UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Southern Division)

DAVID STARR, SANDI COOK, BERNADETTE MAVRIKOS, EDMUND QUIAMBAO, JAMES TETTENHORST, JEREMY HANSEN, KRISTA KARO and ARLENE REED-COSSAIRT, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

VSL PHARMACEUTICALS, INC.; LEADIANT BIOSCIENCES, INC., F/K/A SIGMA-TAU PHARMACEUTICALS, INC., and ALFASIGMA USA, INC.,

Defendants.

Civil Action No. 8:19-cv-2173

COMPLAINT

Plaintiffs David Starr, Sandi Cook, Bernadette Mavrikos, Edmund Quiambao, James Tettenhorst, Jeremy Hansen, Krista Karo and Arlene Reed Cossairt ("Plaintiffs"), by and through undersigned counsel, as and for their Complaint against Defendants VSL Pharmaceuticals, Inc. ("VSL Inc."), Leadiant Biosciences, Inc., f/k/a Sigma-Tau Pharmaceuticals, Inc. ("Leadiant") and Alfasigma USA, Inc. ("Alfasigma") ("Defendants"), allege as follows:

Preliminary Statement

1. This is a class action brought by the Plaintiffs, on behalf of themselves and all other individuals who purchased the probiotic medical food "VSL#3" from June 2016 to the present (the "Class Period"). Plaintiffs are purchasers of VSL#3 during the Class Period. The case arises out of Defendants' false advertising of VSL#3 during the Class Period.

2. In order to understand the nature of Defendants' false advertising, one must understand the history behind the product sold under the "VSL#3" trademark. Prior to the Class Period, from 2002 through May 2016, Defendant VSL Inc., the company that owns the VSL#3 trademark, and Defendant Leadiant,[1] a large pharmaceutical distributor owned by the Cavazza family in Italy (the "Cavazza Family," who was also the ultimate majority owner of VSL Inc.), marketed and sold a version of VSL#3 that used a proprietary formulation invented by Professor Claudio De Simone ("Prof. De Simone"). That proprietary formulation is known as the "De Simone Formulation." In early 2016, however, Defendants VSL Inc. and Leadiant lost the right to sell the De Simone Formulation. That right was granted to a different company, ExeGi Pharma, LLC ("ExeGi"), via an exclusive license from Prof. De Simone to market and sell the De Simone Formulation in the United States under the brand name "Visbiome."

3. Defendant VSL Inc., and its licensees Alfasigma and Leadiant, having lost the right to sell the De Simone Formulation, decided to manufacture, market, and sell a different, inferior formulation (the "Fraudulent Formulation") without conducting any tests to determine if the Fraudulent Formulation would be efficacious in any way. Instead, Defendants simply continued using the VSL#3 mark to sell this inferior product, intentionally passing off the Fraudulent Formulation as the real De Simone Formulation to consumers nationwide. By selling the Fraudulent Formulation under the VSL#3 name, combined with a coordinated campaign to falsely invoke the clinical history and scientific support for the De Simone Formulation as proof

[1] Defendant Leadiant was known as Sigma-Tau Pharmaceuticals, Inc. until February 15, 2017, but is referred to herein as Leadiant.

for the efficacy of the Fraudulent Formulation, Defendants deceived consumers into purchasing a product that was substantially less valuable than the product VSL Inc. represented it to be.

4. Specifically, beginning on or before June 1, 2016, Defendant Leadiant, via a license from Defendant VSL Inc., began selling the Fraudulent Formulation under the brand name "VSL#3," the same brand name consumers understood to be the clinically proven De Simone Formulation. Then, beginning on July 1, 2016, Defendant Alfasigma, also partially owned by the Cavazza Family, superseded Defendant Leadiant as the United States distributor and seller of the Fraudulent Formulation, still under the deceptive brand name "VSL#3." Alfasigma and VSL Inc. continued to market the Fraudulent Formulation as "VSL#3" throughout the Class Period.

5. Throughout the Class Period and to the present day, the product packaging and other marketing materials for the Fraudulent Formulation deceive consumers into believing that VSL#3 is the same as the original De Simone Formulation, which had been the subject of more than sixty published clinical studies and has more than 15 years of successful clinical use. Defendants, by continuing to describe the product as "VSL#3," and by directly usurping the De Simone Formulation's clinical history and scientific support as that of the Fraudulent Formulation, invoked consumers' association with the De Simone Formulation when, in reality, "VSL#3" is the Fraudulent Formulation, not the De Simone Formulation.

6. Moreover, Defendants have engaged in a systematic marketing campaign to reinforce among consumers and medical practitioners that the current version of VSL#3 (the Fraudulent Formulation) contains the same eight distinct strains of bacteria, in the same proportions, as the De Simone Formulation, when in fact it does not. Moreover, Defendants misrepresented VSL#3 as having a 15-year history of clinical use and having extensive clinical

trials supporting its efficacy, but such product claims actually refer only to the De Simone Formulation, not the Fraudulent Formulation. Defendants omitted in their marketing the fact that the post-May 2016 formulation of VSL#3 was materially different from the De Simone Formulation, and the clinical evidence concerning the De Simone Formulation simply does not apply to the Fraudulent Formulation currently sold under the VSL#3 brand name.

7. Defendants' product claims regarding VSL#3 are false, as they misrepresent the facts about the composition, safety, history, and efficacy of the Fraudulent Formulation. Not only are they false, they mislead consumers concerning information about the product that is highly important to consumers, and therefore have a substantial effect on the value of the products. Plaintiffs and other consumers have relied on the De Simone Formulation for years to manage the effects of serious gastrointestinal diseases and conditions, and they have paid substantial money for VSL#3 that is incongruous with the value of a product that no longer contained the clinically proven De Simone Formulation.

8. ExeGi previously sued both Leadiant and Alfasigma for false advertising under the Lanham Act in this Court in May of 2017. *De Simone et al. v. VSL Pharmaceuticals, Inc., et al.*, No. 15-cv-01356-TDC (D. Md.) (the "ExeGi Litigation"). That false advertising claim proceeded to a jury trial. At trial, ExeGi proved the falsity of Defendants' advertisements. For example, Defendants touted the efficacy of the Fraudulent Formulation and the scientific evidence purportedly supporting those claims of efficacy; however, the evidence at trial demonstrated that that scientific evidence of efficacy only supported the De Simone Formulation and did not, and could not, support any claims that the Fraudulent Formulation was safe or efficacious. In fact, there was not even a single clinical study showing that the post-May 2016 formulation of VSL#3 was efficacious or safe. On November 20, 2018, the jury unanimously

found that Leadiant and Alfasigma had engaged in false advertising in violation of the Lanham Act and awarded ExeGi $15 million (representing the jury's determination of Defendant Alfasigma's wrongfully earned profits on sales of the Fraudulent Formulation) as compensatory damages for that false advertising. The Court entered a final judgment on this verdict on November 21, 2018.

9. Despite the jury's verdict, VSL Inc. and Alfasigma continued to deceive consumers. For example, Defendant Alfasigma continued to sell VSL#3 to consumers through the "VSL#3" Facebook page and the VSL#3 website and "online store",[2] which contained numerous false representations about VSL#3, the most important of which, of course, was the continued deception of palming off the Fraudulent Formulation as the De Simone Formulation. In fact, until at least June 21, 2019, the VSL#3 Website and the "VSL#3" Facebook page both continued to make the same deceptive claims that were found to violate the Lanham Act.

10. On June 21, 2019, this Court denied Defendants' Motions for Judgment as a Matter of Law and a New Trial in the ExeGi Litigation. Also on June 21, 2019, this Court granted in part ExeGi's Motion for a Permanent Injunction in that case, permanently enjoining Defendants Leadiant and Alfasigma from (1) stating or suggesting in VSL#3 promotional materials directed at or readily accessible to United States consumers that the present version of VSL#3 produced in Italy continues to contain the same formulation found in the versions of VSL#3 produced before January 31, 2016 (the De Simone Formulation), including but not limited to making statements that VSL#3 contains the "original proprietary blend" or the "same

[2] The VSL#3 website and "online store" (http://www.vsl3.com and https://www.vsl3.com/get-VSL3) are referred to herein as the "VSL#3 Website."

mix in the same proportions" as the earlier version ofVSL#3; and (2) citing to or referring to any clinical studies performed on the De Simone Formulation or earlier versions of VSL#3 as relevant or applicable to the current formulation of VSL#3 produced in Italy.

11. Plaintiffs routinely purchased VSL#3 during the Class Period. They all believed, based on the product's packaging and marketing materials—and Defendants' omission of any information to the contrary—that the version of VSL#3 they purchased during the Class Period was the same, and was proven to be as clinically effective as, the version of VSL#3 that was available prior to that time. This impression was reasonable, given Defendants' continued and unqualified use of "VSL#3" branding, together with Defendants' continuous efforts to deny and downplay the real differences between the prior formulation and the new formulation.

12. Because Defendants presented to consumers a product that purported to be the same VSL#3 that consumers had come to trust, while delivering to consumers an inferior product that was unsupported by clinical evidence, the product Defendants promised to consumers was substantially more valuable than the product Defendants actually delivered. As such, all of the Plaintiffs were economically harmed insofar as they paid for a product that was an inferior, unproven alternative to the product that Defendants had represented it was, and they would not have bought Defendants' product in the absence of the false advertising.

13. By falsely representing to Plaintiffs and Class members that the version of VSL#3 that Defendants marketed and sold during the Class Period was the same as, and as effective as, the version of VSL#3 that was marketed and sold prior to that time, Defendants: (i) violated the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §1962 ("RICO"); (ii) breached express warranties in violation of the Uniform Commercial Code; (iii) were unjustly enriched as a result of their misconduct insofar as Defendants collected tens of millions of dollars from the

sale of VSL#3 during the Class Period that they would not have otherwise earned, and Plaintiffs and Class members paid substantial amounts of money for a product that is not what it claims to be; (iv) engaged in deceptive and/or unfair acts in violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, §§ 2, 9; (v) engaged in deceptive and/or unfair acts in violation of the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*, the California Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq.* and the California False Advertising Law, Cal. Bus. & Prof. Code § 17500 *et seq.*; (vi) engaged in deceptive acts in violation of the Texas Consumer Protection Act, Tex. Bus. & Com. Code Ann. §§ 17.41 *et seq.*; (vii) engaged in violations of the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1 *et seq.*; (viii) engaged in deceptive and/or unfair acts in violation of the Michigan Consumer Protection Act, Mich. Comp. Laws §§ 445.901, *et seq.*; (ix) engaged in deceptive and/or unfair acts in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/1 *et seq*. and the Illinois Uniform Deceptive Trade Practices Act, 815 Ill. Comp. Stat. 510/1 *et seq*.; (x) engaged in deceptive and/or unfair acts in violation of the Washington Consumer Protection Act, Wash. Rev. Code §§ 19.86.010 *et seq*.; (xi) engaged in deceptive and unfair acts in violation of the Florida Deceptive and Unfair Trade Practices Act, §501.201 *et seq*., Florida Statutes and Florida Statutory False Advertising violations pursuant to §§817.06 and 817.40-817.47, Florida Statutes; and (xii) engaged in deceptive and unfair acts in violation of the Idaho Consumer Protection Act, Idaho Code Ann. §§ 48-601 *et seq*.

14. Defendants are liable to Plaintiffs and all other similarly situated members of the Nationwide Class and State Subclasses defined below for all damages resulting from these violations.

Parties

15. Plaintiff David Starr is a resident of Massachusetts who regularly purchased VSL#3 during the Class Period.

16. Plaintiff Sandi Cook is currently a resident of Texas and has been living there since August 2017. Prior to that time, she was a resident of California. Ms. Cook regularly purchased VSL#3 during the Class Period, in California from June 2016 through August 2017, and in Texas in August 2017 and thereafter.

17. Plaintiff Bernadette Mavrikos is a resident of New Jersey who regularly purchased VSL#3 during the Class Period.

18. Plaintiff Edmund Quiambao is a resident of Michigan who regularly purchased VSL#3 during the Class Period.

19. Plaintiff James Tettenhorst is a resident of Illinois who regularly purchased VSL#3 during the Class Period.

20. Plaintiff Jeremy Hansen is a resident of Washington who regularly purchased VSL#3 during the Class Period.

21. Plaintiff Krista Karo is a resident of Florida who regularly purchased VSL#3 during the Class Period.

22. Plaintiff Arlene Reed-Cossairt is a resident of Idaho who regularly purchased VSL#3 during the Class Period.

23. Defendant VSL Inc. is a corporation organized and incorporated under the laws of Delaware, with its principal place of business in Rome, Italy. VSL Inc.'s principal place of business was previously in Herndon, Virginia and before that was Gaithersburg, Maryland, from where many of the unlawful acts described below eminated. Defendant VSL Inc., through its corporate hierarchy, is majority-owned and controlled by the Cavazza Family and their

surrogates. Throughout the Class Period, Defendant VSL Inc. itself directly engaged in the false advertising of VSL#3, as well as indirectly engaged in the false advertising of VSL#3 by deliberately providing false information about the product to Defendants Leadiant and Alfasigma, which used such false information to market and sell VSL#3.

24. Defendant Leadiant, which was known as Sigma-Tau Pharmaceuticals, Inc. until February 15, 2017, is a corporation organized and incorporated under the laws of Nevada, with its principal place of business in Gaithersburg, Maryland. Defendant Leadiant is part of the Sigma-Tau Group of companies and therefore is owned and controlled, directly or indirectly, by the Cavazza Family and their surrogates. For the sake of clarity, this Complaint will refer to this entity as Leadiant throughout, although some of the actions referred to herein took place at a time when the entity was then known as Sigma-Tau Pharmaceuticals, Inc. Defendant Leadiant marketed and sold VSL#3 using false advertisements, misrepresentations and omissions at the beginning of the Class Period, in June 2016.

