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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

AMARIN PHARMA, INC. AND AMARIN PHARMACEUTICALS IRELAND, LTD.

Plaintiffs,

v.

OMAX HEALTH, INC.,

Defendant.

Case No. 2:18-cv-09239

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

DEMAND FOR JURY TRIAL

Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland, Ltd. ("Amarin") bring this action against Omax Health, Inc. ("Omax") and allege the following:

1. Amarin brings this action to stop Omax from engaging in false and misleading advertising by promoting its omega-3 products, which are marketed as dietary supplements, as reducing the risk of cardiovascular disease and as being comparable to, or substitutes for, Amarin's Food and Drug Administration (FDA)-approved prescription drug, Vascepa® (icosapent ethyl) capsules. Among other things, Omax falsely and deceptively advertises that its purported omega-3 dietary supplements are effective in treating or preventing cardiovascular disease and that they confer the same disease-related benefits as Amarin's Vascepa®. Last month, Amarin reported the results of its REDUCE-IT™ trial, a landmark, more than $360 million cardiovascular outcomes study which showed that Vascepa reduced, by approximately 25%, the risk of major adverse cardiovascular events ("MACE") (a composite of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or unstable angina requiring hospitalization) in at-risk patients on statin therapy. *See* REDUCE-IT *Cardiovascular Outcomes Study of Vascepa® (Icosapent Ethyl) Capsules Met Primary Endpoint*, AMARIN CORP., Sept. 24, 2018, https://investor.amarincorp.com/news-releases/news-release-details/reduce-ittm-cardiovascular-outcomes-study-vascepar-icosapent (hereinafter "REDUCE-IT Press Release"), submitted herewith as Exhibit 1. Among other things, Omax has made false and misleading claims that the REDUCE-IT results "validate" the safety and efficacy of its omega-3 "dietary supplements" in reducing cardiovascular disease in the general population when that is not true. The REDUCE-IT results are limited to Vascepa, and they cannot be extrapolated to omega-3 products like Omax's that are materially different based on composition, dosage, and regulatory status.

2. Section 43(a) of the Lanham Act protects those engaged in commerce from precisely this type of unfair competition and false advertising by creating a

cause of action for those like Amarin who are harmed by it. *See* 15 U.S.C. § 1125(a)(1).

3. Under California law, products that purport to treat or prevent disease are "drugs," and manufacturers of such products must demonstrate that their drugs are safe and effective in order to obtain regulatory approval to market them. Although Omax touts its products as being effective at treating and preventing cardiovascular disease, upon information and belief, Omax has not demonstrated their safety and efficacy to FDA or the State of California. Nor, upon information and belief, has Omax demonstrated to FDA or the State of California that its products are manufactured in compliance with stringent manufacturing requirements applicable to drug products that are designed to ensure drugs deliver the effects demonstrated in their clinical trials. Omax's false and deceptive advertising, as well as its violation of California's drug approval requirements, distracts patients from seeking appropriate medical attention, diverts limited healthcare resources from proven medications, poses serious risks to the safety and health of the consuming public, and harms Amarin, a legitimate manufacturer of an FDA-approved omega-3 prescription drug.

4. California's Unfair Competition Law ("UCL") also exists to prevent these unscrupulous practices by "prohibiting unfair, dishonest, deceptive, destructive, fraudulent and discriminatory practices by which fair and honest competition is destroyed or prevented." Cal. Bus. & Prof. Code §§ 17001, 17200.

5. California regulates the manufacture and sale of prescription drugs under the state's Sherman Food, Drug, and Cosmetic Law (the "Sherman Law"). As relevant here, the Sherman Law specifies that "[n]o person shall sell, deliver, or give away any new drug" that has not been approved by FDA or by the State of California. Cal. Health & Safety Code § 111550(a)–(b). A "drug" is defined to include any product that is "used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." Cal. Health & Safety Code §

109925.

6. Amarin introduced Vascepa®, an FDA-approved prescription drug, in 2012, after over a decade of clinical trials and development. Vascepa's active ingredient, icosapent ethyl, is the ethyl ester form of eicosapentaenoic acid. Eicosapentaenoic acid is the omega-3 fatty acid commonly known as "EPA." Vascepa is approved for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. *See* Vascepa® *Full Prescribing Information*, 1 (2016) https://www.vascepa.com/assets/pdf/Vascepa_PI.pdf, (hereinafter "Vascepa Full Prescribing Information"), submitted herewith as Exhibit 2.

7. Vascepa is materially different from Omax's omega-3 products because, on information and belief with respect to Omax's products: (1) Vascepa has been proven to lower cardiovascular risk, based on the more than $360 million REDUCE-IT cardiovascular outcomes study, whereas the Omax products have not; (2) Vascepa is an FDA-approved drug designated by FDA as a new chemical entity based on its unique molecular structure, whereas the Omax products are marketed as "dietary supplements," *see FDA Letter to Robert A. Dormer*, May 31, 2016, http://www.fdalawblog.net/wp-content/uploads/archives/docs/VASCEPA%20-%20Exclusivity%20Determination%20on%20Remand.pdf (hereinafter "Dormer Letter") (designating Vascepa as a new chemical entity), submitted herewith as Exhibit 3; (3) Vascepa contains only purified EPA (icosapent ethyl), whereas the Omax products contain a mix of EPA, docosahexaenoic acid ("DHA"), other fatty acids, and a variety of other components; (4) because omega-3 fatty acids are highly prone to oxidation (i.e., spoilage), Vascepa is manufactured, encapsulated, and packaged through a stringent and complex FDA-regulated process designed to effectively eliminate impurities and isolate and protect the fragile single-molecule active ingredient from degradation, whereas the Omax products are not; (5)

Vascepa was developed as a prescription-only drug to be administered at a high dosage and has a demonstrated safety profile at that high dosage, whereas the Omax products are sold in lower dosages; and (6) Vascepa is marketed for use in populations for which it has been proven to be safe and effective (e.g., adult patients with severe hypertriglyceridemia), whereas the Omax products are marketed to the general public (including diseased populations). Vascepa is the only omega-3 prescription drug that is pure EPA.

