UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DAVID JOHNS, an Individual and MARC BORDMAN, an Individual, on Behalf of Themselves and All Others Similarly Situated and the General Public,

Plaintiffs,

v.

BAYER CORPORATION, an Indiana Corporation and BAYER HEALTHCARE, LLC, a Delaware Limited Liability Company,

Defendants.

Civil No.09cv1935 AJB (DHB)

ORDER:

(1) DENYING PLAINTIFFS' MOTION TO EXCLUDE DR. BLUMBERG'S EXPERT TESTIMONY, (Doc. Nos. 141);

(2) DENYING DEFENDANTS' MOTION TO EXCLUDE DR. MILMAN'S EXPERT TESTIMONY, (Doc. No. 142);

(3) GRANTING DEFENDANTS' MOTION TO EXCLUDE DR. MARONICK'S EXPERT TESTIMONY, (Doc. No. 155);

(4) GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT, (Doc. No. 172); AND

(5) DENYING AS MOOT DEFENDANTS' MOTION TO EXCLUDE MR. ELMORE'S EXPERT TESTIMONY, (Doc. No. 157), DEFENDANTS' MOTION TO STRIKE MR. ELMORE'S SUPPLEMENTAL REPORT, (Doc. No. 161), PLAINTIFFS' MOTION TO EXCLUDE DR. DHAR'S EXPERT TESTIMONY, (Doc. No. 162), AND PLAINTIFFS' MOTION TO EXCLUDE DR. HUGHES' EXPERT TESTIMONY, (Doc. No. 156).

Presently before the Court are Plaintiffs' motions to exclude Defendants' expert testimony and opinions, (Doc. Nos. 141, 156 & 162), Defendants' motions to exclude Plaintiffs' expert testimony and opinions, (Doc. Nos. 142, 155 & 157), Defendants' motion to strike the supplemental report of Plaintiffs' expert, (Doc. No. 161), and Defendants' motion for summary judgment, (Doc. No. 172). All matters were fully briefed.[1] On March 7, 2013, the Court heard oral argument on Defendants' motion to exclude Mr. Elmore's expert opinions and testimony, Defendants' motion to strike Mr. Elmore's supplemental report, and Defendants' motion for summary judgment.[2] Timothy Gordon Blood and Thomas Joseph O'Readon II appeared on behalf of Plaintiffs, and Julie LeMaye Hussy, Shirli Fabbri Weiss, and Ryan T. Hansen appeared on behalf of Defendants. (Doc. No. 226.)

For the reasons set forth below, the Court DENIES Plaintiffs' motion to exclude the expert testimony and opinions of Jeffrey B. Blumberg ("Dr. Blumberg"), (Doc. No. 141); DENIES Defendants' motion to exclude the expert testimony and opinions of Harry A. Milman ("Dr. Milman"), (Doc. No. 142); GRANTS Defendants' motion to exclude the expert testimony and opinions of Thomas J. Maronick ("Dr. Maronick"), (Doc. No. 155); GRANTS Defendants' motion for summary judgment, (Doc. No. 172); and DENIES AS MOOT Plaintiffs' motion to exclude the expert testimony and opinions of James W. Hughes ("Dr. Hughes"), (Doc. No. 156), Defendants' motion to exclude the expert testimony and opinions of Ravi Dhar ("Dr. Dhar"), (Doc. No. 162), Defendants'

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[1] Bayer also made five evidentiary objections to the admission of evidence offered by Plaintiffs. Specifically, Bayer argued the following evidence should be excluded: (1) results and findings made by third-party market research firms commissioned by Bayer both before and during the Class Period; (2) the 2005 FDA Decision Letter; (3) a letter addressed to Bayer from the National Advertising Division ("NAD"); (4) an email from dzenka@pcf.org; and (5) a brief filed by Bayer in *McKinney v. Bayer*, No. 1:10-cv-00224 (N.D. Ohio). (Doc. No. 222 at 10.) Bayer briefly addressed these objections at oral argument and provided the Court and opposing counsel with copies of their objections and the documents to which Bayer objected. The Court filed these documents to ensure the record accurately reflected all materials reviewed by the Court. (Doc. No. 230.) Therefore, to the extent the Court does not explicitly rule on Bayer's evidentiary objections, such objections are overruled.

[2] On January 24, 2013, the Court took the remaining five *Daubert* motions under submission pursuant to Civil Local Rule 7.1.d.1. (Doc. Nos. 141, 142, 155, 156 & 162.)

motion to exclude the expert testimony and opinions of David R. Elmore, Jr. ("Mr. Elmore"), (Doc. No. 157), and Defendants' motion to strike Mr. Elmore's supplemental report, (Doc. No. 161). The Clerk of Court is instructed to enter judgment and close the case.

BACKGROUND

This is a consumer class action brought by Plaintiffs David Johns ("Johns") and Marc Bordman ("Bordman") on behalf of themselves and a class of similarly situated California consumers (collectively, "Plaintiffs"). The Second Amended Class Action Complaint ("Second Amended Complaint") alleges that Defendants Bayer Corporation and Bayer Healthcare, LLC (collectively, "Bayer" or "Defendants") violated the Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750 *et seq*., and California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq*., by making false and deceptive advertising claims regarding prostate health benefits in two of Bayer's men's One-A-Day ("OAD") vitamin products—OAD Men's Health Formula ("OAD Men's Health") and OAD Men's 50+ Advantage ("OAD Men's 50+ Advantage") (collectively, "Vitamin Products" or "Products"). (Doc. No. 22, SAC ¶¶ 74 & 83.) Specifically, Plaintiffs contend that despite mounting scientific evidence that the ingredients in the Vitamin Products do not support prostate health and do not reduce the risk of prostate cancer, Bayer marketed the Products as having such benefits, thereby engaging in deceptive marketing practices to capitalize on the growing awareness of prostate health concerns among men. (*Id.* at ¶¶ 43, 45, 48, 49 & 74.) As a result, Plaintiffs allege Bayer gained an unfair advantage over other vitamin manufacturers who did not engage in similar deceptive advertising practices. (*Id.*)

I. The Challenged Prostate Statements

Plaintiffs challenge two representations made by Bayer: (1) representations that the Products support overall prostate health ("Prostate Health Claim"); and (2) representations that emerging research suggests selenium may reduce the risk of prostate cancer

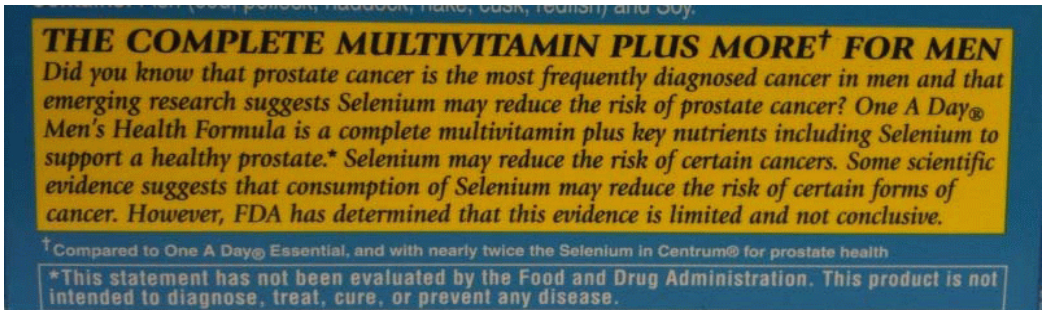
("Prostate Cancer Claim") (collectively, "Prostate Claims").[3] (*Id*. at ¶¶ 2 & 12-19; Doc. No. 172, Ackerman Decl., Exs. A-G, I & K.) Both Prostate Claims were made with respect to OAD Men's Health, whereas only the Prostate Health Claim was made with respect to OAD Men's 50+ Advantage. (SAC ¶¶ 17-19; Doc. No. 172 at 3.)

A. Prostate Claims Made with Respect to OAD Men's Health

Bayer first launched a men's gender-specific multivitamin in 1994. (Doc. No. 172, Ackerman Decl. ¶¶ 2 & 3.) At this time, Bayer began to advertise and market the multivitamin as specifically formulated for men, with representations relating to heart health and metabolism. (*Id*.) In 2002, Bayer reformulated and re-branded the men's gender-specific multivitamin to include representations that the product supports eye health, heart health, increases energy, helps lower blood pressure, and supports prostate health. (Doc. No. 172, Ackerman Decl. ¶ 5, Ex. A; Doc. No. 212, Blood Decl., Ex. 17.) This new product was labeled OAD Men's Health, and was one of many sub-brands within Bayer's OAD multivitamin line. (*Id*.)

In or around November 2006, some of the packaging for OAD Men's Health also included the following representation: "Complete Multivitamin Plus More† for Men - Did you know that prostate cancer is the most frequently diagnosed cancer in men and that emerging research suggests Selenium may reduce the risk of prostate cancer? One A Day® Men's Health Formula is a complete multivitamin plus key nutrients including Selenium to support a healthy prostate." (SAC ¶ 16; Doc. No. 172, Ackerman Decl., Ex. F, G, I & K; Doc. No. 212, Blood Decl., Ex. 17.) This representation was located on the back of the product package, and was highlighted, bolded, and italicized. (*Id*.) The images below depict examples of OAD Men's Health product packaging during the Class Period. (SAC ¶¶ 15, 17; Doc. No. 212, Blood Decl., Ex. 17.)

[3] These representations appeared on the front, back, and sides of the product packaging and/or in television advertising. (SAC ¶¶ 2, 12-19.)



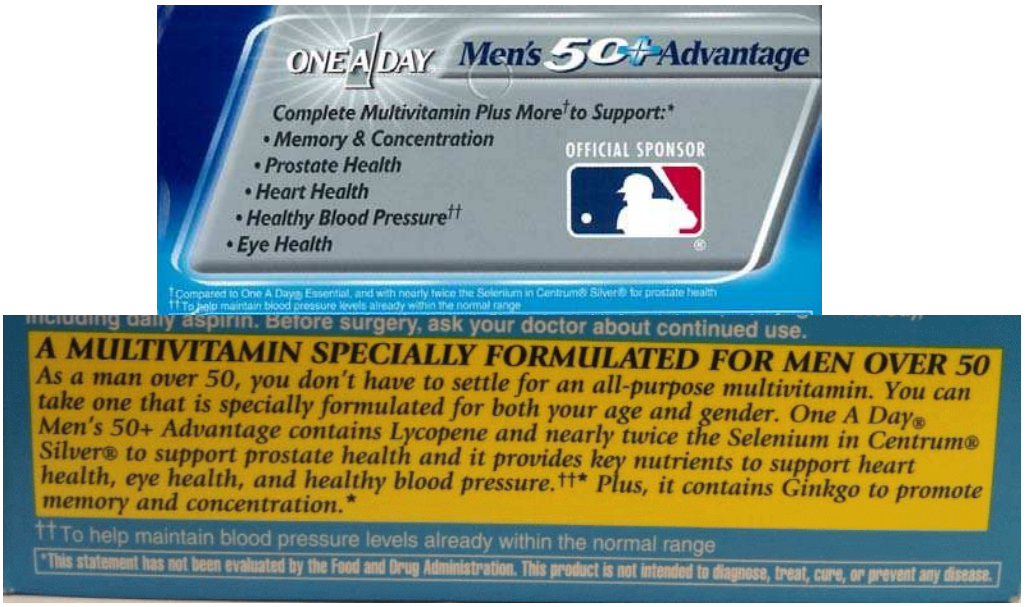
In addition to the Prostate Claims located on OAD Men's Health product packaging, Bayer ran multiple television advertisements that communicated the same or similar messages. (SAC ¶¶ 17 & 18; Doc. No. 212, Blood Decl., Exs. 5, 9, 15 & 16.) For example, one commercial, commonly referred to as the "Mustang" commercial, made the following representations through both dialog and visual depictions:

> Did you know one in three men will face prostate issues? One in three, really? That's why One-A-Day Men's is a complete multivitamin . . . with Lycopene, which . . . Harvard studies suggest may help prostate health.

(Doc. No. 212, Blood Decl., Ex. 15.) Another television commercial, commonly referred to as the "Striking Out Prostate Cancer" commercial, also communicated the Prostate Health Claim, which Plaintiffs allege was aired by Bayer a "a fully integrated marketing plan that aim[ed] at 'Manning Up' the brand and communicat[ing Bayer's] prostate health message." (Doc. No. 212, Blood Decl., Ex. G, Nunziata Depo. at 17:12-24 & 43-45.) The Prostate Cancer Claim, which first appeared on OAD Men's Health product packaging in or around November 2006, never appeared in television advertisements, and was only made on the product packaging.

B. Prostate Claims Made with Respect to OAD Men's 50+ Advantage

Bayer first launched OAD Men's 50+ Advantage in or around May 2007. (Doc. No. 172, Ackerman Decl. ¶ 12; Doc. No. 212, Blood Decl., Ex. 18.) OAD Men's 50+ Advantage included the Prostate Health Claim, as well as representations relating to memory and concentration, heart health, healthy blood pressure, and eye health.[4] (*Id.*) The product packaging for OAD Men's 50+ Advantage never included the Prostate Cancer Claim, or any other representation relating to prostate cancer. (Doc. No. 172, Ackerman Decl., Exs. H, J & L.) The images below depict examples of OAD Men's 50+ Advantage product packaging during the Class Period. (SAC ¶¶ 15 & 17; Doc. No. 212, Blood Decl., Ex. 17.)



C. Purchase of the Men's Vitamin Products

Plaintiff Johns allegedly purchased OAD Men's Health in July 2009 for the retail price of approximately $8.00 a bottle. (SAC ¶¶ 6 & 50; Doc. No. 73, Syverson Decl., Ex. 52, Johns Depo. at 11.) Plaintiff Johns read the representations on the product packaging

[4] Similar representations with respect to OAD Men's 50+ Advantage were made by Bayer via television advertisements. (Doc. No. 22 ¶ 19.)

for OAD Men's Health, and contends he purchased the product for various reasons, including the Prostate Health Claim. (Doc. No. 73, Syverson Decl., Ex. 52, Johns Depo. at 22-25.) Plaintiff Bordman allegedly purchased several bottles of OAD Men's 50+ Advantage in 2008, each time paying the full retail price. (SAC ¶¶ 50 & 54; Doc. No. 73, Syverson Decl., Ex. 53, Bordman Depo.) In addition to the representations made on the Products' packaging, both Plaintiffs allege they have seen and heard television commercials advertising and marketing the Prostate Claims, and that they relied on such representations when deciding to purchase the Products. (SAC ¶¶ 51 & 55; Doc. No. 73, Syverson Decl., Ex. 52, Johns Depo., Ex. 53, Bordman Depo.)

II. Procedural History

Plaintiffs originally brought this action on September 3, 2009, alleging: (1) violations of the UCL; and (2) unjust enrichment. (Doc. No. 1.) Plaintiffs filed a First Amended Complaint ("FAC") as a matter of right on October 16, 2009, thereby adding a cause of action under the CLRA. (Doc. No. 10.) On October 30, 2009, Bayer filed a motion to dismiss and a motion to strike portions of the FAC. (Doc. Nos. 13 & 14.) On February 9, 2010, the Court granted in part and denied in part Bayer's motion to strike, and granted Bayer's motion to dismiss.[5] (Doc. No. 21.) Specifically, the Court granted Bayer's motion to strike paragraphs of the FAC that amounted to "borrowed allegations" from a prior FTC action involving Bayer, denied Bayer's motion to strike paragraphs of the FAC seeking disgorgement, and granted Bayer's motion to dismiss.[6] (*Id.*) Plaintiffs filed the operative Second Amended Complaint ("SAC") on March 11, 2010. (Doc. No. 22.) Thereafter, on March 29, 2010, Bayer filed a motion to dismiss and a motion to strike portions of the SAC. (Doc. Nos. 23 & 24.) On June 24, 2010, the Court granted in part and denied in part Bayer's motion to strike (striking ¶ 42), and denied Bayer's

[5] Judge Dana M. Sabraw was presiding over the case at that time. The instant matter was not transferred to the undersigned until March 14, 2011. (Doc. No. 55.)

[6] Plaintiffs were not provided leave to amend the unjust enrichment cause of action as the Court held this was not a viable cause of action. (Doc. No. 21 at 8:11-16.)

motion to dismiss. (Doc. No. 35.) Bayer filed an answer to the SAC on August 10, 2010 and discovery commenced shortly thereafter. (Doc. No. 38.)

On August 17, 2011, Plaintiffs filed a motion to certify the class. (Doc. No. 73.) On February 3, 2012, the Court granted the motion, certifying a class of all persons who purchased the Vitamin Products in the state of California from the date the Vitamin Products were first sold in California with the Prostate Claims until May 31, 2010 ("Class Period"). (Doc. No. 105 at 2:21-23.) Therefore, the relevant Class Period with respect to OAD Men's Health is June 2002 to May 31, 2010 ("Men's Health Class Period"), and the relevant Class Period with respect to OAD Men's 50+ Advantage is August 2007 to May 31, 2010 ("Men's 50+ Advantage Class Period"). (Doc. No. 172, Ackerman Decl. ¶¶ 4, 5, 10, 11 & 16; Doc. No. 212, Blood Decl., Ex. 17.) Presently before the Court are the parties respective *Daubert* motions, (Doc. Nos. 141, 142, 155, 156, 157 & 162), Bayer's motion to strike Mr. Elmore's supplemental report, (Doc. No. 161), and Bayer's motion for summary judgment, (Doc. No. 172).

LEGAL STANDARD

Summary judgment is proper where the pleadings and materials demonstrate "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A genuine dispute as to a material fact is a question a trier of fact must answer to determine the rights of the parties under the applicable substantive law. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp*., 475 U.S. 574, 586 (1986) (stating that a material fact is one that is relevant to an element of a claim or defense and whose existence might affect the outcome of the suit). *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* The court must review the record as a whole and draw all reasonable inferences in favor of the non-moving party. *Hernandez v. Spacelabs Med. Inc.*, 343 F.3d 1107, 1112 (9th Cir. 2003). However, unsupported

conjecture or conclusory statements are insufficient to defeat summary judgment. *Id.*; *Surrell v. Cal. Water Serv. Co.*, 518 F.3d 1097, 1103 (9th Cir. 2008).

The moving party has the initial burden of demonstrating that summary judgment is proper. *See Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 152 (1970). The burden then shifts to the opposing party to provide admissible evidence beyond the pleadings to show that summary judgment is not appropriate. *See Celotex*, 477 U.S. at 322, 324. To avoid summary judgment, the opposing party cannot rest solely on conclusory allegations of fact or law. *See Berg v. Kincheloe*, 794 F.2d 457, 459 (9th Cir. 1986). Instead, the non-movant must designate which specific facts show that there is a genuine issue for trial. *See Anderson*, 477 U.S. at 256. The opposing party's evidence is to be believed, and all justifiable inferences are to be drawn in their favor. *See id.*

DISCUSSION

I. Motions To Exclude Expert Testimony

Plaintiffs and Bayer each identified three experts to assist the trier of fact. Plaintiffs designated Mr. Elmore to calculate damages under the UCL and CLRA, Dr. Maronick to opine on Bayer's marketing research and promotion of the Vitamin Products before and during the Class Period, and Dr. Milman to evaluate the truth, falsity, and/or deceptive nature of the Prostate Claims in light of the scientific research available during the Class Period. To rebut Plaintiffs' experts and independently contest the viability of Plaintiffs' claims, Bayer designated Dr. Hughes to evaluate Mr. Elmore's findings, Dr. Dhar to evaluate Dr. Maronick's findings, and Dr. Blumberg to evaluate Dr. Milman's findings and opine on the scientific substantiation for the Prostate Claims during the Class Period. The parties now move to exclude the testimony and opinions of each parties' respective experts. Plaintiffs move to exclude the testimony and opinions of Dr. Hughes, Dr. Dhar, and Dr. Blumberg, (Doc. Nos. 156, 162 & 141); and Bayer moves to exclude the testimony and opinions of Mr. Elmore, Dr. Maronick, and Dr. Milman, (Doc. 157, 155 & 142). Bayer also moves to strike Elmore's supplemental expert report as untimely. (Doc. No. 161.)

Because the parties' exhaustive challenges under *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed. 2d 469 (1993) will necessarily impact the evidence the Court may properly consider in adjudicating Bayer's pending motion for summary judgment, the Court first addresses the parties' respective evidentiary challenges and then considers the parties' substantive arguments under the UCL and CLRA. However, because the Court finds Plaintiffs' claims are based on "lack of substantiation" rather than proof of falsity or deception, and summary judgment in favor of Bayer is warranted on this ground alone, the Court need not address whether Plaintiffs have proffered a valid measure of damages under the UCL and CLRA. Therefore, the Court DENIES AS MOOT the parties' respective motions to exclude the testimony and opinions of Dr. Hughes and Mr. Elmore, and DENIES AS MOOT Bayer's motion to strike Mr. Elmore's supplemental report. Likewise, because the Court finds Dr. Maronick's testimony and opinions will not aid the trier of fact, and therefore must be excluded, Plaintiffs' corresponding motion to exclude Dr. Dhar's testimony—Bayer's rebuttal expert—is also DENIED AS MOOT. Accordingly, the Court only addresses the merits of the parties' respective motions to exclude the expert testimony and opinions of Dr. Milman, Dr. Blumberg, and Dr. Maronick.

A. Legal Standard

Rule 702 governs the admissibility of expert testimony. Pursuant to Rule 702:

> [a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. "The party offering the expert bears the burden of establishing that Rule 702 is satisfied." *Sundance Image Tech., Inc. v. Cone Editions Press, Ltd.*, No. CV 02–2258 JM (AJB), 2007 WL 935703, at *4 (S.D. Cal. Mar. 7, 2007) (citing *Allison v. McGhan Med. Corp*., 184 F.3d 1300, 1306 (11th Cir. 1999) (in turn citing *Daubert*, 509 U.S. at 592 n.10, 113 S.Ct. 2786)); *see also Walker v. Contra Costa Cnty.*, No. C

03–3723 TEH, 2006 WL 3371438, *1 (N.D. Cal. Nov. 21, 2006) (citing *Bourjaily v. United States*, 483 U.S. 171, 172 (1987)).

Prior to admitting expert testimony, the trial court must make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592-93. The trial court acts as a "gatekeeper" by making a preliminary determination of whether the expert's proposed testimony is not only relevant but reliable. *Elsayed Mukhtar v. Cal. State Univ. Hayward*, 299 F.3d 1053, 1063 (9th Cir. 2002), *amended by* 319 F.3d 1073 (9th Cir. 2003). This two-step assessment requires consideration of whether: (1) the reasoning or methodology underlying the testimony is scientifically valid (the reliability prong); and (2) whether the reasoning or methodology properly can be applied to the facts in issue (the relevancy prong). *Daubert*, 509 U.S. at 592-93; *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1228 (9th Cir. 1998).

