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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA – NORTHERN DIVISION

KATHLEEN SONNER, individually and on behalf of all others similarly situated,

Plaintiff,

v.

PREMIER NUTRITION COMPANY, LLC; and DOES 1-25, inclusive,

Defendant.

Case No.

CLASS ACTION

CLASS ACTION COMPLAINT FOR:
1. **VIOLATION OF CONSUMERS LEGAL REMEDIES ACT, CIVIL CODE §§ 1750, *et seq.*; and**
2. **VIOLATION OF THE UNFAIR COMPETITION LAW, BUSINESS AND PROFESSIONS CODE §§ 17200, *et seq.*;**

(*UNLIMITED MATTER*-Amount demanded exceeds $25,000)

DEMAND FOR JURY TRIAL

BLOOD HURST & O' REARDON, LLP

Plaintiff Kathleen Sonner ("Plaintiff") brings this class action complaint against Defendant Premier Nutrition Company, LLC f/k/a Premier Nutrition Corporation ("Premier" or "Defendant"), on behalf of herself and all others similarly situated, and complains and alleges upon personal knowledge as to herself and her own acts and experiences, and, as to all other matters, upon information and belief, including investigation conducted by her 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 joint health products.

2. Defendant distributes, markets, and sells a glucosamine-based dietary supplement named "Joint Juice" which it advertises for the treatment, prevention, and cure for osteoarthritis and to treat the symptoms commonly associated with osteoarthritis, whether the purchaser believes he or she has osteoarthritis or not.[1] Primarily through deceptive product labeling, Defendant promises that Joint Juice will support and nourish cartilage, lubricate joints, and improve joint flexibility. Defendant's advertising claims, however, are false, misleading, and likely to deceive a reasonable consumer.

3. The false and misleading implied advertising messages are communicated on the labels of all Joint Juice-branded products and throughout Joint Juice marketing materials. It's labels prominently state that Joint Juice "helps keep cartilage lubricated and flexible," and that consumers should "drink daily for healthy, flexible joints."

4. Plaintiff brings this action individually and on behalf of all other similarly situated consumers to halt Defendant's dissemination of this false and misleading advertising message, correct the false and misleading perception it has created in the minds of consumers, and to obtain restitution for those who have purchased Joint Juice during the class period.

5. The Class is defined as all consumers who purchased Joint Juice in California from March 1, 2009 to June 20, 2016, inclusive of those dates.

[1] The Joint Juice line consists of: (1) Joint Juice supplement drink; (2) Joint Juice On-The-Go Drink Mix; and (3) Joint Juice Easy Shot Supplement (collectively, "Joint Juice" or the "Products"). Plaintiff reserves the right to include other Products as a result of discovery.

JURISDICTION AND VENUE

6. This Court has jurisdiction pursuant to Article VI, Section 10 of the California Constitution, because this case is not a cause given by statute to other trial courts. Federal jurisdiction does not exist because greater than two-thirds (90% or more) of the members of the Class in the aggregate are citizens of California, and Defendant is a citizen of the State of California. The injuries resulting from the conduct of Defendant occurred in California. Further, federal courts lack jurisdiction to adjudicate the claims alleged.

7. This Court has personal jurisdiction over Defendant because Defendant is authorized to and does conduct business in California. Defendant has marketed, promoted, distributed, and sold Joint Juice in California, and Defendant's headquarters and primary place of business is in California, rendering exercise of jurisdiction by California courts permissible.

8. Venue is proper in this Court because Defendant is headquartered in this County, Defendant transacts substantial business in this County, and a substantial part of the events or omissions giving rise to the claim occurred in this County.

PARTIES

9. At all times relevant to this action, Kathleen Sonner was a citizen of the State of California and she resided in San Diego County, California. In late 2013, Plaintiff Sonner was exposed to and saw Defendant's representations by reading the label of a Joint Juice "Weekly Pack" of six, eight-ounce beverage bottles at a Ralph's grocery store located at 101 G Street, San Diego, CA 92101. Prior to that, Plaintiff Sonner was also exposed to and saw Defendant's representations by viewing the Joint Juice television commercial featuring spokesman Joe Montana. In reliance on the joint health benefit representations Plaintiff Sonner purchased the Joint Juice "Weekly Pack" for approximately $7. By purchasing the deceptively advertised Joint Juice products, Plaintiff Sonner suffered injury-in-fact and lost money because Joint Juice does not provide the promised benefits. Had Plaintiff Sonner known the truth about Defendant's advertisements at the time of her purchase, she would not have purchased Joint Juice.

10. Premier Nutrition Company, LLC ("Premier") f/k/a Premier Nutrition Corporation is a corporation organized and existing under the laws of the state of Delaware. Premier's headquarters is at 1222 67th Street, Suite 210, Emeryville, CA 94608. Premier is owned by BellRing Brands Inc., a public company traded on the New York Stock Exchange and spin-off of the multi-billion dollar processed food conglomerate Post Holdings, Inc. Post continues to hold a majority interest in BellRing. Premier is a manufacturer of high-protein nutrition products, including ready-to-drink shakes, bars, powders and cookies. Premier's primary brands include Premier Protein and Joint Juice. Premier manufactures, advertises, markets, distributes, and/or sells the Joint Juice products to many thousands of consumers in California.

11. The conduct at issue substantially emanates from California. From its headquarters and offices in California, Defendant creates the false and deceptive advertising campaign at issue, and promotes, markets, distributes, and sells Joint Juice to many thousands of consumers throughout California and the United States, including through its retail website. Joint Juice, Inc. n/k/a Premier Nutrition Company, LLC was a San Francisco-based corporation organized and existing under the laws of the state of California. Joint Juice, Inc. was headquartered at 120 Howard Street, Suite 600, San Francisco, California 94105. Joint Juice, Inc. was a leading provider of ready-to-drink glucosamine supplements. Up until becoming known as Premier in 2011, and from its headquarters and offices in California, Joint Juice, Inc. manufactured, advertised, marketed, distributed, and/or sold the Joint Juice products to tens of thousands of consumers in California and throughout the United States. On October 12, 2011, Joint Juice Inc. announced the acquisition of Premier Nutrition.

FACTUAL ALLEGATIONS

The Joint Juice Products and the Symptoms Joint Juice Purports to Treat

12. Since 1999, Defendant has distributed, marketed, and sold Joint Juice.

13. Joint Juice is sold by a variety of third-party retailers, including Costco, Sam's Club, Walgreens, Wal-Mart, and Target. Defendant also sells Joint Juice directly to consumers through its website.

14. Joint Juice is or was available in 1) drink mix packets, which retail for approximately $22 for a thirty-count box, 2) eight-ounce beverage bottles, which retail for approximately $30 for a thirty-pack, or approximately $6 for a six-pack, and 3) Easy Shot™ bottles, which retail for approximately $15 for a twenty-ounce bottle containing sixteen servings.

15. Joint Juice contains glucosamine hydrochloride and chondroitin sulfate, which Premier falsely represents on each label are Joint Juice's active ingredients. Each serving consists of 1,500 mg of glucosamine hydrochloride and 200 mg of chondroitin sulfate.

16. Glucosamine hydrochloride is a combination of glucosamine (an amino sugar that is produced by the body in abundance) and hydrochloric acid. Unlike other glucosamine-infused products that often contain glucosamine sulfate, which is a combination of glucosamine and sulfur molecules. Glucosamine hydrochloride is less expensive than glucosamine sulfate. Glucosamine is one the most abundant monosaccharides (sugars) in the body.