25. Sigma-Tau HealthScience USA, Inc. is a corporation that was incorporated under the laws of Delaware, which, prior to April 1, 2017, had a principal place of business of Gaithersburg, Maryland. Effective April 1, 2017, on information and belief, Sigma-Tau HealthScience USA, Inc. was merged into Defendant Alfasigma and ceased operating independently. Therefore, for every wrongful act alleged against Sigma-Tau HealthScience USA, Inc., Plaintiffs seek to hold Defendant Alfasigma liable under the doctrine of successor liability. For the sake of clarity, this Complaint will refer to this entity as Alfasigma throughout, although some of the actions referred to herein took place at a time when the entity was then known as Sigma-Tau HealthScience USA, Inc.

26. Defendant Alfasigma is a corporation organized and incorporated under the laws of Delaware, with its principal place of business in Covington, Louisiana. Defendant Alfasigma therefore is a citizen of Delaware and Louisiana. Defendant Alfasigma is partially owned by the Cavazza Family. Defendant Alfasigma marketed and sold VSL#3 using false advertisements, misrepresentations and omissions from July 2016 through the present.

Jurisdiction and Venue

27. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, because Plaintiffs' claims arise under the RICO statute. 18 U.S.C. §1962.

28. This Court also has jurisdiction pursuant to 28 U.S.C. §§ 1332(d) and 1453, because (1) this action is a "class action," which contains class allegations and expressly seeks certification of a proposed class of individuals; (2) the putative Nationwide Class and State Subclasses consist of more than one hundred proposed class members; (3) the citizenship of at least one class member is different from Defendants' citizenship; and (4) the aggregate amount in controversy by the claims of Plaintiffs and the putative Nationwide Class and State Subclasses exceeds $5,000,000, exclusive of interest and costs.

29. This Court has personal jurisdiction over Defendants because Defendants and/or their predecessors are or were headquartered in Maryland, and many of the actions of the Defendants that gave rise to the claims against them in this action took place and emanated from Maryland. Defendants also purposefully availed themselves of the privilege of conducting business activities in Maryland (e.g., marketing and selling VSL#3 in Maryland), Plaintiffs' claims arise out of those activities, and the exercise of jurisdiction over them is constitutionally reasonable.

30. Venue is proper in this jurisdiction pursuant 28 U.S.C. § 1391 because Defendants are subject to personal jurisdiction in this District, and the actions of the Defendants

that give rise to the claims against them in this action took place and emanated this District. Venue is also proper in this jurisdiction pursuant to 18 U.S.C. § 1965.

Factual Allegations

A. The Development, Marketing and Sale of VSL#3 Prior to June 2016

31. This case involves the use of live bacterial cultures for consumers with disorders such as Inflammatory Bowel Disease ("IBD"), including Ulcerative Colitis ("UC"), Pouchitis, and Irritable Bowel Syndrome ("IBS"). Therapeutic and dietary formulations that contain such live bacterial cultures are commonly referred to as "probiotics."

32. Probiotics are formulations that comprise live microorganisms, most often live bacterial cultures, which may be similar to those normally present in the human gastrointestinal tract and which have a beneficial effect on the person consuming the probiotic (for example, a person with an intestinal disorder). Probiotics are supplied commercially in a variety of forms including capsules, tablets, and sachets containing a powder dosage form, as well as in some foods such as yogurt.

33. The consumption of probiotics can help to reestablish a healthy balance of bacteria in the intestine by replenishing beneficial bacterial strains. The ingestion of some probiotics has been proven useful for the dietary management of patients with IBD and IBS in particular.

34. Not all probiotics are similarly or equally beneficial, and the clinical benefits of particular probiotics are highly specific to the particular formulation used in the probiotic. Even minor variations in the bacterial strains used in a probiotic or the specific process for preparing a particular probiotic may have a substantial impact on the therapeutic value of the probiotic.

35. During the 1980s and early 1990s, Prof. De Simone, a medical researcher and clinician in Italy, conducted research into the clinical use of bacterial strains to treat the

symptoms associated with IBD, IBS, enteral feeding, liver diseases, and many other conditions. Prof. De Simone's work resulted in the synthesis of several probiotic formulations, which clinical experience and data demonstrated had beneficial effects on those suffering from these maladies. Prof. De Simone obtained several patents and other intellectual property rights relating to his probiotic work in various countries, including in the United States.

36. Over the ensuing years, one of Prof. De Simone's probiotic formulations, the formulation known as the De Simone Formulation and branded prior to the Class Period as VSL#3 (the subject of this case), became the "gold standard" in its therapeutic class. More than 60 human clinical trials of the De Simone Formulation were successfully completed, the results of which were published in peer-reviewed medical and scientific journals. These trials demonstrated that the De Simone Formulation is effective in the dietary management of, *inter alia*, IBD, IBS, and a very serious and rare chronic disorder called Pouchitis. With respect to Pouchitis, the De Simone Formulation ultimately was recognized by the world's professional gastroenterology societies as a "standard of care"—an achievement that no other probiotic previously had attained.

37. VSL#3, at the time it contained the De Simone Formulation, was manufactured, marketed, and sold beginning in 2002 through a set of supply and licensing agreements involving Prof. De Simone, the Cavazza Family and Defendants and/or their predecessors. From that time until May 2016, the version of VSL#3 that contained the De Simone Formulation was manufactured by Danisco USA, Inc., a Missouri corporation whose principal place of business is in Madison, Wisconsin ("Danisco").

B. Defendants and Their Owners and Affiliates Develop a Fraudulent Plan to Change VSL#3 to a Cheaper, Inferior Formulation Unsupported by Clinical Evidence

38. Beginning on our about mid-2013, representatives of the Carvazza Family sought to persuade Prof. De Simone to agree to renew an operative License Agreement for an additional five-year term beyond 2015 on terms that were extremely favorable to Defendant Leadiant.

39. In or about November 2013, Prof. De Simone and Dr. Beth Park ("Dr. Park"), who were on the board of directors of VSL Inc. at the time, met with Andrea Montevecchi ("Mr. Montevecchi"), Chief Executive Officer of the Sigma-Tau Group (which includes Defendant Leadiant) and a director of Leadiant. During this meeting, Mr. Montevecchi complained about the high cost of VSL#3 and how this was causing Defendant Leadiant's profit margins to be too low. Mr. Montevecchi proposed reducing VSL#3's production cost (thus increasing profit) by changing the product's composition and substituting cheaper bacterial strains. He argued that since VSL#3 was not being marketed as a drug in the United States, no one would notice the change in composition if everyone remained quiet about it.

40. Prof. De Simone rejected this idea. He replied that he would never participate in a scheme to dilute the product secretly, which would violate the trust that consumers had placed in VSL#3 and could lead to adverse health consequences. Mr. Montevecchi, however, warned that unless VSL Inc. offered Leadiant a better profit margin on VSL#3, Prof. De Simone was risking confrontation with the Cavazza Family.

41. On November 21, 2013, Prof. De Simone met with Paolo Cavazza in Rome. Mr. Cavazza explained that Leadiant would be split into two entities, one for "orphan drug" prescription products and the other for nutraceuticals. Mr. Cavazza stated that VSL#3 would be assigned to the nutraceutical division, probably to be called "Sigma Health Sciences," and that the brand VSL#3 would be used to include new formulations, with cheaper bacterial strains and

concentrations. Mr. Cavazza also again suggested changing the formulation of VSL#3 in order to obtain higher profitability.

42. By mid-2014, based on his conversations described in the three paragraphs above, together with other mounting evidence from multiple independent sources, Prof. De Simone became convinced that Defendant Leadiant and related companies planned to market a fraudulent version of VSL#3 that was different than the version that had been tested and proven effective in clinical studies. This reckless conduct gravely concerned Prof. De Simone, who considered these actions to be unethical, deceptive, and in disregard for the safety of consumers who are immunosuppressed and rely on VSL#3 to manage their medical conditions.

43. Due to mounting pressure to accede to the demands of the Cavazza family, Dr. Park and Prof. De Simone, unwilling to participate in the proposed fraudulent and dangerous scheme to change the VSL#3 formulation to a cheaper, inferior, untested formulation, resigned from VSL Inc.'s board of directors, and Prof. De Simone also resigned as Chief Executive Officer of the company.

44. Then, on or about November 14, 2014, Prof. De Simone provided written notice to VSL Inc. that he was terminating a "Know How Agreement" that provided VSL Inc.'s rights to sell VSL#3 using the De Simone Formulation after the expiration of the operative License Agreement.

45. The expiration of the operative License Agreement and the termination of the Know How Agreement left VSL Inc. and Leadiant without any authority to use, sell, or disclose Prof. De Simone's proprietary Know-How, including but not limited to the selection and ratios of the eight strains of bacteria comprising VSL#3, which were (and remain) valuable trade secrets.

C. Defendants VSL Inc.'s and Leadiant's Supply of the De Simone Formulation is Cut Off, Professor De Simone Enters Exclusive Licensing Agreement with ExeGi, and Defendant Leadiant Begins A Campaign of False Advertising

46. In 2015, Prof. De Simone instructed the manufacturer Danisco to cut off Leadiant's access to Danisco's supply of VSL#3 as of a date certain. Upon information and belief, Danisco ceased to provide Leadiant with supply of the De Simone Formulation after January 31, 2016, although Leadiant continued to sell its existing stock of the De Simone Formulation (without authorization to do so) until it ran out in May 2016.

47. Also in 2015, ExeGi signed an agreement with Prof. De Simone to produce the probiotic containing the De Simone Formulation. This license agreement permits ExeGi to have manufactured, to market, and to sell the formulation in the United States and elsewhere, using the trade secrets and Know-How owned and possessed by Prof. De Simone. ExeGi launched this product under the name "Visbiome" on February 1, 2016. Since that time, ExeGi has been, and currently is, the only rightful supplier of the De Simone Formulation in the United States. In or about May 2016, when Leadiant ran out of its stock of the De Simone Formulation and began selling its new version of VSL#3 using the Fraudulent Formulation, Visbiome became the only authentic version of the De Simone Formulation in the market.

48. In May 2016, Leadiant publicly announced that production of VSL#3 would move from the Danisco facility in the United States to a new manufacturer in Italy (Centro Sperimentale del Latte, or "CSL"), but failed to disclose that with this change in manufacturer, the VSL#3 product itself would change from the De Simone Formulation to the Fraudulent Formulation. In the months that followed, independent testing (corroborated by anecdotal reports and complaints from consumers) confirmed that the Fraudulent Formulation is demonstrably, materially different from the original De Simone Formulation sold by ExeGi, despite being falsely marketed by Leadiant and later Alfasigma as identical to, and possessing the same history

as, the original formulation. The Cavazza Family and their surrogates, including Defendants, followed through on their threats to produce a different, inferior version of the De Simone Formulation, which they designed to deceive consumers and the medical community.

49. Leadiant's marketing concerning moving the manufacture of VSL#3 to a new manufacturing facility in Italy claimed that the resulting new product will be "the same quality product, containing the same genus and species of bacteria, in the same proportions that you have come to expect." The advertisement goes on to claim, "How will this impact you and your patients? It won't. VSL#3, your first choice probiotic to manage Ulcerative Colitis, IBS and ileal pouch….." These representations were entirely false. In fact, the move of manufacturing to Italy was accompanied by a change in formulation to an inferior, untested formulation.

50. A significant misrepresentation to consumers concerning the new Fraudulent Formulation has been the continued use of the VSL#3 name in all product packaging and marketing. Consumers came to rely on the product called "VSL#3" to connote an effective, clinically tested product–the De Simone Formulation. By replacing the De Simone Formulation with the inferior, untested Fraudulent Formulation, while continuing to use the "VSL#3" name, Defendants falsely communicated to consumers that VSL#3 was the same product as before.

51. As set forth below, Defendants amplified the misleading continued use of the VSL#3 name through a steady stream of communications to consumers and physicians that were designed to, and did in fact, create the false impression that VSL#3 was the same as it was before. In truth, the formulation had changed, and none of the scientific support for the De Simone Formulation could honestly be used to market the Fraudulent Formulation of VSL#3. That is, use of the VSL#3 mark on product packaging, combined with repeated assurances from Defendants that the product was the same as before and misrepresentations about the history of

the product, deceived consumers into buying a different product than they thought they were purchasing—one without the wealth of clinical evidence that supported the De Simone Formulation.

D. Defendant Leadiant Assigns its Rights to A New Entity, Which Continues the False Advertising Campaign

52. Effective June 30, 2016, Defendant Leadiant assigned and transferred to Sigma-Tau HealthScience USA, Inc. (now Alfasigma and referred to herein as Alfasigma) its rights for the marketing and sale of VSL#3.

53. On or about August 31, 2016, in a press release ("August 2016 Press Release"), Alfasigma announced that:

> Legacy brand VSL#3® (www.vsl3.com), distributed in the U.S. by Sigma-Tau Healthscience USA, Inc. under agreement with VSL Pharmaceuticals, has moved the manufacture of its brand, the most studied and recommended high-potency probiotic medical food, back to Italy, where it was originally developed and produced. The move includes the elimination of any traces of dairy in the manufacturing process, making it the only probiotic medical food available that is dairy-free. People who suffer from IBS, ulcerative colitis or an ileal pouch, and who are also among the 30 to 50 million people in the U.S. who have allergies to milk or are lactose intolerant, can now take VSL#3 to manage their IBS, UC or ileal pouch.

The August 2016 Press Release also asserted that "'[m]oving VSL#3 back to the original manufacturing facility in Italy allowed the brand to revert back to an established process that removes all dairy while maintaining the original proprietary mix of eight strains of live bacteria….'" The August 2016 Press Release also falsely emphasized that VSL#3 was "supported by more than 170 published studies over the past 15 years."

54. The August 2016 Press Release was riddled with misrepresentations. The assertions that VSL#3 was "the most recommended high-potency probiotic medical food," that its production was going back to the original manufacturing facility where the product was "developed," and that it was "supported by more than 170 published studies over the past 15

years" were all designed to mislead physicians and consumers into believing that this new product using the Fraudulent Formulation was the same as the VSL#3 product that had been made using the De Simone Formulation, and that Defendant Alfasigma possessed the requisite technical know-how to make and sell the same product.