A district court has broad latitude in deciding how to measure reliability and in making the ultimate reliability determination. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 142 (1999) ("*Kumho Tire*"). In essence, the court must determine whether the expert's work product amounts to "good science." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) ("*Daubert II*") (quoting *Daubert*, 509 U.S. at 593) (internal citations omitted). In *Daubert*, the Supreme Court outlined factors relevant to the reliability prong, including: (1) whether the theory can be and has been tested; (2) whether it has been subjected to peer review; (3) the known or potential rate of error; and (4) whether the theory or methodology employed is generally accepted in the relevant scientific community. *Daubert*, 509 U.S. at 593-94. As later confirmed in *Kumho Tire*: "Daubert's list of specific factors neither necessarily nor exclusively applies to all experts or in every case. Rather the law grants a district court the same broad latitude when it decides how to determine reliability as [the court] enjoys in respect to its ultimate reliability determination." *Kumho Tire*, 526 U.S. at 141-42.

Under the relevancy or "fit" prong, the testimony must be "relevant to the task at hand, . . . i.e., that it logically advances a material aspect of the proposing party's case." *Daubert II*, 43 F.3d at 1315 (quoting *Daubert*, 509 U.S. at 597). Relevancy requires opinions that would assist the trier of fact in reaching a conclusion necessary to the case. *See Kennedy*, 161 F.3d at 1230. In general, the *Daubert* analysis focuses on the principles and methodology underlying an expert's testimony, not on the expert's ultimate conclusions. *Daubert*, 509 U.S. at 595. However, the Supreme Court has cautioned that "conclusions and methodology are not entirely distinct from one another." *Gen. Elec. v. Joiner*, 522 U.S. 136, 146 (1997). As such, "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Id*.

B. Bayer's Motion to Exclude Plaintiffs' Science Expert Dr. Milman

Dr. Milman was retained by Plaintiffs to offer an expert opinion regarding the scientific substantiation for the Prostate Claims during the Class Period. Specifically, Dr. Milman was asked to opine on: (1) whether selenium, lycopene, zinc, and vitamin E promotes prostate health; and (2) whether selenium supplementation reduces the risk of prostate cancer. (Doc. No. 196 at 3:24-28.) Dr. Milman's report offers the following five opinions:

> (1) In my professional opinion, and within a reasonable degree of scientific certainty, there is no credible scientific evidence that supports Bayer's advertising claims that lycopene supplementation supports a healthy prostate.
>
> (2) In my professional opinion, and within a reasonable degree of scientific certainty, scientific evidence available in 2002 about the effect of selenium supplementation in humans was limited, inadequate and insufficient to support advertising health claims begun at the time by Bayer that selenium in One-a-Day Men's Health Formula supports a healthy prostate.
>
> (3) In my professional opinion, and within a reasonable degree of scientific certainty, scientific evidence available in 2006 about the effect of selenium supplementation in humans remained limited, inadequate and insufficient to support advertising health claims by Bayer that selenium in One-a-Day Men's Health Formula and in One-a-Day Men's 50+ Advantage supports a healthy prostate and that selenium in One-a-Day Men's Health Formula also may reduce the risk of prostate and other forms of cancer.

> (4) In my professional opinion, and within a reasonable degree of scientific certainty, convincing scientific evidence published between 2006 and the summer of 2009 showed that selenium supplementation has no effect on the incidence of prostate and other forms of cancer. In addition, available scientific evidence does not support the health claims made by Bayer that selenium in One-a-Day Men's Health Formula and in One-a-Day Men's 50+ Advantage supports a healthy prostate, and that selenium in One-a-Day Men's Health Formula also may reduce the risk of prostate and other forms of cancer.
>
> (5) In my professional opinion, and within a reasonable degree of scientific certainty, selenium supplementation in One-a-Day Men's Health Formula and in One-a-Day Men's 50+ Advantage potentially may be toxic to human health if consumed in large amounts.

(Doc. No. 142, Weiss Decl., Ex. A at 10, 21, 30-31, 35 & 38.)

Bayer seeks to exclude Dr. Milman's expert testimony on the following grounds: (1) Dr. Milman is not qualified to testify in the area of nutritional science because he is a toxicologist; (2) Dr. Milman's third and fourth opinions are preempted under federal law; (3) Dr. Milman's first, second, and third opinions are irrelevant because they are based on "lack of substantiation;" (4) Dr. Milman's testimony is based on unsound methodology because he did not review the actual Product labels before forming his opinions; (5) Dr. Milman's analysis is flawed because he failed to address the impact of zinc and vitamin E; (6) Dr. Milman's standard requiring "definitive proof" has no basis in the scientific community and is thus unreliable; and (7) Dr. Milman's fifth opinion, which states that the Products "potentially may be toxic," is irrelevant because it assumes an overdose contrary to package instructions. The Court first addresses Dr. Milman's qualifications and then addresses Bayer's remaining substantive objections.

1. Dr. Milman's Qualifications

First, Bayer argues Dr. Milman is not qualified to render an opinion in the area of nutritional science because he is a toxicologist and has no experience or expertise in nutritional research. As a result, Bayer contends Dr. Milman's qualifications in the area of toxicology do not automatically render him qualified to offer an expert opinion regarding the nutritional benefits of zinc, vitamin E, lycopene, and selenium, and more

importantly, the nutrients' corresponding effects on the human body.[7] (Doc. No. 142 at 4-8.)

Although Bayer makes a valiant effort to disqualify Dr. Milman based on his qualifications, the Court finds there is substantial overlap in the foundational principles underlying the fields of toxicology, pharmacology, and nutritional science, and Dr. Milman's ample education and experience in these fields render him qualified to offer an expert opinion.[8] *See also United States v. Chang*, 207 F.3d 1169, 1172 (9th Cir. 2000) ("To qualify as an expert, a witness must have knowledge, skill, experience, training or education, relevant to such evidence or fact in issue."); *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1383 (N.D. Cal. 1995) ("The fact that [an expert] is not an expert [in a specific field] does not, in view of [the expert's] other medical experience, [automatically] disqualify him."). For example, Dr. Milman holds a Bachelor of Science (B.S.) in pharmacy from Columbia University, a Master of Science (M.S.) in pharmaceutics from St. John's University, and a Doctorate (Ph.D.) in pharmacology from George Washington University. (Doc. No. 142, Weiss Decl., Ex. A, Milman Report at 5.) Moreover, Dr. Milman has over forty (40) years of experience and training in toxicology, pharmacology, pharmacy, and carcinogensis, including: ten (10) years of experience as a research

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[7] Bayer asserts Dr. Milman's first four opinions should be excluded based on his lack of qualifications in the area of nutritional science, and his fifth opinion, which renders an opinion in the area of toxicology, is irrelevant as contrary to product package instructions.

[8] Toxicology is the study of "identifying and understanding the adverse effects of external chemical and physical agents on biological systems." Federal Judicial Center, Reference Manual on Scientific Evidence, 635 (3d. ed. 2001); *see also* Stedman's Medical Dictionary (27th ed. 2000) (toxicology is "[t]he science of poisons, including their source, chemical composition, action, tests, and antidotes"); Doc. No. 210, Craig Decl., Ex. A, Milman Depo. at 10:3-6) ("Q: toxicology is the study of the effect of toxins on the human body; is that correct? A: Yes.") Pharmacology is the study of "drugs, their sources, appearance, chemistry, actions, and uses." Stedman's Medical Dictionary (27th ed. 2000); *see also In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 802 (N.D. Ohio 2004), *aff'd sub nom. Meridia Prods. Liab. Litig. v. Abbott Lab.*, 447 F.3d 861 (6th Cir. 2006) (pharmacology is the "science of the mechanism of action of chemical entities called drugs on the human organism, and the action of the human organism on the drug"). Nutritional science is the research and study of nutrition, which focuses on the health and disease avoidance effects of food and dietary supplements on the body. (Doc. No. 210 at 1:26-2:2, Blumberg Decl. ¶ 1.)

pharmacist and pharmacologist/toxicologist at the United States National Institute of Health; eighteen (18) years of experience as a Senior Toxicologist and Senior Science Advisor at the United States Environmental Protection Agency; thirteen (13) years of experience as Chief Pharmacist at a community pharmacy; and six (6) years of experience as a pharmacy intern. (*Id*. at 6.) Finally, Dr. Milman has published five (5) books on toxicology and carcinogensis; published seventy (70) articles and abstracts in toxicology, pharmacology, and carcinogensis peer reviewed scientific journals; is a member of several toxicology and pharmacology professional organizations; and has attended, organized, and presented at numerous workshops and conferences on toxicology, pharmacology, pharmacy, and carcinogensis. (*Id*. at 6-7 & 64-73.)

Therefore, based on the above, and a through review of Milman's Curriculum Vitae, the Court finds Dr. Milman qualified to offer an expert opinion regarding the falsity or deceptive nature of the Prostate Claims during the Class Period.[9] *See* Fed. R. Evid. 702 (stating that a witness may offer an expert opinion only if he or she draws on some special "knowledge, skill, experience, training or education to formulate that opinion").

2. Bayer's Substantive Objections to Dr. Milman's Opinions and Testimony

Bayer's remaining six objections, which are based on preemption, lack of substantiation, unsound methodology, or relevancy, each go to the weight rather than the admissibility of Dr. Milman's testimony. *See United States v. Prime*, 431 F.3d 1147, 1153 (9th Cir. 2005); *Kennedy*,161 F.3d at 1230-31 ("In arriving at a conclusion, the

[9] The Court also finds cases cited by Bayer inapposite. For example, in *Mercurio v. Nissan Motor Corp.*, 81 F. Supp. 2d 859, 862-63 (N.D. Ohio 2000), the court excluded a psychologist from testifying as to the effects of alcohol use on the body because the expert lacked the necessary expertise and simply regurgitated the conclusions of scientific journals. Here, however, Milman is not simply parroting or regurgitating the research of others, he is basing his opinions on his education, training, and experience as to the effects of certain substances on the human body. *See Lopez v. I-Flow Inc*., CV 08-1063-PHX-SRB, 2011 WL 1897548, at *5 (D. Ariz. Jan. 26, 2011) ("Rule 702 contemplates a broad conception of expert qualifications") (quoting *Thomas v. Newton Int'l Enters.*, 42 F.3d 1266, 1269 (9th Cir. 1994)).

factfinder may be confronted with opposing experts, additional tests, experiments, and publications, all of which may increase or lessen the value of the expert's testimony. But their presence should not preclude the admission of the expert's testimony—they go to the weight, not the admissibility.").

For example, Bayer's second objection contends Dr. Milman's third and fourth opinions regarding selenium supplementation and a reduction in the risk of prostate cancer are preempted under federal law. (Doc. No. 172, Def.s' RJN, Ex. B, 2003 FDA Decision Letter at 34-35.)[10] Specifically, Bayer contends the 2003 FDA Decision Letter, which approved a "qualified health claim" regarding selenium and the reduction in the risk of certain forms of cancers, preempts Dr. Milman's testimony and warrants exclusion of his opinions under Rule 702.[11] Bayer relies on the following language, which was approved by the FDA in 2003:

> **Claim 1:** Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancers. However, the FDA has determined that this evidence is limited and not conclusive.

(*Id*. at 34.) Although Bayer is correct that any allegations based on language exactly replicating "Claim One" are preempted under federal law, Bayer is incorrect to infer that all of Plaintiffs' allegations, including allegations not based on the exact language of the qualified health claim, are also preempted. Thus, as further explained below, because the

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[10] Plaintiffs do not contest Bayer's request for judicial notice. Accordingly, pursuant to Federal Rule of Evidence 201, the Court takes judicial notice of the 2003 FDA Decision Letter because the document is a matter of public record. *See Emrich v. Touche Ross & Co.*, 846 F.2d 1190, 1198 (9th Cir. 1988); 21 C.F.R. § 10.30(e)(3) (stating that "[t]he decision will be placed in the public docket file in the office of the Division of Dockets Management and may also be in the form of a notice published in the Federal Register").

[11] The FDA issues an "unqualified claim" when a petition presents a claim that meets the "significant scientific agreement standard." (Doc. No. 172, Def.s' RJN, Ex. B at 29.) This standard requires proof that there is "significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." (*Id.*) If the claim does meet this standard, but the science otherwise provides "sufficient evidence," the FDA will issue a "qualified health claim," and exercise enforcement discretion so long as the qualified claim is appropriately worded and placed adjacent to the applicable disclaimer so as to not mislead consumers. (*Id*. at 34-35.)

FDA did not issue a "qualified" or "unqualified" claim specifically linking selenium to a reduction in the risk of prostate cancer, Bayer's representations exceeding the scope of the qualified claim are not immune under federal law. *Cf. Reid v. Johnson & Johnson, et. al*, 11CV1310, 2012 WL 4108114, at *6 (S.D. Cal. Sept. 18, 2012) (finding plaintiff's claims preempted by federal law because defendant used the exact language authorized by the FDA). Accordingly, Bayer's second objection is overruled.

Bayer's third objection contends Dr. Milman's first, second, and third opinions must be excluded because they are based on an improper belief that Bayer must provide scientific substantiation for the Prostate Claims as a result of the instant lawsuit. Although Bayer's assertion of the law is correct, which Plaintiffs do not dispute, such arguments are nonetheless an improper means to exclude expert testimony. *See United States v. 87.98 Acres of Land More or Less in the Cnty. of Merced*, 530 F.3d 899, 904-05 (9th Cir. 2008). Under Rule 702, the district judge is a "gatekeeper, not a factfinder." *United States v. Sandoval-Mendoza*, 472 F.3d 645, 654 (9th Cir. 2006). Thus, if the expert meets the reliability and relevancy threshold established by Rule 702, and explained in *Daubert*, the expert may testify and the factfinder determines how much weight to give the testimony, and whether the testimony satisfies the respective parties' burden of proof. *See Primiano v. Cook*, 598 F.3d 558, 564-65 (9th Cir. 2010). Therefore, because Dr. Milman's testimony is highly relevant to the ultimate determination of whether Plaintiffs will be able to prove that the Prostate Claims were in fact false or deceptive, Bayer's arguments for exclusion are an improper means to seeks summary judgment under Rule 702. *See Norris v. Baxter Healthcare Corp*., 397 F.3d 878, 884 n.2 (10th Cir. 2005) (stating that under the relevance prong of *Daubert* the district court need only ensure that the proposed expert testimony logically advances a material aspect of the case); *Guidroz-Brault v. Miss. Pac. R. Co.*, 254 F.3d 825, 830 (9th Cir. 2001) (finding locomotive engineer's testimony on the appropriate lookout procedure relevant because it was a key issue in the case). Accordingly, Bayer's third objection is overruled.

Bayer's fourth and fifth objections contend that Dr. Milman's testimony must be excluded because he did not review actual product labels before forming his opinions, and thus ignored zinc and vitamin E, two of the nutrients the Prostate Claims are based on. However, as stated above, neither of these contentions warrant exclusion under Rule 702. *See United States v. Chischilly*, 30 F.3d 1144, 1154 (9th Cir. 1994) ("The impact of imperfectly conducted laboratory procedures might therefore be approached more properly as an issue not going to the admissibility, but to the weight of the . . . evidence."). Whether Dr. Milman rendered an opinion regarding zinc and vitamin E does not render his entire testimony irrelevant, To the contrary, whether or not Plaintiffs will be able to meet their burden of proof, through the presentation of evidence and expert testimony, makes Dr. Milman's testimony highly relevant. Moreover, to the extent Bayer argues Dr. Milman never viewed actual product labels, such contentions and possible flaws in Dr. Milman's testimony can be addressed through the presentation of contrary evidence and vigorous cross-examination. *See Primiano*, 598 F.3d at 564 (stating that "shaky but admissible evidence is to be attacked by cross-examination, contrary evidence, and attention to the burden of proof, not by exclusion"); *Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); *Prime*, 431 F.3d at 1153. Accordingly, Bayer's fourth and fifth objections are each overruled.[12]

Bayer's remaining two objections are also easily dispatched. First, Bayer contends Dr. Milman's testimony is unreliable because he demands application of a "definitive proof" standard that has no basis in the scientific community. However, contrary to

[12] The Court finds Bayer's citation to *Collins v. Ashland, Inc.*, No. 06C-03-339, 2011 WL 5042330, at *3 (Del. Sup. Ct. Oct. 21, 2011), wherein Milman's testimony was excluded under Rule 702 distinguishable. In *Collins*, the court excluded Dr. Milman's testimony because Dr. Milman failed to tailor his opinion to the nine-month time period in which the plaintiff was exposed to the defendant's product, and instead based his opinions on the entire twenty-one year time period in which the plaintiff was a painter. Here in contrast, Dr. Milman stated that he considered zinc, vitamin E, lycopene, and selenium when making his determination.

Bayer's contentions, Dr. Milman's report does not assert that definitive proof from a well-controlled randomized clinical trial ("RCT") is required in this case, but does, as does Dr. Blumberg (Bayer's science expert), recognize the importance of RCTs in the area of nutritional science. Thus, although Bayer may disagree with Dr. Milman's ultimate conclusions, these findings are properly attacked through rigorous cross-examination and the presentation of contrary evidence, not exclusion. *See Primiano*, 598 F.3d at 564. Moreover, Bayer contends that Dr. Milman's fifth opinion regarding the potential toxicity of the Products is irrelevant because it assumes an overdose of selenium contrary to the dosage specified on the Products' packaging. Although the Court is cognizant that Dr. Milman admits that the Products present no risk of selenosis or Type 2 diabetes when taken as directed, (Doc. No. 142, Weiss Decl., Ex. B., Milman Depo. at 26:21-27:9, 27:19-24 & 43:21-44:3), the Court finds Dr. Milman's underlying opinion is relevant to whether selenium promotes "prostate health," and is based on reliable scientific research. (Doc. No. 142, Weiss Decl., Ex. A, Milman Report at 38-41.) Thus, whether, and to what extent, the factfinder will give weight to Dr. Milman's toxicity conclusion—in light of the Product packaging and his deposition testimony—is not a basis for exclusion under Rule 702. *See Kennedy*, 161 F.3d at 1230-31. Accordingly, Bayer's sixth and seventh objections are each overruled.

Therefore, the Court finds each of Bayer's objections go to the weight rather than the admissibility of Dr. Milman's testimony. *See Prime*, 431 F.3d at 1153 (9th Cir. 2005) (stating that the proper inquiry focuses "solely on principles and methodology, not on the conclusions that they generate") (internal quotations omitted); *Daubert*, 509 U.S. at 595 (finding that "[a]s long as the process is generally reliable, any potential error can be brought to the attention of the jury through cross-examination and the testimony of other experts"). Accordingly, Bayer's motion to exclude the testimony and opinions of Dr. Milman is DENIED, and the Court will consider such evidence when adjudicating Bayer's pending motion for summary judgement. *See Lust By & Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996).

C. Plaintiffs' Motion to Exclude Bayer's Science Expert Dr. Blumberg

Dr. Blumberg was retained by Bayer to review the scientific evidence supporting the Prostate Claims during the Class Period. Specifically, Dr. Blumberg was asked to: (1) review and opine on the scientific substantiation for Bayer's representation that zinc, vitamin E, lycopene, and selenium "support prostate health;" (2) review and opine on the scientific substantiation for Bayer's representation that "emerging research suggests [that] Selenium may reduce the risk of prostate cancer;" (3) evaluate and explain the bioavailability and effectiveness of different forms of selenium and lycopene, including sodium selenate and synthetic lycopene, both of which were included in the Vitamin Products and tested in the supporting scientific research; and (4) review and rebut certain statements made by Plaintiffs' science expert Dr. Milman. (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 2-3.) Dr. Blumberg's report offers ten opinions. The first opinion is a broad assertion regarding the scientific support for the Prostate Claims during the Class Period, opinions two through six refer to Dr. Blumberg's findings regarding selenium, and the final four opinions relate to Dr. Blumberg's finding regarding lycopene, zinc, and vitamin E. Specifically, Dr. Blumberg concludes that:

> (1) At all times during what I understand to be the class period . . . scientific evidence existed, and still exists to support the statement that each of the Vitamin Products as formulated "Supports Prostate Health" as Bayer indicated on the packaging for One-A-Day Men's Health Formula® and One-A-Day Men's 50+ Advantage®, respectively. I am further aware that several other multivitamin products currently and previously on the market have made and continue to use the structure function claim for prostate health support based on the ingredients selenium, lycopene, zinc, and/or vitamin E.
>
> (2) At all times during the proposed class period, scientific evidence existed and still exists showing that selenium intake can reduce the risk of prostate cancer. As with almost all nutrient supplements, the effect of selenium in specific men can be influenced by many variables, including inherent and environmental factors such as nutrigenomics and lifestyle, respectively, plasma selenium concentrations, and prostate specific antigen (PSA) levels. Men having a baseline level of plasma selenium (prior to selenium supplementation) at <123.2 ng/mL are most likely to benefit from a nutritional supplement that includes selenium. In addition, evidence from some clinical trials indicates that men within a normal range of PSA ng/mL can benefit from a nutritional supplement that includes selenium.

(3) In my opinion, the totality of nutritional and biomedical research indicates that selenium is an essential dietary mineral which plays a beneficial role in reducing the risk of prostate cancer in men and in supporting general prostate health. My opinion is based on my review of the body of clinical trials, observational studies, and supportive basic research addressing the relationship between selenium and prostate health.

(4) Sodium selenate is a naturally occurring inorganic form of the mineral selenium found in soil and alkaline water and used by plants to synthesize selenomethione. Sodium selenate is the form of selenium used in both the One-A-Day Men's Health Formula® and One-A-Day Men's 50+ Advantage® multivitamins. Sodium selenate is readily bioavailable, a process describing the absorption of a nutrient into blood and its distribution to body tissues. Indeed, all forms of selenium, organic as well as inorganic forms, such as sodium selenate, are readily absorbed from the small intestine. Overall, absorption of all forms of selenium ranges from 70 to 95%, but varies according to the source and the selenium status of the individual (Finley 2006). Regardless of its dietary form, selenium is stored and accumulates over time in body tissues.

(5) Selenium as well as other selected nutrients which were present in One-A-Day Men's Health Formula® and One-A-Day Men's 50+ Advantage®, when taken as directed, can support men's health in general and "support prostate health" in particular, including potentially reducing the risk of prostate cancer. The evidence for these benefits is derived from human studies, including certain randomized clinical trials and observational studies explained further below. These benefits are also evidenced through basic research using in vitro (test tube) experiments (de Rosa *et al.* 2012; Gazi *et al.* 2007; Gundimeda *et al.* 2008; Liu *et al.* 2010; Sinha *et al.* 2011; Xiang *et al.* 2008) and animal models (Bhattacharyya *et al.* 2008; Cheng *et al.* 2011; Holmstrom *et al.* 2011; Lindshield *et al.* 2010; Liu *et al.* 2010; Wang *et al.* 2008; Waters *et al.* 2003; Zhang *et al.* 2011). In vitro and animal model research both provide evidence for the biological plausibility and mechanisms of the anti-cancer actions of selenium and, when corroborated with human studies, can strengthen the available evidence to support a relationship with health outcomes.

