MILSTEIN ADELMAN LLP
Gillian L. Wade, State Bar No. 229124
gwade@milsteinadelman.com
Stephanie Mazepa, State Bar No. 263070
smazepa@milsteinadelman.com
2800 Donald Douglas Loop North
Santa Monica, California 90405
Telephone: (310) 396-9600
Fax: (310) 396-9635

Attorneys for Plaintiff,
Robert McCrary
and the Proposed Class

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

ROBERT MCCRARY individually and on behalf of all others similarly situated,

Plaintiffs,

vs.

THE ELATIONS COMPANY, LLC, a Delaware limited liability company; and DOES 1 through 100, inclusive,

Defendants.

CASE NO.: ED CV 13-00242 JGB (OPx)

CLASS ACTION

FOURTH AMENDED COMPLAINT

1. VIOLATION OF CALIFORNIA CIVIL CODE § 1750, *et seq.* (Consumer Legal Remedies Act)
2. VIOLATION OF BUSINESS & PROFESSIONS CODE § 17500, *et seq.*
3. VIOLATION OF BUSINESS & PROFESSIONS CODE § 17200, *et seq.* (UNFAIR AND FRAUDULENT PRONGS)
4. VIOLATION OF BUSINESS & PROFESSIONS CODE § 17200, *et seq.* (UNLAWFUL PRONG)

DEMAND FOR JURY TRIAL

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

Plaintiff Robert McCrary ("McCrary") ("Plaintiff"), individually and on behalf of all other similarly situated purchasers of the Elations Daily Joint Supplement Drink (the "Class"), brings this complaint against The Elations Company, LLC ("Defendant"). Plaintiff seeks certification of this matter as a class action. Plaintiff, by and through his attorneys, submits this Fourth Amended Class Action Complaint (the "Complaint") against Defendant, and alleges as follows:

SUMMARY OF COMPLAINT

1. Defendant markets, distributes and sells the Elations glucosamine/chondroitin supplement beverage ("Elations") it advertises as a "Daily Joint Supplement Drink". The primary purported active ingredients in Elations are glucosamine hydrochloride, chondroitin sulfate and boron. In its marketing and advertising for Elations, including the product packaging and the Elations website, Defendant promises that Elations contains a "clinically proven combination" and "clinically proven formula" that has certain joint health benefits.

2. In particular, Defendant highlights on the product packaging and the Elations website the so-called active ingredients—glucosamine and chondroitin—and asserts Elations contains a "clinically-proven formula" and "clinically proven combination" of glucosamine, chondroitin and boron that should be consumed daily for joint health benefits, even though Elations is not clinically proven to do anything and the product cannot work as advertised.

3. Plaintiff is informed and believes that the foundation of Defendant's marketing scheme consists of product packaging and at least one website that is owned and controlled by Defendant. This principle website is www.elations.com. During the class period, Defendant conveyed its deceptive message to consumers through a wide variety of media, including its website and online promotional materials, print ads, and at the point of purchase on the Elations packaging where it cannot be missed by consumers. The marketing scheme executed by Defendant deceives consumers by making false claims about the uses and benefits of Elations in

order to drive sales of the product. In reality, the claims about the benefits and uses of Elations are false and misleading because Elations is not "clinically proven" and the product does not (because it cannot) work as advertised. In fact, Defendant's own studies dating back to 2002 confirm Elations does not work, but Defendant continued to boldly advertise Elations as a clinically proven product when it knew these claims were false. Some of the claims Defendant makes about Elations include: "Elations Clinically-Proven Combination" and "Clinically-Proven Formula." These claims constitute false and deceptive advertising.

4. In the course of manufacturing, marketing, distributing, and selling Elations, Defendant has committed and continues to commit illicit business practices in direct violation of: (1) California's Unfair Competition Law ("UCL"), *Business & Professions Code* § 17200, *et seq.*; (2) California's False Advertising Law ("FAL"), *Business & Professions Code* § 17500, *et seq.*; and (3) California's Consumer Legal Remedies Act ("CLRA"), *Civil Code* § 1750, *et seq.*

5. By utilizing misrepresentations in the marketing and advertising for Elations, Defendant has violated applicable California consumer protection statutes, including but not limited to the UCL, FAL, and CLRA.

6. Through such false and misleading claims about the purported uses and benefits of Elations, Defendant has wrongfully induced thousands of California consumers to purchase Elations. In doing so, Defendant has reaped millions of dollars in ill-gotten gains.

7. This action seeks to put an end to Defendant's unfair, fraudulent and unlawful business practices.

JURISDICTION AND VENUE

8. This Court has jurisdiction over this action under the Class Action Fairness Act, 28 U.S.C. § 1332(d). As set forth in detail in Defendant's removal papers, the aggregated claims of the individual class members exceed the sum value of $5,000,000, exclusive of interests and costs, and this is a class action in which

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

more than two-thirds of the proposed plaintiff class, on the one hand, and Defendant, on the other, are citizens of different states.

9. This Court has jurisdiction over Defendant because Defendant has sufficient minimum contacts in California, or otherwise intentionally avails itself of the markets within California, through promotion, sale, marketing and distribution of Elations in California, to render the exercise of jurisdiction by this Court proper and necessary. Moreover, Defendant can be brought before this Court pursuant to California's "long-arm" jurisdictional statute.

10. Venue is proper in this District under 28 U.S.C. § 1391 because a substantial part of the events and misrepresentations giving rise to Plaintiff McCrary's claims occurred in this District, Plaintiff McCrary resides in San Bernardino County, and Plaintiff McCrary purchased the subject product in San Bernardino County.

PARTIES

11. Plaintiff McCrary at all times relevant hereto was an individual residing in San Bernardino County, California. McCrary, who suffers from arthritic joint pain, purchased Elations from CVS in 2011. In doing so, he relied upon the advertising which was prepared and approved by Defendant and its agents and disseminated through its packaging and labeling, containing the misrepresentations alleged herein.

12. Defendant The Elations Company, LLC ("Defendant") is a limited liability company organized and existing under the laws of the State of Delaware, with its principle place of business located at 6000 Creek Road, Cincinnati, OH 45242. Defendant, directly and through its agents, has substantial contacts with and receives substantial benefits and income from and through the State of California. Defendant is the registered trademark owner and distributor of Elations, and is the company that created and/or authorized the false, misleading and deceptive advertisements and packaging for Elations.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

13. The true names and capacities, whether individual, corporate, associate or otherwise of certain manufacturers, distributors and/or their alter egos sued herein as DOES 1 through 100 inclusive are presently unknown to Plaintiff who therefore sue these Defendants by fictitious names. Plaintiff will seek leave of this Court to amend the Complaint to show their true names and capacities when the same have been ascertained. Plaintiff is informed and believes and based thereon alleges that DOES 1 through 100 were authorized to do and did business in San Bernardino County. Plaintiff is further informed and believes and based thereon alleges that DOES 1 through 100 were and/or are, in some manner or way, responsible for and liable to Plaintiff for the events, happenings, and damages hereinafter set forth below.

14. Plaintiff is informed and believes and based thereon alleges that at all times relevant herein each of the Defendants were the agent, servant, employee, subsidiary, affiliate, partner, assignee, successor-in-interest, alter ego or other representative of each of the remaining Defendants and were acting in such capacity in doing the things herein complained of and alleged.

15. In committing the wrongful acts alleged herein, Defendants planned and participated in and furthered a common scheme by means of false, misleading, deceptive and fraudulent representations to induce members of the public to purchase Elations.

16. Defendant, upon becoming involved with the manufacture, distribution, advertising, marketing and sale of Elations knew that the claims about Elations and, in particular, the claims that Elations contains a "clinically-proven combination" and/or "clinically-proven formula", were false, deceptive and misleading. Defendant affirmatively misrepresented, and continues to misrepresent, the uses and benefits of Elations in order to convince the public to purchase and use the product, resulting in millions of dollars in profits to Defendant, and significant detriment to the consuming public.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

CLASS ACTION ALLEGATIONS

17. Plaintiff brings this action on his own behalf and on behalf of all other persons similarly situated. The Class which Plaintiff seeks to represent comprises:

> **All persons who purchased Elations in California from May 2009 through December 2012, for personal use and not for resale, when the following claims were on the packaging and/or labeling of Elations: "clinically-proven combination" and/or "clinically-proven formula."**
>
> **Excluded from the Class are governmental entities, Defendants, any entity in which Defendants have a controlling interest, and Defendants' officers, directors, affiliates, legal representatives, employees, co-conspirators, successors, subsidiaries, and assigns. Also excluded from the Class is any judge, justice, or judicial officer presiding over this matter and the members of their immediate families and judicial staff.**

18. This action is maintainable as a class action under Rules 23(a), 23(b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure.

