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, ARLENE REED-COSSAIRT, PETER STAVROS, SCOTT OFFUTT, HEATHER FARKAS and STACEY HOLZ, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

VSL PHARMACEUTICALS, INC.; LEADIANT BIOSCIENCES, INC., F/K/A SIGMA-TAU PHARMACEUTICALS, INC., ALFASIGMA USA, INC., CENTRO SPERIMENTALE DEL LATTE S.R.L., and NUTRILINEA S.R.L.;

Defendants.

Civil Action No. 8:19-cv-02173-TDC

SECOND AMENDED COMPLAINT

Plaintiffs David Starr, Sandi Cook, Bernadette Mavrikos, Edmund Quiambao, James Tettenhorst, Jeremy Hansen, Krista Karo, Arlene Reed-Cossairt, Peter Stavros, Scott Offutt, Heather Farkas, and Stacey Holz ("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"), Alfasigma USA, Inc. ("Alfasigma"), Centro Sperimentale del Latte S.r.l. ("CSL"), and Nutrilinea S.r.l. ("Nutrilinea") (collectively, the "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' scheme to deceive consumers through the false and misleading advertising and marketing of VSL#3 during the Class Period. As detailed below, Defendants VSL Inc., Alfasigma, and Leadiant (the "VSL Defendants"), working in concert and in coordination with Defendants CSL and Nutrilinea (the "Manufacturer Defendants"), knowingly acted and conspired to deceive Plaintiffs and thousands of other consumers throughout the United States by falsely claiming and representing that the new formulation of VSL#3 sold beginning in 2016 was the same as the original, clinically-tested formulation of VSL#3 sold prior to that time, when it was not.

2. In order to understand the nature of Defendants' scheme and the false and misleading advertising and marketing upon which it was based, 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." Defendants VSL Inc. and Leadiant, in their marketing and advertising for VSL#3 from 2002 through May 2016, emphasized the proprietary formulation that VSL#3 contained (*i.e.*, the De

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

Simone Formulation) and the clinical trials performed with that formulation, thus cultivating with consumers and medical professionals the understanding that "VSL#3" refers to a specific formulation that had unique benefits for consumers who consumed the product.

3. In early 2016, however, Defendants VSL Inc. and Leadiant lost the right to sell the De Simone Formulation. That right was granted to a company called 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."

4. Defendant VSL Inc., 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. More specifically, VSL Inc. and Defendants CSL and Nutrilinea, who were well-aware of the change in formulation based on facts detailed below, agreed that CSL and Nutrilinea would manufacture, package, label, and ship the Fraudulent Formulation to the United States for sale to consumers throughout the United States, including consumers in Maryland. Notwithstanding this change in formulation, VSL Inc. continued using the VSL#3® mark to sell this inferior product, despite VSL Inc.'s prior representations to consumers that VSL#3 referred to a particular proprietary blend of bacterial strains (*i.e.*, the De Simone Formulation). That is, VSL Inc. made a strategic decision to invoke consumers' understanding of the particular properties of VSL#3 (an understanding VSL Inc. itself had cultivated) by 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 and misleadingly invoke the clinical history and scientific support for the De Simone Formulation as proof for the efficacy of the Fraudulent Formulation, Defendants deceived consumers into

purchasing a product that was substantially less valuable than the product they represented it to be. Plaintiffs and other consumers relied upon the VSL#3 name (which was presented prominently on every product sold to Class Members) and other representations by Defendants, described herein, to be deceived in believing that VSL#3 continued to contain the same bacterial strains, in the same proportion, that VSL#3 had previously contained (*i.e.*, the De Simone Formulation).

5. 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, as a result of Defendant VSL Inc.'s and Defendant Leadiant's marketing and advertising from before the change, to refer to 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. knowingly continued to market the Fraudulent Formulation as "VSL#3" throughout the Class Period.

6. Defendants CSL and Nutrilinea, knowing of the VSL Defendants' false and deceptive advertising and the change in formulation, manufactured the Fraudulent Formulation for sale in the United States throughout the entire Class Period and continue to manufacture the Fraudulent Formulation for sale in the United States to the present day. Defendant CSL completes the first stage of the production process; Defendant Nutrilinea continues the process and produces the finished VSL#3 product. More specifically, as Defendants had agreed, in this coordinated effort, CSL receives the bacterial strains in vials or ampoules from VSL Inc., then produces replicas of these strains, mixes them according to a specific protocol to obtain a fine powder, and delivers this semi-finished product to Nutrilinea. Upon receiving this blend of probiotic strains,

Nutrilinea adds certain inactive substances to that powder (according to VSL Inc.'s specifications), puts the mixture into consumable capsules and sachets, puts those capsules and sachets into blisters and boxes labeled "VSL#3," inserts the false and misleading VSL#3 product information sheet into those boxes, finalizes the VSL#3 product packaging, and ships the VSL#3 product to the VSL Defendants in the United States for sale to consumers throughout the United States, including consumers in Maryland.

7. Throughout the Class Period and to the present day, the product packaging and other marketing materials for the Fraudulent Formulation, at all times known to all Defendants, deceive consumers into believing that VSL#3 is the same as the original De Simone Formulation, which had been the subject of more than 60 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.

8. 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. 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. And Defendants misled consumers by continuing to use the VSL#3® mark and failing to disclose 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.

9. 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.

10. 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 the VSL Defendants' advertisements. For example, the VSL 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.

11. 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 essentially 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.

12. On June 21, 2019, this Court denied the VSL 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 mix in the same proportions" as the earlier version of VSL#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.

[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."

13. As detailed below, Defendants CSL and Nutrilinea knew of the ongoing false and deceptive advertising and marketing of the Fraudulent Formulation that they were manufacturing. CSL and Nutrilinea continued to manufacture the Fraudulent Formulation for VSL Inc. and Alfasigma regardless. And Defendant Nutrilinea continued to package the Fraudulent Formulation with packaging that contained false and deceptive representations about VSL#3 and continued to ship it to Alfasigma in the United States, where CSL and Nutrilinea knew it would be falsely and deceptively marketed and sold to consumers throughout the United States, including to consumers in Maryland.

14. 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.

15. Because Defendants presented to consumers a product using the VSL#3® mark 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.

16. 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 by continuing to use the VSL#3® mark without disclosing that the product was not the same as the clinically tested product which was sold prior to the Class Period, all of the Defendants violated the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §1962 ("RICO"). In addition, the VSL Defendants: (i) breached express warranties in violation of the Uniform Commercial Code; (ii) were unjustly enriched as a result of their misconduct insofar as the VSL 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; (iii) engaged in deceptive and/or unfair acts in violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, §§ 2, 9; (iv) engaged in deceptive acts in violation of the Texas Consumer Protection Act, Tex. Bus. & Com. Code Ann. §§ 17.41 *et seq.*; (v) 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.*; (vi) engaged in deceptive and/or unfair acts in violation of the Washington Consumer Protection Act, Wash. Rev. Code §§ 19.86.010 *et seq*.; (vii) 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; (viii) engaged in unfair, false, misleading and/or deceptive acts or practices in violation of the Kentucky Consumer Protection Act, KRS §367.170; (ix) engaged in unfair and/or deceptive practices in violation of the Tennessee Consumer Protection Act, Tenn. Code Ann., § 47-18-104; and (x) engaged in deceptive trade practices in violation of the Wisconsin Deceptive Trade Practices Act, Wis. Stat. § 100.18.

17. 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

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

19. 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.