(6) In sum, the totality of the available scientific evidence indicates that selenium is an essential nutrient that is readily bioavailable (regardless of its form, e.g., inorganic or organic) and plays a role in supporting prostate health and potentially reducing the risk of cancer of the prostate as well as potentially reducing the risk of BPH (Muecke *et al.* 2009; Zachara *et al.* 2005).

(7) Natural and synthetic lycopene are equally bioavailable, and therefore the form of lycopene consumed is irrelevant from a nutritional perspective. The synthetic form of lycopene used in One-A-Day Men's Health Formula® and One-A-Day Men's 50+ Advantage® is bioavailable and accumulated and stored by body tissues, including the prostate.

(8) In my opinion, the totality of scientific evidence involving lycopene and prostate health indicates lycopene may decrease the progression of BPH and reduce circulating PSA, thereby promoting prostate health. Lycopene also possesses antioxidant properties that have demonstrated beneficial effects on processes associated with carcinogenesis, which further supports lycopene's

> role in supporting prostate health and potentially reducing the risk of prostate cancer.
>
> (9) Zinc is essential in controlling and facilitating the physiological function of the prostate gland, including controlling the correct production of prostatic fluid, and is present in abundance in healthy prostate glands and is diminished in diseased prostate glands. In my opinion, zinc plays an important role in maintaining prostate health.
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> (10) Vitamin E is a potent dietary antioxidant that has been associated with a reduced risk of prostate cancer in observational studies and randomized clinical trials. In my opinion, vitamin E plays an important role in maintaining prostate health.

(Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 5-7.)

Plaintiffs seek to exclude Dr. Blumberg's testimony and opinions regarding: (1) the scientific substantiation for Bayer's statements that the Vitamin Products support prostate health; (2) the scientific substantiation for Bayer's claims that emerging research suggests that consumption of selenium may reduce the risk of prostate cancer; and (3) the effectiveness of selenium, lycopene, zinc, and vitamin E in reducing the risk of prostate cancer and other prostate related conditions, as well as supporting prostate health in general. (Doc. No. 141 at 1.) Although Plaintiffs' arguments for exclusion vary slightly depending on whether they seek to exclude Dr. Blumberg's testimony regarding selenium, lycopene, zinc, or vitamin E, all of Plaintiffs' arguments essentially conclude that Dr. Blumberg's opinions are based on inconclusive, factually distinguishable, or misleading scientific research.[13]

In response, Bayer contends Plaintiffs' motion should be denied because: (1) Dr. Blumberg is qualified to offer an expert opinion in the area of nutritional science; (2) Dr. Blumberg offers relevant testimony regarding the scientific substantiation for the Prostate Claims during the Class Period; and (3) Dr. Blumberg's methodology in reaching his conclusions is reliable because he considered the totality of the evidence, including both supportive and non-supportive scientific studies. (Doc. No. 192 at 1-2.) Although not

[13] Essentially, Plaintiffs contend that Dr. Blumberg used unreliable methodology to reach conclusions solely for the purposes of litigation, and then conducted a narrow, selective search to support his "pre-formed" opinions, thereby ignoring a vast body of scientific research. (Doc. No. 141 at 2:10-13.)

specifically raised or contested by Plaintiffs, the Court first considers Dr. Blumberg's qualifications, and then addresses Plaintiff's arguments for excluding Dr. Blumberg's testimony as it relates to selenium, lycopene, zinc and vitamin E.

1. Dr. Blumberg's Qualifications

As an initial matter, the Court finds Dr. Blumberg qualified to offer expert testimony regarding the scientific substantiation for the Prostate Claims. *See Jinro Am. Inc. v. Secure Invs., Inc*., 266 F.3d 993, 1004 (9th Cir. 2001) ("[C]are must be taken to assure that a proffered witness truly qualifies as an expert, and that such testimony meets the requirements of Rule 702."). For example, Dr. Blumberg holds a Bachelor of Pharmacy (BPharm) from Washington State University and a Doctorate (PhD) in Pharmacology from Vanderbilt University School of Medicine. He is currently a Professor in the Friedman School of Nutritional Science and Policy at Tufts University and a Senior Scientist and Director of the Antioxidants Research Laboratory at the Jean Mayer USDA Human Nutritional Research Center on Aging at Tufts University. (Doc. No. 192 at 4; Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 1.) Moreover, Dr. Blumberg received postdoctoral training at the Tennessee Neuropsychiatric Institute and completed a National Institutes of Health post-doctoral fellowship at the University of Calgary in biochemistry. (*Id*.) Aside from his education, Dr. Blumberg has published over 300 scientific articles, served on countless editorial boards for prominent research journals, is a member of leading nutritional societies and international nutrition policy boards, and has testified before many prominent organizations, including, but not limited to, the Institute of Medicine/National Academy of Science, the Food and Nutrition Board, the Subcommittee on Health and the Environment of the United States House of Representatives, the FDA Conference on Antioxidant Vitamins, and the Dietary Guidelines for Americans 2005 Committee. (*Id.*) Accordingly, based on his knowledge, experience,

and education, the Court finds Dr. Blumberg qualified to offer his expert opinion regarding the scientific substantiation for the Prostate Claims.[14]

2. Dr. Blumberg's Opinions andTestimony Regarding Selenium

Dr. Blumberg's report includes the following sections to analyze and address the scientific substantiation for Bayer's representations regarding selenium: (1) the relevant history of selenium; (2) selenium intake and its status in the United States; (3) clinical trials involving selenium; (4) observational studies involving selenium; (5) scientific evidence indicating a null effect of selenium on prostate cancer; and (6) the bioavailability and effectiveness of sodium selenate, the form of selenium used by Bayer in the Vitamin Products. (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 9-22.) Based on this information, Dr. Blumberg opines that the totality of the scientific research weighs in favor of finding a beneficial relationship between selenium and a reduction in the risk of prostate cancer. Dr. Blumberg also opines, contrary to Plaintiffs' assertions, that sodium selenate, the form of selenium used in the Vitamin Products, is bioavailable, and thus readily absorbed and distributed into and throughout the human body. (*Id*. at 21.)

Plaintiffs offer five primary objections to Dr. Blumberg's testimony regarding selenium: (1) Dr. Blumberg's reliance on the 1996 and 1998 Nutrition Prevention of Cancer ("NPC") trials are improper and likely to mislead the trier of fact; (2) the results of the NPC trials conflict with the results of the Selenium and Vitamin E Cancer Prevention Trial ("SELECT") and therefore are unreliable; (3) Dr. Blumberg's reliance on observational studies is improper; (4) Dr. Blumberg's reliance on animal and *in vitro* studies is improper; and (5) Dr. Blumberg fails to proffer reliable testimony that the "totality of the evidence" shows that selenium supports prostate health and/or reduces the

[14] Dr. Blumberg's Curriculum Vitae includes a comprehensive list of his professional and academic qualifications, accomplishments, awards, and memberships. (Doc. No. 192, Blumberg Decl., Ex. B.)

risk of prostate cancer.[15] (Doc. No. 141 at 7, 9, 10, 12 & 13.) The Court considers each ground for exclusion in turn.

First, Plaintiffs suggest Dr. Blumberg's emphasis on the 1996 and 1998 NPC trials are improper and likely to mislead the trier of fact because the results were equivocal and expressly limited by their authors.[16] For example, Plaintiffs assert that the authors of the 1996 NPC trial determined that their results "required confirmation in independent trials of appropriate design before public recommendations regarding selenium supplementation can be made," and that the authors of the 1998 NPC trial conceded that their conclusions "needed confirmation in additional independent trials." (Doc. No. 141 at 7:20-24 & 8:1-2.) Plaintiffs state that Dr. Blumberg was aware of the limited findings and conclusions of the NPC trials, yet elected to disregard such cautionary language in an attempt to bolster his "pre-formed" conclusions. (Doc. No. 141, Syverson Decl., Ex. C, Blumberg Depo. at 161:2-9.) Thus, Plaintiffs argue that because the authors of the NPC trials were unwilling to infer that selenium supplementation reduces the instances of prostate cancer, Dr. Blumberg should be prohibited from making that "leap" for them. (Doc. No. 141 at 8:9-14.)

Although Plaintiffs go to great lengths to highlight the inconclusive nature of the NPC trials as a means to exclude Dr. Blumberg's testimony, for the purposes of exclusion under Rule 702, such objections are misplaced. See *Daubert*, 509 U.S. at 590 n.9 ("In a case involving scientific evidence, evidentiary reliability will be based upon scientific validity."). It is common in scientific literature for investigators to hedge their claims or

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[15] Plaintiffs also argue Dr. Blumberg's testimony should be excluded because "Blumberg himself has not conducted any clinical trials related to selenium, lycopene, zinc, or vitamin E." (Doc. No. 141 at 4:24-26.) However, Plaintiffs retreated from this assertion in their reply, acknowledging that Dr. Blumberg need not conduct his own studies to offer an expert opinion on the matter.

[16] The NPC trials were randomized, double-blind, placebo-controlled, clinical trials of 1312 individuals from 1983 to 1991. (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 11.) Plaintiffs do not contest that this study design is the "gold standard for determining the relationship of an agent to a disease or health outcome." (Doc. No. 141 at 7:15-17). *See also* Federal Judicial Center, Reference Manual on Scientific Evidence, 338 (2d ed. 2000).

couch their conclusions prefaced with the need for additional confirmatory research. *See In re Denture Cream Prods. Liab. Litig*., 795 F. Supp. 2d 1345, 1362 (S.D. Fla. 2011) ("Scientists tend to hedge their claims in scientific papers."). Moreover, it is well settled that there are few if any certainties in science, *Daubert*, 509 U.S. at 590, and *Daubert* was not intended to impose an "exacting standard of causality" beyond the preponderance of the evidence "simply because scientific issues are involved." *In re Ephedra Prods. Liab. Litig*., 393 F. Supp. 2d 181, 190 (S.D.N.Y. 2005); *In re Heparin Prods. Liab. Litig*., 803 F. Supp. 2d 712, 743 (N.D. Ohio 2011) (stating that the court "will not exclude expert testimony on the basis that the evidence supporting it does not establish causation to a scientific certainty"). Thus, because the authors of the NPC trials noted that selenium supplementation was or could be positively correlated with a significant reduction in prostate cancer, Dr. Blumberg's opinions did not improperly exceed the NPC authors' conclusions.[17] *See In re Denture Cream Prods. Liab. Litig*., 795 F. Supp. 2d at 1345 ("Because the authors of the Nations Article themselves do not conclude there is a causal relationship between the use of Fixodent and neurological symptoms, it is inappropriate for Plaintiffs' experts to draw that conclusion for them."). Moreover, the result of the NPC trials were further confirmed by the *Duffield-Lillico* study in 2003, wherein the authors stated that selenium supplemental continues to support a reduction in the "incidence of prostate cancer.[18] (Doc. No. 192, Blumberg Decl., Ex. G, *Duffield-Lillico*

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[17] The 1996 NPC trial concluded that selenium supplementation was "associated with significant reductions in secondary end points of total cancer incidence (all-sites combined), lung, colorectal and cancer incidences," and the 1998 NPC trial concluded that "selenium supplementation may be important for both primary and secondary prevention of prostate cancer." (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 12-13.) Furthermore, the 1998 NPC trial found a "statistically significant 63% overall reduction in prostate cancer incidence in participants who took selenium. (*Id.* at 13:1-4.) This is further supported by the fact that the United States National Health and Examination Survey, which is conducted by the United States Center for Disease Control and Prevention, indicates that nearly 50% of the U.S. male population over the age of nineteen has a plasma selenium concentration similar to or less than that of the men experiencing the prostate health benefit in the NPC trials. (Doc. No. 192 at 10:21-11:1; Blumberg Decl., Ex. A, Blumberg Report at 14.)

[18] The *Duffield-Lillico* study also stated that "The Nutritional Prevention of Cancer (NPC) trial [1] is the only randomized clinical trial to date to test the effect of selenium supplementation [SS] on cancer in a Western population." (Doc. No. 192, Blumberg

Study at 16.) Accordingly, this is not the case where a proffered expert is formulating an opinion based on a study that is directly contradicted by that study. (Doc. No. 208 at 3:13-15.) As such, Plaintiffs' objection on this ground is overruled.

Second, Plaintiffs argue Dr. Blumberg's testimony should be excluded because he wholly rejects SELECTs results and conclusions—the largest randomized clinical trial of selenium conducted to date— in addition to other observational studies that do not support his opinion. (Doc. No. 141 at 9.) As such, Plaintiffs contend Dr. Blumberg's conclusions are not based on valid scientific methodology. (*Id*.) The Court is not persuaded and finds Plaintiffs mischaracterize Dr. Blumberg's opinions and testimony. In concluding that all of the scientific evidence to date substantiates a positive correlation between selenium supplementation and prostate health, Dr. Blumberg analyzed SELECT, analyzed observational studies agreeing with SELECT, and then identified what he calls "critical limitations" of SELECT. *See In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1180 (N.D. Cal. 2007). Thus, contrary to Plaintiffs' allegations, Dr. Blumberg did not wholly disregard SELECT and other observational studies that found a null correlation between selenium and prostate health.[19] Instead, as acknowledged by Plaintiffs, Dr. Blumberg recognized the limitations of SELECT and considered whether, in light of SELECTs ultimate conclusions, there was still scientific substantiation for Bayer's representations that selenium promotes prostate health and reduces the risk of prostate cancer.[20]

Therefore, even though Plaintiffs accurately highlight differences in the scientific findings made by the authors of NPC and SELECT, Plaintiffs are free to cross-examine

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Decl., Ex. G, *Duffield-Lillico* Study at 1.)

[19] This is further supported by a post-SELECT report cited by Blumberg, Ledesma *et al.* (2011), which concluded that "pre-SELECT studies as well as continuing post-SELECT studies are still supporting the potential usefulness of selenium and/or vitamin E for prevention of [prostate cancer] and possibly other conditions as well." (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 20:4-8.)

[20] Although Plaintiffs go to great lengths to convince the Court that SELECT negates NPC, both Plaintiffs and Dr. Milman, Plaintiffs' science expert, acknowledge the limitations and criticisms of SELECT. (Doc. No. 208 at 3.)

Dr. Blumberg on his ultimate conclusions. *See In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d at 742 (finding that expert testimony should not be excluded on the basis of "some disagreement in the scientific literature"); s*ee also Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); *Ambrosini v. Labarraque*, 101 F.3d 129, 135 (D.C. Cir. 1996) ("The dispositive question is whether the testimony will 'assist the trier of fact to understand the evidence or to determine a fact in issue,' not whether the testimony satisfies the plaintiff's burden on the ultimate issue at trial.") (citation omitted). Accordingly, Plaintiffs' objection on this ground is also overruled.

Plaintiffs' remaining three objections—that Dr. Blumberg's reliance on observational studies, animal and *in vitro* studies, and that the totality of the evidence does not support his ultimate conclusions—are each contingent on the Court excluding the 1996 and 1998 NPC human clinical trials. However, as stated above, because the Court finds Dr. Blumberg's reliance on the NPC trials at best go to the weight rather than the admissibility of his testimony, Plaintiffs' remaining objections also fail. Thus, Plaintiffs' third objection that Dr. Blumberg's reliance on observational studies is improper, and their fourth objection that Dr. Blumberg's reliance on animal and *in vitro* studies is improper, are each an insufficient basis to exclude Dr. Blumberg's testimony under Rule 702. *See, e.g.*, *Alliance for Natural Health U.S. v. Sebelius*, 714 F. Supp. 2d 48, 70 (D.D.C. 2010) ("After reviewing the scientific literature submitted with plaintiffs' petition, the FDA concluded that it could draw scientific conclusions regarding plaintiffs' prostate claim from eight *observational studies* and one intervention study.") (emphasis added); *Metabolife Int'l, Inc. v. Wornick*, 264 F.3d 832, 842 (9th Cir. 2001) (noting that animal studies can provide "useful data about human health"); *Hopkins v. Dow Corning, Corp.*, 33 F.3d 1116, 1125 (9th Cir.1994) (finding admissible testimony based on scientific studies and "corroborating evidence found in studies conducted on animals"); *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 318 F. Supp. 2d 879, 910-11 (C.D.

Cal. 2004) (noting reliance by researchers and agencies on relevant animal studies); *In re Bausch & Lomb, Inc. Contact Lens Solution Prods. Liab. Litig.*, No. 2:06-MN-77777-DCN, 2009 WL 2750462, at *12 (D.S.C. Aug. 26, 2009) ("*In vitro* tests generate hypotheses but lack sufficient reliability, *standing alone*, to demonstrate causation in humans.") (emphasis added). Accordingly, because there is ample scientific evidence to support Dr. Blumberg's opinions regarding selenium supplementation and prostate health, Plaintiffs cannot credibly argue that his reliance on observational, *in vitro*, and animal studies, in conjunction with human clinical trials, is scientifically invalid in this case.[21]

The same is true for Plaintiffs' final objection to Dr. Blumberg's testimony—that the totality of the evidence does not support a positive correlation between selenium supplementation and prostate health. (Doc. No. 141 at 13.) Once again, Plaintiffs attempt to argue that the scientific studies Dr. Blumberg relies on should be discredited or disregarded because of the conclusions reached by the studies' authors, and not because the studies were conducted contrary to accepted scientific principles or based on unsubstantiated and unpublished scientific articles. *Daubert II*, 43 F.3d at 1318 (finding that reliability under Daubert does not depend on "the correctness of the expert's conclusions but [on] the soundness" of the methodology). Thus, this is not the case where an expert is presenting an untested hypothesis to the jury for final determination. *See In re Denture Cream Products Liab. Litig.*, 795 F. Supp. 2d at 1367 ("Hypotheses are verified by testing, not by submitting them to lay juries for a vote."). Moreover, as stated above, even though the 2008 SELECT study showed a null correlation between selenium supplementation and prostate health benefits, especially in men with elevated selenium concentrations, SELECT did not entirely "cancel-out" pre-SELECT studies, and post-

[21] Plaintiffs are free however to address any inadequacies that may arise from extrapolating the results of observational, *in vitro*, and animal studies to humans in a clinical setting through vigorous cross-examination of Dr. Blumberg at trial.

SELECT studies and scientific articles still support Blumberg's overall conclusion.[22] Thus, Dr. Blumberg's overall conclusion, that about fifty percent (50%) of the male population over the age of nineteen (19) have serum selenium concentrations similar to those men who experienced prostate health benefits from selenium supplementation, is amply supported by scientifically reliable sources. (Doc. No. 192 at 10:21-11:1; Blumberg Decl., Ex. A, Blumberg Report at 14.) Accordingly, Plaintiffs' objections on these grounds are overruled.

Therefore, as articulated above, the Court finds each of Plaintiffs' arguments go to the weight rather than the admissibility of Dr. Blumberg's testimony. *See Kennedy*, 161 F.3d at 1230-31 (9th Cir. 1998) (conflicting data that may increase or lessen the value of the expert's testimony affect the weight and not the admissibility of such testimony). However, to the extent Dr. Blumberg relies on randomized clinical trials, observational studies, or *in vitro* studies conducted after the conclusion of the Class Period (May 31, 2010), the Court finds such evidence irrelevant to the determination of whether the scientific research available during the Class Period substantiated Bayer's representations.[23] (Doc. No. 142, Weiss Decl., Ex. C, Milman Rebuttal Report at 2.) Accordingly, the Court excludes as irrelevant any testimony relating to the following randomized clinical trials: Klein *et al.* (2011); Marshall *et al.* (2011); Zhang *et al.* (2011); Fleshier *et al.* (2010); Stratton *et al.* (2010); and Corcoran *et al.* (2010). The Court also excludes as irrelevant any testimony relating to the following observational studies: Gruzel *et al.* (2012); Grundmark *et al.* (2011); Zhang *et al.* (2010); Steinbrecher *et al.* (2010); Kristal *et al.* (2010); and Penny *et al.* (2010). Notwithstanding exclusion of these studies, the Court finds ample support for Dr. Blumberg's overall conclusions regarding selenium

[22] Bayer further argues that SELECT was not published until December 2008. Thus, even if SELECT is found to be helpful to the trier of fact in determining whether the Prostate Claims were in fact false or misleading, it only applies to the portion of the Class Period from that date forward. (Doc. No. 192 at 14:6-28.)

[23] Dr. Blumberg based his conclusions on eighteen (18) randomized clinical trials and twenty-three (23) observational studies regarding selenium supplementation and prostate cancer. (Doc. No. 192, Blumberg Decl., Ex. A, Blumberg Report at 49-50.)

and prostate health, including a reduction in the risk of prostate cancer. For example, Dr. Blumberg cites to twelve (12) randomized clinical trials between 1996 and 2009—eight of which showed a positive correlation between selenium and improved prostate health—and seventeen observational studies between 1995 and 2009—nine of which showed a positive correlation between selenium and improved prostate health. As a result, to the extent not otherwise excluded, Dr. Blumberg's testimony will be considered in adjudicating Bayer's pending motion for summary judgment. *See Lust By & Through Lust*, 89 F.3d at 598.

3. Dr. Blumberg's Opinions and Testimony Regarding Lycopene

Second, Dr. Blumberg opines that the totality of the scientific evidence available during the Class Period substantiates Bayer's representation that lycopene supports prostate health. (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 30-31.) Specifically, Dr. Blumberg states that lycopene has been associated with reducing or slowing the development of benign prostate hyperplasia ("BHP") and prostate cancer, and that lycopene possesses antioxidant properties that have been shown to protect against oxidative damage to lipids, proteins, and DNA. (*Id*. at 22-23.) Dr. Blumberg also notes that lycopene has also been shown to decrease a variety of processes associated with "carcinogensis, including cell cycle progression, cell communication, cell adhesion, and inflammatory, hormonal, and growth factor signaling. (*Id*. at 23.) To form his opinion, Dr. Blumberg relied on three types of scientific evidence: (1) clinical trials showing that lycopene deters the progression of BPH and high-grade prostate intraepithelial neoplasia ("HGPIN"), two conditions common in men over fifty; (2) observational studies showing that lycopene reduces the incidence of lower urinary tract symptoms ("LUTS"); and (3) food intake studies analyzed in conjunction with lycopene blood plasma studies indicating lycopene potentially reduces the risk of prostate cancer. (Doc. No. 192 at 18:18-24; Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 23-31.)

Plaintiffs raise two primary objections to Dr. Blumberg's testimony and opinions regarding lycopene supplementation and prostate health: (1) he relies on studies involving men previously diagnosed with prostate disorders that cannot be properly extrapolated to healthy men without such preexisting conditions; and (2) he relies on observational studies regarding the consumption of tomatoes or other food products that are irrelevant because such studies are unreliable. (Doc. No. 141 at 15-19.) The Court addresses each ground for exclusion in turn.

