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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

NOAH BRADACH and LAURA CORBETT, On Behalf of Themselves and All Others Similarly Situated,

Plaintiffs,

v.

PHARMAVITE LLC, a California limited liability company,

Defendant.

Case No.: 2:14-cv-03218-GHK(AGRx)

THIRD CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR:

1. VIOLATION OF THE UNFAIR COMPETITION LAW, Business and Professions Code §17200 *et seq.*;
2. VIOLATION OF THE CONSUMERS LEGAL REMEDIES ACT, Civil Code §1750 *et seq.*; and

DEMAND FOR JURY TRIAL

Plaintiffs Noah Bradach and Laura Corbett bring this action on behalf of themselves and all others similarly situated against Defendant Pharmavite LLC, and state:

NATURE OF ACTION

1. Pharmavite manufactures, markets, sells and distributes Vitamin E dietary supplements under its brand name Nature Made.[1] Through an extensive, widespread, comprehensive and uniform nationwide marketing campaign, Pharmavite uniformly claims that its Vitamin E products will help maintain a healthy heart. On each and every bottle of Vitamin E, Pharmavite represents that the Products "help[] maintain a healthy heart" (hereinafter "the heart health representation"). This is the only benefit representation made on the Products' front labels. In truth, Pharmavite's Vitamin E products do not help maintain a healthy heart.

2. Experts in the field recognize that the measure of whether a heart is healthy is that it is free from cardiovascular disease. Thus, experts in the field view the test for whether a substance, such as Vitamin E supplements, provide any heart health benefits is whether the substance helps prevent cardiovascular disease ("CVD").[2] As more fully set forth below, large scale randomized controlled clinical trials ("RCTs") have conclusively shown that Vitamin E supplements such as those sold by Defendant do not prevent CVD and thus the consensus in the scientific community is that Vitamin E supplements do not provide any heart health benefits

[1] (1) Natural Vitamin E 400 IU d-Alpha; (2) Vitamin E 400 IU dl Alpha; (3) Vitamin E 400 I.U. Water Solubilized; (4) Vitamin E 1000 IU dl Alpha; and (5) Vitamin E 200 IU dl Alpha (collectively "the Products" or "Vitamin E").

[2] For example, the American Heart Association defines cardiovascular health as the absence of disease.http://www.heart.org/idc/groups/heartpublic/@wcm/@sop/@smd/documents/downloadable/ucm_319831.pdf. Similarly, the Columbia University Medical web site (http://www.cumc.columbia.edu/cbch/), the Mayo Clinic web site (http://www.mayoclinic.org/cardiovascular-disease-rst/cardioheartclinic.html), and University of Chicago (http://www.ucmc150.uchicago.edu/cardio/) web sites all define cardiovascular health in terms of the prevention of CVD.

and most certainly do not "help maintain a healthy heart."

3. By law, the FDA does not and cannot regulate the pre-market approval of health benefit statements about dietary supplements such as Defendant's Vitamin E products. Instead, it is the manufacturer's responsibility to ensure that the statement "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function…." and that the manufacturer "has substantiation that such statement is truthful and not misleading." 21 U.S.C. 343 (r). As more fully set forth herein, the statement that Defendant's Vitamin E supplements "help[] maintain a healthy heart" does not have a "documented mechanism by which" it acts to provide this heart health benefit. Pharmavite does not and cannot have substantiation for such a representation because the scientific evidence is that Vitamin E supplements do not help maintain a healthy heart.

4. Further, even though the Pharmavite labels – in smaller print – on the back of the bottles – carry a required "disclaimer" that the Products are not "intended to diagnose, treat, cure or prevent any disease", whether reasonable consumers would interpret the disclaimer as negating the front of the label "help[] maintain a healthy heart" main message is a common question of fact.

5. Large scale RCTs have demonstrated that Vitamin E supplements, like Pharmavite's Products, do not provide any cardiovascular or heart health benefits. Thus, the sole "active" ingredient in the Products, Vitamin E, does not work as represented by Pharmavite in that it does not help maintain a healthy heart. Pharmavite's heart health representation is false, misleading, and reasonably likely to deceive the public.

6. That Vitamin E supplementation provides no cardiovascular or heart health benefits is widely recognized by major medical groups including the American Heart Association (AHA) and Mayo Clinic. Likewise, a panel of experts

commissioned by the U.S. Preventive Services Task Force[3] has concluded that Vitamin E supplements have been proven ineffective in preventing cardiovascular disease or its associated outcomes including stroke, heart attack and mortality – the sole measure of heart health.

7. Pharmavite has employed numerous media to convey its uniform, deceptive heart health representation to consumers, including magazines, newspapers, the internet, social media websites, and, importantly, on the front of the Vitamin E Products' packaging and labeling where it cannot be missed by consumers.

8. As a result of Pharmavite's deceptive heart health representation, consumers – including Plaintiffs and members of the proposed Class – have purchased Products that do not perform as advertised.

9. Plaintiffs bring this action on behalf of themselves and other similarly situated consumers who purchased the Vitamin E Products, to halt the dissemination of this false, misleading and deceptive advertising message, correct the false and misleading perception it has created in the minds of consumers, and obtain redress for those who have purchased the Products. Based on violations of California state unfair competition laws and other similar state consumer fraud laws, Plaintiffs seek injunctive and monetary relief for consumers who purchased the Vitamin E Products.

JURISDICTION AND VENUE

10. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). Defendant has admitted its sales of Vitamin E bearing the "helps maintain a healthy heart" statement exceed $5,000,000.00. The matter in controversy, exclusive of interest and costs, exceeds the sum or value of $5,000,000 and is a class action in which there are in excess of 100 class members and some members of the Class are citizens of a state different from Pharmavite.

[3] The U.S. PSTF is a volunteer panel of national experts convened by the Agency for Healthcare Research and Quality.