FRCP 23(a) Factors

19. **Numerosity:** The Class comprises many thousands of persons throughout the State of California. The class is so numerous, that joinder of all members is impracticable, and the disposition of their claims in a Class Action will benefit the parties and the Court.

20. **Commonality:** The questions of law and fact common to the Class have the capacity to generate common answers that will drive resolution of this action. Common questions of law and fact include, but are not limited to, the following:

a. Whether Defendant's conduct is an unfair business act or practice within the meaning of *Business & Professions Code* § 17200, *et seq.*;

b. Whether Defendant's conduct is an unlawful business act or practice within the meaning of *Business & Professions Code* § 17200, *et seq.*

c. Whether Defendant's conduct is a fraudulent business act or practice within the meaning of *Business & Professions Code* § 17200, *et seq*.;

d. Whether Defendant's advertising is untrue or misleading within the meaning of *Business & Professions Code* § 17500, *et seq*.;

e. Whether Defendant made false and misleading representations in its advertising for Elations;

f. Whether Defendant knew or should have known that the representations were false;

g. Whether Defendant represented that Elations has characteristics, benefits, uses or quantities which it does not have;

h. Whether Defendant represented that Elations is of a particular standard, quality, or grade, when it is of another; and

i. Whether Defendant advertised Elations with intent not to sell it as advertised.

21. **Typicality:** Plaintiff's claims and Defendant's defenses thereto, are typical of the claims of the proposed Class, as the representations of clinical proof made by Defendant are consistent, uniform and material, and are contained in advertisements that were seen by all members of the Class. Thus, there exists a presumption that all Class members relied upon said uniform and consistent advertising and representations to their detriment. Additionally, all members of the proposed Class have the same or similar injury (loss of purchase price) based on Defendant's false and misleading marketing and advertising.

22. **Adequacy:** Plaintiff does not have any conflicts with any other members of the proposed Class, and will fairly and adequately represent and protect the interests of the proposed Class. Plaintiff has retained competent and experienced counsel in class action and other complex litigation.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

FRCP 23(b)(2)

23. Defendant has acted on grounds generally applicable to the entire Class, thereby making final injunctive relief and/or corresponding declaratory relief appropriate with respect to the Class as a whole. The prosecution of separate actions by individual Class members would create the risk of inconsistent or varying adjudications with respect to individual member of the Class that would establish incompatible standards of conduct for Defendant.

24. Injunctive relief is necessary to prevent further fraudulent and unfair business practices by Defendant. Money damages alone will not afford adequate and complete relief, and injunctive relief is necessary to restrain Defendant from continuing to commit its deceptive, fraudulent and unfair policies.

FRCP 23(b)(3)

25. **Common Issues Predominate:** As set forth in detail herein, common issues of fact and law predominate because all of Plaintiff's UCL, FAL and CLRA claims are based on a uniform, false and misleading advertising message which all class members were necessarily exposed to: the Elations Daily Joint Supplement Drink contains a "clinically-proven formula" and/or "clinically-proven combination" of ingredients. Whether this claim is true or false is common to all members of the Class and is the predominate issue, and Plaintiff can prove the elements of his 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.

26. **Superiority:** A class action is superior to other available methods for fair and efficient adjudication of this controversy. The expense and burden of individual litigation would make it impracticable or impossible for Class members to prosecute their claims individually. Absent a class action, Defendant will likely retain the benefits of its wrongdoing. Because of the small size of the individual Class members' claims, few, if any, Class members could afford to seek legal redress for the wrongs complained of herein. Absent a representative action, the

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

Class members will continue to suffer losses and Defendant will be allowed to continue these violations of law and to retain the proceeds of its ill-gotten gains.

27. The trial and litigation of Plaintiff's claims are manageable. Individual litigation of the legal and factual issues raised by Defendant's conduct would increase delay and expense to all parties and the court system. The class action device presents far fewer management difficulties and provides the benefits of a single, uniform adjudication, economies of scale, and comprehensive supervision by a single court.

28. **Notice to the Class:** Notice can be accomplished by publication for most class members, and for those who purchased Elations directly from Defendant's website, direct notice can be made because Defendant has customer information from shipping records. Further, publication notice can be easily targeted to the proper retail outlets because Defendant tracks lot and serial numbers through its distribution chain, from the point of manufacturing and/or shipment to the point of sale. Defendant knows when and where each package of Elations was and is sold and whether that package contained the "clinically proven" claims that are at issue through this "track and trace" system.

FACTUAL ALLEGATIONS

A. Overview Of The Causes, Symptoms, And Treatments Of Joint Problems Caused By Arthritis

29. A joint is the point where two or more bones are connected. With a few exceptions (in the skull and pelvis, for example), joints are designed to allow movement between the bones and to absorb shock from movements like walking or repetitive motions. These movable joints are made up of the following parts: cartilage (the hard, but slippery tissue that covers the ends of bones where they meet to form a joint); joint capsule; synovium; synovial fluid (a fluid that lubricates the joint and keeps the cartilage smooth and healthy); and soft tissue (i.e. ligaments, tendons and muscles) that surrounds the bones and joints, and allow the joints to

bend.

30. In a healthy joint, the ends of the bones are encased in smooth cartilage. Together, they are protected by a joint capsule lined with a synovial membrane that produces synovial fluid. The capsule and fluid protect the cartilage, muscles, and connective tissues.

31. Osteoarthritis ("OA") – the most common type of arthritis, impacting an estimated 27 million adults in the United States – primarily affects the cartilage, causing it to break down and wear away. This destruction of the cartilage allows the bones underneath to rub together, which inflames the surrounding soft tissue and leads to joint pain and stiffness.

32. There is no cure for OA, but there are a number of treatments for the disease that have varying levels of success depending on the patient. Most successful treatment programs involve a combination of treatments tailored to the patient's needs, lifestyle, and health, and include ways to manage pain and improve function. The treatments range from exercise and weight control, to non-drug therapies, to medications to control the pain (including acetaminophen, nonsteroidal anti-inflammatory drugs or NSAIDs, and injections), and even surgery.

B. Promotion Of Glucosamine And Chondroitin In The Treatment Of Joint Pain And Osteoarthritis

33. Glucosamine and chondroitin have been widely promoted as a treatment for joint pain and OA. Glucosamine, an amino sugar, was thought to promote the formation and repair of cartilage.[1] Chondroitin, a carbohydrate, is a cartilage

[1] This theory that glucosamine could build and repair cartilage was based on the hypothesis that glucosamine supplementation provides the building blocks necessary to promote the formation of healthy cartilage. However, this "over-simplified" hypothesis does not adequately explain the purported mechanism of action of glucosamine, which remains unknown. *See* Herrero-Beaumont, *et al.*, Use of crystalline glucosamine sulfate in osteoarthritis. *Future Rheumatol.* 2006, 1(4): 397-414. As such, at present there is no bonafide medical treatment capable of rebuilding cartilage. The only way to repair damaged cartilage is to surgically remove it and replace it with healthy cartilage.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

component that is thought to promote water retention and elasticity and to inhibit the enzymes that break down cartilage.

34. Since 1997, the use of glucosamine and chondroitin has exploded. The country's best-selling dietary supplements, which come from animal sources such as crab shells and cow, pig or chicken cartilage, were thought to relieve knee pain and perhaps repair the cells that line the joint, revitalizing worn cartilage.

35. Despite its explosion on the national marketplace, the use of glucosamine in the management of joint pain and OA remains controversial, and its purported mechanism of action in joint pain caused by OA and joint function modification are still unclear. As a result, the American College of Rheumatology ("ACR")[2] and the UK National Institute for Health and Clinical Excellence (NICE) have not recommended glucosamine in the management of OA.[3] While at least one source has recommended *glucosamine sulfate* for the management of hip and knee OA,[4] none of the current guidelines have recommended the use of glucosamine hydrochloride (the ingredient in Elations).

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

[2] American College of Rheumatology Subcommittee on Osteoarthritis: Recommendations for the medical management of osteoarthritis of the hip and knee: 2000 update. *Arthritis Rheum* 2000, 43:1905-1915.

[3] NICE Clinical Guidelines: The care and management of osteoarthritis in adults, *National Institute for Health and Clinical Evidence* 2008.

