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9	UNITED STATES D	DISTRICT COURT
20	CENTRAL DISTRIC	Γ OF CALIFORNIA
21	RAYMOND ALVANDI, on behalf of	Case No: 15-cv-1503
22	himself and others similarly situated,	CLASS ACTION
	Plaintiff,	
23	i iunitiii,	COMPLAINT FOR VIOLATIONS OF CALIFORNIA AND RHODE ISLAND
24	V.	CONSUMER PROTECTION
25	CVS PHARMACY, INC., and LANG	STATUTES AND BREACH OF
26	PHARMA NUTRITION, INC.	EXPRESS AND IMPLIED WARRANTIES
27		
28	Defendants.	DEMAND FOR JURY TRIAL

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Plaintiffs Raymond Alvandi on behalf of himself, all others similarly situated, and the general public, by and through his undersigned counsel, hereby brings this action against defendants CVS Pharmacy, Inc. ("CVS"), and Lang Pharma Nutrition, Inc. ("Lang") and alleges the following upon his own knowledge, or where he lacks personal knowledge, upon information and belief, including the investigation of his counsel.

### INTRODUCTION

- 1. CVS markets and sells a store-brand CoQ10 softgel dietary supplement called "CVS Enhanced Absorption Formula CoQ-10" ("CVS Enhanced"). A true and correct copy of the CVS Enhanced packaging is attached hereto as Exhibit 1.
- 2. In order for a softgel dietary supplement to be absorbed after ingestion, it must first rupture then dissolve. The U.S. Pharmacopeial Convention (USP), an organization that promulgates and publishes testing standards in the drug and dietary supplement industries, has set a minimal threshold of rupture within 15 minutes, and 75% dissolution, for a supplement to exhibit reasonably effective bioavailability through absorption.<sup>1</sup>
- Despite CVS's claim of "Enhanced Absorption," independent laboratory tests 3. demonstrate that the softgels used for the product fail to timely rupture (in some cases, not even rupturing after an hour). In addition, the identical softgels (packaged by the same supplier for other retailers as well as for a different CVS product) exhibit substantially less than the 75% dissolution that USP considers necessary in order to provide sufficient absorption for reasonably effective bioavailability. As a result, CVS' product claim of "Enhanced Absorption" is literally false or highly misleading.
- 4. Further, because these softgels fail to rupture or meet the USP-standard minimum 75% dissolution for effective absorption and bioavailability, CVS' additional product claims based on the alleged effectiveness of its softgels are also false or misleading, including for example CVS's representations that CVS Enhanced is for "HEART &

<sup>&</sup>lt;sup>1</sup> Bioavailability is the propensity of a substance to reach the systemic circulation, which decreases with incomplete absorption (by comparison, medicine intravenously injected is 100% bioavailable).

MUSCLE HEALTH," "Support[s] heart & vascular health," and is "Beneficial for those taking cholesterol-lowering stain drugs."

- 5. In addition, CVS engages in comparative advertising on its packaging, expressly inviting the consumer to "Compare to Qunol Ultra CoQ10," while also using packaging that closely simulates Qunol's packaging trade dress design, and placing CVS Enhanced on the shelf immediately next to Qunol. But CVS's representation that CVS Enhanced is comparable to Qunol is false or at least misleading because, as demonstrated by independent laboratory testing, Qunol does not exhibit the rupture and dissolution failures that CVS Enhanced exhibits.
- 6. Plaintiff brings this class action to remedy the damage caused to him and other consumers by CVS's false advertising and defective CVS Enhanced product.

### **JURISDICTION & VENUE**

- 7. The Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d)(2), the Class Action Fairness Act, because the matter in controversy exceeds the sum or value of \$5,000,000 exclusive of interest and costs, and because more than two-thirds of the members of the class reside in states other than the states in which CVS and Lang are citizens.
- 8. The Court also has jurisdiction pursuant to 28 U.S.C. § 1331 because this action contains claims arising under the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301 *et seq*. The Court has supplemental jurisdiction over the pendent state law claims pursuant to 28 U.S.C. § 1367, as they are so related to the claims within the Court's original jurisdiction that they form part of the same case or controversy.
- 9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because plaintiff resides in and suffered injuries as a result of CVS and Lang's acts in this district, many of the acts and transactions giving rise to this action occurred in this district, and CVS and Lang are authorized to conduct business in this district, do substantial business in this district, have intentionally availed themselves of the laws and markets of this district, and are subject to personal jurisdiction in this district.

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### **PARTIES**

- 10. Plaintiff Raymond Alvandi is a resident of Glendale, California, in Los Angeles County.
- 11. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895.
- 12. Defendant Lang Pharma Nutrition, Inc. is a Rhode Island corporation with its principal place of business at 20 Silva Lane, Middletown, Rhode Island 02842.

### **FACTS**

### A. Coenzyme Q10

- 13. CoQ10 is a vitamin-like, anti-oxidant nutrient produced naturally in the heart, liver, kidneys, and pancreas. It plays a vital role in cellular energy production and is known to provide various benefits, especially to heart health. Although most commonly known in abbreviated form as CoQ10, it is more formally referred to as ubiquinone, ubidecarenone, or uniquinol, depending upon its form.
- 14. Generally, the body produces sufficient CoQ10, but blood levels can be depleted by aging, heart disease, and some medications, especially statins. For those wishing to replace depleted CoQ10 or otherwise increase blood levels to realize the substance's potential health benefits, dietary supplementation is common.
- 15. In order to provide a benefit, a nutrient must first be absorbed into the body's systemic circulation in an adequate amount. Thereafter, it is carried to various organs and tissues for eventual uptake by the cells. Accordingly, to realize any benefits of CoQ10 supplementation at a cellular level, an individual must achieve effective or optimum CoQ10 blood levels.
- 16. While CoQ10 can provide health benefits, it also has a well-known drawback: it is not soluble in water, and poorly soluble in fat. In its raw form, CoQ10 is a crystalline powder. It has been reported that the bioavailability of raw CoQ10 powder is less than 10%. This is problematic for consumers who use CoQ10 supplements because the body and digestive tract are aqueous, and the absorption of a substance depends on its first dissolving.

- To address this problem, some dietary supplement manufacturers have invented technologies for modifying orally-administered CoQ10 to increase its solubility, and thereby its bioavailability.
- 17. Accordingly, the formulation of a CoQ10 dietary supplement is crucial to its bioavailability. CoQ10 supplements have been available to consumers for approximately 20 years, but initial CoQ10 supplements offered on the market, which were little more than raw CoQ10 powder, were not well-absorbed because of CoQ10's hydrophobicity and large molecular weight. It has long been known that the absorbability of CoQ10 can be increased when taken with food. The absorption of poor water-soluble drugs—that is fat soluble vitamins like CoQ10—is increased especially when administered with or after a meal containing fat, in part because fats stimulate bile salt secretion, which assists in drug and vitamin solubilization because bile salts are natural emulsifiers. However, taking such unsophisticated CoQ10 supplements with food does not, alone, significantly enhance absorption.
- 18. Consumers of CoQ10 supplements—who are familiar both with CoQ10's benefits, and its poor absorption—seek out technologies that purport to increase its absorbability. Thus, according to the Better Business Bureau's National Advertising Division, in December 2009, "several manufacturers currently advertise 'absorbability' as one of the features of their CoQ10 supplements."
- 19. Over the past several years, dietary supplement manufacturers have taken a variety of approaches to boosting the bioavailability of orally-administered CoQ10 supplements—some as simple as suspending CoQ10 powder in oil, others complex, patented processes—with varying degrees of success. Because the body is comprised far more of water than fat, in order to enhance the substance's dissolution, and thus absorbability, some companies seeking to enhance CoQ10 dissolution and hence absorption try to make the compound maximally water-soluble. Examples of different patented technologies employed in CoQ10 supplements include Bio-Solv and Hydro-Q-Sorb (Tishcon Corp.), Q-Sorb

(Nature's Bounty), All-Q (DSM Nutritional Products Ltd.), and VESIsorb (SourceOne Global Partners, LLC).