17. Defendant markets Joint Juice to treat, prevent or cure osteoarthritis and to treat the symptoms of osteoarthritis, pain and stiffness, or inflexibility. Sometimes called degenerative joint disease or degenerative arthritis, osteoarthritis is the most common chronic condition of the joints, affecting over 32 million Americans. Osteoarthritis can affect any joint, but it occurs most often in knees, hips, hands, and the spine. According to the Arthritis Foundation, one in two adults will develop symptoms of osteoarthritis. According to the Centers for Disease Control and Prevention, the cardinal signs and symptoms of osteoarthritis include joint pain, joint stiffness, and loss of flexibility or the inability to move your joint through its full range of motion.[2]

18. Many people suffer from the symptoms that characterize osteoarthritis – joint pain, stiffness, and lack of mobility – but do not know they have osteoarthritis. This is because osteoarthritis typically develops slowly, so its symptoms are not severe enough to cause the person to seek medical intervention, but significant enough to cause the person to seek

[2] https://www.cdc.gov/arthritis/basics/osteoarthritis.htm.

remedies for the symptoms. As a result, many Joint Juice purchasers have not yet been diagnosed with osteoarthritis. Knowing this, Defendant targets these consumers by advertising through implied messaging that Joint Juice treats the cardinal symptoms of osteoarthritis.

Defendant's False and Deceptive Advertising

19. Defendant's target audience are middle-age and older consumers with pre- and early to mid-stage osteoarthritis. Based on well-conducted consumer research, Defendant has finely honed its package labeling, its primary medium of advertising Joint Juice, to target this population, becoming a large seller of joint health dietary supplements.

20. Leading with the package label for Joint Juice and reinforced through other advertisements, Defendant conveys to consumers that drinking Joint Juice will improve joint health, reduce recurring joint pain, stiffness, and increase joint mobility and flexibility for anyone who consumes Joint Juice.

21. Joint Juice ready-to-drink packaging has remained materially identical, always focused on the promised joint health benefits: "A bottle a day keeps your joints in play," "**Drink Daily for Healthy, Flexible Joints**," "**HELPS KEEP CARTILAGE LUBRICATED AND FLEXIBLE**," and "For Healthy, Flexible Joints."

22. Joint Juice's packaging appears as follows:

EasyShot™ (Front)

EasyShot™ (Back)

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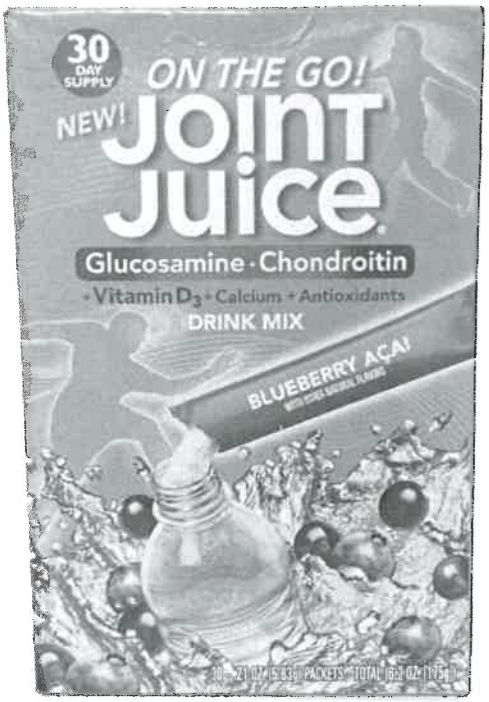
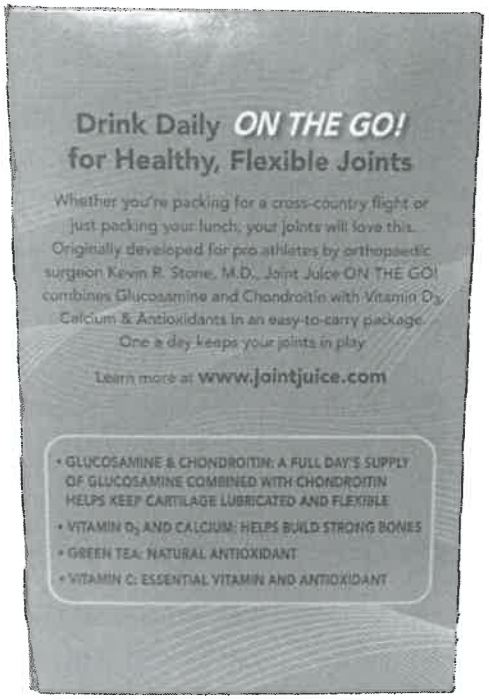
Drink Mix Box (Front)

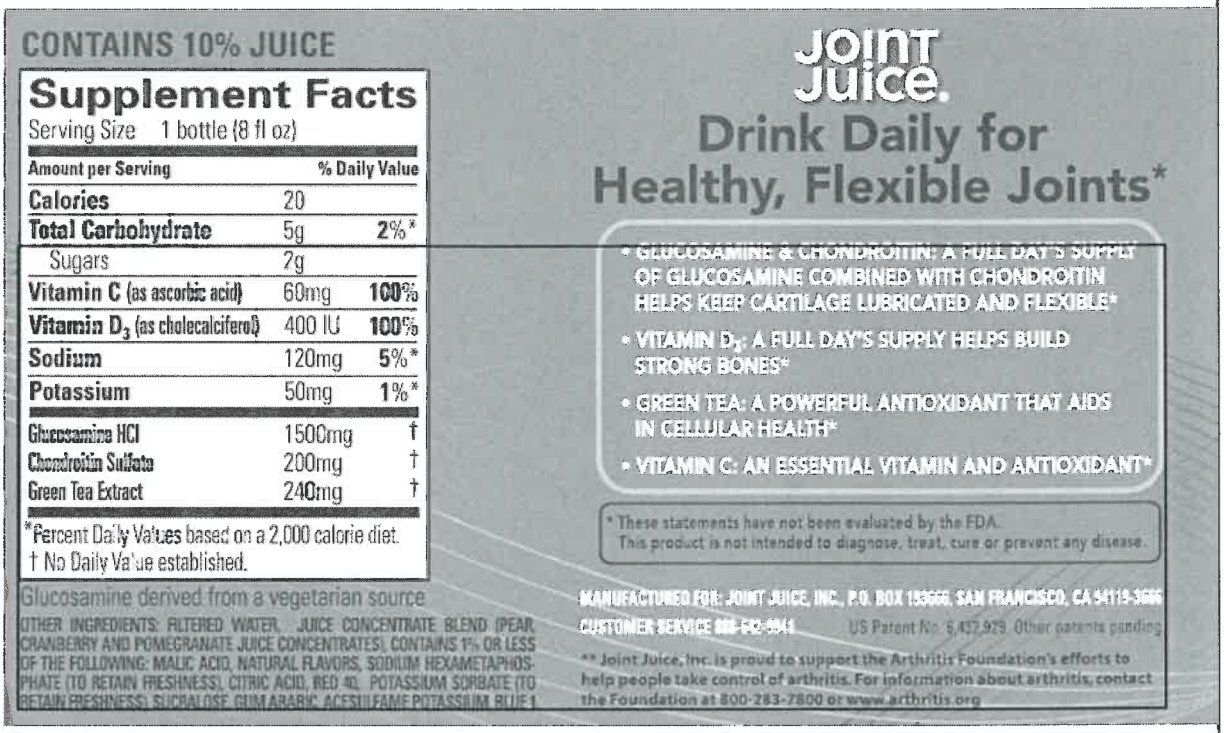


Drink Mix Box (Back)