8. On September 24, 2018, Amarin announced the results of its REDUCE-IT clinical trial, a global study of 8,179 statin-treated adults with elevated cardiovascular risk. REDUCE-IT demonstrated to a statistically significant level that taking 4 grams of Vascepa a day reduced, by approximately 25%, the risk of MACE. *See* REDUCE-IT Press Release, Exhibit 1. The REDUCE-IT results demonstrate that Vascepa, a relatively low cost drug from a consumer perspective, could potentially help healthcare professionals save millions of lives by preventing MACE in appropriate patients.

9. Amarin developed Vascepa legally and invested the significant resources necessary to conduct clinical trials to show that the drug is safe and effective to reduce triglyceride levels in adult patients with severe hypertriglyceridemia, and to submit that data to FDA for review and approval. Amarin also invested significant resources in the REDUCE-IT trial, and is in the process of preparing a submission to FDA for review and approval of those results. All told, the cost of Amarin's clinical trials exceeded $450 million. The total cost for the REDUCE-IT trial alone exceeded $360 million.

10. The REDUCE-IT trial studied only Vascepa and its results are Vascepa-specific. The study cannot be generalized to omega-3 dietary supplements, which come in many different dosages and omega-3 fatty acid compositions. Yet, only three days after September 24, 2018, when Amarin announced the REDUCE-IT results, Omax issued its own press release falsely and

misleadingly stating and suggesting that the results of the REDUCE-IT trial support the safety and efficacy of Omax's different, non-prescription omega-3 products for reducing cardiovascular risk in the general population.

11. Omax's press release falsely and misleadingly stated, for example, that the REDUCE-IT trial "further validates the safety and efficacy of Omax3's pharmaceutical grade omega-3 dietary supplement" for reducing cardiovascular risk. *See Omax3® Celebrates 10 Years as Industry Leader in Omega-3 Formulations*, MARKETS INSIDER (Sept. 27, 2018), https://markets.businessinsider.com/news/stocks/omax3-celebrates-10-years-as-industry-leader-in-omega-3-formulations-1027569395 (hereinafter "Omax Press Release"), submitted herewith as Exhibit 4. The press release also falsely and misleadingly implied that the REDUCE-IT data relates to the effects of Omax's products on the general population, by stating that the REDUCE-IT trial "further validat[es] Omax3®'s 10-year position, that high-concentrate omega3 fatty acids have a profound and lasting effect on cardiovascular health." *Id.*

12. By making these false statements, as well as others in its press release and on its website as described below, Omax is violating the Lanham Act as well as the false advertising provisions in the Sherman Law, in violation of the UCL.

13. In addition, by marketing its omega-3 products as treating or preventing cardiovascular disease and as products that are comparable to prescription drugs like Vascepa, the products meet the definition of "drug" under the Sherman Law, but do not comply with the Sherman Law's requirements for such drugs. Specifically, on information and belief, Omax has never sought nor obtained approval for these "drugs" from the FDA or the State of California. Omax's omega-3 products are therefore unlawful, unapproved "drugs," sold in violation of the Sherman Law and the UCL.

14. In skirting the drug approval process, Omax has improperly avoided the most risky, expensive, and time-consuming requirements for lawfully

marketing drugs—namely, conducting clinical trials to support an application for drug approval.

15. Flouting California's drug approval requirements by marketing its omega-3 products with disease claims—that is, claims that the products treat or prevent cardiovascular disease and claims that the products are comparable to prescription drugs like Vascepa—gives Omax an unfair competitive advantage over law-abiding pharmaceutical manufacturers like Amarin. Worse, it puts patients at risk by exposing them to unapproved drugs that are marketed under the guise of legal dietary supplements and by encouraging consumers to substitute unproven products for medical treatments they may need under a doctor's care.

16. In addition, the statements in the press release cited above (among others) are false and misleading for a number of reasons. For example, these statements falsely and/or misleadingly state—without any substantiation—that Omax's omega-3 "dietary supplements," and omega-3 dietary supplements more generally, are safe and effective in treating or preventing heart disease.

17. The results of the REDUCE-IT trial are relevant only to Vascepa and cannot be extrapolated to support the safety and efficacy of Omax's omega-3 dietary supplements in reducing cardiovascular risk. The REDUCE-IT trial studied the efficacy of a specific prescription *drug* comprised of a unique active ingredient: a single molecule omega-3 fatty acid in ethyl ester form (namely, EPA). That drug was then administered at a specified dose, 4 grams per day, to a particular *statin-treated* population identified as being at high risk for cardiovascular events to evaluate its impact on that population. Thus, the results cannot be extrapolated to *unproven, non-prescription products* that are marketed as "dietary supplements" to the *general population* (i.e., a population that is not taking statins and is not at high risk for cardiovascular events)—particularly when those supplements have loosely regulated manufacturing controls, *different omega-3 fatty acid compositions*, *different omega-3 dosages*, and added ingredients.

18. Omax's statements in the press release (as well as other statements discussed below) are also false and misleading because they equate Omax's omega-3 products with Vascepa. The products are materially different. There is no evidence supporting Omax's claims that the products are comparable.

19. Marketing dietary supplements in a manner that renders them unapproved drugs, and in a manner that deceives consumers—as Omax is doing—can have profound implications for personal and public health. As former Attorney General Loretta Lynch observed:

> What many Americans don't know is that dietary supplements are not subject to testing by the Food and Drug Administration before they reach the store shelves—meaning that every day, millions of Americans are ingesting substances whose safety and efficacy are not guaranteed. Some of these supplements are simply a waste of money, promising results that they can't deliver or advertising ingredients that they don't contain. And too often, these supplements don't just abuse consumer trust—they also endanger public health. Some contain harmful ingredients, causing consumers to fall ill. Others falsely claim to cure illness and disease, leading patients to use them as a substitute for the proven therapies they need. But whether these supplements are deceptive or dangerous, the fact remains that too many companies are making a profit by misleading—and in some cases harming—American consumers.

Attorney General Lynch Discusses Department's Efforts to Protect Consumers From Unsafe Dietary Supplements, DEPARTMENT OF JUSTICE, OFFICE OF PUBLIC AFFAIRS, (March 8, 2016), https://www.justice.gov/opa/pr/attorney-general-lynch-

discusses-departments-efforts-protect-consumers-unsafe-dietary, submitted herewith as Exhibit 5.

