et al.* (2014) included 25 glucosamine trials, which collectively involved 3,458 patients. Eriksen, P *et al.*, *Risk of bias and brand explain the observed inconsistency in trials on glucosamine for symptomatic relief of osteoarthritis: A meta-analysis of placebo-controlled trials*, Arthritis Care & Research 66:1844-1855 (2014). Eriksen and co-authors found that "[i]n accordance with a previous analysis, we found that glucosamine hydrochloride had no effect on pain" and "glucosamine by and large has no clinically important effect."

59. A 2016 scientific review by Vasiliadis, *et al.*, entitled *Glucosamine and chondroitin for the treatment of osteoarthritis*, World J. Orthop., Vol. 8, Issue 1 (Jan. 18, 2017), concluded that "[t]here is currently no convincing information on the efficacy of [glucosamine] or [chondroitin] as treatment options in [osteoarthritis], *id.* at 8, and "when only the information from best quality trials is considered, then none of these supplements seem to demonstrate any superiority [as compared to placebos]," *id.* at 6.

60. In 2017, Runhaar and co-authors presented results from their meta-analysis of six glucosamine studies (1,663 patients) where the original authors agreed to share their study data for critical re-analysis. Runhaar *et al.*, *No Treatment Effects of Oral Glucosamine for Subgroups of Knee and Hip Osteoarthritis Patients: An Individual Patient Data Meta-Analysis from the OA Trial Bank*, Osteoarthritis and Cartilage, Vol. 25 (2017). Runhaar 2017 is an "individual patient data meta-analysis" or IPD, which is considered a gold standard of systematic review. The Runhaar IPD meta-analysis concluded that glucosamine has no effect on pain or physical function.

Professional Guidelines

61. Professional guidelines are also consistent in their recommendation against using glucosamine or chondroitin.

62. For example, the National Collaborating Centre for Chronic Conditions ("NCCCC") reported "the evidence to support the efficacy of glucosamine hydrochloride as a symptom modifier is poor" and the "evidence for efficacy of chondroitin was less convincing." NCCCC, Osteoarthritis National Clinical Guideline for Care and Management of Adults, Royal College of Physicians, London 2008. Consistent with its lack of efficacy findings, the NCCCC Guideline did not recommend the use of glucosamine or chondroitin for treating osteoarthritis. *Id.* at 33.

63. In December 2008, the American Academy of Orthopaedic Surgeons published clinical practice guidelines for the "Treatment of Osteoarthritis of the Knee (Non-Arthroplasty)," and recommended that "glucosamine and sulfate or hydrochloride not be prescribed for patients with symptomatic OA of the knee." Richmond *et al.*, *Treatment of osteoarthritis of the knee (nonarthroplasty)*, J. Am. Acad. Orthop. Surg. Vol. 17 No. 9 591-600 (2009). This recommendation was based on a 2007 report from the Agency for Healthcare Research and Quality (AHRQ), which states that "the best available evidence found that glucosamine hydrochloride, chondroitin sulfate, or their combination did not have any clinical benefit in patients with primary OA of the knee." Samson, *et al.*, *Treatment of Primary and Secondary Osteoarthritis of the Knee*, Agency for Healthcare Research and Quality, 2007 Sep 1. Report No. 157.

64. In 2009, a panel of scientists from the European Food Safety Authority ("EFSA") (a panel established by the European Union to provide independent scientific advice to improve food safety and consumer protection), reviewed nineteen studies submitted by an applicant, and concluded that "a cause and effect relationship has not been established between the consumption of

glucosamine hydrochloride and a reduced rate of cartilage degeneration in individuals without osteoarthritis." EFSA Panel on Dietetic Products, Nutrition and Allergies, *Scientific Opinion on the substantiation of a health claim related to glucosamine hydrochloride and reduced rate of cartilage degeneration and reduced risk of osteoarthritis*, EFSA Journal (2009), 7(10):1358.