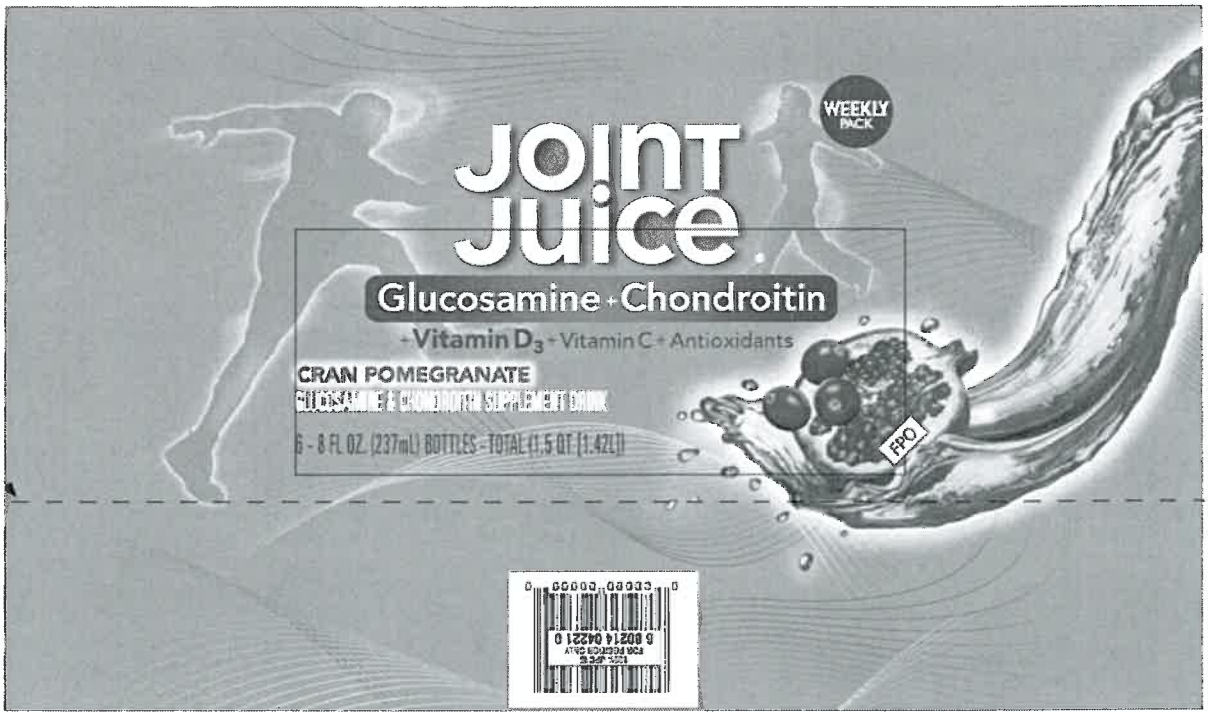


Ready-to-Drink ("RTD") Six-Pack (Top)

Ready-to-Drink ("RTD") Six-Pack (Back)



Ready-to-Drink ("RTD") Six-Pack (Front)



23. To reinforce the joint health message, Defendant repeats similar claims about osteoarthritis symptoms throughout the package label, including that Joint Juice was "originally developed for pro athletes by orthopedic surgeon Kevin R. Stone, M.D." and that "your joints will love this." Similarly, Defendant places silhouettes of people performing activities on the package to imply a promise of pain free, healthier joints.

24. Because it attracts purchasers who suffer from arthritis and joint pain and reinforces the joint health benefit marketing message, the packaging prominently displays the Arthritis Foundation logo. The labeling states: "Joint Juice is proud to support the Arthritis Foundation's efforts to help people take control of arthritis" and Premier "will donate a portion of the proceeds to the Arthritis Foundation … to help people take control of arthritis."

25. To add credibility to the advertising, Defendant provides consumers with an additional "reason to believe" that Joint Juice is effective. Providing a reason to believe advertising is a key psychological component to successful advertising. A reason to believe offered by Defendant and printed on every label of Joint Juice is the Arthritis Foundation logo and its website www.arthritis.org. According to Premier, the "Arthritis Foundation endorsement" is important to consumers who "have issues with joints or are concerned about their joints." This message misleadingly promotes a placebo effect on consumers.

26. Another reason to believe Premier utilized was well-known spokespersons like Joint Montana. In a 60-second television commercial, Joint Juice spokesman Joe Montana, states that "my joints have gotten a little stiff lately and at first I thought I had to live with it because of pro football and just getting older," makes the false and deceptive representations that "the glucosamine and chondroitin lubricates and cushions the cartilage in my joints so I can move more easily . . . it works great for anyone who likes to keep moving!" Further adding unfounded credibility to the deceptive claim, the Joint Juice advertisement also states that Joint Juice "was originally developed by an orthopedic surgeon for pro athletes."[3] According to

[3] "Extraordinary Joe", available at http://www.youtube.com/watch?v=9qOqK_GjoUM (last visited March 15, 2013); *see also* http://www.youtube.com/watch?v=EYN-hoTYELE (30 second version of the "Extraordinary Joe" television ad makes the same representations) (last visited August 28, 2020).

Defendant, "glucosamine and chondroitin have been proven to help maintain joint function and mobility."[4]

27. Although the package label is the single most important component of Defendant's marketing strategy, on the Joint Juice website, Defendant represents that "Research indicates that you should take a minimum of 1,500 mg of glucosamine daily for joint health. That's why we put 1,500 mg in every Joint Juice® product" and "Glucosamine works to lubricate your joints by helping cartilage tissue absorb water. This helps cartilage perform its job of cushioning and mobility."[5]

28. The Joint Juice website provides "Tips" about joints such as: "Chronic shoulder problems usually lead to symptoms of decreased range of motion and pain due to poor mechanics."; "'Oh my aching back!' Those words apply to almost all of us at some point in our lives. Studies show that 4 out of 5 adults will deal with back issues at some point. Fortunately, many causes of back pain are preventable – if you take a proactive approach."; "Muscle imbalance in the hips can lead to abnormal movement, which, over time can lead to cartilage damage."; and, "Take Supplements. Proper nutrition including supplements such as glucosamine, chondroitin" will keep your joints healthy.

29. Defendant's website also contains a prominent link to a "Joint Juice® joint health assessment." This marketing gimmick further reinforces the false and misleading representation that Joint Juice will provide the significant, advertised joint health benefits.

30. The extensive market research performed on the multi-billion-dollar joint supplement category shows that most joint health supplement consumers are older, experience joint pain, suffer from arthritis, consider glucosamine and chondroitin important and specifically associate those ingredients with providing joint pain relief, perceive joint health supplements as fairly undifferentiated, and purchase joint supplements including Joint Juice

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[4] "Joe Montana Partners with Joint Juice, Inc. to Get American on a Health Joint Regimen," available at http://www.bevnet.com/news/2011/joe-montana-partners-with-joint-juice-inc-to-get-americans-on-a-healthy-joint-regimen (last visited August 28, 2020).

[5] http://www.jointjuice.com/faq/general-information (last visited August 28, 2020).

primarily to provide relief from joint pain, joint stiffness, and other cardinal symptoms of arthritis.

31. In 2017, over 1,800 adults were surveyed for the "2017 Gallup Study of Supplements for Joint Health." Gallup reported that one of the strongest likelihoods of continuing/starting joint health supplements is "severe joint pain." 60% of those surveyed indicated they were aware of glucosamine products for prevention and therapeutic use. The study reported that use of joint health supplements peaks among joint pain sufferers who are diagnosed with osteoarthritis.

32. In 2015, global marketing firm Ipsos conducted in-depth market research of joint health supplements including Joint Juice's competitors. It found that the joint health market segment to be significantly skewed towards older consumers seeking to address pain, stiffness, and osteoarthritis. Ipsos found that advertising like Joint Juice's is aimed at consumers suffering from joint pain and that joint pain makes consumers feel frustrated, annoyed and depressed, but they are hopeful a joint health supplement will address these ailments, with one of the top hoped-for benefits of "improved flexibility" and "supports lubrication," which addresses the "need for joints to work the way they are supposed to[.]"