20. CoQ10 has become one of the most popular supplements in the United States, with hundreds of different brands on the market, and sales in 2011 of over \$500 million.

### **B.** The United States Pharmacopeial Convention

- 21. USP is a nonprofit scientific organization founded in 1820 in Washington, D.C., whose participants, working under strict conflict-of-interest rules, and using careful scientific method and consensus, set enforceable standards for the quality of drugs, and voluntary standards for the quality of vitamins and dietary supplements. Known as Reference Standards, these are updated and published annually by USP and the National Formulary in a compendia called the USP-NF, which consists of Monographs, General Chapters, and General Notices. Monographs include the name of an ingredient or preparation; its definition; its packaging, storage, and labeling requirements; and its specification (i.e., a series of tests, procedures for the tests, and acceptance criteria that require use of the official USP Reference Standards). General Chapters set forth tests and procedures referred to in multiple monographs. And General Notices provide definitions for terms used in monographs, as well as information necessary to interpret monograph requirements.
- 22. Although compliance with USP's standards concerning dietary supplements is not required by regulation, USP plays a major role in the multi-billion dollar dietary supplement industry, providing the objective (and only) scientifically-valid industry standards against which all supplements may be tested and measured, providing important information about a supplement's intrinsic qualities, and serving as a "level playing field" for comparing two or more products.
- 23. Compliance with an applicable USP monograph means a tested product contains the ingredients listed in the declared amount and potency, and will break down and release into the body within a specified amount of time. Thus, whether or not required by regulation, the testing and measurement of a dietary supplement by the prescribed USP methodologies

and standards provides an objective idea of whether the supplement is likely to be effective when taken orally by a human.

- 24. The type of information that results from USP testing is important to consumers in determining the relative quality (and value) of competing dietary supplements. For example, in a product review of joint health supplements for pets and animals containing glucosamine, chondroitin, and MSM, ConsumerLab.com, a well-respect consumer watchdog organization that does comparative testing, noted that certain formulations "were analyzed for disintegration utilizing [USP] <2040> recommendations," and to obtain a "Pass," a product must "meet recommended USP <2040> parameters for disintegration for dietary supplements[.]"
- 25. In the case of CoQ10 softgels, the USP tests for rupture and dissolution show whether a product is likely to break up early enough in the digestive process to provide an effective amount of the enclosed CoQ10, and, if the product does timely rupture, whether the supplement is likely to adequately dissolve so as to provide reasonable bioavailability. Moreover, USP distinguishes between water-soluble CoQ10 forms (which are commonly known in the industry and to consumers as "enhanced absorption" formulas), and other, non-water-soluble forms (commonly known in the industry and to consumers as "regular" formulas).
- 26. The process of digesting a CoQ10 softgel supplement begins with the timely rupture, or break up, of the gelatin outer shell. This is a necessary prerequisite to absorption because a pill that does not timely rupture will pass through the gastrointestinal tract without dissolution and then absorption commencing as quickly, or at all. Digestion is a relatively quick process, and in some cases, a softgel may *never* rupture. A person consuming such a capsule would pass it without digesting or absorbing any of its contents, realizing *none* of the product's potential benefits or value.
- 27. Even if a CoQ10 softgel ruptures, it must adequately dissolve, because dissolution is the first step in, and a prerequisite to, the absorption of a supplement. Thus,

- information about a supplement's dissolution rate is important information corresponding to the relative effectiveness of a supplement that is orally ingested.
- 28. A true and correct copy of the USP Monograph for CoQ10, designated "Ubidecarenone Capsules" ("USP CoQ10 Monograph"), is attached hereto as <u>Exhibit 2</u>, and expressly incorporated into this Complaint.
- 29. As can be seen in Exhibit 2, the USP CoQ10 Monograph prescribes a maximum time-to-rupture of 15 minutes, and a minimum dissolution rate of 75% for CoQ10 softgels to achieve reasonably effective absorption and hence bioavailability.
- 30. More specifically, the USP CoQ10 Monograph prescribes the following "Performance Tests": "Disintegration and Dissolution <2040>: Meet the requirements of the test for *Disintegration*, except where the product is labeled to contain a water-soluble form of ubidecarenone. Capsules labeled to contain a water-soluble form of ubidecarenone meet the requirements for *Dissolution* as follows." The Monograph then sets forth a procedure and method of calculation, and requires that "NLT [Not Less Than] 75% of the labeled amount of ubidecarenone . . . dissolve[s]."
- 31. The tests for *Disintegration* (sometimes called Rupture) and *Dissolution* (sometimes called solubilization) are set forth in the USP-NF General Chapter on Disintegration and Dissolution of Dietary Supplements, USP-NF General Chapter <2040>, a true and correct copy of which is attached hereto as <u>Exhibit 3</u>, and expressly incorporated into this Complaint.
- 32. Although Chapter <2040> includes sections on both *Disintegration* and *Dissolution*, the specific dissolution procedure set forth in the USP CoQ10 Monograph supplements or replaces the dissolution section in Chapter <2040>.
- 33. As can be seen in Exhibit 3, for *Disintegration*, Chapter <2040> requires "Soft Shell Capsules," like the CVS Enhanced and Qunol softgels, to "[p]roceed as directed under

<sup>&</sup>lt;sup>2</sup> The USP CoQ10 Monograph requires that, "[w]here the product contains a water-soluble form of ubidecarenone, this is so stated on the label."

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## Rupture Test for Soft Shell Capsules," which in turn requires rupture "in not more than 15 minutes."

#### **CVS Enhanced CoQ10** C.

- CVS sells CVS Enhanced for approximately \$25 for a bottle of 30 (100 mg) 34. softgels.
- 35. CVS purchases the CVS Enhanced softgels from a Rhode Island supplier, Lang. Together, CVS and Lang conceived, devised, and created the packaging, including its claims and representations, which CVS presents to the consuming public at its retail locations.
- Lang also supplies CoQ10 softgels identical to those in the CVS Enhanced 36. product to CVS for use in a different CVS CoQ10 product called CVS Ultra CoQ-10. And Lang supplies the same CoQ10 softgels to at least two other retailers, namely Wal-Mart, which sells its Lang-supplied CoQ10 softgels under Wal-Mart's store brand "Equate High Absorption Co Q-10," and Walgreens, which sells its Lang-supplied CoQ10 softgels under Walgreens' store brand "Well Enhanced Absorption Formula CoQ-10."
- These identical private-label CoQ10 softgel products as supplied by Lang to 37. CVS (as both CVS Enhanced and Ultra), to Wal-Mart (as Equate), and to Walgreens (as Well) all employ a patented technology called VESIsorb, invented by a Swiss company, Vesifact, AG, and owned by SourceOne Global Partners LLC ("SourceOne"), a Chicago company that licenses the VESIsorb patented technology to Lang. These identical softgels used for all four products are sometimes referred to herein as the "VESIsorb CoQ10 softgels."
- Lang outsources manufacturing of the VESIsorb CoQ10 softgels to a company 38. in Florida called Swiss Caps USA, Inc. ("Swiss Caps"). Lang sends Swiss Caps raw CoQ10 powder and raw VESIsorb "paste." Swiss Caps then mixes the two and encapsulates the resulting "medicine" (as Swiss Caps calls it) into a gelatin softgel. Swiss Caps ships the completed softgels to a New Jersey packaging company called Nutra-Med, which packages them for Lang (for example, in either CVS Enhanced, CVS Ultra, Wal-Mart Equate, or Walgreens Well packaging). Lang then distributes the packaged VESISorb CoQ10 softgels to its retailer customers, shelf-ready for sale to consumers.

