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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

NATASHA HERNANDEZ, individually and on behalf of all others similarly situated,

Plaintiff,

v.

KENVUE, INC., MCNEIL CONSUMER HEALTHCARE, and JOHNSON & JOHNSON CONSUMER, INC.,

Defendants.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Natasha Hernandez ("Plaintiff") brings this action on behalf of herself and all others similarly situated against Defendants Kenvue Inc., McNeil Consumer Healthcare, and Johnson & Johnson Consumer, Inc. (collectively, "Defendants"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to allegations specifically pertaining to herself and her counsel, which are based on personal knowledge.

NATURE OF THE ACTION

1. Nasal decongestants are over-the-counter medications that are marketed to alleviate sinus pressure and sinus congestion.

2. Defendants have made millions of dollars selling their nasal decongestant products. Defendants' products include the following oral tablets and/or caplets: 1) Sudafed PE Sinus Congestion; 2) Sudafed PE Head Congestion + Mucus; 3) Sudafed PE Sinus Pressure + Pain; 4) Sudafed PE Head Congestion + Pain; 5) Sudafed PE Head Congestion + Flu Severe; and 6) Sudafed PE Sinus Congestion Day + Night (collectively, the "Products").

3. Defendants market the Products as having the ability to provide relief to "Sinus Pressure," "Sinus Congestion," "Nasal Congestion," and/or "Nasal Swelling."

4. Defendants attribute the Products' ability to provide nasal decongestion relief to the inclusion of one active ingredient: Phenylephrine ("PE").

5. PE, however, is ineffective at providing nasal decongestion relief when it is taken orally.

6. Indeed, on September 12, 2023, an advisory panel to the U.S. Food & Drug Administration ("FDA") unanimously agreed (16-0) that oral PE is not effective at relieving nasal congestion.

7. Accordingly, Defendants' marketing and advertising concerning the Products is false, misleading, and likely to deceive the public.

8. Plaintiff asserts claims on behalf of herself and similarly situated purchasers of Defendants' Products for violations of the California Consumers Legal Remedies Act ("CLRA"),

Civil Code §§ 1750, *et seq.*, Unfair Competition Law ("UCL"), Bus. & Prof. Code §§ 17200, *et seq.*, False Advertising Law ("FAL"), Bus. & Prof. Code §§ 17500, *et seq.*,, breach of implied warranty of merchantability, and unjust enrichment.

PARTIES

9. Plaintiff is a resident of Pittsburg, California, has an intent to remain there, and is therefore a domiciliary of California.

10. Plaintiff purchased the Sudafed Head Congestion + Mucus product multiple times. Her most recent purchase was on approximately August 31, 2023, at a Rite Aid in Pleasant Hill, California. Before purchasing the Product, Plaintiff reviewed information about the Product, including the representation that the Product would be able to provide nasal congestion relief. When reviewing the Product label, disclosures, warranties, and marketing materials, Plaintiff understood them as representations and warranties by Defendants that the Product would be able to provide nasal decongestion relief.

11. Plaintiff relied on Defendants' representations and warranties in deciding to purchase the Product over other nasal decongestant products. Accordingly, Defendants' representations and warranties were part of the basis of the bargain, in that she would not have purchased the Product on the same terms had she known Defendants' representations were not true.

12. Contrary to the representations on the Products' marketing materials, the Products were not able to provide nasal decongestion relief. Plaintiff therefore did not receive the benefit of her bargain.

13. Defendant Kenvue Inc. is an American consumer health company, and formerly the consumer healthcare division of Johnson & Johnson. Kenvue is headquartered in Skillman, New Jersey. It wholly owns Defendant McNeil Consumer Healthcare.

14. Defendant McNeil Consumer Healthcare is wholly owned by Defendant Kenvue, with headquarters in Fort Washington, Pennsylvania. Defendant McNeil Consumer Healthcare manufactures and markets the Products throughout the state of California and the United States.

15. Defendant Johnson & Johnson Consumer, Inc. is a New Jersey based medical

corporation, with its headquarters in New Brunswick, New Jersey. Defendant Johnson & Johnson Consumer, Inc. manufactures, markets, and sells the Products throughout the state of California and the United States.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d)(2)(A) because this case is a class action where the aggregate claims of all members of the proposed class are in excess of $5,000,000.00, exclusive of interest and costs, there are over 100 members of the putative class, and Plaintiff, as well as most members of the proposed class, are citizens of states different than Defendants.