65. In a separate opinion from 2009, an EFSA panel examined the evidence for glucosamine (either hydrochloride or sulfate) alone or in combination with chondroitin sulfate and maintenance of joints. The claimed effect was "joint health," and the proposed claims included "helps to maintain healthy joint," "supports mobility," and "helps to keep joints supple and flexible." Based on its review of eleven human intervention studies, three meta-analyses, 21 reviews and background papers, two animal studies, one in vitro study, one short report, and one case report, the EFSA panel concluded that "a cause and effect relationship has not been established between the consumption of glucosamine (either as glucosamine hydrochloride or as glucosamine sulphate), either alone or in combination with chondroitin sulphate, and the maintenance of normal joints." EFSA Panel on Dietetic Products, Nutrition and Allergies, *Scientific Opinion on the substantiation of health claims related to glucosamine alone or in combination with chondroitin sulphate and maintenance of joints and reduction of inflammation*, EFSA Journal (2009), 7(9):1264.

66. In 2012, EFSA examined the evidence glucosamine sulphate or glucosamine hydrochloride, and a claimed effect of "contributes to the maintenance of normal joint cartilage." Based on its review of 61 references provided by Merck Consumer Healthcare, the EFSA panel concluded that "a cause and effect relationship has not been established between the consumption of glucosamine and maintenance of normal joint cartilage in individuals without osteoarthritis." EFSA Panel on Dietetic Products, Nutrition and Allergies, *Scientific Opinion on the substantiation of a health claim related to glucosamine*

*and maintenance of normal join*t cartilage, EFSA Journal 2012, 10(5): 2691.

67. In 2008 and 2013, the American Academy of Orthopaedic Surgeons ("AAOS") made a "strong" recommendation that neither glucosamine nor chondroitin be used for patients with symptomatic osteoarthritis of the knee. *See* American Academy of Orthopaedic Surgeons, Treatment of Osteoarthritis of the Knee: Evidence-Based Guideline (2d ed. 2013). "Twenty-one studies were included as evidence for this recommendation."

68. Likewise, the American College of Rheumatology ("ACR"), the United Kingdom National Institute for Health and Care Excellence ("NICE"), and the Agency for Healthcare Research and Quality ("AHRQ") (one of the agencies within the United States Department of Health and Human Services) each published clinical guidelines for the treatment of osteoarthritis based on a critical review of published clinical research, including for glucosamine and chondroitin. These professional groups also recommend against using glucosamine or chondroitin for managing the pain, reduced function, and quality of life issues associated with osteoarthritis. Hochberg MC *et al.*, *American College of Rheumatology 2012 Recommendations for the Use of Nonpharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip, and Knee*, Arthritis Care & Research, 64(4):465-474 (2012); NICE National Institute for Health and Care Excellence. *Osteoarthritis: Care and management in adults*. Clinical guideline 177. Methods, evidence and recommendations (February 2014); Samson DJ *et al.*, *Treatment of Primary and Secondary Osteoarthritis of the Knee. Evidence Report/Technology Assessment*, Number 157. Prepared for Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, Publication No. 07-E012 (2007).

69. The AAOS, ACR, NICE and AHRQ guidelines were based on systematic reviews and/or meta-analyses of all of the available study data. For example, the ACR specifically cited its reliance on the GAIT study coupled with

four meta-analyses that "failed to demonstrate clinically important efficacy for these agents": Towheed, 2005; Vlad, 2007; Reichenbach, 2007; and Wandel, 2010. The NICE authors' conclusion that practitioners should "not offer glucosamine or chondroitin products" was based on a review that included Towheed 2005, which included 25 glucosamine RCTs, Reichenbach, 2007, which included 22 chondroitin RCTs, and seven studies that compared glucosamine plus chondroitin versus placebo. The 2007 AHRQ assessment was based on review of 21 glucosamine/chondroitin studies, including GAIT. The AAOS' 2013 "strong" recommendation against glucosamine and chondroitin was based on expert analysis and meta-analyses of 12 glucosamine studies, 8 chondroitin studies, and one study (GAIT) that assessed both.