11. Venue is proper in this Court pursuant to 28 U.S.C. §1391 in that many of the acts and transactions giving rise to the alleged claims occurred in this district and because Pharmavite:

- is headquartered in this district;
- is authorized to conduct business in this district and has intentionally availed itself of the laws and markets within this district through the promotion, marketing, distribution, and sale of its Products in this district; and
- does substantial business in this district

PARTIES

12. The named Plaintiffs in this action are Noah Bradach and Laura Corbett.

a. Plaintiff Noah Bradach resides in San Francisco, California. In July 2013, Plaintiff Bradach was exposed to and saw Pharmavite's heart health representation by reading the label of the Vitamin E 400 I.U. product. Plaintiff Bradach purchased Vitamin E 400 I.U. at a Walgreens in San Francisco, California in reliance on Pharmavite's heart health representation. He paid approximately $15.00 for one bottle of Vitamin E 400 I.U. The Vitamin E 400 I.U. Plaintiff Bradach purchased did not and could not help maintain his heart health as represented because, as discussed herein, the vast weight of scientific evidence and the consensus in the scientific community is that Vitamin E supplements do not provide any heart health benefits. As a result, Plaintiff Bradach suffered injury in fact and lost money. Had Plaintiff Bradach known the truth about Pharmavite's misrepresentations and omissions, he would not have purchased Vitamin E 400 I.U.

b. Plaintiff Laura Corbett is a police officer in the New York Police Department (NYPD) and currently resides in Comack, New York. For several years until approximately 1-1 ½ years ago, Plaintiff Corbett purchased Pharmavite's Vitamin E products in various doses. During this entire time, Plaintiff Corbett purchased Defendant's Vitamin E product solely for its represented heart health

benefits. Plaintiff Corbett saw, was exposed to and relied upon Defendant's representation on the front of the label – that the product "Helps Maintain a Healthy Heart" – and it was this representation that caused Plaintiff to purchase and continue to purchase Defendant's Vitamin E product during the years that she purchased the products. Plaintiff believes that she made most, if not all, of her purchases of Defendant's products at a Rite Aid store near where she resided in Queens, New York. During this time period she believes that she paid approximately $10 for each purchase. The Vitamin E Plaintiff Corbett purchased did not and could not help maintain her heart health as represented because, as discussed herein, the vast weight of scientific evidence and the consensus in the scientific community is that Vitamin E supplements do not provide any heart health benefits. As a result, Plaintiff Corbett suffered injury in fact and lost money. Had Plaintiff Corbett known the truth about Pharmavite's misrepresentations and omissions, she would not have purchased Defendant's Vitamin E product.

13. Defendant Pharmavite LLC, is a limited liability company organized and existing under the laws of the State of California. Pharmavite's headquarters is at 8510 Balboa Boulevard, Mission Hills, California 91325. From its headquarters in Mission Hills, California, Pharmavite manufactures, distributes, markets and sells the Vitamin E products to consumers nationwide and created the deceptive heart health representation which it caused to be disseminated to consumers nationwide.

FACTUAL ALLEGATIONS

14. Pharmavite manufactures, distributes, markets and sells nationwide Vitamin E dietary supplements under its brand name "Nature Made". They are : (1) Natural Vitamin E 400 IU d-Alpha; (2) Vitamin E 400 IU dl Alpha; (3) Vitamin E 400 IU Water Solubilized; (4) Vitamin E 1000 IU dl Alpha; and (5) Vitamin E 200 IU dl Alpha.

15. Pharmavite's Vitamin E products are sold in virtually every major food,

drug, and mass retail outlet in the country. The Vitamin E products are available in 60, 100, 180 and 300 count bottles retailing for between $13 and $30. The following are screen shots of the Products:

16. Throughout the relevant time period, Pharmavite has consistently conveyed the message to consumers throughout the United States that its Vitamin E products "help[] maintain a healthy heart," simply by taking the recommended daily dosage. They do not. Pharmavite's heart health representation is false, misleading and deceptive.

17. Pharmavite represents that the claimed heart health benefit is achieved from the Products' only purported active ingredient - Vitamin E. Vitamin E is a fat-soluble nutrient found in a variety of foods including, nuts, seeds and green leafy vegetables. In the 1980s and 1990s, because Vitamin E was found to slow down the oxidation of LDL cholesterol in a test tube setting (e.g. *in vitro* testing) it, along with certain other vitamins such as C and D, was coined an antioxidant. That Vitamin E carries an "antioxidant" label does not, however, mean that it provides any health benefits. In fact, there is little known about how Vitamin E and other purported antioxidants actually work in the human body.

18. "Basic science" studies (e.g. *in vitro*, *in vivo*, and animal studies) conducted decades ago have led to hypotheses yet to be proven in humans, that

Vitamin E's purported antioxidant properties might provide a whole host of health benefits. It is recognized by experts in the field, however, that such "basic science" studies only create hypotheses that need to be tested and do not constitute scientific substantiation that Vitamin E provides *any* of these health benefits. Basic science studies do not constitute proof that a substance works in humans.

19. The popularity of Vitamin E and sales of the supplement got an additional boost when, in the early 1990s, "observational studies" reported a perceived relationship between the intake of Vitamin E and the prevention of cardiovascular disease. As a result of those studies – and the commonly held perception at the time that Vitamin E supplements were safe – there was a rapid increase in use of Vitamin E supplements.

20. However, like basic science studies, observational studies (also known as "epidemiological or population studies") are not considered by experts in the field to constitute adequate proof of cause and effect in human beings. Like basic science studies, observational studies can only create hypotheses and do not constitute scientific substantiation that Vitamin E provides any heart health benefits. Among other things, observational studies cannot control for confounding factors such as whether the subjects taking Vitamin E were leading healthier lifestyles. As a result, as with basic science studies, observational studies are deemed by experts in the field to provide hypotheses about potential effects which then must be tested through RCTs.

21. The only accepted form of scientific evidence recognized by experts in the field for determining any heart or other human health benefit provided by a substance such as Vitamin E is through RCTs.

22. Since the mid–1990s, Vitamin E has been the subject of numerous, large scale–RCTs, making it one of the most tested substances ever. To date, there have been more than 25 large long–term RCTs or meta–analyses published, involving

collectively over 200,000 subjects.

