

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

DAVID STARR, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	Civil Action No. 19-cv-02173-LKG
v.)	
)	Dated: January 28, 2025
VSL PHARMACEUTICALS, INC., <i>et al.</i> ,)	
)	
Defendants.)	
)	

MEMORANDUM OPINION¹

I. INTRODUCTION

In this putative class action lawsuit, the Plaintiffs allege that the Defendants, VSL Pharmaceuticals, Inc. (“VSL”), Leadiant Biosciences, Inc. (“Leadiant”), Alfasigma USA, Inc. (“Alfasigma”) (collectively, the “VSL Defendants”), Nutrilinea S.R.L. (“Nutrilinea”) and Centro Sperimentale del Latte S.R.L. (“Centro”), violated the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. §§ 1961–68 (2018); the Uniform Commercial Code (“UCC”); and state law, by engaging in a scheme to deceive consumers by, among other things, misrepresenting the chemical formulation of a probiotic known as VSL#3. ECF No. 93. The Plaintiffs have filed a motion for class certification. ECF No. 312. The Defendants have also filed a motion to exclude the opinions of the Plaintiffs’ experts, Samantha Iyengar and Richard J. Eichmann. ECF No. 324. These motions are fully briefed. ECF Nos. 312, 324, 326, 334, 335 and 337.

¹ The Court issued this opinion under seal on January 28, 2025, to allow the parties to review the opinion and request any redactions of sensitive information. ECF No. 339. On February 25, 2025, the parties filed a joint status report outlining the Plaintiffs’ requested redactions. ECF No. 343. The Defendants do not oppose the Plaintiffs’ requests. *See id.* The Court finds that the Plaintiffs’ requested redactions are private, protected personal health information, the release of which would harm the Plaintiffs’ privacy rights. *Virginia Dep’t of State Police v. Washington Post*, 386 F.3d 567, 575 (4th Cir. 2004); *Doe v. Pub. Citizen*, 749 F.3d 246, 272 (4th Cir. 2014) (citing *In re Knight Pub. Co.*, 743 F.2d 231, 234-35 (4th Cir. 1984)). The Court is also satisfied that there are no less restrictive alternatives that would protect the confidentiality of this information. *See id.* And so, the Court issues this public version of the opinion with the Plaintiffs’ requested redactions.

The parties have also filed motions to seal certain filings and exhibits. ECF Nos. 313, 313-1, 318, 321, 321-1, 333, 333-1 and 336-1. Lastly, the Defendants have filed a consent motion to substitute Exhibit 1 to their response in opposition to the Plaintiffs' motion for class certification. ECF No. 328.

No hearing is necessary to resolve these motions. L.R. 105.6 (D. Md. 2021). For the reasons that follow, the Court: (1) **DENIES** the Defendants' motion to exclude (ECF Nos. 324); (2) **GRANTS** the Plaintiffs' motion for class certification (ECF No. 312); (3) **GRANTS** the parties' motions to seal (ECF Nos. 313, 318, 321, 333 and 336); and (4) **GRANTS** the Defendants' consent motion to substitute exhibit (ECF No. 328).

II. FACTUAL AND PROCEDURAL BACKGROUND²

A. Factual Background

Overview Of The Case

The Plaintiffs in this putative class action matter are purchasers of a probiotic medical product, VSL#3, who allege that the Defendants engaged in a scheme to deceive consumers by, among other things, misrepresenting the chemical formulation of VSL#3, from June 2016 to June 19, 2019 (the "Class Period"), through "false and misleading advertising and marketing." ECF No. 93. The Plaintiffs bring RICO, breach of express warranty, unjust enrichment and various state law consumer protection claims related to the Defendants' sale, advertising and manufacturing of VSL#3. *Id.* at ¶¶ 160-299.

This case is the latest litigation in a long-running intellectual property dispute between former business partners Professor Claudio De Simone and VSL regarding who has rightful ownership of a proprietary probiotic formulation ("the De Simone Formulation") used in a product sold for many years under the name "VSL#3," a trademark owned by VSL. ECF No. 205. In November 2018, a jury returned a verdict in favor of Professor De Simone and his new business venture, ExeGi Pharma, LLC. ECF No. 93 at ¶ 10. And so, on June 20, 2019, this Court issued a permanent injunction against Defendants Leadiant and Alfasigma, the companies

² The facts recited in this memorandum opinion are taken from the second amended complaint; the Plaintiffs' motion for class certification; the memorandum in support thereof; and the exhibits attached thereto; and the Defendants' motion to exclude; the memorandum in support thereof; and the exhibits attached thereto. ECF Nos. 93, 312 and 326.

that have marketed and distributed VSL#3 on behalf of VSL, enjoining them from: (1) stating or suggesting in VSL#3 promotional materials directed at United States consumers that the present version of VSL#3 produced in Italy continues to contain the De Simone Formulation, including by stating 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 Italian VSL#3.” ECF No. 93 at ¶ 12; *De Simone v. VSL Pharms., Inc.*, 395 F. Supp. 3d 617 (D. Md. 2019), *aff’d sub nom. De Simone v. Alfasigma USA, Inc.*, 847 F. App’x 174 (4th Cir. 2021).

The Plaintiffs’ Allegations

In this case, the Plaintiffs allege that Defendant VSL lost the right to sell the original formulations of VSL#3 in 2016 and that Professor De Simone granted an exclusive license to ExeGi Pharma, LLC to market and sell the De Simone Formulation in the United States at that time. ECF No. 93 at ¶ 3. But, the Plaintiffs allege that Defendant VSL continued to use the VSL#3 mark to market and sell a different formulation, which they maintain is fraudulent (the “Current Formulation”). *Id.* at ¶ 4.

In this regard, the Plaintiffs allege that the De Simone Formulation had become the gold standard in its therapeutic class and that, prior to June 1, 2016, the De Simone Formulation was sold under the brand name VSL#3 for almost 15 years. ECF No. 312-1 at 29-30. The Plaintiffs contend that the marketing of VSL#3 and the Current Formulation misled consumers to believe that VSL#3 continued to contain the De Simone Formulation. ECF No. 312-1 at 18-31.³

The Alleged Fraud Scheme

With regards to the Defendants’ alleged fraud scheme, the Plaintiffs allege that, in or about November 2013, Professor De Simone met with the managing director of Defendant Leadiant and the Chief Executive Officer of the Sigma-Tau Group, Andrea Montevocchi, and that during this meeting, Mr. Montevocchi complained about how the high cost of VSL#3 caused Defendant Leadiant’s profit margins to be too low. ECF No. 312-1 at 18. The Plaintiffs also

³ Probiotics are therapeutic and dietary formulations that are comprised of live microorganisms, most often live bacterial cultures, that may be similar to those normally present in the human gastrointestinal tract, and which can have a beneficial effect on the person consuming them. ECF No. 312-1 at 3.

allege, that as result of this meeting, Mr. Montevocchi proposed reducing VSL#3's production cost by changing the product's composition and substituting cheaper bacterial strains. *Id.* And so, the Plaintiffs allege that Professor De Simone resigned from VSL's board of directors and as CEO of VSL, because he was unwilling to participate in the proposed scheme. *Id.*

The Plaintiffs also allege that the Defendants then followed through on a plan to produce the Current Formulation and sell it under the name "VSL#3." *Id.* at 20. In this regard, the Plaintiffs allege that the Current Formulation was manufactured in Italy and began being sold in the United States in May 2016. *Id.* The Plaintiffs contend that Defendant VSL knew that the Current Formulation differed materially from the De Simone Formulation. *Id.*

In this regard, the Plaintiffs allege that independent testing of the Current Formula shows that the formulation "was demonstrably, materially, and strikingly different from the original De Simone Formulation." *Id.* at 20-21. The Plaintiffs also allege that "[t]here were also significant performance differences between the [Current Formulation] and the De Simone Formulation." *Id.* at 21.

In addition, the Plaintiffs allege that Defendant Leadiant engaged in a campaign of false advertising regarding the Current Formulation, by falsely marketing the Current Formulation as identical to, and possessing the same clinical trial and clinical history as, the De Simone Formulation. *Id.* at 22. In this regard, the Plaintiffs allege that the false advertising included, prominently displaying the VSL#3® mark "on the packaging of each box of VSL#3 sold to consumers in the United States during the Class Period, communicating to consumers that the product remained the same, clinically tested formulation that had been sold under that brand name prior to the Class Period. Further, each box of VSL#3 sold to consumers during the Class Period [also] contained a product information sheet drafted by Leadiant, which included information about dosing, as well as the clinical research that had purportedly been conducted on VSL#3." *Id.*

Lastly, the Plaintiffs allege that Defendant Alfasigma continued this false advertising campaign, by selling the Current Formulation to consumers in the United States. *Id.* at 25-26. In this regard, the Plaintiffs allege that, "Alfasigma continued to emphasize the continuity of the formulation and falsely represented that the [Current] Formulation was clinically tested when it

was not.” *Id.* at 27. And so, the Plaintiffs allege that this false advertising campaign “continued throughout the Class Period.” *Id.* at 31.