33. In a 2011 report, consumer research group Karlen Williams Graybill Advertising found that "[o]steoarthritis sufferers, diagnosed or not, are the target audience for joint care supplements." These conclusions were based on analysis of multiple quantitative and qualitative market research reports. These included 2009 research from MarketTools where 85% of respondents agreed "loss of flexibility" is how arthritis and joint pain affected their lives.

34. In June and July 2017, Multi-Sponsor Surveys Inc. reported results from "The 2017 Gallup Study of Supplement for Joint Health." The 2017 Gallup Study was conducted in two phases with the first (involving 1,035 respondents) measuring the size of the joint health market, and the second (involving 820 respondents) examining adults' choice of preventative and treatment methods. Gallup found that almost half of US adults suffer from joint problems, which are often associated with both arthritis and joint pain, stiffness or loss of flexibility,

knees are the body part most associated with pain and stiffness, incidence of joint problems rises steadily with age, glucosamine and chondroitin are the nutrients most widely used for joint health, and Joint Juice was one of the most well-known supplements to treat or prevent joint problems, with the top reason for using joint health supplements was to relieve joint pain or discomfort.

35. Over 50 million Americans had arthritis in 2009, and this number is expected to grow to 67 million by 2030, with many more who are undiagnosed.

36. On its packaging, Defendant includes a fine-print statement required by the FDA that the products are not intended to diagnose, treat, cure or prevent any disease. The statement, however, does not disavow the express and implied statements Defendant makes on the packaging and elsewhere and, if it could be interpreted to do so, would contradict these statements in violation of consumer protection law. At any rate, it is well established that consumers regularly do not read and do not consider the fine-print statement when buying dietary supplements. For example, France and Bone (2005) looked at the impact this mandatory statement and the structure/function characterization has on consumer beliefs when interpreting such claims.[6] They found that consumer disease beliefs are not "lower when the [mandatory statement] is used on the package than when it is not." Similarly, Mason et al. (2007) conducted two surveys about the impact of the mandatory statement on consumer perceptions of safety or efficacy of dietary supplements.[7] Professor Mason et al. concluded "No difference was found in efficacy perceptions for subjects exposed to the disclaimer compared to the control." They also noted that "It is particularly noteworthy that the mandated disclaimer did not impact either efficacy perceptions (as intended) or safety perceptions (as

[6] France and Bone, *Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels*, Journal of Consumer Affairs, 39(1):27-51 (2005).

[7] Mason et al., *The Impact of Warnings, Disclaimers, and Product Experience on Consumers' Perceptions of Dietary Supplements*, Journal of Consumer Affairs, 41(1):74-99 (2007).

might be expected, given the nature of the disclaimer) any differently than the control message."[8]

37. Defendant's market research found that "Joint Juice® supplement's association, on the other hand, is with pain-free, flexible joints primarily for those who suffer from arthritis or who are exceptionally hard on their joints." Premier states that "Joint Juice® supplement was developed as and continues to be marketed as a medical supplement specifically for joint pain issues[.]"

38. Defendant's employees state that the Joint Juice advertising implies pain relief. Premier's CEO and President states that Joint Juice consumers "have joint pain[,]" "stiffness" and some "use it as a preventative[.]" Another Premier employee states that the "happy" joints slogan means that joints "don't hurt most of the time."

Scientific Evidence Confirms that Joint Juice Does Not Work As Advertised

39. Despite Defendant's representations, the ingredients in Joint Juice have been extensively studied in large, well-conducted and published studies involving persons with and without diagnosed arthritis and have been shown ineffective at supporting or benefiting joint health, including the signs and symptoms of osteoarthritis.

40. Joint Juice does not play any special or unique role in the synthesis or repair of cartilage molecules. A healthy joint does not need exogenous glucosamine or chondroitin because it maintains its structure and function from the body's abundant source of glucose and proteoglycan synthesis. The process is only disrupted as a result of disease.

41. Likewise, as cartilage in a healthy joint degrades, the joint creates new cartilage at the same rate, so the structure and function of a healthy, non-diseased joint remains the

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[8] *See also* Kesselheim et al., *Mandatory Disclaimers On Dietary Supplements Do Not Reliably Communicate The Intended Issue*, Health Affairs, 34(3):438-446 (2015) at 445 ("We found ample evidence that such disclaimers are often misunderstood or ignored by consumers and had no effects on consumers' ability to understand messages about health care products and critically evaluate potentially unsupported statements about effectiveness or safety."); Tonya Dodge, *Consumers' perceptions of the dietary supplement health and education act: implications and recommendations*, Drug Testing and Analysis, 8:407-409 (2016) at 409 ("research suggests that the labelling requirements of DSHEA have little reliable impact on consumer beliefs about the risk and effectiveness of dietary supplements").

same. As a result, if a substance such as Joint Juice altered this homeostatic state by either stiffening or softening normal cartilage, disease would result. Joint Juice does not "help[] keep cartilage lubricated and flexible."

42. Studies involving people with diagnosed osteoarthritis apply to people who have the symptoms of osteoarthritis, but are not diagnosed with it. People who suffer from the cardinal symptoms of osteoarthritis – recurring joint pain, joint stiffness, and loss of flexibility or mobility that prevents movement of a joint through its full range of motion – have pre-osteoarthritis and early stage osteoarthritis.

Randomized Clinical Trials

43. Well designed and implemented 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.

44. The main ingredients in Joint Juice have been extensively studied and the well-designed and conducted RCTs demonstrate that the ingredients, alone or in combination, are not effective at producing joint health benefits, including reducing joint pain, discomfort, or stiffness, or increasing mobility, range of motion, or flexibility. Yet, Defendant markets Joint Juice to people with and without diagnosed arthritis.

45. As explained below, numerous scientific studies on persons with and without diagnosed arthritis have demonstrated that Joint Juice is incapable of providing the joint health benefits represented by Defendant. For example, the leading series of studies testing glucosamine and chondroitin are known as the "GAIT" studies, proved that glucosamine, with or without chondroitin, does not provide relief from joint pain, reduce joint stiffness, promote flexibility, mobility or range of motion, or help maintain healthy joint cartilage. The GAIT studies were independently conducted and funded by the National Institutes of Health (the "NIH"). The primary GAIT study cost over $12.5 million. Likewise, the studies conducted by Kwoh et al. (2014), Runhaar et al. (2015), Landsmeer et al. (2016), and de Vos et al. (2017)

examined persons without diagnosed arthritis and concluded that glucosamine does not improve overall quality of life or otherwise impact knee pain, joint stiffness, mobility and range of motion, physical function, or the incidence of osteoarthritis.

46. 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"). 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 et al., *Glucosamine, Chondroitin Sulfate, and the Two in Combination for Painful Knee Osteoarthritis*, New England J of Med, 354(8):795-808 (Feb 2006). The authors further explained: "Glucosamine and chondroitin sulfate alone or in combination did not reduce pain effectively in the overall group of patients" and "[a]nalysis of the primary outcome in the sub-group of patients with mild pain showed even smaller treatment effects."

47. The 2006 GAIT Study also concluded that glucosamine hydrochloride (*i.e.*, the version of glucosamine present in the Joint Juice products), chondroitin, and their combination do not relieve joint stiffness, improve joint function, impact joint swelling, or improve health-related quality of life as measured by eight domains: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health.

48. In 2008, findings from another NIH-funded GAIT study were published. *See* Sawitzke et al., *The Effect of Glucosamine and/or Chondroitin Sulfate on the Progression of Knee Osteoarthritis: A GAIT Report*, J Arthritis Rheum, 58(10):3183–91 (Oct 2008). The 2008 GAIT study explored the effects of glucosamine, chondroitin, and their combination on progressive loss of joint space width. Loss of joint space width is a structural condition associated with increased joint pain and decreased joint mobility and flexibility, and is a precursor of arthritis. The researchers examined 572 persons and 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 help maintain or rebuild cartilage.

