IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MILLARD ADKINS; ROSALYN ANDERSON; ELI ERLICK; DONNA BAILEY; ROSALIE JACKSON; RECOA RUSSELL; FRANK ANDERSON; and TINA HALUSZKA, individually and on behalf of all others similarly situated, Plaintiffs, v. RECKITT BENCKISER PHARMACEUTICALS INC.; THE PROCTER & GAMBLE COMPANY; JOHNSON & JOHNSON CONSUMER INC.; KENVUE INC.; BAYER AG; BAYER CORPORATION; GSK PLC; GLAXOSMITHKLINE LLC; HALEON PLC; HALEON US CAPITAL LLC; THE KROGER CO.; TARGET CORPORATION; WALGREENS BOOTS ALLIANCE, INC.; and WALMART INC., Defendants.	Case No. 2:23-CV-20743 **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs Millard Adkins; Rosalyn Anderson; Eli Erlick; Donna Bailey; Rosalie Jackson; Recoa Russell; Frank Anderson; and Tina Haluszka ("Plaintiffs"), individually and on behalf of all others similarly situated (proposed "Class Members"), bring this action against Defendants Reckitt Benckiser Pharmaceuticals Inc.; The Procter & Gamble Company; Johnson & Johnson Consumer Inc.; Kenvue Inc.; Bayer AG; Bayer Corporation; GSK plc; GlaxoSmithKline LLC; Haleon plc; Haleon US Capital LLC; The Kroger Co.; Target Corporation; Walgreens Boots Alliance, Inc.; and Walmart Inc. ("Defendants") and allege as follows based on personal

knowledge as to their own acts and on investigation conducted by counsel as to all other allegations:

INTRODUCTION

1. On September 12, 2023, an FDA advisory panel unanimously voted 16-0 finding that orally administered phenylephrine ("PE") is not effective for treating nasal congestion.[1]

2. Defendants designed, manufactured, advertised, marketed, distributed, and sold orally administered PE-containing drugs which were advertised, marketed, warranted, and indicated as treating nasal congestion ("PE Drugs") despite PE being totally ineffective and worthless in treating nasal congestion when taken orally.

3. PE indicated as an orally administered nasal decongestant is worthless, non-merchantable, not fit for its ordinary purpose, and not effective for treating the indications identified.

4. As a result, Defendants' PE Drugs were misbranded and worthless or worth substantially less than what Plaintiffs and Class Members paid for them.

5. Defendants' claims were false, misleading, and contrary to scientific evidence, leading Plaintiffs and Class Members to purchase PE Drugs which were ineffective and worthless for treating nasal congestion.

6. This case arises out of Plaintiffs and Class Members' purchase of Defendants' PE Drugs. Plaintiffs and Class Members have been injured as a result and are entitled to damages, restitution, and equitable relief.

PARTIES

I. Plaintiffs

[1] https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-results-recent-advisory-committee-meeting-oral-phenylephrine

7. Plaintiff Millard Adkins is a resident of Idamay, West Virginia. He purchases PE Drugs frequently seeking relief from congestion caused by respiratory conditions. Within the last three months, Plaintiff Adkins purchased Mucinex Fast-Max, Mucinex Sinus Max, Mucinex NightShift, and Mucinex NightShift Sinus (designed, manufactured, advertised, marketed, distributed, and sold by Defendant Reckitt Benckiser Pharmaceuticals, Inc.). All of these PE Drugs were purchased in West Virginia. These PE Drugs were ineffective in relieving Plaintiff Adkins's congestion.

8. Plaintiff Rosalyn Anderson is a resident of Stevenson Ranch, California. Due to a lung condition, she purchases PE Drugs several times per year. Between January and March of 2023, Plaintiff Anderson purchased Vicks DayQuil Cough Congestion and Vicks NyQuil Severe Cold & Flu, (designed, manufactured, advertised, marketed, distributed, and sold by Defendant The Procter & Gamble Company). She also purchased Mucinex Sinus Max (designed, manufactured, advertised, marketed, distributed, and sold by Reckitt Benckiser Pharmaceuticals, Inc.), Theraflu (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Haleon plc and Haleon US Capital LLC), and Alka-Seltzer Plus Cold (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Bayer AG and Bayer Corporation). All of these PE Drugs were purchased in California. These PE Drugs were ineffective in relieving Plaintiff Anderson's congestion.