The Individual Plaintiffs

There are eight individually named Plaintiffs in this putative class action. Each of these Plaintiffs allege that they suffer from, or are the parents of children who suffer from, [REDACTED] and that they routinely purchased VSL#3 during the Class Period to treat these ailments. ECF No. 312-1 at 34. The Plaintiffs also allege that they believed that the version of VSL#3 that they purchased during the Class Period was the same formulation as, and was proven to be as clinically effective as, the version of VSL#3 that was available prior to that time, based upon the product’s packaging and marketing materials and the Defendants’ omission of any information to the contrary. *Id.* The relevant background for each Plaintiff is summarized below.

Plaintiff Arlene Reed-Cossairt is a certified special education teacher who works for a school district in Idaho as an instructional coach and she is the parent of a son who [REDACTED] *Id.* Plaintiff Reed-Cossairt began purchasing VSL#3 for her son in 2013, and her son took VSL#3 consistently until February 2019. *Id.* Plaintiff Reed-Cossairt purchased VSL#3 based upon the recommendation of her son’s pediatric [REDACTED] specialist. *Id.*

Plaintiff Krista Karo assists her husband with sales and marketing for a garment factory and she is the parent of a daughter who took VSL#3. *Id.* at 34-35. Plaintiff Karo’s daughter began experiencing [REDACTED] issues around 2017 and Plaintiff Karo first purchased VSL#3 in March 2018, at her daughter’s physician’s suggestion. *Id.* at 35. Her daughter took VSL#3 for approximately three to six months. *Id.*

Plaintiff Jeremy Hansen is a procurement supply specialist for Washington State University and the parent of a son who has [REDACTED] *Id.* at 35. Plaintiff Hansen’s son took VSL#3 daily from approximately 2016 to 2018, based upon a doctor’s recommendation. *Id.*

Plaintiff Peter Stavros is a self-employed attorney and his GI doctor recommended VSL#3 to him for [REDACTED] issues. *Id.* at 35. Plaintiff Stavros took VSL#3 from 2012 through 2019. *Id.*

Plaintiff Edmund Quiambao works in the information technology department for a biotech company and he began purchasing and taking VSL#3 for [REDACTED] issues in 2014. *Id.* at 36.

Plaintiff Heather Farkas is unemployed and she started purchasing and taking VSL#3 in 2008, at the recommendation of her doctor, and she stopped taking the product in August 2019. *Id.* Plaintiff Farkas' physician introduced her to VSL#3 and suggested that she take it to treat her [REDACTED]. *Id.*

Plaintiff James Tettenhorst works in the restaurant business and he began purchasing and taking VSL#3 around 2010 until 2019, to treat [REDACTED]. *Id.* at 37. Plaintiff Tettenhorst learned about VSL#3 from a physician's assistant. *Id.*

Plaintiff David Starr is a history and humanities professor at Hult International Business School and he was first introduced to VSL#3 by his physician and he began purchasing and taking the product around 2012 through the Class Period. *Id.*

Lastly, Plaintiff Bernadette Mavrikos works for Passiac County Technical Institute as an English Language Arts teacher for 11th grade students and she took VSL#3 for approximately eight years at her doctor's recommendation to treat [REDACTED] from 2012 or 2013 until March 2019. *Id.*

The Plaintiffs' Motion For Class Certification And Expert Reports

On June 30, 2024, the Plaintiffs filed a motion for class certification in this matter, seeking certification of the following classes of Plaintiffs, pursuant to Fed. R. Civ. P. 23:

- (1) The "Nationwide Class," consisting of "all persons who purchased VSL#3 in the United States from June 1, 2016 through June 19, 2019," on Count I of the Second Amended Complaint (RICO);
- (2) The "Florida Class," consisting of "all persons who purchased VSL#3 in Florida from June 1, 2016 through June 19, 2019," on Counts II (Express Warranty), III (Unjust Enrichment); and IX and X (Florida Deceptive and Unfair Trade Practices Act and Florida False Advertising law);
- (3) The "Idaho Class," consisting of "all persons who purchased VSL#3 in Idaho from June 1, 2016 through June 19, 2019," on Counts II and III.

- (4) The “Illinois Class,” consisting of “all persons who purchased VSL#3 in Illinois from June 1, 2016 through June 19, 2019,” on Counts II, III and VI and VII (Illinois Consumer Fraud and Deceptive Trade Practices Acts);
- (5) The “Kentucky Class,” consisting of “all persons who purchased VSL#3 in Kentucky from June 1, 2016 through June 19, 2019,” on Counts II, III and XI (Kentucky Consumer Protection Act);
- (6) The “Massachusetts Class,” consisting of “all persons who purchased VSL#3 in Massachusetts from June 1, 2016 through June 19, 2019,” on Counts II, III and IV (Massachusetts Consumer Protection Act);
- (7) he “Michigan Class,” consisting of “all persons who purchased VSL#3 in Michigan from June 1, 2016 through June 19, 2019,” on Count III;
- (8) The “New Jersey Class,” consisting of “all persons who purchased VSL#3 in New Jersey from June 1, 2016 through June 19, 2019,” on Counts II and III;
- (9) The “Washington Class,” consisting of “all persons who purchased VSL#3 in Washington from June 1, 2016 through June 19, 2019,” on Counts II, III and VIII (the Washington Consumer Protection Act); and
- (10) The “Wisconsin Class,” consisting of “all persons who purchased VSL#3 in Wisconsin from June 1, 2016 through June 19, 2019,” on Counts II, III and XIII (the Wisconsin Deceptive Practices Act).

ECF No. 312 at 1-3.

To support their motion for class certification, the Plaintiffs rely upon the opinions of two experts: Dr. Samantha Iyengar and Richard Eichmann. ECF No. 312-48 and 312-49. These experts have developed a model (the “Eichmann/Iyengar Model”) that will use a conjoint survey and a market simulation that incorporates supply-side factors to calculate benefit-of-the-bargain damages for the Plaintiffs’ claims in this matter. *Id.* The Plaintiffs rely upon these experts to show that damages may be measured in this case upon a classwide basis, to satisfy Rule 23’s predominance requirement. ECF No. 312-1 at 61-70.

The Defendants’ Motion to Exclude

Lastly, on August 19, 2024, the Defendants filed a motion to exclude the expert opinions of the Samantha Iyengar and Richard J. Eichmann, pursuant to Fed. R. Evid. 702. ECF Nos. 324 and 326. The Defendants argue that the Court should not consider these expert opinions in

connection with the Plaintiffs' motion for class certification, because Dr. Iyengar's surveys are not reliable and the Plaintiffs cannot show that Mr. Eichmann's proposed market simulation will produce reliable results. ECF No. 326 at 17-28.

B. Relevant Procedural History

The Plaintiffs commenced this putative class action matter on July 23, 2019. ECF No. 1. Thereafter, the Plaintiffs amended the complaint, by leave of the Court, on January 8, 2020, and July 28, 2021, respectively. ECF Nos. 40 and 93.

On June 3, 2024, the Plaintiffs filed a motion for class certification, pursuant to Fed. R. Civ. P. 23, and a memorandum in support thereof. ECF No. 312. On August 16, 2024, the Defendants filed a response in opposition to the Plaintiffs' motion. ECF No. 322. On November 20, 2024, the Plaintiffs filed a reply brief. ECF No. 334.

On August 19, 2024, the Defendants filed a motion to exclude the opinions of Samantha Iyengar and Richard J. Eichmann, pursuant to Fed. R. Evid. 702, and a memorandum in support thereof. ECF Nos. 324 and 326. On November 20, 2024, the Plaintiffs filed a response in opposition to the Defendants' motion to exclude. ECF No. 335. On December 10, 2024, the Defendants filed a reply brief. ECF No. 337.

On June 3, 2024, the Plaintiffs filed a consent motion to file their motion for class certification, the memorandum in support thereof, and the exhibits thereto under seal. ECF No. 313 and 313-1. On August 16, 2024, the Defendants filed a motion to seal their motion to exclude. ECF No. 318. On August 16, 2024, the Defendants also filed a motion to seal portions of the exhibits to their response in opposition to the Plaintiffs' motion for class certification. ECF Nos. 321 and 321-1.

On November 20, 2024, the Plaintiffs filed a consent motion to file their reply brief and response in opposition to the Defendants' motion to exclude under seal. ECF Nos. 333 and 333-1. On December 20, 2024, the Defendants filed a consent interim motion to file portions of their reply in support of their motion to exclude, under seal. ECF No. 336-1. Lastly, on August 28, 2024, the Defendants filed a consent motion to substitute an exhibit to the Defendant's response in opposition to the Plaintiffs' motion for class certification. ECF No. 328.

These motions having been fully briefed, the Court resolves the pending motions.