23. The theory/hypothesis that Vitamin E supplements may provide heart health benefits has been discredited fully by this scientific research. Instead, the conclusions from the large randomized clinical trials have been consistent that Vitamin E supplementation provides no heart health benefits, because these studies demonstrated that Vitamin E supplements were no better than placebo in affecting the markers for heart health, such as reducing the risk for cardiovascular disease and its associated outcomes including heart attacks, stroke, or mortality. In other words, numerous large scale RCT's, making Vitamin E supplements one of the most studied substances ever have established that Vitamin E supplements **do not "help maintain a healthy heart."**

24. Representative examples of studies concluding that Vitamin E supplementation does not provide heart health benefits include: Sesso, H.D., et al., *Vitamins E and C in the Prevention of Cardiovascular Disease in Men, The Physicians' Health Study II Randomized Controlled Trial*, 300(18) JAMA 2123–33 (Nov. 2008) (concluding that long term Vitamin E supplementation does not prevent cardiovascular events in healthy middle–aged and older men and concluding with the recommendation that persons not take Vitamin E supplements); Lee, I–Min, et al., *Vitamin E in the Primary Prevention of Cardiovascular Disease and Cancer. The Women's Health Study: A Randomized Controlled Trial*, 294(1) JAMA 56–65 (July 2005) (concluding that Vitamin E supplementation provided no heart health benefits in healthy women and recommending that women not take Vitamin E supplements); Lonn, E., et al., *Effects of Long–Term Vitamin E Supplementation On Cardiovascular Events And Cancer: A Randomized Controlled Trial*, 293(11) JAMA 1338–47 (Mar. 2005) (concluding that long-term Vitamin E supplementation does not prevent cardiovascular events, and in fact, may increase the risk for heart failure and recommending not taking Vitamin E supplements); Arnold, J., et al., *Prevention of*

Heart Failure in Patients in the Heart Outcomes Prevention Evaluation (HOPE) Study, 107 Circulation J. 1284–290 (Feb. 2003) (concluding that participants taking 400 IU/day of Vitamin E experienced no fewer cardiovascular events or hospitalizations for heart failure or chest pain than participants taking a placebo); Chae C., Albert C., Moorthy, MV, Lee I., Buring, J., *Vitamin E Supplementation and the Risk of Heart Failure in Women*, Circulation: Heart Failure, 5:176 Journal of the American Heart Association 182 (2012) (concluding that "at the present time, the cumulative evidence to date does not support the use of Vitamin E supplementation to reduce the risk of cardiovascular diseases").[4] These large scale and long term RCTs conclusively demonstrate that Vitamin E supplementation provides no heart health benefits. That the results of these large scale/long term studies showed that Vitamin E supplements were no better than placebo demonstrate Defendant's heart health representations are false, misleading or deceptive.

25. Several meta-analyses – which follow accepted statistical protocols to combine the results of multiple RCTs – have likewise concluded that Vitamin E supplements do not provide heart health benefits. Additionally, those meta-analyses indicate that people who take a dosage of 15mgs or more of Vitamin E supplements are more likely to die than those taking a placebo. *See* Miller ER 3rd, Pastor–Barriuso R, Dalal D et al., *Metaanalysis: High–Dosage Vitamin E Supplementation May increase all–cause mortality*, Ann Intern Med 2005; 142(1):37–46; Bjelakovic G, Nikolova D, Gluud LL, Simonetti RG, Gluud C., *Mortality in randomized trials of antioxidant for primary and secondary prevention: systematic review and meta–analysis*, JAMA Feb 28 2007; 297(8):842–857; Bjelakovic G, Nikolova D, Gluud C.,

[4] Consistent with the forgoing allegations regarding the hypotheses presented by basic science and observational studies, each of these studies, in prefatory statements, noted the results of the basic science or observational studies as background for why they were conducting their particular RCT. Ultimately, the RCTs did not support the results of the observational studies.

Meta-Regression Analyses, Meta-Analyses, and Trial Sequential Analyses of the Effects of Supplementation, with Beta-Carotene, Vitamin A, and Vitamin E Singly or in Different Combinations on All-Cause Mortality: Do We Have Evidence for Lack of Harm? PLOS ONE September 2013: Vol. 8, Issue 9, e74558.

26. These large scale and long term RCTs, while addressing whether Vitamin E supplements prevented CVD, conclusively demonstrate that Vitamin E supplementation provides no heart health benefits. Because of their large scope and long term nature, it is recognized by experts in the field that if Vitamin E supplementation were to provide any heart health benefits at all, it would have shown up in the results of these studies – e.g. that long term use of Vitamin E supplements would have prevented CVD in the Vitamin E supplement group more than the placebo group.

27. For example, Plaintiffs' expert Edgar R. Miller, Ph.D. M.D., a Professor of Medicine at Johns Hopkins University with a joint appointment at the Johns Hopkins Bloomberg School of Public Health, has opined that "numerous large randomized controlled clinical trials of vitamin E supplements have failed to show a beneficial effect in the prevention of cardiovascular diseases (primary prevention trials []) or the secondary prevention trials (prevention of subsequent disease in those with established heart diseases []). Given the lack of benefit in heart health in these two populations and the increased risk of mortality associated with high dose vitamin E supplementation (>400 UI) reported in two meta-analyses of all trials combined, it is my opinion that the claims made, i.e. that vitamin E supplementation 'helps maintain a healthy heart' is false." *See* Exhibit A, Class Action Expert Report of Dr. Edgar R. Miller, Ph.D., M.D., at ¶19, *Bohn v. Pharmavite, LLC*, Case No. 2:11-cv-10430-GHK-AGR (C.D. Cal.), attached hereto.

28. In light of the consistent scientific evidence, well-regarded science organizations also have uniformly stated that Vitamin E supplementation does not

provide any cardiovascular or heart health benefits. The American Heart Association has released science advisories, including one in 2004, concluding that "scientific data do not justify the use of antioxidant vitamin supplements for CVD [cardiovascular disease] risk reduction."[5] In reaching its conclusion based upon review of the RCTs, the AHA also recognized that the "positive findings from observational studies with regard to vitamin E supplementation and lower rates of CVD may be a reflection of the generally healthy lifestyles and dietary intakes of supplement users" rather than any true causal effect. *Id.* Consequently, the AHA stated that it did not recommend people take Vitamin E supplements.

