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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JENNIFER BAUGHMAN, on behalf of herself and all others similarly situated,

Plaintiff,

vs.

JOHNSON & JOHNSON CONSUMER INC.; KENVUE INC. a Delaware company; PROCTER & GAMBLE, an Ohio corporation; and RECKITT BENCKISER LLC, a Delaware limited liability corporation,

Defendants.

CASE NO.: 2:13-CV-7737

CLASS ACTION COMPLAINT FOR:

1) **FALSE AND MISLEADING ADVERTISING;**
2) **UNFAIR BUSINESS PRACTICES**
3) **VIOLATION OF THE CALIFORNIA CONSUMER LEGAL REMEDIES ACT;**
4) **UNJUST ENRICHMENT;**
5) **BREACH OF IMPLIED WARRANTY**
6) **VIOLATION OF MAGNUSON-MOSS WARRANTY ACT;**
7) **VIOLATIONS OF CONSUMER FRAUD LAWS; AND**
8) **NEGLIGENT MISREPRESENTATION**

DEMAND FOR JURY TRIAL

Jennifer Baughman ("Plaintiff"), on behalf of herself and all others similarly situated, file this Class Action Complaint ("CAC") against Defendants Johnson & Johnson Consumer Inc. ("J&J"), Kenvue, Inc. ("KI"), Reckitt Benckiser LLC ("RB"); and Procter & Gamble ("P&G")(collectively "Defendants"), and in support states the following:

NATURE OF THE ACTION

1. This is a class action lawsuit brought under California's consumer protection laws by Plaintiff, and others similarly situated, who purchased over-the-counter ("OTC") decongestant products containing phenylephrine (the "Products").

2. These Products are manufactured, sold and distributed by Defendants and have been found by the U.S. Food and Drug Administration ("FDA") to lack efficacy. Defendants have long been aware of the lack of efficacy but have continued to sell the Products. The Products' lack of efficacy was not disclosed to Plaintiff prior to Plaintiff's purchase of the Products. Plaintiff would not have purchased the Products had she known they did not work as advertised. Plaintiff and the putative class suffered economic damages due to Defendants' misconduct (as set forth below). They seek injunctive relief and restitution for the full purchase price of the Products they purchased. Plaintiff alleges the following based upon personal knowledge as well as investigation by counsel, and as to all other matters, upon information and belief. Plaintiff further believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

JURISDICTION AND VENUE

3. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). The matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and is a class action in which there are in excess of 100 class members. Plaintiff is a citizen of a state different from Defendants.

4. This Court has jurisdiction over each Defendant because both Defendants are authorized to conduct business in California. Defendants have marketed, promoted, distributed, and sold the Products in California. This Court may exercise jurisdiction

over Defendants because Defendants have sufficient minimum contacts with this State and/or sufficiently avail themselves of the markets in this State through promotion, sales, distribution and marketing within this State.

5. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred while he resided in this judicial district. Venue is also proper under 18 U.S.C. §1965(a) because Defendants transact substantial business in this District.

THE PARTIES

3. Plaintiff Jennifer Baughman ("Plaintiff" or "Plaintiff Baughman") is a citizen and resident of Los Angeles County, and at all times relevant hereto, has been a resident of Los Angeles County and made her purchases of the Products within that County. Within the Class Period defined below, Plaintiff purchased Sudafed PE, Vick's DayQuil Vick's Nyquil Cold & Flu, Vicks Nyquil Severe Cold & Flu, Vicks Nyquil Cold + Flu plus Congestion and Mucinex Sinus Max for personal and household use to relieve congestion associated with a cold. During that time, based on the false and misleading claims by Defendants, Plaintiff was unaware that Defendants' oral decongestant Products were not an effective remedy for congestion and/or cold symptoms. None of these products was effective in relieving congestion.

4. Plaintiff purchased Defendants' Products on the assumption that the labeling of the Products was accurate and that the Products worked as advertised. Plaintiff would not have purchased Defendants' Products had she known they were not effective and lacked the ability to provide relief for congestion and/or cold symptoms as marketed by Defendants. As a result, Plaintiff suffered injury in fact when she spent money to purchase Products she would not otherwise have purchased absent Defendants' misconduct, as alleged herein.

5. Plaintiff continues to be exposed to Defendants' marketing materials for these ineffective Products. Plaintiff continues to encounter the Products on display for sale to consumers at retail businesses where she regularly shops. Plaintiff would purchase Defendants' Products again in the future if she were assured that Defendants'

Products had been reformulated using GRASE ingredients that are proven effective for decongestant relief as advertised by Defendants.

6. Defendant Johnson & Johnson Consumer Inc., a McNeil Consumer Healthcare Division, is a New Jersey corporation with its headquarters and principal place of business at 199 Grandview Road, Skillman, New Jersey, 08558. J&J manufactures, markets, advertises, labels, distributes and sells phenylephrine products under its Sudafed and Benadryl product lines. J&J may be served via its registered agent, C T Corporation System, 100 Biscayne Blvd., Miami, FL 33132.

7. Defendant Kenvue Inc. is an Delaware consumer health company, and formerly the consumer healthcare division of Johnson & Johnson. Kenvue is headquartered in Skillman, New Jersey. During the Class Period Kenvue acquired Defendant McNeil Consumer Healthcare.

8. Defendant Procter & Gamble is an Ohio corporation with its headquarters and principal place of business at One Procter & Gamble Plaza, Cincinnati, Ohio 45202. Procter & Gamble manufactures, markets, advertises, labels, distributes and sells Vicks NyQuil. Procter & Gamble may be served via its registered agent, CT Corporation System, 1200 South Pine Island Rd., Plantation, FL 33324. P&G manufactures, markets, advertises, labels, distributes and sells phenylephrine products under its Vicks Nyquil product line.

9. Defendant Reckitt Benckiser LLC ("Reckitt") is a Delaware limited liability corporation with its headquarters and principal place of business located in Parsippany, New Jersey. Reckitt is a wholly-owned subsidiary of Reckitt Benckiser Group PLC, a public limited company registered in England and Wales. Reckitt manufactures, markets, advertises, labels, distributes and sells phenylephrine products under its Mucinex product line.

INTRODUCTION AND BACKGROUND

10. Collectively, Defendants J&J and Procter & Gamble marketed and sold the Products to consumers in California and across the United States as an effective nasal decongestant.

11. The main so-called "active ingredient" in the Products is phenylephrine hydrochloride ("PE" or "phenylephrine"). However, "[n]o support has been found in the literature in the public domain for the efficacy of PE as a nasal decongestant when administered orally."[1]

12. Another prominent active ingredient found in OTC cold and cough medicines (but not in the Products at issue in this litigation) is pseudoephedrine hydrochloride ("PDE" or "pseudoephedrine").[2] Unlike PE, "[c]linical studies of PDE provide sufficient information to support the efficacy" of PDE in OTC dosage amounts.[3]

13. Unfortunately, Pseudoephedrine hydrochloride can be converted into methamphetamine. In 2006, the Combat Methamphetamine Act, banned over-the-counter sales of cold medicines that contain the ingredient pseudoephedrine. Since such time, the sale of cold medicine containing pseudoephedrine is limited to behind the counter. The amount of pseudoephedrine that an individual can purchase each month is limited and individuals are required to present photo identification to purchase products containing pseudoephedrine. In addition, stores are required to keep personal information about purchasers for at least two years[4].

14. This has translated into increased sales for decongestants that contain PE. Last year, 242 million packages or bottles of phenylephrine products were sold, resulting in $1.76 billion in sales. In contrast only a little over 50 million packages of pseudoephedrine were sold that same year, resulting in $542 million in sales[5].

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2000711/ (last viewed Sept. 14, 2023).
[2] https://www.mayoclinic.org/drugs-supplements/pseudoephedrine-oral-route/side-effects/drg-20067942?p=1#:~:text=Pseudoephedrine%20is%20used%20to%20relieve,by%20ear%20inflammation%20or%20infection (last viewed Sept. 14, 2023).
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2000711/ (last viewed Sept. 14, 2023).
[4] https://www.fda.gov/drugs/information-drug-class/legal-requirements-sale-and-purchase-drug-products-containing-pseudoephedrine-ephedrine-and
[5]https://www.webmd.com/drug-medication/news/20230913/popular-otc-decongestant-ineffective#:~:text=According%20to%20the%20FDA's%20review,in%20%24542%20million%20in%20sales.

1. The Financial Significance of a GRASE Designation for Defendants

15. As discussed below, the FDA has previously designated PE as generally recognized as safe and effective ("GRASE"), despite the lack of peer-reviewed scientific evidence to support PE's efficacy as an oral decongestant. However, after a two-day meeting on September 11-12, 2023, the FDA concluded that the scientific data do not support a GRASE designation for PE as an ingredient in cough and cold OTC medications.

16. An FDA GRASE designation permits pharmaceutical products companies (like Defendants) to market products (like Sudafed PE, Vicks NyQuil, and Mucinex) that contain GRASE ingredients directly to consumers as OTC medications.

17. "OTC medicines do not require a prescription and are typically freely available from many kinds of retailers."[6] In the United States alone, "there are more than 750,000 retail outlets that sell OTC products."[7]

18. In 2022, PE versions of oral cough and cold decongestant OTC medications accounted for about 80% of "the $2.2 billion market," while PDE versions made up the other 20%.[8]

2. Defendants' Deceptive Marketing Regarding the Efficacy of their PE OTC Products

19. In the many years preceding the filing of this Complaint, Defendants have advertised, and continue to advertise, PE as an effective decongestant that relieves nasal congestion and sinus pressure associated with colds, allergies, and other respiratory conditions, even though Defendants knew or should have known that the current scientific data demonstrate that oral PE is ineffective as a nasal decongestant.