17. The Court has personal jurisdiction over Defendants because Defendants conduct substantial business within California, such that Defendants have significant, continuous, and pervasive contacts with the State of California. Moreover, Defendants have purposefully availed themselves of the laws and benefits of doing business in California, and Plaintiff's claims arise out of the Defendants' forum-related activities.

18. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because Defendants transact significant business within this District and because Plaintiff purchased and used the Products in this District.

FACTUAL ALLEGATIONS

The Market For Decongestants

19. The market for products that allegedly relieve nasal congestion is worth over $2 billion annually and includes over 250 products.

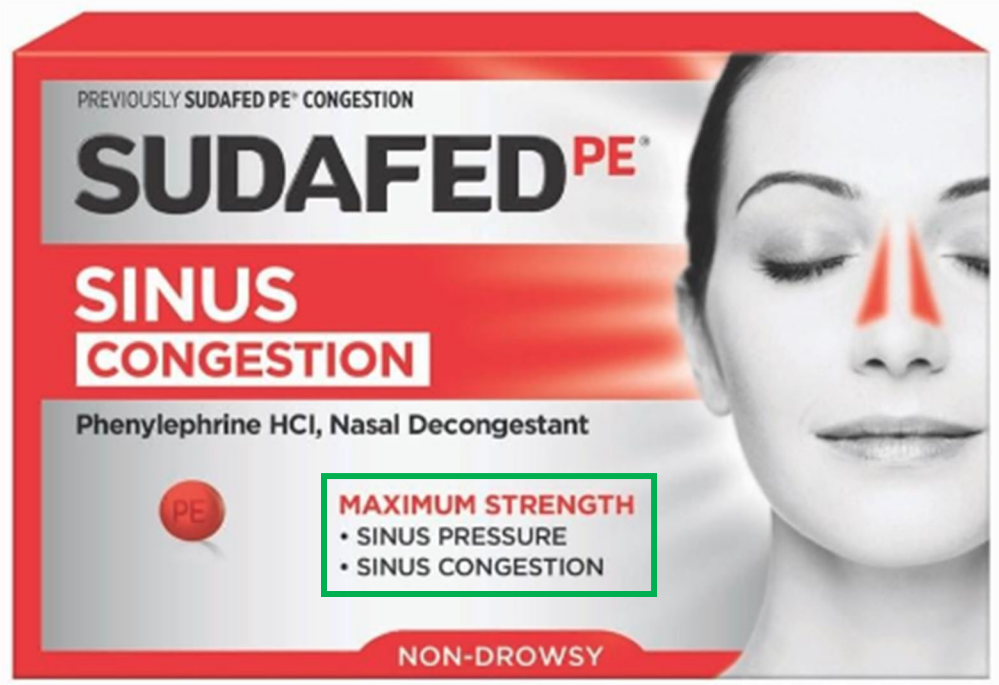
20. The two leading ingredients used to provide relief from nasal congestion are PE and pseudoephedrine. These active ingredients are sold as the only active ingredient in some products, and as one of the active ingredients in multi-symptom products.

21. While pseudoephedrine is effective as a nasal decongestant when taken orally, PE accounts for approximately 80% of the market for over-the-counter decongestants. In the last year alone, nearly $1.8 billion of PE-based decongestants were sold.

Defendants' False Advertising

22. Defendants market, sell, and distribute the Products through numerous brick-and-mortar stores as well as online. On the Products packaging, Defendants represent that the Products are able to provide relief to "Sinus Pressure," "Sinus Congestion," "Nasal Congestion," and "Nasal Swelling."

23. By way of example, the Products include, but are not limited to, those depicted by below:


PREVIOUSLY SUDAFED PE® CONGESTION
SUDAFED PE®
SINUS
CONGESTION
Phenylephrine HCl, Nasal Decongestant
PE
MAXIMUM STRENGTH
• SINUS PRESSURE
• SINUS CONGESTION
NON-DROWSY


SUDAFED PE®
HEAD CONGESTION
+ PAIN
Ibuprofen 200 mg, Phenylephrine Hydrochloride 10 mg Tablets
ONE CAPLET DOSE!
Pain Reliever/Fever Reducer (NSAID),
Nasal Decongestant
SU-PE
• NASAL CONGESTION
• SINUS PRESSURE
• NASAL SWELLING
• HEADACHE
• FEVER
• BODY ACHES
NON-DROWSY

24. By representing that the Products are effective remedies for "Sinus Pressure," "Sinus Congestion," "Nasal Congestion," and "Nasal Swelling," Defendants induced reasonable consumers, such as Plaintiff and the proposed class members into believing that the Products were effective at providing nasal decongestion relief. Those representations, however, are false and misleading, as set forth in greater detail below.