29. Mayo Clinic researchers reached the same conclusion upon evaluating the history of studies of Vitamin E supplements: "The bottom line is that even though initial laboratory studies, animal studies and population research into the health benefits of vitamin E looked promising, the clinical trial findings — which provide the best form of evidence — didn't bear that out. Instead, they uncovered health risks that make it unwise to take separate vitamin E supplements."[6]

30. Despite the overwhelming evidence the Products do not help maintain a healthy heart, each and every Product package and label repeatedly emphasizes that the Products "help[] maintain a healthy heart." Each and every consumer who purchases these Products is exposed to this deceptive heart health representation, which appears prominently and conspicuously on the front and back of each bottle as follows:

[5] American Heart Association Science Advisory on Antioxidant Vitamin Supplements and Cardiovascular Disease *available at* http://circ.ahajournals.org/content/110/5/637.full.

[6] Mayo Clinic Medical Edge Newspaper Column, *Possible Risks Associated with Taking Vitamin E Supplements*, March 18, 2011 *available at* http://www.mayoclinic.org/medical–edge–newspaper–2011/mar–18a.html.

Front

Back

The Impact of Pharmavite's Wrongful Conduct

31. Despite the scientific evidence that Vitamin E supplementation does not help maintain heart health, Pharmavite continues to unequivocally convey through its advertising and labeling one uniform message: its Vitamin E products "help[] maintain a healthy heart."

32. As the manufacturer and distributor of the Vitamin E products, Pharmavite possesses specialized knowledge regarding the content and effect of the ingredients contained in its Products and is in a superior position to learn of the effects – and has learned of the effects – its Products have on consumers.

33. Plaintiffs and Class members have been and will continue to be deceived or misled by Pharmavite's deceptive heart health representation. Plaintiffs purchased and consumed the Vitamin E Products during the Class period and in doing so, read and considered the Products' labels and based his decision to buy the Products on the heart health representation. Pharmavite's heart health representation was a material factor in influencing Plaintiffs' decision to purchase and consume the Products.

Plaintiffs would not have purchased the Products had he known that Pharmavite's heart health representation was false and misleading and that competent and reliable scientific evidence demonstrates that Vitamin E does not help maintain heart health.

34. As a result, Plaintiffs and the Class members have been damaged in their purchases of these Products and have been deceived into purchasing Products that they believed, based on Pharmavite's representations, helped maintain heart health, when, in fact, they do not.

35. Pharmavite, by contrast, reaped enormous profits from its false marketing and sale of these Products.

CLASS DEFINITION AND ALLEGATIONS

36. Plaintiffs bring this action on behalf of themselves and all other similarly situated Class members pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seek certification of the following Class against Pharmavite for violations of California consumer protection laws:

> **Nationwide Class Action**
> All consumers who, within the applicable statutes of limitations, purchased Pharmavite's Vitamin E Products in the United States.
>
> Excluded from the Class are Pharmavite and its officers, directors and employees and those who purchased Nature Made Vitamin E dietary supplements for the purpose of resale.

37. Plaintiffs bring this action on behalf of themselves and all other similarly situated Class members pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seek certification of the following Class against Pharmavite for violations of California consumer protection laws:

> **Multi-State Class Action**
> All consumers who, within the applicable statutes of limitations, purchased Pharmavite's Vitamin E Products in California, Florida, Illinois, Massachusetts, Michigan,

> Minnesota, Missouri, New Jersey, New York, and/or Washington.
>
> Excluded from the Class are Pharmavite and its officers, directors and employees and those who purchased Nature Made Vitamin E dietary supplements for the purpose of resale.

38. In the alternative, Plaintiffs bring this action on behalf of themselves and all other similarly situated consumers pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seek certification of the following Class against Pharmavite for violations of California consumer protection laws:

> **California-Only Class Action**
> All consumers who, within the applicable statute of limitations period, purchased Pharmavite's Vitamin E products in California.
>
> Excluded from this Class are Pharmavite and its officers, directors and employees and those who purchased Nature Made Vitamin E dietary supplements for the purpose of resale.

39. ***Numerosity.*** The members of the Class are so numerous that joinder of all members of the Class is impracticable. Plaintiffs are informed and believe that the proposed Class(es) contain thousands of purchasers of the Vitamin E products who have been damaged by Pharmavite's conduct as alleged herein. The precise number of Class members are unknown to Plaintiffs.

40. ***Existence and Predominance of Common Questions of Law and Fact.*** This action involves common questions of law and fact, which predominate over any questions affecting individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether Pharmavite's heart health representations are misleading, or objectively reasonably likely to deceive;

(b) whether Pharmavite's alleged conduct violates public policy;

(c) whether the alleged conduct constitutes violations of the laws asserted;

(d) whether Pharmavite engaged in false or misleading advertising;

(e) whether Plaintiffs and Class members have sustained monetary loss and the proper measure of that loss; and

(f) whether Plaintiffs and Class members are entitled to other appropriate remedies, including damages, corrective advertising and injunctive relief.

41. ***Typicality***. Plaintiffs' claims are typical of the claims of the members of the Class because, *inter alia*, all Class members were injured through the uniform misconduct described above and were subject to Pharmavite's deceptive heart health representation that accompanied each and every bottle of Vitamin E. Plaintiffs are also advancing the same claims and legal theories on behalf of themselves and all members of the Class. Plaintiffs have standing to advance these claims because Pharmavite is headquartered in California; created and disseminated the deceptive heart health representation nationwide from its California headquarters; and manufactured, distributed, marketed, and/or sold its Vitamin E products from its California headquarters.

42. ***Adequacy of Representation***. Plaintiffs will fairly and adequately protect the interests of the members of the Class. Plaintiffs have retained counsel experienced in complex consumer class action litigation, and Plaintiffs intend to prosecute this action vigorously. Plaintiffs have no adverse or antagonistic interests to those of the Class.

43. ***Superiority***. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Pharmavite. It would thus be virtually impossible for members of the Class, on an individual basis, to obtain effective redress for the wrongs done to them.

Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances here.

44. Plaintiffs seek preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent Pharmavite from engaging in the acts described, and requiring Pharmavite to provide full restitution to Plaintiffs and Class members.

45. Unless a Class is certified, Pharmavite will retain monies received as a result of its conduct that were taken from Plaintiffs and Class members. Unless a Class-wide injunction is issued, Pharmavite will continue to commit the violations alleged, and the members of the Class and the general public will continue to be deceived.