20. As a result of its aggressive and misleading marketing tactics, Defendants'

[6] https://www.goodrx.com/healthcare-access/medication-education/otc-isnt-always-cheaper-when-it-pays-to-get-a-prescription. (last visited Sept. 13, 2023).
[7] https://www.chpa.org/about-consumer-healthcare/research-data/otc-sales-statistics (last visited Sept. 13, 2023).
[8] https://www.pbs.org/newshour/health/popular-nasal-decongestant-doesnt-actually-relieve-congestion-fda-advisers-say (last viewed Sept. 14, 2023).

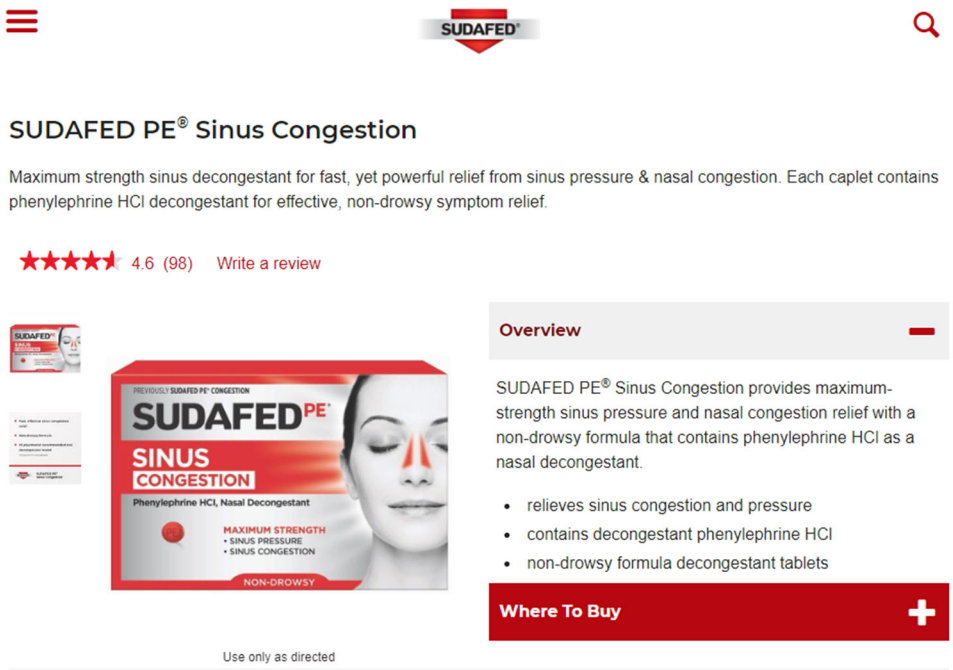
Products "generated nearly $1.8 billion in sales last year alone."[9]

21. According to Defendants, phenylephrine works by constricting blood vessels in the nasal passages, which reduces swelling and congestion.

22. Over the many years preceding the filing of this Complaint, Defendants have made extensive claims in their marketing materials concerning the efficacy of their Products.

23. For Sudafed PE, these claims include:

- Relief from Nasal Congestion: Sudafed PE products provide relief from nasal congestion associated with colds, allergies, or sinus congestion.
- Fast-Acting: Some Sudafed PE products are fast-acting and provide rapid relief from congestion symptoms.
- 24-Hour Relief: Sudafed PE provide up to 24 hours of relief from congestion symptoms, reducing the need for frequent dosing.
- Sinus Pressure Relief: Sudafed PE is highly effective in relieving sinus pressure in addition to congestion.
- Sudafed PE offers relief from multiple cold and allergy symptoms, such as nasal congestion, sinus pressure, sneezing, and runny nose.



[9] https://www.cnn.com/2023/09/12/health/phenylephrine-tablets-ineffective-fda-panel-says/index.html (last viewed Sept. 13, 2023).

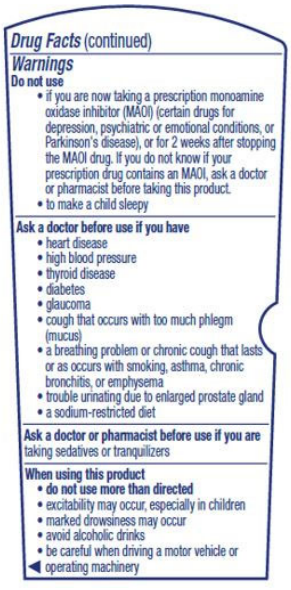
24. For Vicks Nyquil these claims include:

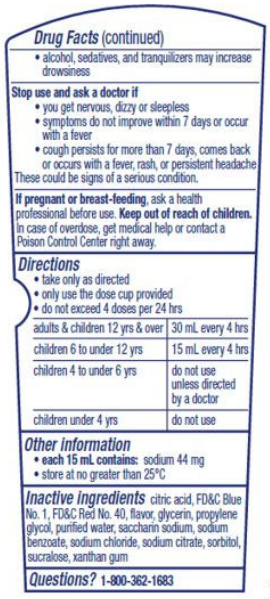
- fast, powerful, maximum strength 9-symptom relief to treat… stuffy nose…sinus congestion.
- Proven relief for your worst cold and flu symptoms;
- Effective cold and flu symptom relief.
- The congestion, pressure & pain, clear your head, medicine.
- Fast Relief- Clear your head with fast acting nighttime relief.
- Powerful congestion, pressure and pain relief.
- Maximum strength sinus relief.
- Fast, powerful cold and congestion relief.


MAX STRENGTH
VICKS
NyQuil
SEVERE
COLD & FLU
Headache, Fever, Sore Throat, Minor Aches & Pains
Nasal Congestion, Sinus Pressure
Sneezing, Runny Nose
Cough
24 LIQUICAPS


VICKS
NyQuil
COUGH DM+
CONGESTION
Dextromethorphan HBr, Phenylephrine HCl, Doxylamine Succinate
Cough
Nasal Congestion
Sneezing, Runny Nose
8 FL OZ (236 mL)
Nighttime Relief

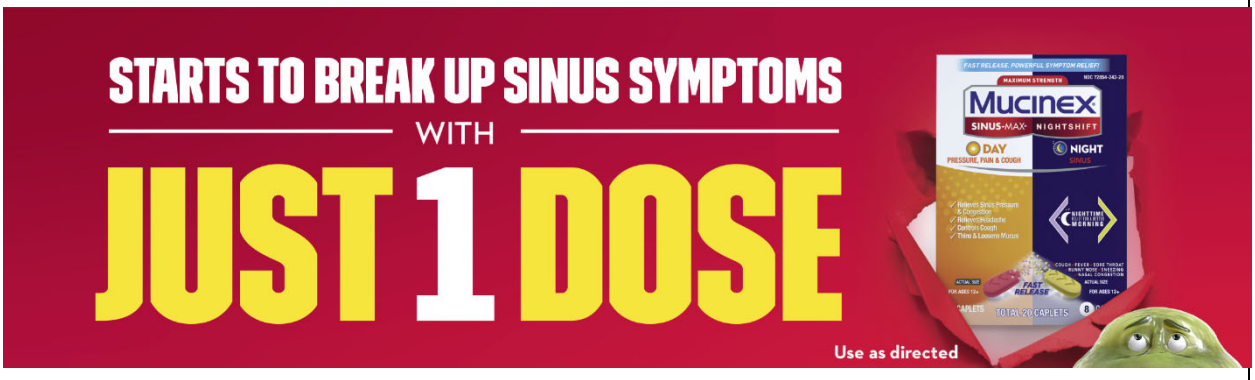

TAMPER EVIDENT:
Do not use if printed shrinkband is broken or missing.
PEEL BACK FOR DRUG FACTS
Drug Facts
Active ingredients (in each 15 mL) Purpose
Dextromethorphan HBr 10 mg ... Cough suppressant
Doxylamine succinate 6.25 mg ... Antihistamine
Phenylephrine HCl 5 mg ... Nasal decongestant
Uses temporarily relieves common cold symptoms:
• nasal congestion
• sinus congestion & pressure
• cough due to minor throat & bronchial irritation
• cough to help you sleep
• runny nose & sneezing
• reduces swelling of nasal passages
• temporarily restores freer breathing through the nose
• promotes nasal and/or sinus drainage
PARENTS:
DIST. BY PROCTER & GAMBLE, CINCINNATI OH 45202
Patents: www.pg.com/patents
www.vicks.com
P&G
www.pg.com
90989547
PLASTIC BOTTLE
23900041202


Drug Facts (continued)
Warnings
Do not use
• if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
• to make a child sleepy
Ask a doctor before use if you have
• heart disease
• high blood pressure
• thyroid disease
• diabetes
• glaucoma
• cough that occurs with too much phlegm (mucus)
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
• trouble urinating due to enlarged prostate gland
• a sodium-restricted diet
Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers
When using this product
• do not use more than directed
• excitability may occur, especially in children
• marked drowsiness may occur
• avoid alcoholic drinks
• be careful when driving a motor vehicle or operating machinery