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

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

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

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

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

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

26. Plaintiff Peter Stavros is a resident of Kentucky who regularly purchased VSL#3 during the Class Period.

27. Plaintiff Scott Offutt is a resident of Tennessee who regularly purchased VSL#3 during the Class Period.

28. Plaintiff Heather Farkas is a resident of Wisconsin who regularly purchased VSL#3 during the Class Period.

29. Plaintiff Stacey Holz is a resident of California who regularly purchased VSL#3 during the Class Period.

30. 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. 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, Alfasigma, and the Manufacturer Defendants, which used such false information to manufacture, package, market, and sell VSL#3. In addition to advertising VSL#3, VSL Inc. owns the intellectual property rights to other products.

31. 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. Leadiant is a pharmaceutical company that dedicates considerable resources to the research, development, and distribution of various therapies to address the needs of people living with multiple rare diseases.

32. 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.

33. 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. Alfasigma is the United States affiliate of a major pharmaceutical group based in Italy and sells multiple pharmaceutical products in the United States.

34. Defendant CSL is a corporation organized and incorporated under the laws of Italy, with its principal place of business in Lodi, Italy. CSL is an international company that studies, develops, and manufactures natural probiotics for the pharmaceutical and nutraceutical sectors in 110 countries worldwide, including the United States. Upon information and belief, CSL had contracts with and for the benefit of Nutrilinea, Leadiant, Sigma-Tau HealthScience USA, Inc., Alfasigma, and/or VSL Inc. to manufacture the Fraudulent Formulation when Leadiant, Sigma-Tau HealthScience USA, Inc., and/or VSL Inc. were headquartered in Maryland. Throughout the Class Period, CSL has produced the strains used in the Fraudulent Formulation and completed the first stage of the manufacturing process of the Fraudulent Formulation, knowing that the falsely-advertised VSL#3 would be (and still is) marketed and sold in the United States, including to consumers in Maryland. Upon information and belief, CSL also conducts business in the United States through CSL Centro Sperimentale del Latte USA, Inc. ("CSL USA"), which is a corporation organized and incorporated under the laws of Wisconsin, with its principal place of business in Racine, Wisconsin. Upon information and belief, CSL USA is a subsidiary of CSL.

35. Defendant Nutrilinea is a corporation organized and incorporated under the laws of Italy, with its principal place of business in Gallarate, Italy. Upon information and belief, Nutrilinea had contracts with and for the benefit of CSL, Leadiant, Sigma-Tau HealthScience USA, Inc., Alfasigma and/or VSL Inc. to manufacture the Fraudulent Formulation when Leadiant, Sigma-Tau HealthScience USA, Inc. and/or VSL Inc. were headquartered in Maryland. Throughout the Class Period, Nutrilinea has manufactured, packaged, and shipped the Fraudulent Formulation to the VSL Defendants in the United States, knowing that the falsely advertised VSL#3 would be (and still is) marketed and sold in the United States, including to consumers in Maryland. Import invoices confirm that, from at least December of 2017 through August of 2020,

Nutrilinea continuously shipped large pallets of the Fraudulent Formulation to Defendant Alfasigma in the United States via container shipments, which departed from the port in Genova, Italy and arrived in the United States at the port in Norfolk, Virginia.

Jurisdiction and Venue

36. 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.

37. 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.

38. This Court has personal jurisdiction over Defendants because the VSL Defendants and/or their predecessors are or were headquartered in Maryland, the Manufacturer Defendants contracted with the VSL Defendants to manufacture VSL#3 when the VSL Defendants and/or their predecessors 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 and were targeted at Maryland consumers. Defendants also purposefully availed themselves of the privilege of conducting business activities in Maryland (*e.g.,* marketing VSL#3 in Maryland, selling a significant volume of VSL#3 in Maryland in a regular course of sales, manufacturing VSL#3 to be sold in Maryland with the knowledge that it would be sold in Maryland, shipping VSL#3 to the United States to be sold in Maryland, and coordinating these activities from offices

in Maryland). Defendants have also benefitted economically from their sales of VSL#3 in Maryland, and Defendants have derived substantial from their products used and consumed in Maryland. Plaintiffs' claims arise out of those activities, and the exercise of jurisdiction over them is constitutionally reasonable.

39. Specifically, this Court has personal jurisdiction over Defendants under Md. Code Ann., Cts. & Jud. Proc. § 6-103(b), as Defendants have, directly and/or by an agent: transacted business in Maryland (§ 6-103(b)(1)); contracted, including with Maryland entities, to supply goods and/or manufactured products in Maryland (§ 6-103(b)(2)); caused tortious injury in Maryland by acts and omissions in Maryland (§ 6-103(b)(3)); and caused tortious injury in Maryland (and outside of Maryland) by acts and omissions outside of Maryland, as Defendants regularly do business in Maryland and derive substantial revenue from goods and/or manufactured products used or consumed in Maryland (§ 6-103(b)(4)).

40. This Court also has personal jurisdiction over Defendants pursuant to 18 U.S.C. § 1965(d) because Defendants have substantial (and sufficient) contacts with the United States, and exercising personal jurisdiction over Defendants is constitutionally permissible.

41. 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 in and emanated from this District. Venue is also proper in this jurisdiction pursuant to 18 U.S.C. § 1965.

Factual Allegations

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

42. 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 which contain such live bacterial cultures are commonly referred to as "probiotics."

43. 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.

44. 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.

45. 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.

46. 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.

47. 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 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.

48. 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 the VSL Defendants and/or their predecessors. From that time until February 1, 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"). During this period, Danisco also shipped the version of VSL#3 that contained the De Simone Formulation to Defendant Nutrilinea. Upon receiving the VSL#3 product from Danisco, Nutrilinea packaged it and made it available for sale in Europe.

B. The Marketing of VSL#3 Prior to June 2016.

49. VSL#3 was introduced into the United States market in or around 2002. Over the next 15 years, Leadiant marketed VSL#3 to consumers and their physicians as a unique blend of eight strains of bacteria, which was effective for the management of ulcerative colitis, irritable bowel syndrome, and pouchitis.

50. Between at least 2006 and 2012, Leadiant promoted VSL#3 as a product "unlike any other product of its kind":

> **What Makes VSL#3® Special?**
>
> VSL#3® is unlike any other product of its kind:
>
> **Supported by Scientific Data**
>
> VSL#3® is supported by "Level One" scientific evidence, meaning the data must be from a double-blind, placebo-controlled study that is published in top peer-reviewed journals. VSL#3® is one of the few probiotic preparations with Level One scientific data. All studies cited to support VSL#3® were conducted with the specialized VSL#3® preparation.
>
> **450 Billion Bacteria**
>
> VSL#3® has the highest available concentration of beneficial bacteria with 450 billion live bacteria per packet. The human gut has thousands of billions of resident bacteria. In order to modulate the composition of this gut flora in a positive way, an extremely large amount of probiotic bacteria is necessary. VSL#3® is the only probiotic preparation that delivers enough bacteria to beneficially affect the gut flora in patients with serious intestinal disorders.
>
> **Strains of Bacteria**
>
> Scientific evidence has proven that not all strains of probiotic bacteria are the same. VSL#3® has eight strains of bacteria in specific concentrations that have been chosen to produce an optimal intestinal flora.[3]

51. Likewise, between 2013 and 2016, Leadiant promoted VSL#3 as a "unique combination" of eight strains of bacteria:

> Unlike other probiotics, VSL#3 is a high potency probiotic medical food that contains eight different strains of live bacteria that have been carefully cultivated and mixed proportionally to optimize the probiotic content. The highest concentration of bacteria (compared to other probiotics) and the unique combination of strains confers upon VSL#3 an unusual degree of potency.[4]

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[3] http://web.archive.org/web/20120513082920/http://vsl3.com/about-vsl-special.asp; http://web.archive.org/web/20060326192311/http://www.vsl3.com/VSL3/about-vsl-special.asp.