46. Pharmavite has acted and refused to act on grounds generally applicable to the Class, making appropriate final injunctive relief with respect to the Class as a whole.

COUNT I
Violation of Business & Professions Code §17200, *et seq.* (Applicable to the Nationwide, Multi-State Class, or Alternatively, to the California-Only Class)

47. Plaintiffs repeat and re-allege the allegations contained in the paragraphs above, as if fully set forth herein.

48. Plaintiffs bring this claim individually, and on behalf of the California-only Class, and on behalf of the Nationwide and Multi-State Class.

49. As alleged herein, Plaintiffs have suffered injury in fact and lost money or property as a result of Pharmavite's conduct because they purchased the Product in reliance on Pharmavite's heart health representation, but did not receive a Product that maintains heart health.

50. 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, Pharmavite committed unlawful business practices by, *inter alia*, 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 and Business & Professions Code §§17200, *et seq.*, 17500, *et seq.*

51. Plaintiffs and the Class reserve 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.

52. Pharmavite's actions also constitute "unfair" business acts or practices because, as alleged above, *inter alia*, Pharmavite engaged in false advertising, misrepresented and omitted material facts regarding its Vitamin E products, and thereby offended an established public policy, and engaged in immoral, unethical, oppressive, and unscrupulous activities that are substantially injurious to consumers.

53. As stated in this Complaint, Plaintiffs allege violations of consumer protection, unfair competition and truth in advertising laws, resulting in harm to consumers. Pharmavite'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*.

54. There were reasonably available alternatives to further Pharmavite's

legitimate business interests, other than the conduct described herein.

55. Business & Professions Code §17200, *et seq*., also prohibits any "fraudulent business act or practice."

56. Pharmavite's actions, claims, nondisclosures 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*.

57. Plaintiffs and the other Class members have suffered injury in fact and lost money as a result of these unlawful, unfair, and fraudulent practices.

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

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

60. Plaintiffs, on behalf of themselves, all others similarly situated, and the general public, seek restitution of all money obtained from Plaintiffs and the members of the Class as a result of unfair competition, an injunction prohibiting Pharmavite from continuing such practices, corrective advertising and all other relief this Court deems appropriate, consistent with Business & Professions Code §17203.

COUNT II
Violations of the Consumers Legal Remedies Act –Civil Code §1750 *et seq.* (Applicable to the Nationwide, Multi-State Class, or Alternatively, to the California-Only Class)

61. Plaintiffs repeat and re-allege the allegations contained in the paragraphs above, as if fully set forth herein.

62. Plaintiffs bring this claim individually and on behalf of the California-only Class, and on behalf of the Nationwide and Multi-State Class.

63. This cause of action is brought pursuant to the Consumers Legal Remedies Act, California Civil Code §1750, *et seq.* (the "Act"). Plaintiffs are

"consumer[s]" as defined by California Civil Code §1761(d). Pharmavite's Vitamin E products are "goods" within the meaning of the Act.

64. Pharmavite violated and continues to violate the Act by engaging in the following practices proscribed by California Civil Code §1770(a) in transactions with Plaintiffs and the Class which were intended to result in, and did result in, the sale of the Vitamin E products:

> (5) Representing that [the Vitamin E products have] . . . approval, characteristics, . . . uses [and] benefits . . . which [they do] not have . . . .
>
> * * *
>
> (7) Representing that [the Vitamin E 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 [the Vitamin E products have] been supplied in accordance with a previous representation when [they have] not.

65. Pharmavite violated the Act by representing and failing to disclose material facts on the Products' labels 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 it was obligated to disclose.

66. Pursuant to California Civil Code §1782(d), Plaintiffs and the Class seek a Court order enjoining the above-described wrongful acts and practices of Pharmavite and for restitution and disgorgement.

67. Pursuant to §1782 of the Act, by letters dated January 27, 2014, and August 12, 2014 Plaintiff Bradach notified Pharmavite in writing by certified mail of the particular violations of §1770 of the Act and demanded that Pharmavite rectify the problems associated with the actions detailed above and give notice to all affected

consumers of Pharmavite's intent to so act.

68. Pharmavite failed to rectify or agree to rectify the problems associated with the actions detailed above and give notice to all affected consumers within 30 days of the date of written notice pursuant to §1782 of the Act. Plaintiffs further seek actual, punitive and statutory damages, as appropriate.

69. Pharmavite's conduct is fraudulent, wanton and malicious.

PRAYER FOR RELIEF

Wherefore, Plaintiffs pray for a judgment:

A. Certifying the Class(es) as requested herein;

B. Awarding Plaintiffs and the proposed Class members damages;

C. Awarding restitution and disgorgement of Pharmavite's revenues to Plaintiffs and the proposed Class members;

D. Awarding injunctive relief as permitted by law or equity, including enjoining Pharmavite from continuing the unlawful practices as set forth herein;

E. Awarding statutory and punitive damages, as appropriate;

F. Ordering Pharmavite to engage in a corrective advertising campaign;

G. Awarding attorneys' fees and costs; and

H. Providing such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial of their claims by jury to the extent authorized by law.

Dated: October 9, 2015

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/s/ Patricia N. Syverson

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CERTIFICATE OF SERVICE

I hereby certify that on October 9, 2015, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the Electronic mail notice list

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on October 9, 2015.

/s/*Patricia N. Syverson*

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EXHIBIT A

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

REBECCA BOHN, On Behalf of Herself and All Others Similarly Situated,

Plaintiff,

v.

PHARMAVITE, LLC, a California limited liability company,

Defendant.

Case No.: 2:11-cv-10430-GHK-AGR

CLASS ACTION

CLASS ACTION EXPERT REPORT OF DR. EDGAR R MILLER PHD M.D.