Drug Facts (continued)
• alcohol, sedatives, and tranquilizers may increase drowsiness
Stop use and ask a doctor if
• you get nervous, dizzy or sleepless
• symptoms do not improve within 7 days or occur with a fever
• cough persists for more than 7 days, comes back or occurs with a fever, rash, or persistent headache
These could be signs of a serious condition.
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
Directions
• take only as directed
• only use the dose cup provided
• do not exceed 4 doses per 24 hrs
adults & children 12 yrs & over | 30 mL every 4 hrs
children 6 to under 12 yrs | 15 mL every 4 hrs
children 4 to under 6 yrs | do not use unless directed by a doctor
children under 4 yrs | do not use
Other information
• each 15 mL contains: sodium 44 mg
• store at no greater than 25°C
Inactive ingredients citric acid, FD&C Blue No. 1, FD&C Red No. 40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum
Questions? 1-800-362-1683

24. For Mucinex, these claims include:

- Clears sinus congestion.
- Relieve sinus pressure.
- Starts to break up Sinus Symptoms with Just 1 Dose.
- 3 maximum strength medicines help thin and loosen mucus, clear nasal passages and sinus congestion



The History of PE's GRASE Designation

25. The FDA "first approved phenylephrine as a safe and effective [OTC] decongestant in the 1970s."[10] In 1994, the FDA issued a final monograph establishing conditions under which OTC nasal decongestant drug products are generally recognized as safe and effective ("GRASE") and not misbranded. (Exh. A, p. 31.) Phenylephrine is included in the final monograph as an OTC oral nasal decongestant.[11]

26. In or around 2006, OTC pharmaceutical products manufacturers, including Defendants, began replacing the ingredient pseudoephedrine in their products with phenylephrine, in response to the passing of a law "requiring all pseudoephedrine products be kept behind pharmacy counters."[12,13]

27. In or around 2007, "researchers at the University of Florida petitioned the government to examine" the use of phenylephrine in popular OTC cold medications, "arguing that there is little evidence the reformulated products [containing PE instead of PDE] work in adults or are safe in children."[14] In response, the FDA held a meeting where it "ask[ed] a panel of outside experts whether new formulations of Sudafed and other [OTC] cold medications actually relieve nasal congestion."[15]

28. At this 2007 meeting, the "advisory panel told the FDA that evidence oral phenylephrine worked was 'murky' and 'not definitive' and recommended further study."[16] Nevertheless, upon the conclusion of the 2007 meeting, the FDA determined

[10] https://www.cato.org/blog/after-50-years-fda-finds-out-oral-phenylephrine-doesnt-work#:~:text=The%20FDA%20first%20approved%20phenylephrine,counter%20decongestant%20in%20the%201970s (last viewed Sept. 14, 2023).

[11] Phenylephrine "was approved by the FDA based on in-house studies provided by pharmaceutical companies, not as a result of clinical trials." https://www.drugs.com/medical-answers/difference-between-phenylephrine-pe-3509033/ (last viewed Sept. 14, 2023).

[12] https://www.nbcnews.com/health/health-news/fda-panel-study-reformulated-cold-meds-flna1c9464568 (last viewed Sept. 14, 2023).

[13] *See also*, https://abcnews.go.com/Health/ColdFlu/story?id=4002807&page=1 (last viewed Sept. 14, 2023) ("Sudafed and other OTC medicines "switched" to phenylephrine "from pseudoephedrine" in response to a "law passed in 2006 [] aimed at curbing the illegal processing of pseudoephedrine into the stimulant methamphetamine.").

[14] https://www.nbcnews.com/health/health-news/fda-panel-study-reformulated-cold-meds-flna1c9464568 (last viewed Sept. 14, 2023).

[15] *Id.*

[16] https://www.cato.org/blog/after-50-years-fda-finds-out-oral-phenylephrine-doesnt-work#:~:text=The%20FDA%20first%20approved%20phenylephrine,counter%20decongestant%20in%20the%201970s (last viewed Sept. 14, 2023).

phenylephrine to be GRASE, but with a clear caveat—specifically, the "FDA allowed the [OTC phenylephrine-containing] products to remain on the market *pending additional research*."[17] To reiterate, PE, unlike PDE, "was approved by the FDA based not on results from clinical trials, but studies conducted by pharmaceutical companies themselves."[18]

No Need for Further Study: the FDA Exposes the Inefficacy of PE Oral Decongestants

29. Years after the FDA reaffirmed PE's GRASE designation in 2007, the FDA issued a new report detailing the efficacy (or, rather, lack thereof) of oral PE "as an active ingredient in [OTC] couch and cold products."[19] During the FDA's two-day meeting on September 11th and 12th, 2023, it revisited studies it initially reviewed in 2007, and considered additional studies obtained since that time. This two-day meeting was "prompted by" the "same [University of Florida] researchers who challenged [PE's] effectiveness in 2007."[20] These researchers again "petitioned the FDA to remove most [PE] products based on recent studies showing [PE products] failed to outperform placebo pills in patients with cold and allergy congestion."[21]

30. Based upon its review of past and new data, the FDA *unanimously* concluded that the "scientific data do not support [its previous conclusion, based on data supplied by pharmaceutical companies] that the recommended dosage of orally administered phenylephrine is effective as a nasal decongestant."[22] A copy of the FDA's report is attached as Exhibit A.

31. In its re-analysis in 2023, the FDA highlighted fatal flaws in the studies it previously relied upon in 2007, explaining that:

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[17] https://www.pbs.org/newshour/health/popular-nasal-decongestant-doesnt-actually-relieve-congestion-fda-advisers-say (last viewed Sept. 14, 2023) (emphasis added).
[18] https://www.usatoday.com/story/news/health/2023/09/12/fda-panel-declares-decongestant-phenylephrine-ineffective/70835249007/ (last viewed Sept. 14, 2023).
[19] https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-results-recent-advisory-committee-meeting-oral-phenylephrine (last viewed Sept. 14, 2023).
[20] https://www.pbs.org/newshour/health/popular-nasal-decongestant-doesnt-actually-relieve-congestion-fda-advisers-say (last viewed Sept. 14, 2023).
[21] *Id.*
[22] *Id.*

> [w]hen considering the studies through a modern drug review lens, **all of the studies** (both positive and negative) **were highly problematic in both design and methodology.** All used a highly variable endpoint (NAR) to study a drug in the setting of a highly variable disease state (the common cold) that is no longer used as a primary endpoint to evaluate congestion in pivotal trials.[23] Further, all the positive studies (and most of the negative studies) were unpublished and therefore never peer-reviewed. Six of the seven positive studies came from a single study center (funded by the manufacturer of Neo-Synephrine), were very small in size, and (except in one instance) the results could not be duplicated at two other study centers (also funded by the same manufacturer) that used a similar study design and methodology. (emphasis added).
>
> (Exh. A., p. 55 (emphasis added).)

32. The FDA also mentioned a 2017-2018 study conducted by Defendant J&J that suggested that oral PE products have "no beneficial effect when compared with [a] placebo." (Exh. A., p. 53.)

33. For these and other reasons, the FDA unanimously declared on September 12, 2023 that phenylephrine, the active ingredient in the Products, is an ineffective decongestant. (*See*, *e.g.*, Exh. A., p. 55 (the available data do not support "the efficacy of monographed doses of oral PE").)

34. The FDA's 2023 report is supported by large clinical trials disproving PE's efficacy.[24] Those studies provide evidence of the absence of a decongestant effect from the OTC approved doses of 10 mg. For example:

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[23] The FDA's Guidance for Industry on Developing Drug Products for Treatment of Allergic Rhinitis recommends use of symptom scores for the primary endpoint in clinical trials. *See* FDA, 2018, Guidance for Industry; Allergic Rhinitis: Developing Drug Products for Treatment, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/allergic-rhinitis-developing-drugproducts-treatment-guidance-industry (hereafter "FDA Guidance for Industry (2018)").

[24] See, e.g., **Gelotte**, CK and BA Zimmerman, 2015, Pharmacokinetics, safety, and cardiovascular tolerability of phenylephrine HCl 10, 20, and 30 mg after a single oral administration in healthy volunteers, Clin Drug Investig, 35(9):547-558; **Day**, JH, MP Briscoe, JD Ratz, M Danzig, and R Yao, 2009, Efficacy of loratadine-montelukast on nasal congestion in patients with seasonal allergic rhinitis in an environmental exposure unit, Ann Allergy Asthma Immunol, 102(4):328-338; **Horak**, F, P Zieglmayer, R Zieglmayer, P Lemell, R Yao, H Staudinger, and M Danzig, 2009, A placebo-controlled study of the nasal decongestant effect of phenylephrine and pseudoephedrine in the Vienna Challenge Chamber, Ann Allergy Asthma Immunol, 102(2):116-120; **Meltzer**, EO, PH Ratner, and T McGraw, 2015, Oral phenylephrine HCl for nasal congestion in seasonal allergic rhinitis: A randomized, open-label, placebo-controlled study, J Allergy Clin Immunol Pract, 3(5):702-708; (footnote continued)

- Horak et al (2009) found that PE was not significantly different from placebo in the mean change in subjective nasal congestion scores whereas pseudoephedrine, a positive control in the study, decreased congestion significantly greater than placebo and PE.
- Day et al (2009) similarly reported no difference between PE and placebo with respect to decreased nasal congestion scores.
- Gelotte and Zimmerman (2015) likewise reported a lack of local decongestion effect of PE, finding that doses up to three times the labeled OTC for oral phenylephrine are unlikely to be effective as a nasal decongestant.