55. Additionally, the assertion that CSL "originally manufactured" the De Simone Formulation was false, as was the claim that CSL "developed" the VSL#3 product made using the De Simone Formulation. In fact, CSL has never produced the commercially-available VSL#3 using the De Simone Formulation under the VSL#3 trade name or any other trade name. In fact, CSL could not have produced this product, because it never possessed the De Simone trade secrets regarding the De Simone Formulation or relevant Know-How. In addition, the August 2016 Press Release states that CSL is the manufacturer, whereas CSL, in fact, only deals with the first stage of the production process; Nutrilinea, a third-party, is the manufacturer of the final product, as it is the company that continues the process and produces the finished product.

56. The representation that "[p]eople who suffer from IBS, ulcerative colitis or an ileal pouch, and who are also among the 30 to 50 million people in the U.S. who have allergies to milk or are lactose intolerant, can now take VSL#3 to manage their IBS, UC or ileal pouch" was also false insofar as it attempted to equate the effectiveness of the Fraudulent Formulation with the De Simone Formulation.

57. There are significant qualitative differences between the Fraudulent Formulation and the De Simone Formulation. For example, the average live-to-dead bacteria ratios of the two products are significantly different. The Fraudulent Formulation of VSL#3 has high overall bacterial counts but lower total viable (live) cell counts, meaning that the product has a much higher quantity of dead bacteria, which is not an inert ingredient and is therefore detrimental for

a person consuming the formulation. The number of live *streptococcus, bifidobacteium* and *lactobacillus* bacteria species of the two products also is significantly different, showing different ratios of the various species in each product. Additionally, the critical *streptococcus thermophilus* species was almost 100 times less in the Fraudulent Formulation of VSL#3.

58. There also are significant performance differences between the Fraudulent Formulation and the De Simone Formulation. For example, when evaluated for impact on cancer cell activity, the De Simone Formulation was statistically significantly different from the Fraudulent Formulation in its capability to arrest proliferation of common cancer cell lines and in inducing apoptotic cell death in those cells.

59. These significant qualitative and performance differences, and many other such differences, were demonstrated in multiple scientific investigations that have taken place since the launch of the Fraudulent Formulation (first in Europe, then in the U.S. and Canada). These investigators compared the Fraudulent Formulation to the De Simone Formulation and found striking differences between them. This data was peer reviewed and initially published in two journals and at two medical conferences, including the *Journal of Cellular Physiology*, *PLOS One*, the 2017 Digestive Disease Week Conference and the 4th World Congress on Targeting Microbiota at Institut Pasteur in Paris. A common theme of all the data sets is that both the quantitative and performance characteristics of the Fraudulent Formulation versus the De Simone Formulation are fundamentally different.

60. The first article appeared in the journal *Plos One* in September 2016 and was authored by six scientists. Using an in vitro study, they evaluated a variety of qualitative and performance characteristics. As to both qualitative and quantitative differences between the De Simone Formulation and the Fraudulent Formulation, these scientists concluded that the average

live-to-dead bacteria ratios of the two products were significantly different. When ingested by living organisms, the Fraudulent Formulation contained 130-150 percent more dead bacteria (which are not inert ingredients) than are found within the De Simone Formulation. Even more importantly, as noted above when evaluated for impact on cancer cell activity, the De Simone Formulation had a significantly greater capability than the Fraudulent Formulation to arrest the proliferation of cancer cells and in inducing the apoptotic cell death of those cancer cells. *See* Benedetta Cinque, *et al.*, *Production Conditions Affect the In-Vitro Anti-Tumoral Effects of a High Concentration Multi-Strain Probiotic Preparation*, PLOS ONE, Sept. 22, 2016.

61. Since September 2016, more articles have appeared in various peer-reviewed scientific journals that have compared the functional and performance characteristics of the De Simone Formulation and the Fraudulent Formulation, as well as in abstracts at international conferences. All of the articles and abstracts have concluded that there are significant differences between the two products.

62. Several publications have explored the differences between the Fraudulent Formulation and the De Simone Formulation. One such publication appeared in the January 2017 edition of the *Journal of Cellular Physiology*, which featured a report entitled "*VSL#3 probiotic differently influence IEC-6 intestinal epithelial cell status and function.*" In this *in vitro* study, multiple wound healing assays were used to evaluate performance characteristics of the two products using human, non-transformed, small-intestinal epithelial cell lines (IEC-6). Among the key findings:

- The current VSL#3 (i.e., the Fraudulent Formulation) causes clear morphological cell damage on IEC-6 cell lines with reduced cellularity.
- The prior VSL#3 (i.e., the De Simone Formulation) produced product resulting in an enhanced rate of monolayer healing, while current VSL#3 did not influence the closure rate.

- The prior VSL#3 product enhanced the formation of elongated and aligned stress fibers, while current VSL#3 had no effect.
- The prior VSL#3 caused a total inhibition of H_2O_2-induced cytotoxic effects on the cell lines, whereas current VSL#3 was unable to produce such results.

In short, clinical studies have confirmed that beneficial effects caused by the De Simone Formulation are not present in the Fraudulent Formulation. Therefore, Defendants' marketing of the Fraudulent Formation as "VSL#3" and that it is the "same" as the De Simone Formulation deceived consumers concerning the clinical benefits that consumers can expect.

63. Similarly, the October 2016 edition of the *Journal of International Society of Microbiota* featured a report entitled "p24 Levels in vitro are affected positively or negatively depending by the production site of probiotic." P24 is an antigen that makes up the core of the HIV virus. Blood concentrators of p24 go up in humans very shortly after HIV infection. Donor peripheral blood cells (PBMCs) were infected with the HIV-1 virus and incubated with the two different VSL#3 probiotics. The prior version of VSL#3 that contained the De Simone Formulation and the current version of the VSL#3 formulation that contains the Fraudulent Formulation had different effects on the HIV infected cultures. The De Simone Formulation had an inhibitory effect as measured by p24, while the Fraudulent Formulation actually ***increased*** the levels of p24 (+8%). This data was presented at the famous Institut Pasteur in Paris and raises serious safety related questions for the HIV community.

64. Additionally, in May 2017, a different group of scientists conducted an *in vivo* animal (mice) study comparing the De Simone Formulation with the Fraudulent Formulation. Animal models of gastrointestinal colitis are critical to comparing the performance similarities and differences of the two products, and mice with an induced colitis are the preferred and accepted standard experimental models. The methods and results are summarized below:

- The study used the classic dextran sulfate sodium ("DDS") induced colitis in mice. This is a classic animal model of intestinal colitis and inflammation, which has been applied in scientific analysis of medicinal compounds for decades.

- Colitis was induced in three groups of mice, who were then fed the De Simone Formulation, the Fraudulent Formulation, or no treatment, respectively.

- Mice treated with the De Simone Formulation (Batch A) experienced a reduction in weight loss and intestinal inflammation, a reduction in intestinal permeability, and a reduction in severity of the colitis disease activity index (CDAI). Histopathology analysis also demonstrated an amelioration of colitis with respect to the untreated animals.

- Mice treated with the Fraudulent Formulation (Batch B) showed a worsening CDAI index compared to the mice fed with the De Simone Formulation. Shockingly, the animals treated with Fraudulent Formulation did worse than the animals with colitis that constituted the control group and had no probiotic treatment at all.

- Fraudulent Formulation-treated animals had a worsening histopathology analysis and a six to seven-fold increase in intestinal permeability.

65. Defendant Alfasigma also deceived consumers by claiming that clinical evidence concerning the De Simone Formulation applied to the Fraudulent Formulation. For example, on the *www.VSL3.com* website, under the section "Evidence Based Science," Alfasigma stated the following:

> VSL#3 is one of the few probiotic preparations supported by Level One (double-blind, placebo-controlled) scientific data. VSL#3 has a 15-year track record of demonstrated clinical benefits as well as commercial use. Over 170 published studies and reviews have been released. The following studies have provided us with the educational content on this website.

The site then goes on to provide links to numerous clinical studies in the field of IBS, UC and Pouchitis. Each link, however, pointed to studies concerning the De Simone Formulation, and not the Fraudulent Formulation for VSL#3. As noted above, the De Simone Formulation and the Fraudulent Formulation of VSL#3 are materially different products; invoking clinical citations on one product to market another, untested product is false and misleading.

66. The VSL#3 Website also included the statement that "[m]oving VSL#3 back to the original manufacturing facility in Italy allowed the brand to revert back to an established process that removes all dairy while maintaining the original proprietary mix of eight strains of live bacteria." For the reasons described herein, this statement was false.

67. Alfasigma's false advertising campaign extended to numerous deceptive statements on its Facebook platform as well. As just one example, on March 19, 2017, a Facebook user asked Alfasigma, "When did you reformulate VSL#3 Thanks!" on the VSL#3 Facebook page. In response, Alfasigma publicly replied with the following statement:

> VSL#3 Hi Timmy- VSL#3 contains the same 8 diverse strains and high potency that have effectively managed the symptoms of IBS, UC and an ileal pouch for 15 years. By upgrading the manufacturing process, we are also happy to share that that VSL#3 is dairy-free, making it one of the few dairy-free probiotics available to patients. Now 30-50 million people who have allergies to milk or are lactose intolerant and who suffer with IBS, ulcerative colitis or an ileal pouch will be able to take VSL#3 to help manage their symptoms. To further improve VSL#3, a small amount of cornstarch, an inactive ingredient that reduces moisture and preserves bacterial potency and stability, was added. VSL#3 unflavored packets have always contained cornstarch. Now we have added it to the capsules and DS. The inclusion of cornstarch does not affect the efficacy, potency, composition and strain components of the product. Hope this info helps!

The statement that "VSL#3 contains the same strains" is false. The De Simone Formulation contains strains not present in the new, Fraudulent Formulation of VSL#3. As Dr. Patrick Gillevet, an expert on human gastrointenstial microflora, testified in the ExeGi Litigation, the Fraudulent Formulation of VSL#3 had only seven strains of live bacteria, not eight, and was thus genetically different from the De Simone Formulation used in the original VSL#3. Moreover, the suggestion that the "efficacy" of VSL#3 is the same as it was for the De Simone Formulation is false; the clinical evidence supporting efficacy concerned the De Simone Formulation, not the Fraudulent Formulation.

68. Because the Fraudulent Formulation of VSL#3 was genetically different from the De Simone Formulation (and was manufactured differently and without the benefit of Prof. De Simone's proprietary Know-How), many thousands of consumers purchased and used a version of VSL#3 during the Class Period that was not as effective as the prior version. Numerous consumers have found that the Fraudulent Formulation of VSL#3 was far less effective in managing their G.I. symptoms than the De Simone Formulation of VSL#3. Many of these consumers have since switched to Visbiome, which contains the De Simone Formulation, and found Visbiome to be more effective at managing their G.I. symptoms than the Fraudulent Formulation of VSL#3.

69. Defendants also misled consumers by failing to disclose important information concerning the ingredients of the current formulation of VSL#3. As is common practice in the probiotic industry, Defendant Leadiant previously labeled its products with the genus, species, and strain designation numbers for each of the eight bacterial strains contained in the product. Respected organizations such as the Council for Responsible Nutrition and the International Probiotics Association specifically recommend this practice in its Best Practices Guidelines for Probiotics,[3] as individual strains of the same genus and species can have different functional properties. Prior to Leadiant's change to the VSL#3 formulation, marketing materials such as the VSL#3 Patient Brochure" *did include* the specific strain designation numbers, along with the genus and species. In contrast, the current U.S. marketing statements for the Fraudulent Formulation of VSL#3 state only the genus and species and strategically omit the strain

[3]https://www.crnusa.org/sites/default/files/pdfs/CRN-IPA-Best-Practices-Guidelines-for-Probiotics.pdf

designation numbers. By omitting the strain designation numbers, Defendant Alfasigma avoids making any visible admission to consumers that the Fraudulent Formulation of VSL#3 no longer contains the clinically proven combination of strains used in the De Simone Formulation.

70. Alfasigma also implemented its deceptive scheme through written representations to the medical community, which were designed to influence advice by the medical community to consumers. In or around November 2016, in a memorandum that was directed for use with medical professionals, Alfasigma responded to a then-recently published paper in the peer-reviewed medical journal *Plos One* ("November 2016 Memo"). The study, described above, compared the "old" VSL#3 (the De Simone Formulation) to the "new" VSL#3 (the Fraudulent Formulation).

71. The November 2016 Memo stated:

> VSL#3 was originally produced in Italy until 2006 when it relocated to the U.S. When manufacturing moved to the U.S., VSL#3 was not considered "newfound" and was not any different to the VSL#3 produced in Italy. Our Italian manufacturing facility is not only a GMP facility but, unlike many other medical foods, is also a pharmaceutical grade facility that must follow FDA guidelines. As you know many companies relocate their manufacturing facilities from time to time. This does not mean the products are "newfound" and are different in what they do. The same applies to VSL#3.

72. In fact, "VSL#3" branded probiotics containing the De Simone Formulation were manufactured only at Danisco's plant in Madison, Wisconsin, from the time they were launched in the U.S. in 2002 until January 31, 2016. The assertion that an "original" Italian producer was making "VSL#3" branded products as late as 2006 is false and was intended to confuse physicians and patients.

73. CSL never produced VSL#3-branded products for commercial use. Alfasigma's false statements to the contrary constitute a transparent attempt to falsely associate research not applicable to the product it currently sells to the "historical" probiotic De Simone Formulation

formerly associated with the VSL#3 trademark. Furthermore, these statements are intended to confuse physicians and patients into believing that CSL knows how to make the De Simone Formulation, which CSL's general manager admitted is not true.

E. A Jury Finds Defendants Engaged in False Advertising, Yet They Continued to Falsely Advertise to Consumers

74. As noted, on November 20, 2018, a jury unanimously found that Leadiant and Alfasigma had engaged in false advertising in violation of the Lanham Act and awarded ExeGi $15 million (representing the jury's determination of Defendant Alfasigma's wrongfully earned profits on sales of the Fraudulent Formulation) as compensatory damages for that false advertising. The Court entered a final judgment on this verdict on November 21, 2018.