The Products' Use of Phenylephrine

25. Defendants' Products all attribute the ability to provide nasal decongestion relief to one active ingredient: PE.

26. Defendants do not attribute nasal decongestant relief to any other ingredient in the Products.

Phenylephrine Does Not Provide Nasal Decongestant Relief When Taken Orally

27. PE is ineffective at providing nasal decongestant relief when taken orally. All available scientific authorities support this conclusion.

28. For example, on May 1, 2006, two professors at the University of Florida, Dr. Leslie Hendeles, PharmD Professor, Pharmacy and Pediatrics, and Dr. Randy Hatton, PharmD FCCP BCPS Clinical Professor, Department of Pharmacotherapy and Translational Research College of Pharmacy published a letter in Journal of Allergy and Clinical Immunology titled: Oral phenylephrine: An ineffective replacement for pseudophedrine?[1] The letter questioned the effectiveness of PE for nasal congestion based upon the results of multiple double blind, placebo-controlled studies, that show PE was no more effective than placebo in reducing nasal airway resistance. Moreover, the letter notes that the studies relied on by the FDA to approve PE were unpublished, manufacturer-sponsored studies conducted by commercial testing laboratories.

29. On February 1, 2007, three professors from the University of Florida, Dr. Leslie Hendeles, PharmD Professor, Pharmacy and Pediatrics, Dr. Randy Hatton, PharmD FCCP BCPS Clinical Professor, Department of Pharmacotherapy and Translational Research College of Pharmacy, and Almut G. Winterstein (PhD, Assistant Professor, Department of Healthcare

[1] https://www.jacionline.org/article/S0091-6749(06)00633-6/fulltext (last accessed Sept. 18, 2023).

Administration) filed a Citizens Petition with the FDA concerning PE drugs.[2]

30. As a result of the 2007 Citizens Petition, the FDA's Nonprescription Drugs Advisory Committee met on December 14, 2007 and concluded that the products could continue to be sold, but 9 of 12 of the committee members voted that "new studies on response to higher doses were required."[3]

31. Scherling-Plough Pharmaceuticals responded to the FDA's Nonprescription Drugs Advisory Committee by conducting a multicenter, phase 2, trial among 539 adults with seasonal allergic rhinitis. The results of the study revealed no significant differences between placebo and active treatment groups.[4]

32. In addition, McNeil Consumer Healthcare conducted a pharmacokinetic, safety and cardiovascular tolerability study of phenylephrine. Similarly, this study revealed no difference in safety endpoints between placebo and 10, 20, and 30 mg of phenylephrine even though systemic exposure increased disproportionately with dose. "This is noteworthy since both the relief of congestion and systemic endpoints such as change in blood pressure and pulse are mediated by alpha adrenergic stimulation. The absence of a significant effect on the latter at the higher doses suggest that the concentrations reached are not sufficient to stimulate alpha adrenergic receptors."[5]

33. On November 4, 2015, another Citizens Petition was filed by two professors at the University of Florida, Dr. Leslie Hendeles, PharmD Professor, Pharmacy and Pediatrics, and Dr. Randy Hatton, PharmD FCCP BCPS Clinical Professor, Department of Pharmacotherapy and Translational Research College of Pharmacy. The petition asked the FDA "to remove oral phenylephrine from the Final Monograph for OTC nasal decongestant products."[6] Specifically, the petition asked the FDA to remove Phenylephrine and to remove phenylephrine bitartrate, "both

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[2] https://www.regulations.gov/docket/FDA-2007-P-0108/document (last accessed Sept. 18, 2023).
[3] https://www.jaci-inpractice.org/article/S2213-2198(15)00318-9/fulltext (last accessed Sept. 18, 2023).
[4] chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf (last accessed Sept. 15, 2023).
[5] *Id.*
[6] https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf (last accessed Sept. 18, 2023).

individually and in combination drug products in an effervescent dosage form."[7]

