UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JOHN JEFFREY WARD, an individual; RUTA TAITO, an individual; and KAREN SCHWARTZ, an individual, and on behalf of all others similarly situated,

Plaintiffs,

v.

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

Defendants.

Case No.

CLASS ACTION COMPLAINT
JURY TRIAL DEMANDED

Plaintiffs John Jeffrey Ward, Karen Schwartz, and Ruta Taito (collectively, "Plaintiffs") bring this class action complaint against Defendants Johnson and Johnson, Johnson and Johnson Consumer Inc., Kenvue Inc., and McNeil Consumer Healthcare Inc. (collectively, "Defendants"), individually and on behalf of all others similarly situated, and allege upon personal knowledge as to their acts and experiences, and, as to all other matters, upon information and belief, including investigation conducted by Plaintiff's attorneys.

NATURE OF THE ACTION

1. This is a consumer protection class action arising out of Defendants' false and misleading advertising of its oral PE ("PE") Products.[1]

2. Defendants distribute, market and sell oral PE Products marketed as nasal decongestants. Defendants represent and sell oral PE Products to provide benefits for the indications specified – to provide nasal congestion relief to all consumers who ingest oral PE Products. The claimed nasal congestion health benefits are the only reason a consumer would purchase oral PE Products. Defendants' advertising claims, however, are false, misleading, and reasonably likely to deceive the public.

[1] This Complaint does not include intranasally or topically administered PE products. As referenced in this Complaint, "oral phenylephrine ("PE") products" mean PE products administered orally in either tablet or liquid form.

3. Each of the oral PE Products at issue in Defendants' cold relief product lines, through their labeling and packaging, and through Defendants' other advertising and marketing materials, communicate the same substantive message to consumers: that oral PE Products provide meaningful nasal congestive relief health benefits. Defendants convey this health message through extensive and uniform nationwide marketing campaigns and product labeling through which Defendants represent that oral PE Products provide "Maximum Strength Congestion Relief" and assist with nasal decongestion. Defendants further warrant that oral PE Products are the "#1 Pharmacist Recommended oral Decongestant Brand," constituting an implied advertising claim that the assertion is true and there is legitimate science substantiating the nasal congestive relief health benefits. These representations are designed to induce consumers to believe that Defendants' oral PE Products are capable of providing meaningful nasal congestion relief. These claims are a material reason a consumer would purchase oral PE Products.

4. Defendants' oral PE Products, however, are incapable of supporting or providing nasal congestion health benefits because the ingredient in each of Defendants' oral PE Products at issue cannot support or benefit nasal decongestion. Numerous well designed and well conducted scientific studies have been conducted on the effects and efficacy of oral PE Products. These studies have demonstrated that oral PE Products are ineffective in providing relief of nasal congestion because

PE is too rapidly metabolized by individuals, which does not allow it to reach the nostrils in time to provide relief. These studies apply to oral PE Products' target audience, which includes people with nasal congestion. Accordingly, Defendants' nasal decongestion relief health representations are false, misleading, and deceptive, and its oral PE Products are worthless.

5. Indeed, On September 12, 2023, a U.S. Food and Drug Administration ("FDA") advisory panel agreed, voting unanimously (16-0) that oral PE products are not effective as a nasal decongestant.[2]

6. Defendants have even conducted their own interim analysis in 2017-2018 (and potentially multiple studies) on the efficacy of oral PE and it showed "no benefit . . .. when compared with placebo."[3] Despite knowing this information, Defendants continued to market its oral PE Products as providing nasal congestion relief health benefits, a knowingly false and misleading statement upon which consumers, including Plaintiffs and class members, relied upon in purchasing Defendants' oral PE Products.

[2]Haley Weiss, *With the Decongestant SNAFU, the FDA Tries Something New*, TIME (Sept. 14, 2023), https://time.com/6314120/fda-decongestant-phenylephrine-decision/#:~:text=That%20changed%20on%20Sep.%2012,be%20pulled%20from%20stores%20altogether (last accessed Sept. 22, 2023).
[3]U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT (Sept. 12, 2023), https://www.fda.gov/media/171915/download.

7. Plaintiffs bring this action individually and on behalf of all other similarly situated consumers to obtain redress for those who have purchased Defendants' oral PE Products at issue.

JURISDICTION AND VENUE

8. The Court has original jurisdiction under 28 U.S.C. § 1332(d)(2) because the matter in controversy, exclusive of interest and costs, exceeds the sum or value of $5,000,000 and is a class action in which there are in excess of 100 class members, and some of the members of the class are citizens of states different from Defendants.

9. This Court has personal jurisdiction over Defendants because Defendants (outside of McNeil) are incorporated and have their principal place of business in New Jersey.

10. Further, Defendants, including McNeil, have marketed, promoted, distributed, and sold the oral PE Products at issue in New Jersey, rendering exercise of jurisdiction by New Jersey courts permissible.

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

PARTIES

12. Plaintiff Ruta Taito is a citizen of California, and at all times relevant to this action, resided in Fresno County, California at 1027 W Dakota Avenue, Unit 113, 93705. Plaintiff Taito saw Defendants' representations by reading the label of a SUDAFED PE Maximum Strength Congestion & Sinus Pressure Relief Tablets product package at Walgreens and CVS pharmacies in Fresno, California during the class period. In reliance on the claims at issue made on the label, Plaintiff Taito purchased the oral SUDAFED PE product on several occasions at the Walgreens pharmacy located at 1016 West Shaw Avenue, Fresno, CA 93711 and at the CVS pharmacy located at 1325 West Shields Avenue, Fresno CA 93705. By purchasing the deceptively advertised product, Plaintiff Taito suffered injury-in-fact and lost money because oral SUDAFED PE does not provide the promised benefits. Had Plaintiff Taito known the truth about Defendants' advertisements at the time of her purchases, she would not have purchased oral SUDAFED PE. Plaintiff Taito continues to desire to purchase an oral nasal decongestant product and believes she would purchase an oral nasal decongestant if it worked as advertised. However, as a result of Defendants' ongoing false advertising, Plaintiff Taito will be unable to rely on the advertising when deciding in the future whether to purchase oral SUDAFED PE products.

13. Plaintiff Karen Schwartz is a citizen of the state of New Jersey, and at all times relevant to this action, resided in East Brunswick, New Jersey at 11 Navajo Road, 08816. Plaintiff Schwartz saw Defendants' representations by reading the label of the SUDAFED PE Maximum Strength Congestion & Sinus Pressure Relief Tablets product package at a CVS Pharmacy in Brunswick, New Jersey during the class period. In reliance on the claims at issue made on the label, Plaintiff Schwartz purchased the oral SUDAFED PE products on several occasions at the CVS Pharmacy retail store located at 330 Rues Lane East Brunswick, NJ 08816. By purchasing the deceptively advertised product, Plaintiff Schwartz suffered injury-in-fact and lost money because oral SUDAFED PE does not provide the promised benefits. Had Plaintiff Schwartz known the truth about Defendants' advertisements at the time of her purchases, she would not have purchased oral SUDAFED PE. Plaintiff Schwartz continues to desire to purchase an oral nasal decongestant product and believes she would purchase an oral nasal decongestant again if it worked as advertised. However, as a result of Defendants' ongoing false advertising, Plaintiff Schwartz will be unable to rely on the advertising when deciding in the future whether to purchase oral SUDAFED PE products.

14. Plaintiff John Jeffrey Ward is a citizen of California, and at all times relevant to this action, resided in Los Angeles County, California at 15455 Glenoaks Blvd, Unit 115, 91342. Plaintiff Ward saw Defendants' representations by reading

the label of a SUDAFED PE® product ("SUDAFED PE Product") Maximum Strength Congestion & Sinus Pressure Relief Tablets product package at a Walmart and a Rite-Aid in Los Angeles County, California during the class period. In reliance on the claims at issue made on the label, Plaintiff Ward purchased the SUDAFED PE Product on several occasions at a Walmart located at 19821 Ronaldi Street, Porter Ranch, CA 91320, and a Rite-aid located at 17266 Saticoy Street, Van Nuys, CA 91406. By purchasing the deceptively advertised product, Plaintiff Ward suffered injury-in-fact and lost money because oral SUDAFED PE does not provide the promised benefits. Had Plaintiff Ward known the truth about Defendants' advertisements at the time of his purchases, he would not have purchased oral SUDAFED PE. Plaintiff continues to desire to purchase an oral nasal decongestant product and believes he would purchase an oral nasal decongestant again if it worked as advertised. However, as a result of Defendant's ongoing false advertising, Plaintiff Ward will be unable to rely on the advertising when deciding in the future whether to purchase oral SUDAFED PE products.

15. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business located at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Johnson & Johnson manufactures, advertises, markets, distributes, and sells oral SUDAFED PE Products to hundreds of thousands of consumers throughout the United States. Defendant's principal business is research

and development, manufacturing, and sales of a broad range of products in the health care field. Defendant is a global leader in the health care market with sales of over $95 billion last year.