[4] *See* https://web.archive.org/web/20151229144508/http://www.vsl3.com/ discover/faq/; see also https://web.archive.org/web/20130426015204/ http://vsl3.com/discover/faq.asp ("Unlike other probiotics, VSL#3 is a high potency probiotic medical food that contains eight different strains of live bacteria that have been carefully cultivated and mixed proportionally to optimize the probiotic content").

52. On its website, Leadiant emphasized the uniqueness of the VSL#3 formulation and the rigorous scientific evidence to support its efficacy. Among other things, Leadiant stated:

- VSL#3 is supported by "Level One" scientific evidence, meaning the data must be from double-blind, placebo-controlled studies that are published in top peer-reviewed journals.
- VSL#3 is one of the few probiotic preparations with level one scientific data. All referenced studies to support VSL#3 were conducted with the patented VSL#3 preparation.
- Scientific evidence has proven that not all strains of probiotic bacteria are the same. VSL#3 has eight (8) strains of bacteria in specific concentrations that have been chosen to produce optimal intestinal diversity.
- It provides a unique combination of bacteria which colonize and protect the gastrointestinal (GI) tract with optimal quantities and types of live bacteria which may help enhance the barrier function of the GI tract and in turn help prevent the penetration of harmful substances into the intestinal lining.[5]

53. The VSL Defendants and their predecessors emphasized in particular that VSL#3 was not just a brand name referring to the company that made the product; instead, the term referred specifically to a "proprietary…probiotic," which was "patented" and "unique" in its particular combination of the "number of types of strains" of each bacteria used.[6] That is, the VSL Defendants and their predecessor companies defined the VSL#3 mark to mean a specific proprietary blend of particular bacterial strains—that is, the De Simone Formulation.

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[5] https://web.archive.org/web/20160111141600/http:/www.vsl3.com/discover/why-vsl3; https://web.archive.org/web/20130426063132/http:// vsl3.com/discover/whyvsl3.asp.

[6] https://web.archive.org/web/20030625012117/http://www.vsl3.com/; https://web.archive.org/web/20040808021637/http://www.vsl3.com/vsl3/index.htm.

54. As a result, over the course of 15 years, the VSL#3® mark and brand became associated and identified with the unique, patented, clinically tested and effective formulation (i.e., the De Simone Formulation) in the collective consciousness of consumers and physicians. As multiple experts testified in the ExeGi Litigation, clinicians depend upon these types of clinical studies to prescribe one probiotic formulation versus another for specific indication and would not prescribe a product that had not been proved to be safe and efficacious.

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

55. Beginning on or about mid-2013, representatives of the Cavazza 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.

56. 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.

57. 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.

58. 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.

59. Around the same time, Mr. Cavazza initiated conversations with CSL's CEO, Marco Caspani, and Mr. Cavazza and Mr. Caspani began discussing the possibility of CSL manufacturing the Fraudulent Formulation. Mr. Cavazza informed Mr. Caspani of the Cavazza Family's plan to change the formulation of VSL#3 and to market and sell this new formulation to U.S. consumers as "VSL#3." As the CEO of an international company that studies, develops, and manufacturers natural probiotics for the pharmaceutical and nutraceutical sectors in 110 countries worldwide, Mr. Caspani well knew that any changes to a probiotic formulation, including to its manufacturing process, would result in a very different product that could not rely on the safety and efficacy clinical data pertaining to the original formulation. This knowledge is imputed to CSL as a result of Mr. Caspani's executive role. Mr. Caspani and CSL also knew that the Fraudulent Formulation would contain only seven strains of bacteria (rather than eight, as in the De Simone Formulation), and that the Fraudulent Formulation would be manufactured according to a different manufacturing process than the De Simone Formulation.

60. By mid-2014, based on his conversations described in paragraphs 56-58 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.

D. Prof. De Simone Terminates His Relationship with VSL Inc. and Leadiant, Cuts Off Their Rights to Sell Supply of the De Simone Formulation, and Enters Into an Exclusive Licensing Agreement with ExeGi.

61. 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.

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

63. 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. 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.

64. 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 manufacture, 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 supplier of the De Simone Formulation in the United States. Visbiome is the only authentic version of the De Simone Formulation in the market.

E. Defendants Sell The Fraudulent Formulation to United States Consumers, Which was Qualitatively Different and Inferior to the De Simone Formulation.

65. In 2016, the Cavazza Family and their surrogates, including the VSL 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. By then, the Cavazzas had secured the participation of the Manufacturer Defendants, which was vital to their plan. Defendants CSL and Nutrilinea, knowing of the change in formulation and the fact that it is inferior to the De Simone Formulation and that it could not rely on the safety and efficacy clinical data pertaining to the De Simone Formulation, actively participated in and financially benefitted from this plan throughout the Class Period by manufacturing, packaging, and shipping the Fraudulent Formulation containing the false and deceptive packaging to the United States for the VSL Defendants to sell in the United States.

66. CSL and Nutrilinea's knowledge of the material changes in the composition and manufacturing of the VSL#3 formulation, the fact that the new formulation could not honestly rely on clinical data obtained as to the De Simone Formulation, the fact that the VSL Defendants were

affirmatively marketing and selling, with CSL and Nutrilinea's active assistance, the new formulation falsely claiming its equivalence to the De Simone Formulation, and that these collective marketing and sales efforts were targeted at United States consumers, including consumers in Maryland, is established by, among other things, the following facts: (a) direct written and oral communications among executives of CSL, Nutrilinea, and the Cavazza organization (including the VSL Defendants and Paolo Cavazza personally), (b) direct communications and warnings to executives of CSL and Nutrilinea by Claudio De Simone, his attorneys, and his European distributor (Mendes SA), and its attorneys, (c) direct observation of the marketing materials for the new formulation and knowledge of the composition and manufacturing process for the new VSL#3 formulation, and (d) specific and detailed knowledge beginning in 2015 of ongoing litigation over these matters in the United States, United Kingdom, Italy, and Switzerland, among other jurisdictions.

67. In or about June 2016, Leadiant began selling the Fraudulent Formulation, manufactured by CSL and Nutrilinea, to consumers in the United States, including consumers in Maryland. Effective June 30, 2016, 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. Thereafter, and throughout the Class Period, Alfasigma sold VSL#3 to consumers in the United States using the Fraudulent Formulation manufactured by CSL and Nutrilinea.

68. 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, despite being falsely marketed by Leadiant and later Alfasigma as identical to, and possessing the same history as, the original formulation.

69. 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 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.

70. 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.

71. These significant qualitative and performance 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.

72. 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.

73. 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.

74. 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 a 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.

75. 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.

76. 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.

77. 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 the "same" as the De Simone Formulation deceived consumers concerning the clinical benefits that consumers can expect.

78. 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), 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.

F. Defendants' Continued Use of the VSL#3® Mark, Which Had Come to Be Associated With the Proprietary and Clinically Tested De Simone Formulation, Was False and Misleading.

79. Despite the change in formulation, Leadiant and Alfasigma described the product they sold to consumers in the United States (falsely) as "VSL#3." The most significant misrepresentation, made directly to each Class Member who purchased VSL#3 containing the Fraudulent Formulation through the label of the product and other materials relating to the product, is that the product is, in fact, "VSL#3."

80. As explained above, the VSL Defendants and their predecessors themselves had long defined VSL#3 to consumers as a specific formulation—that is, the De Simone Formulation. Based on the VSL Defendants' own prior marketing and ubiquitous prior representations, Plaintiffs and Class Members relied on the term "VSL#3" to mean the effective, clinically tested product that had long been sold under the name VSL#3—that is, 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.

81. The VSL#3® mark was prominently displayed on the packaging of each box of VSL#3 sold to consumers in the United States during Class Period.