9. Plaintiff Eli Erlick is a resident of New York, New York. In March 2023, he purchased Up&Up Daytime and Nighttime Vapor Ice Cold and Flu (designed, manufactured, advertised, marketed, distributed, and sold by Defendant Target Corporation) and Tylenol Cold & Flu Severe Day & Night Caplets (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Johnson & Johnson Consumer Inc. and Kenvue Inc.). In May 2022, he

purchased Vicks DayQuil & NyQuil Severe Cold & Flu Relief (designed, manufactured, advertised, marketed, distributed, and sold by Defendant The Procter & Gamble Company). All of these PE Drugs were purchased in New York. These PE Drugs were ineffective in relieving Plaintiff Erlick's congestion.

10. Plaintiff Donna Bailey is a resident of Weirton, West Virginia. In March 2023, she purchased Sudafed PE (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Johnson & Johnson Consumer Inc. and Kenvue Inc.), Tylenol Cough & Cold (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Johnson & Johnson Consumer Inc. and Kenvue Inc.), Tylenol Cold Multi-Symptom (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Johnson & Johnson Consumer Inc. and Kenvue Inc.), and generic brands from Kroger (designed, manufactured, advertised, marketed, distributed, and sold by Defendant The Kroger Co.) and Equate (designed, manufactured, advertised, marketed, distributed, and sold by Defendant Walmart Inc.). All of these PE Drugs were purchased in West Virginia. These PE Drugs were ineffective in relieving Plaintiff Bailey's congestion.

11. Plaintiff Rosalie Jackson is a resident of Ashland, Wisconsin. Within the past year, Plaintiff Jackson has purchased Alka-Seltzer Plus PowerMax Gels (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Bayer AG and Bayer Corporation) and a Walgreens generic brand (designed, manufactured, advertised, marketed, distributed, and sold by Defendant Walgreens Boots Alliance, Inc.). In the past, she has also purchased Sudafed PE (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Johnson & Johnson Consumer Inc. and Kenvue Inc.), Vicks DayQuil & NyQuil Severe Cold & Flu Relief and Vicks Sinex (designed, manufactured, advertised, marketed, distributed, and sold by Defendant

The Procter & Gamble Company), various Tylenol products containing phenylephrine including Tylenol Cough & Cold and Tylenol Sinus (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Johnson & Johnson Consumer Inc. and Kenvue Inc.), Benadryl Allergy D Plus (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Johnson & Johnson Consumer Inc. and Kenvue Inc.), Robitussin Multi-Symptom (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Haleon plc and Haleon US Capital LLC), and Theraflu (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Haleon plc and Haleon US Capital LLC). All of these PE Drugs were purchased in Wisconsin. These PE Drugs were ineffective in relieving Plaintiff Jackson's congestion.

12. Plaintiff Recoa Russell is a resident of Mobile, Alabama. In June 2023, he purchased Alka-Seltzer Plus Maximum Strength Day & Night Cold & Flu Liquid Gels designed, manufactured, advertised, marketed, distributed, and sold by Defendant (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Bayer AG and Bayer Corporation) and Tylenol Cold & Flu Severe (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Johnson & Johnson Consumer Inc. and Kenvue Inc.). All of these PE Drugs were purchased in Alabama. These PE Drugs were ineffective in relieving Plaintiff Russell's congestion.

13. Plaintiff Frank Anderson is a resident of Leesburg, Florida. In March of 2023, he purchased Theraflu Severe Cold & Cough (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Haleon plc and Haleon US Capital LLC). Previously, he has purchased Sudafed PE (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Johnson & Johnson Consumer Inc. and Kenvue Inc.), Tylenol Sinus, Tylenol Cough