34. According to the 2015 Citizens Petition, "[t]wo additional studies published in 2009 provide further evidence of the absence of a decongestant effect from the FDA-approved nonprescription does of 10mg," and "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."[8]

The FDA Advisory Panel's Recent Vote on PE

35. Recently, "[t]he FDA held a Non-prescription Drug Advisory Committee meeting … to discuss the effectiveness of oral phenylephrine as an active ingredient in over-the-counter (OTC) cough and cold products that are indicated for the temporary relief of congestion, both as a single ingredient product and in combination with other ingredients."[9]

36. In doing so, the Panel referenced numerous studies demonstrating that PE is not effective for treating nasal congestion when taken orally.

37. As a result, the Panel concluded that "the current scientific data do[es] not support that the recommended dosage of orally administered phenylephrine is effective as a nasal decongestant."[10]

38. In fact, the Panel members voted unanimously (16-0) that PE drugs were ineffective when taken orally.

Misbranded Drugs Are Illegal to Sell

39. As OTC drug products regulated by the FDA, the Products must be both safe *and* effective and are subject to federal current Good Manufacturing Practices ("cGMP") regulations and the FDCA's state law analogues. These cGMP regulations require OTC medications like the Products to meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

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[7] *Id.*
[8] *Id.*
[9] https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-results-recent-advisory-committee-meeting-oral-phenylephrine (last accessed Sept. 15, 2023).
[10] https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-results-recent-advisory-committee-meeting-oral-phenylephrine (last accessed Sept. 15, 2023).

40. The cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." 21 C.F.R. § 210.1(a). In other words, manufacturers, like Defendants, at all phases of the design, manufacture, and distribution chain are bound by these requirements.

41. The cGMPs set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

42. Any drug product not manufactured in accordance with cGMPs is deemed "adulterated" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

43. FDA regulations require a drug product manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

44. A drug product manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

45. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of

identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194(a)(6).

46. Defendants could have avoided any potential for misrepresenting the quality characteristics that it represented the Products possessed by testing the effectiveness of PE in the Products for the purported claims on the Products' labeling.

47. The ineffectiveness of PE in the Products renders the Products both adulterated and misbranded under the FDCA. The Products are adulterated because they are "drug[s] and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. § 351(a)(1).

48. The Products are misbranded because their labeling is "false" and "misleading" because it does not alleviate nasal congestion and/or sinus relief. 21 U.S.C. § 352(a)(1).

49. A product that is "adulterated" or "misbranded" cannot legally be manufactured, advertised, distributed, or sold. 21 U.S.C. § 331(a). Adulterated and misbranded products thus have no economic value and are legally worthless.

50. As alleged herein, Defendants have violated the FDCA, California's Consumers Legal Remedies Act ("CLRA"), California's Unfair Competition Law ("UCL"), California's False Advertising Law ("FAL"), and consumer protection statutes. Defendants engaged in fraudulent, unfair, deceptive, misleading, and/or unlawful conduct stemming from its misrepresentations and omissions surrounding the quality and purity characteristics affecting the Products.

51. If Defendants had disclosed to Plaintiff and putative Class Members that the Products do not have the quality characteristics that it purports or is represented to possess, Plaintiff and putative Class Members would not have purchased the Products or they would have paid less for the Products.

52. As a seller of an OTC drug product, Defendants had and has a duty to ensure that its Products have the identity and strength and meets the quality characteristics that it purports or is represented to possess, including through regular testing, especially before the Products are injected into the stream of commerce for consumers to use on their bodies. But based on the FDA Panel's conclusions set forth above, Defendants made no reasonable effort to test its Products for the nasal decongestant claims it made. Nor did it disclose to Plaintiff in any advertising or marketing that the Products did not conform to the nasal decongestant claims it purported or represented to possess. To the contrary, Defendants represented and warranted, expressly and impliedly, that the Products were of merchantable quality, complied with federal and state law, and did have the identity and strength and meet the quality characteristics that it purports or is represented to possess.

Injuries to Plaintiff and Class Members

53. When Plaintiff purchased Defendants' Products, Plaintiff did not know, and had no reason to know, that Defendants' Products did not have the identity and strength and meet the quality characteristics that it purported to possess (*i.e.*, the ability to alleviate nasal congestion). Not only would Plaintiff not have purchased Defendants' Products had Plaintiff known the Products did not have the ability to alleviate nasal congestion, but Plaintiff would also not have been capable of purchasing them if Defendants had done as the law required and tested the Products for its ability to alleviate nasal congestion.