16. 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. Johnson & Johnson Consumer, Inc., markets, sells, and distributes SUDAFED PE® globally, including in New Jersey.

17. Defendant Kenvue, Inc., is a New Jersey corporation with its principal place of business located at 199 Grandview Road, Skillman, New Jersey 08558. Kenvue, Inc., markets, sells, and distributes SUDAFED PE Products globally, including in New Jersey.

18. Defendant McNeil Consumer Healthcare, Inc. is a Pennsylvania corporation with its principal place of business and headquarters located at 7050 Camp Hill Road, Fort Washington, Pennsylvania 19034. McNeil Consumer Healthcare markets, sells, and distributes SUDAFED PE Products globally, including in New Jersey.

FACTUAL ALLEGATIONS

I. Defendants' PE Products

19. Defendants sell SUDAFED PE Products through its website, www.sudafed.com, and through various retail stores, including, but not limited to, Walgreens, CVS, Walmart, Rite Aid, and Target. Defendants' oral PE Products are sold both online and at physical retail outlets.

20. Defendants' oral SUDAFED PE products at issue (collectively, the "Products") include, but are not limited to:

i. SUDAFED PE® Sinus Congestion
ii. SUDAFED PE® for Head Congestion + Pain Relief
iii. SUDAFED PE® Sinus Congestion Day + Night
iv. SUDAFED PE® Sinus Pressure + Pain
v. Children's SUDAFED PE® Nasal Decongestant, Berry Liquid
vi. Children's SUDAFED PE® Cough + Cold, Grape Liquid
vii. SUDAFED PE® Head Congestion + Flu Severe
viii. SUDAFED PE® Head Congestion + Mucus

21. Oral SUDAFED PE Products contain anywhere from 2.5mg-10mg of PE per serving.

22. Defendants market SUDAFED PE Products to provide the purported health benefit of nasal congestion relief.[4] Nasal congestion is a symptom of allergies, hay fever, and the common cold. These symptoms are also connected with several other conditions, including nasal polyps, deviated nasal septum, cystic fibrosis, HIV, and other immune system-related diseases.[5] A consumer research study found that there has been a rise in purchases of nasal decongestants since the start of the Covid-19 pandemic.[6] According to a consumer analysis by Profitero, searches for cold and flu medicine exploded at the onset of the pandemic in early 2020.[7]

23. According to the FDA, estimates of 2022 retail sales data show an estimated 242 million over-the-counter ("OTC") cough, cold, and allergy oral products containing PE were sold from retail stores, representing approximately $1.763 billion in sales.[8]

24. PE is a specific alpha-1 adrenergic receptor agonist that works as a nasal decongestant by temporarily constricting blood vessels.[9] However, a recent

[4] SUDAFED explains on their website: "PE is a nasal decongestant that works by narrowing the blood vessels in the nose that are expanded during the common cold or allergies. When the blood vessels in the nose and sinuses narrow, the tissue shrinks and allows the normal flow of air and mucus. This results in a temporary relief of nasal congestion, sinus congestion, and sinus pressure." *See* https://www.sudafed.com/faq#how-does-sudafed-pe-work.
[5] *Chronic sinusitis*, Mayo Clinic (Sept. 19, 2023), https://www.mayoclinic.org/diseases-conditions/chronic-sinusitis/symptoms-causes/syc-20351661.
[6] *Cold And Flu Sales On Amazon To Reach Record Highs In 2022*, Profitero (Jan. 25, 2022), https://www.profitero.com/blog/cold-and-flu-sales-on-amazon-2022.
[7] *Id.*
[8] *U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 68 (Sept. 12, 2023), https://www.fda.gov/media/171915/download.*
[9] *Id.* at 13.

advisory panel brief to the FDA has confirmed that orally administered PE at monographed dosages is not effective as a decongestant.[10] In other words, oral SUDAFED PE Products' active ingredient for nasal decongestion is worthless and does not provide the health benefits claimed by Defendants.

25. Because nasal congestion is associated with a large range of conditions, many people purchase OTC cold medicine containing oral PE Products without any formal medical diagnosis. Knowing this, to induce consumers (including Plaintiffs and Class Members) to purchase its oral PE products, Defendants advertise through its messaging that SUFAFED PE Products provide maximum-strength nasal congestion relief.

26. In addition to the fact that Oral PE products do not provide their indicated health benefits, oral PE products also have side effects, including anxiety, nervousness, headache, trouble sleeping, heart palpitations, increased blood pressure and possible allergic reactions.[11]

II. Defendants' False and Deceptive Advertising

27. Defendants market their products at all major pharmaceutical retailers and through television and internet advertisements, along with a Sudafed-specific website. Based on well-conducted consumer research, Defendants have finely honed

[10] *Id.* at 9.

[11] *Q&A: As FDA panel deems decongestants ineffective, experts discuss impact on allergy care*, healio.com (Sept. 22, 2023), https://www.healio.com/news/allergy-asthma/20230922/qa-as-fda-panel-deems-decongestants-ineffective-experts-discuss-impact-on-allergy-care.

their package labeling to ensure their oral PE products are a household product by promising to relieve nasal congestion symptoms associated with the common cold or flu.

28. Beginning with the package label for oral SUDAFED PE Products and reinforced through other advertisements, Defendants convey to consumers that its oral SUDAFED PE Products will provide nasal congestion health benefits for anyone who takes oral SUDAFED PE Products.

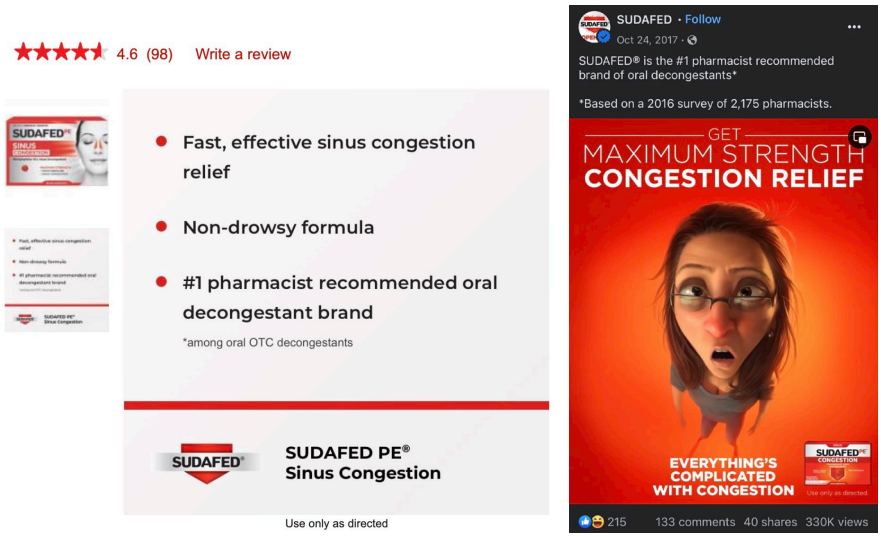
29. The front panels of the packaging for all oral SUDAFED PE Products are materially the same and communicate the same implied advertising message. On the front label, immediately below "SUDAFED PE®," is printed prominently and in all caps, "MAXIMUM STRENGTH," and, included as subcategories, "SINUS PRESSURE" and "SINUS CONGESTION." Among other things, this statement conveys the implied message that consumption of oral SUDAFED PE Products can provide the health benefits of relief from sinus pressure and nasal congestion.

30. An example of the front label for a SUDAFED PE Product appears as follows:

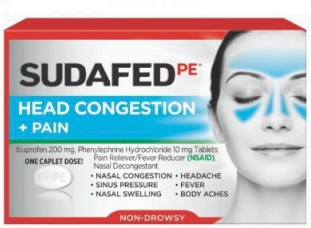
31. To reinforce the nasal decongestant message, Defendants repeats similar claims about cold and flu symptoms throughout its packaging and marketing, including that oral SUDAFED PE Products provide "fast, effective sinus congestion relief" as well as "powerful head congestion relief."

32. To add credibility to the advertising, Defendants provide consumers with an additional "reason to believe" the nasal decongestant message. Providing a "reason to believe" advertising is a key psychological component to successful advertising. A "reason to believe" offered by Defendants is that SUDAFED PE is the "#1 Pharmacist Recommended Oral Decongestant Brand." This message misleadingly promotes Defendants' oral PE Products as having decongestion benefits, despite the fact that this claim is clearly false.[12]

[12] *See* https://www.sudafed.com/products/sudafed-pe-sinus-congestion.