82. Each box of VSL#3 sold to consumers during the Class Period also contained a product information sheet inserted by Nutrilinea, which included information about dosing, as well as the clinical research which had purportedly been conducted on the VSL#3 accompanying the product information sheet. According to the product information sheet, the VSL#3® that Defendants marketed and sold during the Class Period had been subject to extensive clinical research demonstrating is efficacy in the dietary management of IBS, UC and ileal pouch. These representations were not true. While the De Simone Formulation had been subject to extensive clinical research, the Fraudulent Formulation had not. The product information sheet stated:

Clinical Experience
VSL#3® has been the subject of extensive clinical research in the dietary management of IBS, UC and an ileal pouch. In one study, the consumption of VSL#3® was associated with a 39% reduction in bloating in patients with diarrhea-predominant IBS[2]. In the same study, fecal urgency scores showed a trend toward reduction vs. placebo. In a second study, the consumption of VSL#3® was associated with reduced flatulence (gas) by 25% vs. placebo [3]. In both IBS studies, the consumption of VSL#3® was well tolerated with no

adverse events reported. In a pediatric IBS study[1], the consumption of VSL#3® was significantly superior to placebo ($p < 0.05$) in the primary endpoint, the subjective assessment of relief of symptoms; as well as in 3 of 4 secondary endpoints: abdominal discomfort ($p < 0.05$), abdominal bloating/gassiness ($p < 0.05$), and family assessment of life disruption ($p < 0.01$). No significant difference was found ($p < 0.06$) in the stool pattern. No untoward adverse effect was recorded in any of the patients. The World Gastroenterology Organization Global Guideline for Irritable Bowel Syndrome, April 2009 states that VSL#3® has "clinical trial evidence of efficacy for bloating, distension, and flatulence"[24]. Published studies[4-8] suggest that daily ingestion of VSL#3® can aid in the dietary management of UC in both adults and pediatric patients. These studies have also demonstrated that VSL#3® can be utilized along with standard pharmaceutical UC therapies such as 5-ASA, immunosuppressants, immunomodulatory drugs and steroids[4,5,8]. An adult study concluded that 77% of the patients consuming VSL#3® in the dietary management of active UC had a positive response to the product with no adverse events[6]. In a second study with VSL#3® in dietary management of adult UC patients intolerant or allergic to 5-ASA, 75% of patients had a positive response to the product for 12 months[7]. A pediatric study looked at maintenance of remission in children aged between 2 and 16, with UC[4]. All 29 patients responded to the inflammatory bowel disease (IBD) therapy. Remission was achieved in 13 children (92.8%) treated with traditional IBD therapy and VSL#3® and in 4 children (36.4%) treated with placebo and traditional IBD therapy ($P<0.001$). Overall, 3 of 14 (21.4%) children treated with traditional IBD therapy and VSL#3® and 11 of 15 (73.3%) children treated with placebo and traditional IBD therapy relapsed within 1 year of follow-up ($P=0.014$; RR=0.32; CI=0.025-0.773; NNT=2). Of the relapsed children, all 3 children treated with VSL#3® and 6 of 11 (54.5%) children treated with placebo relapsed within 6 months of diagnosis. At 6 months, 12 months, or at time of relapse, endoscopic and histological scores were significantly lower in the VSL#3® group than in the placebo group ($P<0.05$). There were no biochemical or clinical adverse events related to VSL#3®. In a second pediatric study, 13 of 18 children completed 8 weeks of VSL#3® treatment and 5 patients were withdrawn due to lack of improvement[5]. Remission (defined as SCCAI ≤3) was achieved in 56% of children (n = 10); response (decrease in SCCAI ≥2, but final score ≤5) in 6% (n = 1); and no change or worsening in 39% (n = 7). Post-VSL#3® treatments demonstrated a bacterial taxonomy change in rectal biopsy. VSL#3® was well tolerated in clinical trials and no biochemical and clinical adverse effects attributed to VSL#3® were identified. The American Academy of Pediatrics in its "Clinical Report - Probiotics & Prebiotics in Pediatrics" 2010 mentions VSL#3® as showing 'promising results' for children with UC[25]. VSL#3® is also recognized for the dietary management of UC in the following guidelines: WGO Global Guidelines October, 2011 - Probiotics and Prebiotics[26]; the European Crohn's and Colitis Organization (ECCO) and the European Society of Pediatric Gastroenterology Hepatology and Nutrition (ESPGHAN - Management of Pediatric Ulcerative Colitis: Joint ECCO and ESPGHAN Evidence-Based Consensus Guidelines, September, 2012[27]; and the Second European evidence-based Consensus on the diagnosis and management of ulcerative colitis part 2: Current management[28]. Three doubleblind, placebo-controlled trials have been published that show that VSL#3® aids in the dietary management of pouchitis[9-11]. VSL#3® is the only probiotic recognized as an effective tool for the dietary management of pouchitis by The American College of Gastroenterology April, 2010[29]. The use of VSL#3® for the dietary management of pouchitis is also mentioned in the German Society of Digestive and Metabolic Diseases, 2004[30]; The British Society of Gastroenterology, 2011[31]; WGO Global Guidelines October, 2011 - Probiotics and Prebiotics[26] and the Cochrane Library, June 2010 in its review of the use of probiotics for the dietary management of pouchitis[32]. A recent meta-analysis looked at of the effect of probiotics in remission of UC and in maintaining of therapy in UC and pouchitis. Only VSL#3® maintained remission rates compared to controls in patients with active UC. VSL#3® significantly reduced the clinical relapse rates for maintaining remission in patients with pouchitis[33].

83. By continuing to market the Fraudulent Formulation under the VSL#3® mark, Defendants misrepresented and misled consumers into believing that the formulation had not changed. The continued use of the VSL#3® mark to promote the Fraudulent Formulation was false and misleading by reason of Defendants' failure to disclose that the formulation had changed. Defendants had a duty to disclose that the formulation had changed, in order to make the representations they made not misleading.

84. Moreover, Defendants' deceptive use of the VSL#3® mark on product packaging was amplified by Defendants' removal from labeling of information concerning the bacterial strains contained in the product. The removal of that information was deliberately designed to prevent detection of the change in formulation. Specifically, the VSL Defendants had previously labeled VSL#3 with the genus, species, and strain designation numbers for each of the eight bacterial strains contained in the product, consistent with the recommendations of respected organizations such as the Council for Responsible Nutrition and the International Probiotics Association,[7] given that individual strains of the same genus and species can have different functional properties. Prior to the 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 designation numbers. By omitting the strain designation numbers, Defendants avoided making any visible admission to consumers that the Fraudulent Formulation of VSL#3 no longer contained the clinically proven combination of strains used in the De Simone Formulation.

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

85. Moreover, as described below, the VSL Defendants, with the knowledge and participation of the Manufacturer 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 the VSL 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.

G. Defendant Leadiant Engaged in a Campaign of False Advertising to Reinforce the Belief That VSL#3 Was the Same Clinically Tested Product, When it Was Not.

86. 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: CSL.

87. Leadiant's marketing concerning moving the manufacture of VSL#3 to a new manufacturing facility in Italy claimed in a May 17, 2016 letter 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." According to the ExeGi Litigation testimony of Mary Ocnean, formerly a Vice President of Leadiant, the May 17, 2016 letter was sent to all health care providers who previously prescribed VSL#3, numbering hundreds of doctors across the United States. The letter 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 the inferior, untested Fraudulent Formulation.

88. Similarly in a script, Leadiant prepared to respond to "potential future [health care provider] objections, misconceptions, questions or concerns… and answers," Leadiant falsely stated:

> Doctor: Did VSL#3 change its name?
>
> Response: No. VSL#3 is the same multi-strain probiotic designated as a medical food for the dietary management of your patients with IBS, UC and ileal pouch.