III. LEGAL STANDARDS

A. Rule 23

Rule 23(a) of the Federal Rules of Civil Procedure governs class actions and provides that: One or more members of a class may sue or be sued as representative parties on behalf of all members only if:

- (1) the class is so numerous that joinder of all members is impracticable;
- (2) there are questions of law or fact common to the class;
- (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
- (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). To meet the numerosity requirement under Rule 23(a), there must be a showing that the proposed class is so numerous that “joinder of all members is impractical.” *Starr v. Credible Behav. Health, Inc.*, No. CV 20-2986 PJM, 2021 WL 2141542, at *3 (D. Md. May 26, 2021) (quoting Fed. R. Civ. P. 23(a)). In this regard, the United States Court of Appeals for the Fourth Circuit has held that a class with more than 30 members generally satisfies this requirement. *See id.* (citing *Williams v. Henderson*, 129 F. App’x 806, 811 (4th Cir. 2005)).

The commonality requirement is satisfied when the prospective class members share the same central facts and applicable law. *Id.* (citing *Cuthie v. Fleet Rsrv. Ass’n*, 743 F. Supp. 2d 486, 499 (D. Md. 2010)). In addition, to meet the typicality requirement, “[t]he claims need not be identical, but the claims or defenses must have arisen from the same course of conduct and must share the same legal theory.” *Id.* (citing *Peoples v. Wendover Funding, Inc.*, 179 F.R.D. 492, 498 (D. Md. 1998)). In addition, “the adequacy-of-representation requirement centers on: (1) class counsel’s competency and willingness to prosecute the action and (2) whether any conflict of interest exists between the named parties and the class they represent.” *Id.* (citing *Robinson v. Fountainhead Title Grp. Corp.*, 252 F.R.D. 275, 288 (D. Md. 2008)). And so, “[r]epresentation is adequate if the [Plaintiff’s] attorneys are qualified and able to prosecute the action on behalf of the class.” *Id.* (citing *Cuthie*, 743 F.2d at 499).

Lastly, Federal Rule of Civil Procedure 23(b)(3) also provides that:

- A class action may be maintained if Rule 23(a) is satisfied and if: . . .
. . . (3) the court finds that the questions of law or fact common to class members predominate over any questions affecting only

individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

Fed. R. Civ. P. 23(b)(3). “Where the purported class members were subject to the same harm resulting from the defendant’s conduct and the ‘qualitatively overarching issue’ in the case is the defendant’s liability, courts generally find the predominance requirement to be satisfied.” *Starr*, 2021 WL 2141542, at *4 (citing *Stillmock v. Weis Mkts., Inc.*, 385 F. App’x 267, 273 (4th Cir. 2010)). In addition, the Court must consider:

- (A) the class members’ interests in individually controlling the prosecution or defense of separate actions;
- (B) the extent and nature of any litigation concerning the controversy already begun by or against class members;
- (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and
- (D) the likely difficulties in managing a class action.

Fed. R. Civ. P. 23(b)(3)(A)-(D).

B. Fed. R. Evid. 702

Rule 702 of the Federal Rule of Evidence governs the admissibility of expert testimony.

Fed. R. Evid. 702. In this regard, Rule 702 provides that:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principle and methods;
- and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.⁴ The proponent of the expert testimony bears the burden of establishing admissibility. *Brasko v. First Nat’l Bank of Pa.*, 700 F. Supp. 3d 354, 366 (D. Md. 2023).

⁴ The Notes of the Advisory Committee for the 2023 amendments to Fed. R. Evid. 702 provide, in relevant part, that:

[S]ome challenges to expert testimony will raise matters of weight rather than admissibility.... But this does not mean, as certain courts have held, that arguments about the sufficiency of an expert’s basis always go to weight and not admissibility. Rather, it means that once the court has

Relevant to the pending motion to exclude, this Court has held that, where a proffered expert’s model for determining damages is “essential to Plaintiffs’ efforts to certify classwide damages classes[,]” the Court should undertake a “full *Daubert* analysis.” *In re Marriott Int’l, Inc., Customer Data Sec. Breach Litig.*, 602 F. Supp. 3d 767, 773 (D. Md. 2022); *see also Childress v. JPMorgan Chase & Co.*, No. 5:16-CV-298-BO, 2019 WL 2865848, at *2 (E.D.N.C. July 2, 2019) (“The Court is persuaded by authorities which have concluded that where a movant has proffered expert testimony in support of its motion for class certification, and such testimony is critical to the issue of class certification, a full *Daubert* inquiry is appropriate.”). An expert’s testimony is “critical” where it is “important to an issue decisive for the motion for class certification.” *Messner v. Northshore Univ. HealthSystem*, 669 F.3d 802, 812 (7th Cir. 2012).

The Court, in its gatekeeping function, must ensure that expert testimony “rests on a reliable foundation and is relevant to the task at hand.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). To accomplish this, the Supreme Court has identified five non-exhaustive factors for the Court to consider in determining whether expert evidence is scientifically valid: “(1) whether the particular scientific theory can be (and has been) tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique’s operation; and (5) whether the technique has achieved general acceptance in the relevant scientific or expert community.” *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94); *see also Hickerson v. Yamaha Motor Corp.*, 882 F.3d 476, 480 (4th Cir. 2018).

The Court’s analysis should focus “on the ‘principles and methodology’ employed by the expert, not on the conclusions reached” and “whether the reasoning or methodology” is “scientifically valid” and “properly can be applied to the facts in issue.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (quoting *Daubert*, 509 U.S. at 594-95); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (quoting *Daubert*, 509 U.S. at 592-93). This Court has held that, when an expert’s broad methodology is sound, the lack of

found it more likely than not that the admissibility requirement has been met, any attack by the opponent will go only to the weight of the evidence. . .

Fed. R. Evid. 702 Advisory Committee’s note to 2023 amendments.

considerations of unproduced data cannot provide a basis to strike the expert’s testimony. *Robinson v. Nationstar Mortgage LLC*, No. CV TDC-14-3667, 2019 WL 4261696, at *14 (D. Md. Sept. 9, 2019) (holding that “where the [expert’s] broad methodology is sound, the lack of considerations of unproduced data cannot provide a basis to strike the expert’s testimony. Rather than striking the testimony, the Court may need to consider permitting supplemental discovery to correct for the lack of relevant data not previously made available’ to the expert.”) But, the Court “must exclude expert testimony that is based only on belief or speculation[.]” *Casey v. Geek Squad Subsidiary Best Buy Stores, L.P.*, 823 F. Supp. 2d 224, 340 (D. Md. 2011) (quoting *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999).

C. Standing

Lastly, to establish standing, a plaintiff must have (1) “suffered an ‘injury in fact’ that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical[;]” (2) “fairly traceable to the challenged action of the defendant[;]” and (3) “likely. . . [to] be redressed by a favorable decision.” *Bishop v. Bartlett*, 575 F.3d 419, 423 (4th Cir. 2009) (citations omitted); *see also Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992) (same).

IV. LEGAL ANALYSIS

The Plaintiffs have moved for the certification of 10 classes of Plaintiffs in this putative class action, pursuant to Fed. R. Civ. P. 23. ECF Nos. 312 and 312-1. The Plaintiffs argue that the Court should certify these Classes, because: (1) the class is identifiable; (2) the proposed classes are so numerous that joinder of all members is impracticable; (3) there are common questions of law and fact; (4) the claims and defenses of the Plaintiffs are typical of those of the Classes; (5) the Plaintiffs will fairly and adequately represent the Classes; (6) common issues predominate; and (7) a class action is superior to other methods of adjudication.⁵ ECF No. 312-1

⁵ The Plaintiffs request that they be appointed as the representatives of the Classes as follows:

- (a) All Plaintiffs appointed as class representatives for the Nationwide Class;
- (b) Plaintiff Krista Karo appointed as class representative for the Florida Class;
- (c) Plaintiff Arlene Reed-Cossairt appointed as class representative for the Idaho Class;
- (d) Plaintiff James Tettenhorst appointed as class representative for the Illinois Class;
- (e) Plaintiff Peter Stavros appointed as class representative for the Kentucky Class;
- (f) Plaintiff David Starr appointed as class representative of the Massachusetts Class;
- (g) Plaintiff Edmund Quiambao appointed as class representative for the Michigan Class; Case
- (h) Plaintiff Bernadette Mavrikos appointed as class representative for the New Jersey Class;
- (i) Plaintiff Jeremy Hansen appointed as class representative for the Washington Class; and

at 26-58. Lastly, the Plaintiffs also requests that the Court appoint the law firms of Shapiro, Haber & Urmey LLP and Schulman Bhattacharya, LLC as Class Counsel in this matter, pursuant to Fed. R. Civ. P. 23(g). ECF No. 312-1 at 59-60.