First, Plaintiffs contend Dr. Blumberg's testimony regarding lycopene supplementation and prostate health should be excluded because he relies on studies involving men previously diagnosed with certain prostate disorders—Mohanty *et al.* (2005), Schwarz *et al.* (2008), Schroder *et al.* (2005), Kim *et al.* (2003), Ansari & Gupta *et al.* (2003), and Rohrmann *et al.* (2004)—and such studies cannot be properly extrapolated to primary prevention effects in healthy men.[24] In support, Plaintiffs point to an expert report submitted by Dr. Blumberg in another case, *Godec v. Bayer*, No.1:10-CV-224, 2011 WL 5513202 (N.D. Ohio Nov. 11, 2011), wherein Dr. Blumberg stated, in reference to the *POM Wonderful* line of cases, that "it is not possible to extrapolate findings obtained in secondary prevention trials . . . to potential benefits that might exist in the situation of primary prevention (i.e., reducing the risk of prostate cancer in men without the disease)." (Doc. No. 145, Ex. U., Blumberg Report in *Godec v. Bayer* at 12.) Based on this testimony, Plaintiffs argue that because Bayer's internal documents and Dr. Blumberg himself recognizes that extrapolating results from secondary prevention trials to primary prevention in healthy men is inappropriate, Dr. Blumberg should not be permitted to introduce testimony based on that exact premise in this case.[25]

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[24] Primary prevention trials are conducted on healthy individuals, whereas secondary prevention trials are conducted in individuals who already have a specific condition or disease. (Doc. No. 141 at 16; Doc. No. 141, Syverson Decl., Ex. B, Blumberg Depo. at 184:17-22, 185:7-10.)

[25] Plaintiffs point to Bayer's internal documents (Nutritional Science: Plan of Principles, February 2, 2006), which state that "[i]f studies for a particular ingredient were done in an elderly population and the product we are working on is a children's chewable, the studies may not be appropriate to substantiate the product." (Doc. No. 144,

Although Plaintiffs are correct that studies involving men previously diagnosed with prostate cancer may not be properly extrapolated to primary prevention effects in healthy men, Plaintiffs' arguments for exclusion are based on a fundamental misunderstanding of BHP, HGPIN, and LUTS—the three prostate related disorders at issue in Mohanty *et al.* (2005), Schwarz *et al.* (2008) and Rohrmann *et al.* (2004).[26] Neither BPH, HGPIN, nor LUTS are prostate cancer, represent a form of prostate cancer, or represent a disease other than prostate cancer.[27] (Doc. No. 192, Blumberg Decl., Ex. F at 111:23-112:3, 115:13-116:20, 131:6-7; Craig Decl., Ex. B., Milman Depo. at 23:24-24:22.) To the contrary, all three of these prostate related conditions are common in men over the age of fifty (50) and are generally associated with the male aging process. (*Id.*) Thus, because the male prostate naturally begins to enlarge after the age of twenty (20), and

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Ex. R at 4.)

[26] Mohanty *et al.* (2005) was a randomized, controlled parallel design study of forty men clinically identified as having BPH and HGPIN. (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 23.) The trial subjects were given either 8 mg/day of lycopene (4 mg twice daily) or no lycopene for twelve months. At the conclusion of the study, the authors stated that "[lycopene is an effective chemopreventive agent in the treatment of HGPIN, with no toxicity and good patient tolerance." (*Id.*)

Schwarz *et al.* (2008) was a double-blind, randomized, placebo-controlled trial of forty men with historically proven BPH, who were otherwise free of prostate cancer. (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 23.) The trial subjects were randomized to receive either synthetic lycopene at a dose of 15 mg/day or a placebo capsule for six months. (*Id.*) At the conclusion of the study the authors found that the serum total PSA in the lycopene group decreased, whereas there was no change in the placebo group. (*Id.*) The authors also found that prostate enlargement occurred in the placebo group but did not occur in the lycopene group. (*Id.* at 24.) Thus, the authors concluded that these results reflected the ability of lycopene to inhibit the progression of BPH to malignant disease, and also inhibit BPH symptoms, as determined via a questionnaire of the trial subjects. (*Id.*)

Rohrmann *et al.* (2004) utilized a cross-sectional analysis of the Third National Health and Nutrition Examination Survey (1998-1994) to evaluate the association of serum micro nutrients with LUTS that typically result from BPH in men. (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 25.) The authors studied a cohort of 2,497 men over the age of sixty who reported at least three of the four symptoms: nocturia, hesitancy, incomplete emptying, and weak stream, but who had never had non-cancer prostate surgery. (*Id.*) The authors concluded that men with higher serum concentrations of lycopene, vitamin E, and selenium were found to have reduced odds of LUTS by 57%, 49%, and 44% respectively. (*Id.*)

[27] Plaintiffs argue that Bayer's characterization of these conditions does not change that fact that individuals who suffer from these conditions exhibit serious prostate cancer risk factors, and are therefore not "healthy" individuals.

most males will eventually suffer from one of these conditions, the Court finds Dr. Blumberg's ultimate conclusions are based on reliable scientific principles and methodology.[28] (Doc. No. 192, Blumberg Decl., Ex. F, Blumberg Depo. at 116-117.) Therefore, even though Dr. Milman and Dr. Blumberg disagree over whether "healthy men" includes men who suffer from BPH, HGPIN, or LUTS, such disagreement between experts is not grounds for exclusion. *See McHugh v. United Serv. Auto. Ass'n*, 164 F.3d 451, 454 (9th Cir. 1999) (finding that disagreement among experts does not warrant exclusion of such testimony).

Furthermore, Plaintiffs' contention that Dr. Blumberg's testimony in this case contradicts his testimony offered in *Godec v. Bayer* is also misplaced. In *Godec*, Dr. Blumberg testified that the primary study relied on in the *POM Wonderful* line of cases, which involved participants who were given POM juice but who already had prostate cancer, was inadequate to show that administering POM juice to men without prostate cancer would also prevent the disease. (Doc. No. 145, Ex. U., Blumberg Report in *Godec v. Bayer* at 12.) Here, however, three of the studies Dr. Blumberg relied on to form his ultimate conclusions regarding lycopene and prostate health were conducted in men without prostate cancer, but instead were suffering from prostate related conditions generally associated with the male aging process (BPH, HGPIN, or LUTS). Although the Court is cognizant that Dr. Blumberg also relied on three studies involving men who had previously been diagnosed with prostate cancer, and were suffering from prostate cancer during the course of these studies, the Court finds exclusion of these studies does not effect Dr. Blumberg's overall conclusion regarding lycopene.[29] Thus, this is not the case

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[28] This is further supported by the fact that the authors of Schwarz *et al.* (2008) recommended that additional lycopene analysis may "serve as a basis for recommending supplementation with lycopene in the long-term management of prostate health." (Doc. No. 192, Blumberg Decl, Ex. K at 53.)

[29] Dr. Blumberg separates his conclusions regarding lycopene supplementation and prostate health benefits into separate categories— (1) benign prostate hyperplasia; (2) prostate cancer; and (3) lower urinary tract symptoms and serum lycopene, vitamin E, and seleium—and makes a conclusion regarding the substantiation for Bayer's representation at the conclusion of each section. (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 23-26.) Thus, the Court finds exclusion of the three studies cited to

where Dr. Blumberg is attempting to employ a different level of academic rigor in the courtroom than what is expected by him in his relevant field. *In re Bextra and Celebre Mktg. Sales Practices and Prods. Liab. Litig*., 524 F. Supp. 2d at 1171. Accordingly, Plaintiffs' arguments for exclusion on these grounds are also overruled.

Second, Plaintiffs contend Dr. Blumberg's reliance on observational studies linking the consumption of tomatoes or other food products to prostate health and/or a reduction in the risk of prostate cancer are unreliable and thus should be excluded. (Doc. No. 141 at 18.) In support, Plaintiffs rely on: (1) a 2005 FDA Decision Letter denying two petitions for qualified health claims regarding tomatoes, lycopene, and a reduction in the risk of certain forms of cancer, including prostate cancer, (Doc. No. 141, Syverson Decl., Ex. D, 2005 FDA Decision Letter); and (2) a recent district court decision in *Alliance for Natural Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 19 (D.C.C. 2011), wherein the court stated that "scientific conclusions from observational studies cannot be drawn about a relationship between a food component and a disease." Based on the above, Plaintiffs seek to exclude the following studies relied upon by Dr. Blumberg: Trottier *et al.* (2010); Chan *et al.* (2009); World Cancer Research Fund and the American Institute for Cancer Research (2007); Mills *et al.* (1989); Etminan *et al.* (2004); Giovannucci *et al.* (1995 and 2002); McCann *et al.* (2005); and Jian *et al.* (2005 and 2007). (Doc. No. 141 at 19:6-11.)

Although Bayer does not disagree with Plaintiffs that the FDA will not consider or rely on food intake studies as evidence of a particular nutrients's effect on a disease, Bayer nonetheless contends Plaintiffs' objections are unwarranted because: (1) the 2005 FDA Decision Letter, and therefore by implication also the court's reasoning in *Alliance*, are inapplicable because Bayer never represented that the Products contained lycopene to reduce the risk of prostate cancer; (2) disagreement in the scientific community regarding the import of food intake studies is not an appropriate basis on which to exclude expert

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by Dr. Blumberg in the "prostate cancer" section, Kim *et al.* (2003), Ansari and Gupta *et al.* (2003), and Schroder *et al.* (2005), do not affect or change the reliability of Dr. Blumberg's overall conclusion regarding lycopene. (*Id*. at 24-25.)

testimony; and (3) Dr. Blumberg's opinion that lycopene supports prostate health is based on the totality of the evidence, not just on food intake studies. Moreover, Bayer argues four of the eight studies Plaintiffs seek to exclude—Trottier *et al.* (2010); Chan *et al.* (2009); World Cancer Research Fund and the American Institute for Cancer Research (2007); and Etminan *et al.* (2004)—are meta-analyses studies that include plasma and/or serum lycopene analysis in conjunction with lycopene food intake studies.

Although the parties do not dispute the FDA's stance on the correlation of food intake studies and the substantiation of proposed health claims submitted to the FDA, the parties disagree as to the import, in the instant case, of the FDA's decision to disregard such studies. For example, Plaintiffs contend the FDA's stance on the issue is dispositive of whether the Court should exclude food intake studies relied upon by Dr. Blumberg, whereas Bayer contends the FDA's stance is contrary to the stance taken by the World Cancer Research Fund and the authors of Chan *et al.* (2008).[30] Moreover, Bayer contends that the FDA's decision to exclude food intake studies is inapposite to the instant case because Bayer never represented that lycopene reduces the risk of prostate cancer. Instead, Bayer only represented that lycopene supports prostate health, a "structure/function" claim, which does not need to be approved or evaluated by the FDA.[31]

Taking all the evidence into consideration, the Court finds Plaintiffs' arguments go to the weight rather than the admissibility of Dr. Blumberg's testimony. *See Milward v. Acuity Specialty Prods. Gp., Inc.*, 639 F.3d 11, 22 (1st Cir. 2011) ("There is an important

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[30] The World Cancer Research Fund (2007) concluded that "the strongest evidence, corresponding to judgments of 'convincing' and 'probable,' shows that foods containing lycopene . . . probably protect against prostate cancer." (Doc. No. 192, Blumberg Decl., Ex. N at 305.) Agreeing with the World Cancer Research Fund, Chan *et al.* (2008) noted that "it is proposed that the measurement of lycopene concentration in blood may provide a useful link between dietary lycopene intake and risk assessment in epidemiological studies." (Doc. No. 192, Blumberg Decl., Ex. O at 204.)

[31] A structure function claim is a statement that describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans. *See* 21 U.S.C. § 343(r)(6)(A). Structure function claims do not require pre-approval by the FDA, but must include a mandatory disclaimer stating that the FDA has not evaluated the claim and that the product is not intended to "diagnose, treat, cure, or prevent any disease." *See Stanley v. Bayer Healthcare LLC*, No. 11cv862-IEG (BLM), 2012 WL 1132920, at*7 (S.D. Cal. Apr. 3 2012.)

difference between what is unreliable support and what a trier of fact may conclude is insufficient support for an expert's conclusion."). In concluding that lycopene promotes prostate health, Dr. Blumberg considered a variety of different scientific studies, including the clinical trials noted above—Mohanty *et al.* (2005), Schwarz *et al.* (2008) and Rohrmann *et al.* (2004)—retrospective observational food intake studies, and studies analyzing plasma lycopene levels in conjunction with the intake of lycopene-rich foods.[32] (Doc. No. 192, Blumberg Decl., Ex. F. Blumberg Depo. at 59:20-61:9, 62:5-24.) Thus, Plaintiffs' request for piecemeal exclusion of selected studies based solely on their allegations that such studies, taken in isolation, are unreliable, is an inappropriate ground for exclusion and exceeds the court's gatekeeping function under Rule 702. *In re Heparin Prods. Liab. Litig*., 803 F. Supp. 2d 712, 743 (N.D. Ohio 2011) ("Neither of these sources, taken alone, would reliably demonstrate that it is more likely than not that contaminated heparin substantially increases the likelihood of HIT. But again, taken together with Dr. Jeske's knowledge and experience, these studies are the type of information on which pharmacologists typically rely."); *Milward*, 639 F.3d at 22 ("In this, the court overstepped the authorized bounds of its role as gatekeeper."). However, as stated above, to the extent Dr. Blumberg relies on scientific studies not available during the Class Period (i.e., studies published after May 31, 2010), such studies are excluded, as irrelevant to the determination of whether the Prostate Claims were false or misleading during the Class Period. Accordingly, Plaintiffs' arguments for exclusion on this ground are also overruled.

Therefore, as further articulated above, because the Court finds Dr. Blumberg's opinions and testimony regarding the scientific substantiation for Bayer's representations regarding lycopene and the promotion of prostate health are both relevant and reliable—aside from the studies relied upon by Dr. Blumberg that were published after the Class Period—the Court overrules each of Plaintiffs' objections. As a result, to the extent

[32] These later studies provide a stronger inference that lycopene is indeed the nutrient responsible for the beneficial effect observed in the food studies. (Doc. No. 192, Blumberg Decl., Ex. F. Blumberg Depo. at 65:5-24.)

not otherwise excluded, Dr. Blumberg's testimony regarding lycopene supplementation and prostate health will be considered in adjudicating Bayer's pending motion for summary judgment.

4. Dr. Blumberg's Opinions and Testimony Regarding Zinc and Vitamin E

Dr. Blumberg also opines that zinc and vitamin E support overall prostate health by helping to maintain a healthy prostate. (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 7.) With regard to zinc, Dr. Blumberg states that observational studies affirm the essential role of zinc in controlling the physiological function of the prostate gland while also demonstrating the importance of plasma zinc concentrations in reducing the risk of cancer and the onset or progression of BPH. (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 34.) Moreover, Dr. Blumberg opines that zinc's antioxidant properties have been shown to contribute to the overall health of the prostate gland by inhibiting cell damage, especially because zinc has been shown to accumulate in the prostate gland. (*Id*.) With regard to vitamin E, Dr. Blumberg states that basic research studies have shown that vitamin E may affect prostate cancer risk by altering sex hormone concentrations and by providing chemoprevention by bolstering the immune system. (*Id*. at 36.) Accordingly, Dr. Blumberg opines that the scientific evidence available during the Class Period substantiates Bayer's representations that both zinc and vitamin E support prostate health.

Plaintiffs raise two primary objections to the admission of Dr. Blumberg's testimony regarding zinc and vitamin E: (1) Dr. Blumberg's opinions are irrelevant because the advertising statements at issue concern only selenium and lycopene, not zinc and vitamin E; and (2) Dr. Blumberg's opinions are unreliable because they are based on unsound methodology. The Court addresses each in turn.

First, Plaintiffs suggest that Dr. Blumberg' opinions regarding zinc and vitamin E should be excluded because they are irrelevant to the material issues in the litigation and were only added by Bayer as a last minute attempt to substantiate the prostate health claim. Specifically, Plaintiffs maintain that the only representation "at issue" is whether

lycopene and selenium—and not zinc and vitamin E—support prostate health. (Doc. No. 141 at 9:18-28.) In support of this contention, Plaintiffs point to language employed by the Court in its prior order granting Plaintiffs' motion for class certification, wherein the Court stated that "Bayer asserted that its Men's Vitamins provide the prostate health benefits because they contained the antioxidant lycopene and later, the trace mineral selenium." (Doc. No. 105 at 2:7-9.) Based on the above, and Plaintiffs' argument that Bayer intended to, and did, convey a marketing campaign promoting lycopene and selenium, and not zinc and vitamin E, Plaintiffs allege that the focus of this litigation has been, up until now, whether lycopene and selenium support prostate health, and not whether zinc and vitamin E support prostate health. Accordingly, Plaintiffs assert that Bayer cannot now attempt to substantiate its representations with nutrients that have never been "at issue" in the litigation.

The Court finds these allegations disingenuous at best. As acknowledged by the Plaintiffs throughout this litigation, in a false advertising case brought under the UCL and CLRA, the products advertised benefits, as expressed through the products' packaging and advertisements, are the claims that are "at issue" in the litigation. *See Brockey v. Moore*, 107 Cal. App. 4th 86, 100, 131 (Cal. Ct. App. 2003) (stating that "the primary evidence in a false advertising case is the advertising itself"). Thus, as confirmed and acknowledged by the Court in its prior order granting Plaintiffs' motion for class certification, "[t]he advertising claim—the message conveyed by the labeling and advertisements—is at issue here . . . ." (Doc. No. 105 at 10:25-26.) Moreover, this advertised message is the "overall message conveyed" and not parsed out segments of that message, which have been selected by a party based on a desire to substantiate a particular argument.[33] (*Id.* at 10:28.) Thus, Plaintiffs cannot hide behind language used

[33] *See Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1248 (11th Cir. 2002) (stating that a court "must analyze the message conveyed in full context" and "must view the face of the statement in its entirety . . ."); *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1180 (8th Cir. 1998) ("[A] court must analyze the message conveyed within its full context"); *Avis Rent A Car Sys., Inc. v. Hertz Corp.*, 782 F.2d 381, 385-86 (2d Cir. 1986) (noting importance of context and viewing the advertisement in its entirety).

by Bayer in prior court filings, or select language from a prior order, albeit out of context, to suit and support their particular arguments. To the contrary, the advertisement—Prostate health with Lycopene, more Selenium, Vitamin E and Zinc—is what is "at issue" here.

Moreover, Plaintiffs' argument that Bayer marketed the Vitamin Products with the intent that lycopene and selenium were the key ingredients linked to the prostate health message, rather than zinc and vitamin E, is also unavailing. (Doc. No. 208 at 9.) As stated above, false advertising claims brought under the UCL and CLRA, focus on the representations made on the products or advertised in conjunction with the products; intent of the defendant is irrelevant. *See Chamberlan v. Ford Motor Co.*, 369 F. Supp. 2d 1138, 1144 (N.D. Cal. 2005) (rejecting argument that plaintiff must prove intent to deceive under the CLRA). Therefore, the Court finds Plaintiffs' arguments for exclusion of Dr. Blumberg's testimony based on the relevancy of zinc and vitamin E without merit. Accordingly, Plaintiffs' objections on this ground is overruled.

Second, Plaintiffs contend Dr. Blumberg's opinions regarding zinc and vitamin E are unreliable and therefore should be excluded. With respect to zinc, Plaintiffs argue Dr. Blumberg's opinions utilize unreliable methodology because: (1) he admits there are no human clinical trials examining the relationship between zinc and prostate health, (Doc. No. 141, Syverson Decl., Ex. C, Blumberg Depo. at 29:13-15, 196:24-197); (2) he relies exclusively on observational studies even though he admits that observational studies "do not support causation," (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 9:2-3); and (3) he concedes that zinc supplementation may actually increase the risk of prostate cancer, (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 33:1-3). Additionally, Plaintiffs maintain that studies based on men previously diagnosed with prostate cancer, Epstein *et al.* (2011); studies based on food intake questionnaires, Gonzales *et al.* (2011); and studies based on a correlation between zinc and a reduction in BPH risk, Kristal *et al.* (1999 and 2008), should also be excluded as unreliable.

Although Plaintiffs make a valiant effort to exclude Dr. Blumberg's testimony by parsing selected sentences and phrases from his deposition and expert report, the Court

finds such arguments without merit and exceed the Court's "gatekeeping" function. *See Sargon Enters., Inc. v. Univ. of S. Cal.*, 55 Cal. 4th 747, 772, 288 P.3d 1237, 1252 (2012) ("The trial court's gatekeeping role does not involve choosing between competing expert opinions. The [United States Supreme Court] warned that the gatekeeper's focus 'must be solely on principles and methodology, not on the conclusions that they generate.' ") (citing *Daubert*, 509 U.S. at 595). Here, the representation at issue is whether lycopene, selenium, zinc, and vitamin E support prostate health. As stated above, this is considered a structure/function claim that does not require independent FDA evaluation, but only requires submission of the claim to the FDA, non-opposition by the FDA, and placement of a disclaimer on the product packaging stating that the FDA has not evaluated the claim and that the product is not intended to "diagnose, treat, cure or prevent any disease." *Stanley v. Bayer Healthcare LLC*, No.11CV862-IEG (BLM), 2012 WL 1132920 (S.D. Cal. Apr. 3, 2012), appeal dismissed (June 19, 2012) (citing 21 U.S.C. § 343(r)(6)(C); 21 C.F.R. § 101.93).

Thus, as stated by Dr. Blumberg, a structure/function claim does not look at the correlation between a particular nutrient and the ability of that nutrient to treat or cure a disease. (Doc. No. 192, Blumberg Decl., Ex. F, Blumberg Depo. at 199:1-6.) Instead a structure/function claim looks at whether a nutrient is essential to the function of a particular body system or organ, here the prostate gland. (*Id.* at 199-200.) As such, Dr. Blumberg opines that zinc supports prostate health based on zinc's supportive role in prostate physiology, specifically, that normal, healthy prostate glands contain a high accumulation of zinc, and maintaining high zinc levels is essential to inhibiting the proliferation and invasive/migration activities of malignant prostate cells. (*Id.*; Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 31.) Dr. Blumberg bases this opinion on several observational studies, Franklin and Costello *et al.* (2007), Leone *et al.* (2006), Wu *et al.* (2004), Ito *et al.* (2002), Kristal *et al.* (1999 and 2008), and Leitzmann *et al.* (2003); and a controlled clinical trial, Meyer *et al.* (2005). Therefore, because the level of substantiation for a structure/function claim and a health claim is markedly different, and Dr. Blumberg provides reliable scientific support for his conclusions, the Court finds

Plaintiffs' contentions go to the weight rather than the admissibility of Dr. Blumberg's testimony. *See Abarca v. Franklin Cnty Water Dist.*, 761 F. Supp. 2d 1007, 1028 (E.D. Cal. 2011) ("Sears is qualified to opine on air emissions, analysis and modeling in this case and her calculations can be challenged through cross-examination and presentation of contrary evidence.").