The Impact of Defendant's Wrongful Conduct

70. Despite clinical studies demonstrating the Osteo Bi-Flex Products' ineffectiveness, Defendant conveyed and continues to convey one uniform joint health message: that the Osteo Bi-Flex Products are joint health supplements capable of supporting and benefiting joint health.

71. As the inventor, manufacturer, and distributor of the Osteo Bi-Flex Products, Defendant possesses specialized knowledge regarding their content and effects of their ingredients, and Defendant is in a superior position to know whether the Osteo Bi-Flex Products work as advertised.

72. Specifically, Defendant knew, but failed to disclose, or should have known, that the Osteo Bi-Flex Products cannot benefit joint health and that well-conducted, clinical studies have found the Osteo Bi-Flex Products' primary ingredients unable to support or benefit joint health.

73. Plaintiff and the class members have been and will continue to be deceived or misled by Defendant's false and deceptive joint health representations.

74. Defendant's joint health representations and omissions were a material factor in influencing Plaintiff's and the class members' decision to

purchase the Osteo Bi-Flex Products. In fact, the only purpose for purchasing the Osteo Bi-Flex Products is to obtain the represented joint health benefits.

75. Defendant's conduct has injured Plaintiff and the class members because Defendant's Osteo Bi-Flex Products are worthless and cannot support or benefit joint health in any way.

76. Had Plaintiff and the class members known the true nature of Defendant's Osteo Bi-Flex Products, they would not have purchased the Products and would not have paid the prices they paid for the Products.

77. Plaintiff and each class member were harmed by purchasing Defendant's Osteo Bi-Flex Products because they are not capable of providing their advertised benefits. As a result, Plaintiff and each class member lost money and property by way of purchasing Defendant's ineffective and worthless joint health supplements.

CLASS DEFINITION AND ALLEGATIONS

78. Plaintiff, pursuant to Fed. R. Civ. Pro. 23(b)(2) and 23(b)(3), asserts this action on behalf of the following class: "All persons who purchased in the state of California any of the Osteo Bi-Flex Products, within the applicable statute of limitations, for personal use until the date notice is disseminated."

79. Excluded from each Class is Defendant, its parents, subsidiaries, affiliates, officers, and directors, those who purchased the Osteo Bi-Flex Products for resale, all persons who make a timely election to be excluded from the Class, the judge to whom this case is assigned and any immediate family members thereof, and those who assert claims for personal injury.

80. Certification of Plaintiff's claims for class wide treatment is appropriate because Plaintiff can prove the elements of her claims on a class wide basis using the same evidence as would be used to prove those elements in individual actions alleging the same claims.

81. **Numerosity – Federal Rule of Civil Procedure 23(a)(1).** The

members of the Class are so numerous that individual joinder of all Class members is impracticable. Defendant has sold many thousands of units of the Osteo Bi-Flex Products to Class members.

82. **Commonality and Predominance – Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3).** This action involves common questions of law and fact, which predominate over any questions affecting individual Class members. Specifically, whether Defendant's representations regarding its Products and their joint health benefits are misleading and deceptive is a question common to the class. Similarly, the Products either are capable of providing joint health benefits or they are not, and Defendant's uniform representation that the Products are joint health supplements capable of providing joint health benefits either is true of false. These questions and others like them are common to the class and predominate over individual issues.

83. **Typicality – Federal Rule of Civil Procedure 23(a)(3).** Plaintiff's claims are typical of the other Class members' claims because, among other things, all Class members were comparably injured through the uniform prohibited conduct described above.

84. **Adequacy of Representation – Federal Rule of Civil Procedure 23(a)(4).** Plaintiff is an adequate representative of the Class because Plaintiff's interests do not conflict with the interests of the other Class members Plaintiff seeks to represent; Plaintiff has retained counsel competent and experienced in complex commercial and class action litigation; and Plaintiff intends to prosecute this action vigorously. The interests of the Class members will be fairly and adequately protected by Plaintiff and her counsel.