75. Extensive testimonial and documentary evidence was elicited at trial of the ExeGi Litigation that demonstrated the falsity of Defendants' above enumerated statements, such as those on the VSL#3 Website. For example, the falsity of the statements that the Fraudulent Formulation has "a 15-year track record of demonstrated clinical benefits and 170 published clinical studies and reviews" and "has been supported by numerous studies" was at issue in the trial. These same claims appeared on the VSL#3 Website prior to the trial. ExeGi showed the falsity of those statements by showing that it was the De Simone Formulation, not the Fraudulent Formulation, that enjoyed that history, and that the Fraudulent Formulation does not get to usurp that history because genetic testing, journal articles, and expert testimony confirmed the two products are neither genetically identical nor functionally equivalent.

76. As expert witness Dr. Patrick Gillevet opined in the trial: "it is clear that the original De Simone strain product has eight strains and … [the] new VSL#3 product that has been tested has only seven strains." That much was equally clear to VSL Inc., who promoted VSL#3 in Canada as a seven-strain product; disclosed to Health Canada that their product only

had seven strains; drafted letters to CSL that showed there were only seven strains in the Fraudulent Formulation; and confirmed that the Drug Master File for the Fraudulent Formulation listed only seven ingredients. In their best effort to argue that the Fraudulent Formulation has eight strains, despite their own representations to the contrary, Defendants could offer only the testimony of Franco Pirovano, who had never tested the product,[4] and Marco Caspani. However, Mr. Caspani, the general manager of CSL, the manufacturer of the Fraudulent Formulation, admitted that he merely acted—upon the request of a VSL Inc. affiliate—as if there were two distinct *B.lactis* strains; to him, when tested at CSL, it appeared that there was only one unique *B.lactis* strain. Although Defendants also proffered the testimony of Dr. Barrangou, who had previously opined that VSL#3 had eight strains based on the DeVos study, at trial, Dr. Gillevet analyzed the same reports and concluded (with "100%" confidence) that VSL#3 had seven strains. And Dr. Barrangou did not challenge Dr. Gillevet's conclusion.[5]

77. As Dr. Gillevet concluded, genetically, the two formulas "are very distinct." The De Simone Formulation contains the strains BI-07 and BL-04; the Fraudulent Formulation only contains BI-07. Accordingly: "They are genetically different. They are missing a piece of DNA." And where, as here, "you have two different genes, you are going to have … different functions." Simply put, the two formulas "have different functions," which "has medical implications" because the two products will not perform identically. Dr. Barrangou agreed with Dr. Gillevet on these points, noting that the genetic testing showed two isolates of the same BI-

[4] Dr. Pirovano only claimed that he gave Dr. Caspani eight vials; he never tested their contents.

[5] At trial, Dr. Barrangou distanced himself from the position he had maintained throughout the litigation—that the DeVos study proved that VSL#3 had eight strains.

07 strain in the Fraudulent Formulation, while two distinct strains in the De Simone Formulation, and that these two different strains had different functional properties.

78. Another expert witness, Dr. Christian Loch, confirmed the same: "the two products [a]re very different." As his proteomic testing revealed: "Of the roughly 4,000 proteins that we identified, about 1,000, [or] 25 percent of them or so, were indeed different."[6] The formulas' "different protiums [sic] will result in different performance." Dr. Alessio Fasano also confirmed that the two products are "very different," and given their "substantial differences," their efficacy "will be very different." Dr. Fasano further detailed the multiple peer-reviewed studies supporting the same conclusion: "the new formulation from Italy is not … comparable to the formulation that is from United States." Among other things, "the [De Simone] formulation was able to accelerate the process of wound repair and to mitigate the stress in use by this chemical on the cells while [VSL#3] was not."[7]

79. Further supporting the distinction between the two products, there was also uncontroverted evidence that the Fraudulent Formulation was made via an attempt to reverse

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[6] Notably, Alfasigma originally pursued a false advertising claim against Prof. De Simone and ExeGi, alleging that Prof. De Simone and ExeGi falsely stated that "VSL#3 had undergone a formula change"; that VSL Inc. "changed the formula of VSL#3"; and that "VSL#3 did not have the same formulation as Visbiome." It is very telling that Alfasigma voluntarily dismissed that claim (with prejudice) during the trial, as that shows Alfasigma was not able to support its claim that such statements are false. Indeed, all of the evidence at trial made it clear that such statements are true; the Fraudulent Formulation does not have the same formula as Visbiome (the De Simone Formulation).

[7] As Dr. Fasano elaborated, that due to the changes in manufacturing, the protein expression would be different, since "the final outcome of the functionality of … probiotics really depends on what you feed them." Dr. Loch confirmed that changes in manufacturing would change the product's proteins. Further, a change in fermentation "would change statistically significant expression of certain proteins."

engineer the De Simone Formulation, and that attempt failed. By admission of the CEO of VSL Inc., Luca Guarna, VSL Inc. could only determine the amount of each strain used within a 30% margin of error – ***per strain***. In addition to Mr. Guarna, Paolo Cavazza agreed: it would be "impossible" to create an actual replica of the De Simone Formulation "or to copy it." The dairy experts Defendants hired to attempt to reverse engineer the De Simone Formulation reaffirmed as much.

80. Additionally, the testimony at trial established that the claims on the VSL#3 Website of proven clinical benefits and a robust set of studies supporting the claims of efficacy were literally false. Trial testimony clearly established that there is not a single scientific study that has "proven" that the Fraudulent Formulation is efficacious or safe in any way. Luca Guarna admitted that VSL Inc. conducted no efficacy testing at all, much less testing that could establish the Fraudulent Formulation as equally efficacious as the De Simone Formulation. Nor did Alfasigma conduct any efficacy testing, although Alfasigma advertised the Fraudulent Formulation's supposed efficacy and equivalency regardless. Indeed, the lack of efficacy studies on the Fraudulent Formulation of VSL#3 was an uncontested fact in that trial.

81. The testimony thus established that the Fraudulent Formulation was not equivalent to the De Simone Formulation, and all statements on the VSL#3 Website (and elsewhere) that assert the De Simone Formulation's history, characteristics, and efficacy as that of the Fraudulent Formulation are literally false. In the ExeGi Litigation, Alfasigma offered no evidence to the contrary, because none exists. Instead, Alfasigma relied on a very poor argument. While conceding that neither it, nor VSL Inc., nor Leadiant had performed efficacy testing to compare the Fraudulent Formulation to the De Simone Formulation and that the two products were not identical, Alfasigma simplistically argued that the two products were similar enough

that the jury should find that it was not false for Alfasigma to usurp the history of the De Simone Formulation and pass it off as the history of the Fraudulent Formulation. This argument was thoroughly dismantled in the litigation and after three weeks of trial, ExeGi's significant evidence of the falsity of the statements made about the Fraudulent Formulation carried the day.

82. Even prior to the jury verdict, the conclusion that the Fraudulent Formulation was not functionally equivalent to the De Simone Formulation version of VSL#3 had wide ranging acceptance and the implications of that conclusion were adopted throughout the world. As examples:

(a) Health Canada canceled the license to sell VSL#3® in Canada for ulcerative colitis and pouchitis, and Ferring (the same company selling the same VSL#3 in Germany) has withdrawn the product from the Canadian market, effective November 15, 2018.

(b) On January 25, 2018, the Court of Justice in Hamburg assessed the VSL#3 product distributed by Ferring (that is the Fraudulent Formulation) and concluded: "It is no longer to be considered identical, at least in effect" to the original principle, with respect to the active ingredient to which the Guidelines refer [2]. The German court came to this conclusion, "as the preparation put into circulation by the defendant [Ferring Germany, which distributes the Fraudulent Formulation] cannot (anymore) be identical to that mentioned in the Guidelines already for the reason, peaceful, that the cultivation methods have changed substantially and the change of the production method changes its effect." The German court concluded that "such misleading indications to the Guidelines are also likely to influence the purchase decision because the special indication to the associations of specialists arouses increased confidence in the effectiveness and seriousness of the product."

(c) The mention of the VSL#3 product was removed from the WGO (World Gastroenterology Organization) and the ESPEN (European Society for Clinical Nutrition and Metabolism) Guidelines and replaced by the list of bacteria quoted in the referenced papers.

(d) The CEO of VSL Inc, Luca Guarna, is under investigation by the Prosecutor of the Tribunal of Rome, Italy for the crimes referred to in art. 515 (fraud in commerce) and 440 (adulteration or counterfeiting of food substances) of the Italian penal code as well as for all the other offenses related to the distribution of the Fraudulent Formulation in Italy.

83. Despite the foregoing, Defendants VSL Inc. and Alfasigma continued their steady campaign of false advertising. For example, until at least June 20, 2019, the VSL#3 Website, controlled and operated by Alfasigma (with content derived from VSL Inc.), contained most of the same false advertising materials it contained prior to the trial, including touting that VSL#3 has been "Used by physicians for more than 15 years and" has been "Widely studied in multiple trials," even though these statements referred to the prior, not current, formulation of VSL#3.

84. Defendants VSL Inc. and Alfasigma also made available online, featured prominently on the VSL#3 Website, a bogus "litigation fact sheet" relating to the ExeGi Litigation that is riddled with falsehoods.[8] As just one example amongst many, the "fact sheet" states: "The court has not made any specific finding concerning the extensive clinical studies from VSL#3®'s over 15-year history. This rich clinical history, particularly for specific gastrointestinal conditions, is supportive of the VSL#3® product sold by Alfasigma." As set forth above, however, the jury issued a general verdict that Defendants engaged in false advertising and awarded $15 million in damages after hearing extensive evidence that the "clinical history" did not support the post-May 2016 version of VSL#3, and instead only supported the prior version of VSL#3. There is no rational way to interpret the jury's verdict other than as agreement with the position of the plaintiffs in that case—that Defendants falsely advertised the VSL#3 product by equating the prior VSL#3 product (the De Simone Formulation) with the post-May 2016 product (the Fraudulent Formulation). In fact, in its June 21, 2019 decision granting ExeGi a permanent injunction against Defendants Leadiant and

[8]https://www.vsl3.com/; https://shop.vsl3.com/assets/v1/patient/files/VSL3FactSheetFactCheck.pdf.

Alfasigma, the Court specifically stated "that the jury did not credit [Defendants'] evidence on the genetic and functional equivalence of the products."

85. As noted, on June 21, 2019, this Court both denied Defendants' Motions for Judgment as a Matter of Law and a New Trial and granted in part the plaintiffs' Motion for a Permanent Injunction in the ExeGi Litigation. The injunction entered by this Court permanently enjoined Defendants Leadiant and Alfasigma from (1) stating or suggesting in VSL#3 promotional materials directed at or readily accessible to United States consumers that the present version of VSL#3 produced in Italy continues to contain the same formulation found in the versions of VSL#3 produced before January 31, 2016 (the De Simone Formulation), including but not limited to making statements that VSL#3 contains the "original proprietary blend" or the "same mix in the same proportions" as the earlier version ofVSL#3; and (2) citing to or referring to any clinical studies performed on the De Simone Formulation or earlier versions of VSL#3 as relevant or applicable to the current formulation of VSL#3 produced in Italy.

F. Plaintiffs Purchased VSL#3 During the Class Period Believing it to be the Same Formulation as was Available Prior to the Class Period

86. Plaintiffs routinely purchased VSL#3 during the Class Period. They all believed, based on the product's packaging and marketing materials and Defendants' omission of any information to the contrary, that the version of VSL#3 they purchased during the Class Period was the same, and was proven to be as clinically effective as, the version of VSL#3 that was available prior to that time. This impression was reasonable, given Defendants' continued and unqualified use of "VSL#3" branding, together with Defendants' continuous efforts to deny and downplay the real differences between the prior formulation and the new formulation.

87. Because Defendants presented to consumers a product that purported to be the same VSL#3 that consumers had come to trust, while delivering to consumers an inferior product that was unsupported by clinical evidence, the product Defendants promised to consumers was substantially more valuable than the product Defendants actually delivered. As such, all of the Plaintiffs were economically harmed insofar as they paid for a product that was an inferior, unproven alternative to the product that Defendants had represented it was.

88. Plaintiff Starr regularly purchased VSL#3 in Massachusetts from approximately 2014 through 2019. Plaintiff Starr paid approximately $100 a month for the product. During the Class Period, he paid approximately $3,000 for VSL#3.

89. Plaintiff Cook regularly purchased VSL#3 in California from at least 2010 through August 2017. After moving from California to Texas, she regularly purchased VSL#3 in Texas from approximately August 2017 through the end of 2018. Plaintiff Cook paid approximately $100 per month for the product. During the Class Period, she paid approximately $3,000 for VSL#3.

90. Plaintiff Mavrikos regularly purchased VSL#3 in New Jersey from approximately 2012 through 2019. Plaintiff Mavrikos paid approximately $50 a month for the product. During the Class Period, she paid approximately $1,500 for VSL#3.

91. Plaintiff Quiambao regularly purchased VSL#3 in Michigan at various points between approximately 2014 and 2019. Plaintiff Quiambao paid approximately $1,000 for VSL#3 during the Class Period.

92. Plaintiff Tettenhorst regularly purchased VSL#3 in Illinois from approximately 2010 through early 2019. Plaintiff Tettenhorst paid approximately $2,600 per year on VSL#3,

which both he and other family members used. During the Class Period, he paid approximately $12,000 for VSL#3.

93. Plaintiff Hansen regularly purchased VSL#3 in Washington from approximately 2016 through early 2019 for his young son. He paid $120 for a three-month supply of VSL#3, spending a total of approximately $1,000-$1,500 on VSL#3 during the Class Period.

94. Plaintiff Karo regularly purchased VSL#3 in Florida from approximately early 2018 through early 2019 for her daughter. She paid approximately $100 per package of VSL#3, spending a total of approximately $1,000 on VSL#3 during the Class Period.

95. Plaintiff Reed-Cossairt regularly purchased VSL#3 in Idaho from approximately 2012 through early 2019 for her son. She paid approximately $40 a month for VSL#3, spending a total of approximately $1,600 on VSL#3 during the Class Period.

Class Action Allegations

96. Plaintiffs re-allege and incorporate the allegations contained in the paragraphs above.

97. Plaintiffs bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of themselves and a Nationwide Class consisting of "All persons who purchased VSL#3 anywhere in the United States from June 1, 2016 through the present."