- 39. The VESIsorb technology is described in U.S. Patent No. 8,158,134, a true and correct copy of which is attached hereto as <u>Exhibit 4</u>, and expressly incorporated into the Complaint; and German Patent No. EP1249230B1, a true and correct copy of which is attached hereto as <u>Exhibit 5</u>, and expressly incorporated into the Complaint.
- 40. VESIsorb's U.S. patent states that the "invention relates to compositions in the form of microemulsion preconcentrates," which, "[w]hen contacted with water or with an aqueous medium . . . form microemulsions," which themselves, when "[i]n the aqueous phase, . . . may contain water-soluble substances." (Ex. 4.)
- 41. SourceOne's website for VESIsorb quotes a Dr. Andrew Halpner as saying of VESIsorb, that its "ability to offer bio-enhanced, water-soluble ingredients such as CoQ10... to dietary supplement, functional food and beverage markets, has set a new benchmark for the industry." On the same webpage, SourceOne depicts a product called "Pure encapsulations Ubiquinol VESIsorb." A brochure for the product states that the VESIsorb technology "increases bioavailability of a bioactive that is fat soluble or that has poor water solubility," by creating "[n]anosized water-soluble droplets" that "allow the bioactive to cross the water layer of the GI tract for absorption."
- 42. In an effort to prove its technology, Vesifact commissioned a study to compare the bioavailability of CoQ10 capsules made with VESIsorb to other commercially-available CoQ10 supplements. The results were reported in the March-April 2009 issue of Alternative Therapies in Health & Medicine, in an article titled *Relative Bioavailability Comparison of Different Coenzyme Q10 Formulations with a Novel Delivery System*, <sup>4</sup> a true and correct copy of which is attached hereto as Exhibit 6, and expressly incorporated into this Complaint.

<sup>&</sup>lt;sup>3</sup> See, "Products Offered / VESIsorb Delivery System," at <a href="http://source-1-global.com/products-offered/vesisorb-delivery-system">http://source-1-global.com/products-offered/vesisorb-delivery-system</a> (last visited March 2, 2015).

<sup>&</sup>lt;sup>4</sup> Z. Xia-Lui et al., *Relative Bioavailability Comparison of Different Coenzyme Q10 Formulations with a Novel Delivery System*, Alternative Therapies in Health & Medicine 15(2) 2009, 42-46.

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- 43. Relative Bioavailability describes the VESIsorb "delivery system" as "a lipidbased formulation that self-assembles on contact with an aqueous phase into a colloidal delivery system," which it says is an example of "enhancement of the rate and extent of dissolution," rather than "facilitation of an absorption process."
- All of the VESIsorb CoQ10 softgels supplied by Lang to CVS, Wal-Mart and 44. Walgreens are water-soluble formulations. But despite that CVS Enhanced softgels are based on the same VESIsorb technology that purports to make the CoQ10 contained therein watersoluble, and thus contain a water-soluble form of ubidecarenone, CVS does not state on CVS Enhanced's packaging that the product is a water-soluble formulation. Nevertheless, CVS does state on the packaging that the product is an "ENHANCED ABSORPTION FORMULA," which, as noted above, is commonly understood in the marketplace as meaning a water-soluble formula. (See Ex. 1).
- In addition to prominently advertising and claiming that CVS Enhanced 45. provides "Enhanced Absorption," CVS and Lang also represent on the packaging (see Ex. 1) that the product provides several health benefits, such as the following:
  - "Beneficial for those taking cholesterol-lowering statin drugs"
  - "Supports heart & vascular health"
  - "Promotes healthy blood pressure levels"
  - "Important for energy production"
  - "CVS/pharmacy Enhanced Absorption Formula CoQ-10 100mg may help support heart and vascular health, as well as may help support healthy blood pressure levels with an enhanced absorption formula."
- 46. Based on USP standards, in order for the CVS Enhanced softgels to be reasonably effective, the softgels must rupture within 15 minutes, and achieve no less than 75% dissolution.
- 47. Finally, CVS and Lang represent that CVS Enhanced is comparable to the leading CoQ10 product on the market, by stating on its packaging "Compare to Qunol<sup>TM</sup> Ultra CoQ-10." This comparative claim is bolstered by CVS and Lang using packaging

deceptively similar to that of Qunol, and by CVS's practice of placing CVS Enhanced immediately next to Qunol on its retail shelves. The packaging of CVS Enhanced contains several claims identical or substantially similar to claims that first appeared on Qunol's packaging. The sum effect of CVS and Lang's comparative claim, package design and product placement is to suggest that CVS Enhanced is a store-brand or generic version of the brand-name Qunol product, perhaps identically formulated (as with many store-brands and generics), and/or at the very least offering the same benefits.

D. Qunol CoQ10

48. Qunol is sold by Quten Research Institute, LLC, a New Jersey company. The technology employed in enhancing dissolution of the so-called "O-Gel" CoQ10 (a trade

48. Qunol is sold by Quten Research Institute, LLC, a New Jersey company. The technology employed in enhancing dissolution of the so-called "Q-Gel" CoQ10 (a trade name) in Qunol softgels is described in U.S. Patent Nos. 6,056,971, 6,300,377, and 6,740,338, and registered under the trademark, "Bio-Solv." The process used to manufacture Qunol produces sub-micron size CoQ10 molecules, increasing the surface area of the CoQ10, and thereby enhancing its interaction with bile salts, for enhanced micellization and absorption. This makes Qunol water-soluble. Qunol is also formulated with 150 IU of Vitamin E, which enhances the solubility of its CoQ10. Qunol's packaging, a true and correct copy of which is attached hereto as Exhibit 7 and expressly incorporated into the Complaint, notes that Qunol passes the USP dissolution test and is both water- and fat-soluble.

### E. Independent Laboratory Testing

49. The Lang-supplied VESIsorb CoQ10 softgels that CVS sells as CVS Enhanced (as well as CVS Ultra, Wal-Mart Equate, and Wallgreens Well CoQ10) have been subject to numerous independent laboratory tests in 2013 and 2014, including by both plaintiff and Lang. Several tests show USP failures. By contrast, in directly comparative testing, Qunol showed far superior results to CVS Enhanced.

<sup>&</sup>lt;sup>5</sup> Qunol's packaging includes the following claims: "Supports heart and vascular health," "Promotes healthy blood pressure levels," "Essential for energy production," "Beneficial to Statin drug users," and "Powerful all-natural antioxidant."

### 1. Eurofins Testing (January 2015)

- 50. From about December 24, 2014 to January 21, 2015, Eurofins Scientific, Inc.'s Supplement Analysis Center in Petaluma, California tested:
  - (a) a sample of CVS Ultra CoQ10 100mg softgels, from Lot J13NM22, bearing an expiration date of September 2015, which was purchased on December 22, 2014 from the CVS located at 4829 Clairemont Drive, San Diego, California 92117;
  - (b) a sample of CVS Ultra CoQ10 100mg softgels, from Lot C14NM50, bearing an expiration date of February 2016, which was also purchased on December 22, 2014 from the CVS located at 4829 Clairemont Drive, San Diego, California 92117;
  - (c) a sample of CVS Enhanced 100mg softgels, from Lot #G14NM32, bearing an expiration date of June 2016, which was also purchased on December 22, 2014 from the CVS located at 4829 Clairemont Drive, San Diego, California 92117;
  - (d) another sample of CVS Enhanced 100mg softgels, from Lot #G14NM32, bearing an expiration date of June 2016, which was also purchased on December 22, 2014 from the CVS located at 4829 Clairemont Drive, San Diego, California 92117;
  - (e) a sample of Qunol Ultra CoQ10, from Lot #2071-4130, bearing an expiration date of October 2017, which was purchased on December 23, 2014 from the CVS located at 4829 Clairemont Drive, San Diego, California 92117; and
  - (f) a sample of Qunol Ultra CoQ10, from Lot #2021-4130, bearing an expiration date of October 2017, which was purchased on December 23, 2014 from the CVS located at 4829 Clairemont Drive, San Diego, California 92117.