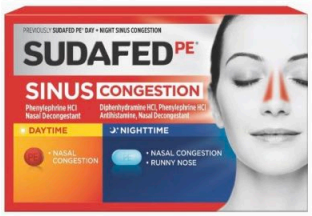


33. Nasal congestion can be felt in the forehead, nose, and sides of the nose. Knowing this, Defendants put on every label of oral SUDAFED PE Products a graphic of a woman's face with the nose highlighted in a distinct color to communicate to consumers that SUDAFED PE Products will relieve pressure in those areas. Some examples of the label panels are as follows:



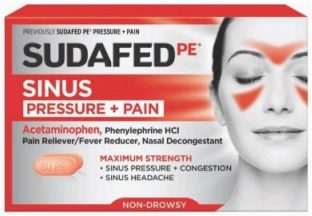
Use only as directed

SUDAFED PE® for Head Congestion + Pain Relief | SUDAFED®



Use only as directed

SUDAFED PE® Sinus Congestion Day + Night



Use only as directed

SUDAFED PE® Sinus Pressure + Pain

III. The FDA Finds Orally Administered PE Products Are Not Effective Nasal Decongestants Based on Scientific Studies

34. Despite Defendants' representations, an advisory panel to the FDA has found that orally administered PE — as is used in Defendants' Products — is not an

effective treatment for nasal congestion.[13]

35. On September 12, 2023, the FDA published the Non-Prescription Drug Advisory Committee ("NDAC") Briefing Document (the "FDA Briefing"), which outlined the NDAC's findings and analysis supporting its conclusion that oral PE is not effective as a nasal decongestant.[14] The FDA Briefing detailed the NDAC's analysis of all the relevant scientific support of the efficacy of oral PE and the history of PE's approval by the FDA. The NDAC's extensive examination included an analysis of the following: (1) the fourteen original clinical trials that were the basis for the FDA's approval of PE, (2) the 2007 Citizen's Petition, (3) the 2007 NDAC meeting and two meta-analyses presented there, (4) bioavailability data which demonstrated that less than one percent (<1%) of an oral dose of PE is systemically available, (5) two Environmental Exposure Unit ("EEU") studies, (6) three modern clinical studies done since the 2007 NDAC meeting, and (7) the 2015 Citizen's Petition.[15] After reviewing this voluminous scientific evidence, the NDAC concluded that orally administrated PE is not an effective treatment for nasal congestion, and that oral PE usage for treatment of congestion has no scientific merit.[16] The NDAC voted 16-0 "that scientific evidence doesn't prove that the nasal

[13] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 9 (2023), https://www.fda.gov/media/171915/download.
[14] *Id.*
[15] *Id.* at 8.
[16] *Id.* at 9.

decongestant is effective when taken orally at recommended doses."[17]

Introduction to PE

36. PE is a specific alpha-1 adrenergic receptor agonist.[18] PE can be used in both single ingredient and combination products, so long as the combination products comply with the FDA's list of permitted combinations. There are two forms of PE discussed by the NDAC: (1) orally administered phenylephrine hydrochloride ("PEH"), and (2) phenylephrine bitartrate ("PEB").

37. Alpha-1 adrenergic agonists, such as PE, pseudoephedrine ("PSE") and phenylpropanolamine ("PPA") can temporarily constrict the blood vessels in the nasal passages and reduce swelling in the sinuses and nose as a result.[19]

38. However, extensive scientific studies have shown that orally administered PE, such as when taken in a tablet or a syrup form, is not effective at providing nasal congestion relief benefits. The NDAC agreed, stating "we have now come to the initial conclusion that orally administered PE is not effective as a nasal decongestant at the monographed dosage (10 mg of PE hydrochloride every 4 hours) as well as at doses up to 40 mg (dosed every 4 hours).[20]

[17]Cailley Lapara, *Common Nasal Decongestant Doesn't Actually Work, According to FDA Advisors*, TIME, https://time.com/6313449/nasal-decongestant-phenylephrine-efficacy-fda/ (last accessed Sept. 22, 2023).
[18] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 13 (2023), https://www.fda.gov/media/171915/download.
[19] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 13 (2023), https://www.fda.gov/media/171915/download.
[20]*Id.* at 9.

Previous Approvals

39. In 1976, PE, PSE, and PPA were reviewed as possible over-the-counter ("OTC") products for nasal congestion treatment by the FDA. In 1994, PE, PSE, and PPA were approved by the FDA, at their respective monograph dosages,[21] and added to the FDA's Cough, Cold, Allergy, Bronchodilator, and Anti-Asthmatic Drug Products ("CCABAP") Final Monograph (the "Final Monograph," "FM" or "CCABAP Monograph") for OTC nasal decongestant drug products.[22] The CCABAP Monograph regulates and provides a list of permitted nasal decongestants, among other therapeutic classes of drugs. The FDA approved dosage of orally administered PE was 10 mg.[23]

40. In 2000, PPA was removed from the market after it was found to cause hemorrhagic strokes in women.[24] Additionally, in 2006, the Combat Methamphetamine Epidemic Act ("CMEA") limited the availability of PSE by requiring the sale of PSE products to "behind-the-counter" sales made only to people with a prescription.[25] This restriction on OTC availability of PSE made by the CMEA was a result of the use of PSE to illegally produce methamphetamine.[26]

41. Consequently, by 2006, PE became the only OTC oral decongestant

[21] A "monograph dosage" is the dosage of the drug the FDA has officially approved for use.
[22] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 12 (2023), https://www.fda.gov/media/171915/download.
[23] *Id.* at 9.
[24] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 12 (2023), https://www.fda.gov/media/171915/download.
[25] *Id.*
[26] *Id.*

listed in the CCABAP Monograph as FDA approved for OTC sales. As a result, manufacturers replaced or reformulated their PSE OTC oral decongestant products to now be formulated with PE. This was done to maintain OTC availability of products and reduce the new barrier to sales the CMEA created by requiring consumers to purchase PSE products "behind-the-counter."

42. However, there have been continuous concerns raised to the FDA by the scientific community regarding the lack of scientific merit of the original clinical studies done in 1976 that formed the basis for the FDA's approval of orally administered PE. These concerns have been expressed and reviewed by FDA advisory panels by virtue of a 2007 Citizen's Petition, a 2007 Non-Prescription Drug Advisory Committee ("NDAC") Meeting, a 2015 Citizen's Petition, and a 2023 NDAC Meeting.[27] After the 2023 NDAC meeting, the FDA advisory panel voted 16-0 on September 12, 2023 that oral PE is not an effective treatment for nasal congestion.[28]

Summary of the FDA Review Process

43. The 1972 Kefauver-Harris Amendment to the Food, Drug, and Cosmetic Act requires drug manufacturers provide proof of the effectiveness and safety of their drugs before FDA approval.[29] The FDA's administrative process on

[27] *Id.*
[28] *Id.*
[29] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 11 (2023), https://www.fda.gov/media/171915/download.

reviewing OTC drugs[30] involves convening an Advisory Panel to review data relating to claims and active ingredients.[31] The Advisory Panel's reports and comments are published in the Federal Registrar as Advanced Notice(s) of Proposed Rulemaking ("ANPR" or "Proposed Rules") which, after FDA review, are published in a Tentative Final Monograph ("TFM") for each therapeutic class of drugs.[32] Each TFM establishes the conditions under which an ingredient within a drug class, or permitted combination of ingredients, is considered to be Category I "generally recognized as safe and effective" ("GRASE").[33] The final step is the publication of a Final Monograph ("FM") for each class of drugs, which provides a list of permitted ingredients, and ingredient combinations, along with required labeling, dosing, and marketing requirements.[34] Drugs manufactured and marketed in accordance with the FM requirements are considered GRASE.[35] This process allows for the FDA to amend the FM in response to a Citizen's Petition ("CP").

44. Inclusion of ingredients, including PE, in the CCABAP Monograph was based on recommendations made by an Advisory Review Panel on Over-the-Counter Cold, Cough, Allergy, Bronchodilator, and Anti-asthmatic Products ("the

[30] The FDA's administrative review process for OTC drugs is often referred to as the Drug Efficacy Study Implementation ("DESI") process.
[31] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 11 (2023), https://www.fda.gov/media/171915/download.
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 11 (2023), https://www.fda.gov/media/171915/download.

"Panel" or the "Cough-Cold Panel").[36] The Panel was convened by the National Academy of Sciences / National Research Council, on behalf of the FDA, to review and provide recommendations to the FDA regarding the safety and efficacy of therapeutic groups of products, including PE.[37] The FDA published the Panel's recommendations as a Proposed Rule (ANPR) in 1976 and issued the CCABAP TFM in segments between 1982 and 1988.[38] The CCABAP Final Monograph for nasal decongestants was published in 1994.[39]

45. The Advisory Panel first reviewed PEH for OTC use as a nasal decongestant in 1976. The Agency then published the Panel's findings in the Federal Registrar as a Proposed Rule, and the CCABAP FM, which included PEH, was published in 1994.[40] The CCABAP FM classified PEH as a GRASE nasal decongestant when administered intranasally[41] or when administered orally.[42]

46. In 2004, the FDA issued a Proposed Rule to add PEB as a GRASE OTC oral treatment for nasal decongestion in response to a drug manufacturer's Citizen Petition citing pharmacokinetic ("PK") data which represented PEB had similar bioavailability to PEH.[43] PEB is an immediate release ("IR") orally