49. In 2010, a third set of results from the GAIT studies were reported. *See* Sawitzke et al., *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*, Ann Rhem Dis, 69(8):1459-64 (Aug 2010). Authors of the 2010 GAIT report examined 662 persons over a two-year period and concluded that glucosamine and chondroitin, alone or in combination, 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.

50. In addition to the three 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.

51. In 2007, Messier et al. published results from their 12-month, double-blind RCT examining 89 subjects in the United States. Messier 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 does not improve knee extension strength or provide joint pain, function, stiffness, mobility or balance benefits.

52. Fransen et al. (2015) was a double-blind, randomized, placebo-controlled clinical trial examining 605 participants over a 2-year period. Fransen 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 (May 2015). 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"). Fransen and her co-authors also concluded "[t]here were no significant differences" between consumption or glucosamine and/or chondroitin versus a placebo pill for any secondary measures. These measures included pain, physical function, and health-related quality of life as measured by physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality (energy/fatigue), social functioning, role limitations due to emotional problems, and mental health (psychological distress and psychological well-being).

53. Using data obtained from NIH-funded initiatives, Yang et al. (2015) analyzed 1,625 participants over a 4-year period 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., *Effects of glucosamine and chondroitin on treating knee osteoarthritis: an analysis with marginal structural models*, Arthritis & Rheumatology, 63(3):714-23 (Mar 2015). In their report, which was published in the official journal of the American College of Rheumatology, Yang, et al. reported that glucosamine and chondroitin combinations provided no clinically significant benefits in terms of reducing pain or stiffness, improving physical function or mobility, or delaying the progression of joint space narrowing or osteoarthritis.

54. In 2016, Lugo et al., also published the results from a study comparing a combination of glucosamine and chondroitin versus placebo. Lugo 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 Journa, 15:14 (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 (the same glucosamine version in the Joint Juice products) and chondroitin sulfate was no better than placebo in terms of joint pain, stiffness, mobility or physical function.

55. Roman-Blas et al. (2017), was a multi-center, randomized, double-blind, placebo-controlled clinical trial involving 164 participants who received a combination of glucosamine and chondroitin or placebo for six months. Roman-Blas et al., *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, 69(1):77-85 (Jan 2017). Roman-Blas and co-authors found that a combination of glucosamine and chondroitin was inferior to a placebo pill in terms of reducing global pain. Glucosamine and chondroitin were also no better than a placebo pill "in any of the secondary outcomes measures," which included improvement in physical function, reduction in joint pain, or improvement in investigator's global assessment of the participant.

56. 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 clinical studies.

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

58. Rindone et al. performed a randomized, double-blind, controlled trial of 98 subjects in 2000. The investigators concluded that glucosamine "was no better than placebo in reducing pain[.]" Rindone et al., *Randomized, controlled trial of glucosamine for treating osteoarthritis of the knee,* The Western Journal of Medicine, 172(2):91-94 (Feb 2000).

59. Likewise, a 2004 study of 205 participants by McAlindon et al. concluded that "glucosamine was no more effective than placebo in treating symptoms of knee osteoarthritis," meaning glucosamine is ineffective. McAlindon et al., *Effectiveness of Glucosamine For Symptoms of Knee Osteoarthritis: Results From and Internet-Based Randomized Double-Blind Controlled Trial*, Am J Med, 117(9):643-49 (Nov 2004). Dr. McAlindon and his co-authors assessed and found no difference between glucosamine and placebo in terms of pain, stiffness, physical function, or any other assessed outcome. *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.").

60. A 2004 study by Cibere et al. studied users of glucosamine who claimed to have experienced at least moderate improvement after starting glucosamine. Cibere et al., *Randomized, Double-Blind, Placebo-Controlled Glucosamine Discontinuation Trial In Knee Osteoarthritis*, Arthritis Care & Research, 51(5):738-45 (Oct 2004). 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.").

61. Kawasaki et al. (2008) reports the results of a randomized trial among 142 subjects with knee osteoarthritis. Kawasaki et al., *Additive effects of glucosamine or risedronate for the treatment of osteoarthritis of the knee combined with home exercise: a prospective randomized 18-month trial*, Journal of Bone and Mineral Metabolism, 26:279-287

(Feb 2008). Subjects were given 1500 mg glucosamine hydrochloride per day, and researchers assessed its impact on pain, function, and changes in joint space width. Results showed no effect "regarding any of the scales indicating no significant additive effect of glucosamine[.]" *Id.* at 279. This credible, large study found that glucosamine is ineffective.

62. A 2008 study by Rozendaal et al. assessed the effectiveness of glucosamine on the symptoms and structural progression of hip osteoarthritis during two years of treatment. Rozendaal et al., *Effect of Glucosamine Sulfate on Hip Osteoarthritis*, Ann Intern Med, 148(4):268-77 (Feb 2008). 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.

63. 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*, JAMA, 304(1):45-52 (July 7, 2010).

64. In 2011, Cahlin et al. published a study evaluating the clinical effects of glucosamine on osteoarthritis in the temporomandibular joints. Cahlin et al., *No effect of glucosamine sulfate on osteoarthritis in the temporomandibular joints – a randomized, controlled, short-term study,* Oral Surg Oral Med Oral Pathol Oral Radiol Endod, 112:760-766 (2011). The trial concluded "[n]o differences in improvement between" glucosamine and a dummy pill. *Id.* at 760.

65. A 2017 study by Roman-Blas et al. 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. Roman-Blas et al., *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, 794:8-14 (Jan 2017).

66. Large, well-conducted clinical trials on persons without diagnosed arthritis have also been conducted, and these studies also demonstrate that glucosamine does not provide any joint health benefits, including reducing joint pain or stiffness, improving mobility, or slowing the progression of arthritis.

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

> In this 24-week study, we did not find any evidence that glucosamine is more effective than placebo in improving joint health, when assessed according to the outcomes of decreased cartilage deterioration on MRI, improvement of BMLs on MRI, decreased excretion of urinary CTX-II, and decreased pain or improved function.

Id. at 935.

68. Runhaar et al. (2015) also examined subjects not diagnosed with arthritis and found no benefits from glucosamine. Runhaar was an independently-analyzed double-blind, placebo-controlled, factorial design trial testing a diet-and-exercise program and 1500 mg oral glucosamine or placebo on 407 subjects. 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 (Aug 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.

69. Eraslan and Ulkar (2015) examined the impact of glucosamine versus placebo on knee pain, physical function (including range of motion) and muscular performance over an 8-week period in 30 athletes who did not have osteoarthritis. Eraslan A & Ulkar B, *Glucosamine supplementation after anterior cruciate ligament reconstruction in athletes: a randomized placebo-controlled trial*, Research in Sports Medicine, 23:14-26 (2015). Glucosamine was not effective in terms of any of the joint health parameters: "no significant differences were found regarding pain (VAS), functional status (IKDC, LYS) and muscular strength (isokinetic test) between the glucosamine and placebo groups."

70. Landsmeer et al. (2016) evaluated 407 (687 knees) middle-aged women without clinical signs of knee osteoarthritis, free of inflammatory rheumatic diseases, and not under the treatment of a physical therapist or general practitioner for knee complaints for a 2.5-year period. Landsmeer et al., *Reducing progression of knee OA features assessed by MRI in overweight and obese women: secondary outcomes of a preventive RCT*, Osteoarthritis and Cartilage, 24(6):982-990 (Jun 2016). The authors concluded that glucosamine "did not show preventive effects on progression of any of the MRI features [of early osteoarthritis] under investigation."