The samples were provided to Eurofins blindly, in sealed bottles whose labels were completely obscured. Eurofins tested the samples for rupture and dissolution according to the methods prescribed by USP. Eurofins' testing showed that the first CVS Ultra CoQ10 sample achieved 1% dissolution and did not rupture after 60 minutes; and, with the addition of pepsin, achieved 3.2% dissolution, but still did not rupture after 60 minutes. Eurofins' testing also showed that the second CVS Ultra CoQ10 lot 3.8% dissolution, and did not rupture after 60 minutes; and, with the addition of pepsin, achieved 74.2% dissolution, but took 51 minutes to rupture. Eurofins testing showed that the first CVS Enhanced sample took 50 minutes to

rupture, and with the addition of pepsin, took 28 minutes to rupture; and that the second CVS Enhanced sample took 43 minutes to rupture, and 26 minutes with pepsin. Finally, Eurofins testing showed the first Qunol sample dissolved 98% and ruptured in 14 minutes (all without the addition of pepsin), while the second sample achieved 100% dissolution and ruptured in 12 minutes (without the addition of pepsin). A true and correct copy of the January 21, 2015 Eurofins Certificates of Analysis for these six samples are attached hereto as Exhibit 8.

### 2. Eurofins Testing (December 2014)

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51. From about December 2 to December 10, 2014, Eurofins' Supplement Analysis Center tested: (a) a sample of Walgreens Well 100mg softgels, from Lot E14NM12, bearing an expiration date of February 2016, which was purchased on November 19, 2014 from the Walgreens located at 301 University Avenue, San Diego, California 92103; and (b) a sample of Walgreens WEll 200mg softgels, from Lot E14NM20, bearing an expiration date of March 2016, which was also purchased on November 19, 2014 from the Walgreens located at 301 University Avenue, San Diego, California 92103. The softgels used in Walgreens Well CoQ10 are the identical Lang-supplied VESIsorb CoQ10 softgels as in CVS Enhanced. The samples were provided to Eurofins blindly, in sealed bottles whose labels were completely obscured. Eurofins tested both samples for rupture and dissolution according to the methods prescribed by USP. Eurofins' testing showed that the 100mg Well CoQ10 softgels did not rupture after more than 60 minutes in water, and took 49 minutes to rupture during a retest using pepsin, an enzyme that breaks down proteins and promotes solubilization. Eurofins testing also showed the 100mg Well CoQ10 sample achieved just 2.21% dissolution in water, and 75.4% dissolution during a retest using pepsin. Similarly, Eurofins' testing showed the 200mg Well CoQ10 sample took 58 minutes to rupture in water, and 35 minutes to rupture during a retest using pepsin. Eurofins' testing also showed the 200mg Well CoQ10 sample achieved just 28.9% dissolution in water (61.2 mg/softgel ÷ 212 mg/softgel based on a corresponding strength test, which shows the amount of CoQ10 actually in a sample and often varies from the labeled amount), and 87.7% dissolution during a retest using pepsin. A true

and correct copy of the December 10, 2014 Eurofins Certificates of Analysis for Walgreens Well CoQ10 Lots E14NM12 and E14NM20 are attached hereto as Exhibit 9.

### 3. Eurofins Testing (July 2014)

From about July 7 to July 21, 2014, Eurofins Scientific, Inc.'s Supplement 52. Analysis Center in Petaluma, California tested a sample of Wal-Mart's Equate CoQ10 softgels, from Lot G13NM13, bearing an expiration date of March 2015, which was purchased on August 15, 2013 from the Wal-Mart located at 4840 Shawline St., San Diego, California 92111. From August 2013 to July 2014, the sample was maintained, sealed in the bottle, in its outer cardboard packaging, inside a file cabinet, in an office whose temperature was generally maintained between 69 and 74 degrees Fahrenheit. The Equate sample was provided to Eurofins blindly, in a sealed bottle whose label was completely obscured. Eurofins tested the sample for rupture and dissolution according to the methods prescribed by USP. Eurofins testing shows Equate failed to rupture after more than 60 minutes in water, and took 47 minutes to rupture during a retest using pepsin. The Eurofins testing also shows the Equate sample achieved less than 2% dissolution in water, and 47% dissolution on a retest using pepsin (e.g., 45.3 mg/softgel ÷ 96.3 mg/softgel). A true and correct copy of the July 21, 2014 Eurofins Certificate of Analysis for Equate Lot G13NM13 is attached hereto as Exhibit 10.

### 4. Advanced Botanical Testing (February 2014)

53. On August 8, 2012, Advanced Botanical Consulting & Testing, Inc. received from Lang a sample of CVS Ultra softgels (*i.e.*, the same VESIsorb CoQ10 softgels as CVS Enhanced) for a long-term stability study. The sample was identified as "Lot #: F12NM10." At 18 months, in February 2014, Advanced Botanical tested the softgels' "Rupture (USP)." The results: "Fail, >30 min." Advanced Botanical had not previously tested for rupture since receiving the sample in August 2012. A true and correct copy of the Advanced Botanical testing report, dated February 18, 2014, is attached hereto as Exhibit 11.

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### 5. Tampa Bay Analytical Research Testing (November 2013)

On November 18, 2013, Tampa Bay Analytical Research, Inc. (TBAR) tested 54. samples from two different lots of CVS Ultra CoQ10, Lots F12NM09 and F12NM10, which are the identical Lang-supplied VESIsorb CoQ10 softgels as in CVS Enhanced. The samples were purchased on June 9, 2013 (Lot F12NM09), and August 15, 2013 (Lot F12NM10), from the CVS/pharmacy store located at 4829 Clairemont Drive, San Diego, California, 92117. From June and August 2013, respectively, until early November 2013, the samples were maintained, sealed in the bottles, in their outer cardboard packaging, in an office whose temperature is generally maintained between 69 and 74 degrees Fahrenheit. The samples were provided to TBAR blindly, in sealed bottles whose labels were completely obscured. For each lot, TBAR analyzed 6 capsules, following USP protocols for testing rupture and dissolution. TBAR's testing showed that 7 out of 12 of the soft gel capsules tested did not rupture at all, even after 60 minutes; 3 out of the 12 experienced at best an immaterial, de minimis leakage of contents, perhaps from a pinhole-size opening, but no discernable, visible rupture was observed, even after 60 minutes; and only 2 softgel capsules (1 from each lot) actually ruptured, but only after approximately 50 minutes. The 2 capsules that ruptured showed only 27.6%, and 27.9% dissolution. A true and correct copy of TBAR's two testing reports, each an "Assay Result Form," is attached hereto as Exhibit 12.

### 6. Advanced Botanical Testing (September 2013)

55. Between September 6, 2013 and September 10, 2013, Advanced Botanical performed USP dissolution testing for Lang on a sample identified as "CoQ10 w/ VesiSorb," and identified as "Item#: C13NM29," with an expiration date of January 2015. Using the standard USP procedure, Advanced Botanical's testing showed the VESIsorb CoQ10 sample achieved only 39% dissolution. The report describes the reason for the poor dissolution:

CoQ10 in the softgels once ruptured was physically suspended in the dissolution medium, not chemically solublized. If the solution is directly filtered and injected, the unsolublized portion is removed by the filtration step, which lead to low result. The dissolution sample needs to be properly diluted

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27 28 with organic solvent like isopropyl alcohol to assure complete solublization of the CoQ10, prior to injection into the HPLC.

The USP methods and procedures applicable to CoQ10 do not permit the use of isopropyl alcohol to enhance CoQ10 dissolution. A true and correct copy of Advanced Botanical's September 10, 2013 testing report as described above is attached hereto as Exhibit 13.

#### 7. **Covance Testing (August 2013)**

56. Between August 2 and 12, 2013, Covance Laboratories analyzed samples from two different lots of Wal-Mart Equate CoQ10, which uses the identical Lang-supplied VESIsorb CoQ10 softgels as in CVS Enhanced. Following USP procedures, for each lot Covance measured six softgels, determining that one lot offered an average of 41.18% dissolution, and the second, and average of 41.3% dissolution. A true and correct copy of the Covance Laboratories Certificates of Analysis relating to this testing (one per lot) are attached hereto as Exhibit 14.