35. Thus, the results of several studies reported after the initial efficacy determination of the Products in 2007 clearly demonstrate that PE is no more effective than placebo in decreasing nasal congestion and, thus, lacks efficacy.

Defendants Knew or Should Have Known that their PE OTC Product Claims Were Misleading and False

36. As of 2007, nasal airway resistance ("NAR") was the principle methodology used to assess the effectiveness of oral PE. This methodology used measurements of airflow and air pressure in the nasal passage to calculate NAR as an indirect measure of the level of nasal congestion.

37. However, in 2018, the FDA issued new guidance for industry as it related to the use of nasal congestion symptom scores to evaluate congestion,[25] meaning that NAR was no longer used as a primary endpoint to evaluate congestion in studies.

38. Based on the FDA's new 2018 guidance, Defendants knew or should have known that their marketing claims regarding the Products' efficacy were false and misleading. This is because the primary endpoint for evaluating the efficacy of the

Meltzer, EO, PH Ratner, and T McGraw, 2016, Phenylephrine hydrochloride modified-release tablets for nasal congestion: a randomized, placebo-controlled trial in allergic rhinitis patients, Ann Allergy Asthma Immunol, 116(1):66-71.

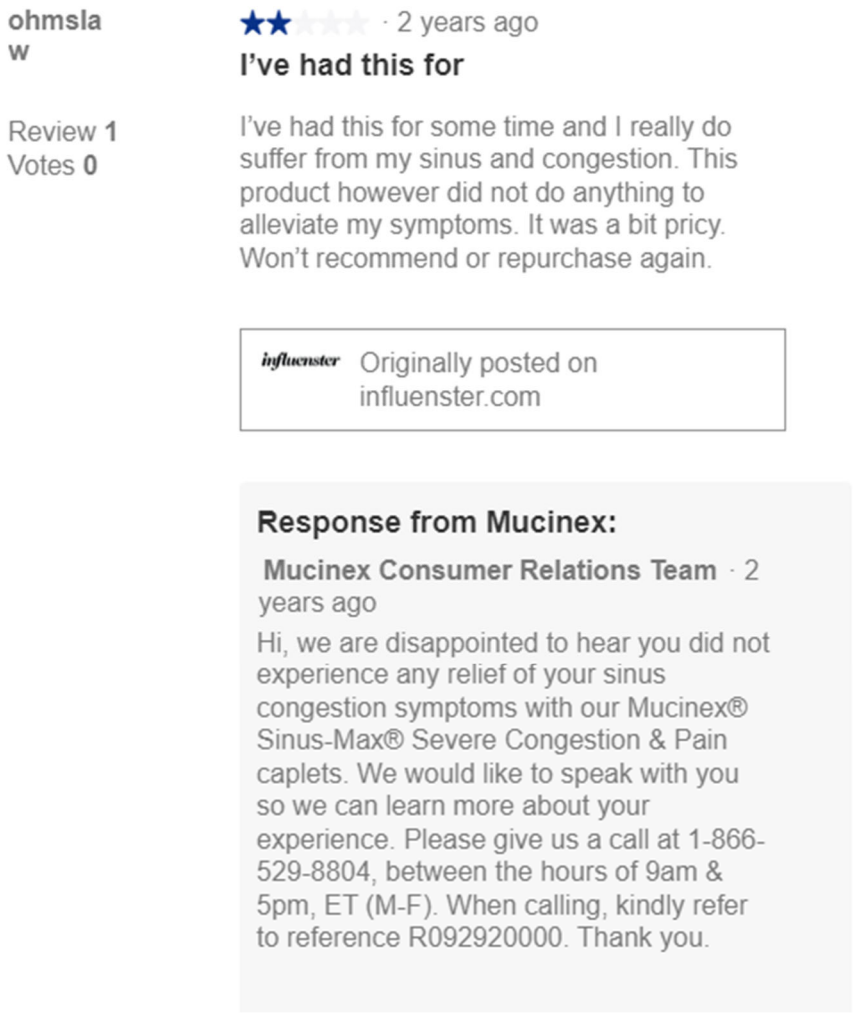
[25] FDA Guidance for Industry (2018).

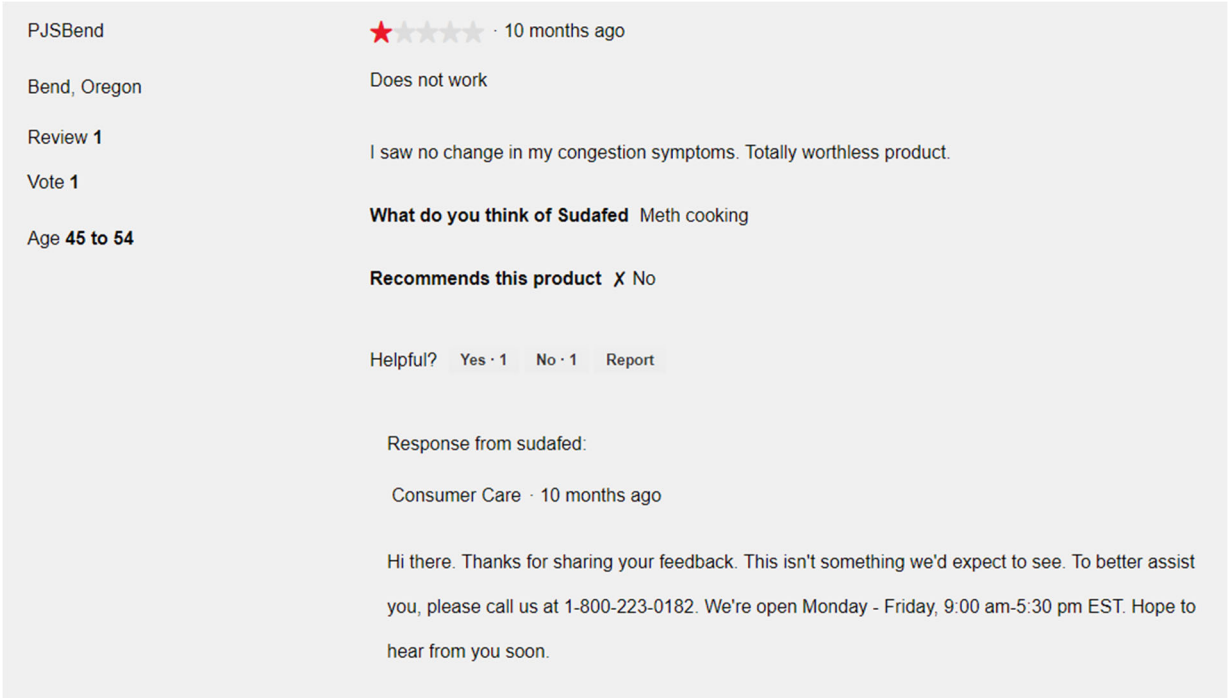
Products had changed since the FDA's 2007 NDAC meeting, meaning that the previous data under which the Products were approved as GRASE no longer supported efficacy.

39. Additionally, Defendants—as manufacturers of OTC PE-based Products—knew or should have known that there have been no published studies since the FDA's revised 2008 guidance for the industry released which demonstrate the effectiveness of oral PE as a decongestant. Rather, the body of scientific literature has consistently shown oral PE to be clinically ineffective.

40. Accordingly, Defendants knew or should have known by at least 2018 that their marketing claims regarding the Products' efficacy were false and misleading.

41. Additionally, consumers routinely reported that such products lacked efficacy via consumer complaints submitted, *inter alia,* on the Defendants' websites





PJSBend

Bend, Oregon

Review **1**

Vote **1**

Age **45 to 54**

★☆☆☆☆ · 10 months ago

Does not work

I saw no change in my congestion symptoms. Totally worthless product.

What do you think of Sudafed Meth cooking

Recommends this product ✗ No

Helpful? Yes · 1 No · 1 Report

Response from sudafed:

Consumer Care · 10 months ago

Hi there. Thanks for sharing your feedback. This isn't something we'd expect to see. To better assist you, please call us at 1-800-223-0182. We're open Monday - Friday, 9:00 am-5:30 pm EST. Hope to hear from you soon.

42. Plaintiff and the class members purchased the Products in reliance on Defendants' false and deceptive marketing claims.

43. As a result of Defendants' false and deceptive marketing, Plaintiff and the class members suffered economic damages, including the cost of purchasing the Products.

TOLLING OF THE STATUTE OF LIMITATIONS, FRAUDULENT CONCEALMENT, EQUITABLE TOLLING, AND CONTINUING VIOLATIONS

25. Plaintiff did not discover, and could not have discovered through the exercise of reasonable diligence, the existence of the claims sued upon herein until immediately prior to commencing this civil action.

26. Any applicable statutes of limitation have been tolled by Defendants' affirmative acts of fraudulent concealment and continuing misrepresentations, as the facts alleged above reveal.

27. Because of the self-concealing nature of Defendants' actions and their affirmative acts of concealment, Plaintiff and the Classes assert the tolling of any

applicable statutes of limitations affecting the claims raised herein.

28. Defendants continue to engage in the deceptive practice, and consequently, unwary consumers are injured on a daily basis by Defendants' unlawful conduct. Therefore, Plaintiff and the Classes submit that each instance that Defendants engaged in the conduct complained of herein and each instance that a member of any Class purchased Defendants' Product constitutes part of a continuing violation and operates to toll the statutes of limitation in this action.