20. In addition, marketing dietary supplements in a manner that renders them unapproved drugs, and that deceives consumers can cause significant reputational harm to legitimate manufacturers of approved omega-3 prescription drugs, like Amarin. Consumers encountering Omax's false advertising who have paid attention to these and other warnings about dietary supplements may discredit all omega-3 products including Amarin's, without realizing that Amarin is selling legitimate, tested products with proven results. On the other hand, consumers encountering Omax's false advertising who do not know about the noted problems with the dietary supplement industry are likely to rely—to their detriment and Amarin's—on Omax's false and misleading statements regarding the safety, efficacy, and treatment value of its products.

21. Amarin has suffered and is suffering from competitive injuries as a result of Omax's unlawful activities. Amarin's drug, Vascepa, competes with Omax's omega-3 line of products, which include (1) Omax3 Ultra-Pure, (2) Omax3 Pro Strength ("Omax3 Pro"), (3) Omax Cognitive Boost, (4) Omax Sleep & Stress Remedy – Hemp Blend, and (5) Omax3 MAX Recovery Clinical Strength ("Omax3 MAX").

22. Amarin brings this action to stop Omax from engaging in false and misleading advertising in violation of the Lanham Act and the UCL and from illegally promoting and selling unlawful and unapproved drugs in violation of the Sherman Law.

PARTIES

23. Amarin Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 1430 Route 206, Bedminster, NJ 07921. Amarin Pharmaceuticals Ireland, Ltd. is organized under the laws of the Republic of Ireland, with its principal place of

business located at 2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2 Ireland.

24. Defendant Omax Health, Inc. is a corporation incorporated in Delaware, with its principal place of business located at 2601 Ocean Park Blvd., Santa Monica, CA, 90405.

25. Omax owns and operates offices in Los Angeles, California and Lambertville, New Jersey. Omax has previously done business as Prevention Pharmaceuticals.

26. Omax sells its products primarily online, and ships them throughout California, including in this District, nationwide, and internationally.

JURISDICTION

27. This Court has subject matter jurisdiction under 15 U.S.C. § 1121(a) and 28 U.S.C. §§ 1331 and 1367.

28. This Court has personal jurisdiction over Omax because Omax's principal place of business is in California and Amarin's claims arise out of or relate to Omax's contacts with California.

29. Venue in this District is proper under 28 U.S.C. § 1391.

FACTUAL ALLEGATIONS

A. Omax's False and Misleading Advertising and Promotion of Its Omega-3 Products.

30. Omax manufactures and sells a number of omega-3 products that purport to effectively treat or prevent cardiovascular disease, among other things. Those products include Omax3 Ultra-Pure, Omax Cognitive Boost, Omax Sleep & Stress Remedy – Hemp Blend, Omax3 MAX, and Omax3Pro. *See Shop*, OMAX HEALTH (last visited Oct. 25, 2018), https://omaxhealth.com/collections/all (hereinafter "Omax Products"), submitted herewith as Exhibit 6.

31. Omax claims that all of its omega-3 products contain EPA and DHA in a 4:1 EPA to DHA ratio. *See Our Story*, OMAX HEALTH (last visited Oct. 25,

2018), https://omaxhealth.com/pages/omax3-story (hereinafter "Our Story"), submitted herewith as Exhibit 7; *see also* Omax Products, Exhibit 6, at 0005. This claimed composition of omega-3 fatty acids in the Omax products, all of which include some DHA, is materially different from the composition of Vascepa, which is pure EPA.

32. Each of the Omax omega-3 products appears to contain a different dosage of omega-3 fatty acids. Omax3 Ultra-Pure purportedly contains a dosage of 1.5 grams per day; Omax Cognitive Boost purportedly contains a dosage of 1 gram per day; Omax Sleep & Stress Remedy – Hemp Blend purportedly contains a dosage of 530 milligrams per day; Omax3 MAX purportedly contains a dosage of 2 grams per day; and Omax3 Pro purportedly contains a dosage of 3 grams per day. *See* Omax Products, Exhibit 6, at 0006-0013; Omax3 Pro, Exhibit 28, at 0945-46.

33. Because neither California nor the FDA reviews products marketed as "dietary supplements" before they are marketed, it is unclear whether the omega-3 content advertised on Omax's nutrition labels reflects the actual content found in Omax's "dietary supplements." Indeed, at least two studies have shown that a majority of omega-3 dietary supplements do not contain the labeled amount of omega-3. *See* Alison Kleiner et al., *A Comparison of Actual Versus Stated Label Amounts of EPA and DHA in Commercial Omega-3 Dietary Supplements in the United States*, 95 J. SCI. FOOD & AGRIC. 1260 (2015) (abstract), submitted herewith as Exhibit 8 (finding that over 70% of the 47 omega-3 dietary supplements tested did not contain the amount of EPA or DHA claimed on the label); Jenna Sullivan Ritter et al., *Quality Analysis of Commercial Fish Oil Preparations*, 93 J. SCI. FOOD & AGRIC. 1935 (2012) (abstract), submitted herewith as Exhibit 9 (finding that over half of the 16 top selling liquid fish oil products in the U.S., which were sold by nine different manufacturers, did not contain the amount of EPA and DHA claimed on the label).

34. In any event, none of the purported omega-3 dosages in Omax's omega-3 dietary supplements (which are a mix of EPA, DHA, and other ingredients) are as high as the prescription dose of Amarin's Vascepa drug, which is 4 grams per day of pure EPA.

35. Omax has made, and is continuing to make, false and misleading statements regarding its omega-3 products in advertising and promotional materials. These false and misleading statements appear to fall into three categories: (1) unsubstantiated claims that Omax's omega-3 products treat or prevent heart disease; (2) improper and unsubstantiated comparisons of Omax's omega-3 products to Amarin's Vascepa (and other prescription drugs); and (3) unsubstantiated claims that Omax3 has been formulated so that it does not increase low-density lipoproteins ("LDL"), often referred to as bad cholesterol.

i. Omax's Unsubstantiated Cardiovascular Treatment and Prevention Claims Are False and Misleading.