85. **Declaratory and Injunctive Relief – Federal Rule of Civil Procedure 23(b)(2).** Defendant has acted or refused to act on grounds generally applicable to Plaintiff and the other Class members, thereby making appropriate final injunctive relief and declaratory relief, as described below, with respect to

Class as a whole.

86. **Superiority – Federal Rule of Civil Procedure 23(b)(3).** A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The damages or other financial detriment suffered by Plaintiff and the other Class members are relatively small compared to the burden and expense that would be required to individually litigate their claims against Defendant, so it would be impracticable for Class members to individually seek redress for Defendant's wrongful conduct. Even if Class members could afford individual litigation, the court system could not. Individualized litigation creates a potential for inconsistent or contradictory judgments, and increases the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

CLAIMS ALLEGED

COUNT I

Violation of the California Unfair Competition Law ("UCL") – Cal. Bus. & Prof. Code §§ 17200, *et seq.*

87. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

88. Plaintiff brings this claim individually and on behalf of the Class.

89. Plaintiff and Defendant are "persons" within the meaning of the UCL. Cal. Bus. & Prof. Code § 17201.

90. The UCL defines unfair competition to include any "unlawful, unfair or fraudulent business act or practice," as well as any "unfair, deceptive, untrue or misleading advertising." Cal. Bus. Prof. Code § 17200.

91. In the course of conducting business, Defendant committed unlawful

business practices by, among other things, making the representations (which also constitutes advertising within the meaning of §17200) and omissions of material facts, as set forth more fully herein, and violating Civil Code §§1572, 1573, 1709, 1711, 1770(a)(5), (7), (9) and (16) and Business & Professions Code §§17200, et seq., 17500, et seq., and the common law.

92. Plaintiff reserves the right to allege other violations of law, which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.

93. In the course of conducting business, Defendant committed "unfair" business practices by, among other things, making the representations (which also constitute advertising within the meaning of §17200) and omissions of material facts regarding Osteo Bi-Flex Products in its advertising and labeling, including on the Osteo Bi-Flex Products' packaging, as set forth more fully herein. There is no societal benefit from false advertising – only harm. Plaintiff and the other Class members paid for a valueless product that is not capable of conferring the benefits promised. While Plaintiff and the other Class members were harmed, Defendant was unjustly enriched by its false misrepresentations and omissions. As a result, Defendant's conduct is "unfair," as it offended an established public policy. Further, Defendant engaged in immoral, unethical, oppressive, and unscrupulous activities that are substantially injurious to consumers.

94. Further, as set forth in this Complaint, Plaintiff alleges violations of consumer protection, unfair competition, and truth in advertising laws in California and other states, resulting in harm to consumers. Defendant's acts and omissions also violate and offend the public policy against engaging in false and misleading advertising, unfair competition, and deceptive conduct towards consumers. This conduct constitutes violations of the unfair prong of Business & Professions Code §17200, et seq.

95. There were reasonably available alternatives to further Defendant's

legitimate business interests, other than the conduct described herein. Business & Professions Code §17200, et seq., also prohibits any "fraudulent business act or practice." In the course of conducting business, Defendant committed "fraudulent business act or practices" by, among other things, making the representations (which also constitute advertising within the meaning of §17200) and omissions of material facts regarding the Osteo Bi-Flex Products in its advertising, including on the Osteo Bi-Flex Products' packaging and labeling, as set forth more fully herein. Defendant made the misrepresentations and omissions regarding the efficacy of its Osteo Bi-Flex Products, among other ways, by misrepresenting on each and every Osteo Bi-Flex Product's packaging and labeling that the Products are effective when taken as directed, when, in fact, the representations are false and deceptive, and the Osteo Bi-Flex Products are not capable of conferring the promised health benefits.