The preceding testing results concerning rupture and dissolution are summarized 57. in the following table:

Laboratory, Date, & Item Tested	Disintegration (Rupture)	Dissolution
Eurofing (January 2015 CVS Enhanced)	50 min	100%
Eurofins (January 2015 – CVS Enhanced)	(28 min w/ pepsin retest)	(97% w/ pepsin retest)
Eurofing (January 2015 CVS Enhanced)	43 min	78.4%
Eurofins (January 2015 – CVS Enhanced)	(26 min w/ pepsin retest)	(98% w/ pepsin retest)
Eurofing (January 2015 CVC Ultra)	>60 min	1%
Eurofins (January 2015 – CVS Ultra)	(>60 min w/ pepsin retest)	(3.2% w/ pepsin retest)
anofing (January 2015 CVC Liltus)	>60 min	3.8%
Eurofins (January 2015 – CVS Ultra)	(51 min w/ pepsin retest)	(74.2% w/ pepsin retest)
Eurofins (January 2015 – Qunol Ultra)	14 min	98.1%
Eurofins (January 2015 – Qunol Ultra)	12 min	100%
Eurofing (December 2014 Welgroons Well)	> 60 min	2.21%
urofins (December 2014 – Walgreens Well)	(49 min w/ pepsin retest)	(75.4% w/ pepsin retest)
wro fing (Docombor 2014 Wolgrooms Wall)	58 min	28.9%
Eurofins (December 2014 – Walgreens Well)	(35 min w/ pepsin retest)	(87.7% w/ pepsin retest)
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Laboratory, Date, & Item Tested	Disintegration (Rupture)	Dissolution
Eurofins (July 2014 – Wal-Mart Equate)	> 60 min	< 2%
	(47 min w/ pepsin retest)	(45.3% w/ pepsin retest)
Eurofins (July 2014 – Qunol Ultra)	13 min	92.7%
Advanced Botanical (February 2014 – Wal- Mart Equate)	> 30 min	-
Tampa Bay Analytical (November 2013 – CVS Ultra)	> 60 min (10 capsules) 50 min (2 capsules)	27.75% (avg)
Advanced Botanical (September 2013 – Generic "CoQ10 w/ VesiSorb" with lot number corresponding to Wal-Mart Equate)	-	39%
Covance (August 2013 – Wal-Mart Equate)	-	41.24% (avg)

### CVS' DECEPTIVE ACTS & UNFAIR BUSINESS PRACTICES

### A. CVS Sells Defective CVS Enhanced Dietary Supplements

- 58. CVS Enhanced fails to rupture within 15 minutes, instead taking at least 26 minutes, and at times up to 50 minutes to rupture. These results are consistent with the rupture of identical VESISorb CoQ10 softgels used in CVS Ultra, Wal-Mart Equate, and Walgreens Well CoQ10 supplements. By its failure to rupture, CVS Enhanced provides consumers with little or no benefit, making them ineffective, and indeed defective.
- 59. But even if CVS Enhanced timely ruptures, the identical Lang-supplied softgels in other packaging fail to adequately dissolve as shown by the testing of identical VESISorb CoQ10 softgels, frequently exhibiting less than 50% dissolution (and at times less than 2%), well below the USP standard of 75%, further providing little or no benefit to consumers, also rendering the product defective.
- 60. CoQ10 supplements manufactured in full compliance with Good Manufacturing Practices, and exercising adequate quality control, will measure far more consistently than do the VESIsorb CoQ10 softgels used in CVS Enhanced across batches and lots, and over time (e.g., without degradation during the product's lifetime preceding its expiration date). The wide divergence in the VESIsorb CoQ10 softgels' dissolution results—less than 2%, 28%, 39%, 41%, 45%, etc.—suggest some defect in its formulation, manufacturing (including 17

possibly relating to its outer softgel gelatin coating), packaging, distribution or other handling 1 2 resulting in inconsistent batches of CVS Enhanced, many of which provide the consumer little or no effect, and which may degrade quickly during the product's shelf life. 3 4 В. 5 6 7 8 9

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### CVS and Lang's Claim of "Enhanced Absorption" is False & Misleading

- CVS and Lang's claim of "Enhanced Absorption" is based on the *Relative* Bioavailability study. However, unlike the packaging of the CVS Ultra CoQ10 product, the packaging of CVS Enhanced deceptively omits any reference to Relative Bioavailability as the alleged support for CVS's enhanced absorption claim, providing consumers with no means of investigating the basis for such claim. CVS, Lang, and/or SourceOne likely decided to remove such express attribution because Relative Bioavailability does not establish CVS's enhanced absorption claim.
- First, Relative Bioavailability's small sample size (just 20 subjects) allows for 62. distortion by random chance, and magnifies bias. This is especially true because the human body is a complex environment. Thus, the results cannot possibly be considered reliable.
- Second, Relative Bioavailability employed improper exclusion criteria. The packaging of CVS Enhanced advertises it is "Beneficial for people taking cholesterollowering statin drugs," but Relative Bioavailability excluded as test subjects those taking "Medication affecting cholesterol (e.g., statins)." CoQ10 is often taken by those with heart conditions seeking to improve and promote heart health, and the CVS Enhanced package states it "Support heart & vascular health," but *Relative Bioavailability* excluded subjects with heart conditions. And while CoQ10 supplements are most popular with those over 55, Relative Bioavailability excluded subjects over 60, and did not state the age of the subjects chosen. The exclusion of test subjects with certain conditions and characteristics undermines the study's reliability in predicting the "real world" absorption claimed by CVS on the label of CVS Enhanced.
- Moreover, Relative Bioavailability represents only limited initial results with no 64. verification of clinical response. The article concludes that "[a]dditional clinical studies are indicated to verify that the improved absorption with [VESIsorb] correlated with clinical

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27 28 response to treatment." Thus, by its own admission, the *Relative Bioavailability* study does not actually "verify" anything, and certainly not any "clinical response" to VESIsorb CoQ10 softgels, especially when extrapolated to the general population.

- *Relative Bioavailability* is also undermined by bias and sponsorship, and cannot 65. be considered independent. Besides Vesifact supplying the VESIsorb capsules for use in the study, "[t]he work was funded by Vesifact AG, Baar, Switzerland." And one of the two authors of the study, Carl Artmann, "served as paid consultant[] to Vesifact in monitoring and analyzing this study . . . . "The other author, Zheng-Xian Liu, "served as a paid consultant to SourceOne Global Partners in the preparation of th[e] manuscript . . . ." Despite stating that both authors of the study hold "no other financial interest in the products or technologies studied or in either Vesifact or SourceOne," the study's having been funded by and conducted on behalf of companies that in fact have a significant financial interest in its outcome undermines the study's credibility and reliability. And at the time Dr. Liu was paid by SourceOne to prepare the *Relative Bioavailability* manuscript, he had an ongoing relationship with, and was being compensated as a consultant on several different projects for SourceOne.
- But even if *Relative Bioavailability* supported the conclusion that the VESIsorb 66. capsules tested in Germany in 2008—likely fresh samples, carefully-manufactured by someone other than Swiss Caps, provided directly to the study's administrators by Vesifact exhibited increased absorption, this does not support CVS's claim that CVS Enhanced, as formulated, mass-manufactured, and distributed in the United States and available on retail shelves to consumers, offers equivalent "enhanced absorption."
- To the contrary, a substantial body of testing based on USP protocols and 67. standards shows CVS Enhanced, and the same VESIsorb CoQ10 softgels, frequently fails to timely rupture or rupture at all, offering consumers little or no efficacy, and inadequately dissolves, making little CoQ10 even available for absorption and bioavailability.
- This is especially significant because Relative Bioavailability discusses the 68. importance of water solubility, and the technology purportedly employed in CVS Enhanced claims to enhance the water solubility of CoQ10, yet the USP test designed by independent

scientists to determine whether a CoQ10 supplement is water soluble—the special dissolution test prescribed in the USP CoQ10 Monograph requiring 75% dissolution to pass—shows the VESIsorb CoQ10 softgels used in CVS Enhanced not only consistently fail dissolution, but sometimes fail miserably, with as little as 1% dissolution.