& Cold, and Tylenol Cold Multi-Symptom (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Johnson & Johnson Consumer Inc. and Kenvue Inc.), Vicks NyQuil Severe Cold & Flu (designed, manufactured, advertised, marketed, distributed, and sold by Defendant The Procter & Gamble Company), Benadryl Allergy D Plus (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Johnson & Johnson Consumer Inc. and Kenvue Inc.), Mucinex Sinus Max, Mucinex Fast-Max, Mucinex Free From Cold & Flu, and Mucinex Nightshift Sinus (designed, manufactured, advertised, marketed, distributed, and sold by Defendant Reckitt Benckiser Pharmaceuticals, Inc.), Robitussin Multi-Symptom (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Haleon plc and Haleon US Capital LLC), and Delsym Multi-Symptom (designed, manufactured, advertised, marketed, distributed, and sold by Defendant Reckitt Benckiser Pharmaceuticals, Inc.). All of these PE Drugs were purchased in Florida. These PE Drugs were ineffective in relieving Plaintiff Frank Anderson's congestion.

14. Plaintiff Tina Haluszka is a resident of Worthington, Minnesota. In January 2023, she purchased Vicks Sinex (designed, manufactured, advertised, marketed, distributed, and sold by Defendant The Procter & Gamble Company), Mucinex Sinus max (designed, manufactured, advertised, marketed, distributed, and sold by Defendant Reckitt Benckiser Pharmaceuticals, Inc.), Alka-Seltzer Plus Multi-Symptom (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Bayer AG and Bayer Corporation), Robitussin Multi-Symptom (designed, manufactured, advertised, marketed, distributed, and sold by Defendants Haleon plc and Haleon US Capital LLC), and a generic Equate brand (designed, manufactured, advertised, marketed, distributed, and sold by Defendant Walmart Inc.). Plaintiff Haluszka uses these products daily due

to allergies and makes the purchases several times per year. All of these PE Drugs were purchased in Minnesota. These PE Drugs were ineffective in relieving Plaintiff Haluszka's congestion.

II. Defendants

15. Defendant Reckitt Benckiser Pharmaceuticals Inc. is a Delaware limited liability corporation with its principal place of business in Parsippany, New Jersey.

16. Defendant The Procter & Gamble Company is an Ohio corporation with its principal place of business in Cincinnati, Ohio.

17. Defendant Johnson & Johnson Consumer Inc. is a Delaware corporation with its principal place of business in Montgomery Township, New Jersey.

18. Defendant Kenvue Inc. is a Delaware corporation with its principal place of business in Montgomery Township, New Jersey. Kenvue Inc., including its subsidiaries and PE Drug brands, were spun off from Johnson & Johnson Consumer Inc. on February 23, 2022.

19. Defendant Bayer AG is a German corporation with its principal place of business in Leverkusen, Germany.

20. Defendant Bayer Corporation is an Indiana corporation with its principal place of business in Whippany, New Jersey. Bayer Corporation is a wholly owned subsidiary and the United States operational entity of Bayer AG.

21. Defendant GSK plc is a United Kingdom corporation with its principal place of business in Brentford, United Kingdom.

22. Defendant GlaxoSmithKline LLC is a Delaware limited liability company with its principal place of business in Philadelphia, Pennsylvania. GlaxoSmithKline LLC is a wholly owned subsidiary and the United States operational entity of GSK plc.

23. Defendant Haleon plc is a United Kingdom corporation with its principal place of business in Weybridge, United Kingdom. Haleon plc, including its subsidiaries and PE Drug brands, were spun off from GSK plc on July 18, 2022.

24. Defendant Haleon US Capital LLC is a Delaware limited liability company with its Warren, New Jersey. Haleon US Capital LLC is a wholly owned subsidiary and the United States operational entity of Haleon plc.

25. Defendant The Kroger Co. is an Ohio corporation with its principal place of business in Cincinnati, Ohio.

26. Defendant Target Corporation is a Minnesota corporation with its principal place of business in Minneapolis, Minnesota.

27. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business in Deerfield, Illinois.

28. Defendant Walmart Inc. is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

JURISDICTION AND VENUE

29. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1332(a) because the matter in controversy exceeds $75,000 and is between citizens of different states.

30. This Court has subject-matter jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d) because (1) the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, (2) the action is a class action, (3) there are members of the proposed Class who are diverse from Defendants, and (4) there are more than 100 Class Members.

31. This Court has general personal jurisdiction over Defendants because Defendants are residents of this state.

32. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(1) because Defendants are residents of this district.