Furthermore, the Court finds Plaintiffs inappropriately parse sentences from Dr. Blumberg's report to fit their respective arguments, and therefore, such arguments are both unpersuasive and unavailing in light of Dr. Blumberg's actual representations. For example, Plaintiffs cite to a selected sentence in Dr. Blumberg's report, wherein he states that "observational studies alone do not prove causation." (Doc. No. 141, Syverson Decl., Ex. A at 9:2-3.) However, Plaintiffs fail to include the surrounding language, which describes and defines Dr. Blumberg's opinion, especially as it relates to the weight given observational studies in the context of structure/function claims. Dr. Blumberg's complete statement reads as follows:

> Clinical trials try to minimize some of these variables by creating highly specific inclusion and exclusion criteria for selecting subjects and controlling the intervention with only one or two nutrients or doses. Nutrition supplement claims ***do not*** require randomized clinical trials to draw an inference of causation to substantiate the supplement claims. In the context of nutrition supplements, ***observational studies are particularly important*** because they have the capacity to examine a diversity of volunteers in very large cohorts and investigate many interacting associations between diet and lifestyle factors. While observational studies alone do not prove causation, they can be used to draw an inference of causation when viewed in conjunction with the totality of the evidence and are commonly used to substantiate structure function claims. Thus, nutrition supplement claims can be substantiated through a combination of observational studies, basic research experiments, and/or randomized clinical trials, the combination of which is known as the totality of the evidence.

(Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 8:24-9:7) (emphasis added).

Similarly, in an attempt to persuade the Court that Dr. Blumberg has actually opined that zinc may increase the risk of prostate cancer, Plaintiff's cite the following sentence from his report: "other cohort and case-control studies have observed that long-term and/or high dose zinc supplements . . . may increase the risk of prostate cancer." (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 31:1-3.) However, the words Plaintiffs elected to omit are telling, especially in light of the fact that Dr. Blumberg

explicitly stated that the Vitamin Products represented no risk when taken as directed. (*Id*.) Thus, the complete sentence included in Dr. Blumberg's report states the following: "other cohort and case-control studies have observed that long-term and/or high dose zinc supplements (in amounts not found in daily doses of the Vitamin Products) may increase the risk of prostate cancer." (*Id*.) Accordingly, the Court finds Plaintiffs' arguments for exclusion of Dr. Blumberg's testimony regarding zinc supplementation and prostate health without merit and potentially deceptive.

With respect to vitamin E, Plaintiffs contend Dr. Blumberg's testimony is unreliable because: (1) he relies on observational and *in vitro* studies without the appropriate foundational evidence supporting his extrapolation; and (2) he relies on clinical and observational studies involving trial subjects previously diagnosed with prostate cancer. Thus, Plaintiffs argue Dr. Blumberg's testimony regarding vitamin E should be excluded because there is conflicting evidence regarding the beneficial effects of vitamin E supplementation and the promotion of prostate health. (Doc. No. 141 at 21:15-27.)

Again, Plaintiffs' arguments go to the weight rather than the admissibility of Dr. Blumberg's testimony. *See Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1319 (2011) ("A lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events."); *Hopkins v. Dow Corning, Corp*., 33 F.3d 1116, 1125 (9th Cir. 1994) (finding admissible testimony based on scientific studies and "corroborating evidence found in studies conducted on animals"). In forming his opinion regarding vitamin E, Dr. Blumberg considered the totality of the evidence, including controlled clinical trials, and observational and *in vitro* studies. (Doc. No. 141, Syverson Decl., Ex. A, Blumberg Report at 34-37.) Specifically, Dr. Blumberg relied on: (1) the Alpha-Tocopherol, Beta-Carotene ("ATBC") study, a randomized clinical trial finding a statistically significant 32% decrease in the incidence of prostate cancer for men receiving vitamin E supplementation as compared to a placebo, (*Id.* at 34-35; Doc. No. 192, Blumberg Decl., Ex. R, Heinonen *et al.* (1998)); (2) the Supplementation en Vitamins et Mineraux Antioxidants ("SU.VI.MAX") study, a randomized double-blind, placebo controlled primary prevention trial finding beneficial

effects of vitamin E supplementation on men but not in women; and (3) countless observational and *in vitro* studies. Thus, this is not the case where an expert is presenting unreliable and baseless conclusions. *See Primiano*, 598 F.3d at 564, 566 ("[T]he test under *Daubert* is not the correctness of the expert's conclusions but the soundness of his methodology.") (internal citation omitted).

Therefore, as stated above, the Court finds Dr. Blumberg's testimony regarding zinc and vitamin E are relevant to the legal and factual issues presented in the litigation, and are based on reliable and sound scientific principles. However, to the extent Dr. Blumberg relies on scientific studies conducted or published after the end of the Class Period, such studies are excluded as irrelevant to the determination of whether there was scientific support for Bayer's prostate health representation during the Class Period.

In conclusion, the Court finds each of Plaintiffs' objections go to the weight rather than the admissibility of Dr. Blumberg's testimony. *See Prime*, 431 F.3d at 1153 (stating that the proper inquiry focuses "solely on principles and methodology, not on the conclusions that they generate") (internal quotations omitted); *Daubert*, 509 U.S. at 595 (finding that "[a]s long as the process is generally reliable, any potential error can be brought to the attention of the jury through cross-examination and the testimony of other experts"). Accordingly, Plaintiffs' motion to exclude the testimony and opinions of Dr. Blumberg is DENIED, and the Court considers this evidence when adjudicating Bayer's pending motion for summary judgement. *See Lust By & Through Lust*, 89 F.3d at 598 (9th Cir. 1996).

D. Bayer's Motion to Exclude Plaintiffs' Marketing Expert Dr. Maronick

Dr. Maronick was retained by Plaintiffs to independently review and analyze Bayer's marketing materials and the extensive body of market research conducted and/or commissioned by Bayer for the purpose of marketing and advertising the Vitamin Products during the Class Period. (Doc. No. 199 at 4:10-12; Doc. No. 189, Ex. A, Maronick Report ¶ 4.) Specifically, Dr. Maronick focused on: (1) Bayer's research and marketing strategies prior to the launch of OAD Men's Health in 2002; (2) the evolution of Bayer's marketing message regarding OAD Men's Health from 2002 to 2009; (3)

Bayer's research and marketing strategies prior to the launch of OAD Men's 50+ Advantage in 2007; (4) the evolution of Bayer's marketing message regarding OAD Men's 50+ Advantage from 2007 to 2009; and (5) the ultimate decision by Bayer to remove the Prostate Claims from the Products' packaging beginning in 2009. (Doc. No. 189, Ex. A, Maronick Report ¶ 6.) Based on a review of Bayer's internal documents, declarations from Bayer's executives and Bayer's marketing expert (Dr. Ravi Dahr), and third-party market research reports commissioned by Bayer during and before the Class Period, Dr. Maronick concluded that:

> [t]hrough consideration of various changes in the message to add additional claims (lycopene, selenium, ginko, Omega-3), the *one constant* was that at all times throughout 2002-2009 and 2007-2009, both OAD Men's Health Formula and OAD Men's 50+ Advantage, respectively, stressed that the product promoted prostate health and/or reduced the risk of prostate cancer. In fact, even when other ingredients were added, the research showed the "driving force" or "Reason to Believe" (RTB) the two sub-brands was the fact that they were specifically formulated for prostate health. Moreover, Bayer's promotion of lycopene and later selenium as added ingredients were based on the, allegedly false, proposition that these ingredients promoted prostate health and/or reduced the risk of prostate cancer.[34]

(Doc. No. 189, Ex. A., Maronick Report ¶ 8) (emphasis added).

Bayer seeks to exclude Dr. Maronick's testimony on the following grounds: (1) his opinions are unreliable because they are not based on accepted scientific principles and methodology and contradict undisputed facts; (2) his testimony is nothing more than a narrative history and he improperly parrots the conclusions reached by third-party market research firms; and (3) his opinions are irrelevant because they fail to address any material issues in the case, specifically, whether consumers were deceived by the actual Prostate Claims made by Bayer during the Class Period.[35] (Doc. No. 155 at 3-4.) Although not specifically raised by Bayer, the Court first addressees Dr. Maronick's qualifications and then addresses Bayer's remaining substantive objections.

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[34] Maronick has one primary opinion—that the prostate health and/or prostate cancer message was a constant in the promotion of the Vitamin Products. (Doc. No. 179, Ex. B, Maronick Depo. at 43:13-44:1.) The rest of his opinion is really a "sub-set" of this primary opinion. (*Id.*)

[35] Bayer made five separate objections to Maronick's testimony. However, the Court combined the first and fourth objections and the second and third objections.

1. Dr. Maronick's Qualifications

It is undisputed that Dr. Maronick is qualified to render an expert opinion in the field of marketing.[36] (Doc. No. 155 at 4:16-17; Doc. No. 199 at 6-7; Doc. No. 189, Ex. A, Maronick Report at 2 n.1.) Dr. Maronick received a Master of Science in Business Administration (MBA) from the University of Denver, a Doctorate in Business Administration (DBA) with a major in marketing from the University of Kentucky, and a Juris Doctorate (JD) from the University of Baltimore School of Law. (Doc. No. 189, Ex. A, Maronick Report ¶ 1.) He currently teaches undergraduate and graduate courses in strategic marketing and marketing research at Towson University, where he has been since 1987, and has taught graduate and executive development courses at a number of other universities in the Baltimore and Washington, D.C. areas. (*Id*.) Moreover, from 1987 to 1997, Dr. Maronick was the Director of Impact Evaluation in the Bureau of Consumer Protection at the Federal Trade Commission ("FTC"). (*Id.* at ¶ 2; Doc. No. 199, Ex. G, Maronick Depo. at 50:5-51:5.) In this position, Dr. Maronick served as the in-house marketing expert for all divisions, wherein he was responsible for evaluating information submitted by firms being investigated by the FTC, and for the design and implementation of all consumer research undertaken by the Agency. (*Id.* at ¶ 2; Doc. No. 199, Ex. G, Maronick Depo. at 50:5-51:5.) Furthermore, Dr. Maronick has reviewed, designed, and overseen approximately 350 consumer surveys, (Doc. No. 199, Ex. G, Maronick Depo. at 20:6-22:9), and published peer-reviewed articles on marketing and advertising principles and the impact of marketing on consumer behavior, (Doc. No. 189, Ex. A, Maronick Report Ex. 1 at 3.) Accordingly, the Court finds Dr. Maronick qualified to offer an expert opinion in this case.

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[36] Neither party asserts that Dr. Maronick is qualified to give an expert opinion regarding the validity or scientific support for the Prostate Claims during the Class Period. (Doc. No. 155 at 4; Doc. No. 199 at 6.)

2. Bayer's Substantive Objections to Dr. Maronick's Testimony and Opinions

As stated above, Bayer contends Dr. Maronick's testimony is: (1) not reliable because he did not independently review the underlying methodology employed in the third-party market research reports; (2) not relevant because none of the research he reviewed is determinative of whether consumers were actually deceived by the representations at issue; and (3) not useful to the trier of fact because his report is nothing more than a narrative history of Bayer's marketing of the Vitamin Products both before and during the Class Period. Although Dr. Maronick's testimony is arguably reliable—as experts may rely upon "facts and data" of others so long as the opinions and conclusions were developed by another expert for purposes other than litigation[37]—and relevant—as Plaintiffs must prove that the representations at issue were "material" to a reasonable consumer[38]—Dr. Maronick's testimony must nevertheless be excluded.

Under Federal Rule of Evidence 702(a), expert testimony is admissible if it is based on "scientific, technical, or other specialized knowledge" that "will help the trier of fact [] understand the evidence or [] determine a fact in issue." Fed. R. Evid. 702(a); *see also Moses v. Payne*, 555 F.3d 742, 756 (9th Cir. 2009) ("Under Rule 702, expert

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[37] *In re Imperial Credit Indus., Inc. Sec. Litig*., 252 F. Supp. 2d 1005, 1012 (C.D. Cal. 2003) ("Such documents therefore bear independent indicia of reliability, unlike an opinion which is generated solely for the purposes of litigation."); *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1142 (9th Cir. 1997) ("The fact that Engelke's opinions are based on data collected by others is immaterial."). Moreover, objections based on the inadequacies and flaws in an underlying survey go to the weight rather than the admissibility of expert testimony. *Hemmings v. Tidyman's Inc*., 285 F.3d 1174, 1188 (9th Cir. 2002) ("[O]bjections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence rather than its admissibility."); *Daubert*, 509 U.S. at 596 (stating that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means" of attacking expert testimony). Plaintiffs also contend that Bayer is simply wrong that Dr. Maronick "knew nothing about the underlying details of the market research." (Doc. No. 190 at 10-11.)

[38] *Davis-Miller v. Auto. Club of S. Cal.*, 201 Cal. App. 4th 106, 122, 134 Cal. Rptr. 3d 551, 563 (Cal. Ct. App. 2011), *as modified* (Nov. 22, 2011) ("This provision requires that plaintiffs in a CLRA action show not only that a defendant's conduct was deceptive but that the deception caused them harm. Causation, on a classwide basis, may be established by materiality.").

testimony is helpful to the jury if it concerns matters beyond the common knowledge of the average layperson and is not misleading."); *United States v. Hanna*, 293 F.3d 1080, 1086 (9th Cir. 2002) (quoting *United States v. Morales*, 108 F.3d 1031, 1039 (9th Cir. 1997) (en banc)). Thus to the extent an expert simply rehashes "otherwise admissible evidence about which he has no personal knowledge, such evidence—taken on its own—is inadmissible. *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 468 (S.D.N.Y. 2005) (stating that even though an expert may rely upon the facts or data of others in formulating an expert opinion, "an expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence").

Here, as acknowledged by Dr. Maronick, his report provides a "chronological picture" of the development of the prostate health message throughout the history of OAD Men's Health and OAD Men's 50+ Advantage. (Doc. No. 189, Blood Decl., Ex. A, Maronick Report ¶ 7.) Thus, apart from his short conclusion and summary opinion, 11½ pages of Dr. Maronick's 12 page report is nothing more than a synopsis of Bayer's marketing of the Vitamin Products during and before the Class Period, quoting extensively from both third-party market research reports and Bayer's own internal documents.[39] Therefore, to the extent such underlying evidence would be admissible at trial, either as a business record, admission by a party opponent, or probative of Bayer's knowledge regarding the reasons the Products were marketed with specific representations, Dr. Maronick's report offers nothing more than a factual narrative of these documents.[40] *See In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 551 (S.D.N.Y.

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[39] Dr. Maronick's report contains six sections organized in paragraph format: (1) Background and Qualifications ¶¶ 1-7; (2) Summary Opinion ¶ 8; (3) Theoretical Foundation for Opinions ¶¶ 9-11; (4) Pre-Launch Period (2001-2002) ¶¶ 12-17; (5) OAD Men's Health Formula (2004-2009) and OAD Men's 50+ Advantage (2007-2009) ¶¶ 18-18-38; (6) Conclusion ¶¶ 39-40. (Doc. No. 189, Blood Decl., Ex. A, Maronick Report.)

[40] *See Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 454 F. Supp. 2d 966, 974 (C.D. Cal. 2006) ("Documents that bear StreamCast's trade names, logos, and trademarks are statements by StreamCast itself, and are admissible as admissions by a party-opponent under Rule 801(d)(2), or alternatively as non-hearsay to show StreamCast's state of mind."); *Sea-Land Serv., Inc. v. Lozen Int'l, LLC.*, 285 F.3d 808, 819 (9th Cir. 2002) ("Rule 803(6) allows the admission of business records when two foundational facts are proved: (1) the writing is made or transmitted by a person with

2004) (rejecting portions of plaintiffs' expert's testimony that was "a narrative reciting selected regulatory events" because "[s]uch material, to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence"); *LinkCo, Inc. v. Fujitsu Ltd.*, No. 00Civ7242 (SAS), 2002 WL 1585551, at *1-2 (S.D.N.Y. July 16, 2002) (where expert's report was based on a review of, *inter alia*, "documents, computer documents, computer files, deposition transcripts and exhibits," the "testimony by fact witnesses familiar with those documents would be far more appropriate . . . and renders [the expert witness'] secondhand knowledge unnecessary for the edification of the jury") (citation and internal quotations omitted).

Moreover, although, Plaintiffs adamantly argue that Dr. Maronick's testimony will help the trier of fact understand over a "decade's worth of complex market research," the Court is not persuaded. Exclusion of Dr. Maronick's testimony does not prohibit Plaintiffs from calling Bayer executives to the stand at trial, or questioning representatives from Bayer regarding the results and conclusions reached by the third-party market research firms, and the impact these results had on Bayer's marketing of the Vitamin Products in this case. Nor would there be any prohibition for Plaintiffs to call the authors of the research reports with regard to the information provided to Bayer. None of this evidence or testimony requires the providence of an expert. *See Media Sport & Arts s.r.l. v. Kinney Shoe Corp.*, No. 95-CIV-3901(PKL), 1999 WL 946354, at *3 (S.D.N.Y. Oct. 19, 1999) (stating that where expert's testimony "is not based on personal knowledge, but instead on his review of documents and depositions produced by the parties," the expert's testimony "may not take the place of that of the individuals who actually negotiated the deal") (citations omitted); *Taylor v. Evans*, No.94CIV 8425 (CSH), 1997 WL 154010, at *2 (S.D.N.Y. Apr. 1, 1997) (rejecting portions of expert report on the ground that the

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knowledge at or near the time of the incident recorded, and (2) the record is kept in the course of regularly conducted business activity.") (internal quotations omitted).

testimony consisted of "a narrative of the case which a lay juror is equally capable of constructing"); *United States v. Hamaker*, 455 F.3d 1316, 1331-32 (11th Cir. 2006); *E. Coast Brokers & Packers, Inc. v. Seminis Vegetable Seeds, Inc*., No. 8:07-cv-171 T-26TBM, 2008 WL 5093602 (M.D. Fla. Dec. 2, 2008) (stating that Federal Rule of Evidence 1006 permits a party to present the contents of "voluminous writings, recordings, or photographs which cannot conveniently be examined" in the form of a "chart, summary, or calculation" and that a witness who presents this type of summary testimony qualifies as a lay witness under Rule 701). Accordingly, Bayer's motion to exclude Dr. Maronick's testimony and opinions is GRANTED.[41]

II. Bayer's Motion for Summary Judgment

Plaintiffs allege Bayer violated the UCL and CLRA by misrepresenting that the Vitamin Products support prostate health and reduce the risk of prostate cancer. (SAC ¶ 2.) Specifically, Plaintiffs contend that Bayer represented that zinc, vitamin E, lycopene, and selenium support prostate health (the Prostate Health Claim), and that emerging research suggests selenium may reduce the risk of prostate cancer (the Prostate Cancer Claim), even though Bayer did not have "adequate substantiation" for either representation.[42] (*Id*. at ¶¶ 2, 44 & 61.) Accordingly, Plaintiffs allege that the Prostate Claims are false, misleading, and reasonably likely to deceive the public, (*Id*. at ¶¶ 2, 74 & 75), and

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[41] The Court finds the third-party market research reports admissible as either a business record or probative of Bayer's knowledge regarding the marketing and development of the Vitamin Products during and before the Class Period. However, because manufacturers are not prohibited from marketing products based on consumer preferences—to the extent not otherwise prohibited by law—the Court finds admission of these documents, on their own, do not assist Plaintiffs in meeting their ultimate burden of proof under the UCL and CLRA. *See Ramirez v. Labor Ready, Inc*., No. 836186-2, 2002 WL 1997037, at *7 (Cal. Super. Ct. July 12, 2002) (stating that under the UCL and CLRA "the intent of a defendant and the knowledge of consumers are both irrelevant"); *Chern v. Bank of America,* 15 Cal. 3d 866, 876, 127 Cal. Rptr. 110 (Cal. 1976). This is further supported by the fact that Bayer does not contest that the Vitamin Products were marketed to consumers to promote prostate health and/or reduce the risk of prostate cancer. The Court addresses Bayer's remaining evidentiary objections, to the extent necessary, when adjudicating Bayer's pending motion for summary judgment.

[42] Plaintiffs also allege that the Prostate Claims violate the UCL and CLRA because scientific research actually indicates that selenium supplementation may be harmful. (SAC ¶¶ 23-45.) As stated above, the first claim was made with respect to both Products, whereas the second claim was only made with respect to OAD Men's Health.

seek redress for California consumers in the form of a refund of the purchase price, actual and punitive damages, injunctive relief, and/or an order requiring Bayer to engage in corrective advertising, (*Id.* at ¶¶ 3, 21, 22 & 41.)

Bayer seeks summary judgment on three independent grounds: (1) Plaintiffs' claims are preempted by federal law; (2) Plaintiffs' claims are based on "lack of substantiation" rather than proof of falsity or deception; and (3) Plaintiffs have failed to proffer a viable measure of damages under the UCL and CLRA. Although the Court finds summary judgment is warranted based solely on Plaintiffs' failure to show that the Prostate Claims were false or deceptive when made, the Court nonetheless considers the parties' respective preemption arguments. However, because Plaintiffs have failed to raise a genuine dispute as to the truth, falsity, or deceptive nature of the Prostate Claims, the Court need not addresses the parties' respective arguments regarding damages. Accordingly, the Court first outlines the relevant law under the UCL and CLRA, and then addresses the parties' respective arguments regarding preemption and lack of substantiation.

A. Legal Elements for False Advertising Claims Under the UCL and CLRA

The UCL prohibits any "unlawful, unfair or fraudulent business act or practice [in addition to any] unfair, deceptive, untrue or misleading advertising . . . " Cal. Bus. & Prof. Code §§ 17200 & 17500 (Section 17500 makes it an unlawful for a business to disseminate any statement "which is untrue or misleading, and which is known, or which by the exercise of reasonable care would be known, to be untrue or misleading"). The CLRA prohibits "unfair methods of competition and unfair or deceptive acts or practices." Cal. Civ. Code § 1770; *see also Nagel v. Twin Labs., Inc.*, 109 Cal. App. 4th 39, 51-52 (Cal. Ct. App. 2003) ("Under the CLRA, a defendant may be liable for deceptive practices in the sale of goods or services to consumers including: representing the goods have ingredients they do not have; representing the goods are of a particular standard,

quality or grade, if they are not; and advertising goods with the intent not to sell them as advertised") (citing Cal. Civ. Code § 1770(a)(5), (7) & (9)).

Claims under either the UCL or CLRA are governed by the "reasonable consumer" test, which requires plaintiffs to prove that "members of the public are likely to be deceived." *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 938 (9th Cir. 2008) (citing *Freeman v. Time, Inc.*, 68 F.3d 285, 289 (9th Cir. 1995)). "Whether a practice is deceptive, fraudulent, or unfair is generally a question of fact which requires consideration and weighing of evidence from both sides . . . ." *Linear Tech. Corp. v. Applied Materials, Inc.*, 152 Cal. App. 4th 115, 134 (Cal. Ct. App. 2007) (internal citations omitted). The UCL and CLRA prohibits "not only advertising which is false, but also advertising which although true, is either actually misleading or which has the capacity, likelihood or tendency to deceive or confuse the public." *Kasky v. Nike, Inc.*, 27 Cal. 4th 939, 951 (Cal. 2002).