[4] *See* W. Zhang, *et al.*, EULAR evidence based recommendations for the management of hip osteoarthritis: Report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). *Ann Rheum Dis* 2005, 64: 669-681; W. Zhang, *et al.*, EULAR Recommendations 2003: an evidence based approach to the management of knee osteoarthritis: Report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). *Ann Rheum Dis* 2003, 62: 1145-1155. Another organization, the Osteoarthritis Research Society International ("OARSI"), originally recommended the use of glucosamine sulfate for the management of knee OA. *See* W. Zhang, *et al.*, OARSI recommendations for the management of hip and knee osteoarthritis, Part I: Critical appraisal of existing treatment guidelines and systematic review of current research evidence. *Osteoarthritis Cartilage* 2010, 18:476-499. However, glucosamine sulfate is no longer recommended in the most recent OARSI guidelines. *See* W. Zhang, *et al.*, OARSI recommendations for the management of hip and knee osteoarthritis: Part III: changes in evidence following systematic cumulative update of research published through January 2009. *Osteoarthritis Cartilage* 2010, 18:476-499.

36. Nevertheless, seeking to cash in on the ever-increasing popularity of glucosamine and chondroitin, Defendant introduced Elations, asserting that the Daily Joint Supplement beverage contains a "clinically-proven formula" and "clinically-proven combination" of chondroitin and glucosamine. This could not be further from the truth.

C. Overview Of Elations' Marketing And Advertising

37. Targeting consumers in need of joint pain relief, including those suffering from arthritis and the elderly, Defendant promised its Elations Daily Joint Supplement Drink contains a "clinically-proven formula" and a "clinically-proven combination" of ingredients.

38. Throughout its marketing and advertising, Defendant links Elations' ingredients to the characteristic signs and symptoms of OA (i.e. breakdown of cartilage leading to joint pain and stiffness). For instance, under the "News & Events" tab on www.elations.com, Defendant highlights a press release in the August 2006 edition of Medical News, which states that: "Elations promises 'joint flexibility' and contains the nutritional supplements glucosamine, which is believed to play a role in cartilage formation and repair, and chondroitin, a natural component of cartilage that is thought to help with elasticity." Rick Zimmerman, Defendant's Senior Vice President of Marketing and Innovation and General Manager, goes on to state that "[t]he ingredients in Elations are known to actually help renew joint cartilage, cushion joints, and improve joint flexibility." Defendant also focused on the identifiable signs and symptoms of OA in its literature regarding the "Health Professionals Program," which was intended to market Elations to physicians, pharmacists and other licensed healthcare professionals. *See* Ex. A. As part of the "Product Insight" directed at healthcare professionals, Defendant stated that "**1,500 mg Glucosamine**, which improves healthy joints, thickens joint fluid for better lubrication, and helps form the building blocks of joint cartilage" and "**1,200 mg Chondroitin**, which is a major component of joint cartilage, acts as an antioxidant

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

to reduce joint damage, and stimulates cartilage production." *Id.* (emphasis in original). Defendant further explained to healthcare professionals that Elations can "rejuvenate" joints, because "[d]rinking Elations daily ensures that joint cartilage and joint fluid have an abundant, continuous supply of the essential building blocks needed to optimize joint health." *Id.*

39. Moreover, Defendant's advertising highlights "research" regarding the purported joint health benefits of daily supplementation with 1,500 mg glucosamine and 1,200 mg chondroitin. The "research" Defendant references in its advertising is comprised entirely of clinical studies and meta-analyses investigating the role of glucosamine and chondroitin—alone or in combination—in treating the signs or symptoms of arthritis, specifically OA. This is because arthritis studies are the sole context in which the efficacy (or lack thereof) of glucosamine and chondroitin—the so-called active ingredients in Elations—have ever been tested.

40. Published studies concerning the effectiveness of Elations' ingredients in treating OA—which Defendant references in its advertising—affirmatively prove Elations is not clinically proven and cannot work as advertised.

41. In addition, Defendant's own "confidential" studies of its product—one conducted in 2002 and one conducted in 2008—actually confirm Elations is no more effective than placebo and is incapable of delivering the advertised benefits. Defendant's studies actually show Elations is clinically proven to *not* work. This is not surprising, given that decades of peer reviewed, well-conducted, published studies on the ingredients in Elations establish they have no effect whatsoever on joint pain.

D. Overwhelming Scientific Evidence Demonstrates Defendant's Claims Regarding "Glucosamine" And "Chondroitin" Are False And Misleading

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

42. According to Defendant's marketing and advertising, the two primary active ingredients in the Elations Daily Joint Supplement Drink are "Glucosamine 1,500 mg" and "Chondroitin 1,200 mg."

(1) No positive clinical trials of glucosamine hydrochloride—the form of glucosamine in Elations—exist

43. Defendant is careful to disclose the form of "glucosamine" used in the product—glucosamine hydrochloride ("GH")—only as required in the nutrition facts on the label. This is because the only studies done on glucosamine that have returned positive results were actually done on a different form of glucosamine, namely crystalline glucosamine sulfate ("CGS").

44. CGS, a pharmaceutical-grade product, is the stabilized form of glucosamine sulfate ("GS").[5] CGS was developed by the Italian manufacturer Rottapharm-Madaus and is used as a prescription drug for OA in Europe.

45. The earliest clinical trials with glucosamine were undertaken in Europe during the early 1980s and 1990s, and involved almost exclusively CGS. Many of these studies done during this period, however, failed to meet the well-recognized

[5] CGS is commonly referred to as "glucosamine sulfate," but it should not be confused with the dietary supplement glucosamine sulfate preparations available in the United States. *See* Herrero-Beaumont G, *et al*., Use of crystalline glucosamine sulfate in osteoarthritis. *Future Rheumatol.* 2006, 1(4): 397-414 ("At present, it is unclear how other preparations of glucosamine sulfate, mainly available in countries where the substance is regulated as a dietary supplement, compare with this prescription formulation [crystalline glucosamine sulfate] in terms of active ingredient content, purity and stability, since this information is generally not available. When formulations are unknown, and especially in view of the absence of appropriate bioequivalence studies… it is not known how the clinical efficacy and safety results obtained with crystalline glucosamine sulfate apply to these uncontrolled nutraceutical or generic preparations, and *vice versa*."). Indeed, a number of high-quality clinical studies using dietary supplement grade GS were unable to replicate the favorable results obtained with pharmaceutical-grade CGS. *See* David T. Felson, Glucosamine sulfate might have no pain or structural changes associated with osteoarthritis. *Nature Clinical Practice Rheumatology* 4, 518-19 (October 2008); McAlindon T, *et al*., Effectiveness of glucosamine for symptoms of knee osteoarthritis: results from an internet-based randomized double-blind controlled trial. *Am. J. Med.* 2004, 117: 643-49; Cibere J, *et al*., Randomized, double-blind, placebo-controlled glucosamine discontinuation trial in knee osteoarthritis. *Arthritis Care Res.* 2004, 51: 738-45; Hughes R, *et al*., A randomized, double-blind, placebo-controlled trial of glucosamine sulfate as an analgesic in osteoarthritis of the knee. *Rheumatology* 2002, 41: 279-84.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

standards for good clinical practice; there were significant methodological limitations, as well as small sample sizes, which significantly reduce the confidence in the reported outcomes. Nevertheless, this lack of confidence in the data was accepted within the scientific community at the time and expressed in the conclusions of a review and meta-analysis published at the time which called for additional well designed and well conducted studies to be undertaken by investigators independent of the manufacturers.[6]

46. In fact, all of the clinical trials of glucosamine that have produced positive results used CGS, *not GH as in Elations*, and were limited exclusively to those carried out by Rottapharm. Accordingly, there is now widespread agreement in the scientific community that the efficacy and safety data obtained using CGS cannot be extrapolated to dietary supplement GS and GH:

- "[The Rotta preparation of glucosamine sulfate] has shown positive effects on symptomatic and structural outcomes of knee OA. These results should not be extrapolated to other glucosamine salts (hydrochloride or preparations (over-the-counter or food supplements)) in which no warranty exists about content, pharmacokinetics and pharmacodynamics of the tablets."[7]
- "Perhaps the major limitation with extrapolating the generally favorable results from the glucosamine RCTs lies in the fact that most of the studies (65%) in the Cochrane review evaluated exclusively the prescription medicine made by the Rotta Pharmaceutical Company (a GS preparation that is approved as a prescription drug for OA in the European Union countries). In North America, glucosamine is not considered a conventional prescription drug, rather it is considered as a

[6] *See* McAlindon TE, *et al.*, Glucosamine and chondroitin for treatment of osteoarthritis: a systematic quality assessment and meta-analysis. *JAMA* 2000, 283:1469-1475.