- 69. For example, *Relative Bioavailability* explains that bile salts "enhance drug solubilization" because they help form "micelles" that "transport the lipophilic molecules though the aqueous environment of the gastrointestinal (GI) tract and across the unstirred water layer to the absorptive epithelium," and that VESIsorb supposedly "mimics this natural absorption process to improve bioavailability of poorly water-soluble drugs" like CoQ10.
- 70. As *Relative Bioavailability* notes, "[t]he absorption of most drugs depends on 2 processes: (1) the dissolution of the drug in physiological fluids and (2) the absorption process itself (ie, the process by which a drug in solution enters the cells at the absorption site and finally enters general blood circulation).") Thus in sum, "the dissolution of [a] drug is the first step in the absorption process . . . ." For poorly-absorbed drugs like CoQ10, one technique used to "increase the extent to which the administered drug is absorbed" is "enhancement of the rate and extent of dissolution," with VESIsorb an "example of the . . . technique."
- 71. *Relative Bioavailability* also notes that "VESIsorb was designed to address the poor bioavailability of . . . natural bioactives like CoQ10 exhibiting poor water solubility," by using a process in which the "bioactive will be solubilized . . . ."
- 72. If *Relative Bioavailability* requires water solubility in order for a CoQ10 supplement using VESIsorb technology to properly function, and industry standard testing based on scientifically-sound principles developed by an independent expert organization demonstrates CVS Enhanced is not water soluble, then by definition *Relative Bioavailability* cannot support CVS's claims of "Enhanced Absorption" for CVS Enhanced (even if, *arguendo*, the study might otherwise support the claim for a VESIsorb-based CoQ10 supplement that practiced the patented technology correctly and was free from any formulation, manufacturing, or handling errors or defects).

73. CVS also deceptively omits the products, by comparison, over which CVS 1 2 Enhanced supposedly offers "Enhanced Absorption." If CVS uses the claim to compare CVS Enhanced to all or any given solubilized CoQ10 dietary supplement in the market, this is 3 false: even Relative Bioavailability only compared the VESIsorb product to three others, and 4 5 no other clinical studies comparing any other products to competing CoQ10 supplements much less any studies comparing them to CVS Enhanced, itself—have been conducted. But 6 7 if CVS intends the "Enhanced Absorption" claim to make a comparison to regular, 8 unsolubilized CoQ10, this is also false because CVS Enhanced fails the USP dissolution test 9

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#### C. CVS and Lang's Benefit Claims Are False & Misleading

just as any such "regular," unsolubilized CoQ10 supplement inevitably will.

While CVS's benefit claims (like "Supports heart & vascular health" and 74. "Promotes healthy blood pressure levels") may be literally true since CoQ10 can offer such benefits if supplements are carefully formulated, manufactured, and handled, defects in the formulation, manufacturing, or distribution chain for CVS Enhanced, resulting in CoQ10 softgels with rupture and dissolution failures, render the statements as used on CVS Enhanced misleading, especially in combination with the "Enhanced Absorption" efficacy claim.

#### CVS and Lang's Comparison to Qunol is False & Misleading D.

Qunol is a highly-respected, "high end" or "name" brand CoQ10 supplement, 75. well-known to CoQ10 consumers. Its Q-Gel-branded CoQ10 supplements have been shown to effectively increase absorption in at least five bioavailability studies, and its "3X" claim has been investigated and upheld by the National Advertising Division, a respected industry organization. CVS's statement comparing CVS Enhanced to Qunol is false because testing shows that Qunol, unlike CVS Enhanced, timely ruptures, and offers substantially more dissolution than CVS Enhanced. The products are also formulated differently and employ different techniques to solve the CoQ10 dissolution problem. For example, Qunol includes 150 International Units (IU) of Vitamin E to promote solubility, while CVS Enhanced contains only 10 IU of Vitamin E (in the form of d-alpha Tocopherol) (which CVS does not even disclose).

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### PLAINTIFF'S PURCHASES, RELIANCE, AND INJURY

- 76. On several occasions within approximately the past three or four months, plaintiff purchased approximately 5 bottles of CVS Enhanced from a CVS store located at either 1122 E. Broadway, Glendale, California, or 3943 San Fernando Rd., Glendale, California. In purchasing CVS Enhanced, plaintiff relied on CVS's representation that CVS Enhanced offers "Enhanced Absorption," or is an "Enhanced Absorption Formula," which plaintiff took to mean it would absorb fast in the body, and much better than competing products. Plaintiff also relied on CVS's various health claims, such as its representations that CVS Enhanced "Supports heart & vascular health," "Promotes healthy blood pressure levels," and is "Important for energy production." Finally, plaintiff was familiar with, and had previously used the Qunol brand, and believed it to be a good, effective brand. Plaintiff relied on CVS's representation that he could "Compare" CVS Enhanced "to Qunol Ultra CoQ10," essentially understanding that to mean that CVS Enhanced is as effective as Qunol.
  - But these claims were false and misleading for the reasons described herein. 77.
- Because it frequently fails even to rupture, CVS Enhanced is actually 78. ineffective, so plaintiff did not receive what he paid for, and lost money in the full amount of his CVS Enhanced purchases. Because the softgels supplied by Lang also fail to adequately dissolve, CVS Enhanced is actually only partially effective, so plaintiff did not receive what he paid for, and lost money in amount of his CVS Enhanced purchases or some portion thereof.
- And CVS Enhanced does not provide anywhere near the rupture and dissolution 79. results, and hence the effectiveness, of Qunol.
- Plaintiff purchased CVS Enhanced instead of competing products based on the 80. false statements and misrepresentations described herein.
- CVS Enhanced was unsatisfactory to plaintiff because it did not provide the full 81. benefit advertised, and may have provided no benefit.
- Plaintiff would not have purchased CVS Enhanced absent CVS's false and 82. misleading claims, or would not have paid the price he did for CVS Enhanced if he knew that

CVS Enhanced does not timely rupture, does not dissolve at all or to any substantial degree (and certainly far less than the industry standard as reflected in the USP CoQ10 Monograph), does not provide "Enhanced Absorption" over other brands he may have otherwise purchased, and cannot compare adequately in quality and effectiveness to Qunol.

- 83. Plaintiff would not have paid the price he did for CVS Enhanced, and may not have been willing to purchase CVS Enhanced at all, if he knew that it fails to timely rupture and provides substantially less dissolution than the USP CoQ10 Monograph specifies.
- 84. Plaintiff paid a price premium due to CVS's fraudulent conduct, in that CVS was able to command a higher price in the marketplace for CVS Enhanced than it otherwise could have absent its false and misleading claims.

### **CLASS ACTION ALLEGATIONS**

- 85. Pursuant to Rule 23, plaintiff seeks to represent a nationwide class comprised of all persons in the United States who purchased CVS Enhanced primarily for personal, family, or household use, and not for resale, and a California subclass comprised of all persons in California who purchased CVS Enhanced primarily for personal, family, or household use, and not for resale.
- 86. Plaintiff nevertheless reserves the right to divide into subclasses, expand, narrow, or otherwise modify the class definition prior to (or as part of) filing a motion for class certification.
- 87. The members in the proposed class and subclass are so numerous that individual joinder of all members is impracticable, and the disposition of the claims of all class members in a single action will provide substantial benefits to the parties and Court.
- 88. Questions of law and fact common to plaintiff and the class include, without limitation:
  - A. Whether CVS Enhanced fails to timely rupture, or rupture at all, and whether it exhibits at least 75% dissolution;

- B. Whether CVS and Lang statements concerning the absorption or benefits of CVS Enhanced were likely to deceive the public or consumers acting reasonably;
- C. Whether CVS or Lang made any statement it knew or should have known was false or misleading;
- D. Whether any of CVS or Lang's practices were immoral, unethical, unscrupulous, or substantially injurious to consumers;
- E. Whether the utility of any of CVS or Lang's practices, if any, outweighed the gravity of the harm to its victims;
- F. Whether CVS or Lang's conduct violated public policy, including as declared by specific constitutional, statutory or regulatory provisions;
- G. Whether the consumer injury caused by CVS or Lang's conduct was substantial, not outweighed by benefits to consumers or competition, and not one consumers themselves could reasonably have avoided;
- H. Whether CVS or Lang's policies, acts, and practices with respect to CVS Enhanced were designed to, and did result in the purchase and use of CVS Enhanced by the class members primarily for personal, family, or household purposes;
- I. Whether CVS and Lang represented that CVS Enhanced has characteristics, uses, or benefits which it does not have, within the meaning of Cal. Civ. Code § 1770(a)(5);
- J. Whether CVS and Lang represented that CVS Enhanced is original or new if it has deteriorated unreasonably or is altered, within the meaning of Cal. Civ. Code § 1770(a)(6);
- K. Whether CVS and Lang represented CVS Enhanced is of a particular standard, quality, or grade, when it was really of another, within the meaning of Cal. Civ. Code § 1770(a)(7);
- L. Whether CVS and Lang advertised CVS Enhanced with the intent not to sell it as advertised, within the meaning of Cal. Civ. Code § 1770(a)(9);
- M. Whether CVS and Lang represented that CVS Enhanced has been supplied in accordance with a previous representation when it has not, within the meaning of Cal. Civ. Code § 1770(a)(16);