Moreover, in a false advertising case under the UCL and CLRA, the plaintiff "bears the burden of proving that the defendant's advertising claim is false or misleading." *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336, 1342 (Cal. Ct. App. 2003). Private individuals may not bring an action demanding substantiation for advertising claims. Instead, pursuant to California Business & Professions Code § 17508, only prosecuting authorities may require an advertiser to substantiate its advertising claims. *Id*. at 1343; *see also Chavez v. Nestle USA, Inc.*, No.CV09-9192 GW(CWx), 2011 WL 2150128, at *5–6 (C.D. Cal. May 19, 2011)(dismissing plaintiff's claim for false advertising because plaintiff's factual allegation that defendant did not possess requisite scientific evidence for claims was insufficient to state a claim under California false advertising law) (affirmed in part and reversed in part); *Fraker v. Bayer Corp.*, 2009 WL 5865687, No. CVF 08-1564 AWI GSA, at *8–9 (C.D. Cal. Oct. 6, 2009) (dismissing plaintiff's claim for false advertising because plaintiff alleged only that defendant had "no reasonable basis, consisting of competent and reliable scientific evidence to substantiate" its health-benefit claim related

to "WeightSmart" multivitamin). The purpose of allowing only prosecuting authorities, and not private persons, to seek substantiation of advertising claims under California Business & Professions Code § 17508 is to "prevent undue harassment of advertisers" and provide "the least burdensome method of obtaining substantiation for advertising claims."

B. Federal Preemption Under the Nutrition Labeling and Education Act

First, Bayer argues that Plaintiff's UCL and CLRA claims are preempted under the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343 *et seq*., which is administered by the FDA. Specifically, Bayer contends that because the FDA drafted and approved the statement "selenium may reduce the risk of certain forms of cancer" any claims based on this approved language are preempted.[43] (Doc. No. 172, Def.s' RJN, Ex. B.) Bayer then extends this contention to argue that because "prostate cancer" is just a specific "form of cancer," and that "some scientific evidence" is essentially synonymous with "emerging research," Bayer's representation that "emerging research suggests selenium may reduce the risk of prostate cancer" is squarely within the ambit of the language approved by the FDA.[44] In response, Plaintiffs do not dispute or contest the

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[43] Section 403A of the NLEA, 21 U.S.C. § 343-1(a)(5), which is the preemption provision, states:

> (a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce. . .
> (5) any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

[44] Specifically, Bayer argues that: (1) all claims based on class members who purchased OAD Men's Health from 2006 (when the Prostate Cancer Claim was first added to the products' packaging) until June 2009 (when the FDA issued its revised decision) are preempted by the 2003 FDA Decision Letter; and (2) all claims based on class members who purchased OAD Men's Health from June 2009 until May 2010 (when the Prostate Cancer Claim were removed from the products' packaging) are nonetheless still preempted by the 2003 FDA Decision Letter because the 2009 FDA Decision Letter has no force in light of the court's decision in *Alliance*, 714 F. Supp. 2d at 58 (finding revised language authorized by FDA in the June 2009 Decision Letter unconstitutional as an impermissible infringement on commercial speech). Moreover, Bayer argues that even after the 2009 FDA Decision Letter the FDA still permitted claims based on the

language actually approved by the FDA, but instead argue that preemption under the NLEA does not apply because Bayer's representations exceeded the narrow language actually authorized by the FDA. The Court is inclined to agree.

Federal law preempts state law when: (1) a congressional statute explicitly preempts state law (express preemption); (2) federal law occupies a legislative field to an extent that it is reasonable to conclude that Congress left no room for the state to regulate in that field (field preemption); or (3) state law conflicts with federal law (conflict preemption). *See Chae v. SLM Corp.*, 593 F.3d 936, 941 (9th Cir. 2010). In contrast to express preemption, field and conflict preemption are examples of implied preemption because there is an inference that Congress left no room for state regulation or that state law actually conflicts with federal law.[45] *See Ting v. AT&T*, 319 F.3d 1126, 1136 (9th Cir. 2003). Bayer seeks summary judgment based on express and implied preemption under the NLEA.

Here, although the Court finds Plaintiffs' claims would be preempted under NLEA if they were based solely on representations exactly replicating and not exceeding the language actually approved by the FDA, the representations at issue clearly included

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qualified health claims permitted in the 2003 FDA Decision Letter. The 2009 FDA Decision Letter approved the following qualified health claim: "Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer." *See Alliance*, 714 F. Supp. 2d at 58.

[45] A federal law impliedly preempts a state law "where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Field preemption may be implied from a "scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, or where an Act of Congress touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Id.* (internal citations omitted) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). "Conflict preemption analysis examines the federal statute as a whole to determine whether a party's compliance with both federal and state requirements is impossible or whether, in light of the federal statute's purpose and intended effects, state law poses an obstacle to the accomplishment of Congress's objectives." *Whistler Invs., Inc. v. Depository Trust and Clearing Corp.*, 539 F.3d 1159, 1166 (9th Cir. 2008) (citing *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000)).

additional language never approved or even considered by the FDA.[46] *See Lam v. Gen. Mills*, 859 F. Supp. 2d 1097, 1103 (N.D. Cal. 2012) (UCL and CLRA claims challenging food labeling preempted because such claims were "expressly permitted by FDA regulations"); *Dvora v. Gen. Mills*, No. CV 11-1074-GW(PLAx), 2011 WL 1897349, at *3-6 (C.D. Cal. May 16, 2011) (same); *Ackerman v. Coca-Cola Co.*, No. CV-09-0395 (JG) (RML), 2010 WL 2925955, at *7-8 (E.D.N.Y. July 21, 2010) (UCL and CLRA claims preempted because challenged labeling complied with "the FDA's express decision"). For example, the 2003 FDA Decision Letter authorized the following language:

> Claim One: Selenium may reduce the risk of ***certain cancers***. ***Some scientific evidence*** suggests that consumption of selenium may reduce the risk of ***certain forms of cancers***. However, the FDA has determined that this evidence is limited and not conclusive.

(Doc. No. 172, Def.s' RJN, Ex. B at 34, 2003 FDA Decision Letter) (emphasis added). This language was approved by the FDA in response to a petition filed by a non-party to this litigation, who requested approval of health claims based on the relationship between selenium and a reduced risk of ceratin forms of cancers, and between selenium and possible anticarcinogenic effects. (Doc. No. 172, Def.s' RJN, Ex. B at 34, 2003 FDA Decision Letter at 1.) Although the petition examined studies analyzing selenium supplementation and a reduction in the risk of prostate cancer, the petition never requested, and the FDA never issued, a qualified health claim specifically linking selenium supplementation to a reduction in the risk of prostate cancer.

In comparison, the product packaging for OAD Men's Health, which included the representation Bayer now argues is preempted based on the 2003 FDA Decision Letter, included the following language:

> Did you know that prostate cancer is the most frequently diagnosed cancer in men and that emerging research suggests Selenium may reduce the risk of prostate cancer? One-A-Day Men's Health Formula is a complete multivitamin plus key nutrients including Selenium to support a healthy prostate.

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[46] "Federal agency action short of formal notice and comment rulemaking can preempt state law." *Reid v. Johnson & Johnson*, No.11CV1310 L BLM, 2012 WL 4108114 (S.D. Cal. Sept. 18, 2012); *see also Holk v. Snapple Bev. Corp.*, 575 F.3d 329 (3d Cir. 2009); *Geier v. Am. Honda*, 539 U.S. 861 (2000).

> Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of Selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.

(Doc. No. 142, Weiss Decl., Ex E, packaging exemplar) (emphasis added).

Therefore, based on even a cursory juxtaposition of the language actually approved by the FDA in 2003 and the language actually used by Bayer on the product packaging for OAD Men's Health, it is clear that Bayer exceeded the bounds of the language authorized by the FDA. Although Bayer makes a valiant effort to convince the Court that preemption nonetheless applies to the entire representation because the statement is simply a more specific reference to one of the cancers upon which the FDA-approved statements are clearly based, the Court is not persuaded. Under the UCL and CLRA it is the overall representations that matters and not parsed out segments of the overall message. *See In re Clorox Consumer Litig*., No.12-00280 SC, 2012 WL 3642263, at *6 (N.D. Cal. Aug. 24, 2012) ("The overall message of the commercials is that cats prefer Fresh Step because they are "smart enough to choose the litter with less odors."). Thus, because the statement "emerging research suggests selenium may reduce the risk of prostate cancer" was never considered or approved by the FDA, Bayer's argument that preemption applies to the entire representation included on the product packaging for OAD Men's Health is unavailing.[47] *Cf. POM Wonderful, LLC v. Coca-Cola-Co.*, 679 F.3d 1170, 1176-78 (9th Cir. 2012) (finding preemption applicable where "private parties are undermining, through private litigation, the FDA's considered judgments"). Accordingly, Bayer's motion for summary judgment based on preemption is DENIED.

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[47] Although the Court is cognizant that prostate cancer is a "certain form of cancer," the Court finds preemption does not apply to the entire representation included on the product packaging for OAD Men's Health because the FDA elected not to authorize a qualified health claim based on this specific language. Bayer acknowledged this point at oral argument, recognizing that the Prostate Cancer Claim is more specific than the language actually approved by the FDA, and that the FDA elected not to approve this "more specific" language. Nevertheless, Bayer requested preemption based on the "specific language" actually approved by the FDA.

C. "Lack of Substantiation"

Second, Bayer contends summary judgment should be granted with respect to each claim—the Prostate Health Claim and the Prostate Cancer Claim—because Plaintiffs have no evidence that the claims were false or deceptive when made, and instead both claims are based on an improper "lack of substantiation" theory.[48] In support, Bayer relies on two unreported federal district court cases that have rejected similar claims: *Stanley v. Bayer Healthcare LLC*, No.11cv862-IEG (BLM), 2012 WL 1132920, at *3 (S.D. Cal. Apr. 3, 2012) and *Scheuerman v. Nestle Healthcare Nutrition*, Inc., Nos. 10-3684 (FSH)(PS), 10-5628(FSH)(PS), 2012 WL 2916827, *8 (D.N.J. July 17, 2012).[49] Bayer also cites to many instances in the record where Plaintiffs contend that Bayer's representations were false or deceptive because they were based on inadequate or insufficient scientific evidence, essentially arguing that Bayer's representations violate the UCL and CLRA because they are unsubstantiated.[50]

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[48] Bayer seeks summary judgment on the Prostate Health Claim with respect to each of the four nutrients that form the basis of the representation—zinc, vitamin E, lycopene, and selenium.

[49] In *Stanley*, the plaintiff brought UCL and CLRA claims alleging that the defendant's advertising for digestive health products was false and/or misleading because the defendant allegedly made unsubstantiated claims. *Stanley*, 2012 WL 1132920, at * 2. The plaintiff argued that these claims were false and misleading because "a majority of data generated in peer reviewed, double blind, placebo controlled studies, relating to probiotics, largely suggests that probiotics have little effect on human digestive or immune health." *Id.* at * 5. The court granted defendants' motion for summary judgment, finding that "the alleged lack of substantiation [did] not render claims false and misleading under the UCL or CLRA." *Id.* at * 4. Similarly, the *Scheuerman* court granted summary judgment on plaintiffs' UCL and CLRA claims, finding that "[w]hile Plaintiffs' experts [took] issue with the strength and significance of [Nestle's studies in support of its position], their criticisms [did] not satisfy Plaintiffs' burden of demonstrating that the "clinically shown" advertising claims are false or misleading." *Id*.

[50] Bayer cites to the following instances in the record wherein Plaintiffs appear to base their allegations on a "lack of substantiation" theory: "Defendants do not have a single properly conducted clinical trial that ***substantiates*** their claim" (SAC, Doc. No. 22 at ¶ 2) (emphasis added); "Scientific research does not ***substantiate*** Defendants' Prostate Claim, including the claim that the Products with the 'key nutrient' selenium reduce the risk of prostate cancer and support prostate health" (*Id.* at ¶ 22) (emphasis added); "Whether Defendants had adequate ***substantiation*** for the Prostate Claim prior to making it" (*Id*. at ¶ 61) (emphasis added);"Bayer tried to conceal its lack of ***substantiation*** for the prostate health claim" (Mot. for Class Cert., Doc. No. 73 at 3) (emphasis added); "Bayer lacked any ***substantiation*** for the implied claim that more selenium resulted in an increased benefit to men" (*Id.* at 6) (emphasis added); "Bayer never had clinical proof

In response, Plaintiffs do not dispute that private plaintiffs under the UCL and CLRA are prohibited from bringing a "lack of substantiation" claim, but contend that the instant action is not based on "lack of substantiation" because the Prostate Claims were provably false and/or reasonable likely to deceive consumers. Plaintiffs also maintain that *Stanley* and *Scheuerman*, the two unpublished district court cases Bayer relies upon, are readily distinguishable. Plaintiffs argue *Stanley* is distinguishable because in *Stanley*: (1) plaintiffs' first expert never explained why the defendant, as opposed to anyone else, would have to independently conduct clinical studies to render the advertisements at issue false or misleading; (2) plaintiffs' second expert only asserted that the claims lacked substantiation; (3) both of plaintiffs' experts admitted that the products at issue could be beneficial to many users; and (4) neither of plaintiffs' experts reviewed any of the 161 articles defendant had produced regarding the usefulness of the product at issue. Similarly, Plaintiffs argue *Scheuerman* is distinguishable because in that case the plaintiffs alleged that defendant's advertising was false simply because it was not substantiated. Therefore, Plaintiffs argue that neither *Stanley* nor *Scheuerman* are on point because substantial evidence exists that zinc, vitamin E, lycopene, and selenium do not support prostate health and do not reduce the risk of prostate cancer. As such, Plaintiffs argue this is not a case where Bayer's representations have no evidentiary support one way or the other—and thus an improper lack of substantiation case—but a case where Bayer's claims have actually been disproved.

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substantiating its prostate health claim" (*Id*. at 10) (emphasis added); "Bayer was well aware of its inability to ***substantiate*** its claims" (*Id*. at 12) (emphasis added); "[T]here is ***no credible scientific evidence*** that supports Bayer's advertising claims that lycopene supports a health prostate" (Doc. No. 172, Weiss Decl. Ex. A, Milman Report at 6) (emphasis added); "[S]cientific evidence available in 2002 about the effect of selenium supplementation in humans ***was limited, inadequate, and insufficient to support advertising health claims*** begun at the time by Bayer that selenium in One-A-Day Men's Health Formula supports a healthy prostate" (*Id.* at 17) (emphasis added); "[S]cientific evidence available in 2006 about the effect of selenium supplementation in humans ***remained limited, inadequate and insufficient to support advertising health claims*** by Bayer that selenium in One-A-Day Men's Health Formula and in One-A-Day Men's 50+ Advantage supports a healthy prostate and that selenium in One-A-Day Men's Health Formula also may reduce the risk of prostate and other forms of cancer" (*Id*. at 26-27) (emphasis added).

The Court first addresses whether the Prostate Claims were provably false in light of the scientific research available during the Class Period—with respect to each of the four nutrients—and then addresses whether Plaintiffs have proffered sufficient evidence to raise a genuine dispute as to whether the Prostate Claims were likely to deceive a reasonable consumer. *Nissan Fire & Marine Ins. Co., Ltd. v. Fritz Co., Inc.*, 210 F.3d 1099, 1106 (9th Cir. 2000) ("The moving party may produce evidence negating an essential element of the nonmoving party's case, or, after suitable discovery, the moving party may show that the nonmoving party does not have enough evidence of an essential element of its claim or defense to carry its ultimate burden of persuasion at trial.").

1. Whether the Prostate Statements Were Provably False When Made

As an initial matter, Bayer argues Plaintiffs cannot prove that: (1) zinc and vitamin E ***do not*** support prostate health; (2) lycopene and selenium ***do not*** support prostate health; and (3) selenium ***does not*** reduce the risk of prostate cancer. Accordingly, Bayer contends that each claim is based on "lack of substantiation" and seeks summary judgment on each allegation as it relates to representations regarding each nutrient for the relevant segment of the Class Period. Bayer's first two contentions argue summary judgment should be granted with respect to the Prostate Health Claim, also referred to by Bayer as the structure/function claim, and Bayer's third contention argues summary judgment should be granted with respect to the Prostate Cancer Claim. The Court addresses each in turn, dividing the arguments into smaller segments of the overall Class Period where applicable.

a. Zinc and Vitamin E and the Prostate Health Claim

First, Bayer argues summary judgment should be granted with respect to representations relating to zinc and vitamin E because Plaintiffs have admitted that these claims are based on lack of substantiation rather than proof of falsity. In support, Bayer relies on Dr. Milman's report and deposition transcript, wherein Dr. Milman states that he is "aware there is a lack of substantiation for [the statements that zinc and vitamin E play a role in maintaining prostate health]." (Doc. No. 172, Weiss Decl., Ex. A, Milman Report

at 46 n.2; Ex. B, Milman Depo. at 53:10-23.) More importantly, Bayer argues Dr. Milman, who is Plaintiffs' designated science expert, admits that there is no proof that zinc and vitamin E ***do not*** support prostate health. (Doc. No. 172 at 13:3-20) (emphasis added). Bayer cites the following deposition testimony of Dr. Milman in support.

> Q. I'm asking you to point me to convincing—what you have considered convincing research that the zinc in those products and, let me add during the class period, did not support prostate health?
>
> . . .
>
> A. You're asking me to provide you examples of studies that prove a negative, and there are no such studies, to the best of my knowledge, studies that have proven that—people just don't publish negative studies, in general.

(Doc. No. 172, Weiss Decl., Ex. B, Milman Depo. at 75:5-14.)

> Q. Correct. So my statement is correct, you can't point me to studies that you personally conclude provide convincing evidence that zinc in Men's Health and Men's 50+ do not support prostate health, correct?
>
> A. Correct. I cannot point you to a study, a zinc supplementation study in healthy men with healthy prostates to answer the question whether zinc supplementation maintains prostate health.

(*Id.* at 77:2-10.)

> Q. There's no convincing evidence that vitamin E in the context of Men's Health and Men's 50+ that is taken with selenium does not support prostate health, correct?
>
> A. Correct. I'm not aware of any evidence in which selenium and vitamin E were tested concurrently in well-conducted studies at the doses in the products and answer the question that you proposed.

(*Id*. at 82:7-15.)

Notwithstanding Plaintiffs' inability to point to any proof that zinc and vitamin E ***do not*** support prostate health, Bayer contends there is a large body of scientific research that proves that these nutrients ***do support*** prostate health. (Doc. No. 172 at 13.) In support, Bayer relies on Dr. Blumberg's report and the following excerpts from Dr. Blumberg's deposition. (Doc. No. 172, Blumberg Decl., Ex. A at 31-37.)[51]

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[51] Although not cited to directly by Bayer, Blumberg states the following conclusions regarding the zinc, vitamin E, and prostate health.

> Despite a lack of human trials isolating the effects of zinc supplementation and mixed data as it relates to prostate cancer risk, observational studies affirm the essential role of zinc in controlling the physiological function of the prostate gland while also demonstrating the importance of plasma zinc

Q. Qkay. Absent any type of clinical trial on trial zinc's effects on prostate health, we're still basically speculating on the cause and effect relationship of zinc on prostate health, correct?

A. No. It's a structure function claim in this case for zinc. So we're not talking about a cause and effect of any disease. We're just saying that zinc is important for the function of the prostate gland.
So it's clear from lots of studies that zinc is an essential mineral to support the proper functioning of the — seminal fluid. If there's no zinc, seminal fluid will not protect sperm. It will not be of the correct viscous nature. So it won't work to promote reproduction when that's going to happen.
So it's absolutely clear, and any textbook will tell you, that zinc concentrates in the prostate at higher levels than any other tissue, and that zinc is absolutely essential for the function of the prostate gland, this particular function of maintaining levels of citrate in the seminal fluid. That is a function of the prostate gland.
My evaluation, I'm trying to cover all BPH and prostate cancer, and so on, when I'm talking about all of these nutrients. But in a structure function claim, I'm basing my statement that zinc is essential to the function of the prostate gland because of its essential role in maintaining and producing healthy seminal fluid, which is a major function of the prostate gland.

(Doc. No. 172, Weiss Decl., Ex. F, Blumberg Depo. at 198:23-200:3.)

Q. And I wasn't referring to the claim. I guess what I was trying to get at was, you said earlier when we talked about clinical trials give us the cause and effect, sort of, relationship, we get a hypothesis, and some evidence from observational, and so therefore without any clinical trials, I was saying we still don't know the cause and effect on zinc, do we?
. . .

A. That's correct. I'm talking about zinc playing a role in supporting a healthy prostate, and it does so, I know, I mean the evidence is unequivocal, in supporting the function of the production of healthy seminal fluid.

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concentrations in reduced cancer and BPH risk. Furthermore, zinc's antioxidative properties contribute to overall health by inhibiting cell damage, and particularly to the health of the prostate given zinc's affinity for accumulating in the prostate gland. Therefore, zinc plays an important role in promoting and maintaining prostate health.

(Doc. No. 172, Blumberg Decl., Ex. A, Expert Report at 34:5-11.)

While some of the above studies indicate a null effect, the mixed data does not nullify those observational studies and randomized clinical trials demonstrating a beneficial relationship between vitamin E and prostate health and potentially the reduction of prostate cancer risk. Additionally, the evidence appears strongest that vitamin E has a beneficial effect on the risk of prostate cancer in smokers. In my opinion, the overall body of vitamin E data in conjunction with the well-established antioxidant properties of vitamin E indicates vitamin E supports prostate health.

(*Id*. at 36:1-7.)

(*Id*. at 200:4-20.)

In response, Plaintiffs argue that zinc and vitamin E do not support prostate health and may actually hurt prostate cancer patients, and that the advertising "at issue" centered only on lycopene and selenium, and not on zinc and vitamin E. With regard to the first argument, Plaintiffs cite to Zhang *et al.* (2009) and Lawson *et al.* (2007). Specifically, Plaintiffs contend that the Zhang study showed that "[l]ong-term zinc intake from multivitamins . . . was associated with a ***doubling in risk***" of prostate cancer," (Doc. No. 212, Blood Decl., Ex. 34, Zhang Study), and that the Lawson study found an "increased risk of prostate cancer mortality among men with heavy multivitamin use who took a zinc supplement," (Doc. No. 212, Blood Decl., Ex. 35, Lawson Study). Plaintiffs also state that Dr. Milman testified that "SELECT provides convincing evidence that vitamin E" increases the "risk of prostate cancer." (Doc. No. 212, Blood Decl., Ex. 31, Milman Depo. at 78:23-79:10.) Moreover, notwithstanding the potential harmful effects of zinc, Plaintiffs argue that Dr. Milman testified that there is no evidence that zinc or vitamin E supplementation plays a role in maintaining prostate health.