36. Omax falsely and misleadingly states that Omax's omega-3 products treat or prevent cardiovascular disease. Omax's claims made in connection with the marketing of the Omax omega-3 products at issue include, for example, assertions that:

- "Omega-3s can . . . help reduce the risk of coronary heart disease." *Omega 3 Benefits*, OMAX HEALTH, https://omaxhealth.com/pages/why-omega-3, (hereinafter "Omega 3 Benefits"), submitted herewith as Exhibit 10.
- "Today, Amarin released the long-awaited results of the Vascepa® (icosapent ethyl) REDUCE-IT trial, further validating Omax3®'s 10-year position, that high-concentrate omega3 fatty acids have a profound and lasting effect on cardiovascular health." *Omax Press Release*, Exhibit 4.
- "Amarin reported that the omega-3 fish oil prescription capsule called Vascepa significantly reduced the risk of serious cardiovascular events in 8,179 statin-treated patients over nearly 5 years. . . . Although Vascepa is a

> pharmaceutical drug, this groundbreaking [REDUCE-IT] study further validates the safety and efficacy of Omax3's pharmaceutical grade omega-3 dietary supplement." *Id.*

37. These statements are false and misleading for at least three reasons. First, on information and belief, Omax has no reliable studies supporting the claim that omega-3 dietary supplements generally (regardless of dosage or composition) can reduce the risk of coronary heart disease or have a "profound and lasting effect on cardiovascular health" in general healthy populations. In fact, three recent meta-analyses published in highly respected medical journals show that there is no scientific consensus that omega-3 dietary supplements such as those sold by Omax have any beneficial effect on cardiovascular disease risks, or even cardiovascular health more generally, in healthy populations. *See* David S. Siscovick et al., *Omega-3 Polyunsaturated Fatty Acid (Fish Oil) Supplementation and the Prevention of Clinical Cardiovascular Disease: A Science Advisory From the American Heart Association*, 135 CIRCULATION e867, e8804, Table 8 (2017), http://circ.ahajournals.org/content/early/2017/03/13/CIR.0000000000000482, submitted herewith as Exhibit 11 ("available evidence does not support the use of [omega-3] supplements in the general population who are not at high risk [for cardiovascular disease]"); *see also* Ethan M. Balk et al., *Omega-3 Fatty Acids and Cardiovascular Disease: An Updated Systematic Review*, EVIDENCE REPORT/TECHNOLOGY ASSESSMENT Number 223, vi (Aug. 2016), https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/fatty-acids-cardiovascular-disease_research.pdf (last accessed Oct. 26, 2018), submitted herewith as Exhibit 12 (concluding that omega-3 supplements do not affect "major adverse [cardiovascular] events, all-cause death, sudden cardiac death, coronary revascularization, atrial fibrillation, or [blood pressure]" *in populations at risk for or with cardiovascular disease*, or in "general healthy populations"); Asmaa S. Abdelhamid et al., *Omega-3 Fatty Acids for the Primary and Secondary*

Prevention of Cardiovascular Disease, COCHRANE DATABASE OF SYSTEMATIC REVIEWS 1, 3 (July 2018), https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003177.pub3/full, submitted herewith as Exhibit 13 ("There is evidence that taking omega-3 capsules does not reduce heart disease, stroke or death.").

38. In addition, there is currently no scientific consensus that omega-3 dietary supplements are beneficial even in diseased patients. Another meta-analysis, published in the Journal of the American Medical Association ("JAMA"), in 2018, called into question the validity of guidelines recommending the use of omega-3 dietary supplements for the prevention of coronary heart disease ("CHD") and major vascular events in people with CHD. *See* Theingi Aung, et al., *Associations of Omega-3 Fatty Acid Supplement Use with Cardiovascular Disease Risks: Meta-analysis of 10 Trials Involving 77,917 Individuals*, 3 JAMA CARDIOLOGY 225 (Jan. 31, 2018), https://jamanetwork.com/journals/jamacardiology/fullarticle/2670752, submitted herewith as Exhibit 14. After reviewing 10 studies involving 77,917 patients, the authors stated that "[t]his meta-analysis demonstrated that omega-3 fatty acids had no significant association with fatal or nonfatal coronary heart disease or any major vascular events. It provides no support for current recommendations for the use of such supplements in people with a history of [CHD]." *Id.* at 225.

39. Second, on information and belief, Omax has no reliable studies supporting the extrapolation of the REDUCE-IT results to Omax's omega-3 dietary supplements.

40. The REDUCE-IT results show that Amarin's Vascepa, a prescription drug of a particular composition and dosage, reduced major cardiovascular events in a very specific patient population—i.e., *statin-treated* patients with persistently high triglycerides, who also had either (1) a history of cardiovascular events, such as heart attacks, strokes and angina, or (2) Type 2 diabetes and other risk factors

like high blood pressure. *See generally* Deepak L. Bhatt et. al, *Rationale and Design of REDUCE-IT: Reduction of Cardiovascular Events with Icosapent Ethyl-Intervention Trial*, 40 CLINICAL CARDIOLOGY 138 (2017), https://onlinelibrary.wiley.com/doi/epdf/10.1002/clc.22692, submitted herewith as Exhibit 15.

41. These results cannot be extrapolated to Omax's omega-3 products—unproven, non-prescription products that are marketed as "dietary supplements" to the general population (i.e., a population that is not taking statins and is not at high risk for cardiovascular events)—particularly when those supplements have different omega-3 fatty acid compositions, different omega-3 dosages, and added ingredients.

42. It is false and misleading for Omax to suggest that clinical trial results involving a prescription drug can be extrapolated to dietary supplements at all because the regulatory regimes are so different. Before FDA approves a drug it verifies that the drug is safe and effective for its labeled uses. 21 U.S.C. § 355(d)(1), (5). FDA also verifies, pre-market, that the drug is labeled properly and that it is manufactured in accordance with quality controls that ensure that each lot of the drug has the same "identity, strength, quality, and purity" as the lots of the drug that were tested in the clinical studies that formed the basis for the drug's approval, *see* 21 U.S.C. § 355(d)(3), (7). In other words the quality controls for drugs ensure that the clinical trial results for the drug may be properly extrapolated to subsequent lots of the *same drug*.

43. By contrast, FDA does not review dietary supplements before (or even after) they are marketed to the public. Thus, there can be no assurance that dietary supplements are safe and effective for their labeled and advertised uses. Moreover, FDA does not verify that a dietary supplement is labeled properly, or that it has the identity, strength, quality, or purity claimed before (or after) it is marketed. Further, dietary supplements are subject to less stringent manufacturing

controls than drugs. *Compare* Cal. Health & Safety Code § 110105 (adopting 21 C.F.R. pts. 210, 211 (drug good manufacturing practices), *to* 21 C.F.R. pt. 111 (dietary supplement good manufacturing practices)). Thus, the identity, strength, quality and purity of a dietary supplement may vary from lot to lot.