Judge: The Hon. George H. King
Courtroom: 650

1. My name is Edgar R Miller III PhD, MD. I am currently a Professor of Medicine at Johns Hopkins University with a joint appointment at the Johns Hopkins Bloomberg School of Public Health. I received my medical degree from Jefferson Medical College, trained in Internal Medicine at the Medical University of South Carolina and as a fellow in General Internal Medicine at Johns Hopkins. Since fellowship I have been on the full time faculty of Johns Hopkins University for 15 years with the exception of one year where I was part-time faculty at Johns Hopkins while working full time at the National Institute of Aging. I currently serve as deputy director of the Johns Hopkins Institute for Clinical and Translational research, Director of the Education, Training and Career Development Program, and am the director of the Clinical Scholars Program. My area of expertise in research is in hypertension, kidney disease and nutritional epidemiology- particularly as it pertains to antioxidant and dietary supplements. The subject of many of my primary research publications, editorials, and book chapters, has been the health effects of antioxidants. I have led and published seven meta-analyses of the effects of nutritional supplements (fish-oil, folic acid, vitamin E, and vitamin C) on cardiovascular disease risk and mortality. I have been a lead or co-investigator of several randomized trials of dietary supplements including vitamin E and have an expertise in the use of outcomes such as oxidative stress markers, blood pressure, lipids, or clinical outcomes such as stroke, heart attack or mortality. I currently work as a consultant to University of Ottawa Evidence Based Practice Center on the topic of "Dietary Supplements in Adults Taking Cardiovascular Drugs".

2. A copy of my curriculum vitae is attached as Exhibit A, presenting my Publications. I have never testified as an expert witness at any trial or by deposition in any matters.

3. I have been retained to provide expert analysis and expert testimony in this matter, and I am being compensated at a rate of $550 per hour plus expenses. My compensation is in no way dependent on the outcome of this litigation.

4. I have been asked to provide my opinions regarding the efficacy of Pharmavite vitamin E dietary supplement products, when used by people either with or free of cardiovascular disease, who have purchased them. Pharmavite manufactures, markets, sells and distributes five Vitamin E dietary supplements under its brand name "Nature Made": (1) Natural Vitamin E 400 IU d-Alpha; (2) Vitamin E 400 IU dl Alpha; (3) Vitamin E 400 I.U. Water Solubilized; (4) Vitamin E 1000 IU dl Alpha; and (5) Vitamin E 200 IU dl Alpha. Specifically, I have been asked to provide my opinion regarding the statements appearing on the labeling of the product. Pharmavite claims that its Vitamin E products will help maintain a healthy heart in adults of all ages. On each and every bottle of Vitamin E, Pharmavite represents that the Products "help maintain a healthy heart". Contrary to their claim, I contend that the evidence of benefit of vitamin E supplementation on heart health from large randomized trials is very strong and has been consistent: vitamin E supplementation does not reduce risk for cardiovascular disease, stroke, or mortality. In other words, it does not "help maintain a healthy heart."

5. There is a very mature body of literature that addresses the effects of vitamin E supplementation on health outcomes. In fact, the large number of randomized trials and number of individuals enrolled in trials of vitamin E supplementation makes vitamin E supplements one of the best tested therapies in the medical literature–bar none. Early studies examining the antioxidant properties of vitamin E suggested biological plausibility of a benefit and early observational studies where vitamin E supplementation was used in individuals was initially associated with reduced rates of cardiovascular and other chronic diseases, thereby providing a justification for randomized trials. However, ultimately, the highest form of scientific evidence comes

from the randomized controlled clinical trials. Trials are necessary to establish cause and effect and results from the many vitamin E supplement trials, collectively, have demonstrated no benefit on cardiovascular and mortality end points. Thus, in my opinion, Pharmavite's claim that Vitamin E products help to maintain a healthy heart, is false.

6. There is strong biological plausibility the vitamin E may prevent risk of cardiovascular disease. Vitamin E is a fat-soluble vitamin found in cell membranes and lipoprotein assemblies including low-density lipoprotein (LDL) particles. Vitamin E's imminence with the LDL particle makes supplementation an appealing choice of therapy. Some vitamin E in the diet is essential to maintain health. There, it acts as a chain-breaking, free-radical trapping anti-oxidant, inhibiting non-enzymatic damage to polyunsaturated fatty acids. Several lines of evidence suggest oxidative modification of LDL-cholesterol (oxLDL) is thought to be an important step in the pathogenesis atherosclerosis [1]. Experimental studies of LDL oxidation repeatedly have shown the Vitamin E supplementation, including a trial that we performed, reduces lipid oxidation [2]. However, the clinical relevance of this finding is only speculative. While the findings from trials that vitamin E supplementation lowers oxidation of lipids (a surrogate marker of cardiovascular disease) provides important supporting evidence to justify large scale clinical trials, it is my opinion and the opinion of evidence based medicine standards that this is not the type of evidence that can be used to recommend therapy or to make health benefit claims.

7. An overview of the early observational studies documents a consistent relationship between dietary intake or blood levels vitamin E and vascular disease [3]. Those studies with the strongest design and methods (e.g. The Nurses' Health Study [4] and the Health Professionals Follow-up Study [5]) demonstrated an inverse relationships between vitamin E intake and prevalent and incident cardiovascular disease (i.e. the higher the intake of vitamin E, the lower the risk of heart disease).

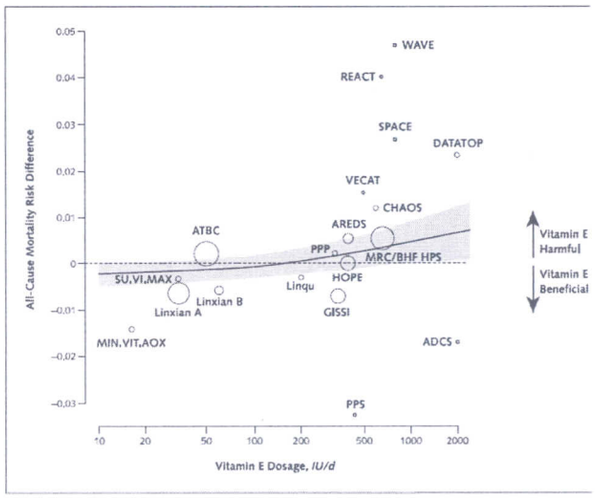
While these findings are consistent, and studies are adjusted for traditional cardiovascular disease risk factors, there is considerable concern over the possibility of residual confounding in these studies; specifically, users of vitamin E displayed a number of desirable health habits (i.e., less smoking and more frequent aspirin use and exercise). Because of the risk of confounding, findings of associations between vitamin E supplement use and benefit or risk of harm can never assume to be causal. It is for this reason the use of observational studies (as opposed to trials) findings as a basis of making therapeutic recommendations, is flawed.