> Q: . . . . So is it your opinion that there is a lack of substantiation for the claim that vitamin E supports prostate health?
> . . . .
> A. My opinion is that vitamin E, supplements or vitamin E as part of the two products given to men who are – who are otherwise healthy and with a normal prostate, there's no evidence that vitamin E supplements to such people plays a role in maintaining prostate health.
> Q. All right. So let's talk about – and do you have the same opinion with respect to zinc?
> A. Yes.

(*Id*. at 53:10-23.)

With regard to the second argument, Plaintiffs contend that Bayer did not "concoct a vitamin E/zinc strategy until expert reports" were exchanged, and thus any "post hoc" untimely "Hail Mary" attempt should be rejected by the Court.[52] This argument is then

[52] Plaintiffs cite to many instances in the record when, according to Plaintiffs, Bayer stated that lycopene and selenium were the driving nutrients behind the Prostate Claims. *See*, *e.g.*, (Doc. 190, Blood Decl., Ex. A, Maronick Report ¶ 40) (stating that Bayer promoted lycopene and selenium "as the ingredients which promoted prostate health and/or reduced the risk of prostate cancer"); (*Id*. at ¶35) (discussing the transition

re-enforced by Dr. Milman's rebuttal report, wherein he states that: "It is my understanding that Bayer's labeling and marketing representations do not link supposed prostate health benefits to vitamin E and/or zinc. Dr. Blumberg, however, opines that vitamin E and zinc also play a role in maintaining prostate health. However, based on my experience and expertise, I am aware that there is a lack of substantiation for Dr. Blumberg's claims." (Doc. No. 142, Weiss Decl., Ex., C at 3 n.8)

Although Plaintiffs make a valiant effort to stress the potential harmful effects of zinc and vitamin E, and argue that neither nutrient should be considered when assessing the truth or falsity of the Prostate Health Claim, the Court finds both arguments without merit. First, Plaintiffs' argument that zinc and vitamin E may actually hurt prostate cancer patients is unsupported, misconstrues the evidence, and does not take into account recommended dosage instructions displayed on the Products' packaging. This was confirmed by Dr. Milman in his deposition:

> Q. Well, so, Lawson is irrelevant on two levels. Number one, it deals with men who report an excessive use of multivitamins, and that's – that would be not the products when taken as directed here. So Lawson dealt with multivitamins ingested more than seven times per week. In addition, Lawson is a study that specifically had to do with multivitamins and not specifically selenium and lycopene; is that right?
> A. That is correct.

(Doc. No. 222, Hussy Decl., Ex. C, Milman Depo. at 51:6-14.)

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from lycopene, as the key ingredient, to selenium); (Doc. 190, Blood Decl., Ex. N, 10/13/11 Nunziata Depo. at 13:16-14:5) (describing that the introduction of the prostate health claims were tied to lycopene); (*Id.* at 32:19-33:1) (stating that lycopene was the ingredient that supports the prostate health message at 2005); (*Id.* at 80:8-15) (finding that Bayer began using selenium as the support for the prostate health claims in 2006); (*Id.* at 108:16-109:7) (stating "selenium to support prostate" was the "reason to believe"); (Ex. 6, 5/11/10 Nunziata interview at 19:21-20:4) ("My advertising clearly was around one in three men will develop prostate issues. One-A-Day Men's was specially formulated with selenium to support prostate health. That is consistent with all of the messaging that I produced while I was on the brand."); (Ex. 40, 2008 email) (stating that selenium was adopted as the "support ingredient" in place of lycopene); (Ex. 41) (depicting the labeling transition from lycopene to selenium); (Ex. 42) (showing the dramatic growth behind the new "lycopene/prostate" message); (Ex. 43) (stating that the "Special Ingredient" was selenium); and (Doc. No. 73, Ex. 25) (citing television ads "with Lycopene, which Harvard studies suggest may help prostate health").

Moreover, Bayer clearly represented that zinc and vitamin E support prostate health, not that the nutrients prevent against or reduce the risk of prostate cancer. Thus, Plaintiffs' argument that the nutrients may in fact hurt prostate cancer patients does not raise a genuine dispute regarding the false or deceptive nature of Bayer's representations. Finally, although Plaintiffs claim that Dr. Blumberg improperly relies on limited *in vitro*, animal, observational, or small-scale studies to conclude that vitamin E helps support a healthy prostate, Dr. Milman, Plaintiffs' science expert, explicitly states that such studies can be used when evaluating a structure/function claim such as this. (Doc. No. 212, Blood Decl., Ex. 31, Milman Depo. at 209:18-211:24.) Thus, Plaintiffs seems to contradict their own arguments regarding the types of studies and research that can be considered when evaluating a structure/function claim. Nonetheless, even if the Court found Dr. Blumberg's testimony unpersuasive on this ground, Plaintiffs have the ultimate burden to show that the statements at issue are false or misleading, not Bayer.[53]

Second, Plaintiffs' argument that Bayer should not be permitted to rely on zinc and vitamin E to substantiate the Prostate Health Claim is misguided. In a false advertising claim, whether or not the representations at issue are false or misleading must be made based on the entirety of the representation. *See Brockey*, 107 Cal. App. 4th at 100, 131 Cal. Rptr. 2d 746, 756 (stating that "the primary evidence in a false advertising case is the advertising itself."). Thus, Plaintiffs cannot elect to disregard certain parts of the representation to prove or disprove their claims. Furthermore, and perhaps more telling, although Plaintiffs try to mischaracterize Bayer's reliance on zinc and vitamin E as a "Hail Mary" attempt that should not be allowed, the record is clear that Plaintiffs were aware that Bayer based this representation on all four nutrients—zinc, vitamin E, lycopene, and selenium. For example, at the January 25, 2010 deposition of Sefali Patel, which Plaintiffs attached to their opposition, Patel was questioned about the effectiveness

[53] Additionally, because Bayer's representations regarding zinc and vitamin E only relate to "prostate health" and not the prevention of "prostate cancer," any studies cited by Plaintiffs showing that zinc and/or vitamin E do not prevent prostate cancer are inapplicable.

of zinc, vitamin E, lycopene, and selenium with regards to the Prostate Health Claim. Thus, it is disingenuous for Plaintiffs to now argue that they had no knowledge, prior to the disclosure of expert reports, that the Prostate Health Claim was made in reliance on all four nutrients. Accordingly, in the absence of affirmative scientific evidence available during the Class Period that proves that zinc and vitamin E did not support prostate health, the strength of Bayer's evidence is irrelevant and Plaintiffs' claims are based on "lack of substantiation" rather than proof of falsity.

b. Selenium and Lycopene and the Prostate Health Claim

Second, Bayer contends that Plaintiffs' challenge to the statement that lycopene and selenium support prostate health is based on lack of substantiation because Plaintiffs have admitted that they have no proof the statement is actually false. Bayer cites the following deposition testimony of Dr. Milman in support.

> Q. It is also true to say that with respect to lycopene, your Opinion Number 1, it is not your opinion that there is convincing scientific evidence establishing that Lycopene does not support prostate health, correct?
> A. Correct, to the best of my knowledge, there haven't been any supplemental studies of lycopene in healthy men looking at the maintenance of a healthy prostate.

(Doc. No. 172, Weiss Decl., Ex. B, Milman Depo. at 147:7-15.)

> Q. And you have not rendered an opinion that there existed from the period 2002 through the end of 2005 convincing scientific evidence that selenium did not support prostate health, correct?
> A. Right, I think that's correct. I think we already discussed the issue that I'm not aware of any studies in the time period that – supplemental studies in healthy men without prostate cancer that proved that selenium does not maintain prostate health.

(*Id.* at 123:24-124:9.)

> Q. [I]s there any study that was published in 2006 which you are testifying provides convincing scientific evidence that selenium does not support prostate health?
> A. In 2006, and I'm not aware of any.

(*Id.* at 149:21-150:1.)

Bayer further states that regardless of Plaintiffs' failure to cite to any scientific evidence showing that lycopene and selenium do not support prostate health, there is

ample scientific data that provides support for the Prostate Health Claim. For example, Bayer states that there are well-designed, randomized controlled trials that provide credible evidence that lycopene supplementation inhibits benign prostatic hyperplasia ("BPH") or lower urinary tract symptoms ("LUTS"), both of which are adverse conditions associated with male aging that afflict a significant portion of the otherwise healthy male population. (Doc. No. 172, Blumberg Decl., Ex. A, Blumberg Report at 23-24.) Moreover, Bayer cites to observational data based on the Third National Health and Nutrition Examination Survey, which demonstrated that men with higher serum concentrations of lycopene had a 57% less chance of experiencing LUTS, and experienced pronounced benefits from greater concentrations of lycopene in combination with selenium and/or vitamin E—a combination that was present in the Products throughout the entire Class Period. (Doc. No. 172, Blumberg Decl., Ex. A, Blumberg Report at 25.)

In response, Plaintiffs contend that Dr. Milman plainly testified that there is no evidence that lycopene supplementation plays a role in maintaining a healthy prostate. (Doc. No. 142, Weiss Decl., Ex. A, Milman Report at 6) ("In my professional opinion, and within a reasonable degree of scientific certainty, there is no credible scientific support for Bayer's advertising claims that lycopene supports a healthy prostate and may reduce the risk of prostate and other forms of cancer."). In support, Plaintiffs cite the following excerpts of Dr. Milman's deposition testimony:

> Q. Page 6 of your main report. Now, your terminology is slightly different here than some of the other things I think I've read in your reports, and what you say here is, "In my professional opinion, and within a reasonable degree of scientific certainty, there is no credible scientific evidence that supports Bayer's advertising claims that lycopene supplementation supports a healthy prostate." Do you see that?
> A. I do.
> Q. Now, credible, it's a value laden word, so what's credible to you might not be credible to me and vice versa. So let's take that adjective out, just for purposes of my next question. Is it your opinion that for the time period 2002 through 2009, there is no scientific evidence that supported Bayer's advertising claim that lycopene supplementation supports a healthy prostate?
> A. Yes. And even though it doesn't say it there, the assumption is supports a healthy prostate in an otherwise healthy male.

(Doc. No. 212, Blood Decl., Ex. 31, Milman Depo. at 189:7-190:4.)

Additionally, Plaintiffs contend that the following evidence supports and/or was the basis for Dr. Milman's opinion regarding lycopene: (1) the 2005 FDA Decision Letter; (2) the 2004 National Advertising Division Letter ("2004 NAD Letter"); and (3) countless internal emails and/or documents relied upon by Bayer during the Class Period. First, Plaintiffs contend that the 2005 FDA Decision Letter is proof that lycopene does not support a reduction in the risk of prostate cancer, and thus by implication, also provides definitive proof that lycopene does not promote overall prostate health. (Doc. No. 212, Ex. 22, FDA Letter Nov. 8, 2005.) In support of this contention, Plaintiffs rely on language utilized by the FDA in the 2005 Decision Letter, wherein the FDA stated that "no studies provided information about whether lycopene may reduce the risk of prostate cancer" and "there is no credible evidence supporting a relationship between lycopene consumption . . . and prostate cancer." (*Id.*) Second, with regard to the 2004 NAD Letter, Plaintiffs contend this evidence proves that Bayer knew its representations in the Firehouse Commercial were false and not supported by the evidence. (Doc. No. 212, Ex. 23, 2004 NAD Letter) (stating that the firehouse commercial included the following representation: "by taking One-A-Day with lycopene, men could reduce their risk of prostate cancer or other prostate problems"). Finally, with respect to Bayer's internal documents, Plaintiffs highlight these documents in an attempt to show that Bayer knew that lycopene supplementation was not shown to support prostate health, (Doc. No. 212, Blood Decl., Ex. 32 at JOHNSBAY-265702) ("[N]o clinical data like interventional studies with lycopene supplementation are available and health benefits [of lycopene are] still hypothetical"), and that Bayer knew such claims were false and/or deceptive, (Doc. No. 212, Blood Decl., Ex. 33, July 2007 Email regarding lycopene article/tomato claims).[54]

[54] The email discusses a JNCI article, which stated there was no credible evidence that tomatoes prevent lung, colorectal, breast, cervical or uterine cancers, and that there was very limited evidence that tomatoes can reduce the risk of prostate, ovarian, gastric, and pancreatic cancer. The email also noted that this finding was consistent with the 2005 FDA Letter. (Doc. No. 212, Ex. 24, July 2007 JNCI Article) (finding no credible evidence supporting a relationship between lycopene and cancers). This is not the same email Bayer argued should be excluded on evidentiary grounds.

As stated above, Plaintiffs' conclusory arguments do not raise a genuine dispute as to whether lycopene and selenium support prostate health. With regard to lycopene, although Plaintiffs adamantly argue that there was no "credible evidence" to support Bayer's contentions, the Court finds such arguments contrary to the evidence and based on "lack of substantiation" rather than proof of falsity. *See Stanley*, 2012 WL 1132920, at *3. First, although Plaintiffs' arguments regarding the 2005 FDA Decision Letter are factually correct, they are once again not relevant to the representations at issue in this case. The 2005 FDA Decision Letter was in response to a petition submitted on behalf of the American Longevity, Inc., requesting health claims characterizing the relationship between the consumption of lycopene, tomatoes, and lycopene-containing tomato-based foods, and the reduction in the risk of certain forms of cancer, including prostate cancer. Here, however, Bayer only represented that lycopene supported a healthy prostate, not that emerging research suggested that lycopene supplementation reduced the risk of prostate cancer. Moreover, even though the FDA denied the request in 2005, the Agency did authorize the following qualified health claim: "Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim." (Doc. No. 212, Ex. 22, FDA Letter Nov. 8 2005.) Thus, Plaintiffs reliance on the 2005 FDA Decision Letter is unavailing, and in fact lends support for Bayer's representation.[55]

Second, Plaintiffs reliance on the 2004 NAD Letter is also misplaced. Plaintiffs only cite half of the NAD's conclusions, leaving out material findings made by the NAD

[55] Bayer's objection to the admission of the 2005 FDA Decision Letter is overruled. To the extent relevant, such evidence goes to Bayer's knowledge during the relevant Class Period regarding the scientific substantiation for the Prostate Health Claim. *See United States v. Tamura*, 694 F.2d 591, 598 (9th Cir. 1982) (finding that statements offered to show "knowledge" are non-hearsay under Federal Rule of Evidence 801(d)). However, as stated below, to the extent Plaintiffs attempt to use this information to sustain their burden of proof regarding consumer deception, such arguments are unavailing. *See Haskell v. Time, Inc.*, 965 F. Supp. 1398, 1406-07 (E.D. Cal. 1997) (finding that the "plaintiff must demonstrate by extrinsic evidence, such as consumer survey evidence, that the challenged statements tend to mislead consumers").

regarding lycopene and prostate health, which is the representation at issue in this case. For example, after reviewing the Firehouse Commercial, the NAD stated that the "express claim" concerning lycopene and prostate health is literally accurate because the scientific studies relied upon by Bayer showed a correlation between intake of lycopene and prostate health. The NAD did however also recommend that any "implied claims" that lycopene has a cancer preventive effect be discontinued because the message is much broader than the research at that time could support. Thus, although Plaintiffs' excerpts from the 2004 NAD Letter is factually correct, Bayer never represented that lycopene prevents prostate cancer—instead, Bayer explicitly linked any claims relating to prostate cancer prevention to selenium supplementation.[56]

Finally, the Court finds Plaintiffs inappropriately pluck quotes from internal Bayer documents in an attempt to convey a particular message. The entire lycopene message states:

> "Lycopene facts: Known as a very potent antioxidant. Epidemiological cancers, e.g., incidence of prostate cancer is lower in men with [a] diet rich in tomatoes (excellent source of Lycopene). The suggested Intake Level is 3 mg - 7 mg and deduced from recommended 5-6 servings of fruits and vegetables. However, no clinical data like intervention studies with lycopene supplementation are available and health benefits therefore still hypothetical."

(Doc. No. 212, Blood Decl., Ex. 32 at JOHNSBAY-265702.)

Moreover, Plaintiffs do not state when these internal documents were produced and/or how such documents do not support the structure/function claim linking lycopene to prostate health; a claim that the NAD did not find to be false in 2004. (Doc. No. 212, Ex. 23, NAD Findings.) Thus, because Bayer only represented that lycopene supports "prostate health," the JNIC article and the corresponding 2007 email, both of which were highlighted by Plaintiffs, do not raise a genuine dispute of a material fact regarding Plaintiffs' claims as they relate to lycopene supplementation. Accordingly, in the

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[56] The Court also overrules Bayer's objection to the admission of the 2004 NAD Letter. To the extent relevant, such evidence goes to Bayer's knowledge during the relevant Class Period regarding the scientific substantiation for the Prostate Heath Claim. *See Tamura*, 694 F.2d at 598. Plaintiffs' arguments regarding deception are addressed below.

absence of affirmative scientific evidence available during the Class Period that proves that lycopene does not support prostate health, the strength of Bayer's evidence is irrelevant and Plaintiffs' claims are based on "lack of substantiation" rather than proof of falsity.

c. Selenium and the Prostate Cancer Claim/Prostate Health Claim

Next, Bayer contends summary judgment is warranted regarding its representation that selenium may reduce the risk of prostate cancer (the "Prostate Cancer Claim"). This representation was made in connection with OAD Men's Health from 2006 until the end of the Class Period. Bayer separates the OAD Men's Health Class Period into two separate time periods: (1) claims based on consumer purchases from 2006 until December 2008 (when SELECT was published); and (2) claims based on consumer purchases after December 2008 until the end of the Class Period (May 31, 2010). Bayer argues summary judgment is warranted with regard to both time periods. The Court addresses each in turn.

i. Falsity of the Prostate Cancer Claim from 2006 until December 2008

First, Bayer contends Plaintiffs have not presented any evidence negating the Prostate Cancer Claim from the date the representation was first displayed on OAD Men's Health product packaging in 2006 until publication of the SELECT study in December 2008. In support, Bayer relies on Dr. Blumberg's testimony, which highlights three (3) randomized clinical trials prior to the publication of SELECT, all of which showed a positive correlation between selenium supplementation and a reduction in the risk of prostate cancer, and Dr. Blumberg's findings that no similar studies conducted during that period showed a negative or null result.[57] (Doc. No. 142, Weiss Decl., Ex. F, Blumberg Report at 42.) Moreover, Dr. Blumberg cites to seven (7) observational studies prior to the publication of SELECT that showed a positive correlation between selenium

[57] Clark, *et al.* (1996); Clark *et al* (1998); and Reid *et al.* (2008)

supplementation and prostate cancer prevention, and six (6) similar studies during that same time period that showed a null result. (*Id*. at 43.)

Thus, because the studies Plaintiffs refer to in their Opposition were available to and reviewed by Dr. Milman, Plaintiffs' science expert, prior to his testimony that there was no evidence that selenium supplementation did not reduce the risk of prostate cancer, Bayer contends Plaintiffs' claims for this time period are based purely on an impermissible "lack of substantiation" theory. Bayer cites the following excerpts of Dr. Milman's deposition testimony to support their contention:

> Q. All right. And same thing with respect to reduce the risk of cancer. You have not rendered the opinion that there was convincing scientific evidence from 2002 through the end of 2005 that showed that selenium did not reduce the risk of cancer?
> A. Again, I don't recall any studies, and I'm not sure that I'm aware of any studies in that time period that looked at that question.

(Doc. No. 172, Weiss Decl., Ex. B, Milman Depo. at 124:10-19.)

> Q. So now is my chance to ask you about your opinions, and when you wrote these opinions, you wrote main opinion and a rebuttal opinion. And, as I understand it, when you wrote those opinions and today, you cannot point to any study that was published in 2006 that supports your statement that convincing scientific evidence published in 2006 showed that selenium supplementation has no effect on the incidence of prostate cancer and other forms of cancer, correct?
> A. I believe that's correct.

(*Id*. at 148:19-149:14.)

> Q. And all I asked was as to the statement that selenium supports prostate health, is there any study that was published in 2006 which you are testifying provides convincing scientific evidence that selenium does not support prostate health?
> A. In 2006, and I'm not aware of any.

(*Id*. at 149:20-150:1.)

> Q. As I understand your testimony, in 2007 and in 2008, before the time that SELECT was published, you are not testifying that there was convincing scientific evidence showing that selenium supplementation has no effect on the incidence of prostate and other forms of cancer; is that right?
> A. Correct. There was evidence but not ---
> Q. Not what you would consider convincing scientific evidence?
> A. Right.

(*Id*. at 152:16-153:1.)

Moreover, although Plaintiffs did not organize their Opposition accordingly to the scientific research available pre and post SELECT, Dr. Milman's fourth opinion states: "In my professional opinion, and within a reasonable degree of certainty, convincing scientific evidence published between 2006 and the summer of 2009 showed that selenium supplementation has no effect on the incidence of prostate and other forms of cancer." (Doc. No. 142, Weiss Decl., Ex. A, Milman Report at 31.) Dr. Milman based this opinion on the following studies: Lawson *et al.* (2007) (a study of 295,344 men who were cancer free that found that multivitamin use was not associated with a decreased risk of localized prostate cancer);[58] Allen *et al.* (2008) (a nested case-control study that found that overall plasma selenium concentration was not associated with prostate cancer risk in European men); Tsavachidou *et al.* (2008) (a randomized placebo-controlled phase IIA study of prostate cancer patients that found that selenium supplementation provided little, if any, evidence that selenium supplementation helps maintain a healthy prostate in men who already have prostate cancer); Meyer *et al.* (2009) (a study conducted on men with prostate cancer that found that decreased SEPP concentration in serum might represent a valuable marker for prostate cancer diagnosis); and Gill *et al.* (2009) (a study that examined the association of antioxidants with the risk of prostate cancer that found an inverse association of selenium with prostate cancer in African-American men) (*Id*. at 32-34.)

Dr. Milman also analyzed the differences between SELECT and the NPC Trials, the latter of which was heavily relied upon by Dr. Blumberg, in an attempt to undercut Dr. Blumberg's conclusions that there was substantial scientific support for the Prostate Cancer Claim prior to the publication of SELECT. For example, Dr. Milman states:

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[58] Plaintiffs' Opposition relied on Lawson *et al.* (2007) to show that studies demonstrated that there was no association between selenium use and the incidence of prostate cancer, and that there was actually an increased risk of cancer and diabetes. (Doc. No. 212, Ex. 29, Lawson Study at JOHNSBAY-1490 (finding no correlation and "an increased risk of advanced and fatal prostate cancer").