[7] J.-Y. Reginster, *et al.*, Current role of glucosamine in the treatment of osteoarthritis. *Rheumatology* 2007, 46: 731-35.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

dietary supplement, which is widely available as an over the counter preparation. Since the content and purity of the various over the counter preparations is known to vary markedly, the relative efficacy and safety of the various preparations may also vary markedly[.]"[8]

- "In this study, [crystalline glucosamine sulfate] was approved as a prescription drug, therefore, our results cannot be generalized to other glucosamine products (or compound mixtures) such as those available in some countries as dietary supplements."[9]
- "Glucosamine derivatives are popular dietary supplements in the United States and other countries, exploiting the opportunity provided by the American Dietary Supplement Health and Education Act and the clinical research data obtained with glucosamine sulfate approved as a prescription drug for the treatment of osteoarthritis in Europe and elsewhere. The latter was used in our study and in most of the previous clinical experiences; at present, it is difficult to generalize these results to the highly variable and uncontrolled formulations of the other nutritional products claiming a glucosamine content."[10]
- "Differences in the clinical effects with generic or dietary supplement glucosamine hydrochloride formulations may indeed be related to differences in dose regimens and in pharmacokinetics, which may lead to differences in the pharmacological properties. In addition, the presence of sulfates in the prescription drug formulation [crystalline glucosamine sulfate], which is stabilized according to a patented

[8] Towheed TE, *et al*., Glucosamine therapy for treating osteoarthritis (Review). The Cochrane Database of Systematic Reviews, Issue 2. Art. No.: CD002946. ("2005 Cochrane Review").

[9] Reginster, *et al.*, Long-term effects of glucosamine sulfate on osteoarthritis progression: a randomized, placebo-controlled clinical trial. *Lancet* 2001, 357 (9252): 251 – 56.

[10] Pavelka, *et al.*, Glucosamine Sulfate Use and Delay of Progression of Knee Osteoarthritis: A 3-Year, Randomized, Placebo-Controlled, Double-blind Study. *Arch. Intern. Med.* 2002, 162(18): 2113-23.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

process, has also been suggested to be important from the point of view of favoring some of the compound pharmaco-metabolic characteristics, which might not be shared by glucosamine hydrochloride. Conversely, preparations of glucosamine sulfate, other than the prescription formulation, manifest differences in quality and dose regimens that would require appropriate pharmacokinetic and bioequivalence assessment. Since this is not currently available, it is impossible to apply the efficacy and safety results obtained with crystalline glucosamine sulfate to these other preparations and *vice versa*[.]"[11]

- "The present study has been conducted using the once-a day soluble powder formulation of crystalline glucosamine sulfate used in pivotal clinical trials, which is a prescription drug in most European countries. Transfer of the efficacy and safety data obtained with this substance and formulation to common dietary supplements, has already been discouraged. In fact, these uncontrolled formulations often have a much lower glucosamine content than reported in their label claims and are thus commonly underdosed. In addition, there is currently no clinical justification to use different glucosamine compounds or even glucosamine salts, e.g., hydrochloride, as pivotal trials failed to show the same benefit."[12]
- "Crystalline glucosamine sulfate is the only pharmaceutical product that has demonstrated consistently that it is effective against the symptoms and progression of knee osteoarthritis…. Glucosamine hydrochloride and other glucosamine sulfate preparations have produced inconsistent clinical efficacy results, probably owing to different pharmacokinetics,

[11] Herrero-Beaumont G, *et al*., Use of crystalline glucosamine sulfate in osteoarthritis. *Future Rheumatol.* 2006, 1(4): 397-414.

[12] Persiani, *et al.*, Glucosamine oral bioavailability and plasma pharmacokinetics after increasing doses of crystalline glucosamine sulfate in man. *Osteoarthritis and Cartilage* 2005, 13(12): 1041–1049.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

> suboptimal dosing schedule, study design and, in some studies, quality of the products…. Future studies should directly compare the pharmacokinetics and therapeutic effects of glucosamine hydrochloride or other glucosamine sulfate preparations with the reference crystalline glucosamine sulfate product and regimen in suitably designed, placebo-controlled trials in OA patients, before the former are further used to assess the role of glucosamine in OA since their results may be misleading."[13]

(2) Scientific evidence affirmatively establishes that glucosamine hydrochloride—the ingredient in Elations—is no more effective than placebo

47. On Elations packaging during the class period, Defendant represented Elations contains a "clinically-proven formula" and a "clinically-proven combination" of ingredients. No information is or was included during the class period to enable consumers to locate and review this alleged proof. By advertising Elations is "clinically-proven," the burden is on Defendant to prove what it cannot: that Elations has indeed been clinically proven to work as advertised.

48. However, credible scientific evidence confirms Elations is not effective. Indeed, as a recent article discussing the body of scientific evidence on glucosamine explained, "***[t]here appears to be consensus that GlcN.HCl [glucosamine hydrochloride] lacks efficacy for the palliation of pain or function in OA [osteoarthritis].***"[14]

49. This "consensus" is reiterated throughout the scientific literature regarding GH:

- "[T]wo of the major published guidelines recommended glucosamine

[13] Roy D Altman, Glucosamine therapy for knee osteoarthritis: pharmacokinetic considerations. *Expert Rev. Clin. Pharmacol.* 2009, 2(4): 359-71.

[14] Block, *et al.*, The effects of oral glucosamine on joint health: is a change in research approach needed? *Osteoarthritis and Cartilage* 2010, 18: 5-11.

sulfate in the treatment of OA pain while another integrating more recent data did not consider glucosamine sulfate. At this time, glucosamine hydrochloride cannot be recommended based on the available clinical data."[15]

- "In other pharmaceutical-grade products, glucosamine is supplied as hydrochloride, that is, a more readily available and easier to manufacture salt that is also present in several dietary supplements available in the markets around the world. This salt is often supplied in combination with chondroitin sulfate (CS) and has not proven effective in several trials."[16]
- "Trials using glucosamine hydrochloride had a very small summary effect size that was statistically indistinguishable from the null. The finding that heterogeneity among these trials was absent suggests that this summary effect is valid. Therefore, we conclude that glucosamine hydrochloride has no effect on pain and that future studies of this preparation are unlikely to yield useful results."[17]
- "The best available evidence found that glucosamine hydrochloride, chondroitin sulfate, or their combination provide no clinical benefit in patients with primary [Osteoarthritis] of the knee."[18]

50. The lack of effectiveness of GH was demonstrated recently in the GAIT Study, the lone, large-scale clinical trial to use GH. Under the direction of the

[15] Henrotin, *et al.*, Is there any scientific evidence for the use of glucosamine in the management of human osteoarthritis?, *Arthritis Research & Therapy* 2012, 14:201.
[16] Roy D Altman, Glucosamine therapy for knee osteoarthritis: pharmacokinetic considerations. *Expert Rev. Clin. Pharmacol.* 2009, 2(4): 359-71.
[17] Vlad, *et al.*, Glucosamine for Pain in Osteoarthritis: Why Do Trial Results Differ? *Arthritis & Rheumatism* 2007, 56(7): 2267-77.
[18] U.S. Department of Health and Human Services – Agency for Healthcare Research and Quality, *Treatment of Primary and Secondary Osteoarthritis of the Knee*, Evidence Report/Technology Assessment No. 157, Sept. 2007, at 106 (systematic review of the scientific literature – including study-level meta-analyses and randomized controlled trials – examining the clinical effectiveness of glucosamine, chondroitin sulfate, and a combination of the two ingredients in relieving joint pain associated with osteoarthritis).

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

National Institutes of Health (NIH), one of the world's foremost medical research centers, 13 highly prestigious research universities in the US performed the GAIT Study, which was a randomized, double-blind, placebo controlled, parallel assignment efficacy study on approximately 1,600 Osteoarthritis sufferers.