71. Based on data from 245 people without osteoarthritis, de Vos et al. (2017) determined the impact of glucosamine consumption over an average time period of 6.6 years. de Vos et al., *Long-term effects of a lifestyle intervention and oral glucosamine sulphate in primary care on incident knee OA in overweight women*, Rheumatology, 56(8):1326-1334 (Aug 2017). Study participants consumed placebo or 1500 mg daily glucosamine and periodically reported knee pain, physical activity and quality of life, and had their joint space width was measured by radiograph. Based on six-year analysis, de Vos and co-researchers concluded that glucosamine consumption is not effective at preventing knee osteoarthritis as measured according to either joint space width changes or based on symptomatic changes that included impact on knee pain or joint stiffness.

72. The other ingredients in Joint Juice, Vitamins C and D have also been scientifically studied and demonstrated to not provide joint health benefits.

73. Hughes et al. (2002) is a 6-month randomized, double-blinded, placebo-controlled trial of a glucosamine preparation that also contained 300 mg vitamin C and 5 mg manganese per day among 80 subjects. Hughes et al., *A randomized, double-blind, placebo-controlled, trial of glucosamine sulphate as an analgesic in osteoarthritis of the knee*, Rheumatology, 41:279-284 (Mar 2002). The study found there was no difference between the placebo and glucosamine plus vitamin C groups in terms of relieving knee pain or stiffness or improving physical function.

74. Felson et al. (2007) conducted an observational study among 992 subjects from two longitudinal cohort studies (715 from the Framingham Osteoarthritis Study and 277 from the Boston Osteoarthritis of the Knee Study). Felson et al., *Low level of vitamin D and worsening of knee osteoarthritis: Results of two longitudinal studies*, Arthritis and Rheumatology, 56:129-136 (Jan 2007). The purpose of the study was to confirm reports that vitamin D deficiency is associated with an increased risk of joint space narrowing or cartilage loss in OA. No association was found between vitamin D levels and radiographic worsening of joint space indicative of joint pain, stiffness and progression of OA.

75. McAlindon et al. (2013) conducted a randomized, double-blind, controlled trial among 146 subjects with knee osteoarthritis. McAlindon et al., *Effect of Vitamin D Supplementation on Progression of Knee Pain and Cartilage Volume Loss in Patients With Symptomatic Osteoarthritis*, JAMA, 309(2):155-162 (Jan 2013). Subjects were assigned to daily consumption of vitamin D or placebo for two years. The study assessed and found no differences at any time between vitamin D and placebo in terms of knee pain severity, cartilage volume loss, physical function, knee function, cartilage thickness, bone marrow lesions, or radiographic joint space width.

76. Chaganti et al. (2014) conducted a study among 3,026 participants of the Multicenter Osteoarthritis (MOST) Study, which involved persons with and without knee OA. Chaganti et al., *High plasma levels of vitamin C and E are associated with incident radiographic knee osteoarthritis,* Osteoarthritis and Cartilage, 22(2):190-196 (Feb 2014). The study aimed to examine the association of levels of vitamin C and knee OA. Results showed

that persons who possessed the highest tertile of vitamin C levels had a higher incidence of knee OA. That is, the presence of vitamin C was associated with knee OA.

77. Jin et al. (2016) conducted a two-year, randomized, double-blind, controlled trial among 413 subjects with knee osteoarthritis and low levels of vitamin D. Jin et al., *Effect of Vitamin D Supplementation on Tibial Cartilage Volume and Knee Pain Among Patients With Symptomatic Knee Osteoarthritis,* JAMA, 315(10):1005-1013 (Mar 2016). Results showed no significant differences between those consuming vitamin D and placebo in terms of changing cartilage volume, pain or biomarkers associated with OA progression, and the authors "findings do not support the use of vitamin D supplementation" for preventing cartilage loss or improving knee pain. *Id.* at 1005.

78. Cooper et al. (2016) conducted a randomized, double-blind, controlled trial among 474 subjects with knee osteoarthritis. Cooper et al., *Maternal gestational vitamin D supplementation and offspring bone health (MAVIDOS): a multicentre, double-blind, randomised placebo-controlled trial*, Lancet Diabetes and Endocrinology, 4(5):393-402 (May 2016). Subjects were assigned to vitamin D or placebo consumption for three years. The study assessed and found no differences in the rate of joint space narrowing, or changes in pain, physical function, or stiffness.

79. MacFarlane et al. (2020) reported results from a double-blind RCT which evaluated 1,398 U.S. adults suffering from knee pain. MacFarlane et al., *The Effects of Vitamin D and Marine Omega-3 Fatty Acid Supplementation on Chronic Knee Pain in Older U.S. Adults: Results from a Randomized Trial*, Arthritis & Rheumatology, doi:10.1002/art.41416 (June 25, 2020). After supplementation with vitamin D for an average of 5.3 years, the study found that vitamin D "did not reduce knee pain or improve function or stiffness" more than a placebo at any recorded timepoint. Vitamin D also did not "alter the use of analgesics including opioids over the study period" and had no effect on the incidents of knee replacements. The authors noted that the negative results were in agreement with previous RCTs.

80. Many studies have also confirmed there is a significant "placebo" effect with respect to consumption of products represented to be effective in providing joint health benefits such as Defendant's Joint Juice products. 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. Zhang et al., *The placebo effect and its determinants in osteoarthritis: meta-analysis of randomised controlled trials*, Annals of the Rheumatic Diseases, 67(12):1716-23 (Dec 2008) (Analyzing the placebo effect size from 198 trials relating to joint health benefits and concluding that "[p]lacebo is effective in the treatment of OA, especially for pain, stiffness and self-reported function.").

Meta-Analyses and Scientific Review Articles

81. Well-designed and conducted meta-analyses are also considered a high level of evidence because they provide a method to evaluate the aggregated results of all relevant studies according to their pooled effects and methodological quality.

82. In a 2007 meta-analysis, Vlad et al. reviewed all studies involving glucosamine hydrochloride and concluded that "[g]lucosamine hydrochloride is not effective." Vlad et al., *Glucosamine for Pain in Osteoarthritis*, Arthritis & Rheumatology, 56(7):2267-77 (July 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.").

83. In 2009, Towheed et al. published an updated Cochrane Collaboration Review (first published in 2001 and previously updated in 2005). Towheed et al., *Glucosamine therapy for treating osteoarthritis*, Cochrane Database Sys Rev. (2009). Like its earlier versions, the 2009 Cochrane Review and meta-analysis also found that pooled results from studies using non-Rotta preparations of glucosamine (e.g., studies involving the form of glucosamine in Joint Juice) or adequate concealment (e.g., patient or investigator blinding) failed to show benefits for joint pain or joint function. The evidence amassed since Towheed's study inclusion cutoff (January 2008) strengthens its conclusion even more. Indeed, in 2017, Pratt and co-authors from the Clinical Epidemiology Program at Ottawa Hospital Research Institute (OHRI), officially tasked with analyzing Cochrane reviews, specifically examined whether

results from studies published after the Towheed meta-analysis merit updating the Cochrane Review. Pratt et al., *Signal detection report: glucosamine therapy for treating osteoarthritis* (2017). Pratt and co-authors observed that new findings from Fransen (2015), Kwoh (2014), Petersen (2011), and Sawitzke (2010) met the original inclusion criteria, but determined "[p]ooling of [this] new evidence did not change the overall pooled estimates of the original review" by Towheed et al. concerning glucosamine's lack of an effect on joint pain and joint function:

> This is similar to the original review findings of no significant difference between the treatment and placebo for WOMAC pain. One study also reported no statistically significant results for maximum knee pain between the groups. For WOMAC function, three studies reported similar results to the original review findings of no statistically significant difference between glucosamine and placebo.