8. The biological mechanistic studies, combined with the results of the above observational studies, provided a strong justification for clinical trials to test whether reducing oxidative stress with vitamin E supplementation, could prevent heart disease. Importantly, in terms of a public health approach to prevent cardiovascular disease, vitamin E supplements were thought to be very safe. As a result, there was a rapid uptake of use by the general population with virtually no empiric evidence of benefit. However, the risk of recommending dietary supplements on the basis of associations reported in observational studies are well documented. The classic example is the divergence between the finding of an inverse association between serum concentrations of β-carotene and lung cancer risk and the finding of increased risk of lung cancer in subjects assigned β-carotene supplements in controlled clinical trials (as reviewed in reference 6). The lesson of the β-carotene example is that the unreliability of drawing strong cause-and-effect conclusions from correlation data has evolved into an important teaching example for students of epidemiology.

9. The foundations of evidence-based medicine are direct and consistent evidence of benefit from well-designed randomized controlled clinical trials to inform recommendations for any therapy or treatment. Ideally you want to demonstrate the effect of vitamin E supplementation on reducing outcomes like heart attacks, strokes or death rates –clinically relevant outcomes. To show benefit, the vitamin E supplement

trial group must have a lower event rate than the placebo group, resulting in a risk reduction due to the supplement. Because of the cost of conducting large scale trials and the length of time that is needed to expect an effect on these clinical outcomes, there is often insufficient evidence from trials to make these types of health claims. However, the benefit of vitamin E supplementation has been tested in an extraordinarily large number of clinical trials, in hundreds of thousands of individuals, in groups at risk for chronic disease (healthy without apparent disease) and with established disease (e.g. a prior heart attack), and in trials of sufficient duration to assess clinical cardiovascular outcomes.

Dose–response relationship between vitamin E supplementation and all-cause mortality in randomized, controlled trials.



10. To date, there have been over 25 large long-term clinical trials published that have collectively randomized over 200,000 individuals. In 2005, we published a meta-analysis of randomized trials of vitamin E supplementation on all-cause mortality - an unambiguous end point, combining results from nineteen well conducted clinical trials of vitamin E supplementation in populations with established disease or at risk for disease [7]. A meta-analysis is a pooling technique where results from multiple clinical trials are combined. We reported that high-dose vitamin E supplementation (>400 IU/day for at least 1 year) resulted in a small but statistically significant increase in all-cause mortality (relative risk comparing vitamin E supplementation to control 1.04; 95% confidence interval 1.01 to 1.08) [figure]. Our findings were reaffirmed in a Cochrane Collaboration meta-analysis with updated evidence published a year later by Bjelakovic et al. [8] Unlike our meta-analysis, Bjelakovic et al. included trials of <1 year duration and trials that reported <10 deaths. In their meta-analysis, among 26 trials of low risk for bias, those assigned to vitamin E had a significantly increased risk of mortality (RR 1.04, 95% CI: 1.01-1.07) compared to placebo, an effect that was independent of dose. Both of these meta-analyses report a significant, albeit small (~4%) increased risk of mortality in those assigned to vitamin E compared to those taking placebo. In our meta-analysis the increase risk was in trials that used >400IU/day of vitamin E. As a point of reference, usual intake in adults from dietary sources is ~10 IU/day: hence someone who purchases 400 or 1000 IU capsules of vitamin E is consuming a dose that is 40-100 times the typical intake from diet (i.e. high dose).

11. While effects of vitamin E supplementation on total mortality provides an unambiguous end point and would provide strong justification for supplementation if found to be beneficial, many trials proposed cardiovascular disease events (non-fatal MI or stroke, or CVD mortality) as these end points are more closely related to proposed mechanistic benefits (reducing oxidation of LDL cholesterol and atherosclerosis). We performed a meta-analysis of vitamin E supplementation trials that examined effects on progression of atherosclerosis as measured by imaging techniques. The progression of atherosclerosis was evaluated by B-mode ultrasound, intravascular ultrasound, or angiography. Effect sizes were calculated for the difference in slope of atherosclerosis progression between participants assigned to supplements and those assigned to the control group. In a pooled analysis of seven trials, there was no benefit of vitamin E supplementation on atherosclerotic progression (pooled effect size; -0.02 (95% CI: - 0.15, 0.10) [9]. These findings of a lack of benefit of vitamin E supplementation on subclinical disease (risk factor for cardiovascular disease) further highlight the lack of a "heart health" effect.

12. Many of the randomized vitamin E supplement trials pre-specified examining effects on cardiovascular disease outcomes and are most informative and relevant to address the health claim made by the Nature Made brand, i.e., "helps maintain a healthy heart". There have been a large number of clinical trials of vitamin E supplementation on clinical cardiovascular events (non-fatal MI, non-fatal stroke, and CVD mortality). The first large trial of Vitamin E supplementation reported was the ATBC study completed in 1994 [10]. In this 2 X 2 factorial design clinical trial (alpha-tocopherol and beta carotene), the Finish smokers assigned 50 mg/day of alpha-tocopherol had similar deaths rates from ischemic heart disease and ischemic stroke and more deaths ($P<0.05$) from hemorrhagic stroke than the placebo group after five to eight years. The latter finding, if true, may be explained by the possibility, albeit controversial, of an anti-platelet effect of vitamin E.

13. The second large published clinical trial of vitamin E supplementation was a secondary prevention trial of 2002 patients with previous heart attack, the Cambridge Heart Antioxidant Study (CHAOS) [11]. This study reported a 47% significant reduction in non-fatal MI after only 1.4 years of intervention. However, there was a non-significant 24% higher risk of total mortality and 18% higher risk of cardiovascular mortality in those assigned to vitamin E compared with placebo groups. As a consequence of the publication of this one trial, vitamin E supplementation became commonplace. Of note, this trial represents <1% of all participants who have participated in vitamin E supplement trials and highlights the importance of using the totality of evidence rather than cherry picking individual trials that support claims.

14. Subsequent trials that followed the CHAOS trial findings show that there was no benefit from Vitamin E. The GISSI-Pevenzionne trial was also a secondary prevention trial of 11,324 men and women who had had a recent heart attack [12]. In this trial, vitamin E supplementation failed to protect against any of the major outcomes including stroke, heart attack or death, after 3.5 years of follow-up.