44. Therefore, even if the labeling of a drug and a dietary supplement suggested that the products had identical formulations (which is not the case here), there would be no way of knowing—short of well-controlled and scientifically rigorous head-to-head testing—whether any given lot of a dietary supplement actually has the advertised identity, strength, quality, or purity, and thus whether that lot has the same safety and efficacy profile as the drug. And, in all likelihood, given the less stringent manufacturing and quality controls that apply to dietary supplements, it would not.

45. Manufacturing controls are particularly important for omega-3 products because omega-3 fatty acids are highly prone to oxidation (spoilage typically evidenced by a fishy smell) that is believed to convert their antioxidant properties to pro-oxidant properties resulting in the potential for reduced efficacy, or even negative effects on health. *See, e.g.*, Preston Mason & Samuel C.R. Sherratt, *Analysis of Omega-3 Fatty Acid Dietary Supplements With Respect to Content: Are They Appropriate for Patients?* J. MANAGED CARE & SPECIALTY PHARMACY (2015), submitted herewith as Exhibit 16; Rufus Turner, Carlene H. McLean, & Karen M. Silvers, *Are the Health Benefits of Fish Oils Limited by Products of Oxidation?*, 19 NUTRITION RESEARCH REVIEWS 53 (2006), submitted herewith as Exhibit 17; *Supplements and Safety*, PBS: FRONTLINE (Jan. 19, 2016) at 39:30, http://www.pbs.org/video/frontline-supplements-and-safety/ (last accessed Oct. 27, 2018) (discussing the difference between FDA-approved omega-3 drug products and fish oil dietary supplements, and related negative effects of oxidized lipids in fish oil).

46. Moreover, the REDUCE-IT results cannot be extrapolated to Omax's

omega-3 products because they have wholly and materially different fatty acid compositions and dosages, as well as additional ingredients. As mentioned, Vascepa is purified EPA dosed at 4 grams per day in capsule form. The Omax products, by contrast, contain combinations of EPA, DHA, and other omega-3 fatty acids; and their dosages range from 530 milligrams to 3 grams per day.

47. Nor can the results of REDUCE-IT be extrapolated from the diseased population studied to healthy populations with Omax's products, as Omax wrongly claims, particularly given that the diseased population in the REDUCE-IT trial was also taking Vascepa with statins, another drug.

48. Upon information and belief, Omax is aware that the REDUCE-IT results cannot be extrapolated to its products, and that as a result, its advertising is false and misleading.

49. In 2016, the National Advertising Division ("NAD") of the Better Business Bureau reviewed several of Omax's advertising claims, and advised the company that for Omax to legitimately rely on studies about certain ingredients in its products, "those ingredients must be present in [Omax's] products in the same amount, formulation and route of administration as the underlying ingredient studies**."** *See* NAD Decision Case #5966, Prevention Pharmaceuticals, Inc., Omax3 Ultra Pure Dietary Supplement, July 6, 2016, at 16 (hereinafter "NAD Case #5966"), submitted herewith as Exhibit 18.

50. NAD's recommendations are particularly relevant here because they were triggered in part by Omax's misplaced reliance on other clinical trials involving *Vascepa*—the MARINE trial and the ANCHOR trial. *See id*. at 0017, n. 31. Omax had attempted to use those trials to support a claim that its omega-3 dietary supplements (like Vascepa) were superior to others on the market. Because Omax's dietary supplements, however, differed from Vascepa based on dosage, composition (EPA to DHA ratio), study population, and product type (non-prescription versus prescription drugs), NAD concluded that it was false and

misleading for Omax to attempt to use those studies to support claims for its products. *See id.* (NAD also concluded that Omax had insufficient evidence to support its inflammation reduction claims for Omax3, but Omax has yet to remove those claims from its website). *See id.* at 0019. Omax's reliance on REDUCE-IT's results (regarding a materially different prescription drug) to support safety and efficacy claims for its omega-3 "dietary supplements" is even more egregious than the company's reliance on the MARINE and ANCHOR trials because in the REDUCE-IT trial, the patients were taking Vascepa in addition to statins, which further confounds Omax's attempt to extrapolate the results of the study to the effect of its omega-3 products.

51. Similarly, the Federal Trade Commission ("FTC"), in its 2001 guide for advertising dietary supplements, specifically advised dietary supplement companies that "[c]laims that do not match the science, no matter how sound that science is, are likely to be unsubstantiated" and thereby false and misleading. DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, FEDERAL TRADE COMMISSION (2001), https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf, submitted herewith as Exhibit 19. The FTC also specifically recognized that promotional claims for dietary supplements "do not match the science" when the research was conducted on a product that differs from the dietary supplement—with regard to the dosage, the formulation, additional ingredients, and the study population.

52. FDA also has confirmed that formulation, serving size, route of administration, length of exposure, frequency in exposure, whether one product contains additional ingredients, study population, and regulated product type (e.g., conventional food compared to a dietary supplement) all affect the accuracy of claims made comparing a studied ingredient with an advertiser's product. *See Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act*, U.S. Food

& Drug Admin. (Dec. 2008), https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm, submitted herewith as Exhibit 20.

53. Using the results from a study involving a purified EPA product to support the safety and efficacy of a different omega-3 product (or indeed, a line of omega-3 products), as Omax is doing, is false and misleading when the advertised products have different fatty acid compositions (EPA, DHA, and other fatty acid rations) and different dosages as they do here. These differences are not small or immaterial. Indeed, FDA treats drugs with different omega-3 fatty acid compositions—as having wholly different active ingredients. *See* Dormer Letter, Exhibit 3.

54. Third, the Omax Press Release falsely states that Omax or its products are somehow connected with Amarin's products and the REDUCE-IT™ trial by stating that Amarin's REDUCE-IT trial "further validat[es] Omax3®'s 10-year position, that high-concentrate omega3 fatty acids have a profound and lasting effect on cardiovascular health." *Omax Press Release*, Exhibit 4.