The Defendants oppose the Plaintiffs' motion for class certification, upon the grounds that: (1) the Plaintiffs cannot satisfy the predominance and superiority requirements under Rule 23(b)(3); (2) the proposed Class Representatives fail the typicality and adequacy requirements of Rule 23(a); (3) the proposed Classes are not ascertainable; and (4) the Plaintiffs cannot establish standing on a classwide basis. ECF No. 322 at 30-73. And so, the Defendants requests that the Court deny the Plaintiffs' motion. *Id.* at 73.

The Defendants have also moved to exclude the opinions of Samatha Iyengar and Richard J. Eichmann, pursuant to Fed. R. Evid. 702, upon the grounds that: (1) the Court should not consider Dr. Iyengar's Consumer Survey and Physician Survey in deciding the Plaintiffs' motion for class certification, because: (a) Dr. Iyengar's surveys do not rest on a reliable methodology; (b) Dr. Iyengar does not know how the results of her surveys will be used; and (c) the survey results would not be meaningful or reliable and (2) the Court should also exclude Mr. Eichmann's expert report, because: (a) his proposed market simulation is too speculative; (b) he fails to identify the details underlying the proposed market simulation; and (c) the proposed market simulation is unreliable. ECF No. 326 at 17-29. And so, the Defendants request that the Court exclude these expert opinions in deciding the Plaintiffs' motion for class certification. *Id.* at 31.

The Plaintiffs counter that the Court should not exclude these expert opinions, because: (1) the Eichmann/Iyengar Model uses an indisputably proper method for proving classwide damages in a consumer deception cases; (2) they have provided sufficient detail on the Eichmann/Iyengar Model to aid the Court in resolving their motion for class certification; (3) Dr. Iyengar and Mr. Eichmann understand their models; and (4) Dr. Iyengar and Mr. Eichmann reliably apply their methodologies. ECF No. 335 at 17-37. And so, the Plaintiffs request that the Court deny the Defendants' motion to exclude. *Id.* at 30.

(j) Plaintiff Heather Farkas appointed as class representative for the Wisconsin Class.
ECF No. 312 at 3-4.

For the reasons that follow, the Plaintiffs have shown that the expert opinions of Dr. Iyengar and Mr. Eichmann are based upon a reliable method for proving classwide damages in a consumer deception case. A careful review of these expert reports also shows that the Eichmann/Iyengar Model contains sufficient information to assist the Court in determining whether damages are capable of being measured on a classwide basis in this case.

The Plaintiffs have also met their burden to show that the requirements of Rule 23 are satisfied with regards to the proposed Classes and Class Counsel. Lastly, the parties have shown that it is appropriate to seal certain filings and exhibits filed in connection with the briefing of the parties' motions, to protect the confidentiality of sensitive business and/or proprietary information, and to substitute the Defendants' exhibit. And so, for the reasons that follow, the Court: (1) **DENIES** the Defendants' motion to exclude (ECF No. 324); (2) **GRANTS** the Plaintiffs' motion for class certification (ECF No. 312); (3) **GRANTS** the parties' motions to seal (ECF Nos. 313, 318, 321, 333 and 336); and (4) **GRANTS** the Defendants' consent motion to substitute exhibit (ECF No. 328).

A. The Court Will Not Exclude The Plaintiffs' Expert Opinions

As an initial matter, the Court is satisfied that the opinions of the Plaintiffs' experts, Dr. Samantha Iyengar and Richard J. Eichmann, are based upon sufficient facts or data and are the product of reliable principle and methods that have been reliably applied to the known facts of this case. And so, the Court will not exclude these expert opinions in deciding the Plaintiffs' motion for class certification. Fed. R. Evid. 702.

Rule 702 of the Federal Rule of Evidence governs the admissibility of expert testimony and provides that:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principle and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Relevant here, this Court has held that, where a proffered expert's model for determining damages is "essential to Plaintiffs' efforts to certify classwide damages classes," the Court should undertake a "full *Daubert* analysis." *In re Marriott Int'l, Inc., Customer Data Sec. Breach Litig.*, 602 F. Supp. 3d 767, 773 (D. Md. 2022).

To accomplish this, the Court considers five non-exhaustive factors: "(1) whether the particular scientific theory can be (and has been) tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; and (5) whether the technique has achieved general acceptance in the relevant scientific or expert community." *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94); *see also Hickerson v. Yamaha Motor Corp.*, 882 F.3d 476, 480 (4th Cir. 2018). In this regard, this Court has also held that, "where the [expert's] broad methodology is sound, the lack of considerations of unproduced data cannot provide a basis to strike the expert's testimony." *Robinson v. Nationstar Mortgage LLC*, No. CV TDC-14-3667, 2019 WL 4261696, at *14 (D. Md. Sept. 9, 2019). But, the Court "must exclude expert testimony that is based only on belief or speculation." *Casey v. Geek Squad Subsidiary Best Buy Stores, L.P.*, 823 F. Supp. 2d 224, 340 (D. Md. 2011) (quoting *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999)).

In this case, the Plaintiffs submit the expert reports and opinions of their two experts, Dr. Samantha Iyengar and Richard Eichmann, to show that damages can be measured on a classwide basis, to satisfy Rule 23's predominance requirement. ECF No. 312-1 at 61-70; ECF Nos. 312-48 and 312-49. These expert reports show that the Plaintiffs' experts have developed a model (the "Eichmann/Iyengar Model") that will employ a conjoint survey and a market simulation to calculate benefit-of-the-bargain damages related to the Plaintiffs' claims in this matter. ECF No. 312-1 at 65.

In this regard, Dr. Iyengar states in her 36-page expert report (the "Iyengar Report") that she has designed a conjoint survey that measures consumers' preferences and purchase decision-making relating to VSL#3 and other probiotics (the "Consumer Survey"), and a separate survey of doctors to evaluate the effect of the Defendants' alleged deception on physician recommendations and to account for the role of physician recommendations in consumer decision-making (the "Physician Survey"). ECF No. 312-49 at ¶¶ 18-64. Dr. Iyengar also

explains in her expert report that, “while I was not asked to offer an opinion on how my research may be incorporated into the calculation of damages (if any), I understand that an economist will opine on how results from my proposed surveys could be used for this purpose.” ECF No. 312-49 at ¶ 66.

In this regard, Mr. Eichmann has provided a 35-page expert report (the “Eichmann Report”) which shows that he has designed a market simulation to incorporate the surveys’ results into an econometric model, to calculate classwide damages. ECF No. 312-48. In his expert report, Mr. Eichmann explains the theoretical underpinning of market simulations and their fit to measure benefit-of-the-bargain damages in a consumer deception case. *Id.* at ¶¶ 44-55 and App. 3. Notably, Mr. Eichmann explains how consumers’ willingness to pay, which will be measured by the conjoint survey prepared by Dr. Iyengar, can be used to measure aggregate demand for a product, and when considered together with supply-side evidence, a market simulation can be used to calculate the difference in market values between the product promised and the product delivered. *Id.* at ¶¶ 48-50.

As the Plaintiffs acknowledge, Mr. Eichmann has not yet completed the damages calculation for his expert report. ECF No. 335 at 8, 12. But, the Plaintiffs maintain that Mr. Eichmann “has analyzed all evidence necessary to perform the damages calculation (including extensive data and documents obtained in discovery).” *Id.* at 12.

The Defendants seek to exclude the expert opinions of Dr. Iyengar and Mr. Eichmann upon the following grounds: (1) the Court should not consider Dr. Iyengar’s consumer survey and physician survey in deciding the Plaintiffs’ motion for class certification, because Dr. Iyengar’s surveys do not rest on a reliable methodology, Dr. Iyengar does not know how the results of her surveys will be used, and the survey results would not be meaningful or reliable and (2) the Court should also exclude Mr. Eichmann’s expert report, because his proposed market simulation is too speculative, he fails to identify the details underlying the proposed market simulation and the proposed market simulation is unreliable. ECF No. 326 at 17-29. For the reasons that follow, the Defendants’ arguments are unconvincing.

First, Dr. Iyengar’s expert report shows that her surveys rest on a reliable methodology. As the Plaintiffs explain in their response in opposition to the Defendants’ motion to exclude, and the Defendants acknowledge, several courts have allowed the use of conjoint surveys to help

measure damages in consumer deception cases. ECF No. 335 at 18; *see Won v. GM, LLC*, No. 19-11044, 2022 U.S. Dist. LEXIS 134312, at *24-25 and 29 (E.D. Mich. July 27, 2022); *In re FCA US LLC Monostable Elec. Gearshift Litig.*, 382 F. Supp. 3d 687, 697 (2019). And so, other courts have recognized that Dr. Iyengar’s methodology is well-recognized in the field.