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[36] *Id.* at 12.
[37] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 11 (2023), https://www.fda.gov/media/171915/download.
[38] *Id.*
[39] *Id.* at 11-12.
[40] *Id.* at 15.
[41] i.e. when the drug is applied directly into the nose, such as with a nasal spray or topical cream.
[42] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 13 (2023), https://www.fda.gov/media/171915/download.
[43] *Id.*

administered effervescent tablet form of PE.[44] In 2006, the FDA issued a Final Ruling which amended the CCABAP FM and added PEB as GRASE.[45]

47. Amendments to the FM were rarely done until the passage of the Coronavirus, Aid, Relief, and Economic Security Act ("CARES Act") in 2020.[46] The CARES Act created an updated administrative order process and authority for the FDA to issue, revise, and amend monographs, which simplified making any contemplated changes.[47] Additionally, the CARES Act also required the FDA to report to Congress yearly on the status of GRASE determinations or revisions to the CCABAP Monograph, and specifically required updates on any pediatric dosage issues.[48]

48. Since the CCABAP Monograph's pediatric PE dosage was based on adult data and dosages for PE, and also since the FDA had recently received a 2015 Citizen's Petition containing concerns with the scientific merits and validity of the adult PE data, the new pediatric requirement in the CARES Act prompted FDA's 2023 reevaluation of the effectiveness of oral PE as a treatment for nasal

[44] *Id.*
[45] *Id.*
[46] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 13 (2023), https://www.fda.gov/media/171915/download; *see also* https://www.govinfo.gov/content/pkg/COMPS-15754/pdf/COMPS-15754.pdf.
[47] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 13 (2023), https://www.fda.gov/media/171915/download; *see also* https://www.govinfo.gov/content/pkg/COMPS-15754/pdf/COMPS-15754.pdf.
[48] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 13 (2023), https://www.fda.gov/media/171915/download

congestion.[49]

49. On September 12, 2023, the NDAC voted 16-0 that orally administered PE is not effective as a treatment for nasal congestion.[50]

50. The NDAC stated:

> The new data appear compelling that the monographed dosage of oral PE results in no meaningful systemic exposure or evidence of efficacy. Furthermore, the review suggests that higher does . . . have also not shown efficacy. These findings are supported by in vitro and in vivo clinical pharmacology data showing that orally administered phenylephrine undergoes high first-pass metabolism resulting in less than 1% bioavailability.[51]

The NDAC also stated that "studying higher doses would not be a viable option" because of dangerous rises in blood pressure associated with higher doses.[52]

51. Specifically, the advisory panel to the FDA concluded:

> In accordance with the effectiveness standard for determining that a category of over-the-counter (OTC) drugs is generally recognized as safe and effective that is set forth in 21 CFR § 330.10(a)(4)(ii), which defines effectiveness as: "a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed", **we have now come to the initial conclusion that orally administered PE is not effective as a nasal decongestant at the monographed dosage (10 mg of PE hydrochloride every 4**

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[49] *Id.* at 13.
[50] Haley Weiss, *With the Decongestant SNAFU, the FDA Tries Something New*, TIME (Sept. 14, 2023), https://time.com/6314120/fda-decongestant-phenylephrine-decision/#:~:text=That%20changed%20on%20Sep.%2012,be%20pulled%20from%20stores%20altogether (last accessed Sept. 22, 2023).
[51] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 14 (2023), https://www.fda.gov/media/171915/download.
[52] *Id.*

hours) as well as at doses up to 40 mg (dosed every 4 hours).[53] (emphasis added).

The Original Clinical Trials Reviewed by the FDA

52. The 1976 advisory panel's initial evaluation of oral PEH in 1976 included a review of seventeen safety studies and fourteen effectiveness studies.[54]

53. All fourteen effectiveness studies used a methodology, nasal airway resistance ("NAR"), that is no longer used in modern medicine and that does not meet the FDA's current standards for FDA approval.[55] Thus, even if a study showed that oral PE products were "effective" in 1976, they were based on a now invalid methodology.[56]

54. Two of the fourteen studies evaluated by the advisory panel in 1976 on oral PE did not provide evaluable efficacy information.[57] Eleven of the fourteen effectiveness studies were from a single manufacturer of PE products, Sterling-Winthrop Labs ("Sterling-Winthrop").[58] These studies were small, single-center crossover studies that had significant issues.

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[53] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 14 (2023), https://www.fda.gov/media/171915/download.
[54] *Id.* at 15, 17.
[55] The 1976 studies measured the level of nasal congestion by using measurements of airflow and air pressure in the nasal passage to calculate NAR as an indirect measure of the level of nasal congestion as their endpoint. However, modern medicine no longer supports the NAR methodology, as science has evolved since these studies were reviewed in 1976. As a result, NAR is no longer used to evaluate congestion in clinical trials, and the FDA now recommends the use of nasal congestion symptom scores to evaluate congestion and other symptoms related to allergic rhinitis.
[56] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 17-18 (2023), https://www.fda.gov/media/171915/download.
[57] *Id.*
[58] *Id.* at 18.

55. Of the fourteen studies, half (seven) of the studies showed that oral PE did not have measurable efficacy results.[59] Six of the seven positive studies came from Sterling-Winthrop and formed "a large part of the basis for the original Panel's recommendations" to approve oral PE.[60] Additionally, five of the six studies done by Sterling-Winthrop were done in the same laboratory, Elizabeth Biochemical, which the NDAC stated had "potential bias and data integrity issues."[61]

56. When the 1976 advisory panel requested public comment as part of their review process, two comments of note argued that oral PE should not be approved because the 1976 advisory panel based its decision on numerous unpublished studies and that the studies considered were "split evenly between mild successes and total failures," and that a published study in a peer-reviewed journal demonstrated no efficacy of oral PE; the comments also included two references which supported the notion that PE had no oral bioavailability.[62]

57. After the 1976 advisory panel's review of these studies, the Panel stated that the data was "not strongly indicative of efficacy."[63] However, because the other safety trials reviewed demonstrated no apparent safety concerns, because

[59] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 18 (2023), https://www.fda.gov/media/171915/download.
[60] *Id.*
[61] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 32 (2023), https://www.fda.gov/media/171915/download.
[62] *Id.* at 22.
[63] *Id.*

seven of the ten studies presented to the FDA were "positive," and because the scientific community did not yet know NAR was an ineffective measurement, the Panel approved oral PE and it was published in the FM in 1994.[64]

Meta-Analyses in 2007 Citizen's Petition & 2007 NDAC Meeting

58. On February 1, 2007, Leslie Hendeles, PharmD, Randy C. Hatton, PharmD, and Jonathan J. Schuster, PharmD, ("Petitioners") filed a Citizen's Petition ("2007 Petition") with the FDA requesting that the dosage of oral phenylephrine be re-evaluated for patients over the age of 12 years old and that approval for use in children under the age of 12 years old also be withdrawn.[65]

59. The basis for this 2007 Petition was Petitioners' systematic review and meta-analysis of the aforementioned clinical studies considered by the Agency when the FDA included oral PE in the FM for OTC nasal decongestant drug products, in addition to the fact that there is no data on the safety of PE in children under the age of 12 years old.[66]

60. Well-conducted meta-analyses are considered a higher level of evidence than individual clinical trials as they provide a method to evaluate the aggregated results of all relevant studies according to their pooled effects and methodological quality.

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[64] *Id.* at 23.
[65] *Id.* (citing Hendeles, Hatton & Winterstein, Citizen Petition — Phenylephrine, https://www.regulations.gov/docket/FDA-2007-P-0108).
[66] *Id.*

61. Petitioners obtained all the data used for these studies through the Freedom of Information Act ("FOIA") and performed a meta-analysis of the data.[67] This meta-analysis resulted in a different conclusion than that of the original Cough-Cold Advisory Panel data, as it instead found that oral PE is not effective at the monographed dosages.[68]

62. In response to the 2007 Petition, the FDA convened a NDAC Committee ("2007 NDAC") on December 14, 2007.[69] The 2007 NDAC reviewed the 2007 Petition and the associated meta-analysis performed by Petitioners.[70] In addition, the 2007 NDAC attended a presentation done by Petitioners discussing the findings of their meta-analysis, and a presentation by the Consumer Healthcare Products Association ("CHPA"). CHPA, predictably, presented a second meta-analysis that they believed supported the findings of the original Panel to approve oral PE.[71] The data presented in both meta-analyses was then reviewed and presented by an FDA statistician, who then discussed his findings with the 2007 NDAC.[72] Lastly, the Committee also attended presentations by several industry speakers from Scherling-Plough and Scheing-Plough Merck, who provided

[67] *Id.*
[68] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 23 (2023), https://www.fda.gov/media/171915/download.
[69] *Id.*
[70] *Id.*
[71] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 23 (2023), https://www.fda.gov/media/171915/download.
[72] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 25-26 (2023), https://www.fda.gov/media/171915/download.

previously unpublished data that confirmed the proposition behind Petitioners' petition to withdraw PE from the FM — that oral PE is ineffective as a nasal decongestant.[73]