55. Omax's false and misleading statements regarding the efficacy of its omega-3 dietary supplements are particularly concerning from a public health perspective in light of the fact that the company does not appear to disclose any information regarding the potential risks associated with the products. Indeed, the FDA-approved labeling for Vascepa as well as the FDA-approved labeling for Lovaza, a competing omega-3 drug, contain warnings and disclosures, as applicable, regarding the facts that (1) omega-3 products may prolong bleeding time (particularly in conjunction with drugs affecting coagulation), (2) omega-3 products may increase liver enzyme levels in people with poor liver function, and (3) omega-3 products that contain DHA may increase bad cholesterol and lead to more frequent recurrences of atrial fibrillation. *See* Vascepa® Full Prescribing Information, Exhibit 2; Lovaza Full Prescribing Information,

https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Lovaza/pdf/LOVAZA-PI-PIL.pdf, submitted herewith as Exhibit 21.

ii. Omax's Claims that Its Omega-3 Products Are Comparable to Amarin's Vascepa Prescription Drugs Are False and Misleading.

56. Omax also makes a number of claims that falsely express or imply that Omax's Omega-3 products are comparable to Amarin's prescription Vascepa product. These include:

- The REDUCE-IT trial, which studied Amarin's prescription drug Vascepa®, "further validat[es] Omax3®'s 10-year position, that high-concentrate omega3 fatty acids have a profound and lasting effect on cardiovascular health." *See* Omax Press Release, Exhibit 4.
- "Amarin reported that the omega-3 fish oil prescription capsule called Vascepa significantly reduced the risk of serious cardiovascular events in 8,179 statin-treated patients over nearly 5 years. . . . Although Vascepa is a pharmaceutical drug, this groundbreaking study further validates the safety and efficacy of Omax3's pharmaceutical grade omega-3 dietary supplement." *Id.*
- "Omax3® is a proprietary and patented omega-3 fish oil supplement developed by Yale-affiliated scientists to provide potent, natural anti-inflammatory benefits *without a prescription*," *FAQs*, OMAX HEALTH, https://omaxhealth.com/pages/faqs (last visited Oct. 25, 2018) (emphasis added) (hereinafter "Omax FAQs"), submitted herewith as Exhibit 22.

57. These claims are false and misleading because they convey that Omax's Omax3 line of products, as well as its other high concentrate omega-3 products, such as Omax Cognitive Boost and Omax Sleep & Stress Remedy – Hemp Blend, are comparable to Amarin's Vascepa, when they are not.

58. On information and belief, Omax has no reliable studies supporting the extrapolation of the REDUCE-IT results to Omax's omega-3 dietary

supplements. As explained above, the results of REDUCE-IT cannot be extrapolated from the tested Vascepa prescription product to Omax's omega-3 products, or to omega-3 dietary supplements generally, because of numerous confounding factors.

59. For the same reasons, the three statements cited above, or any similar claims suggesting that Omax's omega-3 "dietary supplements" are somehow comparable to Vascepa, or any prescription drug with a materially different omega-3 fatty acid composition and dosage (among other things), are false and misleading.

60. Omax's false and misleading statements that its "dietary supplements" are comparable to Vascepa are particularly concerning from a public health perspective in light of the fact that the company does not disclose any information regarding the potential risks associated with Omax's omega-3 dietary supplements products, which when taken at doses similar to Vascepa may have similar risks.

iii. Omax's Claim that Its Omega-3 Products Do Not Raise LDL Levels Is False and Misleading.

61. Despite the fact that all of its omega-3 "dietary supplements" contain DHA, Omax is falsely and misleadingly stating that "Omax3 has been formulated so it doesn't increase LDL levels, or bad cholesterol." Omega 3 Benefits, Exhibit 10.

62. As the medical community knows, omega-3 products that include DHA, like Omax's products, can raise levels of bad cholesterol (LDL-C) in diseased patients for whom omega-3 drugs are typically prescribed. *See* H. S. Weintraub, *Overview of Prescription Omega-3 Fatty Acid Products for Hypertriglyceridemia*, 126 POSTGRADUATE MED. 7 (2014) (abstract), submitted herewith as Exhibit 23; *see also* FDA MEDICAL REVIEW OF OMTRYG, CENTER FOR DRUG EVALUATION AND RESEARCH 19 (Jan. 24, 2014), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204977Orig1s000Med

R.pdf, submitted herewith as Exhibit 24; *see also* Melissa Y. Wei & Terry A. Jacobson, *Effects of Eicosapentaenoic Acid Versus Docosahexaenoic Acid on Serum Lipids: A Systematic Review and Meta Analysis*, 13 CURRENT ATHEROSCLEROSIS REPORTS 474 (2011) (abstract), https://www.ncbi.nlm.nih.gov/pubmed/21975919, submitted herewith as Exhibit 25.

63. Moreover, a recent meta-analysis of the scientific literature on the effects of the omega-3 ingredient on cholesterol, conducted by AHRQ, indicates that omega-3 supplements (with DHA) *increase both HDL and LDL* by approximately 0.9 mg/dL and 2.0 mg dL, respectively. *See Omega-3 Fatty Acids and Cardiovascular Disease: Current State of Evidence*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (July 25, 2017), https://effectivehealthcare.ahrq.gov/topics/fatty-acids-cardiovascular-disease/clinician/ (last visited on Oct. 26, 2018), submitted herewith as Exhibit 26.

64. Accordingly, manufacturers of prescription omega-3 drug products that contain DHA, such as Lovaza®, are required to include the following statement, or similar language, in the Warnings and Precautions section of the prescribing information: "In some patients, LOVAZA increases LDL-C levels. LDL-C levels should be monitored periodically during therapy with LOVAZA." Lovaza Prescribing Information, Exhibit 21.

65. Indeed, in 2016, NAD specifically recommended that Omax discontinue making this same claim—"unlike other fish oils, Omax3 will not raise low-density lipoproteins (LDL)"—because the claim was not adequately supported. *See* NAD Case #5966, Exhibit 18. Two years later, Omax still has not heeded this advice.