89. In a May 24, 2016, Press Release, entitled, "15 Years And Going Strong, VSL#3® Maintains Leadership In The Probiotic Medical Food Category; VSL#3 is the Most Studied and Recommended High-Potency Probiotic Medical Food in the U.S.; Trusted and Recommended by Healthcare Professionals for Serious Digestive Issues," Leadiant falsely emphasized the continuity of the "VSL#3® brand," the strong legacy of the product, and the clinical studies which purported supported its efficacy in treating digestive disorders:

- For more than 15 years, VSL#3® (http://www.VSL3.com) continues to rise to the top in the ever-growing category of probiotics as the high-potency probiotic medical food brand clinically proven in numerous studies to be beneficial for serious digestive disorders.
- VSL#3 has been used in more than 170 studies and is mentioned by several healthcare organizations and associations worldwide, including the Triennial Yale/Harvard Workshop for the past 10 years showing benefit for patients who suffer from ulcerative colitis.
- 'The success of the VSL#3 brand not only signifies strong confidence in the brand but is a prime example of our dedication to continuously support healthcare professionals by providing them with the quality and trusted brand they've been recommending to their patients with IBS, ulcerative colitis or ileal pouch so they can lead healthier and happier lives.'
- VSL#3's strong legacy and loyalty is based on recognized scientific principles and backed by a company that has been dedicated to manufacturing the most high

quality brand that physicians can depend on for their patients with serious digestive disorders.

- 'Not only is the VSL#3 brand supported by more than 170 studies and reviews, many of which are published in peer-reviewed journals, but experience with the brand for patients with ulcerative colitis and ileal pouch has proven to be extremely effective,' says Dr. Raymond, who recommends VSL#3 for its efficacy and strong track record. 'Like myself, doctors prescribe the VSL#3 brand for some of the toughest digestive issues out there,' adds Dr. Raymond. 'That shows the trust and is the reason why healthcare professionals recommend the brand as one of the most potent probiotics on the market.'

- For 15 years, patients have trusted the VSL#3 brand as their probiotic medical food of choice….

H. Defendant Alfasigma Continues the False Advertising Campaign.

90. After Leadiant transferred marketing rights to VSL#3 to Alfasigma, Alfasigma continued to falsely describe the Fraudulent Formulation as VSL#3 on its packaging, misleading consumers into believing that VSL#3 contained the De Simone Formulation.

91. Alfasigma also continued to emphasize the continuity of the formulation on its website, emphasizing on its home page that "The leader in probiotic medical foods for the past 15 years, VSL#3 has proven it works."

92. Alfasigma also continued to market VSL#3 using the product information sheet inserted by Nutrilinea and quoted in paragraph 82 above, even though none of the studies cited tested the efficacy of the Fraudulent Formulation. Each package of VSL#3 distributed by Alfasigma during the Class Period contained a product information sheet which misrepresented that its efficacy had been established by clinical tests, which was not true.

93. 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.

94. 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." The August 2016 Press Release was riddled with misrepresentations since VSL#3 did not maintain "the original mix of eight strains of live bacteria."

95. The assertions in the August 2016 press release 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.

96. Additionally, the assertion in the August 2016 press release 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. 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 is the manufacturer of the final product, as it is the company that continues the process and produces the finished product.

97. The representation in the August 2016 press release 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.

98. 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.

99. 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 above, this statement was false.

100. 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 that is manufactured by Defendants CSL and Nutrilinea. As Dr. Patrick Gillevet, an expert on human gastrointestinal microflora, testified in the ExeGi Litigation with 100% certainty, 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.

101. 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 recently published paper in the peer-reviewed medical journal *Plos One* ("November 2016 Memo"). The study compared the "old" VSL#3 (the De Simone Formulation) to the "new" VSL#3 (the Fraudulent Formulation).

102. 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.

103. 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, meaning, Defendant CSL, was making "VSL#3" branded products as late as 2006 is false and was intended to confuse physicians and patients.

104. CSL never produced VSL#3-branded products for commercial use prior to June 2016. 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.

105. This false advertising campaign continued throughout the Class Period. In a VSL#3 patient brochure, posted on the VSL#3 website in 2018, Alfasigma continued to represent that "Dietary management with VSL#3®, in addition to certain medications, has been shown to deliver

clinical benefits in UC, IBS, and pouchitis, and has demonstrated over 15 years of success in patients with UC, IBS, and pouchitis." This representation was false and misleading because none of the scientific evidence pertained to the Fraudulent Formula that Alfasigma and VSL were marketing.

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

106. 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.

107. Extensive testimonial and documentary evidence was elicited at trial of the ExeGi Litigation that demonstrated the falsity of the VSL 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.

108. 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 prepared by CSL 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,[8] and Marco Caspani. However, Mr. Caspani, the CEO of Defendant CSL, the manufacturer of the Fraudulent Formulation, admitted that he merely acted—upon the request of a VSL Inc. affiliate[9]—as if there were two distinct *B.lactis* strains; however, to him, when tested at CSL, and as revealed in a February 20, 2017 letter from a VSL Inc. affiliate to him and in CSL's own Drug Master File for the product, it was clear that there was only one unique *B.lactis* strain in the Fraudulent Formulation.[10]

109. Although the VSL Defendants also proffered the testimony of Dr. Barrangou, who had previously opined that VSL#3 had eight strains based on one study, 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.[11]

110. 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

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

[9] The VSL Inc. affiliate made this request of CSL, then Defendants used CSL's acting as if there were two distinct *B.lactis* strains to deceive consumers by continuing to claim that the Fraudulent Formulation had eight strains like (and was otherwise equivalent to) the De Simone Formulation.

[10] By doing so, Mr. Caspani also essentially conceded that CSL knew of the VSL Defendants' false advertising and that CSL followed the instructions of VSL Inc. and the Cavazzas.

[11] 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.

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-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.

111. 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."[12] 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

[12] 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).

the process of wound repair and to mitigate the stress in use by this chemical on the cells while [VSL#3] was not."[13]

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

113. 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.

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[13] 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."

114. 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 and 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.

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

- 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.

- 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."

- 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.

- 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.

116. 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.), touted that VSL#3 has been "Used by physicians for more than 15 years and" has been "[w]idely studied in multiple trials," but these statements referred to the prior, not current, formulation of VSL#3. The VSL#3 Website contained most of the same false advertising materials it contained prior to the trial.

117. Despite knowing of the VSL Defendants' ongoing false advertising, Defendants CSL and Nutrilinea continued manufacturing the Fraudulent Formulation. Nutrilinea also continued packaging the Fraudulent Formulation with the false and deceptive packaging and inserts, and Nutrilinea continued shipping it to Defendant Alfasigma in the United States. For example, in August of 2020 alone, Nutrilinea shipped Alfasigma 12 pallets of the VSL#3 with a total weight of 5065 kilograms, which arrived in the port of Norfolk, Virginia.

118. 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.[14] For example, 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 the VSL 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, but only 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 the VSL 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 plaintiffs a permanent injunction against Defendants Leadiant and Alfasigma, the Court specifically stated "that the jury did not credit [Defendants'] evidence on the genetic and functional equivalence of the products."

119. As noted, on June 21, 2019, this Court both denied the VSL 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

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

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.

120. As a result of the injunction, the VSL Defendants were forced to change the misleading product information sheet which was contained in the packages of VSL#3 sold during the Class Period, and is quoted in paragraph 82 above. The revised product information sheet removed all of the language quoted in paragraph 82 above.

J. Plaintiffs Purchased VSL#3 During the Class Period Believing It to Be the Same Formulation as Sold and Marketed Prior to the Class Period.

121. Plaintiffs routinely purchased VSL#3 during the Class Period. They all relied upon 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. They each relied in particular upon Defendants' continued and unqualified use of "VSL#3" branding, which, combined with the VSL Defendants' continuous efforts to deny and downplay the real differences between the prior formulation and the new formulation, caused consumers to believe the product continued to contain the same formulation as it had previously.