29. Defendants are estopped from relying on any statute of limitations defense because of their unfair or deceptive conduct.

30. Defendants' conduct was and is, by its nature, self-concealing. Still, Defendants, through a series of affirmative acts or omissions, suppressed the dissemination of truthful information regarding their illegal conduct, and actively have foreclosed Plaintiff and the Classes from learning of their illegal, unfair, and/or deceptive acts. These affirmative acts included concealing that the Product is pasteurized.

31. By reason of the foregoing, the claims of Plaintiff and the Classes are timely under any applicable statute of limitations, pursuant to the discovery rule, the equitable tolling doctrine, and fraudulent concealment.

CLASS ALLEGATIONS

44. Plaintiff brings this action on behalf of herself and all other similarly situated class members (the "Class" or "Classes") pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Class against Defendants for violations of California state laws and/or similar laws in other states:

Multi-State Classes

The "McNeill/J&J Nationwide Class"
All consumers who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendants McNeill Consumer Healthcare/Kenvue in the United States of America and its territories from September 13, 2018, to the present for personal use or consumption.

The "P&G Nationwide Class"
All consumers who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Proctor & Gamble in the United States of America and its territories from September 13, 2018, to the present for personal use or consumption.

The "Reckitt Nationwide Class"
All consumers who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Reckitt Benckiser in the United States of America and its territories from September 13, 2018 to the present for personal use or consumption.

Excluded from the Classes are Defendants, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

45. In the alternative, Plaintiff brings this action on behalf of herself and all other similarly situated California consumers pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Sub-Classes:

California Sub-Classes

The "McNeill/J&J Nationwide Class"
All consumers who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendants McNeill Consumer Healthcare/Kenvue in the State of California from September 13, 2018, to the present for personal use or consumption.

The "P&G Nationwide Class"
All consumers who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Proctor & Gamble in the State of California from September 13, 2018, to the present for personal use or consumption.

California Reckitt Sub-Class

> All consumers who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Reckitt Benckiser in the State of California from September 13, 2018, to the present for personal use or consumption.
>
> Excluded from the Classes are Defendants, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

46. Plaintiff reserves the right to amend the definition as the case proceeds.

47. The members of the Class are so numerous that joinder of all members of the Class is impracticable. Plaintiff is informed and believes that the proposed Class/Sub-Classes contains thousands of purchasers of Defendants' Products who have been damaged by Defendants' conduct as alleged herein. The precise number of Class members is unknown to Plaintiff at this time.

48. Plaintiff's claims are typical to those of all Class members because members of the Class are similarly injured through Defendants' uniform misconduct described above and were subject to Defendants' deceptive marketing claims that accompanied each and every Product. Plaintiff is advancing the same claims and legal theories on behalf of h and all members of the Class/Sub-Class.

49. Plaintiff's claims raise questions of law and fact common to all members of the Class, and they predominate over any questions affecting only individual Class members. The claims of Plaintiff and all prospective Class members involve the same alleged defect. These common legal and factual questions include the following:

(a) whether Defendants' Products contained phenylephrine;

(b) whether Defendants' marketing statements are false, misleading, or objectively reasonably likely to deceive;

(c) whether the alleged conduct constitutes violations of the laws asserted;

(d) whether Defendants' alleged conduct violates public policy;

(e) whether Defendants engaged in false or misleading advertising;

(f) whether Defendants were unjustly enriched as a result of its labeling, marketing, advertising and/or selling of the Products;

(g) whether Plaintiff and the Class members are entitled to damages and/or restitution and the proper measure of that loss; and

(h) whether an injunction is necessary to prevent Defendants from continuing to market and sell Products that lack efficacy.

50. Plaintiff and his counsel will fairly and adequately protect and represent the interests of each member of the class. Plaintiff has retained counsel experienced in complex litigation and class actions. Plaintiff's counsel has successfully litigated other class action cases similar to that here and have the resources and abilities to fully litigate and protect the interests of the class. Plaintiff intends to prosecute this claim vigorously. Plaintiff has no adverse or antagonistic interests to those of the Class, nor is Plaintiff subject to any unique defenses.

51. A class action is superior to the other available methods for a fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by the Plaintiff and individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendants. It would thus be virtually impossible for Plaintiff and Class members, on an individual basis, to obtain meaningful and effective redress for the wrongs done to them. Further, it is desirable to concentrate the litigation of the Class members' claims in one forum, as it will conserve party and judicial resources and facilitate the consistency of adjudications. Plaintiff knows of no difficulty that would be encountered in the management of this case that would preclude its maintenance as a class action.

52. The Class also may be certified because Defendants have acted or refused to act on grounds applicable to the Class, thereby making appropriate final declaratory

and/or injunctive relief with respect to the members of the Class as a whole.

53. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent Defendant from engaging in the acts described above, such as continuing to market and sell Products that lack efficacy, and requiring Defendants to provide a full refund of the purchase price of the Products to Plaintiff and Class members.

54. Unless a Class is certified, Defendants will retain monies received as a result of their conduct that were taken from Plaintiff and the Class members. Unless a Class-wide injunction is issued, Defendants will continue to commit the violations alleged and the members of the Class and the general public will continue to be misled. Indeed, to this day, Defendants continues to market and sell the Products that have been determined by a unanimous FDA panel to lack efficacy.

FIRST CLAIM FOR RELIEF

False and Misleading Advertising in Violation of California Law

Business & Professions Code §17500, *Et Seq*.

(By Plaintiff Baughman and the California Class)

55. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

56. Plaintiff Baughman brings this Count individually on behalf of herself and on behalf of the California Class.

57. The California False Advertising Law prohibits the dissemination of any advertisement which is untrue or misleading, and which is known, or which by exercise of reasonable care should be known, to by untrue or misleading. Cal. Bus. & Prof. Code §17500.

58. At all material times, Defendants engaged in a scheme of offering ineffective oral PE nasal decongestants to Plaintiff Baughman and other members of the California Class by way of commercial marketing, advertising, internet content, and other promotional materials.

59. Defendants' conduct is substantially injurious to consumers. Consumers are purchasing using Defendants' Products without knowledge that they lack efficacy. This conduct has caused, and continues to cause, substantial injury to consumers because consumers would not have paid for nasal decongestant Products that do not work as advertised but for Defendants' false labeling, advertising, and promotion.

60. These materials, advertisements, and other inducements misrepresented and/or omitted the true nature of the ineffective Products as alleged herein. Specifically, in the course of Defendant's business, Defendant concealed and suppressed material facts, including that the so-called "active ingredient" phenylephrine is ineffective as a cold and cough decongestant medicine when taken orally. This information is not disclosed on Defendants' Products' label.

61. As set forth above, Defendant labels its products as providing relief for nasal congestion when, in fact, the Contaminated Products are no more effective than a placebo pill.

62. Defendant knew, or in the exercise of reasonable care should have known, that the statements regarding its advertisements and other inducements regarding its Products were false, misleading, and/or deceptive.

63. Yet, as demonstrated in the FDA's September 11-12, 2023 report and the clinical trials referenced herein, Defendant sold OTC nasal decongestant Products that failed to provide relief for cough and cold symptoms as advertised. Based on the FDA's 2018 guidance regarding NAR, as well as readily available scientific data, Defendant knew or should have known that its Products containing PE were ineffective as decongestant medicine.

64. The above acts of Defendants, in disseminating said misleading and deceptive statements throughout the State of California to consumers, including to Plaintiff Baughman and the other members of the California Class, were and are likely to deceive reasonable consumers by obfuscating the true nature of the so-called "active ingredient" in Defendants' PE-based decongestants, and thus were violations of Cal.

Bus. Prof. Code §§ 17500, *et seq*

65. Through its deceptive and/or misleading acts and practices, Defendants improperly obtained money from Plaintiff Baughman the other members of the California Class. But for Defendants' misrepresentations and omissions, Plaintiff and Class members would have paid nothing for Products that do not work as advertised. Indeed, there is no discernible "market" for an over-the-counter nasal decongestant that is no more effective than a placebo at decreasing congestion. As a result, the Defendant's Products are rendered valueless.

66. Pursuant to Business & Professions Code §§17203 and 17535, Plaintiff Baughman seeks, on behalf of herself and the other members of the California Class, an order of this Court awarding Plaintiff Baughman the other members of the California Class restitution of the money wrongfully acquired by Defendants and enjoining Defendants from continuing to violate California's False Advertising Law. Plaintiff Baughman further seeks prejudgment interest on the money wrongfully acquired and withheld by Defendants pursuant to California Civil Code §3287(a) and attorneys' fees and costs pursuant to California Code Civil Procedure §1021.5.

SECOND CLAIM FOR RELIEF

Unfair Businesses Practices in Violation of California Law

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

(By Plaintiff Baughman and the California Class)

67. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

68. Plaintiff Baughman brings this Count individually on behalf of herself and on behalf of the California Class.

69. California Business & Professions Code § 17200 prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising."

70. The acts and practices of Defendants as alleged herein constitute "unfair" business acts and practices under the California Unfair Competition Law in that

Defendants' conduct is unconscionable, immoral, deceptive, unfair, illegal, unethical, oppressive, and/or unscrupulous. Further, the gravity of Defendants' conduct outweighs any conceivable benefit of such conduct.