51. After six months, researchers reported that, overall, GH and chondroitin sulfate (whether alone, or in the exact combination found in Elations) are no more effective than placebo.[19]

52. When the GAIT Study was published in the New England Journal of Medicine, it was accompanied by an editorial which concluded the following:

> The finding that glucosamine hydrochloride was not more efficacious than placebo is not surprising. Several systematic reviews and meta-analyses have examined the efficacy of glucosamine in the treatment of osteoarthritis of the knee. In the most recent meta-analysis of eight randomized trials in which either glucosamine hydrochloride or glucosamine sulfate not manufactured by Rottapharm was compared with placebo, differences between the groups in the WOMAC[20] scores did not reach significance…. On the basis of the results from GAIT, it seems prudent to tell our patients with symptomatic osteoarthritis of the knee that neither glucosamine hydrochloride nor chondroitin sulfate alone has been shown to be more efficacious than placebo for the treatment of knee pain. If patients choose to take dietary supplements to control their symptoms, they should be advised to take glucosamine sulfate rather than glucosamine hydrochloride and, for

[19] The combination of GH and chondroitin sulfate appeared to help a small subset of participants with moderate-to-severe pain. However, because of the small size of the subset, researchers specified that such findings should be considered "preliminary" and could not be confirmed without further testing designed for that purpose. The hypothesis that these ingredients may help a subset of the population was undermined by the 2-year ancillary GAIT study and another study utilizing GAIT participants, both of which found that GH and chondroitin sulfate do not provide clinically significant relief from OA pain. *See* Sawitzke, A.D., *et al.*, The effect of glucosamine and/or chondroitin sulfate on the progression of knee osteoarthritis: A report from the glucosamine/chondroitin arthritis intervention trial. *Arthritis Rheum*. 2008, 58(10): 3183-91; Sawitzke, A.D., *et al.*, Clinical efficacy and safety over two years use of glucosamine, chondroitin sulfate, their combination, celecoxib or placebo taken to treat osteoarthritis of the knee: a GAIT report, *Ann Rheum Dis.* 2010, 69(8): 1459-64.

[20] WOMAC stands for Western Ontario and McMaster University Osteoarthritis Index, which is a set of standardized questionnaires used by health professionals to evaluate the condition of patients with osteoarthritis of the knee and hip.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

> those with severe pain, that taking chondroitin sulfate with glucosamine sulfate may have an additive effect.[21]

53. To study whether GH and/or chondroitin sulfate could diminish the structural damage caused by OA, interested GAIT patients were offered the opportunity to continue their original study treatment for 18 more months, for a total of two years.[22] The ancillary study enrolled 572 GAIT participants with moderate or severe knee Osteoarthritis, and the final sample included 357 subjects with Osteoarthritis in one or both knees. Each of these subjects was randomly assigned to receive one of the five treatments used in the first GAIT study.

54. The second GAIT analysis used x-rays to measure the physical effects of these supplements on knee joints. Knee images from the 357 subjects were analyzed to see if daily GH/chondroitin supplements prevented a loss of joint space—the distance between the ends of bones in the joint.

55. Once again, researchers found that there were no meaningful differences among people taking the combination of GH/chondroitin sulfate and a placebo. In fact, researchers observed that loss of joint space width was greater with the combined treatment than with either treatment alone, which raised the possibility that the combination of GH and chondroitin sulfate (in identical amounts to that found in Elations) may actually interfere with absorption.[23]

56. Since the conclusion of the ancillary GAIT study, there was another study conducted involving 662 GAIT participants with moderate-to-severe knee osteoarthritis.[24] This subset continued to receive their randomized treatment:

---

[21] Hochberg, Marc C., Nutritional Supplements for Knee Osteoarthritis – Still No Resolution, *N Engl J Med* 2006, 354(8): 858-60.

[22] Sawitzke, A.D., *et al.*, The effect of glucosamine and/or chondroitin sulfate on the progression of knee osteoarthritis: A report from the glucosamine/chondroitin arthritis intervention trial. *Arthritis Rheum*. 2008, 58(10): 3183-91.

[23] This hypothesis is supported by another recent study establishing that chondroitin sulfate inhibits GH absorption and decreases its bioavailability. *See* Jackson, *et al.*, The human pharmacokinetics of oral ingestion of glucosamine and chondroitin sulfate taken separately or in combination. *Osteoarthritis Cartilage* 2010, 18: 297-302.

[24] *See* Sawitzke, A.D., *et al.*, Clinical efficacy and safety over two years use of glucosamine, chondroitin sulfate, their combination, celecoxib or placebo taken to treat osteoarthritis of the knee: a GAIT report, *Ann Rheum Dis.* 2010, 69(8): 1459-64.

glucosamine HCl (500 mg three times daily), chondroitin sulfate (400 mg three times daily), glucosamine and chondroitin sulfate combined (same doses), celecoxib (Celebrex, 200 mg once daily), or a placebo. Over two years, no treatment achieved a clinically significant difference in WOMAC pain or function as compared with placebo.

57. Notably, at least during 2007 until a time that is unknown, Defendant advertised on its website and with the product itself on a leaflet that the GAIT Study was proof of Elations' effectiveness, even though the GAIT study actually proves that 1,500 of glucosamine hydrochloride and 1,200 mg of chondroitin (the amounts of these ingredients in Elations) is not effective. Defendant continued to claim Elations is clinically proven and contains proven levels of glucosamine and chondroitin in its advertising during the class period, but did not reference any studies when doing so.

58. Further, additional studies show that an oral dosage of 1,500 mg of glucosamine produces an insignificant trace amount of glucosamine in human blood cells, an amount which does not contribute directly to chondroitin synthesis.[25]

(3) Recent scientific evidence undermines the effectiveness of chondroitin sulfate

59. As with GH, recent evidence demonstrates chondroitin sulfate does nothing for the joints:

- "Efficacy of chondroitin sulfate over placebo for treating pain in OA was reported in many of the smaller, earlier studies, but the estimates varied considerably from study to study. In recent years, larger-scale trials have reported little to no effect of chondroitin sulfate treatment on the symptoms of OA."[26]

[25] Silbert, J.E., Dietary Glucosamine Under Question, *Glycobiology*, 2009, Vol. 19 no. 6 pp. 564-567

[26] *See* Miller, *et al.*, Glucosamine and Chondroitin Sulfate, *Rheum Dis Clin N Am* 2011, 37: 103-118.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

- "No robust evidence supports the use of chondroitin in osteoarthritis. Large-scale, methodologically sound trials indicate that the symptomatic benefit is minimal to nonexistent. The effect of chondroitin on joint space narrowing was assessed in only a few trials. This effect is likely to be small, and its clinical significance is uncertain. In patients with low-grade osteoarthritis, the use of chondroitin should be restricted to randomized, controlled trials. For patients with advanced osteoarthritis, a clinically relevant benefit is unlikely and the use of chondroitin should be discouraged."[27]

60. In touting the efficacy of Elations' ingredients, Defendant simply ignores this scientific evidence which clearly demonstrates that the product cannot work as advertised.

E. Defendant's "Clinically-Proven" Claims Are Literally False, And Completely Undermined By Prevailing Scientific Evidence And Defendant's Own "Clinical" Testing

61. Defendant touts Elations' "clinically-proven formula" and "clinically-proven combination" of ingredients throughout its advertising and product packaging.

62. However, Defendant has no clinical tests that prove the combination of glucosamine, chondroitin and boron in Elations is capable of or effective in improving joint health or comfort, and Defendant's "clinically-proven" claims are literally false because no such clinical proof exists. The only clinical proof regarding Elations is clinical proof that Elations does not work.

63. Defendant has conducted two "clinical studies" on various forms of Elations. Defendant first commissioned a study of Elations in 2002. A dermatologist conducted an opinion survey where subjects assessed their own pain

[27] *See* Reichenbach, *et al.*, Meta-analysis: Chondroitin for Osteoarthritis of the Knee or Hip, *Ann Intern Med.* 2007, 146: 580 – 590.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

levels after using the provided test product. Half of the subjects were given a formulation of Elations without chondroitin sulfate, and half were given a placebo. The overall observation from the study is that there was no difference between the control group and placebo group. In other words, Elations did not make a difference on joint pain (or anything for that matter).

64. Further, as noted, this initial study tested a form of Elations that contained Glucosamine HCL 1,500 mg, vitamin C 60 mg, CCM 300 mg, and Boron 3 mg, but did not contain any chondroitin. Thus, in addition to the fact that the results of the study were negative, this 2002 study does not and cannot support any claims concerning the clinical efficacy of Elations while it contained 1,200 mg of chondroitin (which it did throughout the class period).

65. Dissatisfied with the results of the first study, Defendant hired a research company to test the product a second time in or about 2008. This time, anticipating the negative result that had occurred earlier, Defendant used its own product as the placebo *and* the control product. In doing so, Defendant intentionally eliminated the placebo response and thus concluded Elations is effective. But this is nonsense and decidedly not "clinical proof" of anything at all. The entire study is useless without a placebo control.

66. Further, regardless of the flawed design of the study since it lacks a placebo control, the results of this study still do not prove the combination or formula of chondroitin, glucosamine and boron are any more effective than a supplement containing glucosamine and chondroitin (which scientific consensus has shown is not effective in treating joint pain or improving joint health), and does not provide "clinical proof" that Elations will or can improve joint health.