The Defendants argue that Dr. Iyengar offers no information regarding the model or methodology she intends to use to convert the survey responses for the Consumer Survey into parts-worth or other metrics that can be used by Mr. Eichmann in his proposed economic market simulation. ECF No. 326 at 18. The Defendants further argue that Dr. Iyengar also fails indicate how the results of her Physician Survey will be quantified in a manner that Mr. Eichmann would be able to incorporate in his market simulation. *Id.* at 19. And so, the Defendants maintain that these alleged deficiencies render Dr. Iyengar’s surveys too unreliable to withstand scrutiny. *Id.*

But a careful reading of Dr. Iyengar’s expert report makes clear that she addresses the methodology that she will use for the surveys in significant detail. ECF No. 312-49 at ¶¶ 23-52, 53-61. While Dr. Iyengar acknowledges that she was not asked to offer an opinion on how her research may be incorporated into the calculation of damages by an economist, this fact goes to the weight that the Court should afford her expert opinion. And so, the Court does not find that this acknowledgment renders the proposed surveys too speculative, as the Defendants suggest.

Dr. Iyengar’s expert report also makes clear that her survey results will be reliable. The Defendants argue that the design of the Consumer Survey and the Physician Survey improperly limits the pool of “qualified respondents” in a manner that is not representative of the proposed Classes in this case. ECF No. 322 at 20, 60-61. Specifically, the Defendants argue that the target population which Dr. Iyengar’s proposes to survey for her Consumer Survey is not representative of the proposed Classes, because Dr. Iyengar limits the survey population to individuals who are past and potential purchasers of digestive health and/or dietary supplements, who purchase these products for the management of specific gastrointestinal conditions. *Id.* at 21, 61. But, Dr. Iyengar addresses this concern in her expert report and she explains that the proper population in a deceptive advertising case consists of “those consumers to whom the ad is directed.” ECF No. 312-49 at 29. While the Defendants understandably disagree with this view, this dispute does not undermine the reliability of Dr. Iyengar’s expert opinion and methodology. Fed. R. Evid. 702; *Allegra v. Luxottica Retail N. Am.*, 341 F.R.D. 373, 456 (E.D.N.Y. 2022)

(holding that “criticism of the...survey population” used in the conjoint survey incorporated into Eichmann’s model “ultimately goes to the weight, not the admissibility, of [Eichmann’s model]”).

The Defendants’ critique of Dr. Iyengar’s proposed Physician Survey is also not a matter that goes to reliability. The Defendants argue that the Physician Survey incorrectly limits the categories of physicians to be surveyed to those who specifically treat patients for irritable bowel syndrome, ulcerative colitis, or pouchitis. ECF No. 326 at 22. The Defendants further argue that such an approach is “completely at odds with the proposed class definition, which is not limited to individuals with those specific health conditions[.]” *Id.* But, as the Plaintiffs correctly observe, the market research related to this case shows that VSL#3 users during the Class Period include individuals suffering from irritable bowel syndrome, ulcerative colitis, or pouchitis and the doctors who treated these individuals. ECF No. 335 at 21. Given this, the Defendants have not shown that Dr. Iyengar’s focus on this physician population renders her Physician Survey unreliable.

The Defendants have also not shown that the Court should exclude Mr. Eichmann’s expert opinion. The Defendants first argue that Mr. Eichmann’s proposed market simulation is too speculative, because the simulation it is predicated upon the results of Dr. Iyengar’s Consumer Survey and Physician Survey. ECF No. 326 at 23-25. But for same the reasons discussed above, this argument is unconvincing.

The Defendants’ argument that Mr. Eichmann fails to identify the details underlying the proposed market simulation is also belied by his expert report. ECF No. 312-48 at ¶¶ 21-54. While the Defendants disagree about the usefulness of the data upon which Mr. Eichmann relies, such concerns do not show that his expert opinion and methodology are unreliable. Fed. R. Evid. 702. The Defendants’ argument that Mr. Eichmann’s opinion is unreliable, because he fails to properly account for a market’s supply-side factors, is equally unavailing. Mr. Eichmann’s expert report shows that his analysis will combine the demand and supply sides of the market. *Id.* at ¶¶ 44-54. Again, the Defendant’s concerns go to the weight that the Court should afford to this expert opinion, not reliability. And so, for each of the above reasons, the Court DENIES the Defendants’ motion to exclude.

B. The Court Grants The Plaintiffs’ Motion To Certify

Turning to the Plaintiffs' motion for class certification, the Plaintiffs have shown that they satisfy the requirements of Rule 23. And so, the Court will GRANT the Plaintiffs' motion. Fed. R. Civ. P. 23.

Pursuant to Rule 23(a) of the Federal Rules of Civil Procedure, one or more members of a class may sue or be sued as representative parties on behalf of all members only if:

- (1) the class is so numerous that joinder of all members is impracticable;
- (2) there are questions of law or fact common to the class;
- (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
- (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). To obtain class certification here, the Plaintiffs must satisfy these four elements. The Plaintiffs must also show that the requirements of predominance and superiority under Rule 23(b) are met, because they seek class certification pursuant to Rule 23(b)(3).

To meet the numerosity requirement under Rule 23(a), there must be a showing that the proposed class is so numerous that "joinder of all members is impractical." *Starr v. Credible Behav. Health, Inc.*, No. CV 20-2986 PJM, 2021 WL 2141542, at *3 (D. Md. May 26, 2021) (quoting Fed. R. Civ. P. 23(a)). In this regard, the Fourth Circuit has held that a class with more than 30 members generally satisfies this requirement. *See id.* (citing *Williams v. Henderson*, 129 F. App'x 806, 811 (4th Cir. 2005)). The commonality requirement is satisfied when the prospective class members share the same central facts and applicable law. *Id.* (citing *Cuthie v. Fleet Rsrv. Ass'n*, 743 F. Supp. 2d 486, 499 (D. Md. 2010)). In addition, to meet the typicality requirement, "[t]he claims need not be identical, but the claims or defenses must have arisen from the same course of conduct and must share the same legal theory." *Id.* (citing *Peoples v. Wendover Funding, Inc.*, 179 F.R.D. 492, 498 (D. Md. 1998)). "[T]he adequacy-of-representation requirement centers on: (1) class counsel's competency and willingness to prosecute the action and (2) whether any conflict of interest exists between the named parties and the class they represent." *Id.* (citing *Robinson v. Fountainhead Title Grp. Corp.*, 252 F.R.D. 275, 288 (D. Md. 2008)). And so, "[r]epresentation is adequate if the [Plaintiff's] attorneys are qualified and able to prosecute the action on behalf of the class." *Id.* (citing *Cuthie*, 743 F.2d at 499).

Lastly, a class action may be maintained under Rule 23(b), if the requirements of Rule 23(a) are satisfied and the Court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy. Fed. R. Civ. P. 23(b)(3). Given this, “[w]here the purported class members were subject to the same harm resulting from the defendant’s conduct and the ‘qualitatively overarching issue’ in the case is the defendant’s liability, courts generally find the predominance requirement to be satisfied.” *Starr v. Credible Behav. Health, Inc.*, No. CV 20-2986 PJM, 2021 WL 2141542, at *4 (D. Md. May 26, 2021) (citing *Stillmock v. Weis Mkts., Inc.*, 385 F. App’x 267, 273 (4th Cir. 2010)). And so, the Court must consider:

- (A) the class members’ interests in individually controlling the prosecution or defense of separate actions;
- (B) the extent and nature of any litigation concerning the controversy already begun by or against class members;
- (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and
- (D) the likely difficulties in managing a class action.

Fed. R. Civ. P. 23(b)(3)(A)-(D). The Plaintiffs have met their burden here.

1. The Classes Are Identifiable

As an initial matter, the Plaintiffs have shown that the proposed Classes are readily identifiable. *Krakauer v. Dish Network, LLC*, 925 F.3d 643, 658 (4th Cir. 2019) (“The goal [of the ascertainability requirement] is not to identify every class member at the time of certification . . . but to define the class in such a way as to ensure there will be some ‘administratively feasible [way] for the court to determine whether a particular individual is a member at some point.’”) (citation omitted). To show that the proposed Classes are ascertainable the Plaintiffs must demonstrate that the Classes are defined with an objective criteria. *Id.* at 655; *EQT Prod. Co. v. Adair*, 764 F.3d 347, 358 (4th Cir. 2014). The Plaintiffs have done so here, because they define the proposed Classes as being limited to Plaintiffs who were individual purchasers of VSL#3 during the Class Period and within certain discrete geographic locations. ECF No. 312-1 at 39.

The Plaintiffs also show that there is a reliable and administratively feasible way to determine whether the proposed Class Members fall within the definition of the Classes. *See Krakauer*, 925 F.3d at 658. The Plaintiffs inform the Court that they have “obtained

confirmation from major retailers that sold VSL#3” that these retailers have and have preserved records regarding purchases of VSL#3, including credit card transactional records and retail rewards programs records. ECF No. 312-1 at 39. The Defendants also possess records regarding their sales of VSL#3 to consumers. *Id.* Given this, the Plaintiffs are in a position to obtain the records needed to identify the Class Members, should the Court certify the proposed Classes. And so, the Court is satisfied that the proposed Classes are identifiable.