FACTUAL ALLEGATIONS

III. PE Drugs

33. Phenylephrine ("PE") is a specific alpha-1 adrenergic receptor agonist that works by temporarily constricting blood vessels.

34. PE is an over-the-counter (OTC) ingredient marketed in both single ingredient and combination products. It has been available in the United States more than 75 years as well as globally.

35. The PE drugs at issue in this case are produced in two forms:

a. Phenylephrine hydrochloride

b. Phenylephrine bitartrate

36. Phenylephrine hydrochloride was first approved on August 23, 1994. *See* FR Doc. 94-20456.

37. Phenylephrine bitartrate was first approved on August 1, 2006. *See* 71 FR 43358.

38. PE has largely been approved for the temporary relief of nasal congestion due to the common cold, hay fever, or other respiratory allergies, or allergic rhinitis under the cough, cold, allergy, bronchodilator, and anti-asthmatic drug products monograph ("final monograph" or "CCABADP").

IV. Efficacy of Orally Administered PE for Nasal Decongestion

39. 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 pseudoephedrine?"[2] The letter questions 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.

40. On February 1, 2007, three professors from the University of Florida, Leslie Hendeles (PharmD, Professor, Department of Pharmacy and Pediatrics), Randy C. Hatton (PharmD FCCP BCPS, Co-Director, Drug Information and Pharmacy Resource Center, College of Pharmacy Clinical Professor) and Almut G. Winterstein (PhD, Assistant Professor, Department of Pharmacy Healthcare Administration) filed a Citizens Petition with the FDA concerning PE Drugs.[3]

41. Specifically, the Petition requested the dosage of oral phenylephrine (PE) be re-evaluated and that approval for use in children under twelve years old be withdrawn.[4] The Petition further stated that there was no data on the safety of PE in children under twelve years old.[5]

42. 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

[2] https://www.jacionline.org/article/S0091-6749(06)00633-6/fulltext
[3] https://www.regulations.gov/docket/FDA-2007-P-0108/document
[4] https://www.regulations.gov/docket/FDA-2007-P-0108/document
[5] https://www.regulations.gov/docket/FDA-2007-P-0108/document

doses were required." Further, a member of the Division of Nonprescription Drug Products expressed a preference for subjective symptom scores over objective measurement of nasal airway resistance to support the use of PE for temporary relief of nasal congestion.[6]

43. Schering-Plough Pharmaceuticals responded to the recommendations of the Committee and the Division by conducting a multicenter, phase 2, parallel trial among 539 adults with seasonal allergic rhinitis. The results of the study revealed no significant differences between placebo and active treatment groups.[7]

44. Another manufacturer, McNeil Consumer Healthcare, conducted a pharmacokinetic, safety and cardiovascular tolerability study of PE. Similarly, this study revealed no difference in safety endpoints between placebo and 10, 20 and 30 mg of PE even though systemic exposure increased disproportionately with dose. According to the petitioners, "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."[8]

45. On November 4, 2015, yet 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." Specifically, the

[6] https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf
[7] https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf
[8] https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf

petition asked the FDA to remove Phenylephrine and to remove phenylephrine bitartrate (PEB), "both individually and in combination drug products in an effervescent dosage form."[9]

46. According to the 2015 Citizens Petition, "Two additional studies published in 2009 provide further evidence of the absence of a decongestant effect from the FDA-approved nonprescription dose of 10 mg. Horak et al conducted a 3-way crossover, placebo-controlled study of the nasal decongestant effect of single doses of PE 12 mg, pseudoephedrine 60 mg or placebo among 39 grass-sensitive adults exposed to grass pollen in the Vienna Challenge Chamber. 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.

47. The 2015 Citizens Petition was further supported by the American Academy of Allergy, Asthma & Immunology.[10]

48. On information and belief, at this time, Defendants did not do additional testing and quality oversight of their PE Drugs to ascertain the true effectiveness for treating nasal congestion, or deliberately suppressed or avoided doing so. Had they done so and disclosed the results, the data would lead to the same inexorable conclusion reached on September 12, 2023, by an FDA Advisory Panel: PE administered orally is not effective for treating nasal congestion at all.