67. Thus, Defendant's own internal "clinical studies" demonstrate Elations is no more effective than placebo[28] and is incapable of providing the advertised

[28] A placebo, by definition, is an inactive substance or preparation used as a control in an experiment or test to determine the effectiveness of a medicinal drug.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

benefits. Currently and at all times while making the "clinically-proven" claims, Defendant knew no such proof existed because its own test on Elations intentionally lacked a placebo control and provided a null result.

68. As the foregoing analysis establishes, GH and CS—whether alone or in the exact combination found in Elations—are no more effective than placebo in relieving joint pain and stiffness. Similarly, there is no clinically significant evidence that the other "active ingredients" in Elations—calcium and boron—provide any joint health benefits.

69. Looking first to calcium, Defendant links calcium supplementation to bone health, not joint health. Indeed, under the "How It Works" tab of its official website, Defendant asserts that calcium is the "key to healthy, strong bones." There is no reference to the ability of calcium to improve joint health because, as Defendant is well aware, calcium has never been studied as a joint health supplement.

70. As with calcium, there is no clinically significant evidence that boron provides any joint health benefits.[29]

71. There is one boron study that indicates a positive result for joint health, Travers RL, *et al.*, Boron and arthritis: the results of a double-blind pilot study. *J Nutr Med* 1990, 1:127 – 132. This study—which has been described as the "most convincing evidence that boron may be useful in the treatment of arthritis"—enrolled *only 20 patients*. *See* Rex E. Newnham, *Essentiality of Boron for Healthy Bones and Joints*. *Environmental Health Perspectives* 1994, 102(7): 83-85. Of those

[29] A determination of statistical significance indicates to investigators the probability that an apparent difference between two or more treatment groups in a study is real and did not occur merely by chance. Accordingly, statistical significance has nothing at all to do with whether or not the hypothesis being tested in a study (i.e. boron relieves the pain and stiffness associated with osteoarthritis) is true or false. In other words, statistical significance does not "prove" one's hypothesis, it merely helps an investigator choose whether a perceived treatment effect is more or less likely to have occurred by chance, with a calculated probability that his or her choice was, in fact, wrong. Clinical significance, by comparison, is defined in the scientific community as denoting whether or not an observed treatment effect is of therapeutic, or practical, importance.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

20 patients, one in each the placebo group and the boron group dropped out before the second examination, and neither had improved or worsened during their brief participation in the trial. *Id.* Of the remaining 18 patients, 3 more (2 who were on boron, and 1 on placebo) dropped out between week 3 and the last examination, "apparently because of a *significant deterioration in condition*." *Id.* (emphasis added). In the end, only 15 patients (7 taking boron and 8 taking placebo) completed the study.

72. While the study did find a *statistically* significant difference in the responses between the 7 patients in the boron group and the 8 patients taking a placebo, these results are preliminary at best, and certainly don't rise to the level of *clinically* significant evidence that could support the assertion that boron is "proven" to improve joint comfort and/or flexibility.

73. Simply put, Defendant's claims that Elations contains a "clinically-proven formula" and "clinically-proven combination" are lies because no such proof exists. Scientific consensus—including Defendant's own "clinical studies"—confirm the "active" ingredients in Elations, including the exact combination of ingredients in Elations, cannot provide relief from joint pain or improve joint health. Whether tested separately or in combination, the "active" ingredients in Elations, glucosamine hydrochloride, glucosamine sulfate, and boron, do not, because they cannot, provide the advertised benefits, and claims the product is "clinically-proven" are false and deceptive

F. Plaintiff McCrary's Experience With Elations

74. Plaintiff Robert McCrary suffers from arthritic joint pain.

75. While shopping at CVS in August 2011, McCrary saw a six-pack of Elations on the shelf. Before deciding to purchase Elations, McCrary thoroughly reviewed the front and back of the packaging of the Elations six-pack. The packaging included the claims that Elations contains a "clinically-proven formula" and "clinically-proven combination" of ingredients.

76. In reliance on the representations on the Elations packaging, McCrary purchased a 30-day supply of Elations.

77. McCrary followed all of the instructions with the product and used it as directed. However, he did not receive any of the advertised benefits.

78. If McCrary had known Elations is not a "clinically-proven formula" and does not contain a "clinically proven combination" of ingredients, and that scientific evidence and Defendant's own studies demonstrate Elations is not effective as represented by Defendant, McCrary would not have purchased Elations.

FIRST CAUSE OF ACTION

VIOLATION OF CALIFORNIA CIVIL CODE § 1750, *et seq*.

79. Plaintiff incorporates by this reference the allegations contained in the preceding paragraphs as if fully set forth herein.

80. Plaintiff brings this claim under *Civil Code* § 1750, *et seq*., the CLRA, on behalf of himself and the Class, who were subject to Defendant's above-described unfair and deceptive conduct.

81. As alleged hereinabove, Plaintiff has standing to pursue this claim as Plaintiff has suffered injury in fact and lost money or property as a result of Defendant's actions as set forth herein.

82. Specifically, prior to the filing of this action, Plaintiff McCrary purchased Elations in reliance on Defendant's material, false and misleading statement that Elations contains a "clinically-proven formula" and "clinically-proven combination" of ingredients, capable of delivering joint health benefits. McCrary used Elations, but the product did not work as advertised and was worthless.

83. Plaintiff McCrary filed the declaration of venue required by *Civil Code* § 1780(d) with the original complaint. Plaintiff and members of the putative Class are individuals who have purchased goods (i.e., Elations) for personal use. This cause of action is asserted on behalf of a subclass of the putative Class, comprised of

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

those members who purchased Elations within three (3) years of the commencement of this action.

84. Defendant's conduct described herein was intended to result in the sale of Elations to the consuming public, and constituted the following practices proscribed by *Civil Code* § 1770:

a. By representing that Elations contains a "clinically-proven combination" of ingredients and is a "clinically-proven formula", Defendant is representing that Elations is of a particular standard, quality, or grade, when it is of another;

b. By representing that Elations is clinically-proven to work as advertised, Defendant is "[a]dvertising goods... with intent not to sell them as advertised."

85. Defendant knew that neither Elations nor the combination of ingredients in Elations is capable of working as advertised.

86. Defendant's actions as described herein were done with conscious disregard of Plaintiff's rights, and Defendant was wanton and malicious in its concealment of the same.

87. Defendant's wrongful business practices constituted, and constitute, a continuing course of conduct in violation of the CLRA since Defendant is still representing that Elations has characteristics and abilities which the product does not have, and has thus injured Plaintiff and the Class.

88. Plaintiff and other members of the putative Class have suffered injury in fact and have lost money as a result of Defendant's false representations. Indeed, Plaintiff and the Class purchased Elations in reliance on Defendant's false and misleading material claims that the product contains a "clinically-proven combination" and is a "clinically proven formula." Plaintiff would not have purchased Elations if he had known about the massive fraud perpetrated by Defendant.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

89. Pursuant to *Civil Code* § 1780(a), Plaintiff seeks injunctive relief in the form of enjoining Defendant from expressly or impliedly representing to current and potential purchasers of Elations as follows:

a. Remove all references, in all of Defendant's labeling, packaging, marketing and advertising, to Elations "Clinically-Proven Combination"; and

b. Remove all references, in all of Defendant's labeling, packaging, marketing and advertising, that Elations is a "Clinically-Proven Formula."

90. Plaintiff and members of the Class shall be irreparably harmed if such an order is not granted.

91. Pursuant to *Civil Code* § 1782, Plaintiff McCrary notified Defendant on or about June 19, 2012 (via letter) of the alleged violations of section 1770 and demanded that the same be corrected. Defendant would not agree to the requested relief. Thus, Plaintiff now also seeks an award of restitution and damages in accordance with *Civil Code* § 1782(a) & (d).

92. In addition, the CLRA has enhanced penalties for acts perpetrated against senior citizens and disabled persons. If the defendant's conduct is directed at a class of persons who are senior citizens and/or "disabled," a $5,000.00 civil penalty may be awarded to "each class member." *Civ. Code* § 1780(b). A "disabled person" is someone who has a "physical or mental impairment which substantially limits one or more major life activities." *Civ. Code* § 1761(f), (g). Under California law, individuals suffering from arthritis are "disabled." Defendant's conduct is clearly directed at senior citizens (the primary demographic afflicted with arthritis) and the disabled (i.e. those suffering from arthritis), as Elations advertising targets those with arthritic conditions. Accordingly, the trier of fact may award a civil penalty of up to $5,000 for each class member.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

SECOND CAUSE OF ACTION

VIOLATION OF BUSINESS & PROFESSIONS CODE § 17500, *ET SEQ.*

(False and Misleading Advertising)

93. Plaintiff incorporates by this reference the allegations contained in the preceding paragraphs as if fully set forth herein.