63. In Petitioners' presentation of their meta-analysis, they noted that the data from one company, Elizabeth Biochemical, drove the majority of the Panel's original decision.[74] Petitioners also noted that the studies done in other labs had not only found no difference between the effects of oral PE and a placebo, but when they did find any difference in effect, it was nowhere near the magnitude of the effect reported by Elizabeth Biochemical; Petitioners therefore believed this indicated an Elizabeth Biochemical reporting bias.[75] Petitioners also reviewed the literature and several negative studies that supported the ineffectiveness of oral PE, which provided further support to Petitioners' conclusion that oral PE was ineffective.[76]

64. The industry presentations included two presentations by Schering-Plough and Schering-Plough Merck, which, the FDA advisory panel said "counterintuitively" presented data that supported Petitioners' belief that the monograph approved dose of oral PE is not effective, and they argued that higher doses would be needed.[77] The Advisory Panel notes that it appears these companies

[73] *Id.* at 23.
[74] *Id.* at 23-24.
[75] *Id.*
[76] *Id.* at 24.
[77] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 25-28 (2023), https://www.fda.gov/media/171915/download.

performed subsequent studies that they "hoped" supported the efficacy of oral PE in higher monographed doses.[78] However, their studies showed that oral PE was not even effective at up to four-fold (40 mg) of the FDA monograph dose — the maximum dose that could be safely marketed.[79] In other words, *even recent industry participant studies show that Oral PE at its maximum possible safe dosage is not effective at providing nasal congestion relief health benefits.*

65. John, O'Mullane, PhD, the Group Vice-President of Consumer Healthcare Research and Development at Schering-Plough, presented to the 2007 NDAC data that showed 10 mg of oral PE is not "sufficient to provide efficacy."[80]

66. The second presentation by Schering-Plough Merck reviewed the findings from two studies published in 2009. Both studies showed that "PE failed to provide any benefit over placebo."[81]

67. Lastly, FDA statistician Dr. Stan Lin reviewed both sets of meta-analyses and four unpublished studies from Wyeth Consumer Healthcare and Schering-Plough and presented his conclusion to the Committee.[82] Dr. Lin noted that all of original studies used NAR as their primary clinical measure, which was sufficiently problematic because the FDA no longer accepts it as a clinical

[78] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 25-28 (2023), https://www.fda.gov/media/171915/download.
[79] *Id.* at 26.
[80] *Id.*
[81] *Id.* at 28.
[82] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 28 (2023), https://www.fda.gov/media/171915/download.

endpoint.[83] In summary, Dr. Lin noted that the small size, the lack of multicenter representation, the lack of reproducibility, and the problematic nature of the methodology used by the original studies suggest that the data reviewed by the original Panel is not conclusive of PE efficacy.[84]

68. After the Committee's review of all of the presented material, it noted the inconsistent results, but due to the limitations of the data, nine of the twelve Committee members voted to recommend that additional clinical data was necessary before making any changes to the FDA's stance on PE, including new studies needed to evaluate the effect of higher doses of oral PE, new studies which do not use NAR as an endpoint, along with other recommended design elements for future trials.[85]

69. In response to the 2007 NDAC Meeting, the Agency's Clinical Pharmacology team reviewed all of the "new" bioavailability data (data that had become available since the Agency's original GRASE determination in 1994) **and confirmed that the actual oral bioavailability of PE is less than one percent (<1%).**[86] This effect was found to be due to the high-first pass metabolism effect that occurs when PE is administered orally.[87]

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[83] *Id.*
[84] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 29 (2023), https://www.fda.gov/media/171915/download.
[85] *Id.*
[86] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 9 (2023), https://www.fda.gov/media/171915/download (citing Hendeles & Hatton, Citizen Petition — Phenylephrine (2015), https://www.regulations.gov/docket/FDA-2015-P-4131).
[87] *Id.*

2015 Citizen's Petition

70. On November 4, 2015, Leslie Hendeles, PharmD, and Randy C. Hatton, PharmD, FCCP, BCPS, filed a Citizen's Petition (the "2015 Petition") under 21 CFR Part 10.30 to request the removal of oral PE, both individually and in combination drug products, from the FM for OTC nasal decongestant products, and to remove phenylephrine bitartrate ("PEB") from the 2006 Amendment to the FM.[88]

71. The 2015 Citizen's Petition cited their previously filed 2007 Citizen's Petition which requested the dosage of oral PE be re-evaluated and the approval for use in children under twelve years old be withdrawn.[89]

72. The 2015 Petition outlined the results of the three new additional studies which were performed and published since the 2007 NDAC meeting and presented evidence which "provide further evidence of the absence of a decongestant effect from the FDA-approved nonprescription dose of 10mg," and showed that "PE was not significantly different from placebo in the mean change in subjective nasal congestion scores."[90]

73. In response to the 2015 Citizen's Petition, the American Academy of Allergy, Asthma and Immunology also filed a letter with the FDA citing their support of the 2015 Citizen's Petition's findings.[91]

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[88] *Id.*
[89] *Id.*
[90] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 9 (2023), https://www.fda.gov/media/171915/download.
[91] *Id.* at 8.

The Three Modern Clinical Trials

74. Three large, adequately controlled modern clinical trials have been conducted on PE.[92] These three trials represent the largest and most carefully conducted studies on the effects of oral PE.

75. In 2011, Merck (formerly Schering-Plough Pharmaceuticals), conducted a multicenter, double-blind, placebo-controlled, multiple-dose crossover Phase 2 parallel trial on 539 subjects with allergic rhinitis to evaluate the potential for a higher than monographed dose of IR PE up to 40 mg.[93] The results of Merck's trial demonstrated not only demonstrated no effect of a higher than monographed dose of PE up to 40 mg, but also demonstrated no effect of orally administered PE at any dosage.[94]

76. Merck also conducted a Phase 3, multicenter, randomized, double-blind, placebo-controlled, two-arm, parallel-group trial on 575 adult subjects with pollen allergens to evaluate the effect of 30 mg of a modified-release formulation of PEH. This study was conducted in 2011, and later published in 2016 in a peer-reviewed journal. The NDAC noted in its 2023 review that this study likely was an attempt to support an application for an extended-release PE product at a higher than monographed dose. However, the results of this study showed no statistically

[92] *Id.* at 43.
[93] *Id.*
[94] *Id.*

meaningful difference in nasal symptoms between the PE and placebo treatment groups. The NDAC notes in its 2023 review of this study that the results "clearly demonstrate that active treatment was numerically no better than placebo at any timepoint in the trial" and "the placebo arm had numerically more mean improvement over the course of the study." Further, the 2023 NDAC concluded that "this study provides high-quality (Level 1) evidence that PE is not an effective nasal decongestant when administered orally in a 30 mg formulation."

77. In addition, the Agency noted a third, additional interim analysis conducted in 2017-2018 by Defendant Johnson and Johnson in Canada on subjects with the common cold to evaluate a 30 mg ER oral PE product taken twice daily, along with a 12 mg IR product taken four times daily.[95] This analysis was a randomized, double-blind, double-dummy, placebo controlled, parallel group, which enrolled 193 subjects, although it had planned to enroll 450 subjects;[96] because of this, it was terminated as a study and was designed as an interim analysis. In addition, this study used nasal symptom scores, not NAR, for its primary endpoint, thus aligning with the FDA's modern guidelines.[97] While only deemed an interim analysis, it was significant in that it **demonstrated that oral PE also had**

[95] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 51 (2023), https://www.fda.gov/media/171915/download.
[96] *Id.*
[97] *Id.*

no effect on subjects with colds.[98]

78. All three trials used the clinically acceptable designs and endpoints that were missing in the original studies considered.

79. All three of these trials demonstrate lack of efficacy of IR oral PE doses up to 40 mg as well as no efficacy of extended-release ("ER") doses of oral PE up to 30 mg. As a result, all three of these trials demonstrated that there was no difference between the effects of a placebo in comparison to either the monographed dose of PE or a higher than monograph dose of PE.

80. In the NDAC's 2023 review, the NDAC notes that these studies are consistent, substantial, and believable and they confirm that orally administered PE is not effective at any dose that can be developed.[99]

September 2023: FDA Advisory Panel Votes 16-0 on Inefficacy of Oral PE as Nasal Decongestant

81. The 2020 CARES Act provides that the CCBAP Monograph may be amended via a new administrative order process established under Section 505G of the Food, Drug, and Cosmetic Act (rather than the ANRP process).[100] The NDAC states this provides a "simplified" process to contemplate changes to the CCBAP Monograph.[101] The NDAC readily admitted that past changes to the monograph

[98] *Id.* at 51-52.
[99] *Id.* at 42.
[100] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 12 (2023), https://www.fda.gov/media/171915/download.
[101] *Id.*

were delayed by the "time and resources needed to fully review the issues."