49. On September 12, 2023, the FDA Advisory Panel on the Division of Nonprescription Drugs recommended that PE Drugs not be sold due to lack of efficacy.[11]

[9] https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf
[10] https://college.acaai.org/wp-content/uploads/2022/05/oral-phenylephrine-final-statement-insupport-of-citizens-petition-05-4-22.pdf
[11] https://www.fda.gov/media/171915/download

50. In the FDA's Briefing Document regarding the hearing that took place on September 11-12, 2023, the FDA notes that it has been reviewing the clinical studies on the efficacy of PE since the 2007 Citizens Petition.[12]

51. The Advisory Panel 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 hours) as well as at doses up to 40 mg (dosed every 4 hours).[13]

52. The Advisory Panel met for two days on September 11-12, 2023. During this meeting, FDA scientists presented the results of five studies conducted over the past two decades on the effectiveness of oral phenylephrine. All the studies concluded that the decongestant was no more effective than a placebo. The Advisory Panel further reevaluated the initial findings which supported PE Drugs' use and found that the results were inconsistent, did not meet modern study design standards and further that these studies may have data integrity issues:

> "In conclusion, we do believe that the original studies were methodologically unsound and do not match today's standard. By contrast, we believe the new data are credible and do not provide evidence that oral phenylephrine is effective as a nasal decongestant," said Dr. Peter Starke, an FDA official who led the review of phenylephrine.[14]

[12] *Id.*
[13] *Id.*
[14] https://www.nbcnews.com/health/health-news/fda-panel-says-common-counter-decongestantphneylephrine-doesnt-work-rcna104424

53. At the conclusion of the meetings, members voted unanimously (16-0) that PE drugs were ineffective, paving the way for the drugs to be removed from the market.

54. Following this vote by the Advisory Panel, the FDA will now need to decide whether PE Drugs can still be sold and whether drugs should lose their designation as Generally Recognized as Safe and Effective (GRASE).

V. Misbranded Drugs Are Illegal and Worthless

55. Any drug 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.

56. A drug is misbranded[15]:

a. "If its labeling is false or misleading in any particular";

b. "If any word, statement, or other information required … to appear on the label or labeling is not prominently placed thereon…in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use";

c. If the labeling does not contain, among other things, "the proportion of each active ingredient";

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users";

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein";

f. "if it is an imitation of another drug";

g. "if it is offered for sale under the name of another drug";

[15] 21 U.S.C. § 352

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof";

i. If the drug is advertised incorrectly in any manner; and/or

j. If the drug's "packaging or labeling is in violation of an applicable regulation."

57. The manufacture and sale of any misbranded drug is prohibited under federal law. 21 U.S.C. § 331(g).

58. The introduction into commerce of any misbranded drug is also prohibited. 21 U.S.C. § 331(a).

59. Similarly, the receipt in interstate commerce of any misbranded or misbranded drug is also unlawful. 21 U.S.C. § 331(c).

60. As articulated in this Complaint, Defendants' sale of PE Drugs that were not effective for treating the indications identified were misbranded in violation of the above-cited reasons.

61. References to federal law in this Complaint are not an attempt to enforce it, but to demonstrate that Plaintiffs' state-law tort claims do not impose any additional obligations on any Defendants, beyond what is already required of them under federal law.

62. A manufacturer must give adequate directions for the use of a pharmaceutical drug so that a "layman can use a drug safely and for the purposes for which it is intended," 21 C.F.R. § 201.5, and conform to requirements governing the appearance of the label, 21 C.F.R. § 801.15..

63. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device, and therefore broadly includes nearly every form of promotional activity, including not only "package inserts" but also advertising. 65 FR 14286.

64. Because the labels on Defendants' PE drugs indicate that PE can be used to treat nasal congestion, the subject drugs were misbranded.

65. It is unlawful to introduce a misbranded drug into interstate commerce. Thus, the PE Drugs ingested by Plaintiffs were unlawfully distributed and sold.

VI. Plaintiffs and Class Members Have Been Injured by Defendants' Conduct

66. Each Defendants made and breached express and implied warranties and made affirmative misrepresentations and omissions to consumers about their PE Drugs.

67. Plaintiffs' and Class Members' causes of action accrued on the date the FDA announced that PE was not effective at treating the indications identified in Defendants' PE Drug labeling and packaging, that is, September 12, 2023.