54. Consumers lack the ability to test or independently ascertain or verify whether a product has the identity and strength and meets the quality characteristics that it purports to possess, especially at the point of sale, and therefore must rely on Defendants to truthfully and honestly report what the Products can do on the Products' packaging or labels.

55. Further, given Defendants' position in the health and medication market as an industry leader, Plaintiff and reasonable consumers trusted and relied on Defendants' representations and omissions regarding the ability to alleviate nasal congestion in the Products.

56. Yet, when consumers look at the Products' packaging, the Products are represented as having the ability to alleviate nasal congestion. This leads reasonable consumers to believe the Products have the ability to alleviate nasal congestion.

57. No reasonable consumer would have paid any amount for products that do not have the ability to alleviate nasal congestion, when the Products are marketed to consumers as having the ability to alleviate nasal congestion.

58. Thus, if Plaintiff and Class members had been informed that Defendants' Products do not have the ability to alleviate nasal congestion, they would not have purchased or used the Products, or would have paid significantly less for the Products, making such omitted facts material to them.

59. Defendant's false, misleading, omissions, and deceptive misrepresentations regarding the Products' ability to alleviate nasal congestion are likely to continue to deceive and mislead reasonable consumers and the public, as it has already deceived and misled Plaintiff and the Class Members.

60. Plaintiff and Class members bargained for a Product that has the ability to alleviate nasal congestion. Plaintiff and Class members were injured by the full purchase price of the Products because the Products are worthless, as they do not have the ability to alleviate nasal congestion, and Defendants failed to warn consumers of this fact. Such illegally sold products are worthless and have no value.

61. As alleged above, Plaintiff and Class members' Products do not have the ability to alleviate nasal congestion, despite the Products' representations to the contrary.

62. Plaintiff and Class members are further entitled to statutory and punitive damages, attorneys' fees and costs, and any further relief this Court deems just and proper.

CLASS ALLEGATIONS

63. Plaintiff, individually and on behalf of all others, brings this class action pursuant to Fed. R. Civ. P. 23.

64. Plaintiff seeks to represent a class defined as:

> All persons who purchased one or more of Defendants' Products in the United States for personal or household use within any applicable limitations period ("Nationwide Class").

65. Plaintiff also seek to represent a subclass defined as:

> All persons who purchased one or more of Defendants' Products in California for personal or household use within any applicable limitations period ("California Subclass").

66. Excluded from the Class and Subclass are: (1) any Judge or Magistrate presiding over this action and any members of their families; (2) Defendants, Defendants' subsidiaries, parents, successors, predecessors, and any entities in which Defendants or its parents and any entities in which Defendants have a controlling interest and its current or former employees, officers, and directors; and (3) individuals who allege personal bodily injury resulting from the use of the Products.

67. Plaintiff reserves the right to modify, change, or expand the definitions of the Class and/or Subclass based upon discovery and further investigation.

68. *Numerosity*: The Class is so numerous that joinder of all members is impracticable. The Class likely contains thousands of members based on publicly available data. The Class is ascertainable by records in Defendants' possession.

69. *Commonality*: Questions of law or fact common to the Class include, without limitation:

- Whether the Products have the ability to alleviate nasal congestion;
- Whether a reasonable consumer would consider the Products inability to alleviate nasal congestion to be material;
- Whether Defendants knew or should have known that the Products do not have the ability to alleviate nasal congestion;
- Whether Defendants misrepresented whether the Products have the ability to alleviate nasal congestion;

- Whether Defendants failed to disclose that the Products do not have the ability to alleviate nasal congestion;
- Whether Defendants concealed that the Products do not have the ability to alleviate nasal congestion;
- Whether Defendants engaged in unfair or deceptive trade practices;
- Whether Defendants violated the state consumer protection statutes alleged herein;
- Whether Defendants were unjustly enriched; and
- Whether Plaintiff and Class members are entitled to damages.

70. *Typicality*: Plaintiff's claims are typical of the claims of Class members. Plaintiff and Class members were injured and suffered damages in substantially the same manner, have the same claims against Defendants relating to the same course of conduct, and are entitled to relief under the same legal theories.