- N. Whether CVS or Lang's conduct or any of its acts or practices violated the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, the Rhode Island Unfair Trade Practices & Consumer Protection Act, §§ R.I. Gen. L. § 6-13.1-1, *et seq.*, the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.*, the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*; or any other law;
- O. The proper equitable and injunctive relief;
- P. The proper amount of actual or compensatory damages;
- Q. The proper amount of restitution or disgorgement;
- R. The proper amount of actual and punitive damages; and
- S. The proper amount of reasonable litigation expenses and attorneys' fees.
- 89. Plaintiff's claims are typical of class members' claims in that they are based on the same underlying facts, events, and circumstances relating to CVS and Lang's conduct.
- 90. Plaintiff will fairly and adequately represent and protect the interests of the class, has no interests incompatible with the interests of the class, and has retained counsel competent and experienced in class action litigation.
- 91. The class is sufficiently numerous, as both the class and subclass contain at least thousands of members who purchased the CVS Enhanced at issue in this action.
- 92. Class treatment is superior to other options for resolution of the controversy because the relief sought for each class member is small such that, absent representative litigation, it would be infeasible for class members to redress the wrongs done to them.
- 93. Questions of law and fact common to the class predominate over any questions affecting only individual class members.
- 94. As a result of the foregoing, class treatment is appropriate under Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), and may be appropriate for certification "with respect to particular issues" under Rule 23(b)(4).

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### **FIRST CAUSE OF ACTION**

# VIOLATIONS OF THE CALIFORNIA FALSE ADVERTISING LAW,

### CAL. BUS. & PROF. CODE §§ 17500 ET SEQ.

### (By the California Subclass)

- 95. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.
- 96. The FAL prohibits any statement in connection with the sale of goods "which is untrue or misleading," Cal. Bus. & Prof. Code § 17500.
- 97. CVS and Lang's claim that CVS Enhanced provides "Enhanced Absorption," that it generally supports heart health and benefits statin users, and that it is comparable to Qunol, is untrue or misleading in that, unlike Qunol, CVS Enhanced does not timely rupture or sufficiently dissolve for effectiveness.
- 98. CVS and Lang knew, or reasonably should have known, that the claims were untrue or misleading.

### **SECOND CAUSE OF ACTION**

# VIOLATIONS OF THE CALIFORNIA CONSUMERS LEGAL REMEDIES ACT, CAL. CIV. CODE §§ 1750 ET SEQ.

### (By the California Subclass)

- 99. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.
- 100. The CLRA prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.
- 101. CVS and Lang's policies, acts, and practices were designed to, and did, result in the purchase and use of the products primarily for personal, family, or household purposes, and violated and continue to violate the following sections of the CLRA:
  - a. § 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have;

- b. § 1770(a)(6): representing that goods are original or new if they have deteriorated unreasonably;
- c. § 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another;
- d. § 1770(a)(9): advertising goods with intent not to sell them as advertised; and
- e. § 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.
- 102. In compliance with Cal. Civ. Code § 1782, plaintiff sent written notice to CVS and Lang of his claims. Although plaintiff does not currently seek damages for his claims under the CLRA, if CVS or Lang refuses to remedy the violation within 30 days of notice, plaintiff may amend this Complaint to seek damages.
- 103. In compliance with Cal. Civ. Code § 1782(d), plaintiff's affidavit of venue is filed concurrently herewith, attached to the Complaint as <u>Exhibit 15</u>.

### **THIRD CAUSE OF ACTION**

# VIOLATIONS OF THE CALIFORNIA UNFAIR COMPETITION LAW, CAL. BUS. & PROF. CODE §§ 17200 *ET SEQ*.

### (By the California Subclass)

- 104. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if fully set forth herein.
- 105. The UCL prohibits any "unlawful, unfair or fraudulent business act or practice," Cal. Bus. & Prof. Code § 17200.

#### Fraudulent

106. CVS and Lang's claims that CVS Enhanced provides "Enhanced Absorption," that it generally supports heart health and benefits statin users, and that it is comparable to Qunol, are false and misleading, and fraudulent under the UCL, because CVS Enhanced is ineffective in that, unlike Qunol, it does not rupture, thus passing through the body's digestive tract and providing no benefit, or at most is only partially effective due to its substandard dissolution. Thus, the label of CVS Enhanced is likely to deceive a reasonable consumer.

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107. CVS and Lang's omissions of material facts (for example, failing to identify to consumers the study on which CVS's "Enhanced Absorption" claim is based) are also prohibited by the UCL's "fraudulent" prong.

### Unfair

- 108. CVS and Lang's conduct with respect to the labeling, advertising, and sale of CVS Enhanced was unfair because CVS and Lang's conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.
- 109. CVS and Lang's conduct with respect to the labeling, advertising, and sale of CVS Enhanced was also unfair because it violated public policy as declared by specific constitutional, statutory or regulatory provisions, including the False Advertising Law.
- 110. CVS and Lang's conduct with respect to the labeling, advertising, and sale of CVS Enhanced was also unfair because the consumer injury was substantial, not outweighed by benefits to consumers or competition, and not one consumers themselves could reasonably have avoided.

### Unlawful

- 111. The acts alleged herein are "unlawful" under the UCL in that they violate the following laws:
  - The False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 et seq.;
  - The Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 et seq.;
  - The Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2103 et seq.;
  - The Lanham Act, 15 U.S.C. §§ 1501 et seq.; and
  - The Rhode Island Unfair Trade Practice and Consumer Protection Act, R.I. Gen. L. §§ 6-13.1-1, *et seq*.

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### **FOURTH CAUSE OF ACTION**

# VIOLATION OF THE RHODE ISLAND UNFAIR TRADE PRACTICE AND CONSUMER PROTECTION ACT, R.I. GEN. L. §§ 6-13.1-1 *ET SEQ*.

### (By the Nationwide Class)

- 112. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.
- 113. The Rhode Island Consumer Protection Act provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." R.I. Gen. L. § 6-13.1-2.
- 114. CVS and Lang's claims that CVS Enhanced provides "Enhanced Absorption," generally supports heart and muscle health, and is comparable to Qunol, are false and misleading because CVS Enhanced is actually ineffective.
- 115. This advertising is a deceptive act or practice committed while engaged in a business of trade or commerce, within the meaning of the statute. *See* R.I. Gen. L. § 6-13.1-1(6)(i)-(iii), (v), (vii)-(ix), (xii)-(xiv), (xvi)-(xvii).
- 116. Moreover, CVS and Lang's practices affront public policy, as delineated by the common law, statutes, and other established concepts of unfairness; are immoral, unethical, oppressive, or unscrupulous; and cause substantial injury to consumers.

### FIFTH CAUSE OF ACTION

### **BREACH OF EXPRESS WARRANTY**

### (By the Nationwide Class)

- 117. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.
- 118. In selling CVS Enhanced to plaintiff and the class members, CVS and Lang made an affirmation of fact or promise that CVS Enhanced provides "Enhances Absorption." This affirmation of fact, promise or description formed part of the basis of the bargain. CVS and Lang thus expressly warranted the goods sold.

- 119. CVS Enhanced was in the defective condition alleged herein, causing the breach of warranty, when it left CVS, *i.e.*, when plaintiff and other consumers purchased it. This was the proximate cause of plaintiff's injuries and those of the class.
- 120. Prior to filing the lawsuit, plaintiff, on behalf of himself and the class, gave CVS and Lang notice of the breach.