68. Alternatively, any statute of limitations or prescriptive period is equitably tolled because of fraudulent concealment. Each Defendants affirmatively concealed from Plaintiffs and Class Members its unlawful conduct. Each Defendants affirmatively strove to avoid disclosing their knowledge of the ineffectiveness of their respective PE Drugs for treating the indications identified, and that such products were misbranded.

69. For instance, Defendants did not reveal to the public that their PE Drugs were not effective at treating the indications identified, despite their superior knowledge and position as the manufacturer or seller of the PE Drugs.

70. To the contrary, Defendants continued to represent and warrant that their PE Drugs were effective for treating the indications identified, principally nasal decongestion.

71. Because of this, Plaintiffs and Class Members did not discover, nor could they have discovered through reasonable and ordinarily diligence, Defendants' deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations,

lulled Plaintiffs and Class Members into believing that the prices paid for their PE Drugs were appropriate for what they believed to be non-misbranded drugs despite their exercise of reasonable and ordinary diligence.

72. As a result of each Defendants' affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiffs and Class Members has been tolled. Plaintiffs and Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiffs and Class Members were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

CLASS ALLEGATIONS

73. This action is brought as a class action pursuant to Fed. R. Civ. P. 23.

74. The proposed Class is defined as follows:

> **Nationwide Class:** All individuals and entities in the United States and its territories and possessions who paid any amount of money for any Defendants' PE Drugs (intended for personal or household use).
>
> **Alabama Subclass:** All individuals and entities in Alabama who paid any amount of money for PE Drugs (intended for personal or household use).
>
> **California Subclass:** All individuals and entities in California who paid any amount of money for PE Drugs (intended for personal or household use).
>
> **Florida Subclass:** All individuals and entities in Florida who paid any amount of money for PE Drugs (intended for personal or household use).
>
> **Minnesota Subclass:** All individuals and entities in Minnesota who paid any amount of money for PE Drugs (intended for personal or household use).

> **New York Subclass:** All individuals and entities in New York who paid any amount of money for PE Drugs (intended for personal or household use).
>
> **West Virginia Subclass:** All individuals and entities in West Virginia who paid any amount of money for PE Drugs (intended for personal or household use).
>
> **Wisconsin Subclass:** All individuals and entities in Wisconsin who paid any amount of money for PE Drugs (intended for personal or household use).

75. The proposed Class excludes the following: Defendants, its affiliates, and its current and former employees, officers and directors, and the Judge assigned to this case.

76. The definition of the proposed Class may be modified, changed, or expanded based upon discovery and further investigation.

77. *Numerosity*: The proposed Class is so numerous that joinder of all members is impracticable. The proposed Class may be ascertained through business records.

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

a. Whether the PE Drugs are defective;

b. Whether a reasonable consumer would consider the misbranding of the PE Drugs to be material;

c. Whether Defendants knew or should have known that the PE Drugs were misbranded;

d. Whether Defendants failed to disclose that the PE Drugs were misbranded;

e. Whether Defendants concealed that the PE Drugs were misbranded;

f. Whether Defendants engaged in unfair or deceptive trade practices;

g. Whether Defendants breached an express warranty;

h. Whether Defendants breached an implied warranty;

i. Whether Defendants engaged in fraud;

j. Whether Defendants breached a duty of care; and

k. Whether Defendants were unjustly enriched.

79. *Typicality*: Plaintiffs' claims are typical of the claims of Class Members. Plaintiffs 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.

80. *Adequacy*: Plaintiffs will fairly and adequately protect the interests of the proposed Class and have no interests antagonistic to those of the proposed Class. Plaintiffs' counsel are experienced in the prosecution of complex class actions, including actions with issues, claims, and defenses similar to the present case.

81. *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 members of the proposed Class 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. There are no difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

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

83. Defendants has acted, and refused to act, on grounds generally applicable to the proposed Class, thereby making appropriate final equitable relief with respect to the proposed Class as a whole.