122. 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.

123. 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. Plaintiff Starr's G.I. doctor specifically recommended that he take VSL #3. His G.I. doctor advised Plaintiff Starr that VSL #3 was the only probiotic that had a critical mass of scientists who agreed it was helpful.

124. 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. Plaintiff Cook took VSL#3 at the recommendation of her G.I. doctor.

125. 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. Plaintiff Mavrikos took VSL#3 at the recommendation of her G.I. doctor.

126. 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.

127. 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. Plaintiff Tettenhorst took VSL#3 at the recommendation of a health care provider who had treated him for G.I. issues.

128. 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.

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

130. 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.

131. Plaintiff Stavros regularly purchased VSL#3 in Kentucky from approximately 2012 through approximately June 2019. He paid approximately $183 for a three month supply of VSL#3, spending a total of approximately $2,200 on VSL#3 during the Class Period. Plaintiff Stavros took VSL#3 at the recommendation of his G.I. doctor.

132. Plaintiff Offutt regularly purchased VSL#3 in Tennessee from approximately 2014 through April 2019. He paid approximately $65 a month for VSL#3, spending a total of approximately $1,750 on VSL#3 during the Class Period. Plaintiff Offutt took VSL#3 at the recommendation of his doctor.

133. Plaintiff Farkas regularly purchased VSL#3 in Wisconsin from approximately 2008 through approximately August 2019. She paid approximately $1,200 a year for VSL#3, spending a total of approximately $3,000 on VSL#3 during the Class Period. Plaintiff Farkas took VSL#3 at the suggestion of her G.I. doctor.

134. Plaintiff Holz regularly purchased VSL#3 in California from approximately 2015 through April 2019. She paid approximately $50 per month for VSL#3, spending a total of approximately $1,400 on VSL#3 during the Class Period. Plaintiff Holz took VSL#3 at the recommendation of her G.I. doctor.

Class Action Allegations

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

136. 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."

137. 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."

138. Plaintiffs Cook and Holz also bring 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."

139. 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."

140. 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."

141. 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."

142. 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."

143. 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."

144. 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."

145. 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."

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

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

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

149. 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, the Idaho Class, the Kentucky Class, the Tennessee Class, and the Wisconsin Class together as the "Classes."

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

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

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

153. 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 the VSL Defendants breached express warranties in violation of the Uniform Commercial Code;

e) With respect to the Nationwide Class, whether the VSL 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 the VSL 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 Texas Class, whether the VSL 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.*;

h) With respect to the Illinois Class, whether the VSL 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.*;

i) With respect to the Washington Class, whether the VSL 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.*;

j) With respect to the Florida Class, whether Defendants VSL Inc. and Alfasigma, 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;

k) With respect to the Kentucky Class, whether Defendants VSL Inc. and Alfasigma, in their marketing and sale of VSL#3 during the Class Period, violated the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110 *et seq.*;

l) With respect to the Tennessee Class, whether the VSL Defendants, in their marketing and sale of VSL#3 during the Class Period, violated the Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101 *et seq.*;

m) With respect to the Wisconsin Class, whether the VSL Defendants, in their marketing and sale of VSL#3 during the Class Period, violated the Wisconsin Deceptive Trade Practices Act, Wis. Stat. § 100.18 *et seq.*; and

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

154. 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, and the VSL Defendants 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.

155. 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.

156. 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.

157. 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.

158. The members of the Classes are readily identifiable through Defendants' and other records.

159. 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)

(Against All Defendants)

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

161. This Count is pled on behalf of Plaintiffs and the Nationwide Class.

162. 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.

163. 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).

164. The "VSL#3 Enterprise" was an association in fact of the VSL Defendants, representatives of the Cavazza Family, and manufacturers in Italy, including Defendants CSL and Nutrilinea, to deceptively manufacture and market and sell VSL#3. It was used as a tool to coordinate and 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 the false representation that the current formulation of VSL#3 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.

165. 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.

166. 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 the VSL Defendants 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. Defendant CSL produced and mixed the strains used in VSL#3, and Defendant Nutrilinea otherwise manufactured, packaged, and shipped VSL#3 to the United Sates for sale to consumers throughout the United States, including consumers in Maryland. And the Cavazza Family spearheaded the scheme using the VSL Defendant companies, which it owned and controlled to effectuate the scheme.

167. 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 in a coordinated effort to manufacture, market, package, sell, and ship VSL#3 containing the Fraudulent Formulation into the United States, including through a campaign of false advertising and false representations and shared the ill-gotten profits realized as a result of their scheme.

168. 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.

169. 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.

170. 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.

171. 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 which 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."

172. 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 and misleading information.

173. 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 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. Despite knowing of these ongoing falsities, Defendants CSL and Nutrilinea are also continuing to manufacture the Fraudulent Formulation. 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.

174. 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 and inserts; 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.

175. 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, the VSL Defendants, with the knowledge and participation of the Manufacturer 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.

176. 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.

177. 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.

178. 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.

179. 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.

180. 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 and inserts, telephone calls, marketing materials and virtually uniform representations or omissions. Plaintiffs' and the Class's reliance is evidenced by their purchases.

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

182. 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.

183. 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.

184. 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 California, Florida, Idaho, Illinois, Kentucky Massachusetts, New Jersey, Texas, Washington, and Wisconsin Classes)

(Against the VSL Defendants)

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

186. This Count is pled on behalf of Plaintiffs and the California, Florida, Idaho, Illinois, Kentucky Massachusetts, New Jersey, Texas, Washington, and Wisconsin Classes.

187. The VSL 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 California, Florida, Idaho, Illinois, Kentucky Massachusetts, New Jersey, Texas, Washington, and Wisconsin Classes.

188. The VSL 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," the VSL Defendants made an affirmation of fact and promise under Section 2-313 of the Uniform Commercial Code that the version of VSL#3 that the VSL Defendants marketed and sold during the Class Period was the same as the previous version. The VSL Defendants' warranties were express warranties which became part of the basis of the bargain Plaintiffs and members of the California, Florida, Idaho, Illinois, Kentucky Massachusetts, New Jersey, Texas, Washington, and Wisconsin Classes entered into when they purchased VSL#3.

189. The VSL Defendants breached their express warranties to Plaintiffs and the California, Florida, Idaho, Illinois, Kentucky Massachusetts, New Jersey, Texas, Washington, and Wisconsin Classes 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.

190. As a result of the VSL Defendants' breaches of their express warranties, Plaintiffs and the California, Florida, Idaho, Illinois, Kentucky Massachusetts, New Jersey, Texas, Washington, and Wisconsin Classes have suffered actual damages in that they have purchased products that are less valuable than the products would have been had the VSL Defendants' representations been true, and Plaintiffs and the California, Florida, Idaho, Illinois, Kentucky

Massachusetts, New Jersey, Texas, Washington, and Wisconsin Classes paid prices for VSL#3 that were higher than they would have paid had the VSL 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 California, Florida, Idaho, Illinois, Kentucky, Massachusetts, Michigan, New Jersey, Tennessee, Texas, Washington, and Wisconsin Classes, in the Alternative)

(Against the VSL Defendants)

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

192. This Count is pled on behalf of Plaintiffs and the California, Florida, Idaho, Illinois, Kentucky, Massachusetts, Michigan, New Jersey, Tennessee, Texas, Washington, and Wisconsin Classes.

193. The VSL Defendants were unjustly enriched by the false and deceptive marketing and sale of VSL#3 as alleged herein. The VSL Defendants, through their false and misleading 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 the VSL Defendants to obtain profits directly from those purchases.