84. A 2010 meta-analysis by Wandel et al. 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. Wandel et al., *Effects of Glucosamine, Chondroitin, Or Placebo In Patients With Osteoarthritis Or Hip Or Knee: Network Meta-Analysis*, BMJ, 341:c4675 (Sep 2010). 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.*

85. 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).

86. The meta-analysis by Eriksen et al. (2014) included 25 glucosamine trials, which collectively involved 3,458 patients. Eriksen 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 (Dec 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."

87. Singh et al. (2015) is Cochrane Systematic Review of the efficacy of chondroitin involving results from 43 trials. Singh et al., *Chondroitin for osteoarthritis (Review)*, Cochrane Database of Systematic Reviews, 1:CD005614 (2015). Statistically insignificant results for pain scores were seen when the analysis was limited to studies with appropriate allocation concealment, a large study sample, or without pharmaceutical funding. No physical function benefits were found either.

88. A 2016 scientific review by Vasiliadis et al. concluded that "[t]here is currently no convincing information on the efficacy of [glucosamine] or [chondroitin] as treatment options in [osteoarthritis]," 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]." Vasiliadis et al., *Glucosamine and chondroitin for the treatment of osteoarthritis*, World J Orthop, 8(1):1-11 (Jan 2017).

89. 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., *Subgroup analyses of the effectiveness of oral glucosamine for knee and hip osteoarthritis: a systematic review and individual patient meta-analysis from the OA trial bank*, Osteoarthritis and Cartilage, 76(11):1862-1869 (Nov 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 joint pain or physical function.

90. A 2018 review published in The Journal of Family Practice examined the RCT by Roman-Blas et al. (2018) and conclude that the study "found evidence of a lack of efficacy." Lyon et al., *Time to stop glucosamine and chondroitin for knee OA?,* The Journal of Family Practice, Vol 67:9 (Sept 2018). "In patients with more severe OA of the knee, placebo was more effective than CS/GS, and CS/GS had significantly more adverse events. Therefore, it may be time to advise patients to stop taking their CS/GS supplement."

Evidence-Based Professional Guidelines

91. Professional guidelines are also consistent in their recommendation against using glucosamine or chondroitin. These "evidence-based" guidelines are based on systematic reviews and/or meta-analyses of all the available study data.

92. In 2009, the American Academy of Orthopaedic Surgeons ("AAOS") published clinical practice guidelines for the "Treatment of Osteoarthritis of the Knee (Non-Arthroplasty)," and recommended that "glucosamine and/or chondroitin sulfate or hydrochloride not be prescribed for patients with symptomatic OA of the knee." This recommendation was given a grade A, the highest level of recommendation. Richmond et al., *Treatment of osteoarthritis of the knee (nonarthroplasty)*, Journal of the American Academy of Orthopedic Surgeons, 17(9):591-600 (Sep 2009).

93. In 2011, the Cochrane Collaboration published a decision aid for arthritis patients. *See* The Cochrane Collaboration, *What are my options for managing hip or knee osteoarthritis? A stepped decision aid to discuss options with your practitioner,* (2011).[9] Glucosamine and chondroitin were given a "Level 0" meaning that they "have the same benefits and harms as a placebo (fake treatment)."

94. In 2013, the AAOS published an update to its 2009 evidence-review and 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." *Id.* at 6.

[9] available at https://musculoskeletal.cochrane.org/decision-aids

95. Based on the AAOS recommendations, in 2014 the American Board of Internal Medicine Foundation issued a publication as part of its "Choosing Wisely" initiative. American Board of Internal Medicine Foundation, *Treating osteoarthritis of the knee Popular supplements don't work,* (2014).[10] The article states that "[m]any studies have shown that glucosamine and chondroitin sulfate do not help to relieve arthritic knees. … people get similar results if they take a placebo–a 'sugar pill' with no active ingredients." It also warns that "[t]hese supplements are a waste of money. You will spend about $130 a year if you take glucosamine/chondroitin supplement every day. To make matters worse, often labels on the bottles are misleading."

96. Likewise, the American College of Rheumatology ("ACR"), the United Kingdom National Institute for Health and Care Excellence ("NICE"), and the National Health Service England ("NHS England") (part of England's Department of Health) 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.

97. In 2014, the U.S. Department of Veteran Affairs Department of Defense ("VA/DoD") issued a Clinician Guideline Summary based upon the best information available and designed to assist healthcare professionals. The VA/DoD recommended that "[c]linicians should not prescribe chondroitin sulfate, glucosamine, and/or any combination of the two, to treat joint pain or improve function." *Va/DoD clinical practice guideline for the non-surgical management of hip & knee osteoarthritis*, Department of Veterans Affairs Department of Defense, Version 1.0-2014.

98. In 2014, NICE published clinical guidelines based on the "best available research evidence." NICE National Institute for Health and Care Excellence. *Osteoarthritis: Care and management in adults*. Clinical guideline 177. The guidelines state that "[h]ealthcare

[10] available at https://www.choosingwisely.org/wp-content/uploads/2018/02/Treating-Osteoarthritis-Of-The-Knee-AAOS.pdf

professionals are expected to take NICE clinical guidelines fully into account when exercising their clinical judgement[,]" and "[d]o not offer glucosamine or chondroitin products for the management of osteoarthritis." *Id.* at 3, 42.

99. The National Collaborating Centre for Chronic Conditions ("NCCCC"), a center established by the United Kingdom's National Institute for Health and Care Excellence, produced National Health Service healthcare guidelines stating that "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.

100. In November 2017, NHS England submitted a Board Paper to the England Secretary of State. *Items which should not be routinely prescribed in primary care: findings of consultation and next steps – for decision*, NHS England, PB.30.11.2017/05. Glucosamine and chondroitin combination products made "the list of 18 products which they consider to be ineffective, unnecessary, inappropriate or unsafe for prescription[.]" *Id.* at 4. The group also recommended "that the Secretary of State formally consider blacklisting … Glucosamine and Chondroitin[.]" *Id.* at 9. In addition to the recommendations, the working group performed a survey of clinicians, organizations and patients. The survey found that 98% of clinical commissioning groups agree that glucosamine and chondroitin should not be prescribed to new patients. *Id.* at 60.

101. In 2018, the American Academy of Family Physicians ("AAFP") published a "Rapid Evidence Review." Ebell, *Osteoarthritis Rapid Evidence Review*, American Family Medicine, 97(8):523-526 (2018). It recommended that the "Best Practices in Orthopedics" was "[d]o not use glucosamine and chondroitin to treat patients with symptomatic osteoarthritis of the knee." The author also concluded that vitamin D supplement is "ineffective for OA."

102. In 2019, the American College of Rheumatology (ACR) and Arthritis Foundation (AF) organized a panel of nationally recognized academic and practicing

physicians to update the 2012 ACR guidelines and recommendations for physicians treating hand, hip, and knee OA patients. The panel of experts "strongly recommended against" health care providers using glucosamine to manage the symptoms of hand, knee or hip osteoarthritis or using chondroitin or "combination products that include glucosamine and chondroitin sulfate" to manage the symptoms of knee and hip osteoarthritis. Kolasinski et al., *2019 American College of Rheumatology / Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee*, Arthritis & Rheumatology, 72(2):220-233 (Feb 2020). With respect to glucosamine, the 2019 ACR / AF expert consensus guidelines note "[t]he data that were deemed to have the lowest risk of bias fail to show any important benefits over placebo", "[t]he weight of the evidence indicates a lack of efficacy and large placebo effects", and "as with glucosamine there was clear evidence of industry bias" for studies involving chondroitin.