84. Accordingly, this class action may be maintained pursuant to Fed. R. Civ. P. 23(b)(2).

CAUSES OF ACTION

COUNT I
BREACH OF EXPRESS WARRANTY
(on behalf of the Class)

85. All preceding paragraphs are hereby incorporated by reference as though fully set forth herein.

86. Defendants represented and warranted through its advertising, labeling, and other statements that its PE Drugs were fit for their ordinary purpose, effective in treating their listed indications, including nasal congestion, and not misbranded.

87. Defendants' representations and written warranty are an express warranty within the meaning of U.C.C. § 2-313.

88. All fifty States and the District of Columbia and Puerto Rico have codified and adopted U.C.C. § 2-313: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law

Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313; and Wyo. Stat. § 34.1-2-313.

89. The PE Drugs fail to conform to Defendants' representations that formed part of the basis of the bargain because they are ineffective in treating nasal congestion.

90. Defendants breached the warranty because they are unwilling or unable to provide a remedy for the ineffectiveness and misbranding of the PE Drugs within a reasonable time.

91. Defendants' breach deprived Plaintiffs and Class Members of the benefit of the bargain.

92. Defendants' attempt to disclaim or limit the warranty is unconscionable and unenforceable under the circumstances here because Defendants knowingly and deceptively sold ineffective and misbranded PE Drugs without informing consumers.

93. A gross disparity in bargaining power existed between Defendants and purchasers of the PE Drugs.

94. The essential purpose of the warranty failed because Plaintiffs and Class Members are unable to reasonably obtain a workable remedy, so Plaintiffs and Class Members are entitled to a remedy that is not limited by the terms of the warranty. U.C.C. § 2-719(2).

95. Plaintiffs and Class Members have complied with all obligations under the warranty or otherwise have been excused from performance of said obligations as a result of Defendants' conduct described herein.

96. Plaintiffs and Class Members were the intended third-party beneficiaries of a Defendants' contracts with suppliers, manufacturers, resellers, and distributors of the PE Drugs as Plaintiffs and Class Members were the intended end users of the PE Drugs.

97. As a direct and proximate result of Defendants' conduct, Plaintiffs and Class Members have been injured and sustained damages.

COUNT II
BREACH OF IMPLIED WARRANTY
(on behalf of the Class)

98. All preceding paragraphs are hereby incorporated by reference as though fully set forth herein.

99. Defendants impliedly warranted that its PE Drugs were fit for their ordinary purpose, effective in treating their listed indications, including nasal congestion, and not misbranded.

100. Defendants' sale of the PE Drugs created an implied warranty within the meaning of U.C.C. § 2-314.

101. All fifty States and the District of Columbia and Puerto Rico have codified and adopted U.C.C. § 2-314: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. §

672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Art. 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314; and Wyo. Stat. § 34.1-2-314.

102. The PE Drugs are unmerchantable, not fit for their ordinary purpose, and do not conform to standards generally applicable for such drugs because they are ineffective in treating nasal congestion.

103. Defendants breached the warranty because they are unwilling or unable to provide a remedy for the ineffectiveness and misbranding of the PE Drugs within a reasonable time.

104. Defendants' breach deprived Plaintiffs and Class Members of the benefit of the bargain.

105. Defendants' attempt to disclaim or limit the warranty is unconscionable and unenforceable under the circumstances here because Defendants knowingly and deceptively sold ineffective and misbranded PE Drugs without informing consumers.

106. A gross disparity in bargaining power existed between Defendants and purchasers of the PE Drugs.

107. The essential purpose of the warranty failed because Plaintiffs and Class Members are unable to reasonably obtain a workable remedy, so Plaintiffs and Class Members are entitled to a remedy that is not limited by the terms of the warranty. U.C.C. § 2-719(2).

108. Plaintiffs and Class Members have complied with all obligations under the warranty or otherwise have been excused from performance of said obligations as a result of Defendants' conduct described herein.

109. Plaintiffs and Class Members were the intended third-party beneficiaries of a Defendants' contracts with suppliers, manufacturers, resellers, and distributors of the PE Drugs as Plaintiffs and Class Members were the intended end users of the PE Drugs.

110. As a direct and proximate result of Defendants' conduct, Plaintiffs and Class Members have been injured and sustained damages.