82. As a result of the 2015 Citizen's Petition and the simplified monograph review process established by the CARES Act, the FDA's NDAC met on September 11, and 12, 2023.[102] As a result of an extensive review of all the relevant material (as summarized above), the NDAC members voted unanimously (16-0) that orally administered PE is not effective as a nasal decongestant.[103]

83. The NDAC's conclusion was made after extensive review of the following: (1) the fourteen original clinical trials that were the basis for the FDA's approval of PE, (2) the 2007 Citizen's Petition, (3) the 2007 NDAC meeting and two meta-analyses presented there, (4) bioavailability data which demonstrated that less than one percent (<1%) of an oral dose of PE is systemically available, (5) two EEU studies, (6) three modern clinical studies done since the 2007 NDAC meeting, and (7) the 2015 Citizen's Petition.[104]

84. The NDAC found that this information demonstrated that oral PE is ineffective as a nasal decongestant, especially after considering the results of the new data from the three modern studies, the significant methodological and statistical issues with the design and conduct of the original studies, and the use of

[102] *Id.* at 9-13.
[103] *Id.* at 9-14.
[104] *Id.*

NAR rather than nasal symptom scores as an endpoint.[105] The NDAC also noted that all but one of the original studies evaluated the common cold, not allergy symptoms; the common cold has significant symptomatic variation between individuals and is therefore not an efficient barometer to study whether oral PE provides its stated benefits.[106] In addition, thirteen of the fourteen original studies evaluated extremely small sample sizes, and no original study controlled for bias or multiplicity.[107]

85. The NDAC also noted that ten of the original studies were all from one sponsor and were small, single-center crossover studies with significant issues; six of these ten studies formed the basis to support oral PE's GRASE designation; two of the single sponsor studies were the most positive and their results were unable to be replicated.[108]

86. The NDAC also reviewed the EEU studies presented at the 2007 NDAC meeting and concluded that in both studies, PE failed to provide any benefit over placebo, while PSE provided good relief of congestion symptoms in one of the studies.[109]

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[105] In 2018, the FDA issued new guidance instructing the industry to use nasal congestion symptom scores, not NAR, as a primary endpoint to evaluate nasal congestion in studies moving forward. *See* https://www.fda.gov/files/drugs/published/Allergic-Rhinitis--Developing-Drug-Products-for-Treatment-Guidance-for-Industry.pdf.
[106] U.S. FOOD & DRUG ADMIN., EFFICACY OF ORAL PHENYLEPHRINE AS A NASAL DECONGESTANT 32-34 (2023), https://www.fda.gov/media/171915/download.
[107] *Id.*
[108] *Id.* at 32-33.
[109] *Id.* at 32.

87. The NDAC also reviewed the findings of three large clinical trials since the 2007 meeting.

88. The NDAC concluded that as a result of their evaluation of all the aforementioned scientific evidence, they believe the new efficacy data outweighs the outdated data provided for the original Panel's review, and, along with the modern clinical trials and data, their evaluation demonstrated that: (1) oral PE at monographed dosages is not effective as a decongestant, (2) oral doses up to 40 mg would also not be effective, (3) finding an effective oral dose that is also safe is not feasible, and (4) an appropriate dosing interval for oral PE has not been established. Therefore, the Agency concluded that "in addition to lack of efficacy, there may be no path to evaluating higher doses of oral PE as a nasal decongestant."[110]

IV. Misbranded/mislabeled and/or Adulterated Drugs are Illegal to Sell

89. Drugs in the United States that are not manufactured in accordance with Current Good Manufacturing Practices ("cGMPs") are deemed "adulterated" or "misbranded" and thus many not be distributed or sold in the United States.[111] States have similar laws adopting or mirroring these federal standards. Defendants, as manufacturers of oral PE products sold OTC, are bound by these requirements.

[110] *Id.* at 33.

[111] 21 U.S.C. §§ 331(a), 351(a)(2)(B). 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).

90. Oral PE products are OTC drug products regulated by the FDA and thus would be required to meet specified safety, quality, purity, identity and strength standards.[112] The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

91. Defendants' oral PE products are "adulterated" as defined by the Food, Drug and Cosmetic Act ("FDCA") because they are a "drug" 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**." (emphasis added).

92. Because Defendants' oral PE products do not have the identity and strength claimed, its products cannot be distributed or sold in the United States under federal law.

93. A drug is considered "misbranded" if: "its labeling is false or misleading in any particular…."[113] The manufacture and sale of misbranded drugs

[112] 21 U.S.C. § 351(a)(2)(B).
[113] 21 U.S.C. § 352(a)(1)

is prohibited under federal law, as is the introduction of any misbranded product into the stream of interstate commerce.

94. Because Defendants' oral PE products do not provide the stated nasal decongestion health benefits as labeled on its oral PE products, its products are misbranded and are in violation of federal law.

95. Plaintiff's reference to federal law in this Complaint is to demonstrate that its state law tort claims do not impose additional obligations on Defendants beyond what they are already required to comply with under federal law for the distribution of oral PE products.

V. The Impact of Defendants' Wrongful Conduct

96. Despite clinical studies demonstrating oral PE Products' ineffectiveness, Defendants conveyed and continue to convey one uniform nasal congestion relief health message: that oral PE Products are nasal decongestion over-the-counter medicines capable of providing nasal decongestion health benefits.

97. As the manufacturer of the oral PE Products, Defendants possess specialized knowledge regarding their content and effects of their ingredients, and Defendants are in a superior position to know whether the oral PE Products' work as advertised.

98. Specifically, Defendants knew, but failed to disclose, or should have known, that the oral PE Products cannot provide nasal decongestion health benefits,

and that well-conducted clinical studies have found the oral PE Products' primary ingredients are unable to support or benefit nasal decongestion.

99. Plaintiff and the class members have been and will continue to be deceived or misled by Defendants' false and deceptive nasal decongestion health representations.

100. Defendants' nasal decongestion health representations and omissions were a material factor in influencing Plaintiffs and the class members' decision to purchase the oral PE Products. In fact, the only purpose for purchasing the oral PE Products is to obtain the represented nasal decongestion health benefits.

101. Defendants' conduct has injured Plaintiffs and the class members because Defendants' oral PE Products are worthless and cannot support or benefit nasal decongestion health in any way.

102. Had Plaintiffs and the class members known the true nature of Defendants' oral PE Products, they would not have purchased the oral PE Products and would not have paid the prices they paid for the oral PE Products.

103. Plaintiffs and each class member were harmed by purchasing Defendants' oral PE Products because they are not capable of providing their advertised benefits. As a result, Plaintiffs and each class member lost money and property by way of purchasing Defendants' ineffective and worthless nasal decongestion over-the-counter medicines.

CLASS DEFINITION AND ALLEGATIONS

104. Plaintiffs, pursuant to Fed. R. Civ. Pro. 23(b)(2) and 23(b)(3), bring this action on behalf of the following Class:

> All persons who purchased in the United States any of Defendants' oral PE Products for personal or household use.

105. Excluded from the Class is Defendants, its parents, subsidiaries, affiliates, officers, and directors, those who purchased the oral PE Products for resale, all persons who make a timely election to be excluded from the Class, the judge to whom this case is assigned and any immediate family members thereof, and those who assert claims for personal injury.

106. Plaintiffs reserve the right to amend the definition of the Class if discovery or further investigation reveals that the Class should be expanded or otherwise modified.

107. Plaintiffs, pursuant to Fed. R. Civ. Pro. 23(b)(2) and 23(b)(3), also bring this action on behalf of the following Subclass:

> **California Subclass**
>
> All persons who purchased in the state of California any of Defendants' oral PE Products for personal or household use.

108. Excluded from the Subclass are Defendants, its parents, subsidiaries, affiliates, officers, and directors, those who purchased the PE Products for resale, all persons who make a timely election to be excluded from the Class, the judge to

whom this case is assigned and any immediate family members thereof, and those who assert claims for personal injury.

109. Certification of Plaintiffs' claims for class wide treatment is appropriate because Plaintiffs can prove the elements of their claims on a class wide basis using the same evidence as would be used to prove those elements in individual actions alleging the same claims.

110. **Numerosity – Federal Rule of Civil Procedure 23(a)(1).** The members of the Class are so numerous that individual joinder of all Class members is impracticable. Defendants has sold many thousands of units of the oral PE Products to Class members.

111. **Commonality and Predominance – Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3).** This action involves common questions of law and fact, which predominate over any questions affecting individual Class members. Specifically, whether Defendants' representations regarding its oral PE Products and their health benefits are misleading and deceptive is a question common to the class. Similarly, oral PE Products are either capable of providing nasal decongestive health benefits or they are not, and Defendants' uniform representation that oral PE Products are OTC medicines capable of providing nasal decongestive health benefits either is true or false. These questions and others like them are common to the Class and predominate over individual issues.

112. **Typicality – Federal Rule of Civil Procedure 23(a)(3).** Plaintiffs' claims are typical of the other Class members' claims because, among other things, all Class members were comparably injured through the uniform prohibited conduct described above.

113. **Adequacy of Representation – Federal Rule of Civil Procedure 23(a)(4).** Plaintiffs are adequate representatives of the Class because Plaintiffs' interests do not conflict with the interests of the other Class members Plaintiffs seek to represent; Plaintiffs have retained counsel competent and experienced in complex commercial and class action litigation; and Plaintiffs intend to prosecute this action vigorously. The interests of the Class members will be fairly and adequately protected by Plaintiffs and their counsel.