2. The Plaintiffs Have Shown That Requirements Of Rule 23(a) Are Met

a. The Proposed Classes Are Numerous

Turning to the specific elements of Rule 23(a), the Plaintiffs have shown that the proposed Classes are so numerous that the joinder of all members of these classes would be impracticable. As discussed above, Rule 23(a)(1) requires that the class be “so numerous that joinder of all members is impracticable.” Fed. R. Civ. P. 23(a)(1). In this regard, the Fourth Circuit has held that a class with more than 30 members generally satisfies this requirement. *See id.* (citing *Williams v. Henderson*, 129 F. App’x 806, 811 (4th Cir. 2005)). This Court has also recognized that classes of as few as 40 members are sufficiently large to make joinder impracticable. *Mitchell-Tracey v. United Gen. Title Ins. Co.*, 237 F.R.D. 551, 556 (D. Md. 2006).

Here, the Plaintiffs explain that the evidence amassed during discovery shows that approximately 2.4 million units of VSL#3 were sold during the Class Period. ECF No. 312-1 at 40. The Plaintiffs also explain that they have received lists of the Defendants’ consumers who purchased VSL#3 directly from the Defendants, which contain thousands of purchasers of VSL#3 within the United States. *Id.* at 41 (explaining that a single document produced by Leadiant lists more than 50,000 VSL#3 purchasers from the United States, including 3,333 from Florida; 195 from Idaho; 1,828 from Illinois; 325 from Kentucky; 1,859 from Massachusetts; 2,434 from New Jersey; 1,670 from Washington; and 539 from Wisconsin). Given this, the Plaintiffs estimate that the number of Class Members could be in the hundreds of thousands. *Id.* And so, the numerosity requirement of Rule 23(a) is also satisfied. Fed. R. Civ. P. 23(a).

b. There Are Common Questions Of Fact And Law

The Court is also satisfied that there are common questions of law and fact among the proposed Class Members. In this regard, Rule 23(a)(2) requires that there be “questions of law

or fact common to the class” and that the class members “have suffered the same injury.” *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 50, 369 (2011) (citation omitted). This Court has held that the commonality requirement is satisfied when the prospective class members share the same central facts and applicable law. *Id.* (citing *Cuthie v. Fleet Rsrv. Ass’n*, 743 F. Supp. 2d 486, 499 (D. Md. 2010)). In addition, many courts have found commonality of questions of fact and law in RICO class actions. *See, e.g., In re JUUL Labs, Inc., Mktg. Sales Pracs. and Prods. Liab. Litig.*, 609 F. Supp. 3d 942, 960 (N.D. Cal. 2022) (finding common questions including “the existence of a RICO Enterprise and whether each defendant engaged in a scheme to defraud” consumers); *Compound Prop. Mgmt. LLC v. Build Realty, Inc.*, 343 F.R.D. 378, 398 (S.D. Ohio 2023) (holding that commonality was satisfied where the Plaintiffs showed that “Defendants carried out a uniform business plan with investors for years, using similar advertising, forms, practices, and legal entities” and noting that “Plaintiffs attack Defendants’ overarching business practices, practices that all putative class members experienced[.]”).

Here, the Plaintiffs allege a fraud scheme involving the false and deceptive advertising of the Current Formulation of VSL#3 during the Class Period. *See generally* ECF No. 93. As the Plaintiffs explain, the claims of the Class Members will share common issues of fact regarding, among other issues: (1) whether the Defendants participated in the RICO Enterprise; (2) whether the Defendants are collaterally estopped from arguing that they did not falsely advertise that the VSL#3 they sold during the Class Period contained the same formulation and was supported by clinical testing; (3) whether the Defendants falsely and misleadingly represented that the VSL#3 they sold during the Class Period contained the same formulation and was supported by clinical testing as was the original, clinically-tested formulation of VSL#3; (4) whether the Defendants falsely and misleadingly represented that the VSL#3 they sold during the Class Period was clinically proven; (5) whether the Defendants misled the Class Members by omitting the material fact that the Current Formulation of VSL#3 was different from the De Simone Formulation, in violation of RICO and various state consumer protection statutes. ECF No. 312-1 at 43-44. And so, the commonality requirement under Rule 23(a) is also met. Fed. R. Civ. P. 23(a).

c. The Plaintiffs’ Claims And Defenses Are Typical

The Plaintiffs have also shown that the claims of the individual Plaintiffs in this case are typical of the claims of the proposed Class Members. As discussed above, Rule 23(a)(3)

requires that the Plaintiffs' claims be "typical" of other class members. Fed. R. Civ. P. 23(a)(3). To establish typicality, a representative plaintiff "must be part of the class and possess the same interest and suffer the same injury as the class members." *In re Titanium Dioxide Antitrust Litig.*, 284 F.R.D. 328, 338 (D. Md. 2012) (citation omitted). This Court has held that typicality exists where the representative plaintiff's "interest in prosecuting his own case . . . simultaneously tend[s] to advance the interests of the absent class members." *Remsnyder v. MBA Mortg. Servs.*, 2023 U.S. Dist. LEXIS 158435, at *10 (D. Md. Sept. 6, 2023) (citation omitted). And so, the "plaintiff's claim must be sufficiently similar to the claims of the absent class members [so] that the 'plaintiff's proof of his own individual claim' will advance the claims of all of the class members." *Id.* at *10-11.

In this case, the Plaintiffs persuasively argue that their claims arise from a common course of conduct and under common legal theories with regards to the alleged fraud scheme and that they possess the same interest and suffer the same injury as the proposed Class Members. *See* ECF No. 312-1 at 44-45. The Plaintiffs maintain in this putative class action that the Defendants misrepresented to them, and other purchasers of VSL#3, that the Current Formulation of VSL#3 sold during the Class Period was the same as the De Simone Formulation of VSL#3. *See generally* ECF No. 93. Given this, the alleged injury is the same for the Plaintiffs and the proposed Class Members, because they all allegedly purchased a product that was not the one that they expected, based upon the Defendants' alleged misrepresentations. ECF No. 312-1 at 45. And so, the Court is satisfied that the typicality requirement under Rule 23(a) has also been satisfied. Fed. R. Civ. P. 23(a).

d. The Plaintiffs Will Fairly And Adequately Represent The Classes

Lastly, the Court is satisfied that individual Plaintiffs "will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). To satisfy this element, the Plaintiffs must show that "(1) the interests of the plaintiff and other members of the class must coincide; and (2) it must appear that plaintiff and his attorney will vigorously prosecute the action." *City of Cape Coral Mun. Firefighters' Ret. Plan v. Emergent Biosolutions, Inc.*, 322 F. Supp. 3d 676, 683 (D. Md. 2018) (citations omitted). The Plaintiffs have shown that their interests align with those of the proposed Class Members.

As discussed above, the Plaintiffs' claims and injuries arise from the same alleged fraudulent conduct and their claims are based upon the same legal theories. The Plaintiffs commenced this case in 2019, and the litigation history of this case makes clear that they have actively participated in this litigation since that time. Indeed, as the Plaintiffs explain, they have "actively monitored and supervised experienced counsel" who have, among other things: (1) investigated the claims; (2) prepared and filed the complaint and amended complaints; (3) researched, briefed, and argued the opposition to the Defendants' motion to dismiss; (4) obtained discovery, including documentary evidence and depositions from the Defendants and third parties; (5) produced discovery, including the Plaintiffs' medical records and other documents, responses to interrogatories and the Plaintiffs' testimony at depositions; (6) briefed discovery issues; and (7) prepared and filed the pending motion for class certification. ECF No. 312-1 at 46. The Plaintiffs and their counsel also state that they will "continue in this fashion by overseeing further motion practice and preparing for and conducting trial." *Id.* And so, the Court is also satisfied that individual Plaintiffs will fairly and adequately protect the interests of the proposed Class Members, as required by Rule 23(a). Fed. R. Civ. P. 23(a).

3. The Plaintiffs Have Shown That The Requirements Of Rule 23(b)(3) Are Met

Having determined that the Plaintiffs have satisfied the requirements of Rule 23(a), the Court next considers whether the Plaintiffs also meet the requirements of Rule 23(b). Under Rule 23(b)(3), the Court should certify a class if common questions of law or fact predominate over individual issues and a class action would be superior to other methods of resolving the claims. Fed. R. Civ. P. 23(b). The Plaintiffs have made this showing.

a. Common Issues Predominate

First, the Plaintiffs persuasively argue that common issues predominate in this case. This Court has recognized that, "[w]here the purported class members were subject to the same harm resulting from the defendant's conduct and the 'qualitatively overarching issue' in the case is the defendant's liability, courts generally find the predominance requirement to be satisfied." *Starr v. Credible Behav. Health, Inc.*, No. CV 20-2986 PJM, 2021 WL 2141542, at *4 (D. Md. May 26, 2021) (citing *Stillmock v. Weis Mkts., Inc.*, 385 F. App'x 267, 273 (4th Cir. 2010)). In considering the question of predominance, the Court also considers:

- (A) the class members' interests in individually controlling the prosecution or defense of separate actions;
- (B) the extent and nature of any litigation concerning the controversy already begun by or against class members;
- (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and
- (D) the likely difficulties in managing a class action.