94. This cause of action is brought pursuant to *Business & Professions Code* § 17500, *et seq*., on behalf of Plaintiff and a Class consisting of all persons who purchased Elations in California from May 2009 through December 2012, for personal use and not for resale, when the following claims were on the packaging and/or labeling of Elations: "clinically-proven combination" and/or "clinically-proven formula."

95. *Business & Professions Code* § 17200 provides that "unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice." Additionally, *Business & Professions Code* § 17500 provides that it is unlawful for any person or corporation, or any employee thereof "with intent directly or indirectly to dispose of real or personal property ... or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated before the public in this state, or 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, concerning that real or personal property ... , or concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading ..."

96. In its advertising for Elations, Defendant makes false and misleading statements that Elations is a "clinically-proven combination" of ingredients and its "clinically proven formula" works as advertised.

97. Defendant engaged in the deceptive conduct alleged hereinabove, which included deceptive and untrue representations regarding Elations, representations made to induce the public to purchase the product.

98. In its marketing and advertising, Defendant makes knowingly false and misleading statements regarding the uses and benefits of Elations. The claims that Elations contains a "clinically-proven combination" and is a "clinically-proven formula" are false, because no such clinical proof exists. Scientific consensus—including Defendant's own "clinical studies"—demonstrates the "active" ingredients in Elations, including the exact combination of ingredients in Elations, do not provide relief from join pain or improve joint health. Whether tested separately or in combination, the "active" ingredients in Elations (glucosamine hydrochloride, glucosamine sulfate, and boron), do not, because they cannot, provide the advertised benefits. Additionally, overwhelming scientific evidence demonstrates the false and misleading nature of Defendant's claims regarding glucosamine and chondroitin, as well as claims that Elations is capable of joint health benefits. In reality, Elations is not "clinically proven" to do anything.

99. Defendant is aware that the claims that it makes about Elations are false and misleading.

100. In addition, Defendant's use of various forms of advertising media to advertise, call attention to or give publicity to the sale of goods or merchandise which are not as represented in any manner constitutes unfair competition, unfair, deceptive, untrue or misleading advertising, and an unlawful business practice within the meaning of *Business & Professions Code* § 17200, *et seq*.

101. There were reasonably available alternatives to further Defendant's legitimate business interests, other than the conduct described herein.

102. Plaintiff and the putative class members were misled into purchasing Elations by Defendant's deceptive conduct as alleged hereinabove.

103. Plaintiff and other putative class members were mislead and, because

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

the misrepresentations and omissions were uniform and material, presumably believed that Elations contained a "clinically-proven combination" of ingredients and was a "clinically-proven formula."

104. Pursuant to *Business & Professions Code* §§ 17203 and 17535, Plaintiff and the members of the Class seek an order of this Court enjoining Defendant from engaging in the unfair competition and false advertising alleged herein in connection with the sale of Elations. Additionally, Plaintiff requests an order awarding Plaintiff and the Class restitution of the money wrongfully acquired by Defendant by means of the unfair competition and false advertising alleged herein.

105. Plaintiff and other members of the putative Class have suffered injury in fact and have lost money as a result of Defendant's false representations. Indeed, Plaintiff and the Class purchased Elations in reliance on Defendant's false and misleading material claims that the product contains a "clinically-proven combination" and is a "clinically proven formula." Plaintiff would not have purchased Elations if he had known about the massive fraud perpetrated by Defendant.

THIRD CAUSE OF ACTION

VIOLATION OF BUSINESS & PROFESSIONS CODE § 17200, *ET SEQ.*

(Unfair and Fraudulent Conduct Prongs of the Act)

106. Plaintiff incorporates by this reference the allegations contained in the preceding paragraphs as if fully set forth herein.

107. This cause of action is brought pursuant to *Business & Professions Code* § 17200, *et seq.*, on behalf of Plaintiff and a Class consisting of all persons who purchased Elations in California from May 2009 through December 2012, for personal use and not for resale, when the following claims were on the packaging and/or labeling on Elations: "clinically-proven combination" and/or "clinically-proven formula."

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

108. As alleged hereinabove, Plaintiff has standing to pursue this claim as Plaintiff has suffered injury in fact and has lost money or property as a result of Defendant's actions as set forth herein. Specifically, prior to the filing of this action, Plaintiff purchased Elations for his own personal use. In so doing, he relied upon the false representations referenced above. Plaintiff used Elations, but the product did not work as advertised and was worthless.

109. In its marketing and advertising, Defendant makes false and misleading statements regarding the uses and benefits of Elations, namely that Elations contains a "clinically-proven combination" and is a "clinically-proven formula."

110. Defendant is aware that the claims that it makes about Elations are false and misleading.

111. The misrepresentations by Defendant are material facts and constitute an unfair and fraudulent business practice within the meaning of *Business & Professions Code* § 17200, *et seq.*

112. Defendant's business practices, as alleged herein, are unfair because: (1) the injury to the consumer is substantial; (2) the injury is not outweighed by any countervailing benefits to consumers or competition; and (3) consumers could not reasonably have avoided the information because Defendant intentionally mislead the consuming public by means of the claims made with respect to Elations as set forth herein.

113. Defendant's business practices as alleged herein are fraudulent because they are likely to deceive customers into believing that Elations has uses and benefits that it does not have, and the "clinically-proven" claims are false.

114. In addition, Defendant's use of various forms of advertising media to advertise, call attention to or give publicity to the sale of goods or merchandise which are not as represented constitutes unfair competition, unfair, deceptive, untrue or misleading advertising, and an unlawful business practice within the meaning of *Business & Professions Code* § 17200, *et seq*.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

115. Defendant's wrongful business practices constituted, and constitute, a continuing course of conduct of unfair competition since Defendant is marketing and selling Elations in a manner likely to deceive the public.

116. Defendant has peddled, and continues to peddle, its misrepresentations through a nationwide advertising campaign.

117. There were reasonably available alternatives to further Defendant's legitimate business interests, other than the conduct described herein.

118. Plaintiff and the putative class members were misled into purchasing Elations by Defendant's deceptive and fraudulent conduct as alleged hereinabove.

119. Plaintiff and other putative class members were mislead and, because the misrepresentations and omissions were uniform and material, presumably believed that Elations contained a "clinically-proven combination" of ingredients and was a "clinically-proven formula" for joint health.

120. Pursuant to *Business & Professions Code* § 17203, Plaintiff and the members of the Class seek an order of this Court enjoining Defendant from engaging in the unfair competition alleged herein in connection with the sale of Elations. Additionally, Plaintiff requests an order awarding Plaintiff and the Class restitution of the money wrongfully acquired by Defendant by means of the unfair competition alleged herein.

121. Plaintiff and other members of the putative Class have suffered injury in fact and have lost money as a result of Defendant's false representations. Indeed, Plaintiff and the Class purchased Elations in reliance on Defendant's false and misleading material claims that the product contains a "clinically-proven combination" and is a "clinically proven formula." Plaintiff would not have purchased Elations if he had known about the massive fraud perpetrated by Defendant.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

FOURTH CAUSE OF ACTION

VIOLATION OF BUSINESS & PROFESSIONS CODE § 17200, *ET SEQ.*

(Unlawful Conduct Prong of the Act)

122. Plaintiff incorporates by this reference the allegations contained in the preceding paragraphs as if fully set forth herein.

123. The actions of Defendant, as alleged herein, constitute illegal and unlawful practices committed in violation of *Business & Professions Code* § 17200, *et seq.*

124. Defendant has unlawfully marketed, advertised and sold Elations because: (1) it is violating sections 1770(a)(5), 1770(a)(7), and 1770(a)(9) of the CLRA, *Civil Code* § 1750, *et seq.*; and (2) it is violating *Business & Professions Code* § 17500.

125. In addition, Defendant has unlawfully advertised and/or distributed Elations in violation of the California Health & Safety Code in that:

a. Defendant has disseminated false advertisements for Elations in that the product advertising contains false or misleading statements as to the purported clinical proof regarding the benefits of Elations in violation of *Business & Professions Code* § 17500 and *Health & Safety Code* § 110390, which govern Defendant's conduct;

b. Defendant has manufactured, sold, delivered, held or offered for sale a product that is falsely advertised in violation of *Health & Safety Code* § 110395, which governs Defendant's conduct; and

126. Defendant has received in commerce a product that is falsely advertised or delivered or proffered for delivery such a product in violation of *Health & Safety Code* § 110400, which governs Defendant's conduct. There were reasonably available alternatives to further Defendant's legitimate business interests, other than the conduct described herein.