194. Specifically, the VSL Defendants receive a direct financial benefit from the sale of their products to end consumers. The VSL 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 the VSL Defendants' products to end consumers results in revenues which are either paid directly to Defendants or used

by the intermediaries to pay the VSL Defendants for their products. That is, the VSL 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 Members.

195. Plaintiffs and the members of the California, Florida, Idaho, Illinois, Kentucky, Massachusetts, Michigan, New Jersey, Tennessee, Texas, Washington, and Wisconsin Classes were damaged by their purchases of VSL#3 during the Class Period that was 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 the VSL Defendants (i.e., payments for fake VSL#3), which, under the circumstances, it would be unjust for the VSL Defendants to retain. Plaintiffs through this unjust enrichment claim seek recovery of profits that the VSL 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)

(Against the VSL Defendants)

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

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

198. At all relevant times, the VSL 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.

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

200. The VSL 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.

201. The VSL Defendants misled consumers by continuing to use the VSL#3® mark and failing to disclose to 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. The VSL Defendants owed a duty to disclose the fact that the post-May 2016 formulation had changed, in order to make their continued use of the VSL#3® mark not misleading.

202. The VSL Defendants' conduct was objectively deceptive, and had the capacity to deceive reasonable consumers under the circumstances. The fact that the formulation of VSL#3 the VSL 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.

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

204. 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. The VSL

Defendants responded to Plaintiff Starr's demand between May 6, 2019 and May 24, 2019. The VSL Defendants' responses, and any offers to resolve this matter contained therein, were neither adequate nor reasonable.

205. As a direct and proximate result of the VSL 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 the VSL Defendants are liable for, the VSL Defendants' actions in violation of Chapter 93A.

206. The VSL Defendants' violations of Chapter 93A, § 2 were willful and knowing.

207. The VSL 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 the Texas Consumer Protection Act,

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

(On behalf of Plaintiff Cook and the Texas Class)

(Against the VSL Defendants)

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

209. Plaintiff Cook brings this claim against the VSL Defendants on behalf of herself and the Texas Class.

210. 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.

211. The VSL 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.

212. The VSL 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.

213. The VSL Defendants misled consumers by continuing to use the VSL#3® mark and failing to disclose to 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. The VSL Defendants owed a duty to disclose the fact that the post-May 2016 formulation had changed, in order to make their continued use of the VSL#3® mark not misleading.

214. The VSL 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 the VSL Defendants' misrepresentations and omissions in purchasing VSL#3 during the Class Period.

215. The VSL 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*.

216. Plaintiffs Cook and the members of the Texas Class relied upon the VSL#3® mark in purchasing the product, and were misled into believing the formulation used by Defendants was the same unique, scientifically tested, combination of ingredients, which had been sold prior to June 1, 2016. Plaintiffs Cook and members of the Texas Class relied to their detriment on the VSL Defendants' misrepresentations and omissions in purchasing VSL#3 during the Class Period.

217. Plaintiff Cook served the VSL 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.

218. As a direct and proximate result of the VSL 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, 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). 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.

219. Plaintiff Cook and the Texas Class are entitled to recover damages, including treble damages insofar as the VSL Defendants' conduct was committed knowingly and/or intentionally, for the VSL Defendants' misconduct.

Count VI

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)

(Against the VSL Defendants)

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

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

222. 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.

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

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

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

226. 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.

227. The VSL 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.

228. The VSL Defendants misled consumers by continuing to use the VSL#3® mark and failing to disclose to 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. The VSL Defendants owed a duty to disclose the fact that the post-May 2016 formulation had changed, in order to make their continued use of the VSL#3® mark not misleading.

229. The VSL Defendants' conduct was objectively deceptive, and had the capacity to deceive reasonable consumers under the circumstances. The fact that the formulation of VSL#3 the VSL 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.

230. The VSL Defendants' practices, as detailed herein, constituted unfair or deceptive acts or practices in violation of the ICFA.

231. As a direct and proximate result of the VSL 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, 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). 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.

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

233. Plaintiff Tettenhorst, on behalf of himself and the Illinois Class, seeks an order (1) requiring the VSL 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 the VSL Defendants to restore to Plaintiff Tettenhorst and each Illinois Class member any money acquired by means of their wrongful conduct.

Count VII

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)

(Against the VSL Defendants)

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. 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.

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

238. 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.

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

240. The VSL 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.

241. Accordingly, Defendants have violated the Illinois DTPA.

242. As set forth above, Plaintiff Tettenhorst and the Illinois Class was damaged and are likely to be damaged in the future by the VSL 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 the VSL Defendants' continued deceptive conduct, as well as reasonable attorney's fees and costs.

Count VIII

Violation of the Washington Consumer Protection Act

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

(On behalf of Plaintiff Hansen and the Washington Class)

(Against the VSL Defendants)

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

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

245. The VSL 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).

246. The VSL 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.

247. The VSL 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.

248. The VSL Defendants misled consumers by continuing to use the VSL#3® mark and failing to disclose to 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. The VSL Defendants owed a duty to disclose the fact that the post-May 2016 formulation had changed, in order to make their continued use of the VSL#3® mark not misleading.

249. The VSL Defendants' conduct was objectively deceptive, and had the capacity to deceive reasonable consumers under the circumstances. The fact that the formulation of VSL#3 the VSL 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.

250. The VSL Defendants' deceptive and unfair acts or practices occurred in their trade or business and have injured and are capable of injuring a substantial portion of the public. The VSL 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.

251. As a direct and proximate result of the VSL 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, 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).

252. Plaintiff Hansen and members of the Washington Class are entitled to an order enjoining the conduct complained of herein and ordering the VSL Defendants 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 IX

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)

(Against Defendants VSL Inc. and Alfasigma)

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

254. Plaintiff Karo brings this claim against Defendants VSL Inc. and Alfasigma on behalf of herself and the Florida Class.

255. Defendants VSL Inc. and Alfasigma 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).

256. 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.

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

258. By reason of the conduct alleged herein, Defendants VSL Inc. and Alfasigma engaged in unfair and deceptive business practices in violation of FDUTPA, Fl. St. §§501.201, *et seq*.

259. Defendants VSL Inc. and Alfasigma 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.

260. Defendants VSL Inc. and Alfasigma misled consumers by continuing to use the VSL#3® mark and failing to disclose to 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. Defendants VSL Inc. and Alfasigma owed a duty to disclose the fact that the post-May 2016 formulation had changed, in order to make their continued use of the VSL#3® mark not misleading.

261. Plaintiff Karo and the members of the Florida Class relied upon the VSL#3® mark in purchasing the product, and were misled into believing the formulation used by Defendants VSL Inc. and Alfasigma was the same unique, scientifically tested, combination of ingredients, which had been sold prior to June 1, 2016. Plaintiff Karo and members of the Florida Class relied to their detriment on Defendants' misrepresentations and omissions in purchasing VSL#3 during the Class Period.

262. Plaintiff Karo and the Florida Class have been aggrieved by Defendants' misleading advertising of VSL#3, in that they incurred costs for a product which was not the one that had been represented to them, and received a fake, inferior, version of VSL#3, which was less valuable than the product represented to them (the real, De Simone Formulation VSL#3).

263. As a result of Defendants VSL Inc.'s and Alfasigma's 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.

264. As redress for Defendants VSL Inc.'s and Alfasigma's 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 X

Florida Statutory False Advertising Violations,

§§817.06 and 817.40-817.47., Florida Statutes

(On behalf of Plaintiff Karo and the Florida Class)

(Against Defendants VSL Inc. and Alfasigma)

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

266. Plaintiff Karo brings this claim against Defendants VSL Inc. and Alfasigma on behalf of herself and the Florida Class.

267. 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.

268. As fully explained herein, Defendants VSL Inc. and Alfasigma 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 VSL Inc.'s and Alfasigma's 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.