103. The AAOS, ACR / AF, NICE, AAFP, VA/DoD and NHS England guidelines were based on systematic reviews and/or meta-analyses of all the available study data. For example, the conclusions of the 2019 ACR / AF Guidelines rely on 17 RCTs for glucosamine, 18 RCTs for chondroitin, and 10 RCTs involving a combination of glucosamine plus chondroitin. 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 2013 AAOS "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

104. Despite the scientific evidence demonstrating Joint Juice's ineffectiveness, Defendant conveyed and continues to convey that Joint Juice is a joint health supplement capable of benefiting joints, including improving the symptoms of osteoarthritis.

105. As the inventor, manufacturer, and distributor of Joint Juice, Defendant possesses specialized knowledge regarding the content and effects of the ingredients contained in Joint Juice, and Defendant is in a superior position to know whether Joint Juice works as advertised.

106. Specifically, Defendant knew, but failed to disclose, that Joint Juice cannot provide the joint health benefits represented and that well-conducted, clinical studies, meta-analyses and evidence-based guidelines have determined Joint Juice's ingredients are unable to support or benefit joint health.

107. Class members have been and will continue to be deceived or misled by Defendant's false and deceptive joint health benefit representations.

108. Defendant's joint health representations and omissions were a material factor in influencing Plaintiff's and the class members' decision to purchase Joint Juice. In fact, the only purpose for purchasing Joint Juice is to obtain the promised joint health benefits.

109. Defendant's conduct has injured Plaintiff and the class members because Joint Juice does not provide the advertised benefits.

110. Had Plaintiff and other reasonable consumers known this, they would not have purchased Joint Juice or would not have paid the prices they paid.

111. The vast majority of sales are the Joint Juice ready-to-drink product which retails for approximately $16 per 30-count package. Because of Defendant's false and deceptive advertising, consumers have paid over $32 million for Joint Juice in California alone during the class period.

CLASS DEFINITION AND ALLEGATIONS

112. Plaintiff brings this class action on behalf of herself and all others similarly situated pursuant to Civil Code § 1781, and asserts this action on behalf of the following class:

> All persons who purchased in California any Joint Juice product from March 1, 2009 until June 20, 2016 (the "Class").

Excluded from the Class is the Defendant, its parents, subsidiaries, affiliates, officers, and directors; those who purchased the Joint Juice products for the purpose of 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.

113. Certification of Plaintiff's claims for classwide 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.

114. Members of the Class are so numerous that joinder of all class members is impracticable. The Class contains many thousands of members.

115. Common questions of law and fact exist as to all members of the Class and predominate over questions affecting only individual Class members. The common legal and factual questions include, but are not limited to, the following:

(a) Whether the representations discussed herein that Defendant made about its Joint Juice products were or are true, misleading, or likely to deceive;

(b) Whether Defendant's conduct violates public policy;

(c) Whether Defendant engaged in false or misleading advertising;

(d) Whether Defendant's conduct constitutes violations of the laws asserted herein;

(e) Whether Plaintiff and the other Class members have been injured, and the proper measure of their losses as a result of those injuries; and

(f) Whether Plaintiff and the other Class members are entitled to injunctive, declaratory, restitutionary or other equitable relief.

116. The claims asserted by Plaintiff in this action are typical of the claims of the members of the Class, as the claims arise from the same course of conduct by Defendant, and the relief sought is common. Plaintiff and Class members suffered uniform monetary loss caused by their purchase of the Joint Juice products marketed and sold by Defendant.

117. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Plaintiff has retained counsel competent and experienced in both consumer protection and class litigation.

118. 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 money lost 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.

119. Defendant has acted or refused to act on grounds generally applicable to the Class thereby making final declaratory and/or injunctive relief with respect to the members of the Class as a whole, appropriate.

120. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the Class, on grounds generally applicable to the Class, to enjoin and prevent Defendant from engaging in the acts described, and to require Defendant to provide full restitution to Plaintiff and Class members.

121. Unless the Class is certified, Defendant will retain monies that were taken from Plaintiff and Class members as a result of Defendant's wrongful conduct. Unless a classwide injunction is issued, Defendant will continue to commit the violations alleged and the members of the Class and the general public will continue to be misled.

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CLAIMS ALLEGED

COUNT I

Violation of Business & Professions Code §§ 17200, *et seq.*
(On behalf of the Class)

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

123. As alleged herein, Plaintiff has suffered injury in fact and lost money or property as a result of Defendant's conduct because she purchased one of Defendant's falsely advertised Joint Juice in reliance on the false advertisements.

124. The Unfair Competition Law, Business & Professions Code §§ 17200, *et seq.* ("UCL"), prohibits any "unlawful," "fraudulent" or "unfair" business act or practice and any false or misleading advertising. 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.*, the Sherman Food, Drug, and Cosmetic Laws, Cal. Health & Safety Code §§ 109875, *et seq.*, including Cal. Health & Safety Code §§ 110390, 110395, 110760, 110765, 111440, 111445, the Food Drug & Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, and the common law.

125. Plaintiff, individually and on behalf of the other Class members, 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.

126. 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 Joint Juice in its advertising campaign, including the Joint Juice packaging, as set forth more fully herein. There is no societal benefit from false advertising – only harm. Plaintiff and other Class members paid for a valueless product that does not confer the benefits it promises. While Plaintiff and 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.

127. Further, as set forth in this Complaint, Plaintiff alleges violations of consumer protection, unfair competition, and truth in advertising laws in California, 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*.

128. 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 Joint Juice in its advertising campaign, including on the Joint Juice packaging and labeling, as set forth more fully herein. Defendant made the misrepresentations and omissions regarding the efficacy of its products, among other ways, by misrepresenting on each and every Joint Juice 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 products do not confer the promised health benefits.

129. 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*.

130. 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 Joint Juice products. Plaintiff and the other Class

members have suffered injury in fact and lost money as a result of purchasing the products and Defendant's unlawful, unfair, and fraudulent practices.

131. Defendant knew, or should have known, that its material representations and omissions would be likely to deceive the consuming public and result in consumers purchasing Joint Juice products and, indeed, intended to deceive consumers.

132. As a result of its deception, Defendant has been able to reap unjust revenue and profit.

133. Unless restrained and enjoined, Defendant will continue to engage in the above-described conduct. Accordingly, injunctive relief is appropriate.

134. Plaintiff, on behalf of herself, all others similarly situated, and 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 unfair competition, an injunction prohibiting Defendant from continuing such practices, corrective advertising, and all other relief this Court deems appropriate, consistent with Business & Professions Code § 17203.

COUNT II

Violation of the Consumers Legal Remedies Act – Civil Code §1750, *et seq.*
(On behalf of the Class)

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

136. This cause of action is brought pursuant to the Consumers Legal Remedies Act, California Civil Code §§ 1750, *et seq.* (the "Act"). Plaintiff is a consumer as defined by California Civil Code § 1761(d). The products are "goods" within the meaning of the Act.

137. Defendant violated and continues to violate the Act by engaging in the following practices proscribed by California Civil Code § 1770(a) in transactions with Plaintiff and the Class which were intended to result in, and did result in, the sale of its Joint Juice products:

> (5) Representing that [Joint Juice products have] . . . approval, characteristics, . . . uses [and] benefits . . . which [they do] not have . . . .

* * *

(7) Representing that [Joint Juice products 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 [Joint Juice products] have been supplied in accordance with a previous representation when [they have] not.

138. Defendant violated the Act by representing and failing to disclose material facts on its Joint Juice labeling and associated advertising, as described above, when it knew, or should have known, that the representations were false and misleading and that the omissions were of material facts they were obligated to disclose.

139. Pursuant to California Civil 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 and all other relief this Court deems proper.

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

REQUEST FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the other members of the Class proposed in this Complaint, respectfully requests that the Court enter judgment in her 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 Defendant to pay restitution and disgorgement to Plaintiff and the other members of the Class;

C. Awarding 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.

Respectfully submitted,

Dated: August 31, 2020

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