### SIXTH CAUSE OF ACTION

#### **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

### (By the Nationwide Class)

- 121. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.
- 122. In selling CVS Enhanced to plaintiff and the class members, CVS and Lang impliedly warranted that the goods sold were merchantable, but laboratory testing demonstrates CVS Enhanced does not rupture, and its dissolution may be negligible or substandard, giving the consumer virtually no benefit.
- 123. Plaintiff and the class members suffered injury as a result of CVS and Lang's breach in that they paid money for a product that does not timely rupture and may not adequately dissolve, and therefore does not provide the benefits advertised.
- 124. Prior to filing the lawsuit, plaintiff, on behalf of himself and the class, gave CVS and Lang notice of the breach.

### **SEVENTH CAUSE OF ACTION**

#### **BREACH OF IMPLIED WARRANTY OF FITNESS**

### (By the Nationwide Class)

- 125. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.
- 126. In selling CVS Enhanced to plaintiff and the class members, CVS and Lang impliedly warranted that the goods sold were fit for their particular purpose, *i.e.*, supplementing the body's CoQ10 levels.

- 127. CVS and Lang breached the warranty. Laboratory testing demonstrates CVS Enhanced fails to rupture and its dissolution may be negligible or substandard, giving the consumer virtually no benefit.
- 128. Plaintiff and the class members suffered injury as a result of CVS and Lang's breach in that they paid money for a product that did not adequately dissolve to be fit for its purpose of supplementing their CoQ10 levels.
- 129. Prior to filing the lawsuit, plaintiff, on behalf of himself and the class, gave CVS and Lang notice of the breach.

### **EIGHTH CAUSE OF ACTION**

# BREACH OF EXPRESS WARRANTY, CAL. COMM. CODE § 2313 (By the California Subclass)

- 130. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.
  - 131. There was a sale of goods from CVS to plaintiffs and the subclass members.
- 132. CVS and Lang made an affirmation of fact or promise that CVS Enhanced provides "Enhanced Absorption." This affirmation of fact, promise or description formed part of the basis of the bargain. CVS and Lang thus expressly warranted the goods sold.
- 133. CVS Enhanced was in the defective condition alleged herein, causing the breach of warranty, when it left CVS, *i.e.*, when plaintiff and other consumers purchased it. This was the proximate cause of plaintiff's injuries and those of the subclass, who paid money for an ineffective product.
- 134. Prior to filing this lawsuit, plaintiff, on behalf of himself and the subclass, gave CVS and Lang notice of the breach.

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### **NINTH CAUSE OF ACTION**

## BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY,

**CAL. COMM. CODE § 2313(1)** 

### (By the California Subclass)

- 135. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.
- 136. "Unless excluded or modified . . . a warranty that goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Cal. Comm. Code § 2314(1).
  - 137. There was a sale of goods from CVS to plaintiff and the subclass members.
  - 138. CVS and Lang impliedly warranted the goods sold were merchantable.
- 139. In selling CVS Enhanced to plaintiff and the class members, CVS and Lang impliedly warranted that the goods sold were merchantable, but laboratory testing demonstrates CVS Enhanced does not timely rupture, and its dissolution may be negligible or substandard, giving the consumer virtually no benefit.
- 140. Plaintiff and the subclass members suffered injury as a result of CVS and Lang's breach in that they paid money for a product that does not rupture or adequately dissolve, and therefore does not provide the benefits advertised.
- 141. Prior to filing this lawsuit, plaintiff, on behalf of himself and the subclass, gave CVS and Lang notice of the breach.

### **TENTH CAUSE OF ACTION**

# BREACH OF IMPLIED WARRANTY OF FITNESS, CAL. COMM. CODE § 2315

### (By the California Subclass)

- 142. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.
- 143. "Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or

- judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." Cal. Comm. Code § 2315.
  - 144. There was a sale of goods from CVS to plaintiff and the subclass members.
- 145. CVS and Lang impliedly warranted the goods sold were fit for their particular purpose, *i.e.*, supplementing the body's natural Coenzyme Q10 production.
- 146. CVS and Lang breached the warranty. Laboratory testing demonstrates that CVS Enhanced fails to timely rupture, and its dissolution may be negligible or substandard, giving the consumer virtually no benefit.
- 147. Plaintiff and the subclass members suffered injury as a result of CVS and Lang's breach in that they paid money for a product that did not adequately rupture or dissolve to be fit for its purpose of supplementing their CoQ10 levels.
- 148. Prior to filing this lawsuit, plaintiff, on behalf of himself and the subclass, gave CVS and Lang notice of the breach.

### **ELEVENTH CAUSE OF ACTION**

## VIOLATIONS OF THE MAGNUSON-MOSS WARRANTY ACT,

### 15 U.S.C. §§ 2301 *ET SEQ*.

### (By the Nationwide Class)

- 149. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.
- 150. CVS Enhanced is a consumer product within the meaning of 15 U.S.C. § 2301(1).
- 151. Plaintiff and the class members are consumers within the meaning of 15 U.S.C. § 2301(3).
- 152. Defendants CVS and Lang are suppliers and warrantors as defined in 15 U.S.C. §§ 2301(4) & (5).
- 153. The Magnuson-Moss Warranty Act permits a consumer to recover damages caused "by the failure of a supplier, warrantor, or service contractor to comply with any

obligation under his [Act], or under a written warranty, implied warranty, or service contract." 15 U.S.C. § 2310(d)(1).

- 154. CVS and Lang's claims that CVS Enhanced provides "Enhanced Absorption" is a "written warranty" within the meaning of the Act because it is an "affirmation of fact or written promise made in connection with the sale of' the product, "which relates to the nature of the material . . . and affirms or promises that such material . . . is defect free or will meet a specified level of performance . . . ." 15 U.S.C. § 2301(6)(A).
- 155. As set forth herein, CVS Enhanced does not provide "Enhanced Absorption" as warranted.
- 156. Although CVS Enhanced does not meet the "Enhanced Absorption" specification, CVS and Lang have so far failed to refund CVS Enhanced purchasers their money.
- 157. By reason of CVS and Lang's breach of these express written warranties, CVS and Lang have violated the statutory rights due plaintiff and the class members pursuant to the Magnuson-Moss Warranty Act, thereby damaging plaintiff and the class members. 15 U.S.C. §§ 2301 *et seq*.
- 158. Plaintiffs and the class were injured as a direct and proximate result of CVS and Lang's breach because: (a) they would not have purchased CVS Enhanced on the same terms if they had known the true facts concerning its purported "Enhanced Absorption"; (b) they paid a price premium due to CVS and Lang's misleading representations that CVS Enhanced provides "Enhanced Absorption," and (c) CVS Enhanced does not perform as promised.

### **PRAYER FOR RELIEF**

- 159. Wherefore, plaintiff, on behalf of himself, all others similarly situated, and the general public, prays for judgment against CVS and Lang as to each and every cause of action, and the following remedies:
  - A. An Order certifying this as a class action and appointing plaintiff and his counsel to represent the class and subclass;

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- B. An Order enjoining CVS and Lang from labeling, advertising, or packaging CVS Enhanced with any absorption, benefit, efficacy, or comparative claim challenged herein;
- D. An Order compelling CVS and Lang to conduct a corrective advertising campaign to inform the public that CVS Enhanced did not provide the advertised efficacy or benefits;
- E. An Order requiring CVS and Lang to disgorge or return all monies, revenues, and profits obtained by means of any wrongful or unlawful act or practice;
- F. An Order requiring CVS and Lang to pay all actual and statutory damages permitted under the causes of action alleged herein;
- G. An Order requiring CVS and Lang to pay restitution to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, untrue or misleading advertising, or a violation of the UCL, FAL or CLRA, plus pre-and post-judgment interest thereon;
- H. Costs, expenses, and reasonable attorneys' fees; and
- I. Any other and further relief the Court deems necessary, just, or proper.

### **JURY DEMAND**

160. Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: March 2, 2015 /s/ Jack Fitzgerald

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