71. *Adequacy*: Plaintiff will fairly and adequately protect the interests of the Class and have no interests antagonistic to those of the Class. Plaintiff has retained counsel experienced in the prosecution of complex class actions, including actions with issues, claims, and defenses similar to the present case. Counsel intends to vigorously prosecute this action.

72. *Predominance and superiority*: Questions of law or fact common to Class members predominate over any questions affecting individual members. A class action is superior to other available methods for the fair and efficient adjudication of this case because individual joinder of all Class members is impracticable and the amount at issue for each Class member would not justify the cost of litigating individual claims. Should individual Class members be required to bring separate actions, this Court would be confronted with a multiplicity of lawsuits burdening the court system while also creating the risk of inconsistent rulings and contradictory judgments. In contrast to proceeding on a case-by-case basis, in which inconsistent results will magnify the delay and expense to all parties and the court system, this class action presents far fewer management difficulties while providing unitary adjudication, economies of scale and comprehensive supervision by a single court.

Plaintiff is unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

73. Accordingly, this class action may be maintained pursuant to Fed. R. Civ. P. 23(b)(3).

COUNT I
VIOLATIONS OF THE CALIFORNIA UNFAIR COMPETITION LAW ("UCL")
Cal. Bus. & Prof. Code § 17200, *et seq.*
(On behalf of Plaintiff and the California Subclass)

74. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

75. Plaintiff brings this Count on behalf of herself and the California Subclass against Defendants.

76. The UCL prohibits any "unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising…." Cal. Bus. & Prof. Code § 17200.

Fraudulent Acts and Practices

77. Any business act or practice that is likely to deceive members of the public constitutes a fraudulent business act or practice under the UCL. Similarly, any advertising that is deceptive, untrue or misleading constitutes a fraudulent business act or practice under the UCL.

78. Defendants have engaged in conduct that is likely to deceive members of the public. This conduct includes representing on its Products' labels that its Products have the ability to alleviate nasal congestion.

79. As alleged above, Defendants have engaged in deceptive, untrue, and misleading advertising by making representations regarding the quality of the Products and material omissions regarding the Products' ability to alleviate nasal congestion.

80. Plaintiff and the putative Class members were exposed to one or more of these representations and/or omissions during the class period and relied on one or more of these representations and/or omissions in deciding to purchase Defendants' Products. Indeed, although the Products were found to not have the ability to alleviate nasal congestion, Defendants make

representations on the Products' packaging and labels to the contrary. Again, such misrepresentations and omissions mislead consumers regarding the quality of the Products.

81. By committing the acts alleged above, Defendants have engaged in fraudulent business acts and practices, which constitute unfair competition within the meaning of Business & Professions Code §17200.

Unlawful Acts and Practices

82. The violation of any law constitutes an unlawful business practice under Business & Professions Code §17200.

83. Defendants' conduct also violates Cal. Health & Safety Code § 111730, which prohibits the sale of any misbranded product. By selling Products that do not accurately reflect the quality of the Products, the labeling is "false and misleading in any particular" in violation of Health & Safety Code § 111730.

84. By violating Cal. Health and Safety Code § 111730, Defendants have engaged in unlawful business acts and practices which constitute unfair competition within the meaning of Cal. Bus. & Prof. Code § 17200.

Unfair Acts and Practices

85. Any business practice that offends an established public policy or is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers constitutes an "unfair" practice under the UCL.

86. Defendants have engaged in unfair business practices. This conduct includes representing that the Products have the ability to alleviate nasal congestion.

87. Defendants have engaged in conduct that violates the legislatively declared policies of the FTC Act against committing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. Defendants gained an unfair advantage over its competitors, whose advertising for products must comply with the FTC Act.

88. Defendants' conduct, including misrepresenting the qualities of the Products, is substantially injurious to consumers. Plaintiff and the Class would not have paid for nasal

decongestant products that do not have the ability to alleviate nasal congestion but for Defendants' false labeling, advertising, and promotion. Thus, Plaintiff and the putative Class have "lost money or property" as required for UCL standing, and such an injury is not outweighed by any countervailing benefits to consumers or competition.

89. Indeed, no benefit to consumers or competition results from Defendants' conduct. Since consumers reasonably rely on Defendants' representation of the qualities described in the Products' labels and injury resulted from ordinary use of the Products, consumers could not have reasonably avoided such injury.