98. Plaintiff Starr also brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a Massachusetts Class consisting of "All persons who purchased VSL#3 in Massachusetts from June 1, 2016 through the present."

99. Plaintiff Cook also brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a California Class consisting of "All persons who purchased, in California, VSL#3 from June 1, 2016 through the present."

100. Plaintiff Cook also brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a Texas Class consisting of "All persons who purchased VSL#3 in Texas from June 1, 2016 through the present."

101. Plaintiffs Mavrikos also brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a New Jersey Class consisting of "All persons who purchased VSL#3 in New Jersey from June 1, 2016 through the present."

102. Plaintiff Quiambao also brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a Michigan Class consisting of "All persons who purchased VSL#3 in Michigan from June 1, 2016 through the present."

103. Plaintiff Tettenhorst also brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a Illinois Class consisting of "All persons who purchased VSL#3 in Illinois from June 1, 2016 through the present."

104. Plaintiff Hansen also brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a Washington Class consisting of "All persons who purchased VSL#3 in Washington from June 1, 2016 through the present."

105. Plaintiff Karo also brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a Florida Class consisting of "All persons who purchased VSL#3 in Florida from June 1, 2016 through the present."

106. Plaintiff Reed-Cossairt brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of an Idaho Class consisting of "All persons who purchased VSL#3 in Idaho from June 1, 2016 through the present."

107. Plaintiffs refer to the Nationwide Class, the Massachusetts Class, the Texas Class, the California Class, the New Jersey Class, the Michigan Class, the Illinois Class, the Washington Class, the Florida Class and the Idaho Class together as the "Classes."

108. Plaintiffs reserve the right to amend the definition of the Classes.

109. This action is properly maintainable as a class action.

110. There are hundreds if not thousands of members in each of the Classes. Accordingly, joinder of all members is impractical.

111. Common questions of law and fact exist as to all members of the Classes and predominate over any questions solely affecting individual members of the Classes. Among questions of law and fact in common to the Classes are:

(a) Whether Defendants falsely represented and advertised that the version of VSL#3 that Defendants marketed and sold during the Class Period was the same as, and as effective as, the version of VSL#3 that was marketed and sold prior to that time;

(b) Whether Defendants misled members of the Classes by omitting the fact that the post-May 2016 formulation of VSL#3 was different from the prior formulation;

(c) With respect to the Nationwide Class, whether Defendants violated the RICO statute, 18 U.S.C. §1962(c) and (d);

(d) With respect to the Nationwide Class, whether Defendants breached express warranties in violation of the Uniform Commercial Code;

(e) With respect to the Nationwide Class, whether Defendants were unjustly enriched by the false and deceptive marketing of VSL#3 during the Class Period, as alleged herein;

(f) With respect to the Massachusetts Class, whether Defendants, in their marketing and sale of VSL#3 during the Class Period, violated Mass. Gen. Laws ch. 93A § 2;

(g) With respect to the California Class, whether Defendants, in their marketing and sale of VSL#3 during the Class Period, violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*, the California Unfair Competition Law, Cal. Bus. & Prof. Code §§

17200 *et seq.* and the California False Advertising Law, Cal. Bus. & Prof. Code § 17500 *et seq.*;

(h) With respect to the Texas Class, whether Defendants, in their marketing and sale of VSL#3 during the Class Period, violated the Texas Consumer Protection Act, Tex. Bus. & Com. Code Ann. §§ 17.41 *et seq.*;

(i) With respect to the New Jersey Class, whether Defendants, in their marketing and sale of VSL#3 during the Class Period, violated the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1 *et seq.*;

(j) With respect to the Michigan Class, whether Defendants, in their marketing and sale of VSL#3 during the Class Period, violated the Michigan Consumer Protection Act, Mich. Comp. Laws §§ 445.901, *et seq.*;

(k) With respect to the Illinois Class, whether Defendants, in their marketing and sale of VSL#3 during the Class Period, violated the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/1 *et seq.* and/or the Illinois Uniform Deceptive Trade Practices Act, 815 Ill. Comp. Stat. 510/1 *et seq.*;

(l) With respect to the Washington Class, whether Defendants, in their marketing and sale of VSL#3 during the Class Period, violated the Washington Consumer Protection Act, Wash. Rev. Code §§ 19.86.010 *et seq.*;

(m) With respect to the Florida Class, whether Defendants, in their marketing and sale of VSL#3 during the Class Period, violated the Florida Deceptive and Unfair Trade Practices Act, §501.201 *et seq.*, Florida Statutes and/or engaged in Florida Statutory False Advertising violations pursuant to §§817.06 and 817.40-817.47, Florida Statutes;

(n) With respect to the Idaho Class, whether Defendants, in their marketing and sale of VSL#3 during the Class Period, violated the Idaho Consumer Protection Act, Idaho Code Ann. §§ 48-601 *et seq.*; and

(o) Whether the members of the Classes are entitled to damages for Defendants' violations of law and, if so, the proper measure of damages.

112. Plaintiffs' claims are typical of the claims of each member of each of the Classes in that Plaintiffs allege a common course of conduct by Defendants toward each member of the Classes. Specifically, Defendants violated the RICO statute, breached express warranties, were unjustly enriched and violated the consumer protection laws of various states by falsely

representing and advertising that the version of VSL#3 that Defendants marketed and sold during the Class Period was the same as, and as effective as, the version of VSL#3 that was marketed and sold prior to that time, and omitting the fact that the post-May 2016 formulation of VSL#3 was different from the prior formulation. Plaintiffs and the other members of each of the Classes seek identical remedies under identical legal theories. There is no antagonism or material factual variation between Plaintiffs' claims and those of the Classes.

113. Plaintiffs will fairly and adequately protect the interests of the members of the Classes and have retained counsel who have extensive experience prosecuting class actions and who, with Plaintiffs, are fully capable of, and intent upon, vigorously pursuing this action. Plaintiffs do not have any interest adverse to the Classes.

114. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Furthermore, the damage that has been suffered by any individual Class member is likely not enough to sustain the expense and burden of individual litigation. Hence it would be impracticable for all members of the Classes to redress the wrongs done to them individually. There will be no difficulty in the management of this action as a class action.

115. The prosecution of separate actions against Defendants would create a risk of inconsistent or varying adjudications with respect to the individual Class members, which could establish incompatible standards of conduct for Defendants. In addition, adjudications with respect to individual members of the Classes could, as a practical matter, be dispositive of the interests of the other members of the Classes not parties to such adjudications, or could substantially impede or impair their ability to protect their interests.

116. The members of the Classes are readily identifiable through Defendants' records.

117. Defendants have acted on grounds generally applicable to the Classes with respect to the matters complained of herein, thereby making appropriate the relief sought herein with respect to the Classes as a whole.

Count I

Violations of the Racketeer Influenced and Corrupt Organizations Act

18 U.S.C. §1962(c) - (d)

(On behalf of all Plaintiffs and the Nationwide Class)

118. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

119. This Count is pled on behalf of Plaintiffs and the National Class.

120. This claim arises under 18 U.S.C. §1962(c) and (d), which provides in relevant part:

> It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . . .
>
> It shall be unlawful for any person to conspire to violate any of the provisions of subsection . . . (c) of this section.

121. At all relevant times, Defendants were "persons" within the meaning of 18 U.S.C. §1961(3), because each Defendant was "capable of holding a legal or beneficial interest in property." Defendants were associated with an illegal enterprise, as described below, and conducted and participated in that enterprise's affairs though a pattern of racketeering activity, as defined by 18 U.S.C. §1961(5), consisting of numerous and repeated uses of the interstate mails and wire communications to execute a scheme to defraud in violation of 18 U.S.C. §1962(c).

122. The "VSL#3 Enterprise" was an association in fact of Defendants, representatives of the Cavazza Family and manufacturers in Italy including CSL and Nutrilinea, to deceptively

manufacture and market and sell VSL#3. It was used as a tool to carry out the elements of Defendants' illicit scheme and pattern of racketeering activity. The VSL#3 Enterprise has ascertainable structures and purposes beyond the scope and commission of Defendants' predicate acts and conspiracy to commit such acts. The enterprise is separate and distinct from Defendants, and the enterprise engages in activities distinct from the pattern of racketeering activity alleged herein. The members of the enterprise possess other intellectual property rights and manufacture, market and sell other pharmaceutical products, and associate to manufacture, market and sell medical probiotic foods. That being said, by marketing and selling VSL#3 through a series of acts of mail and wire fraud designed to deceive consumers into purchasing VSL#3 based on material false representations, including that the current formulation is the same as, and as effective as, the prior formulation, Defendants committed a pattern of racketeering, from which it may also be inferred that they associated as an enterprise.

123. The members of the VSL#3 Enterprise all had the common purpose to increase and maximize revenues and profits for Defendants by falsely marketing and selling VSL#3 during the Class Period as if it were the same formulation sold prior to the Class Period, when Defendants knew that it was not.

124. Throughout the Class Period, there were relationships between and among the VSL#3 Enterprise as the members were working together to market and sell VSL#3 and were affiliated with the Cavazza Family. Each member of the VSL#3 Enterprise conducted a specific and important role in operating and managing the enterprise during the Class Period. Defendants Leadiant and Alfasigma marketed and sold VSL#3 at different points during the Class Period on the basis of false advertising, false representations and omissions. Defendant VSL Inc. licensed to Defendants Leadiant and Alfasigma the right to market and sell VSL#3 and assisted them with

the false advertising campaign. CSL and Nutrilinea produced strains used in VSL#3 and/or manufactured it. And the Cavazza Family spearheaded the scheme using the Defendant companies, which it owned and controlled to effectuate the scheme.

125. The VSL#3 Enterprise has existed since at least the beginning of the Class Period, for a period of more than three years, providing more than sufficient time for its members to carry out its purpose. They worked together to market and sell VSL#3 containing the Fraudulent Formulation, including through a campaign of false advertising and false representations and shared the ill-gotten profits realized as a result of their scheme.

126. The VSL#3 Enterprise has engaged in, and its activities affected, interstate and foreign commerce by manufacturing, marketing, distributing and selling the Fraudulent Formulation of VSL#3 during the Class Period to thousands of individuals throughout the United States.

127. The VSL#3 Enterprise actively disguised the nature of Defendants' wrongdoing and concealed or misrepresented Defendants' participation in the conduct of the VSL#3 Enterprise to maximize profits and market share while minimizing their exposure to criminal and civil penalties.

128. Each of the Defendants exerted substantial control over the VSL#3 Enterprise, and participated in the operation and managed the affairs of the enterprise as described herein.

129. Defendants have committed or aided and abetted the commission of at least two acts of racketeering activity, *i.e.*, indictable violations of 18 U.S.C. §§1341 and 1343, within the past ten years. The multiple acts of racketeering activity that Defendants committed and/or conspired to, or aided and abetted in the commission of, were related to each other, pose a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

130. The acts of racketeering were related to each other insofar as they each served to fulfill the members of the VSL#3 Enterprise's common purpose to increase and maximize revenues and profits for Defendants by falsely marketing and selling VSL#3 during the Class Period as if it were the same formulation sold prior to the Class Period, when Defendants knew that it was not, were perpetrated by the same participants and resulted in consumers purchasing VSL#3 based on false information.

131. The acts of racketeering activity posed, and continue to pose, a threat of continued racketeering activity. Defendants engaged in numerous predicate acts of mail fraud and wire fraud over the course of the last three years, victimizing thousands of consumers by defrauding them into spending millions of dollars to purchase a medical probiotic food that was not the one that had been represented, harming such consumers economically. Even after the jury found Leadiant and Alfasigma liable for false advertising on November 20, 2018, Defendants continued perpetrating the exact same wrongful acts and indicated that they would do so indefinitely. Even now, notwithstanding this Court's June 21, 2019 injunction in the ExeGi Litigation, Defendants VSL Inc. and Alfasigma are continuing to market and sell the Fraudulent Formulation of VSL#3 as if it were the De Simone Formulation-version of VSL#3 using the same or similar means of false pretenses, misrepresentations, promises and/or omissions, in particular by continuing to sell VSL#3 to consumers using false advertising messages and without disclosing to them that the current version of VSL#3 uses a different formulation than the prior version, and the current version has not been proven to be clinically effective. Defendants also acted to cover up their scheme throughout the Class Period, such as by falsely telling consumers who contacted them that the formulation of VSL#3 had not changed.

132. Defendants' predicate acts of racketeering within the meaning of 18 U.S.C. §1961(1) include, but are not limited to:

(a) Mail Fraud: Defendants have violated 18 U.S.C. §1341, by sending or receiving materials via U.S. mail or commercial interstate carriers for the purpose of executing their scheme to manufacture, market, distribute and sell VSL#3 by means of false pretenses, misrepresentations, promises, and/or omissions. The materials include, but are not limited to: the VSL#3 products themselves; marketing materials, advertisements and brochures; product packaging; contracts; correspondence; invoices and payments; reports; and other materials relating to the marketing, distribution and sale of VSL#3; and

(b) Wire Fraud: Defendants have violated 18 U.S.C. §1343, by transmitting and receiving materials by wire for the purpose of executing their scheme to defraud and obtain money on false pretenses, misrepresentations, promises, and/or omissions. The materials transmitted and/or received include, but are not limited to, those mentioned in subsection (a) above.

133. Many of the precise dates of Defendants' fraudulent uses of the U.S. mail and wire facilities have been deliberately hidden and cannot be alleged without access to Defendants' books and records. Indeed, the success of Defendants' scheme depends upon secrecy, and Defendants have withheld details of the scheme from Plaintiffs and Class Members. Generally, however, Plaintiffs have described occasions on which the predicate acts of mail and wire fraud would have occurred. They include thousands of communications to perpetuate and maintain the scheme, including, among other things, the materials described in the preceding paragraph, and including the distribution of the products themselves in interstate commerce, which included the core deceptive statements on the product packaging and product insert that the Fraudulent Formulation was "VSL#3" and had a lengthy clinical history and numerous supporting clinical studies when in fact, Defendants changed the product from the true VSL#3 (the De Simone Formulation), which has that clinical history and support, to the imposter—*i.e.*, the Fraudulent Formulation, which does not.