B. Omax's Violation of the Sherman Law's Drug Approval Provisions

66. Omax is making a number of disease claims—claims that express or imply that its omega-3 dietary supplements treat or prevent cardiovascular disease,

and claims that express or imply that its omega-3 dietary supplements are comparable to prescription drugs that treat or prevent disease, such that they may be used as substitutes. Examples of these claims include:

- "Omega-3s can . . . help reduce the risk of coronary heart disease." Omega 3 Benefits, Exhibit 10.
- The results of REDUCE-IT validate that "high-concentrate omega3 fatty acids have a profound and lasting effect on cardiovascular health." Omax Press Release, Exhibit 4.
- "Amarin reported that the omega-3 fish oil prescription capsule called Vascepa significantly reduced the risk of serious cardiovascular events in 8,179 statin-treated patients over nearly 5 years. . . . Although Vascepa is a pharmaceutical drug, this groundbreaking study further validates the safety and efficacy of Omax3's pharmaceutical grade omega-3 dietary supplement." *Id.*
- "Omax3® is a proprietary and patented omega-3 fish oil supplement developed by Yale-affiliated scientists to provide potent, natural anti-inflammatory benefits *without a prescription*" Omax FAQs, Exhibit 22.

67. As discussed, the Sherman Law defines "drug" to include any product that is "used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." Cal. Health & Safety Code § 109925. FDA's definition of "drug" is almost identical to the Sherman Law's definition: under both statutes, disease claims render purported dietary supplements "drugs," subject to all the rigorous requirements that accompany that designation. *Compare* 21 U.S.C. § 321(g) *to* Cal. Health & Safety Code § 109925. The federal agency's regulations at 21 C.F.R. § 101.93(g) provide examples of the types of claims that constitute "disease" claims that in turn subject purported dietary supplements to the drug approval processes. 21 C.F.R. § 101.93(g). These claims include those that explicitly, or implicitly, indicate that the purported dietary supplement, among other things: (1) has an effect on "a specific disease or class of diseases," 21

C.F.R. § 101.93(g)(2)(i); (2) has an effect on "the characteristic signs or symptoms of a specific disease or class of diseases," *id.* § 101.93(g)(2)(ii); or (3) "[i]s a substitute for a product that is a therapy for a disease," *id.* § 101.93(g)(2)(vi). In addition, the Sherman Law expressly incorporates "[a]ll regulations relating to . . . new drug applications . . . adopted pursuant to Section 505" of the Federal Food, Drug and Cosmetic Act ("FDCA"). Cal. Health & Safety Code 110110(a).

68. The first three claims listed above expressly or impliedly indicate that Omax's omega-3 dietary supplements treat or prevent cardiovascular disease and/or can be used as a substitute for Vascepa, a prescription drug that treats and prevents disease. Thus, these claims are "disease" claims that render Omax's omega-3 dietary supplements drugs.

69. The last claim listed above is different because it implies that Omax's omega-3 products are a substitute for prescription drugs that treat inflammation. Notably, anti-inflammatory claims, like cardiovascular disease claims, are "disease" claims as well. *See, e.g.*, FDA Warning Letter to Y.S. Health Corp., FDA.GOV (Aug. 29, 2013), https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm367832.htm (citing the claim "[i]t supports . . . the body's natural anti-inflammatory response" as a "disease" claim that triggers unapproved drug status), submitted herewith as Exhibit 27.

70. Moreover, the anti-inflammatory comparative claim implies that Omax's products are comparable to prescription drugs that treat cardiovascular disease. This is apparent given that elsewhere on Omax's website, the company states that the "inflammation fighting benefits of EPA" lower triglycerides, "improve cardiovascular health," and "even help reduce the risk of coronary heart disease." *Omega-3 Benefits*, Exhibit 10. Thus, that claim, too, is a "disease" claim that renders Omax's Omax3 dietary supplements "drugs."

71. As discussed, California's Sherman Law provides that "[n]o person

shall sell, deliver, or give away any new drug" that has not been approved by FDA or by the State of California. Cal. Health & Safety Code § 111550(a)–(b).

72. Omax is violating California's Sherman Law because, despite advertising and marketing its omega-3 products with "disease" claims rendering those products "drugs," upon information and belief, it has not obtained the approval of either the State of California or FDA to introduce any of the drugs that it is manufacturing, marketing, and selling, such as Omax3, into commerce. *See id.* § 111550(a)–(b).

C. Omax's Activities Violate the Lanham Act's Prohibition on False or Misleading Descriptions or Representations of Fact

73. The Lanham Act protects those engaged in commerce from unfair competition by the use of false or misleading descriptions of fact, or false or misleading representations of fact, in commercial advertising or promotion. 15 U.S.C. § 1125(a)(1).

74. The Lanham Act creates a cause of action against "[a]ny person who, on or in connection with any goods or services . . . uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . is likely to cause confusion, or to cause mistake, or to deceive as to the . . . approval of his or her goods, services, or commercial activities by another person, or . . . in commercial advertising or promotion, misrepresents the nature, characteristics [or] qualities . . . of his or her . . . goods, service, or commercial activities." 15 U.S.C. § 1125(a).

75. Omax is violating the Lanham Act because its advertising and promotion for its omega-3 dietary supplements is materially misleading to consumers. Omax "misrepresents the nature, characteristics [or] qualities" of its omega-3 dietary supplements and deceives consumers into believing that Omax's omega-3 products are effective at treating or preventing cardiovascular disease and are comparable to pharmaceutical drugs like Vascepa, when that is not the case.

Omax also falsely advertises its omega-3 dietary supplements, which contain DHA, as not raising LDL, or bad cholesterol.

76. Omax's false and misleading advertising and promotion is material and reasonably relied on by consumers. Upon information and belief, these representations have caused, and are likely to continue to cause, consumers to purchase Omax's omega-3 products instead of consulting with their physicians and purchasing Amarin's pharmaceutical drug, Vascepa, when medically necessary. Omax's omega-3 products can be purchased at pharmacies, big box stores, and over the Internet, without restriction. By contrast, Vascepa can only be distributed pursuant to a prescription. Thus, as a result of Omax's misleading advertising, which states that the two products are comparable and equally effective at treating cardiovascular disease, consumers are likely to have purchased Omax's omega-3 products rather than Vascepa to treat their cardiovascular symptoms.

77. On information and belief, but for Omax's false and misleading statements, sales of Vascepa would displace a significant percentage of Omax's sales of its omega-3 products in the direct-to-consumer channel of distribution because consumers would seek prescriptions for Vascepa and other FDA-approved triglyceride-lowering drugs. And in the absence of Omax's actions, sales of Vascepa or other FDA-approved prescription triglyceride-lowering drugs would likely displace all of Omax's sales of its omega-3 products in the physician prescription channel of distribution.