96. Defendant's actions, claims, omissions, and misleading statements, as more fully set forth above, were also false, misleading and/or likely to deceive the consuming public within the meaning of Business & Professions Code §17200, et seq.

97. Plaintiff and the other members of the Class have in fact been deceived as a result of their reliance on Defendant's material representations and omissions, which are described above. This reliance has caused harm to Plaintiff and the other members of the Class, each of whom purchased Defendant's Osteo Bi-Flex Products. Plaintiff and the other Class members have suffered injury in fact and lost money as a result of purchasing the Osteo Bi-Flex Products and Defendant's unlawful, unfair, and fraudulent practices.

98. Defendant knew, or should have known, that its material misrepresentations and omissions would be likely to deceive and harm the consuming public and result in consumers making payments to Defendant for Osteo Bi-Flex Products that are valueless and that are incapable of actually

supporting, maintaining, improving or benefiting joint health.

99. As a result of its deception, Defendant was unjustly enriched by receiving payments from Plaintiff and the Class in return for providing Plaintiff and the Class, the Osteo Bi-Flex Products that do not perform as advertised.

100. Unless restrained and enjoined, Defendant will continue to engage in the unlawful, unfair and fraudulent conduct described herein.

101. Accordingly, Plaintiff, individually and on behalf of all others similarly situated, and on behalf of the general public, seeks restitution from Defendant of all money obtained from Plaintiff and the other members of the Class collected as a result of Defendant's unfair competition, and for an injunction prohibiting Defendant from continuing and further engaging in its unlawful, unfair and fraudulent conduct, requiring corrective advertising, and awarding all other relief this Court deems appropriate..

COUNT II

Violation of the California Consumers Legal Remedies Act ("CLRA") – Cal. Civ. Code §§ 1750, *et seq.*

102. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

103. Plaintiff brings this claim individually and on behalf of the Class.

104. Plaintiff is a "consumer," Defendant is a "person," and the Osteo Bi-Flex Products are "goods" within the meaning of the CLRA. Cal. Civ. Code § 1761(a), (c) and (d).

105. Defendant's sale and advertisement of its Osteo Bi-Flex Products constitutes "transactions" within the meaning of the CLRA. Cal. Civ. Code § 1761(e).

106. The CLRA declares as unlawful the following unfair methods of competition and unfair or deceptive acts or practices when undertaken by any person in a transaction intended to result, or which results in the sale of goods to

any consumer:

> (5) Representing that goods … have . . . approval, characteristics, . . . uses [and] benefits . . . which [they do] not have . . . .
>
> (7) Representing that goods … are of a particular standard, quality or grade . . . if they are of another.
>
> (9) Advertising goods . . . with intent not to sell them as advertised.
>
> (16) Representing that [goods] have been supplied in accordance with a previous representation when [they have] not.

Cal. Civ. Code § 1770(a)(5), (7), (9) and (16).

107. Defendant violated the CLRA by representing that its Osteo Bi-Flex Products are beneficial for joint health, when, in reality, the Osteo Bi-Flex Products cannot provide their advertised benefits and the Osteo Bi-Flex Products' ingredients are ineffective at improving, supporting, maintaining or benefiting the health of human joints.

108. Defendant knew or should have known its joint health representations were false and misleading, and that by omitting the ineffectiveness of its Osteo Bi-Flex Products it was omitting a material fact that would alter any consumer's decision to purchase the Osteo Bi-Flex Products.

109. Defendant's violations of the CLRA proximately caused injury in fact to Plaintiff and the Class.

110. Plaintiff and the Class members purchased Defendant's Osteo Bi-Flex Products on the belief that they would receive the advertised joint benefits from the Osteo Bi-Flex Products. Indeed, no consumer would purchase a joint health supplement unless he or she believed it was capable of providing meaningful joint benefits.