134. Defendants have obtained money and property belonging to Plaintiffs and the Class as a result of these statutory violations. By the VSL#3 Enterprise and Defendants' pattern of racketeering activity, Plaintiffs and Class Members have been injured in their business or property by Defendants' overt acts of mail and wire fraud, and by their aiding and abetting each other's acts of mail and wire fraud. Defendants' conduct of the VSL#3 Enterprise through a pattern of racketeering activity succeeded in deceiving Plaintiffs and the Class into purchasing VSL#3 during the Class Period, even though it was not the same as the product that had been represented, thereby causing economic injury to Plaintiffs and the Class.

135. In violation of 18 U.S.C. §1962(d), Defendants conspired to violate 18 U.S.C. §1962(c), as described herein. Various other persons, firms and corporations, not named as defendants in this Complaint, have participated as coconspirators with Defendants in these offenses and have performed acts in furtherance of the conspiracy. These include entities involved in the manufacture, distribution, and false advertising of VSL#3.

136. Each Defendant aided and abetted violations of the above laws, thereby rendering them indictable as a principal in the 18 U.S.C. §§1341 and 1343 offenses pursuant to 18 U.S.C. §2.

137. Plaintiffs and the Class have been injured in their property by reason of Defendants' violations of 18 U.S.C. §1962(c) and (d), including the purchase price of the product. In the absence of Defendants' violations of 18 U.S.C. §1962(c) and (d), Plaintiffs and the Class would not have incurred these costs and expenses.

138. Plaintiffs and the Class relied, to their detriment, on Defendants' fraudulent misrepresentations and omissions, which were made by means of websites, mass mailings, newspaper advertisements, product packaging, telephone calls, marketing materials and virtually

uniform representations or omissions. Plaintiffs' and the Class's reliance is evidenced by their purchases.

139. Plaintiffs' and the Class's injuries were directly and proximately caused by Defendants' racketeering activity.

140. Defendants knew Plaintiffs and the Class relied on their representations and omissions about the efficacy of VSL#3 during the Class Period. Defendants knew and intended that consumers would incur substantial costs as a result.

141. Under the provisions of 18 U.S.C. §1964(c), Plaintiffs are entitled to bring this action and to recover treble damages, the costs of bringing this suit and reasonable attorneys' fees.

142. Defendants are accordingly liable to Plaintiffs for three times their actual damages as proved at trial plus interest and attorneys' fees.

Count II

Breach of Express Warranty in Violation of the Uniform Commercial Code

(On behalf of all Plaintiffs and the Nationwide Class)

143. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

144. This Count is pled on behalf of Plaintiffs and the National Class.

145. Defendants marketed and sold VSL#3 into the stream of commerce with the intent that it would be purchased by Plaintiffs and members of the Nationwide Class.

146. Defendants expressly warranted that that the version of VSL#3 that Defendants marketed and sold during the Class Period was the same as the version of VSL#3 that was marketed and sold prior to that time. For example, by describing the product as "VSL#3," Defendants made an affirmation of fact and promise under Section 2-313 of the Uniform Commercial Code that the version of VSL#3 that Defendants marketed and sold during the Class

Period was the same as the previous version. Defendants' warranties were express warranties which became part of the basis of the bargain Plaintiffs and members of the Nationwide Classes entered into when they purchased VSL#3.

147. Defendants breached their express warranties to Plaintiffs and the Nationwide Class because the version of VSL#3 they marketed and sold during the Class Period was not, in fact, the same as the version of VSL#3 that was marketed and sold before that time.

148. As a result of Defendants' breaches of their express warranties, Plaintiffs and the Nationwide Class have suffered actual damages in that they have purchased products that are less valuable than the products would have been had Defendants' representations been true, and Plaintiffs and the Nationwide Class paid prices for VSL#3 that were higher than they would have paid had Defendants accurately represented the formulation of VSL#3 marketed and sold during the Class Period.

Count III

Unjust Enrichment

(On behalf of all Plaintiffs and the Nationwide Class)

149. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

150. This Count is pled on behalf of Plaintiffs and the National Class.

151. Defendants were unjustly enriched by the false and deceptive marketing and sale of VSL#3 as alleged herein. Defendants, through their false representation that the formulation of VSL#3 that was sold during the Class Period was the same and as clinically effective as the prior formulation, obtained a benefit directly from Plaintiff and other Class Members when Plaintiff and other Class Members purchased the products, which enabled Defendants to obtain profits directly from those purchases.

152. Specifically, Defendants receive a direct financial benefit from the sale of their products to end consumers. Defendants sell their products directly to end consumers, as well as selling their products to distributors, retailers, pharmacies, and other intermediaries, who then sell products to end consumers. The sale of Defendants' products to end consumers results in revenues which are either paid directly to Defendants or used by the intermediaries to pay Defendants for their products. That is, Defendants' success as a business is directly associated with the volume of the sale of their products to end consumers, such as Plaintiffs and the Class.

153. Plaintiffs and the members of the National Class were damaged by their purchases of VSL#3 during the Class Period that as falsely advertised and represented to be the same as, and as clinically effective as, the prior formulation of VSL#3. Specifically, Plaintiffs conferred benefits on Defendants (i.e., payments for fake VSL#3), which, under the circumstances, it would be unjust for Defendants to retain. Plaintiffs through this unjust enrichment claim seek recovery of profits that Defendants unjustly obtained through their use of deceptive representations.

Count IV

Violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, § 2

(On behalf of Plaintiff Starr and the Massachusetts Class)

154. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

155. Plaintiff Starr brings this claim against Defendants on behalf of himself and the Massachusetts Class.

156. At all relevant times, Defendants were engaged in trade or commerce within the Commonwealth of Massachusetts, including the trade or commerce of marketing and selling VSL#3 within the Commonwealth of Massachusetts during the Class Period.

157. Defendants have engaged in deceptive, unfair, fraudulent and/or misleading commercial practices in the advertising, promotion, marketing, distribution and selling of VSL#3.

158. Defendants falsely represented and advertised that the version of VSL#3 that they marketed and sold during the Class Period was the same as, and as effective as, the version of VSL#3 that was marketed and sold prior to that time.

159. Defendants omitted to tell consumers such as Plaintiff Starr and the Massachusetts Class the fact that the post-May 2016 formulation of VSL#3 was different from, and not proven to be as effective as, the prior formulation.

160. Defendants' conduct was objectively deceptive, and had the capacity to deceive reasonable consumers under the circumstances. The fact that the formulation of VSL#3 Defendants marketed and sold during the Class Period was not the same as, or proven to be as effective as, the version of VSL#3 that they marketed and sold prior to that time was a material fact to which a reasonable consumer would attach importance at the time of purchase.

161. Defendant's practices, as detailed herein, constituted unfair or deceptive acts or practices in violation of Chapter 93A, Mass. Gen. Laws ch. 93A § 2.

162. Between April 25, 2019 and April 29, 2019, Plaintiff Starr sent Defendants written demands for relief pursuant to Chapter 93A, Section 9, identifying himself as the claimant on behalf of a putative class of similarly situated Massachusetts purchasers, and reasonably describing the unfair acts or practices relied upon and the injuries suffered by the putative class. Defendants responded to Plaintiff Starr's demand between May 6, 2019 and May 24, 2019. Defendants' responses, and any offers to resolve this matter contained therein, were neither adequate nor reasonable.

163. As a direct and proximate result of Defendants' violations of Chapter 93A, Plaintiff Starr and other members of the Massachusetts Class have suffered ascertainable losses, which include but are not limited to, the costs they incurred paying for a product which was not the one that had been represented to them, and the fact that the product they received (a fake, inferior, version of VSL#3) was less valuable than the product represented to them (the real, De Simone Formulation VSL#3). Accordingly, Plaintiff Starr and other members of the Massachusetts Class were harmed by, and Defendants are liable for, Defendants' actions in violation of Chapter 93A.

164. Defendants' violations of Chapter 93A, § 2 were willful and knowing.

165. Defendants are liable to Plaintiff Starr and the members of the Massachusetts Class for treble damages caused by their deceptive conduct, and for reasonable attorneys' fees as set forth in Chapter 93A, § 9.

Count V

Violation of California's Consumer Legal Remedies Act,

Cal. Civil Code §§1750, *et seq.*,

(On behalf of Plaintiff Cook and the California Class)

166. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

167. Plaintiff Cook brings this claim against Defendants on behalf of herself and the California Class.

168. Plaintiff Cook and each proposed member of the California Class is a "consumer," as that term is defined in California Civil Code section 1761(d).

169. The VSL#3 products that Plaintiff Cook and the other members of the California Class purchased during the Class Period are "goods," as that term is defined in California Civil Code section 1761(a).

170. Defendants are "persons" as that term is defined in California Civil Code section 1761(c).

171. Plaintiff and each member of the California Class's purchase of VSL#3 constituted a "transaction," as that term is defined in California Civil Code section 1761(e).

172. Defendants' conduct alleged herein violates the following provisions of California's Consumer Legal Remedies Act (the "CLRA"):

(a) Representing that goods have characteristics, uses, and benefits which they do not have (Cal. Civ. Code § 1770(a)(5));

(b) Representing that goods are of a particular standard, quality, or grade, if they are of another (Cal. Civ. Code § 1770(a)(7));

(c) Advertising goods with intent not to sell them as advertised (Cal. Civ. Code § 1770(a)(9)); and

(d) Representing that the subject of a transaction has been supplied in accordance with a previous representation when it has not (Cal. Civ. Code § 1770 (a)(16)).

173. In addition, under California law, a duty to disclose arises in several circumstances, including: (1) when the defendant has exclusive knowledge of material facts not known to the plaintiff; (2) when the defendant actively conceals a material fact from the plaintiff; and (3) when the defendant makes partial representations but also suppresses some material facts.

174. Defendants had a duty to disclose to Plaintiff Cook and the California Class that the formulation of VSL#3 they marketed and sold during the Class Period was not the same as, or proven to be as clinically effective as, the formulation of VSL# prior to that time because: (1) Defendants had exclusive knowledge of the information at the time of sale; (2) Defendants actively concealed the information from Plaintiff Cook and the California Class; and (3) Defendants made partial representations to Plaintiff Cook and the California Class regarding the safety and quality of the formulation of VSL#3 they marketed and sold during the Class Period.

175. Defendants' misrepresentations and omissions alleged herein were likely to mislead an ordinary consumer. Plaintiff Cook and the California Class reasonably understood Defendants' representations and omissions to mean that the formulation of VSL#3 they marketed and sold during the Class Period was the same as, as safe as, of the same quality and, proven to be as effective as, the version of VSL#3 they marketed and sold prior to the Class Period.

176. Defendants' misrepresentations and omissions alleged herein were material in that a reasonable person would attach importance to the information and would be induced to act upon the information in making purchase decisions.

177. Plaintiff Cook and members of the California Class relied to their detriment on Defendants' misrepresentations and omissions in purchasing VSL#3 during the Class Period.

178. Pursuant to Cal. Civ. Code § 1782(a), Plaintiff Cook served Defendants with notice of their alleged violations of the CLRA between May 29, 2019 and May 31, 2019. Defendants have failed to provide appropriate relief for their violations of the CLRA in response.

179. As a direct and proximate result of Defendants' violations of the CLRA, Plaintiff Cook and the other members of the California Class have suffered, and are entitled to recover, ascertainable monetary damages, including without limitation the costs they incurred paying for a product which was not the one that had been represented to them.

180. Defendants are liable to Plaintiffs and the members of the California Class for punitive damages and/or for reasonable attorneys' fees as set forth in the CLRA.

Count VI

Violation of California's False Advertising Law,

California Business & Professions Code, §§17500, *et seq.*

(On behalf of Plaintiff Cook and the California Class)

181. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

182. Plaintiff Cook brings this claim against Defendants on behalf of herself and the California Class.

183. California's False Advertising Law prohibits any statement in connection with the sale of goods "which is untrue or misleading." Cal. Bus. & Prof. Code §17500.

184. Plaintiff Cook, individually and on behalf of the California Class, has standing to pursue this claim because she suffered injury in fact and has lost money or property as a result of Defendants' actions set forth above.

185. Defendants engaged in advertising and marketing to the public and offered for sale VSL#3 in California during the Class Period.

186. Defendants engaged in the advertising and marketing alleged herein with the intent to directly or indirectly induce the sale of VSL#3 to consumers such as Plaintiff Cook and members of the California Class.

187. Defendants' advertising and marketing representations regarding VSL#3 during the Class Period were false, misleading, and deceptive within the definition, meaning and construction of California Business & Professions Code §§ 17500, et seq. (False Advertising Law).

188. Defendants' misrepresentations and omissions alleged herein were the type of misrepresentations that are material, i.e., a reasonable person would attach importance to them and would be induced to act on the information in making purchase decisions.

189. Defendants' misrepresentations and omissions alleged herein are objectively material to a reasonable consumer, and therefore reliance upon such misrepresentations may be presumed as a matter of law.

190. At the time they made the misrepresentations and omissions alleged herein, Defendants knew or should have known that they were untrue or misleading and acted in violation of California Business & Professions Code §§ 17500, *et seq*.

191. As a result of Defendants' conduct and actions, Plaintiff Cook and each member of the California Class has been injured, has lost money or property, and is entitled to relief. Plaintiff Cook and the California Class seek disgorgement, restitution, injunctive relieve, and all other relief permitted under California Business & Professions Code §§ 17500, *et seq*.

Count VII

Violation of California's Unfair Competition Law,

California Business & Professions Code §§ 17200, *et seq.*

(On behalf of Plaintiff Cook and the California Class)

192. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

193. Plaintiff Cook brings this claim against Defendants on behalf of herself and the California Class.

194. California's Unfair Competition Law ("UCL") prohibits unfair competition, defined as "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by [California's False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, et seq.]."

195. Plaintiff Cook and the California Class have standing to pursue this claim because Plaintiff Cook and members of the California Class have suffered injury in fact and have lost money or property as a result of Defendants' actions as set forth above.