71. Defendants have been committing, and continue to commit, acts of unfair competition by engaging in the unlawful, unfair and fraudulent business practices and acts described in this Complaint, including, but not limited to:

a. Making false and misleading statements and material omissions including, as set forth above, representing that the Products provide relief from nasal congestion associated with colds, allergies, or sinus congestion when, in fact, they are no more effective than a placebo.

b. Concealing and failing to disclose the true nature of PE as ineffective for decongestion relief when taken orally, as demonstrated in the FDA's September 11-12, 2023 report and the scientific studies discussed herein;

c. Engaging in conduct, as alleged herein, where the utility of such conduct is outweighed by the gravity of the consequences to Plaintiff Baughman and other members of the California Class;

d. Engaging in conduct, as alleged herein, that is immoral, unethical, oppressive, unscrupulous, or substantially injurious to Plaintiff Baughman and other members of the California Class; and

e. Engaging in conduct, as alleged herein, that undermines or violates state consumer protection laws.

72. Plaintiff Baughman reserves the right to identify additional unfair, fraudulent, and unlawful practices by Defendants as further investigation and discovery warrants.

73. As a result of its unlawful, unfair, and/or fraudulent business acts and practices, Defendants have reaped and continue to reap unfair benefits and illegal profits at the expense of Plaintiff Baughman and other members of the California Class. Defendants' unlawful, unfair, and/or fraudulent conduct has also enabled Defendants to gain an unfair competitive advantage over their law-abiding competitors.

74. Plaintiff Baughman and other members of the California Class have suffered injury in fact and have lost money as a result of Defendants' unfair, fraudulent and unlawful business acts or practices because they purchased Products from Defendants in reliance on Defendants' misrepresentation that the Products were effective.

75. The above-described unfair business acts or practices present a threat and likelihood of harm and deception to Plaintiff Baughman other members of the California Class in that Defendants have systematically perpetrated the unfair, fraudulent and unlawful conduct upon members of the public by engaging in the conduct described herein, thereby making billions of dollars in profits from the sale of its ineffective phenylephrine-based Products.

76. Business and Professions Code §17203 provides that the Court may restore to an aggrieved party any money or property acquired by means of the unlawful, unfair, and/or fraudulent business acts or practices.

77. Plaintiff Baughman seeks, on behalf of herself and the other members of the California Class, an order of this Court awarding Plaintiff Baughman and the other members of the California Class restitution of the money wrongfully acquired by Defendants and enjoining Defendants from the unlawful, unfair, and/or fraudulent activity alleged herein. Plaintiff Baughman further seeks prejudgment interest on the money wrongfully acquired and withheld by Defendants pursuant to California Civil Code §3287(a) and attorneys' fees and costs pursuant to California Code Civil Procedure §1021.5.

THIRD CLAIM FOR RELIEF

Violation of the California Consumers Legal Remedies Act

California Civil Code §1750, *et seq*.

(By Plaintiff Baughman and the California Class)

78. Plaintiff re-alleges and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

79. Plaintiff Baughman brings this Count individually on behalf of herself and

on behalf of the California Class.

80. The California Consumers Legal Remedies Act was enacted to protect consumers against unfair and deceptive business practices. The California Consumers Legal Remedies Act declares unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or that results in the sale or lease of goods to any consumer as unlawful. Cal. Civ. Code § 1770(a).

81. Plaintiff Baughman and the members of the California Class are "consumers" within the meaning of section 1761(d) of the California Civil Code, and engaged in "transactions" within the meaning of sections 1761(e) and 1770 of the California Civil Code, including the purchases of the ineffective phenylephrine-based Products.

82. The Products purchased by Plaintiff Baughman and the members of the California Class constitute "goods" under Civil Code §1761(a).

83. Defendants' conduct of manufacturing, producing, and selling the ineffective PE-based decongestant Products as alleged herein violates the California Consumers Legal Remedies Act including, but not limited to:

> (2) Misrepresenting the source, sponsorship, approval, or certification of goods or services; …
>
> (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have; …
>
> (6) Representing that goods are original or new if they have deteriorated unreasonably or are altered, reconditioned, reclaimed, used, or secondhand; …
>
> (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;
>
> (9) Advertising goods or services with intent not to sell them as advertised; and

> (14) Representing that a transaction confers or involves rights, remedies, or obligations that it does not have or involve, or that are prohibited by law.

Cal. Civ. Code § 1770.

84. Defendants fraudulently deceived Plaintiff Baughman and the members of the California Class by representing that the Products have certain characteristics, benefits, uses and qualities which they do not have. In doing so, Defendants intentionally misrepresented and concealed material facts from Plaintiff Baughman and the members of the California Class, including but not limited to that the Products provide meaningful, measurable relief from nasal decongestion when in reality the Products are no more effective than a placebo at decreasing congestion. Said misrepresentations and concealment were done with the intention of deceiving Plaintiff Baughman and the members of the California Class and depriving them of their legal rights and money. Plaintiff Baughman and the members of the California Class reasonably relied upon misrepresentations, misleading statements, deceptive practices, omissions, and false promises by Defendants, which resulted in injury to them.

85. Defendants knew or should have known that phenylephrine—the so-called "active" ingredient in the Products—did not provide consumers with any relief from nasal congestion, as demonstrated by the FDA's 2023 report and readily available scientific data.

86. Defendant concealed and suppressed material facts, including that orally administered phenylephrine is demonstrably ineffective for providing any decongestive relief. This information was not disclosed on the Products' label.

87. Defendants' violations of Civil Code § 1770 as described above present a continuing threat to the members of the California Class and members of the public in that Defendants continue to engage in these practices, and will not cease until an injunction is issued by the Court.

88. Plaintiff Baughman and the members of the California Class have suffered ascertainable losses of money because of Defendants' unlawful conduct. The actual

out-of-pocket losses of Plaintiff Baughman and the members of the California Class were proximately caused by Defendants' violations of the California Consumers Legal Remedies Act.

89. Pursuant to California Civil Code §1780(a) of the California Consumers Legal Remedies Act, Plaintiff Baughman seeks injunctive relief in the form of an order enjoining the above-described wrongful acts and practices of Defendants including, but not limited to, an order enjoining Defendants from distributing such false advertising and misrepresentations. Plaintiff Baughman and the members of the California Class shall be irreparably harmed if such an order is not granted.

90. Plaintiff Baughman is in the process of complying with the requirements of California Civil Code §1782(a) and thus, does not yet seek damages under the California Consumers Legal Remedies Act or attorneys' fees and costs pursuant to California Civil Code §1780(d). However, Plaintiff Baughman intends to amend her complaint to add such claims once she has so complied.

FOURTH CAUSE OF ACTION

UNJUST ENRICHMENT

(By Plaintiff Baughman behalf of herself, the California Classes and the Multi-State Classes

Against all Defendants)

91. Plaintiff Baughman repeats and realleges the allegations set forth in the preceding paragraphs and incorporates the same as if set forth herein at length.

92. Plaintiff Baughman brings this claim individually, as well as on behalf of members of the Multi-State Classes and California Classes pursuant to California law. Although there are numerous permutations of the elements of the unjust enrichment cause of action in the various states, there are few real differences. In all states, the focus of an unjust enrichment claim is whether the Defendants was unjustly enriched. At the core of each state's law are two fundamental elements – the defendant received a benefit from the Plaintiff and the members of the Multi-State and California Classes and it would be inequitable for the Defendants to retain that benefit without

compensating the Plaintiffs. The focus of the inquiry is the same in each state. Since there is no material conflict relating to the elements of unjust enrichment between the different jurisdictions from which class members will be drawn, California law applies to the claims of the Class.

93. In the alternative, Plaintiff Baughman brings this claim individually as well as on behalf of the California Classes.

94. At all times relevant hereto, Defendants deceptively labeled, marketed, advertised, and sold the Products to Plaintiff Baughman and the Multi-State and California Classes.

95. The Plaintiff and members of the Multi-State and California Classes conferred upon Defendants non-gratuitous payments for Products that they would not have due to Defendants' deceptive labeling, advertising, and marketing. Defendants accepted or retained the non-gratuitous benefits conferred by the Plaintiff and members of the Multi-State and California Classes, with full knowledge and awareness that, as a result of Defendants' deception, Plaintiff and members of the Multi-State and California Class were not receiving a product of the quality, nature, fitness, or value that had been represented by Defendants and reasonable consumers would have expected.

96. Defendants have been unjustly enriched in retaining the revenues derived from purchases of the Products by Plaintiff and members of the Multi-State and California Classes, which retention under these circumstances is unjust and inequitable because the Products are ineffective.

97. Retaining the non-gratuitous benefits conferred upon Defendants by the Plaintiff and members of the Multi-State and California Classes under these circumstances made Defendants' retention of the non-gratuitous benefits unjust and inequitable. Thus, Defendants must pay restitution to the Plaintiff and members of the Multi-State and California Classes for their unjust enrichment, as ordered by the Court.

/ / /

FIFTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

(By Plaintiff on Behalf of Herself and the California Classes and the Multi-State Classes Against All Defendants)

98. Plaintiff repeats and realleges the allegations set forth in the preceding paragraphs and incorporates the same as if set forth herein at length.

99. Plaintiff brings this Count individually under the laws of California and on behalf of the Multi-State Classes (in states having similar laws regarding implied warranties).