> (1) there was a strong possibility that chance alone played a major part in the results of the NPC Trial because of the small sample size of the NPC Trial (e.g., 1,312 men);
> (2) the formulation in the NPC Trial (high selenium yeast) may have been more active than L-selenomethionine given in SELECT. The dose of selenium (e.g., 200 µg/day), however, was the same in both studies;
> (3) there were substantial batch-to-batch variations in specific organoselenium compounds in the samples of yeast given to patients in the NPC Trial;
> (4) potential genotoxicity of highly active inorganic selenium compounds, such as selenite, made them potentially unsuitable for long-term prevention;
> (5) lowering of overall body selenium stores with selenite, which is neither absorbed nor retained well;
> (6) the NPC Trial was conducted in men who were chosen for deficient levels of selenium whereas SELECT men generally were replete in selenium at baseline, with median serum selenium levels of 135 ng/ml vs 113 ng/ml in the NPC Trial; and
> (7) the NPC Trial cutoff for the lowest two tertiles was 121.6 ng/ml whereas 78% of men in SELECT had selenium levels >121.6 ng/ml.

(*Id*. at 34-35.)

Although Plaintiffs make an adamant effort to accentuate flaws in Dr. Blumberg's testimony and opinions, the Court finds Plaintiffs' attempts do not raise a genuine dispute of material fact as to the falsity of the Prostate Cancer Claim from 2006 until December 2008. *See Nat'l Union Fire Ins. Co. of Pittsburgh, Pa. v. Argonaut Ins. Co.*, 701 F.2d 95, 97 (9th Cir. 1983) (finding that "neither a desire to cross-examine an affiant nor an unspecified hope of undermining his or her credibility suffices to avert summary judgment"). Looking at Table 1, a list of randomized clinical trials of selenium and prostate cancer, and Table 2, a list of observational studies of selenium and prostate cancer, which were both attached to Dr. Blumberg's report, it appears that the totality of the evidence supports the Prostate Cancer Claim during this time period. Thus, as acknowledged by Dr. Milman, there was no scientific research available from 2006 until December 2008 that conclusively established, in light of other available studies, that selenium supplementation did not help reduce the risk of prostate cancer.

Moreover, as noted by Bayer, Plaintiffs misconstrue the applicability of the Lawson study. The Lawson study found an increased risk of prostate cancer in men taking high levels of multivitamins along with other supplements. Thus, as noted by Dr. Milman, Plaintiffs' science expert, the Lawson study is inapplicable to the instant action because OAD Men's Health presents no risk when taken as directed:

> Q. Well, so, Lawson is irrelevant on two levels. Number one, it deals with men who report an excessive use of multivitamins, and that's – that would be not the products when taken as directed here. So Lawson dealt with multivitamins ingested more than seven times per week. In addition, Lawson is a study that specifically had to do with multivitamins and not specifically selenium and lycopene; is that right?
> A. That is correct.

(Doc. No. 222, Hussy Decl., Ex. C, Milman Depo. at 51:6-14.)

Thus, Plaintiffs have not produced any evidence to show that the scientific research available from 2006 until December 2008 proved that selenium supplementation could not reduce the risk of prostate cancer; nor could they at this late stage in the proceedings, as discovery has closed and the deadline for disclosure and exchange of expert reports has long since expired. To the contrary, and in addition to pointing out deficiencies in Plaintiffs' evidence, Bayer has presented substantial evidence, through Dr. Blumberg's testimony and opinions, that the scientific evidence available prior to SELECT supported Bayer's representation that selenium supplementation may reduce the risk of prostate cancer. Therefore, in the absence of affirmative evidence that scientific research did not support the Prostate Cancer Claim from 2006 to December 2008, the strength of Bayer's evidence is irrelevant and Plaintiffs' claims are based on "lack of substantiation" rather than proof of falsity.

ii. Falsity of the Prostate Cancer Claim from December 2008 until May 31, 2010

Second, Plaintiffs contend that the state of affairs changed after the SELECT study was published in December 2008. Based on this study, Plaintiffs argue that from December 2008 until the end of the Class Period, there was convincing scientific evidence that selenium supplementation ***did not*** reduce the risk of prostate cancer. (Doc. No. 172, Weiss Decl., Ex. B, Milman Depo. at 153:2-8.) In response, Bayer asserts that SELECT was limited to men with pre-existing high baseline selenium levels, and therefore, the study had obvious limitations that cannot raise a genuine dispute of material fact regarding whether scientific evidence from December 2008 until May 31,

2010 showed that selenium supplementation ***could not*** reduce the risk of prostate cancer. Thus, Bayer maintains summary judgment is warranted because publication of SELECT did not affirmatively disprove the Prostate Cancer Claim.

In support, Bayer relies on Dr. Blumberg's testimony, wherein he lists and explains the limitations and perceived flaws of SELECT, and why SELECT cannot be considered definitive proof that selenium ***does not*** reduce the risk of prostate cancer. (Doc. No. 172, Blumberg Decl., Ex. A, Blumberg Report.) These limitations include:

1. Differences in baseline selenium status between men in SELECT (higher baseline) and men in NPC (lower baseline). Indeed, SELECT included almost no participants within the range of selenium baseline status that had shown benefit in the NPC trial; similarly, due to their higher plasma selenium status before supplementation, it is likely that men in SELECT had near-maximal or maximal selenoprotein activities. These differences support the inference that supplementation with selenium is most effective for men having the range of plasma selenium concentration of men that received the benefits of reduction in incidence of prostate cancer in the NPC trial, specifically men with plasma selenium concentrations less than 123.2 ng/mL;

2. An analysis focused on men with low baseline plasma selenium levels (or with other risk factors such as obesity and smoking or with susceptible genotypes) has not been conducted in SELECT. SELECT investigators have received support from the National Institutes of Health to conduct follow up analyses on the participants to determine the long-term effects of having taken either supplement or placebo. Until all of these analyses are completed it is premature to draw final conclusions from the SELECT study;

3. In contrast to the NPC trial, SELECT was conducted during an era when PSA testing was common. Men with a PSA>4.0 ng/mL, a cut-point for increased risk of prostate cancer, were not enrolled in SELECT; indeed, 78 and 48% of the men had a PSA<2.0 and <1.0 ng/mL, respectively, suggesting they presented with a very low risk of the disease before supplementation. In SELECT, over 80% of men received PSA tests each year and those with values >4.0 ng/mL may have been removed from the cohort to receive treatment, which would have affected the study results;

4. Importantly, the SELECT study found only one death from prostate cancer after ~200,000 person-years. Employing conservative assumptions about age and followup time during this study period, 75 to 100 deaths would have been expected based on the National Institutes of Health Surveillance, Epidemiology and End Results (SEER) database. This means that the study participants had a very low risk of prostate cancer to begin with and may not have been representative of the overall male population in the U.S;

> 5. Also, potentially interfering with the results of the SELECT intervention was the allowance of treatment with a prostate cancer preventative drug, finasteride, in 8% of the men enrolled in SELECT. For example, if more men using this drug were randomized into the control groups, then their lower incidence of prostate cancer would mask a potential benefit in the selenium treatment group.

(*Id.* at 18-19.) Dr. Blumberg's report also references several scientific articles published after SELECT, which each noted problems and/or limitations with SELECT's ultimate conclusions. These include: Hoskote *et al.* (2012) (examining the lack of clarity regarding the formulation of the study placebo); Gaby *et. al.* (2012); Rayman *et. al.* (2012) (examining the choice of the most appropriate inclusion criteria for targeting men most likely to show responses to selenium supplements, e.g., those with obesity, who were smokers, and/or had susceptible genetic backgrounds); Ozten- Kanda, *et al.* (2011); Ledesma *et. al.* (2011) (examining the choice of the nutrient doses and form of the selenium supplement); Grundmark *et. al.* (2011), Ledesma *et. al.* 2011, McNeill *et. al.* (2011).[59] However, as stated in the Court's *Daubert* analysis above, because any scientific evidence relied upon by Dr. Blumberg after the conclusion of the Class Period is irrelevant to the determination of whether the Prostate Cancer Claim was false or deceptive when made, such evidence may not be properly considered by the Court.

In response, Plaintiffs contend SELECT is definitive proof that selenium, taken alone or in combination with vitamin E (400 U/day), ***does not*** prevent prostate cancer. In support, Plaintiffs rely on Dr. Milman's report, wherein he states that SELECT showed that "selenium supplementation did not prevent prostate cancer," (Doc. No. 142, Weiss Decl., Ex. A, Milman Report at 34), and that "[b]ecause of the large sample size, the study had significant statistical power to be able to detect small beneficial effects of selenium," (*Id.* at 38). Therefore, Dr. Milman contends that based on the word choice

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[59] Based on these studies, Dr. Blumberg contends that "pre-SELECT studies as well as continuing post-SELECT studies [Ledesma *et al.* (2011)] are still supporting the potential usefulness of selenium and/or vitamin E for prevention of [prostate cancer] and possibly other conditions as well. They also stated that the existing evidence supporting selenium and vitamin E as potential [prostate cancer] chemopreventive agents is possibly enough to justify further efforts in this direction." (Doc. No. 172, Blumberg Decl., Ex. A, Blumberg Report at 20:4-8.)

used by SELECT authors in section E11, wherein they state that the "study definitively demonstrated that selenium, vitamin E and selenium plus vitamin E ***did not*** prevent prostate cancer in the generally healthy heterogenous population of men in SELECT," SELECT is definitive proof that the Prostate Cancer Claim was false from December 2008 until May 31, 2010. (Doc. No. 212, Blood Decl., Ex. 31, Milman Depo. at 144:18-24) (emphasis added).

In addition, Plaintiffs argue that several scientific articles published after SELECT have each concurred in this result. For example, Plaintiffs point to Gann *et. al.* (2009), wherein the authors noted that given SELECT's statistical power, it is unlikely that the study missed detecting a benefit from selenium of even a very modest size. (Doc. No. 142, Weiss Decl., Ex. A, Milman Rebuttal Report at 35.) Plaintiffs further argue that the Gann study concluded that it now appears more likely that the unexpected results on prostate cancer from the earlier selenium trials (e.g., the NPC Trials) were due to chance. (*Id.* at 41-42.) Accordingly, Plaintiffs contend that Bayer elected to ignore both SELECT, (Doc. No. 212, Ex. 60 at BAYER-332717), and articles commenting on the findings articulated in SELECT, (Doc. No. 212, Ex. 30). Plaintiffs cite to the following excerpts from Sefali Patel's deposition to support this contention.

> Q. As a pharmacist and a healthcare professional, given the concerns raised by the Chan study, the Zhang study, and the Lawson study, that we just discussed, were you at all concerned that some of the patients taking OAD men's vitamins to reduce their risk of developing prostate cancer might be increasing their risk of aggressive prostate cancer as a result of taking the vitamins?
> A. Well these are three studies among a lot of other data and a very small subset of patients were identified in this. I'm not concerned.
> Q. So you guys gave no weight to these studies in your consideration of OAD men's promotional claims?
> A. They were assessed. However, we felt comfortable.

(Doc. No. 212, Ex. 2, Patel Depo. at 164:16-165:13.)

Finally, Plaintiffs maintain that although Bayer's lawyers try to discredit the importance of SELECT, internally Bayer disagrees with its lawyers. For example, Plaintiffs allege that Bayer's internal documents and employees confirm that Bayer viewed SELECT's findings as conclusive and damaging to the Prostate Claims. (Doc.

No. 212, Blood Decl., Ex. 36, Prostate Cancer Foundation email at JOHNSBAY-87220) (noting that after SELECT "Selenium . . . looks like it not only has no effect on prostate health but as a supplement, it may do more harm in prostate cancer patients"); (Doc. No. 80, Hussy Decl., Ex. B, Durkee Depo. at 38:13-19) (acknowledging that by at least April 2008 competent and reliable evidence existed showing there was no association between selenium and prostate cancer); (Doc. No. 212, Blood Decl., Ex. 37, 12/15/08 email) (stating the weak science for the 1 in 3 prostate insight); (Doc. No. 212, Blood Decl., Ex. 38, 2008 email from Bayer's Brand Manager) (stating that "given the recent studies showing negative results," Bayer needs to "start searching for a potential replacement [to selenium] now so we can stay ahead of any developments"). Thus, Plaintiffs allege Bayer cannot now refute these prior concerns.

Although Plaintiffs' arguments regarding the truth or falsity of the Prostate Cancer Claim and the Prostate Health Claim after SELECT raise genuine concerns regarding the "substantiation" and support for the representation from December 2008 until May 31, 2010, Plaintiffs have not raised a genuine dispute as to the continued efficacy of the NPC Trials, at least for the segment of the male population who do not have higher base-line selenium levels. Thus, as stated above, even though Plaintiffs raise potential concerns as to the "substantiation" for Bayer's representations, and whether such representations were based on "credible evidence," litigating such an action is not within the providence of private plaintiffs under the UCL and CLRA. *See Stanley*, 2012 WL 1132920, at *3 (stating that only prosecuting authorities, and not private individuals, can bring an action for lack of substantiation); *Chavez*, 2011 WL 2150128, at *5-7 (dismissing UCL and FAL claims based on lack of substantiation, explaining that "there is no basis in California law to shift the burden of proof to a defendant in a representative false advertising and unlawful competition action").

Moreover, the Court finds that even the evidence submitted by Plaintiffs supports the continued prevalence of the NPC Trials and the possibility that selenium supplementation ***may still*** be crucial in reducing the risk of prostate cancer. For example,

the Chan study noted that even after SELECT, additional research needs to be conducted to further understand the interplay between selenium supplementation, genetics, and prostate cancer prevention. (Doc. No. 212, Ex. 30 at JOHNSBAY-1475.) Specifically, the Chan study noted that although SELECT "provided strong evidence for a null association for oral supplementation with [selenium] and overall prostate cancer risk, it did not address the questions of whether higher selenium levels affect the risk of incident advanced-stage prostate cancer or risk of progression in men who already have prostate cancer and how genetics may modify associations between selenium and prostate cancer." (*Id.*) Thus, the Chan study stated that it "is possible that selenium intervention for prostate cancer may still be important for men with specific genotypes or with specific tumor phenotypes." (*Id.*)

Furthermore, although Plaintiffs are correct, in that Bayer was aware of SELECT's ultimate conclusions, it is also clear that Bayer still believed that the "overall body of the evidence [regarding selenium and prostate health/prevention of prostate cancer] was still positive." (Doc. No. 80, Hussy Decl., Ex. B, Durkee Depo. at 38:17-19.) This is supported by relevant excerpts from Shane Durkee's Deposition:

> Q. Are there studies that are contrary to this study [NPC] that have different results that show there is no association between selenium and prostate cancer?
> A. Yes.
> Q. And in April 4, 2008 were there many studies that showed there was no association between prostate cancer and selenium?
> . . .
> A. What do you mean by "many"?
> Q. Was there competent and reliable scientific evidence in 2008, April 4, that there was no association between selenium and prostate cancer?
> A. Sure. There was trials that show it. But the overall body of evidence was still positive.

(*Id.* at 37:25-38:19.)

Therefore, contrary to Plaintiffs' assertions, this is also not the type of case where Bayer's representations are per se false because they are completely unsubstantiated. *See Novartis Consumer Health, Inc. v. Johnson & Johnson Merck Consumer Pharm. Co.*, 290 F.3d 578, 590 (3d Cir. 2002) ("[A]lthough the plaintiff normally has the burden to

demonstrate that the defendant's advertising claim is false, a court may find that a completely unsubstantiated advertising claim by the defendant is per se false without additional evidence from the plaintiff to that effect."). Accordingly, in the absence of affirmative evidence that scientific research did not support the Prostate Cancer Claim from December 2008 until May 31, 2010, the strength of Bayer's evidence is irrelevant and Plaintiffs' claims are based on "lack of substantiation" rather than proof of falsity.[60]

Thus, as further articulated above, the Court finds Plaintiffs have not presented sufficient evidence to raise a genuine dispute of material fact regarding the falsity of the Prostate Health Claim, as it relates to zinc, vitamin E, lycopene, and selenium, and the falsity of the Prostate Cancer Claim, as it relates to selenium. *See Novartis Consumer Health, Inc.*, 290 F.3d at 590. Accordingly, the Court GRANTS Bayer's motion for summary judgment finding both claims are based on "lack of substantiation" rather than proof of falsity. *Eckler*, 2012 WL 5382218, at *3 ("There is a difference, intuitively, between a claim that has no evidentiary support one way or the other and a claim that's actually been disproved. In common usage, we might say that both are 'unsubstantiated,' but the caselaw (and common sense) imply that in the context of a false advertising lawsuit an "unsubstantiated" claim is only the former."). As a result, any determination regarding the substantiation for the Prostate Claims during the Class Period, in light of the available scientific evidence, must be made by the FDA.

2. Whether the Prostate Statements Were Likely to Deceive

Regardless of whether the Prostate Claims are provably false, Plaintiffs allege they can prevail under the UCL and CLRA by showing that the challenged representations have the capacity or likelihood to "deceive a reasonable consumer." *Day*, 63 Cal. App. 4th at 332; *Brockey*, 107 Cal. App. 4th at 100, 131 Cal. Rptr. 2d 746 (Cal. Ct. App. 2003); *see also Nat'l Council Against Health Fraud, Inc.*, 107 Cal. App. 4th at 1341. Therefore, Plaintiffs maintain Bayer's motion for summary judgment should be denied

[60] This also supports the Court's prior finding regarding selenium and the Prostate Health Claim.

because the determination of whether a reasonable consumer is likely to be deceived is "best left to the jury." *See Asis Internet Servs. v. Subscriberbase Inc*., No. 09-3503(SC), 2010 WL 1267763, at *2 (N.D. Cal. Apr. 1, 2010) (collecting cases). The Court is not persuaded.

Although Plaintiffs are correct that the UCL and CLRA prohibit both false and misleading claims, case law is less than clear as to what a private plaintiff needs to prove to successfully litigate a cause of action alleging misleading or deceptive practices. However, the Court finds the decision in *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 89 (D.N.J. 2011) instructive, and highly applicable to the instant action. In *Smajlaj*, the plaintiffs alleged they were deceived and mislead by the labeling and advertising on Campbell's lower-sodium soups, which claimed to have 25% less sodium. *Id*. at 99. Thus, because the soups actually had the same or nearly equal sodium content of the regular brand of soup of the same variety, the plaintiffs in *Smajlaj* alleged that the representations were actionable because they were likely to deceive a reasonable consumer. *Id.* The *Smajlaj* court agreed, finding that even though the statement was actually true, in that the lower sodium soups did have 25% less sodium than the average sodium content of all Campbell's soups, a reasonable consumer would believe the representation was made in regard to the same type of soup and not the average of all Campbell's soups. *Id*.

Such is not the case here. Plaintiffs' arguments that the Prostate Claims are deceptive and/or misleading are confusing at best and rely on circular reasoning.[61] For example, although Plaintiffs fervently argue that they do not have to prove that Bayer's representations are in fact false to proceed under the UCL and CLRA, (Doc. No. 212 at 11-12), Plaintiffs simultaneously argue that their "evidence is not limited to criticisms

[61] Bayer also makes note of this in its reply: "Plaintiffs also make an argument that they need not show that Bayer's statements are false, only that they are 'likely to deceive.' This argument is circular. Plaintiffs contend that Bayer's statements that the Products' ingredients 'support prostate health' and that selenium may reduce the risk of prostate cancer are 'likely to deceive' because there is 'no credible evidence' or 'inadequate' evidence to support them. Thus Plaintiffs' 'likely to deceive' claims all are squarely based on purported lack of substantiation." (Doc. No. 212 at 7 n.6.)

about the amount of substantiation Bayer had, but that the advertisements are not true," (*Id*. at 15:1-7). Thus, in an attempt to plead around the "lack of substantiation" bar to recovery, it appears Plaintiffs are alleging that Bayer's representations are deceptive because they are unsubstantiated. However, as stated above, Bayer's representations are not provably false, and private plaintiffs under the UCL and CLRA are prohibited from bring a "lack of substantiation" claim. *See Eckler*, 2012 WL 5382218, at *1.

Therefore, although Plaintiffs' arguments would be enough to defeat a motion to dismiss, and were in fact enough to defeat Bayer's prior motion to dismiss, (Doc. No. 35), such arguments are insufficient to defeat Bayer's instant motion for summary judgment under Rule 56. *See Haskell v. Time, Inc*., 965 F. Supp. 1398, 1406-07 (E.D. Cal. 1997) (finding that the "plaintiff must demonstrate by extrinsic evidence, such as consumer survey evidence, that the challenged statements tend to mislead consumers"); *Nissan Fire & Marine Ins. Co., Ltd.*, 210 F.3d at 1106 ("The moving party may produce evidence negating an essential element of the nonmoving party's case, or, after suitable discovery, the moving party may show that the nonmoving party does not have enough evidence of an essential element of its claim or defense to carry its ultimate burden of persuasion at trial."). Thus, in stark contrast to *Smajlaj*, where the plaintiffs clearly articulated how the representations at issue were deceiving, and had proof of actual deception, here, Plaintiffs have not articulated how the Prostate Claims were deceptive, nor have they presented any proof of actual deception. *See William H. Morris Co. v. Group W. Inc*., 66 F.3d 255, 258 (9th Cir. 1995) (per curiam) (finding that the plaintiff had failed to meet its burden of demonstrating that "a significant portion" of recipients were misled by the defendant's letter because plaintiff's evidence consisted solely of the testimony of two of 300 recipients, of the company president, and of an employee who had received phone calls from confused recipients).[62] As a result, there is simply no

[62] *See Merck Consumer Pharm. Co. v. Smithkline Beecham Corp*., 960 F.2d 294, 297, 298 (2d Cir. 1992). In *Merck*, the court concluded that a plaintiff must demonstrate that "a statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement" to state a cognizable claim. 960 F.2d at 298.

evidence to put before the jury on the issue of deception. Accordingly, Bayer's motion for summary judgement regarding the deceptive and misleading nature of the Prostate Claims during the Class Period is GRANTED.

CONCLUSION

For the reasons set forth above, the Court makes the following findings regarding the parties' respective motions:

1. DENIES Plaintiffs' motion to exclude Dr. Blumberg's expert testimony, (Doc. No. 141);
2. DENIES Bayer's motion to exclude Dr. Milman's expert testimony, (Doc. No. 142);
3. GRANTS Bayer's motion to exclude Dr. Maronick's expert testimony, (Doc. No. 155);
4. GRANTS Bayer's motion for summary judgment, (Doc. No. 172); and
5. DENIES AS MOOT Bayer's motion to exclude Mr. Elmore's expert testimony, (Doc. No. 157), Bayer's motion to strike Mr. Elmore's supplemental report, (Doc. No. 161), Plaintiffs' motion to exclude Dr. Dhar's expert testimony, (Doc. No. 162), and Plaintiffs' motion to exclude Dr. Hughes' expert testimony, (Doc. No. 156). The Clerk of Court is directed to enter judgment and close the case.

The Clerk of Court is instructed to enter judgment and close the case.

IT IS SO ORDERED.

DATED: April 10, 2013

Hon. Anthony J. Battaglia
U.S. District Judge