269. Plaintiffs Karo and the members of the Florida Class relied upon the VSL#3® mark in purchasing the product, and were misled into believing the formulation used by Defendants VSL Inc. and Alfasigma was the same unique, scientifically tested, combination of ingredients, which had been sold prior to June 1, 2016. Plaintiffs Karo and members of the Florida Class relied to

their detriment on Defendants VSL Inc.'s and Alfasigma's misrepresentations and omissions in purchasing VSL#3 during the Class Period.

270. Plaintiff Karo and the Florida Class have been aggrieved by Defendants VSL Inc.'s and Alfasigma's misleading advertising of VSL#3, in that they incurred costs for a product which was not the one that had been represented to them, and received a fake, inferior, version of VSL#3, which was less valuable than the product represented to them (the real, De Simone Formulation VSL#3).

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

Count XI

Violation of the Kentucky Consumer Protection Act, KRS § 367.170, *et seq*.

(On behalf of Plaintiff Stavros and the Kentucky Class)

(Against Defendants VSL Inc. and Alfasigma)

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

273. Plaintiff Stavros brings this claim against Defendants VSL Inc. and Alfasigma on behalf of himself and the Kentucky Class.

274. Defendants VSL Inc. and Alfasigma have engaged in unfair, false, misleading and/or deceptive practices in the conduct of trade or commerce, including in Kentucky.

275. Defendants VSL Inc. and Alfasigma falsely and misleadingly 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.

276. Defendants VSL Inc. and Alfasigma misled consumers by continuing to use the VSL#3® mark and failing to disclose to consumers such as Plaintiff Stavros and the Kentucky

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. Defendants VSL Inc. and Alfasigma owed a duty to disclose the fact that the post-May 2016 formulation had changed, in order to make their continued use of the VSL#3® mark not misleading.

277. Defendants VSL Inc.'s and Alfasigma's conduct was objectively deceptive, and had the capacity to deceive reasonable consumers under the circumstances. The fact that the formulation of VSL#3 Defendants VSL Inc. and Alfasigma 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.

278. As a direct and proximate result of Defendants VSL Inc.'s and Alfasigma's violations of the Kentucky Consumer Protection Act, Plaintiff Stavros and other members of the Kentucky 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).

279. Pursuant to KRS § 367.220, Plaintiff Stavros and the Kentucky Class are entitled to an award of actual damages against Defendants VSL Inc. and Alfasigma, equitable relief and attorney's fees and costs.

280. Pursuant to § KRS 411.184(2), Plaintiff Stavros and the Kentucky Class Members are entitled to an award of punitive damages against Defendants VSL Inc. and Alfasigma because Defendants acted toward Plaintiff Stavros and the Class with oppression, fraud and/or malice.

Count XII

Violation of the Tennessee Consumer Protection Act, Tenn. Code Ann., § 47-18-104, *et seq*.

(On behalf of Plaintiff Offutt and the Tennessee Class)

(Against the VSL Defendants)

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

282. Plaintiff Offutt brings this claim against the VSL Defendants on behalf of himself and the Tennessee Class.

283. The VSL Defendants advertised and sold "goods" in "trade" and "commerce," as meant by Tenn. Code § 47-18-103.

284. The VSL Defendants, operating in Tennessee, engaged in unlawful, unfair, and deceptive acts and practices, misrepresentation, and the concealment, suppression, and omission of material facts with respect to the sale and advertisement of goods and services in violation of Tenn. Code Ann. § 47-18-104, including but not limited to the following:

a) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods, in violation of Tenn. Code Ann. § 47-18-104(b)(2);

b) Representing that goods have sponsorship, approval, characteristics, uses, and benefits that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that such person does not have, in violation of Tenn. Code Ann. §§ 47-18-104(b)(5);

c) Representing that goods are of a particular standard, quality or grade, when they are of another, in violation of Tenn. Code Ann. §§ 47-18-104(b)(7); and

d) Advertising goods with intent not to sell them as advertised, in violation of Tenn. Code Ann. §§ 47-18-104(b)(9).

285. The VSL 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. The VSL Defendants misled consumers by continuing to use the VSL#3® mark and failing to disclose to consumers such as Plaintiff Offutt and the Tennessee 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. The VSL Defendants owed a duty to disclose the fact that the post-May 2016 formulation had changed, in order to make their continued use of the VSL#3® mark not misleading.

287. The VSL Defendants' conduct was objectively deceptive, and had the capacity to deceive reasonable consumers under the circumstances. The fact that the formulation of VSL#3 the VSL 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. The above unlawful, unfair and deceptive acts and practices by the VSL Defendants were immoral, unethical, oppressive, and unscrupulous. These acts caused substantial injury to Plaintiff Offutt and Tennessee Class Members that they could not reasonably avoid. This substantial injury outweighed any benefits to consumers or to competition.

289. The VSL Defendants knew or should have known that their business practices were unlawful, unfair, and deceptive. The VSL Defendants' actions in engaging in the above-named deceptive acts and practices were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiff Offutt and Tennessee Class Members.

290. As a direct and proximate result of the VSL Defendants' violations of the Tennessee Consumer Protection Act, Plaintiff Offutt and other members of the Tennessee 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).

291. Plaintiff Offutt and Tennessee Class Members seek injunctive relief, recovery of actual damages, treble damages for each willful or knowing violation and attorneys' fees and costs under Tenn. Code Ann. § 47-18-109.

Count XIII

Violation of the Wisconsin Deceptive Trade Practices Act, Wis. Stat., § 100.18 *et seq*.

(On behalf of Plaintiff Farkas and the Wisconsin Class)

(Against the VSL Defendants)

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

293. Plaintiff Farkas brings this claim against the VSL Defendants on behalf of herself and the Wisconsin Class.

294. The VSL Defendants' conduct violated Wis. Stat. § 100.18, which provides, *inter alia*, that no "firm, corporation or association … with intent to sell, distribute, increase the consumption of … any … merchandise … directly or indirectly, to the public for sale … shall make, publish, disseminate, circulate, or place before the public … in this state, in a … label … or in any other way similar or dissimilar to the foregoing, an advertisement, announcement, statement or representation of any kind to the public … which … contains any assertion, representation or statement of fact which is untrue, deceptive or misleading."

295. The VSL Defendants falsely, deceptively and misleadingly 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, including in Wisconsin.

296. The VSL Defendants misled consumers by continuing to use the VSL#3® mark and failing to disclose to consumers such as Plaintiff Farkas and the Wisconsin 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. The VSL Defendants owed a duty to disclose the fact that the post-May 2016 formulation had changed, in order to make their continued use of the VSL#3® mark not misleading.

297. The VSL Defendants' conduct was deliberately and objectively deceptive, and had the capacity to deceive reasonable consumers under the circumstances. The fact that the formulation of VSL#3 the VSL 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 Farkas and the Wisconsin Class relied upon the VSL Defendants' deceptive, misleading and unlawful marketing practices.

298. As a direct and proximate result of the VSL Defendants' violations of the Wisconsin Deceptive Trade Practices Act, Plaintiff Farkas and other members of the Wisconsin Class have suffered pecuniary losses under Wis. Stat. § 100.18(11)(b)(2), 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).

299. Pursuant to Wis. Stat. § 100.18(11)(b), Plaintiff Farkas and the Wisconsin Class seek to recover from the VSL Defendants such pecuniary loss, costs, reasonable attorney's fees and punitive damages.

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;

(c) Awarding to Plaintiffs and the State Subclasses the amounts by which Defendants were unjustly enriched as a result of their wrongful conduct;

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

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

(f) 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

(g) 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: June 18, 2021

By their attorneys,

SCHULMAN BHATTACHARYA, LLC

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