90. By committing the acts described above, Defendants have engaged in unfair business acts and practices which constitute unfair competition within the meaning of the UCL.

91. As a result of the conduct described above, Defendants have been unjustly enriched at the expense of the Plaintiff and the putative Class.

92. An action for restitution is specifically authorized under Cal. Bus. & Prof. Code 17203.

93. Wherefore, Plaintiff prays for judgment against Defendants, as set forth hereafter. Defendants' conduct with respect to the labeling, advertising, marketing, and sale of the Products is unfair because Defendants' conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

94. On behalf of Plaintiff and the putative Class, Plaintiff seeks an order for the restitution of all monies spent on the Products, which were acquired through acts of fraudulent, unfair, or unlawful competition. In addition, because the Products admittedly do not have the ability to alleviate nasal congestion, the measure of restitution should be rescission and full refund insofar as the Products are worthless. But for Defendants' misrepresentations and omissions, Plaintiff would have paid nothing for Products that do not have the ability to alleviate nasal congestion. Indeed, there is no discernible "market" for an OTC nasal decongestant that does not have the ability to alleviate nasal congestion. As a result, the Products are rendered valueless.

95. Plaintiff and California Subclass Members have no adequate remedy at law for this claim. Plaintiff pleads her claim for equitable relief in the alternative, which inherently would necessitate a finding of no adequate remedy at law.

96. Alternatively, legal remedies available to Plaintiff are inadequate because they are not "equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States v. Bluitt*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence' of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to the end in view … It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

COUNT II
VIOLATIONS OF THE CALIFORNIA FALSE ADVERTISING LAW
Cal. Bus. & Prof. Code § 17500, *et seq.*
(On behalf of Plaintiff and the California Subclass)

97. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

98. Plaintiff brings this Count on behalf of herself and the California Subclass against Defendants.

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

100. As set forth herein, Defendants' marketing claims that its Products are able to provide relief to "Sinus Pressure," "Sinus Congestion," "Nasal Congestion," and/or "Nasal Swelling," are untrue and misleading. To the contrary, the Products do not have the ability to alleviate nasal congestion.

101. Defendants knew, or reasonably should have known, that their claims regarding the quality of its Products and/or omissions regarding the Products inability to alleviate nasal congestion were untrue or misleading.

102. Plaintiff and members of the California Subclass are entitled to monetary relief, and restitution in the amount they spent on the Products.

103. Plaintiff and California Subclass Members have no adequate remedy at law for this claim. Plaintiff pleads her claim for equitable relief in the alternative, which inherently would necessitate a finding of no adequate remedy at law.

104. Alternatively, legal remedies available to Plaintiff are inadequate because they are not "equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States v. Bluitt*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence' of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to the end in view … It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

COUNT III
VIOLATIONS OF THE CALIFORNIA CONSUMERS LEGAL REMEDIES ACT
Cal. Bus. & Prof. Code § 1750, *et seq.*
(On behalf of Plaintiff and the California Subclass)

105. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

106. Plaintiff brings this Count on behalf of herself and the California Subclass against Defendants.

107. Defendants have employed or committed methods, acts, or practices declared unlawful by Cal. Civ. Code §1770 in connection with the Products.

108. In particular, by failing to inform consumers that the Products do not have the ability to alleviate nasal congestion, Defendants have violated the following provisions under California Civil Code § 1770(a):

> (5) by representing that the Products have characteristics, uses and/or benefits which they do not;

> (7) by representing that the Products were of a particular standard, quality, or grade which they are not; and
>
> (9) by advertising the Products with intent not to sell them as advertised.

109. Plaintiff and the putative Class are not presently seeking monetary damages under the CLRA. Plaintiff reserves the right to request amendment of this complaint to include a request for damages under the CLRA after complying with Civil Code 1782(a).

110. Plaintiff and California Subclass Members have no adequate remedy at law for this claim. Plaintiff pleads her claim for equitable relief in the alternative, which inherently would necessitate a finding of no adequate remedy at law.

111. Alternatively, legal remedies available to Plaintiff are inadequate because they are not "equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States v. Bluitt*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence' of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to the end in view … It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

COUNT IV
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(On behalf of Plaintiff and the Nationwide Class)

112. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

113. Plaintiff brings this claim on behalf of herself and the Nationwide Class against Defendants.

114. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose.