111. Defendant's Osteo Bi-Flex Products, however, are worthless and cannot provide any of their advertised benefits. Since the Osteo Bi-Flex Products lack any value, Plaintiff and each Class member was injured by the mere fact of

their purchase.

112. Pursuant to Cal. Civ. Code § 1782(d), Plaintiff, individually and on behalf of the other members of the Class, seeks a Court order enjoining the above-described wrongful acts and practices of Defendant and for restitution and disgorgement.

113. Pursuant to Cal. Civ. Code § 1782(a), Defendant was notified in writing by certified mail of the particular violations of Section 1770 of the CLRA, which notification demanded that Defendant rectify the problems associated with the actions detailed above and give notice to all affected consumers of Defendant's intent to so act. A copy of the letter is attached hereto as Exhibit A.

114. If Defendant fails to rectify or agree to rectify the problems associated with the actions detailed above and give notice to all affected consumers within 30 days of the date of written notice pursuant to §1782 of the Act, Plaintiff will amend this complaint to add claims for actual, punitive and statutory damages, as appropriate, including statutory damages awards under §1780(b)(1) for the members of the Class.

115. Defendant's conduct is fraudulent, wanton, and malicious.

116. Pursuant to §1780(d) of the Act, attached hereto as Exhibit B is the affidavit showing that this action has been commenced in the proper forum.

COUNT III

Violation of the California False Advertising Law ("FAL") – Cal. Bus. & Prof. Code §§ 17500, *et seq.*

117. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

118. Plaintiff brings this claim individually and on behalf of the Class.

119. The FAL, in relevant part, states that "[i]t is unlawful for any … corporation … with intent … to dispose of … personal property … to induce the public to enter into any obligation relating thereto, to make or disseminate or cause

to be made or disseminated … from this state before the public in any state, in any newspaper or other publication, or any advertising device, or by public outcry or proclamation, or in any other manner or means whatever, including over the Internet, any statement … 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[.]" Cal. Bus. & Prof. Code § 17500 (emphasis added).

120. The required intent is the intent to dispose of property, not the intent to mislead the public in the disposition of such property.

121. Defendant violated the FAL by making untrue or misleading representations that its Osteo Bi-Flex Products are beneficial for joint health, when, in reality, the Osteo Bi-Flex Products cannot provide any of their advertised benefits and the Osteo Bi-Flex Products' ingredients are ineffective at improving, supporting or maintaining the health of human joints.

122. As a direct and proximate result of Defendant's untrue and misleading advertising, Plaintiff and the Class members have suffered injury in fact and have lost money.

123. Accordingly, Plaintiff requests that the Court order Defendant to restore the money Defendant has received from Plaintiff and the members of the Class, and that the Court enjoin Defendant from continuing its unlawful practices, and engage in corrective advertising.

JURY DEMAND

124. Plaintiff demands a trial by jury of all claims in this Complaint so triable.

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REQUEST FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the other members of the proposed Class, respectfully requests that the Court enter judgment in Plaintiff's favor and against Defendant as follows:

A. Declaring that this action is a proper class action, certifying the Class as requested herein, designating Plaintiff as Class Representative and appointing the undersigned counsel as Class Counsel;

B. Ordering restitution and disgorgement of all profits and unjust enrichment that Defendant obtained from Plaintiff and the Class members as a result of Defendant's unlawful, unfair and fraudulent business practices;

C. Ordering injunctive relief as permitted by law or equity, including enjoining Defendant from continuing the unlawful practices as set forth herein, and ordering Defendant to engage in a corrective advertising campaign;

D. Ordering Defendant to pay attorneys' fees and litigation costs to Plaintiff and the other members of the Class;

E. Ordering Defendant to pay both pre- and post-judgment interest on any amounts awarded; and

F. Ordering such other and further relief as may be just and proper.

Dated: June 19, 2017

CARLSON LYNCH SWEET KILPELA & CARPENTER, LLP

By: */s/ Todd D. Carpenter*

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