196. Defendants' actions and conduct as alleged in this Class Action Complaint constitute an "unlawful" practice within the definition, meaning, and construction of California's

UCL because Defendants violated California's False Advertising Law (Bus. & Prof. Code §§ 17500, *et seq.*) and the CLRA (Civ. Code §§ 1750, *et seq.*).

197. Defendants' actions and conduct as alleged in this Class Action Complaint constitute an "unfair" practice within the definition, meaning, and construction of California's UCL because they offend established public policy and/or are immoral, unethical, oppressive, unscrupulous, and/or substantially injurious to their customers. The harm caused by Defendants' wrongful conduct outweighs any utility of such conduct and has caused – will continue to cause – substantial injury to Plaintiff Cook and the California Class. Additionally, Defendants' conduct is "unfair" because it violated the legislatively declared policies in California's False Advertising Law (Bus. & Prof. Code §§ 17500, et seq.) and the CLRA (Civ. Code §§ 1750, et seq.).

198. Defendants' actions as alleged in this Class Action Complaint constitute a "fraudulent" practice within the definition, meaning, and construction, of California's UCL because Defendants' representations that the formulation of VSL#3 they marketed and sold during the Class Period were the same as, and as clinically effective as, the formulation of VSL#3 they marketed and sold prior to that time were false and likely to deceive the public.

199. As a result of Defendants' "unlawful," "fraudulent," and "unfair" conduct, Plaintiff Cook and members of the California Class paid inflated prices for VSL#3 during the Class Period, insofar as the VSL#3 products they purchased during the Class Period were worth substantially less than the products promised by Defendants, and Plaintiff Cook and members of the California Class did not obtain the characteristics and specifications of VSL#3 promised by Defendants. Defendants' conduct directly and proximately caused Plaintiff Cook and the California Class actual monetary damages in the form of the price paid for VSL#3 during the Class Period. The injuries, damages, and harm caused to Plaintiff Cook and the California Class

by Defendants' unfair conduct are not outweighed by any countervailing benefits to consumers or competition, and the injury is one that consumers themselves could not reasonably have avoided. Defendants knew or had reason to know that Plaintiff Cook and the California Class could not have reasonably known or discovered that the formulation of VSL#3 marketed and sold during the Class Period was different from the version marketed and sold before that time. Had Defendants disclosed that the formulation of VSL#3 they marketed and sold during the Class Period was not the same as, or proven to be as clinically effective as, the prior formulation, Plaintiff Cook and the California Class would not have purchased VSL#3 during the Class Period.

200. Defendants' wrongful business practices alleged herein constitute a continuing course of unfair competition because Defendants market and sell their products in a manner that offends public policy and/or in a fashion that is immoral, unethical, oppressive, unscrupulous, and/or substantially injurious to its customers. In accordance with California Business & Professions Code § 17203, Plaintiff Cook seeks an order enjoining Defendants from continuing to conduct business through fraudulent or unlawful acts and practices.

201. Plaintiff Cook and the California Class also seek an order requiring Defendants to make full restitution of all moneys they have wrongfully obtained from Plaintiff Cook and the California Class, along with all other relief permitted under the UCL.

Count VIII

Violation of the Texas Consumer Protection Act,

Tex. Bus. & Com. Code Ann. §§ 17.41 *et seq*

(On behalf of Plaintiff Cook and the Texas Class)

202. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

203. Plaintiff Cook brings this claim against Defendants on behalf of himself and the Texas Class.

204. Plaintiff Cook and the other members of the Texas Class are "consumers" under the Texas Consumer Protection Act, Tex. Bus. & Com. Code Ann. §§ 17.45.

205. Defendants have engaged in deceptive, fraudulent and/or misleading commercial practices in the advertising, promotion, marketing, distribution and selling of VSL#3 in violation of the Texas Consumer Protection Act, Tex. Bus. & Com. Code Ann. §§ 17.46 and 17.50, including without limitation the following:

(a) § 17.46(b)(7): representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;

(b) § 17.46(b)(9): advertising goods or services with intent not to sell them as advertised; and

(c) § 17.46(b)(24): failing to disclose information concerning goods or services which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.

206. Defendants falsely represented and advertised that the version of VSL#3 that they marketed and sold during the Class Period was the same as, and as effective as, the version of VSL#3 that was marketed and sold prior to that time;

207. Defendants omitted to tell consumers such as Plaintiff Cook and the Texas Class the fact that the post-May 2016 formulation of VSL#3 was different from, and not proven to be as effective as, the prior formulation.

208. Defendants' conduct was objectively deceptive, and had the capacity to deceive reasonable consumers under the circumstances. The fact that the formulation of VSL#3 Defendants marketed and sold during the Class Period was not the same as, or proven to be as effective as, the version of VSL#3 that they marketed and sold prior to that time was a material

fact to which a reasonable consumer would attach importance at the time of purchase. Plaintiff Cook and members of the Texas Class relied to their detriment on Defendants' misrepresentations and omissions in purchasing VSL#3 during the Class Period.

209. Defendant's practices, as detailed herein, constituted deceptive acts or practices in violation of the Texas Consumer Protection Act, Tex. Bus. & Com. Code Ann. §§ 17.41 *et seq*.

210. Plaintiff Cook served Defendants with notice of their alleged violations of the Texas Consumer Protection Act on behalf of herself and the putative Texas Class between May 29, 2019 and May 31, 2019.

211. As a direct and proximate result of Defendants' violations of the Texas Consumer Protection Act, Plaintiff Cook and other members of the Texas Class have suffered ascertainable economic damages, which include but are not limited to, the costs they incurred paying for a product which was not the one that had been represented to them. Plaintiff Cook and the other members of the Texas Class would not have purchased VSL#3 during the Class Period, or would not have purchased it at the prices they paid, had they known that the formulation of VSL#3 during the Class Period was not the same as, or proven to be as clinically effective as, the prior formulation of VSL#3. Plaintiff Cook and the Texas Class are entitled to recover damages, including treble damages insofar as Defendants' conduct was committed knowingly and/or intentionally, for Defendants' misconduct.

Count IX

Violation of New Jersey's Consumer Fraud Act, N.J.S.A. § 56:8-2, *et seq.*

(On Behalf of Plaintiffs Mavrikos and the New Jersey Class)

212. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

213. Plaintiff Mavrikos brings this claim against Defendants on behalf of herself and the New Jersey Class.

214. Defendants have engaged in deceptive, unfair, fraudulent and/or misleading commercial practices in the advertising, promotion, marketing, distribution and sale of VSL#3 during the Class Period.

215. Defendants represented that the formulation of VSL#3 they marketed and sold during the Class Period had characteristics, uses, benefits, or qualities that they did not have—specifically, that it was the same as, and proven to be as effective as the prior formulation of VSL#3, when, in fact, it was not. Defendants also omitted the material fact that the formulation of VSL#3 they marketed and sold during the Class Period was not the same, or proven to be as effective as, the prior formulation.

216. In their advertising, promotion, and marketing of VSL#3 during the Class Period, Defendants misrepresented material facts to, and omitted material facts from, Plaintiff Mavrikos and other members of the New Jersey Class with respect to the formulation of VSL#3.

217. Defendants' conduct was objectively deceptive and had the capacity to deceive reasonable consumers under the circumstances. The fact that the formulation of VSL#3 Defendants marketed and sold during the Class Period was not the same, or proven to be as effective as, the formulation of VSL#3 marketed and sold prior to that time was a material fact to which a reasonable consumer would attach importance at the time of purchase or lease.

218. Defendants' practices, as detailed herein, violated the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq.

219. As a direct and proximate result of Defendants' violations of the New Jersey Consumer Fraud Act, Plaintiff Mavrikos and other members of the New Jersey Class have suffered ascertainable losses, which include but are not limited to, the difference in value between the product that Defendants purported to sell to them (the version of VSL#3 using the

De Simone Formulation) and the product that Defendants actually provided to them (the version of VSL#3 using the Fraudulent Formulation). Accordingly, Plaintiff Mavrikos and other members of the New Jersey Class were harmed by, and Defendants are liable for, Defendants' actions in violation of the New Jersey Consumer Fraud Act.

220. Defendants are liable to Plaintiff Mavrikos and the members of the New Jersey Class for treble damages caused by their deceptive conduct, and for reasonable attorneys' fees as set forth in the New Jersey Consumer Fraud Act.

Count X

Violation of the Michigan Consumer Protection Act,

Michigan Comp. Laws Ann. § 445.901 *et seq.*

(On Behalf of Plaintiff Quiambao and the Michigan Class)

221. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

222. Plaintiff Quiambao brings this claim against Defendants on behalf of himself and the Michigan Class.

223. Defendants have engaged in deceptive, unfair, fraudulent and/or misleading commercial practices in the advertising, promotion, marketing, distribution and sale of VSL#3 during the Class Period. In doing so, Defendants have engaged in unfair and deceptive acts or practices in the conduct of trade or commerce, in violation of Michigan Comp. Laws Ann. § 445.903 —otherwise known as the "Michigan Consumer Protection Act."

224. Specifically, Section 903 of the Act provides in relevant part as follows:

> Unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce are unlawful and are defined as follows: *** (e) Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another. *** (g) Advertising or representing goods or services with intent not to dispose of those goods or services as advertised or represented. *** (s) Failing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could

> not reasonably be known by the consumer. *** (bb) Making a representation of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is. *** (cc) Failing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner.

225. The Michigan Consumer Protection Act applies to all claims of the members of the Michigan Class because the conduct which constitutes violations of that Act by Defendants occurred within the state of Michigan.

226. Plaintiff Quiambao and members of the Michigan Class, as purchasers of VSL#3, are consumers within the meaning of the Michigan Consumer Protection Act because Defendants' business practices involve trade or commerce, are addressed to the market generally, and otherwise implicate consumer protection concerns.

227. Defendants represented that the formulation of VSL#3 they marketed and sold during the Class Period had characteristics, uses, benefits, or qualities that they did not have—specifically, that it was the same as, and proven to be as effective as the prior formulation of VSL#3, when, in fact, it was not. Defendants also omitted the material fact that the formulation of VSL#3 they marketed and sold during the Class Period was not the same, or proven to be as effective as, the prior formulation.

228. In their advertising, promotion, and marketing of VSL#3 during the Class Period, Defendants misrepresented material facts to, and omitted material facts from, Plaintiff Quiambao and other members of the Michigan Class with respect to the formulation of VSL#3.

229. Defendants' practices, as detailed herein, violated the Michigan Consumer Protection Act.

230. Plaintiff Quiambo and members of the Michigan Class relied on Defendants' representations that the VSL#3 they marketed and sold during the Class Period was the same as, and proven to be as clinically effective as, the prior version of VSL#3. Defendants intended that

Plaintiff Quiambao and the members of the Michigan Class would rely on the deception by purchasing VSL#3 during the Class Period, unaware of the material fact that the formulation had changed. Members of the Michigan Class may be presumed to have relied upon the representation that the VSL#3 they purchased during the Class Period was the same formulation as, and proven to be as clinically effective as, the VSL#3 they purchased before the Class Period.

231. Plaintiff Quiambao and members of the Michigan Class were entitled to know that the formulation of VSL#3 that Defendants marketed and sold during the Class Period was not the same as, or proven to be as clinically effective as, the prior formulation, as that fact would be material in a consumer's purchasing decision.

232. Plaintiff Quiambao and members of the Michigan Class would not have purchased VSL#3 during the Class Period had Defendants represented otherwise.

233. As a direct and proximate result of Defendants' violations of the Michigan Consumer Protection Act, Plaintiff Quiambao and other members of the Michigan Class have suffered ascertainable losses, which include but are not limited to, the costs they incurred paying for a product which was not the one that had been represented to them. Accordingly, Plaintiff Quiambao and other members of the Michigan Class were harmed by, and Defendants are liable for, Defendants' actions in violation of the Michigan Consumer Protection Act.

Count XI

Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act

815 Ill. Comp. Stat. §§ 505/1, *et seq.*

(On behalf of Plaintiff Tettenhorst and the Illinois Class)

234. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

235. Plaintiff Tettenhorst brings this claim against Defendants on behalf of himself and the Illinois Class.

236. The Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 Ill. Comp. Stat. §§ 505/1, *et seq.*, prohibits any deceptive, unlawful, unfair, or fraudulent business acts or practices including using deception, fraud, false pretenses, false promises, false advertising, misrepresentation, or the concealment, suppression, or omission of any material fact, or the use or employment of any practice described in Section 2 of the Uniform Deceptive Trade Practices Act. 815 Ill. Comp. Stat. § 505/2.

237. The ICFA applies to Defendant's acts as described herein because it applies to transactions involving the sale of goods or services to consumers.

238. Defendant is a "person" as defined by section 505/1(c) of the ICFA.

239. Plaintiff Tettenhorst and each member of the Illinois Class are "consumers" as defined by section 505/l(e) of the ICFA.

240. VSL#3 constitutes "merchandise" under the meaning of section 505/l(b) and its sale is within the meaning of "trade" or "commerce" under the ICFA.

241. Defendants falsely represented and advertised that the version of VSL#3 that they marketed and sold during the Class Period was the same as, and as effective as, the version of VSL#3 that was marketed and sold prior to that time.

242. Defendants omitted to tell consumers such as Plaintiff Tettenhorst and the Illinois Class the fact that the post-May 2016 formulation of VSL#3 was different from, and not proven to be as effective as, the prior formulation.

243. Defendants' conduct was objectively deceptive, and had the capacity to deceive reasonable consumers under the circumstances. The fact that the formulation of VSL#3 Defendants marketed and sold during the Class Period was not the same as, or proven to be as

effective as, the version of VSL#3 that they marketed and sold prior to that time was a material fact to which a reasonable consumer would attach importance at the time of purchase.

244. Defendant's practices, as detailed herein, constituted unfair or deceptive acts or practices in violation of the ICFA.

245. As a direct and proximate result of Defendants' violations of the ICFA, Plaintiff Tettenhorst and other members of the Illinois Class have suffered ascertainable losses, which include but are not limited to, the costs they incurred paying for a product which was not the one that had been represented to them. Plaintiff Tettenhorst and the other members of the Illinois Class would not have purchased VSL#3 during the Class Period if they had known it was not the same, or proven to be as effective as, the prior formulation.