114. **Superiority – Federal Rule of Civil Procedure 23(b)(3).** A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The damages or other financial detriment suffered by Plaintiffs and the other Class members are relatively small compared to the burden and expense that would be required to individually litigate their claims against Defendants, so it would be impracticable for Class members to individually seek redress for Defendants' wrongful conduct. Even if Class members could afford individual litigation, the court system could not. Individualized litigation creates a

potential for inconsistent or contradictory judgments and increases the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

CLAIMS ALLEGED

COUNT I
Breach of Express Warranty

115. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

116. Plaintiffs bring this claim on behalf of themselves, and those members of the Class who purchased oral PE Products in states with similar warranty laws as applied to the facts of this case, or, in the alternative, on behalf of the Subclass.

117. Defendants, by affirmation of fact and/or promises set forth in its promotions, advertisements, packaging and/or labeling for oral PE Products created an express warranty that oral PE Products would conform to the affirmation and/or promises.

118. The affirmations of fact and/or promises made by Defendants on the oral PE Products' labels and advertising, which related to the health benefits of oral PE Products, are express warranties, became part of the basis of the bargain, and are

part of a standardized contract between Plaintiffs and the members of the Class on the one hand and Defendants on the other.

119. Plaintiffs and the Class members performed all conditions precedent under the contract between the Parties.

120. Defendants are in privity with Plaintiffs and members of the Class. Plaintiffs and Class members, not the retailers, were the intended beneficiaries of Defendants' products and the associated written warranties. Defendants created the advertising and labeling at issue for oral PE Products and warranted the products to Plaintiffs and members of the Class directly and/or through the doctrine of agency. Defendants' sale of the oral PE Products was either direct or through authorized sellers. Purchase through authorized sellers is sufficient to create privity because such authorized sellers are Defendants' agents for the purpose of the sale of the products. Further, Defendants knew the identity, purpose and requirements of Plaintiffs and members of the Class and manufactured the oral PE Products to meet their requirements.

121. Defendants breached the terms of the express warranty between the Parties including the express warranties related to the benefits of oral PE with Plaintiffs and the Class by not providing the oral PE Products in a manner that conformed to the affirmations and/or promises.

122. Defendants' breach of this express warranty has directly and proximately caused Plaintiffs and members of the Class to suffer damages in the amount of the purchase price of the oral PE Products.

123. Within a reasonable time of discovering the breach of express warranty by Defendants, Plaintiffs through counsel notified Defendants of the breach of warranty.

COUNT II

Unjust Enrichment
(On Behalf of a Multistate Class or the State Subclasses)

124. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

125. Plaintiffs bring this claim on behalf of themselves, and those members of the Class who purchased oral PE Products in states with similar unjust enrichment laws as applied to the facts of this case, or, in the alternative, on behalf of the Subclass.

126. As a direct and proximate result of its misrepresentations concerning the health benefits of the oral PE Products and its failure to disclose that oral PE products are ineffective in providing the advertised nasal decongestion health benefits, Defendants has profited through the sale of its oral PE Products to Plaintiffs and Class members.

127. Defendants' unlawful and wrongful acts, as alleged above, enabled Defendants to unlawfully receive money from Plaintiffs and the Class it would not have otherwise obtained.

128. Plaintiffs and the Class members have conferred benefits on Defendants, which Defendants have knowingly accepted and retained.

129. Defendants' retention of the benefits conferred by Plaintiffs and the Class members would be against fundamental principles of justice, equity, and good conscience.

130. Plaintiffs and the Class members seek to disgorge Defendants' unlawfully retained money resulting from their unlawful conduct and seek restitution and rescission for the benefit of Plaintiffs and the Class members.

131. Plaintiffs and the Class members are entitled to the imposition of a constructive trust upon Defendants, such that its unjustly retained money is distributed equitably by the Court to and for the benefit of Plaintiffs and the Class members.

COUNT III

Negligent Misrepresentation
(On Behalf of a Multistate Class or the State Subclasses)

132. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

133. Plaintiffs bring this claim on behalf of themselves, and those members of the Class who purchased oral PE Products in states with similar negligent misrepresentation laws as applied to the facts of this case, or, in the alternative, on behalf of the Subclass.

134. Defendants represented to Plaintiffs and the other members of the Class that oral PE Products will relieve nasal congestion or its symptoms. These representations were made by Defendants in its advertising, packaging and labeling for oral PE Products disseminated to Plaintiffs and the other members of the Class prior to their purchases of oral PE Products.

135. These representations of the health benefits oral PE Products provide were false and misleading because the scientific evidence demonstrates oral PE Products and their ingredients are incapable and do not provide the advertised nasal decongestion health benefits.

136. Defendants represented that the above-identified facts that oral PE Products will relieve nasal congestion or its symptoms were true when it had no reasonable grounds for believing them to be true.

137. Defendants made the representations concerning the nasal decongestion health benefits of oral PE Products with the intent to induce Plaintiffs and the other members of the Class to purchase oral PE Products.

138. Plaintiffs and the other members of the Class believed that Defendants' representations as to the health benefits of taking oral PE Products were true and materially complete and did not know of the falsity of the representations. In reliance on Defendants' representations and in belief the representations were materially complete, Plaintiffs and the other members of the Class purchased oral PE Products and have been damaged in an amount to be determined at trial.

COUNT IV

Fraud
(On Behalf of a Multistate Class or the State Subclasses)

139. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

140. Plaintiffs bring this claim on behalf of themselves, and those members of the Class who purchased oral PE Products in states with similar common law fraud laws as applied to the facts of this case, or, in the alternative, on behalf of the Subclass.

141. As alleged herein, Defendants knowingly made material misrepresentations and omissions regarding PE Products in its advertisements, labeling and packaging for oral PE Products.

142. Defendants made these material misrepresentations and omissions in order to deceive Plaintiffs and Class members into purchasing oral PE Products.

143. Defendants knew that its representations concerning the health benefits of oral PE Products made to Plaintiffs and the Class were false and untrue at the time the representations were made, or recklessly made the statements with no belief in the truth of the statements, but nevertheless made such representations through the marketing, advertising and oral PE Products' labeling, including through its representation on its packaging that its oral PE Products provide "Maximum Strength Congestion Relief," assist with nasal decongestion and that Defendants' oral PE Products are the "#1 Pharmacist Recommended Decongestant Brand." In reliance on these and other similar misrepresentations, Plaintiffs and Class members were induced to, and did, pay monies to purchase the oral PE Products.

144. Plaintiffs and Class members did not know—nor could they have known through reasonable diligence—that oral PE Products does not provide the advertised nasal decongestion health benefits and is indeed incapable of providing the claimed benefits.

145. Plaintiffs and Class members have been reasonable in relying on Defendants' misrepresentations and omissions in making their decisions to purchase oral PE Products.

146. Had Plaintiffs known the truth about the oral PE Products, including that they do provide the advertised health benefits, they would not have purchased the oral PE Products.

COUNT V

Violation of the New Jersey Consumer Fraud Act
N.J.S.A. §§ 56:8-1, *et seq*.
(On Behalf of a Multistate Class or the New Jersey Subclass)

147. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

148. Plaintiffs bring this claim individually, and on behalf of those members of the Class who purchased oral PE Products in states with state consumer laws that are similar to the New Jersey Consumer Fraud Act, N.J.S.A. §§ 56:8-1, *et seq.* (the "NJCFA") as applied to the facts of this case, or, in the alternative, on behalf of the California Subclass.

149. This cause of action is brought pursuant to the New Jersey Consumer Fraud Act, N.J.S.A. §§ 56:8-1, *et seq.*

150. Section 56:8-2 of the NJCFA provides, in relevant part:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice . . . .

151. Plaintiffs, other members of the Class, and Defendants are "persons" within the meaning of the NJCFA.

152. Plaintiffs and other members of the Class are "consumers" who purchased "merchandise" – oral PE Products – pursuant to a consumer transaction for personal use and are, therefore, subject to protection under the New Jersey Consumer Fraud Act, N.J.S.A. §§ 56:8-1, *et seq*.

153. Defendants conducted trade or commerce within the meaning of the NJCFA.

154. The acts, practices, misrepresentations, concealments, and omissions by Defendants were made in connection with the sale and advertisement of its oral PE Products and with the intent that others rely upon such concealment, suppression and omission, and constitute unlawful, deceptive and unconscionable commercial practices within the meaning of the NJCFA.

155. Defendants also knowingly concealed, suppressed and consciously omitted material facts about the inefficacy of oral PE Products to Plaintiffs and other members of the Class knowing that consumers would rely on the advertisements and packaging to purchase oral PE Products.

156. Defendants' misrepresentations and omissions about oral PE Products were material and were intended to, and likely to, deceive a reasonable consumer.

157. As a result of the use and employment by Defendants of the unlawful acts, Plaintiffs and other Class members have suffered ascertainable losses in the form of, *inter alia*, monies spent to purchase oral PE Products, and they are entitled

to recover such damages, together with appropriate penalties, including treble damages, attorneys' fees and costs of suit pursuant to N.J.S.A. §§ 56:8-2.11, 56:8-2.12 and 56:8-19. As alleged above, oral PE Products do not provide the advertised health benefits to the user and, thus, are worthless.