78. If consumers knew the truth about Omax's dietary supplements, they would not purchase Omax's products and would consult with their physicians to determine whether they have a medical condition or disease that would benefit from an FDA-approved therapy, rather than taking serious health matters into their own hands with purported dietary supplements that are actually unproven drugs.

79. Omax's false or misleading statements were made in interstate commerce.

80. Amarin has suffered and will continue to suffer irreparable harm and actual damages as a result of Omax's unfair competition and false advertising, including but not limited to reputational harm in that Amarin's product is being unfairly associated in the marketplace with unapproved drugs marketed with false and misleading statements and the cost of corrective advertising to address this unfair association.

D. Omax's Activities Violate the False Advertising Provisions of the Sherman Law.

81. The Sherman Law makes it unlawful for anyone to "disseminate any false advertisement [about] any . . . drug," and "[a]n advertisement is false if it is false or misleading in any particular." Cal. Health & Safety Code § 110390. "In determining whether the labeling or advertisement of a . . . drug . . . is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account." *Id.* § 110290. "The extent that the labeling or advertising fails to reveal facts concerning . . .the drug . . .shall also be considered." *Id.*

82. Omax is violating the Sherman Law because the advertising and promotional materials for its unapproved drugs, which are manufactured and marketed under the guise of being dietary supplements (e.g., its line of omega-3 dietary supplements), are misleading to California consumers.

83. Omax makes false and misleading statements in its promotional materials to consumers that lead consumers into believing that Omax's omega-3 products are effective at treating or preventing cardiovascular disease and are comparable to pharmaceutical drugs like Vascepa—when that is not the case. Omax also falsely advertises its omega-3 dietary supplements, which contain DHA, as not raising LDL, or bad cholesterol.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of the Lanham Act

(15 U.S.C. § 1051, et seq.)

84. Amarin realleges and incorporates by reference each and every allegation set forth above as if fully stated herein.

85. Omax's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a).

86. Omax has violated the Lanham Act by using "false or misleading descriptions of fact" and "false or misleading representations of fact" in its commercial advertising or promotion that "misrepresent[] the nature, characteristics, [or] qualities" of its products, as set forth above. These include (by way of example only) its promotion of its omega-3 dietary supplements as effective at treating or preventing cardiovascular disease, and its promotion of its products as being comparable to Amarin's prescription drug product, Vascepa.

87. Omax has violated the Lanham Act by: (1) making false and misleading statements about its products; (2) making unsupported and false or misleading claims about product efficacy, both comparatively and absolutely; (3) making unsupported disease treatment claims; and (4) presenting its products under the false guise of "dietary supplements" while illegally promoting the products with drug treatment claims.

88. Amarin has suffered irreparable reputational harm, injury in fact, and actual damages resulting from Omax's false and misleading advertising and promotion and unfair competitive practices, including but not limited to the cost of corrective advertising needed to counter Omax's false and misleading advertising.

89. Amarin seeks disgorgement of Omax's profits and injunctive relief requiring Omax to cease its false and misleading advertising and promotion and

unfair competitive practices.

SECOND CLAIM FOR RELIEF

Violation of California's Unfair Competition Law (UCL)

(Cal. Bus. & Prof. Code § 17200, et. seq.)

90. Amarin realleges and incorporates by reference each and every allegation set forth above as if fully stated herein.

91. Omax's practices, as described in this complaint, constitute unlawful and/or unfair business practices in violation of California's UCL, Cal. Bus. & Prof. Code, § 17200, *et seq*.

92. Omax's omega-3 products, marketed as "dietary supplements," are "drugs" under California and federal law, namely Health & Safety Code sections 109925(b) –(c), 110110, and 21 U.S.C. § 321(g)(1) and 21 C.F.R. § 310.527(a), because they are intended to cure, mitigate, treat, or prevent disease and are promoted by Omax for these purposes and used by consumers in California for these purposes.

93. Omax's products are "new drugs" under California law, namely Health & Safety Code section 109980 , and 21 U.S.C. § 321(p)(1) and 21 C.F.R. § 310.527(a), as incorporated by Health & Safety Code section 110110, because they are not generally recognized by qualified experts as safe and effective for their intended uses.

94. Omax's products have not been approved by FDA or by the California Department of Health Services as required by 21 U.S.C. § 355 *et seq*, and Health & Safety Code sections 111550(a)–(b).

95. Omax has violated the UCL by unlawfully marketing, selling, and distributing its products in violation of the California Sherman Law.

96. Omax has also violated the UCL by unlawfully marketing and distributing its products in violation of the Sherman Law's false advertising provisions.

97. Omax's practices as alleged in this Complaint constitute unfair business practices in violation of the UCL because they are substantially injurious to consumers and any utility of such practices is outweighed by the harm to consumers. Omax's practices violate California's legislative policy of protecting patients and consumers by prohibiting the marketing, sale, and distribution of Omax's omega-3 products as drugs when such products have not been approved by FDA or the California Department of Health Services. Omax's practices have caused and are causing substantial injuries to Amarin and the public. Those injuries are not outweighed by any benefits.

98. Amarin has suffered irreparable reputational harm, injury in fact, and actual damages because of Omax's unlawful and unfair business practices.

99. Amarin seeks declaratory and injunctive relief requiring Omax to cease the unlawful actions and misconduct alleged.

PRAYER FOR RELIEF

WHEREFORE, Amarin respectfully requests that this Court enter judgment in its favor as follows:

1. A permanent injunction prohibiting Omax from continuing the unlawful and unfair practices alleged in this Complaint.

2. A judgment that Omax violated the Lanham Act, 15 U.S.C. § 1051, et seq.;

3. A judgment that Omax violated California Business and Professions Code section 17200, et seq.;

4. Damages, corrective advertising costs, profits and other monetary relief according to proof;

5. Declaratory relief;

6. Attorneys' fees and costs incurred in this action;

7. Prejudgment interest; and

8. Any further relief the Court may deem just and proper.

REQUEST FOR JURY TRIAL

Amarin demands a trial by jury on all claims and issues so triable.

DATED: October 29, 2018

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