246. Defendants' practices set forth herein offend public policy, were and are immoral, unethical, oppressive, and unscrupulous, and cause substantial injury to consumers.

247. Plaintiff Tettenhorst, on behalf of himself and the Illinois Class, seeks an order (1) requiring Defendants to cease the deceptive and unfair practices described herein; (2) awarding damages, interest, and reasonable attorneys' fees, expenses, and costs to the extent allowable; and/or (3) requiring Defendants to restore to Plaintiff Tettenhorst and each Illinois Class member any money acquired by means of their wrongful conduct.

Count XII

Violation of the Illinois Uniform Deceptive Trade Practices Act

815 Ill. Comp. Stat. §§ 510/1, *et seq.*

(On behalf of Plaintiff Tettenhorst and the Illinois Class)

248. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

249. Plaintiff Tettenhorst brings this claim against Defendants on behalf of himself and the Illinois Class.

250. Section 2 of the Illinois Uniform Deceptive Practices Act, 815 Ill. Comp. Stat. §§ 510/1, *et seq.* ("Illinois DTPA") states in relevant part:

> (a) A person engages in a deceptive trade practice when, in the course of his or her business, vocation or occupation, the person… (5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have .... ; (7) represents that goods or services are of a particular standard, quality, or grade or that goods are a particular style or model, if they are of another; (9) advertises goods or services with intent not to sell them as advertised; (12) engages in any other conduct which similarly creates a likelihood of confusion or misunderstanding.

251. Defendants' foregoing misleading statements and omissions to Plaintiff Tettenhorst and the Class constitute deceptive trade practices in violation of the foregoing statutory provisions.

252. The above-described on-going deceptive and unfair acts and practices were and are used or employed in the conduct of trade or commerce, namely, the sale of VSL#3 to Plaintiff Tettenhorst and members of the Illinois Class.

253. The above-described deceptive and unfair acts offend public policy and cause substantial injury to consumers.

254. Defendants' false and misleading statements set forth above were and are made knowingly and intentionally, with the intent to mislead Plaintiff Tettenhorst and the Illinois Class.

255. Accordingly, Defendant has violated the Illinois DTPA.

256. As set forth above, Plaintiff Tettenhorst and the Illinois Class was damaged and are likely to be damaged in the future by Defendants' deceptive and unfair trade practices to the extent they continue to purchase VSL#3. Plaintiff Tettenhorst and the Illinois Class are thus entitled to an injunction against Defendants' continued deceptive conduct, as well as reasonable attorney's fees and costs.

Count XIII

Violation of the Washington Consumer Protection Act

Wash. Rev. Code §§ 19.86.010*, et seq.*

(On behalf of Plaintiff Hansen and the Washington Class)

257. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

258. Plaintiff Hansen brings this claim against Defendants on behalf of himself and the Washington Class.

259. Defendants are "persons" within the meaning of the Washington Consumer Protection Act, Wash. Rev. Code § 19.86.010(1) and have conducted "trade" and "commerce" within the meaning of Wash. Rev. Code 19.86.010(2).

260. Defendants have engaged in deceptive, unfair, fraudulent and/or misleading commercial practices in the advertising, promotion, marketing, distribution and selling of VSL#3 in violation of the Washington Consumer Protection Act, including without limitation Wash. Rev. Code § 19.86.020.

261. Defendants falsely represented and advertised that the version of VSL#3 that they marketed and sold during the Class Period was the same as, and as effective as, the version of VSL#3 that was marketed and sold prior to that time.

262. Defendants failed to tell consumers such as Plaintiff Hansen and the Washington Class the fact that the post-May 2016 formulation of VSL#3 was different from, and not proven to be as effective as, the prior formulation.

263. Defendants' conduct was objectively deceptive, and had the capacity to deceive reasonable consumers under the circumstances. The fact that the formulation of VSL#3 Defendants marketed and sold during the Class Period was not the same as, or proven to be as

effective as, the version of VSL#3 that they marketed and sold prior to that time was a material fact to which a reasonable consumer would attach importance at the time of purchase.

264. Defendants' deceptive and unfair acts or practices occurred in their trade or business and have and are capable of injuring a substantial portion of the public. Defendants' general course of conduct as alleged herein is injurious to the public interest and the acts complained of herein are ongoing and/or likely to be repeated.

265. As a direct and proximate result of Defendants' violations of the Washington Consumer Protection Act, Plaintiff Hansen and other members of the Washington Class have suffered ascertainable losses, which include but are not limited to, the costs they incurred paying for a product that was not the one that had been represented to them.

266. Plaintiff Hansen and members of the Washington Class are entitled to an order enjoining the conduct complained of herein and ordering Defendant to take remedial measures to prevent similar violations; actual damages; treble damages pursuant to Wash. Rev. Code § 19.86.090; costs of suit, including reasonable attorneys' fees; and such further relief as the Court may deem proper.

Count XIV

Violation of the Florida Deceptive and Unfair Trade Practices Act,

§501.201 *et seq*., Florida Statutes

(On behalf of Plaintiff Karo and the Florida Class)

267. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

268. Plaintiff Karo brings this claim against Defendants on behalf of herself and the Florida Class.

269. Defendants are engaged in commerce in the State of Florida, as defined by §501.203(8), Florida Statutes, and are therefore subject to the provisions contained in §501.201 et seq., Florida Statutes, the Florida Deceptive and Unfair Trade Practices Act (FDUTPA).

270. Plaintiff Karo and the members of the Florida Class are "consumer(s)" as defined by §501.203(7), Florida Statutes, and as such are entitled to the protection of FDUTPA.

271. In marketing and selling VSL#3 in Florida, Defendants were required to be honest in their dealings and not engage in any actions that had the effect of deceiving purchasers of VSL#3.

272. By reason of the conduct alleged herein, Defendants engaged in unfair and deceptive business practices in violation of FDUTPA, Fl. St. §§501.201, et seq. Specifically, Defendants falsely represented and advertised that the version of VSL#3 that they marketed and sold during the Class Period was the same as, and as effective as, the version of VSL#3 that was marketed and sold prior to that time. Defendants also failed to tell consumers such as Plaintiff Karo and the Florida Class the fact that the post-May 2016 formulation of VSL#3 was different from, and not proven to be as effective as, the prior formulation.

273. As a result of Defendants' violations of FDUTPA, Plaintiff Karo and the members of the Florida Class have suffered a substantial injury and have been aggrieved and are, thus, entitled to damages under FDUTPA.

274. As redress for Defendants' repeated violations of FDUTPA, Plaintiff Karo and the members of the Florida Class are entitled to, *inter alia*, damages and declaratory and/or injunctive relief and reasonable attorney's fees and costs.

Count XV

Florida Statutory False Advertising Violations,

§§817.06 and 817.40-817.47., Florida Statutes

(On behalf of Plaintiff Karo and the Florida Class)

275. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

276. Plaintiff Karo brings this claim against Defendants on behalf of herself and the Florida Class.

277. This claim is brought pursuant to Florida's Statutory False Advertising prohibition, Fla. Stat. §§817.06, 817.40 – 817.47. Fla Stat. §817.41(1), provides, in relevant part, that:

> It shall be unlawful for any person to make or disseminate or cause to be made or disseminated before the general public of the state, or any portion thereof, any misleading advertisement. Such making or dissemination of misleading advertising shall constitute and is hereby declared to be fraudulent and unlawful, designed and intended for obtaining money or property under false pretenses.

278. As fully explained herein, Defendants have made, disseminated or caused to be made or disseminated advertising which is false and misleading. Such false and misleading advertising has been made to Plaintiff Karo and Florida Class members. Defendants' misrepresentations and omissions were designed with the intent that Plaintiff Karo and Florida Class members rely on the same and purchase VSL#3 as a result of the false and deceptive advertisements, which they did.

279. Plaintiff Karo and the Florida Class have been aggrieved by Defendants' misleading advertising in that they paid for VSL#3, incurring costs for a product which was not the one that had been represented to them, and which was less valuable than the product represented to them.

280. Plaintiff Karo and the Florida Class are entitled to all available relief, including without limitation restitution, disgorgement, damages, attorneys' fees and costs.

Count XVI

Violation of the Idaho Consumer Protection Act, Idaho Code Ann., § 48-601 *et seq*.

(On behalf of Plaintiff Reed-Cossairt and the Idaho Class)

281. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

282. Plaintiff Reed-Cossairt brings this claim against Defendants on behalf of herself and the Massachusetts Class.

283. Defendants are "person[s]" under the Idaho Consumer Protection Act, Idaho Code Ann. § 48-602(1).

284. Defendants have engaged in deceptive, unfair, fraudulent and/or misleading commercial practices in the advertising, promotion, marketing, distribution and selling of VSL#3 in violation of the Idaho Consumer Protection Act, including without limitation Idaho Code Ann. §§ 48-603(2), (5), (7), (9), (17) and/or (18).

285. Defendants falsely represented and advertised that the version of VSL#3 that they marketed and sold during the Class Period was the same as, and as effective as, the version of VSL#3 that was marketed and sold prior to that time.

286. Defendants omitted to tell consumers such as Plaintiff Reed-Cossairt and the Idaho Class the fact that the post-May 2016 formulation of VSL#3 was different from, and not proven to be as effective as, the prior formulation.

287. Defendants' conduct was objectively deceptive, and had the capacity to deceive reasonable consumers under the circumstances. The fact that the formulation of VSL#3 Defendants marketed and sold during the Class Period was not the same as, or proven to be as

effective as, the version of VSL#3 that they marketed and sold prior to that time was a material fact to which a reasonable consumer would attach importance at the time of purchase.

288. As a direct and proximate result of Defendants' violations of the Idaho Consumer Protection Act, Plaintiff Reed-Cossairt and other members of the Idaho Class have suffered ascertainable losses, which include but are not limited to, the costs they incurred paying for a product which was not the one that had been represented to them, and the fact that the product they received (a fake, inferior, version of VSL#3) was less valuable than the product represented to them (the real, De Simone Formulation VSL#3).

289. Pursuant to Idaho Code Ann. § 48-608, Plaintiff Reed-Cossairt seeks monetary relief against Defendants measured as the greater of (a) actual damages in an amount to be determined at trial and (b) statutory damages in the amount of $1,000 for each Plaintiff and class member. Plaintiff Reed-Cossairt also seeks an injunction against Defendants under this section, enjoining them from future violative practices of the Idaho Consumer Protection Act. Plaintiff Reed-Cossairt and the Idaho Class also seek recovery of reasonable attorney's fees from Defendants.

290. In engaging in the conduct as hereinabove alleged, Defendants engaged in oppressive, fraudulent, malicious and/or outrageous conduct, thereby warranting an assessment of punitive damages in an amount sufficient to punish Defendants and deter others from engaging in similar conduct.

Prayers for Relief

WHEREFORE, Plaintiffs pray for relief in the form of an order as follows:

(a) Certifying this action as a class action under Federal Rule of Civil Procedure 23, and appointing Plaintiffs as class representatives and their attorneys as class counsel;

(b) Awarding actual damages to Plaintiffs and the Members of the Nationwide Class and the State Subclasses and/or awarding to Plaintiffs and the Classes the amounts by which Defendants were unjustly enriched as a result of their wrongful conduct in an amount of not less than tens of millions of dollars;

(c) Awarding double or treble damages pursuant to the RICO statute and/or applicable state statutes;

(d) Enjoining Defendants from continuing to engage in the unlawful and deceptive conduct described herein;

(e) Awarding attorneys' fees, expenses, and the costs of this suit, together with prejudgment and post-judgment interest at the maximum rate allowed by law; and

(f) Awarding such other and further relief which the Court finds just and proper.

Jury Demand

Plaintiffs demand a trial by jury on all claims so triable.

Dated: July 23, 2019

By their attorneys,

SCHULMAN BHATTACHARYA, LLC

/s/ Jeremy W. Schulman

Jeremy W. Schulman (Fed. Bar No. 16787)
Jeffrey S. Gavenman (Fed. Bar No. 19946)
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CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS DAVID STARR, SANDI COOK, BERNADETTE MAVRIKOS, EDMUND QIUIAMBAO, JAMES TETTENHORST, JEREMY HANSEN, KRISTA KARO and ARLENE REED-COSSAIRT, on behalf of themselves and all others similarly situated

(b) County of Residence of First Listed Plaintiff Norfolk County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Schulman Bhattacharya, LLC, 7500 Old Georgetown Rd., Ste. 901, Bethesda, MD 20814, (240) 356-8550
Shapiro Haber & Urmy LLP, Seaport East, Two Seaport Ln., Fl. 6, Boston, MA 02210, (617) 439-3939

DEFENDANTS VSL PHARMACEUTICALS, INC.; LEADIANT BIOSCIENCES, INC., F/K/A SIGMA-TAU PHARMACEUTICALS, INC., and ALFASIGMA USA, INC.,

County of Residence of First Listed Defendant New Castle County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ❒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	❒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 840 Trademark	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	SOCIAL SECURITY	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	❒ 861 HIA (1395ff)	☒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 862 Black Lung (923)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 790 Other Labor Litigation	❒ 863 DIWC/DIWW (405(g))	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 791 Employee Retirement Income Security Act	❒ 864 SSID Title XVI	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise				❒ 865 RSI (405(g))	❒ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	❒ 891 Agricultural Acts
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	Habeas Corpus:	❒ 462 Naturalization Application	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 893 Environmental Matters
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 465 Other Immigration Actions	❒ 871 IRS—Third Party 26 USC 7609	❒ 895 Freedom of Information Act
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence			❒ 896 Arbitration
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			❒ 950 Constitutionality of State Statutes
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	Other:			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
18 U.S.C. §1962

Brief description of cause:
Federal and state causes of action based on false and misleading statements by Defendants

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ Tens of millions of dollars

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Theodore D. Chuang DOCKET NUMBER 8:15-cv-01356

DATE 7/23/19

SIGNATURE OF ATTORNEY OF RECORD /s/ Jeremy W. Schulman

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.