Fed. R. Civ. P. 23(b)(3)(A)-(D). In this regard, other courts have also recognized that “[c]ourts focus on the issue of liability to determine whether a proposed class meets the predominance prong: ‘[i]f the liability issue is common to the class, common questions are held to predominate over individual ones.’” *Chado v. Nat’l Auto Inspections, LLC*, No. ADC-17-2945, 2018 U.S. Dist. LEXIS 117303, at *19 (D. Md. July 13, 2018) (citation omitted). And so, the predominance inquiry requires only “a showing that questions common to the class predominate, not that those questions will be answered, on the merits, in favor of the class.” *Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 459 (2013).

As discussed above, the Plaintiffs in this putative class action share many common questions of law and fact related to their RICO, consumer deception and state common law claims. The Plaintiffs have also shown that these common questions would be shared with the members of the proposed Classes. Notably, with regards to their RICO claim, the Plaintiffs must show the conduct of an enterprise through a pattern of racketeering activity. *See* 18 U.S.C. § 1962(c). As the Plaintiffs persuasively argue, the proof of these elements will involve common evidence regarding the Defendants’ alleged conduct and knowledge of the alleged fraud scheme. ECF 312-1 at 48-49. The Plaintiffs also state that they will present common evidence to show that the Defendants’ alleged conduct proximately caused their injury. *Id.* at 50. Given this, common issues of fact and law predominate in this case regarding the Plaintiffs’ RICO claims.

The Defendants’ arguments to show that the predominance requirement is not satisfied are also unpersuasive. The Defendants first argue that the predominance requirement is not met with regards to the Plaintiffs’ RICO claim, because the Plaintiffs cannot establish causation or reliance on a classwide basis. ECF No. 322 at 31-38. In this regard, the Defendants argue that each Plaintiff must show that he or she relied on the misstatements alleged in this case and that this task cannot be accomplished in a class action litigation. *Id.* at 31-33. But, the amended complaint makes clear that the Plaintiffs’ RICO claim is not based upon the reasons that they purchased VSL#3, but, rather, on the Defendants’ alleged false and misleading advertising which

induced the Plaintiffs to purchase this product. *See* ECF No. 93. Given this, the Court agrees with the Plaintiffs that common issues will predominate with regards to causation in the case.

The Defendants' argument that the Plaintiffs cannot show consumer deception on a classwide basis is also not persuasive. The Defendants argue that the Plaintiffs cannot show deception, because reasonable consumers could disagree about, and have different understandings of, the meaning of the statements made in the advertising and packaging of VSL#3. ECF No. 322 at 46. But, as the Plaintiffs correctly observe, a reasonable consumer standard applies to their claims. ECF No. 312-1 at 54. Given this, any differences of opinion about the meaning of the Defendants' statements among the Class Members would not preclude the Plaintiffs from proving deception on a classwide basis under the law in the Fourth Circuit.

For similar reasons, common issues predominate with regards to the Plaintiffs' state law consumer protection claims. The Plaintiffs assert such claims under several state consumer protection laws. ECF No. 93. There are some differences in the elements of these state laws. But, as the Plaintiffs explain, all of these state consumer protection laws require proof that the Defendants made material representations that would deceive a reasonable consumer. ECF No. 312-1 at 54-57. And so, again, the Plaintiffs have shown that applying the reasonable consumer standard in this case will allow "the core of [the] Plaintiffs' consumer protection claims [to] turn on common evidence of [the] Defendants' conduct." *Id.* at 55.

With regards to the Plaintiffs' UCC (breach of express warranty) claims, the Plaintiffs also assert these claims under several state laws. ECF No. 93 at 61-63 (asserting breach of warranty claims under Florida, Idaho, Illinois, Kentucky, Massachusetts, New Jersey, Washington and Wisconsin law). But these UCC claims are substantively the same. *Compare* N.J. Stat. § 12A:2-313(b); Fla. Stat. § 672.313(b); Idaho Code § 28-2-313; 810 ILCS 5/2-313; KRS § 355.2-313; Mass. Gen. Laws ch. 106, § 2-313; Rev. Code Wash. § 62A.2-313; and Wis. Stat. § 402.313. The Plaintiffs also explain that they will prove that the Defendants promised that the Current Formulation of VSL#3 was clinically proven, despite knowing this claim was limited to the De Simone Formulation of VSL#3, in violation of these laws, through common evidence, including the product label, product information sheet and advertisements.⁶ *Id.* at 58-59.

⁶ The Defendants argue that these claims cannot be litigated on a classwide basis, because the claims require individualized pre-suit notice. ECF No. 322 at 45. But, the Plaintiffs persuasively argue that

The Plaintiffs have also shown that their unjust enrichment claims can be litigated on a classwide basis. ECF No. 312-1 at 59-60. In this case, the Plaintiffs allege that the Defendants received benefits in the form of profits from the sale of VSL#3 to the Class Members, at the expense of Class Members, because they paid more for the Current Formulation of VSL#3 than they would have due to the alleged fraud scheme. ECF No. 93 at ¶¶ 193-95. Given this, the Court agrees with the Plaintiffs that issues related to whether the Defendants unjustly received the alleged benefits, at the expense of Class Members, are also common to the Class and susceptible to classwide resolution.

The Defendants also argue without persuasion that the Plaintiffs cannot show injury, or unjust enrichment, on a classwide basis, because their claims will require individualized proof of the circumstances surrounding each purchase of VSL#3. ECF No. 322-1 at 50. Again, the second amended complaint makes clear that Plaintiffs' claims in this case require a determination about whether a reasonable consumer would be misled or deceived by the Defendants' alleged conduct. The Plaintiffs also explain that proof of the benefit conferred on the Defendants in this case will involve showing that they paid the Defendants in order to purchase VSL#3. ECF No. 312-1 at 59-60. Given this, the Court agrees with the Plaintiffs that such proof need not be individualized.

Lastly, the Plaintiffs have met their burden to show that the damages in this case are capable of measurement on a classwide basis. As the parties agree, a showing that damages are capable of measurement on a classwide basis will bolster the Plaintiffs' claim that that common issues predominate in this case. *Roach v. T.L. Cannon Corp.*, 778 F.3d 401, 402, 405-09 (2d Cir. 2015).

The Plaintiffs advance two methods of proving damages that they contend can be accomplished on a classwide basis: (i) benefit-of-the-bargain damages and (ii) class-wide profit disgorgement remedy. ECF No. 312-1 at 61-70. With regards to benefit-of-the-bargain damages, the Plaintiffs argue that they may recover such damages for their RICO, state consumer protection laws and breach of express warranty claims, because the calculation of these damages

proof of pre-suit notice should not be a bar to class certification in this case, given the relatively short three-year Class Period (June 1, 2016-June 19, 2019), and the fact that the complaint was also filed in 2019, thereby giving notice to the Defendants. ECF No. 334 at 18. And so, the Court agrees that these notification issues do not predominate, or preclude class certification.

is based upon “the difference in the objective, market value between the product class members were promised (here, the version of VSL#3 containing the clinically proven De Simone Formulation) and the product class members received (the Fraudulent Formulation, for which there was no clinical proof).” *Id.* at 61. Because this measure of damages would not depend upon the individual valuations that Class Members attach to the De Simone Formulation, in comparison to the Current Formulation of VSL#3, the Court agrees that damages are measurable in this matter on a classwide basis.⁷

b. The Plaintiffs Have Shown That A Class Action Is Superior

The Plaintiffs have also shown that proceeding in this litigation as a class action is superior to other methods. When assessing the superiority requirement under Rule 23, the Courts to considers the following factors:

- (A) the class members’ interests in individually controlling the prosecution or defense of separate actions;
- (B) the extent and nature of any litigation concerning the controversy already begun by or against class members;
- (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and
- (D) the likely difficulties in managing a class action.