100. The Uniform Commercial Code §2-314 provides that unless excluded or modified, a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. This implied warranty of merchantability acts as a guarantee by the seller that his goods are fit for the ordinary purposes for which they are to be used.

101. The Uniform Commercial Code §2-314 provides that "[g]oods to be merchantable must be at least such as…. Are adequately contained, packaged, and labeled as the agreement may require…[and] conform to the promises or affirmations of fact made on the container or label if any." Cal.Com.Code § 2314(2)(f).

102. Defendants are in the business of manufacturing, marketing, advertising, warranting, and selling the Products. Defendants impliedly warranted to Plaintiffs (and to Plaintiffs' agents) that the Products were of a certain quality, free from defects and fit for the ordinary purpose for which they were sold and confirmed to the standards of trade.

103. But the Products are in fact unfit for ordinary use and were not of merchantable quality as warranted by Defendants.

104. Defendants have failed to provide adequate remedies under their implied warranties, which have caused these implied warranties to fail their essential purpose, thereby permitting remedies under these implied warranties.

105. Defendants have not sufficiently (meaning specifically and conspicuously)

disclaimed the implied warranty of merchantability.

106. At all times, the following states listed below, including the District of Columbia, have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability:

a. Ala. Code §7-2-314;

b. Alaska Stat. §45.02.314;

c. Ariz. Rev. Stat. Ann. §47-2314;

d. Ark. Code Ann. §4-2-314;

e. Cal. Com. Code §2314;

f. Colo. Rev. Stat. §4-2-314;

g. Conn. Gen. Stat. Ann. §42a-2-314;

h. Del. Code Ann. tit. 6 §2-314;

i. D.C. Code §28:2-314;

j. Fla. Stat. §672.314;

k. Ga. Code Ann. §11-2-314;

l. Haw. Rev. Stat. §490:2-314;

m. Idaho Code §28-2-314;

n. 810 Ill. Comp. Stat. Ann. 5/2-314;

o. Ind. Code Ann. §26-1-2-314;

p. Iowa Code Ann. §554.2314;

q. Kan. Stat. Ann. §84-2-314;

r. Ky. Rev. Stat. Ann. §355.2-314;

s. La. Civ. Code Ann. art. §2520;

t. Me. Rev. Stat. Ann. 11 §2-314;

u. Md. Code Ann. Com. Law §2-314;

v. Mass. Gen. Laws Ch. 106 §2-314;

w. Mich. Comp. Laws Ann. §440.2314;

x. Minn. Stat. Ann. §336.2-314;

y. Miss. Code Ann. §75-2-314;

z. Mo. Rev. Stat. §400.2-314;

aa. Mont. Code Ann. §30-2-314;

bb. Nev. Rev. Stat. §104.2314;

cc. N.H. Rev. Stat. Ann. §382-A:2-314;

dd. N.J. Stat. Ann. §12A:2-314;

ee. N.M. Stat. Ann. §55-2-314;

ff. N.Y. U.C.C. Law §2-314;

gg. N.D. Cent. Code §41-02-314;

hh. Okla. Stat. Ann. tit. 12A §2-314;

ii. Or. Rev. Stat. §72.3140;

jj. Pa. Stat. Ann. tit. 13 §2314;

kk. R.I. Gen. Laws §6A-2-314;

ll. S.C. Code Ann. §36-2-314;

mm. S.D. Codified Laws §57A-2-314;

nn. Tenn. Code Ann. §47-2-314;

oo. Tex. Bus. & Com. Code Ann. §2-314;

pp. Utah Code Ann. §70A-2-314;

qq. Va. Code Ann. §8.2-314;

rr. Vt. Stat. Ann. tit. 9A §2-314;

ss. W. Va. Code §46-2-314;

tt. Wash. Rev. Code §62A 2-314;

uu. Wis. Stat. Ann. §402.314; and

vv. Wyo. Stat. Ann. §34.1-2-314.

107. As developer, manufacturer, producer, advertiser, marketer, seller and/or distributor of the Products, Defendants are "merchants" within the meaning of the various states' commercial codes governing the implied warranty of merchantability.

108. Further, Defendants are merchants with respect to the Products.

Defendants developed, manufactured, produced, advertised, marketed, sold, and/or distributed the Products.

109. The Products can be classified as "goods," as defined in the various states' commercial codes governing the implied warranty of merchantability.

110. As a merchant of the Products, Defendants knew that purchasers relied upon them to develop, manufacture, produce, sell, and distribute a decongestant, as promised.

111. Defendants developed, manufactured, produced, sold, and distributed the Products to consumers such as Plaintiff and the Classes. They knew that the Products would be used as as promised.

112. Defendants breached their implied warranties in connection with the sale of the Products to Plaintiff and members of the Classes. The Products are neither adequately represented nor conform to the promises or affirmations of fact.

113. Defendants had actual knowledge that the Products were ineffective, and Plaintiff therefore was not required to notify Defendants of their breach. If notice is required, Plaintiff and the Classes adequately have provided Defendants of such notice through the filing of this lawsuit.

114. Plaintiff gave Defendants actual or constructive notice of the breaches of these warranties, and Defendants have failed to cure these breaches.

115. As a direct and proximate result of the breaches of these implied warranties, Plaintiff and the members of the Classes have suffered damages, injury in fact and ascertainable loss in an amount to be determined at trial, including repair and replacement costs and damages to other property. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff and other members of the Classes have been injured. Plaintiff and the other members of the Classes would not have purchased the Products but for Defendants' representations and warranties. Defendants misrepresented the character of the Products, which caused injuries to Plaintiff and the other members of the Classes because either they paid a price premium

due to the deceptive representations or they purchased products that were not of a character and fitness as promised and therefore had no value to Plaintiff and the other members of the Classes.

116. Plaintiff demands judgment against Defendants for compensatory damages for themselves and each class member, for the establishment of a common fund, plus additional remedies as this Court deems fit.

SIXTH CAUSE OF ACTION

VIOLATION OF MAGNUSON-MOSS WARRANTY ACT

(By Plaintiff on behalf of the Multi-State Class and/or, alternatively, the Consumer Protection Class Against All Defendants)

117. Plaintiff repeats and realleges the allegations set forth in the preceding paragraphs and incorporates the same as if set forth herein at length.

118. Plaintiff seeks to represent the proposed Multi-State Class or, alternatively, the Consumer Protection Subclass.

119. Congress enacted the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 et seq., in response to widespread consumer complaints regarding misleading and deceptive warranties. The Act imposes civil liability on any "warrantor" for failing to comply with any obligation under written and implied warranties. 15 U.S.C. § 2310(d)(1).

120. The Products are a "consumer product," as defined by § 2301(1).

121. Plaintiff, the members of the Multi-State Classes, and the members of the California Subclasses are "consumers" as defined by § 2301(3).

122. Defendants are "warrantors" and "suppliers" as defined by §§ 2301(4) and (5)..

123. Defendants' warranty limitations are not sufficiently set apart by underlining or highlighting. This lack of conspicuousness violates the Act and fails to meet minimum federal warranty standards; thus, the warranty limitations are not enforceable. See §§ 2302(a), 2304(a)(3), 2308(a), and 2308(c). The warranty limitations are also unconscionable as a matter of law under U.C.C. § 2-302, as adopted

by the class jurisdictions.

124. At the time Defendants issued written warranties for the Products, Defendants knew and had notice that the Products were ineffective. Defendants' continued misrepresentations and omissions concerning the products, as well as Defendants' failure to abide by their own written and implied warranties, are "[u]nfair methods of competition in or affecting commerce, and [are] unfair or deceptive acts or practices in or affecting commerce." Accordingly, Defendants' behavior is unlawful under 15 U.S.C. §§ 2310(b), 45(a)(1).

125. Plaintiff seeks to recover damages caused as a direct result of Defendants' breach of their written and implied warranties and their deceitful and unlawful conduct. Damages include labor and costs associated with replacement of the Product and other property damaged thereby.

126. The Act also provides for "other legal and equitable" relief. 15 U.S.C. § 2310(d)(1). Accordingly, Plaintiff seeks reformation of Defendants' written warranty to comport with Defendants' obligations under the Act and with consumers' reasonable expectations. Additionally, Plaintiffs seek to enjoin Defendants from acting unlawfully as further alleged, including discouraging Plaintiffs to seek all available remedies.

127. The Act also provides for an award of costs and expenses, including attorneys' fees, to prevailing consumers in the Court's discretion. 15 U.S.C. § 2310(d)(2). Plaintiff intends to seek such an award as a prevailing consumer at the conclusion of this case.

SEVENTH CAUSE OF ACTION

VIOLATIONS OF CONSUMER FRAUD LAWS

(By Plaintiff, on Behalf of Herself, the California Classes, and the Multi-State Classes against All Defendants)

128. Plaintiff repeats and realleges the allegations set forth in the preceding paragraphs and incorporates the same as if set forth herein at length.

129. Plaintiff brings this Count individually under the laws of the state where she purchased the Products and on behalf of all other persons who purchased the

Products in states having similar laws regarding consumer fraud and deceptive trade practices.

130. Plaintiff and each of the other members of the Classes are consumers, purchasers, or other persons entitled to the protection of the consumer protection laws of the state in which they purchased the Product.

131. The consumer protection laws of the State in which Plaintiff and the other members of the Classes purchased the Product declare that unfair or deceptive acts or practices, in the conduct of trade or commerce, are unlawful.