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

127. Plaintiff and other putative class members were mislead and, because the misrepresentations and omissions were uniform and material, presumably believed that Elations contained a "clinically-proven combination" of ingredients and was a "clinically-proven formula." Pursuant to *Business & Professions Code* § 17203, Plaintiff and the members of the Class seek an order of this Court enjoining Defendant from engaging in the unfair competition alleged herein in connection with the sale of Elations. Additionally, Plaintiff requests an order awarding Plaintiff and the Class restitution of the money wrongfully acquired by Defendant by means of the unfair competition alleged herein. Pursuant to *Business & Professions Code* § 17203, Plaintiff and the members of the Class seek an order of this Court enjoining Defendant from engaging in the unfair competition alleged herein in connection with the sale of Elations. Additionally, Plaintiff requests an order awarding Plaintiff and the Class restitution of the money wrongfully acquired by Defendant by means of the unfair competition alleged herein.

128. Plaintiff and other members of the putative Class have suffered injury in fact and have lost money as a result of Defendant's false representations. Indeed, Plaintiff and the Class purchased Elations in reliance on Defendant's false and misleading material claims that the product contains a "clinically-proven combination" and is a "clinically proven formula." Plaintiff would not have purchased Elations if he had known about the massive fraud perpetrated by Defendant.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and on behalf of the members of the Class defined herein, prays for judgment and relief on all Causes of Action as follows:

A. An order certifying that the action may be maintained as a Class Action;

B. An order enjoining Defendant from pursuing the policies, acts, and practices complained of herein;

C. An order requiring Defendant to pay restitution to Plaintiff and all members of the Class;

D. Actual damages;

E. Punitive damages;

F. For pre-judgment interest from the date of filing this suit;

G. Reasonable attorneys' fees;

H. Costs of this suit; and

I. Such other and further relief as the Court may deem necessary or appropriate.

Dated: January 21, 2014 MILSTEIN ADELMAN, LLP

By: Stephanie Mazepa
Gillian L. Wade
Stephanie Mazepa
Attorneys for Plaintiff, Robert McCrary

JURY TRIAL DEMANDED

Plaintiff demands a jury trial on all triable issues.

Dated: January 21, 2014 MILSTEIN ADELMAN, LLP

By: Stephanie Mazepa
Gillian L. Wade
Stephanie Mazepa
Attorneys for Plaintiff, Robert McCrary

Milstein Adelman, LLP
2800 Donald Douglas Loop North
Santa Monica, California 90405

EXHIBIT A

Product Insight

Read below for Glucosamine and Chondroitin details, product characteristics, Elations® supplement safety facts, and more!

Glucosamine/Chondroitin
Calcium Citrate Malate (CCM)
Boron
Absorbability
Product Ingredients

Glucosamine/Chondroitin

Research indicates that taking 1,500 mg of glucosamine and 1,200 mg of chondroitin daily can help improve joint function and give joints what they need to stay healthy. Each bottle and powder stick of Elations contains these levels of glucosamine and chondroitin. Elations is also more absorbable than pills.

Calcium Citrate Malate (CCM)

CCM is composed of calcium in combination with two organic acids, citric acid, and malic acid, commonly called "fruit acids" because of their natural abundance in fruits. Numerous published studies support greater CCM absorption than milk or calcium carbonate and include:

- A study among women age 21-30 showing calcium absorption from CCM was 26% greater than that of calcium carbonate, a common dietary supplement, and 30% greater than that of milk. (Smith KT, Heaney RP, Flora L, Hinders SM. "Calcium Absorption from a New Calcium Delivery System (CCM). *Calcified Tissue International* (1987); 41:351-52).
- A study among older women (average age 57) which showed CCM absorption was 39%, a level 30-50% greater than typically found in milk (Andon MB, Peacock M, Kanerva RL, De Castro JAS. "Calcium Absorption from Apple and Orange Juice Fortified with Calcium Citrate Malate (CCM)." *Journal of the American College of Nutrition* (1996); 15:313-316).
- A study among children (average age 14) which showed calcium absorption from CCM was 37% greater than for calcium carbonate (Miller JZ, Smith DL, Flora L, Slemenda C, Jiang X, Johnston CC Jr. "Calcium Absorption from Calcium Carbonate and a New Form of Calcium (CCM) in Healthy Male and Female Adolescents", *American Journal of Clinical Nutrition* (1988); 48:1291-94).

back to top

Boron

The Physician's Desk Reference excerpt on boron reviews the pharmacokinetic, epidemiological and clinical data demonstrating boron's potential role in calcium metabolism.
back to top

Absorbability

As a liquid, Elations is inherently more quickly absorbed than supplement pills which need to disintegrate and dissolve in the stomach before passing into the intestines. Further, the calcium in CCM has been shown to be more absorbable into the bone than the calcium used in calcium supplements (calcium carbonate and calcium citrate, specific references listed above). Elations uses high-purity, low molecular weight glucosamine and particularly chondroitin to further accelerate absorption (and to allow the product to be clear and good-tasting).
back to top

Product Ingredients

Each 8 oz. bottle of Elations contains dietary supplement ingredients including:

1,500 mg Glucosamine, which improves healthy joints, thickens joint fluid for better lubrication, and helps form the building blocks of joint cartilage;

1,200 mg Chondroitin, which is a major component of joint cartilage, acts as an antioxidant to reduce joint damage, and stimulates cartilage production;

300 mg Calcium, in the form of Calcium Citrate Malate (CCM), a more absorbable form of calcium which is vital for strong, healthy bones, prevents bone loss, is needed to anchor the cartilage in bone for strong joints, and the deficiency of which can lead to aching joints and muscle cramps;

6 mg Boron, an important dietary trace mineral found in plants, which helps the body utilize calcium, helps to build strong bone, joints and muscles.

The four key components of Elations (Glucosamine, Chondroitin, Calcium, and Boron) are shown to be important for maintaining normal healthy joint function. Supplements are shown to make these components available to the joints. Additional mechanism of action data noted below demonstrates how glucosamine and chondroitin contribute to improved joint health and mobility. All of this could be fairly characterized in consumer terms as rejuvenation.

Drinking Elations daily ensures that joint cartilage and joint fluid have an abundant, continuous supply of the essential building blocks needed to optimize joint health. Therefore, a daily liquid supplement that makes these components available to joints can be considered a way to "rejuvenate" joints every day, and something that should be consumed daily.

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the County of LOS ANGELES, State of CALIFORNIA. I am over the age of 18 and not a party to within action; my business address is **2800 Donald Douglas Loop North, Santa Monica, CA 90405**.

On January 21, 2014, I served the foregoing documents described as:

FOURTH AMENDED COMPLAINT

SUMMONS TO FOURTH AMENDED COMPLAINT

On interested parties in this action by sending a true copy of the document to the following parties as follows:

SHEPPARD, MULLIN, RICHTER & HAMPTON LLP
Sascha Henry,
Paul Seeley
333 South Hope Street, 43rd Floor
Los Angeles, California 90071-1422
Telephone: 213.620.1780
Facsimile: 213.620.1398
shenry@sheppardmullin.com
pseeley@sheppardmullin.com

Attorneys for
The Elations Company, LLC

------ (BY ELECTRONIC MAIL) I caused the document(s) to be successfully transmitted via electronic mail to the offices of the addressees.

------ (BY ELECTRONIC SERVICE) I caused the document(s) to be sent to the offices of the addressees via Online Filing Service.

------ (BY FACSIMILE) I transmitted pursuant Rule 2.306, the above-described document by facsimile machine (which complied with Rule 2003(3)), to the attached listed fax number(s). The transmission originated from facsimile phone number (310) 396-9635 and was reported as complete and without error.

xxxx (BY OVER NIGHT DELIVERY) I caused such envelope(s) thereon fully prepaid to be placed in the Federal Express box at Santa Monica, California.

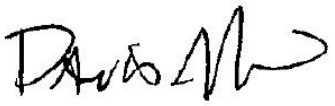
------ (BY PERSONAL SERVICE) I caused such envelope(s) to be hand delivered to the offices of the addressees.

------ (BY US MAIL) I caused such envelope(s) with postage thereon fully prepaid, with return receipt requested, to be placed in the United States mail at Santa Monica, California, pursuant to California Code of Civil Procedure § 415.40. I am readily familiar with this business' practice for collecting and processing correspondence for mailing. On the same day that correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service.

Executed on January 21, 2014 at Santa Monica, California

------ (STATE) I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

xxxx (FEDERAL) I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made.



David Marin