Fed. R. Civ. P. 23(b)(3). As discussed above, the number of Class Members in this matter is in the hundreds of thousands and, thus, too large to litigate this case on an individual basis. *See*

⁷ The Plaintiffs have submitted expert reports prepared by Dr. Samantha Iyengar, a survey expert, and economist Richard Eichmann, to show these they will measure the alleged difference in value between the Current Formulation of VSL#3 and the DeSimone Formulation. ECF No. 312-1 at 65-69. As discussed above, a review of Dr. Iyengar’s expert report shows that she has designed a conjoint survey to measure consumers’ preferences and purchase decision-making relating to VSL#3 and other probiotics and a survey of doctors to account for their role in the consumer’s decision-making process. ECF No. 312-49. Mr. Eichmann has also designed a market simulation to calculate classwide damages that measures “the difference in the objective market value between what Defendants promised to consumers (VSL#3 that included the clinically proven De Simone Formulation) and the product Defendants actually delivered (the materially different, non- clinically-proven Fraudulent Formulation).” ECF No. 312-1 at 66. While the Plaintiffs acknowledge that their experts have not yet performed these surveys, they correctly observe that this fact does not preclude class certification. ECF No. 312-1 at 69; *see James v. Global Tel*Link Corp.*, No. 13-4989, 2018 U.S. Dist. LEXIS 131892, at *22 (D.N.J. Aug. 6, 2018) (quoting *Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013)) (“The question is not whether Plaintiffs have [already] engaged in a complete or accurate calculation, but whether damages are ‘capable of measurement on a classwide basis.’”). The Plaintiffs also argue that their RICO and claims or remedies for unjust enrichment permit an alternative potential classwide monetary remedy of disgorgement of the Defendant’s profits. ECF No. 312-1 at 69.

ECF No. 312-1 at 70.

The Court also agrees with the Plaintiffs that individual claims related to purchases of VSL#3 are too small to litigate as separate cases for each Class Member. *Id.*; *see Stillmock v. Weis Mkts., Inc.*, 385 Fed. Appx. 267, 275 (4th Cir. 2010) (holding that a class action superior where “there is no indication... that class members would have a strong interest in individual litigation”). The Court is also not aware of any unusual circumstances or difficulties in managing this matter as a class action. Given this, the Plaintiffs have shown that class action treatment of their claims is superior to individual adjudications of these claims. Fed. R. Civ. P. 23(b).⁸

4. Proposed Class Counsel Satisfy Rule 23(g)

Lastly, the Court is satisfied that the appointment of the proposed Class Counsel is appropriate under Rule 23(g). The Plaintiffs move for appointment of the law firms of Shapiro Haber & Urmy LLP and Schulman Bhattacharya, LLC as Class Counsel. In considering this request, Rule 23(g)(1)(A) instructs the Court to consider:

- (i) the work counsel has done in identifying or investigating potential claims in the action;
- (ii) counsel’s experience in handling class actions, other complex litigation, and the types of claims asserted in the action;
- (iii) counsel’s knowledge of the applicable law; and
- (iv) the resources that counsel will commit to representing the class.

Fed. R. Civ. P. 23(g).

In this case, the evidence before the Court and the litigation history for this case show that the proposed Class Counsel have performed substantial work in this case, to include identifying potential claims, analyzing the legal issues and obtaining discovery. The evidence before the Court also makes clear that the law firm of Shapiro Haber & Urmy LLP has significant experience and knowledge in handling class action matters and other complex

⁸ The Defendants’ argument that the Plaintiffs lack standing to bring this putative class action is also not convincing. ECF No. 322 at 71-73. The Plaintiffs have shown that they have standing to pursue their RICO claims, because the Plaintiffs allege that they suffered an economic harm, by purchasing and paying for the Current Formulation of VSL#3, which was not the VSL#3 formulation that had been clinically tested, and that the Defendants’ alleged racketeering activity caused their economic harm. ECF No. 334 at 37-39; *Brandenburg v. Seidel*, 859 F.2d 1179, 1187 (4th Cir. 1988) (citations omitted); *see also Bishop v. Bartlett*, 575 F.3d 419, 423 (4th Cir. 2009) (holding that, to establish standing, a plaintiff must have “(1) suffered an injury in fact that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical, (2) fairly traceable to the challenged action of the defendant,” and (3) likely to be redressed by a favorable decision.”) (citations omitted).

litigation. ECF No. 312-61 (Gavenman Decl. Ex. 57.). The evidence also makes clear that the law firm of Schulman Bhattacharya, LLC has significant prior experience representing Professor De Simone and ExeGi in related litigation. ECF No. 312-3 at ¶ 11 (Gavenman Decl.), ECF Nos. 312-36, 312-37 and 312-38 (Gavenman Decl. Exs. 33-35). Given this, the Court is satisfied that proposed Class Counsel are adequate and satisfy Rule 23(g)'s requirements. And so, the Court will APPOINT these law firms as Class Counsel in this matter.

C. The Court Grants The Parties' Motions To Seal

As a final matter, the parties have filed several motions to seal certain filings and exhibits submitting in connection with the briefings of their respective motions, upon the grounds that these documents that contain confidential and/or proprietary business information. ECF Nos. 313, 313-1, 318, 321, 321-1, 333, 333-1 and 336-1. No objections to these motions have been filed. The Court finds that: (1) the proposed sealed documents and/exhibits contain sensitive business and/or proprietary information about the parties and their businesses and (2) there are no less restrictive alternatives to sealing that would sufficiently protect this sensitive information. And so, for good cause shown, the Court GRANTS: (1) the Plaintiffs' consent motion to file their motion for class certification, the memorandum in support thereof, and the exhibits thereto under seal (ECF No. 313 and 313-1); (2) the Defendants' motion to seal their motion to exclude (ECF No. 318); (3) the Defendants' filed a motion to seal portions of the exhibits to their response in opposition to the Plaintiffs' motion for class certification (ECF Nos. 321 and 321-1); (4) the Plaintiffs' consent motion to file their reply brief and response in opposition to the Defendants' motion to exclude under seal (ECF Nos. 333 and 333-1); (5) the Defendants' consent interim motion to file portions of their reply in support of their motion to exclude under seal (ECF No. 336-1); and (6) the Defendants' consent motion to substitute an exhibit to the Defendant's response in opposition to the Plaintiffs' motion for class certification (ECF No. 328).

V. CONCLUSION

For the foregoing reasons, the Court:

- (1) **DENIES** the Defendants' motion to exclude (ECF No. 324);
- (2) **GRANTS** the Plaintiffs' motion for class certification (ECF No. 312);

- (3) **GRANTS** the parties' motions to seal (ECF Nos. 313, 318, 321, 333 and 336);
- (4) **GRANTS** the Defendants' consent motion to substitute exhibit (ECF No. 328);
- (5) **CERTIFIES** a class action on behalf of the following classes, pursuant to Fed. R.

Civ. P. 23:

- (i) The "Nationwide Class," consisting of "all persons who purchased VSL#3 in the United States from June 1, 2016 through June 19, 2019."
 - (ii) The "Florida Class," consisting of "all persons who purchased VSL#3 in Florida from June 1, 2016 through June 19, 2019."
 - (iii) The "Idaho Class," consisting of "all persons who purchased VSL#3 in Idaho from June 1, 2016 through June 19, 2019."
 - (iv) The "Illinois Class," consisting of "all persons who purchased VSL#3 in Illinois from June 1, 2016 through June 19, 2019."
 - (v) The "Kentucky Class," consisting of "all persons who purchased VSL#3 in Kentucky from June 1, 2016 through June 19, 2019."
 - (vi) The "Massachusetts Class," consisting of "all persons who purchased VSL#3 in Massachusetts from June 1, 2016 through June 19, 2019."
 - (vii) The "Michigan Class," consisting of "all persons who purchased VSL#3 in Michigan from June 1, 2016 through June 19, 2019."
 - (viii) The "New Jersey Class," consisting of "all persons who purchased VSL#3 in New Jersey from June 1, 2016 through June 19, 2019."
 - (ix) The "Washington Class," consisting of "all persons who purchased VSL#3 in Washington from June 1, 2016 through June 19, 2019."
 - (x) The "Wisconsin Class," consisting of "all persons who purchased VSL#3 in Wisconsin from June 1, 2016 through June 19, 2019."
- (6) **APPOINTS** the Plaintiffs as the representatives of the Classes as follows:
- (i) All Plaintiffs are appointed as class representatives for the Nationwide Class;
 - (ii) Plaintiff Krista Karo is appointed as class representative for the Florida Class;
 - (iii) Plaintiff Arlene Reed-Cossairt is appointed as class representative for the Idaho Class;
 - (iv) Plaintiff James Tettenhorst is appointed as class representative for the Illinois Class;
 - (v) Plaintiff Peter Stavros is appointed as class representative for the Kentucky Class;
 - (vi) Plaintiff David Starr is appointed as class representative of the Massachusetts Class;

- (vii) Plaintiff Edmund Quiambao is appointed as class representative for the Michigan Class;
- (viii) Plaintiff Bernadette Mavrikos is appointed as class representative for the New Jersey Class;
- (ix) Plaintiff Jeremy Hansen is appointed as class representative for the Washington Class; and
- (x) Plaintiff Heather Farkas is appointed as class representative for the Wisconsin Class; and

(7) **APPOINTS** Shapiro Haber & Urmy LLP and Schulman Bhattacharya, LLC as Class Counsel for each of the Classes.

A separate Order shall issue.

IT IS SO ORDERED.

s/Lydia Kay Griggsby
LYDIA KAY GRIGGSBY
United States District Judge