132. The following States and the District of Columbia have enacted statutes designed to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising and that allow consumers to bring private and/or class actions. These statutes are found at:

a. Alabama Deceptive Trade Practices Act, Ala. Code §8-19-1 *et seq.*;

b. Alaska Unfair Trade Practices and Consumer Protection Act, Alaska Code §45.50.471 *et seq.*;

c. Arkansas Deceptive Trade Practices Act, Ark. Code Ann. §4-88-101 *et seq.*;

d. Arizona Consumer Fraud Act, A.R.S. §44-1521 *et seq.*;

e. California Consumer Legal Remedies Act, Cal. Civ. Code §1750 *et seq.*, and California's Unfair Competition Law, Cal. Bus. & Prof. Code §17200 *et seq.*;

f. Colorado Consumer Protection Act, Colo. Rev. Stat. §6-1-101 *et seq.*;

g. Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §42-110a *et seq.*;

h. Delaware Deceptive Trade Practices Act, Del. Code tit. 6§2511 *et seq.*;

i. District of Columbia Consumer Protection Procedures Act, D.C. Code §28 3901 *et seq.*;

j. Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §501.201 *et seq.*;

k. Georgia Fair Business Practices Act, Ga. Code Ann. §10-1-390 *et seq.*;

l. California Unfair and Deceptive Practices Act, California Revised Statues §480-1 *et seq.*, and California Uniform Deceptive Trade Practices Act, Haw. Rev. Stat. §481A-1 *et seq.*;

m. Idaho Consumer Protection Act, Idaho Code Ann. §48-601 *et seq.*;

n. Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. Ann. 505/1 *et seq.*;

o. Kansas Consumer Protection Act, Kan. Stat. Ann §50 626 *et seq.*;

p. Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §367.110 *et seq.*, and the Kentucky Unfair Trade Practices Act, Ky. Rev. Stat. Ann §365.020 *et seq.*;

q. Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §51:1401 *et seq.*;

r. Maine Unfair Trade Practices Act, Me. Rev. Stat. tit. 5 §205A *et seq.*, and Maine Uniform Deceptive Trade Practices Act, Me. Rev. Stat. Ann. tit. 10, §1211 *et seq.*,

s. Massachusetts Unfair and Deceptive Practices Act, Mass. Gen. Laws ch. 93A;

t. Michigan Consumer Protection Act, Mich. Comp. Laws §445.901 *et seq.*;

u. Minnesota Prevention of Consumer Fraud Act, Minn. Stat. Ann.§325F.68 *et seq.,* and Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. §325D.43 *et seq.*;

v. Mississippi Consumer Protection Act, Miss. Code Ann. §§75-24-1 *et seq.*;

w. Missouri Merchandising Practices Act, Mo. Rev. Stat. §407.010 *et seq.*;

x. Montana Unfair Trade Practices and Consumer Protection Act, Mont. Code Ann. §30-14-101 *et seq.*;

y. Nebraska Consumer Protection Act, Neb. Rev. Stat. §59-1601 *et seq.*,

and the Nebraska Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. §87-301 *et seq.*;

z. Nevada Trade Regulation and Practices Act, Nev. Rev. Stat. §598.0903 *et seq.*;

aa. New Hampshire Consumer Protection Act, N.H. Rev. Stat. §358-A:1 *et seq.*;

bb. New Jersey Consumer Fraud Act, N.J. Stat. Ann. §56:8 1 *et seq.*;

cc. New Mexico Unfair Practices Act, N.M. Stat. Ann. §57 12 1 *et seq.*;

dd. New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §349 *et seq.*;

ee. North Dakota Consumer Fraud Act, N.D. Cent. Code §51 15 01 *et seq.*;

ff. Ohio Consumer Sales Practices Act, Ohio Rev. Code Ann. §1345.02 and 1345.03; Ohio Admin. Code §109:4-3-02, 109:4-3-03, and 109:4-3-10;

gg. Oklahoma Consumer Protection Act, Okla. Stat. tit. 15 §751 *et seq.*;

hh. Oregon Unfair Trade Practices Act, Ore. Rev. Stat §646.608(e) & (g);

ii. Rhode Island Unfair Trade Practices And Consumer Protection Act, R.I. Gen. Laws §6-13.1-1 *et seq.*;

jj. South Carolina Unfair Trade Practices Act, S.C. Code Ann. §39-5-10 *et seq.*;

kk. South Dakota's Deceptive Trade Practices and Consumer Protection Law, S.D. Codified Laws §§37 24 1 *et seq.*;

ll. Tennessee Consumer Protection Act, Tenn. Code Ann. §47-18-101 *et seq.*;

mm. Texas Deceptive Trade Practice Act, V.T.C.A., Tex. Bus. & Com. Code Ann. § 17.41 *et. seq.*;

nn. Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §2451 *et seq.*;

oo. Washington Consumer Fraud Act, Wash. Rev. Code §19.86.010 *et seq.*;

pp. West Virginia Consumer Credit and Protection Act, West Virginia Code §46A-6-101 *et seq.*; and

qq. Wisconsin Deceptive Trade Practices Act, Wis. Stat. §100.18 *et seq.*

133. The products constitute a product to which these consumer protection laws apply.

134. In the conduct of trade or commerce regarding its production, marketing, and sale of the Products, Defendants engaged in one or more unfair or deceptive acts or practices including, but not limited to, uniformly representing to Plaintiff and each member of the Classes that the products are effective decongestants.

135. Defendants' representations and omissions were false, untrue, misleading, deceptive, and/or likely to deceive.

136. Defendants knew, or should have known, that their representations and omissions were false, untrue, misleading, deceptive, and/or likely to deceive.

137. Defendants used or employed such deceptive and unlawful acts or practices with the intent that Plaintiffs and members of the Classes rely thereon.

138. Plaintiff and the other members of the Classes did so rely.

139. Plaintiff and the other members of the Classes purchased the Products produced by Defendants which misrepresented the characteristics and nature of the Products.

140. Plaintiff and the other members of the Classes would not have purchased the Product but for Defendants' deceptive and unlawful acts.

141. As a result of Defendants' conduct, Plaintiff and the other members of the Classes sustained damages in amounts to be proven at trial.

142. Defendants' conduct showed complete indifference to, or conscious disregard for, the rights and safety of others such that an award of punitive and/or statutory damages is appropriate under the consumer protection laws of those states that permit such damages to be sought and recovered.

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EIGHT CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(By Plaintiff, on Behalf of Herself, the California Classes and the Multi-State Classes against all Defendants)

143. Plaintiff repeats and realleges the allegations set forth in the preceding paragraphs, and incorporates the same as if set forth herein at length.

144. As discussed above, Defendants misrepresented the efficacy and qualities of their Products.

145. At the time Defendants made these representations, Defendants knew or should have known that these representations were false or made them without knowledge of their truth or veracity.

146. In making representations of fact to Plaintiff and the members of the California and the Multi-State Classes about the Products, Defendants failed to fulfill their duty to disclose the material facts alleged above. Such failure to disclose on the part of Defendants amounts to negligent misrepresentation.

147. At an absolute minimum, Defendants negligently misrepresented and/or negligently omitted material facts about the Products.

148. The negligent misrepresentations and omissions made by Defendants, upon which Plaintiff and Class members reasonably and justifiably relied, were intended to induce, and actually induced Plaintiff and Class members to purchase the Product.

149. Plaintiff and Class members would not have purchased the Product or would not have purchased the products on the same terms if the true facts had been known.

150. Plaintiff and the other members of the California Classes, as a direct and proximate cause of Defendants' negligent misrepresentations, reasonably relied upon such misrepresentations to their detriment. By reason thereof, Plaintiff and the other Class members have suffered damages in an amount to be proven at trial.

PRAYER FOR RELIEF[26]

WHEREFORE, Plaintiff, on behalf of herself and all others similarly situated, pray for judgment against the Defendants as to each and every count, including:

A. An order declaring this action to be a proper class action, appointing Plaintiff and her counsel to represent the Class, and requiring Defendants to bear the costs of class notice;

B. An order enjoining Defendants from selling the Products;

C. An order enjoining Defendants from suggesting or implying that they are effective for human application;

D. An order requiring Defendants to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief, such as recalling existing Products;

E. An order awarding declaratory relief, and any further retrospective or prospective injunctive relief permitted by law or equity, including enjoining Defendants from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendants' past conduct;

F. An order requiring Defendants to pay restitution/damages to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, untrue or misleading advertising in violation of the above-cited authority, plus pre- and post-judgment interest thereon;

G. An order requiring Defendants to disgorge any ill-gotten benefits received from Plaintiff and members of the Class as a result of any wrongful or unlawful act or practice;

H. An order requiring Defendants to pay all actual and statutory damages permitted under the counts alleged herein;

I. An order awarding attorneys' fees and costs to Plaintiff and the Class; and

[26] Presently, as regards her third cause of action for violation of the Consumer Legal Remedies Act, Plaintiff does not seek monetary damages for such claim. Plaintiff intends however to amend her complaint to add a prayer for such damages once she has complied with the notice requirements.

J. An order providing for all other such equitable relief as may be just and proper.

DEMAND FOR JURY TRIAL

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

DATED: September 15, 2023

BRADLEY/GROMBACHER, LLP

By: _____

Marcus Bradley, Esq.
Kiley Grombacher, Esq.
Lirit King, Esq.
Attorneys for Plaintiff and others similarly situated