115. Defendants were at all times a "merchant" within the meaning of Article 2 of the U.C.C., as codified under applicable law.

116. The Products are and were goods within the meaning of Article 2 of the U.C.C., as codified under applicable law.

117. Defendants were obligated to provide Plaintiff and the other Class Members Products that were of merchantable quality, were reasonably fit for the purpose for which they were sold, and confirmed to the standards of the trade.

118. Defendants impliedly warranted that those drugs were of merchantable quality and fit for that purpose.

119. Defendants breached their implied warranties, because the Products were not of merchantable quality or fit for their ordinary purpose.

120. Defendants' breaches of implied warranties were a direct and proximate cause of Plaintiff's and the other Class members' damages.

COUNT V
UNJUST ENRICHMENT
(On behalf of Plaintiff and the Nationwide Class)

121. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

122. Plaintiff brings this Count on behalf of Plaintiff and the Nationwide Class against Defendants.

123. This claim is brought under the laws of the State of California.

124. Defendants' conduct violated, *inter alia*, state and federal law by manufacturing, advertising, marketing, and selling the Products while misrepresenting and omitting material facts.

125. Defendants' unlawful conduct allowed Defendants to knowingly realize substantial revenues from selling the Products at the expense of, and to the detriment or impoverishment of, Plaintiff and Class members and to Defendants' benefit and enrichment. Defendants have thereby violated fundamental principles of justice, equity, and good conscience.

126. Plaintiff and Class members conferred significant financial benefits and paid substantial compensation to Defendants for the Products, which were not as Defendants represented them to be.

127. Defendants knowingly received and enjoyed the benefits conferred on it by Plaintiff and Class members.

128. It is inequitable for Defendants to retain the benefits conferred by Plaintiff and Class members' overpayments.

129. Plaintiff and Class members seek establishment of a constructive trust from which Plaintiff and Class members may seek restitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, prays for relief and judgment against Defendants as follows:

- Certifying the Class pursuant to Rule 23 of the Federal Rules of Civil Procedure, appointing Plaintiff as representatives of the Class and Subclasses, and designating Plaintiff's counsel as Class Counsel;
- Awarding Plaintiff and Class members compensatory damages, in an amount to be determined at trial;
- Awarding Plaintiff and Class members appropriate relief, including but not limited to actual damages;
- For restitution and disgorgement of profits;
- Awarding Plaintiff and Class members reasonable attorneys' fees and costs as allowable by law;
- Awarding pre-judgment and post-judgment interest;
- For punitive damages; and
- Granting any other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all issues so triable as of right.

Dated: September 19, 2023

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ Sarah N. Westcot*
Sarah N. Westcot

Sarah N. Westcot (State Bar No. 264916)
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Counsel for Plaintiff

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

NATASHA HERNANDEZ, individually and on behalf of all others similarly situated,

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Sarah N. Westcot, Bursor & Fisher, P.A., 701 Brickell Ave., Suite 1420, Miami, FL 33131-2800 Tel.: (305) 330-5512

DEFENDANTS

KENVUE, INC., MCNEIL CONSUMER HEALTHCARE, and JOHNSON & JOHNSON CONSUMER, INC.

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

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

Attorneys *(If Known)*

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

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

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

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

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

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment Of Veteran's Benefits
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury -Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury – Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☒ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities–Employment
- ☐ 446 Amer. w/Disabilities–Other
- ☐ 448 Education

PRISONER PETITIONS

HABEAS CORPUS
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

OTHER
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee–Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC § 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC § 158
- ☐ 423 Withdrawal 28 USC § 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent—Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS–Third Party 26 USC § 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC § 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332(d)

Brief description of cause:
Defendants fraudulently advertise their decongestant products containing phenylephrine.

VII. REQUESTED IN COMPLAINT:

✓ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, Fed. R. Civ. P.

DEMAND $ 5,000,000+

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

VIII. RELATED CASE(S), IF ANY *(See instructions):*

JUDGE

DOCKET NUMBER

IX. DIVISIONAL ASSIGNMENT (Civil Local Rule 3-2)

(Place an "X" in One Box Only) ☒ **SAN FRANCISCO/OAKLAND** ☐ **SAN JOSE** ☐ **EUREKA-MCKINLEYVILLE**

DATE 09/19/2023

SIGNATURE OF ATTORNEY OF RECORD /s/ Sarah N. Westcot