15. Two additional trials of vitamin E supplementation for the prevention of cardiovascular disease in patients at high risk for disease were completed and published in 2000 and 2001. The HOPE trial (Heart Outcome Prevention Evaluation) [13] and PPP (Primary Prevention Program) [14] study randomized 9,541 and 4,495 adults at high risk for cardiovascular disease to 400 IU/day and 300 IU/day, respectively. In both studies, vitamin E had non-significant effect on total mortality, fatal or nonfatal cardiovascular events.

16. A meta-analysis of 14 large trials (including the CHAOS, HOPE and PPP trials) published in 2004, found no benefit of vitamin E supplementation at reducing cardiovascular events [15]. In a stratified analysis by trials that used natural (all-rac-alpha-tocopherol) or RRR-alpha tocopherol (synthetic) forms of vitamin E, there was

no difference in the odds ratio for major cardiovascular events in trials that used either source.

17. Many large trials have been published since publication of this 2004 meta-analysis that provided a unique opportunity to assess the robustness of prior study conclusions on mortality and effects on CVD end points. These trials add important information to the knowledge base of the effects of vitamin E as all of them had a long follow-up (over 5 years) and three of them, the Women's Health Study [16], the SELECT trial [17], and The Physicians Health Study II (PHS II) [18] were conducted with healthy participants, an underrepresented group in previous trials. The six trials had a duration that ranged from 5.5 to 10.1 years. All of these trials showed that there was no protective effect of vitamin E supplementation on all-cause mortality [19]. These trials included participants that were exclusively women: The Women's Health Study [16] (WHS) by far the largest of these trials, the Womens' Antioxidant Cardiovascular Study (WACS) [20], or men SELECT trial [17] and the PHS II trials [18]), in those at high risk for CVD events (the HOPE-TOO [21], and The Prevention of Progression of Arterial Disease and Diabetes (POPABAB) trial [22]. Collectively, and individually, these trials showed that there was no benefit on cardiovascular end points [Table].

Study, Year (reference)	Population	Vitamin E dose	CVD composite end point	Follow-up, Years	Cardiovascular Events/Participants N/N, Vitamin E (E) Control (C)	Relative Risk of CVD Events (95% CI)*
HOPE-TOO, 2005 [21]	High risk for cardiovascular disease	400 IU/day	MI, stroke and CVD death	7.0	(E) 1022/3520 (C) 985/3510	1.04 (0.96,1.14)
WHS, 2005 [16]	Healthy women	600 IU every other day	Nonfatal MI or stroke, CVD death	10.1	(E) 482/19937 (C) 517/19939	0.93 (0.82, 1.05)
WACS, 2007 [20]	Women at Increased risk for cardiovascular disease	600 IU every other day	Nonfatal MI or stroke, coronary revascularization, or CVD death	9.4	(E) 708/4083 (C) 742/4088	0.94 (0.85, 1.04)
POPADAD, 2008 [22] }	Diabetes and peripheral arterial disease	200 IU/day	Nonfatal MI or stroke, death from CHD or stroke	6.7	(E) 117/640 (C) 116/636	1.03 (0.79, 1.33)
SELECT [17]	Healthy Men	400 IU/day	All CVD events including death	5.5	(E) 1034/8737 (P) 1050/8696	0.98 (0.99, 1.09)
PHS II 2012	Male physicians at lower risk for CVD	400 IU every other day	Nonfatal MI, nonfatal stroke, CVD mortality	8	(E) 620/7315 (P) 625/7326	1.01 (0.90, 1.13)
*A Relative risk > 1.00 indicates the direction of harm (e.g. a Relative Risk of 1.04 means a 4% higher risk in the vitamin E compared with the Placebo group. A relative risk > 1.00 means the direction of benefit (less events in the vitamin E group compared with the placebo group,(e.g. a relative risk of 0.98 means a 2 percent reduction in risk). Please note that all the 95% confidence intervals include 1.00 indicating that none showed statically significant evidence of benefit or harm.						

These results reaffirm the earlier reports of no overall effects of vitamin E supplementation on cardiovascular disease outcomes and because of the addition of a large number of participants and events, strengthen our confidence in reporting a lack of benefit of vitamin E on cardiovascular disease outcomes in both primary and secondary prevention trials. Of note, the SELECT trial at the time was the largest on-going trial of vitamin E supplementation (~20,000 men randomized). This trial was stopped early by the study Data Safety and Monitoring Board because of a trend for increased risk of prostate cancer in those assigned to vitamin E [17].

18. In 2012, Bjelakovic et al [23] publish a Cochrane report summarizing all published randomized controlled trials of vitamin E supplementation on mortality. This meta-analysis included >200,000 adult participants. They reported an increased risk of mortality with Vitamin E supplementation contradicting the findings of observational studies claiming that antioxidants improve health. Further they conclude that

"considering that more than 10% to 20% of the adult population (80 million to 160 million people) in North America and Europe may consume the supplements the public health consequences could be substantial." They offer several explanations as to why this paradox of inconsistency between observational studies and trials may occur. "There are several possible explanations for the increased mortality induced by antioxidant supplements. Although oxidative stress has a hypothesized role in the pathogenesis of many chronic diseases it may be the consequence of pathological conditions. By eliminating free radicals from our organism, we interfere with some essential defensive mechanisms like apoptosis, phagocytosis, and detoxification…. As suggested, antioxidant supplements may interfere with reactive oxygen species and interfere with health and longevity" [23].

19. In summary, numerous large randomized controlled clinical trials of vitamin E supplements have failed to show a beneficial effect in the prevention of cardiovascular diseases (primary prevention trials like WHS, HOPE, PHS II) or the secondary prevention trials (prevention of subsequent disease in those with established heart disease -e.g WACS and POPADAD). Given the lack of benefit in heart health in these two populations and the increased risk of mortality associated with high dose vitamin E supplementation (>400 IU) reported in two meta-analyses of all trials combined, it is my opinion that the claims made, i.e. that vitamin E supplementation "helps maintain a healthy heart" is false.

Dated: January 18, 2013

DR. EDGAR R MILLER PHD M.D.

Endnotes

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