158. Additionally, pursuant to N.J.S.A. § 56:8-19, Plaintiff and members of the Class seek injunctive relief to stop the ongoing deceptive advertising and for a corrective advertising campaign.

COUNT VI

Violation of the California Unfair Competition Law ("UCL") Cal. Bus. & Prof. Code §§17200, *et seq.*

159. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

160. Plaintiffs bring this claim individually and on behalf of the Class.

161. Plaintiffs and Defendants are "persons" within the meaning of the UCL. Cal. Bus. & Prof. Code §17201.

162. The UCL defines unfair competition to include any "unlawful, unfair or fraudulent business act or practice," as well as any "unfair, deceptive, untrue or misleading advertising." Cal. Bus. Prof. Code §17200.

163. In the course of conducting business, Defendants committed unlawful business practices by, among other things, making the representations (which also constitutes advertising within the meaning of §17200) and omissions of material

facts, as set forth more fully herein, and violating Civil Code §§1572, 1573, 1709, 1711, 1770(a)(5), (7), (9) and (16) and Business & Professions Code §§17200*, et seq*., 17500, *et seq*., 21 U.S.C. 343(r)(6), and the common law.

164. Plaintiffs reserve the right to allege other violations of law, which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.

165. In the course of conducting business, Defendants committed "unfair" business practices by, among other things, making the implied and express representations (which also constitute advertising within the meaning of §17200) and omissions of material facts regarding oral PE Products in its advertising and labeling, including on the oral PE Products' packaging, as set forth more fully herein. There is no societal benefit from false and misleading advertising – only harm. Plaintiffs and the other Class members paid for a valueless product that is not capable of conferring the benefits promised. While Plaintiffs and the other Class members were harmed, Defendants were unjustly enriched by its false misrepresentations and omissions. As a result, Defendants' conduct is "unfair," as it offended an established public policy. Further, Defendants engaged in immoral, unethical, oppressive, and unscrupulous activities that are substantially injurious to consumers.

166. Further, as set forth in this Complaint, Plaintiffs allege violations of consumer protection, unfair competition, and truth in advertising laws in California

and other states, resulting in harm to consumers. Defendants' acts and omissions also violate and offend the public policy against engaging in false and misleading advertising, unfair competition, and deceptive conduct towards consumers. This conduct constitutes violations of the unfair prong of Business & Professions Code §§17200, *et seq*.

167. There were reasonably available alternatives to further Defendants' legitimate business interests, other than the conduct described herein. Business & Professions Code §§17200, *et seq*., also prohibits any "fraudulent business act or practice." In the course of conducting business, Defendants committed "fraudulent business act or practices" by, among other things, making the implied and express representations (which also constitute advertising within the meaning of §17200) and omissions of material facts regarding the oral PE Products in its advertising, including on the oral PE Products' packaging and labeling, as set forth more fully herein. Defendants made the misrepresentations and omissions regarding the efficacy of its oral PE Products, among other ways, by misrepresenting on each and every oral PE Products' packaging and labeling that the oral PE Products are effective when taken as directed, when, in fact, the representations are false and deceptive, and the oral PE Products are not capable of conferring the promised health benefits.

168. Defendants' actions, claims, omissions, and misleading statements, as

more fully set forth above, were also false, misleading and/or likely to deceive the consuming public within the meaning of Business & Professions Code §§17200, *et seq*.

169. Plaintiffs and the other members of the Class have in fact been deceived as a result of their reliance on Defendants' material representations and omissions, which are described above. This reliance has caused harm to Plaintiffs and the other members of the Class, each of whom purchased Defendants' oral PE Products. Plaintiffs and the other Class members have suffered injury in fact and lost money as a result of purchasing the oral PE Products and Defendants' unlawful, unfair, and fraudulent practices.

170. Defendants knew, or should have known, that its material misrepresentations and omissions would be likely to deceive and harm the consuming public and result in consumers making payments to Defendants for oral PE Products that are valueless and that are incapable of actually supporting, maintaining, improving or benefiting nasal decongestion health.

171. As a result of its deception, Defendants were unjustly enriched by receiving payments from Plaintiffs and the Class in return for providing Plaintiffs and the Class, the oral PE Products that do not perform as advertised.

172. Unless restrained and enjoined, Defendants will continue to engage in the unlawful, unfair and fraudulent conduct described herein.

173. Accordingly, Plaintiffs, individually and on behalf of all others similarly situated, and on behalf of the general public, seeks restitution from Defendants of all money obtained from Plaintiffs and the other members of the Class collected as a result of Defendants' unfair competition, and awarding all other relief this Court deems appropriate.

COUNT VII

Violation of the California Consumers Legal Remedies Act ("CLRA") Cal. Civ. Code §§1750, *et seq.*

174. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

175. Plaintiffs bring this claim individually and on behalf of the Class.

176. Plaintiffs are "consumer(s)," and Defendants are a "person," and the oral PE Products are "goods" within the meaning of the CLRA. Cal. Civ. Code §1761(a), (c) and (d).

177. Defendants' sale and advertisement of its oral PE Products constitutes "transactions" within the meaning of the CLRA. Cal. Civ. Code §1761(e).

178. The CLRA declares as unlawful the following unfair methods of competition and unfair or deceptive acts or practices when undertaken by any person in a transaction intended to result, or which results in the sale of goods to any consumer:

(5) Representing that goods … have . . . approval, characteristics, . . . uses

> [and] benefits . . . which [they do] not have . . . .
> (7) Representing that goods … are of a particular standard, quality or grade . . . if they are of another.
> (9) Advertising goods . . . with intent not to sell them as advertised.
> (16) Representing that [goods] have been supplied in accordance with a previous representation when [they have] not.
> Cal. Civ. Code §1770(a)(5), (7), (9) and (16).

179. Defendant violated the CLRA by representing that its oral PE Products are beneficial for nasal decongestion health, when, in reality, the oral PE Products cannot provide their advertised benefits and the oral PE Products' ingredients are ineffective at improving, supporting, maintaining or benefiting the health of nasal congestion.

180. Defendants knew or should have known its health representations were false and misleading, and that by omitting the ineffectiveness of its oral PE Products it was omitting a material fact that would alter any consumer's decision to purchase the oral PE Products.

181. Defendants' violations of the CLRA proximately caused injury in fact to Plaintiffs and the Class.

182. Plaintiffs and the Class members purchased Defendants' oral PE Products on the belief that they would receive the advertised health benefits from the oral PE Products. Indeed, no consumer would purchase an oral PE Product unless he or she believed it was capable of providing meaningful nasal decongestive benefits.

183. Defendants' oral PE Products, however, are worthless and cannot provide any of their advertised benefits. Since the oral PE Products lack any value, Plaintiffs and each Class member was injured by the mere fact of their purchase.

184. Pursuant to Cal. Civ. Code §1780, Plaintiffs, individually and on behalf of the other members of the Class, seek a Court order to enjoin the Defendants' improper sale and marketing of the PE Products.

185. Pursuant to Cal. Civ. Code §1782(a), Defendants were notified in writing by certified mail of the particular violations of Section 1770 of the CLRA, which notification demanded that Defendants rectify the problems associated with the actions detailed above and give notice to all affected consumers of Defendants' intent to so act. Copies of the letters are attached hereto as Exhibits A-D.

186. If Defendants fail to rectify or agree to rectify the problems associated with the actions detailed above and give notice to all affected consumers within 30 days of the date of written notice pursuant to §1782 of the Act, Plaintiffs will amend this claim to seek actual, punitive and statutory damages, as appropriate.

187. Defendants' conduct is fraudulent, wanton, and malicious.

188. Pursuant to §1780(d) of the Act, attached hereto as Exhibit E is the affidavit showing that this action has been commenced in the proper forum.

JURY DEMAND

189. Plaintiffs demand a trial by jury of all claims in this Complaint so triable.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the other members of the proposed Class, respectfully requests that the Court enter judgment in Plaintiffs' favor and against Defendants as follows:

A. Declaring that this action is a proper class action, certifying the Class as requested herein, designating Plaintiffs as Class Representatives and appointing the undersigned counsel as Class Counsel;

B. Ordering restitution and disgorgement of all profits and unjust enrichment that Defendants obtained from Plaintiffs and the Class members as a result of Defendants' unlawful, unfair and fraudulent business practices;

C. As to the CLRA claim, Plaintiffs seek an order enjoining Defendant's improper sale and marketing of the PE products;

D. Ordering actual, treble, statutory and punitive damages;

E. Ordering Defendants to pay attorneys' fees and litigation costs to Plaintiffs and the other members of the Class;

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F. Ordering Defendants to pay both pre- and post-judgment interest on any amounts awarded; and

G. Ordering such other and further relief as may be just and proper.

Dated: September 29, 2023

Respectfully submitted,

By: */s/Todd D. Carpenter*

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