COUNT III
MAGNUSON-MOSS WARRANTY ACT
15 U.S.C. § 2301 *et seq.*
(on behalf of the Class)

111. All preceding paragraphs are hereby incorporated by reference as though fully set forth herein.

112. Defendants expressly and impliedly warranted the PE Drugs and breached these warranties, as alleged above.

113. Defendants' breach of these warranties is a violation of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et seq.*

114. As a direct and proximate result of Defendants' conduct, Plaintiffs and Class Members have been injured and sustained damages.

115. Plaintiffs and Class Members are entitle an award of damages and attorneys' fees and costs pursuant to 15 U.S.C. § 2310(d)(2).

COUNT IV
FRAUD
(on behalf of the Class)

116. All preceding paragraphs are hereby incorporated by reference as though fully set forth herein.

117. Defendants represented to Plaintiffs and Class Members that the PE Drugs were effective for treating nasal congestion and were not misbranded.

118. The PE Drugs are unable to treat nasal congestion as Defendants represented and are therefore of a substantially lesser quality and value than Defendants represented.

119. Defendants knew that the PE Drugs could not conform to their representations because PE is ineffective in treating nasal congestion.

120. Defendants mispresented, concealed, and omitted material information concerning the effectiveness of PE.

121. The facts mispresented, concealed, and omitted by Defendants are material because a reasonable consumer would have considered them to be important in deciding whether to purchase the PE Drugs or pay a lower price.

122. Defendants mispresented, concealed, and omitted material information concerning the effectiveness of the PE Drugs in order to induce Plaintiffs and Class Members to purchase the PE Drugs at a substantially higher price than what they would have paid.

123. Plaintiffs and Class Members reasonably and justifiably relied on Defendants' representations and advertisements when purchasing the PE Drugs.

124. Plaintiffs and Class Members would not have purchased the PE Drugs if they knew that PE was not effective in treating nasal congestion, or they would have only paid substantially less.

125. As a direct and proximate result of Defendants' conduct, Plaintiffs and Class Members have been injured and sustained damages.

COUNT V
NEGLIGENT MISREPRESENTATION AND OMISSION
(on behalf of the Class)

126. All preceding paragraphs are hereby incorporated by reference as though fully set forth herein.

127. Defendants had a duty to Plaintiffs and Class Members to accurately represent the effectiveness of the PE Drugs in treating nasal congestion.

128. Defendants represented to Plaintiffs and Class Members that the PE Drugs were effective for treating nasal congestion and were not misbranded.

129. The PE Drugs are unable to treat nasal congestion as Defendants represented and are therefore of a substantially lesser quality and value than Defendants represented.

130. Defendants knew that the PE Drugs could not conform to their representations because PE is ineffective in treating nasal congestion.

131. Defendants mispresented, concealed, and omitted material information concerning the effectiveness of PE.

132. The facts mispresented, concealed, and omitted by Defendants are material because a reasonable consumer would have considered them to be important in deciding whether to purchase the PE Drugs or pay a lower price.

133. Defendants mispresented, concealed, and omitted material information concerning the effectiveness of the PE Drugs in order to induce Plaintiffs and Class Members to purchase the PE Drugs at a substantially higher price than what they would have paid.

134. Defendants failed to exercise reasonable care in misrepresenting, concealing, and omitting material information concerning the effectiveness of the PE Drugs, thereby breaching their duties to Plaintiffs and Class Members.

135. Plaintiffs and Class Members reasonably and justifiably relied on Defendants' representations and advertisements when purchasing the PE Drugs.

136. Plaintiffs and Class Members would not have purchased the PE Drugs if they knew that PE was not effective in treating nasal congestion, or they would have only paid substantially less.

137. As a direct and proximate result of Defendants' conduct, Plaintiffs and Class Members have been injured and sustained damages.

COUNT VI
NEGLIGENCE
(on behalf of the Class)

138. All preceding paragraphs are hereby incorporated by reference as though fully set forth herein.

139. Defendants had a duty to Plaintiffs and Class Members to accurately represent the effectiveness of the PE Drugs in treating nasal congestion.

140. Defendants represented to Plaintiffs and Class Members that the PE Drugs were effective for treating nasal congestion and were not misbranded.

141. The PE Drugs are unable to treat nasal congestion as Defendants represented and are therefore of a substantially lesser quality and value than Defendants represented.

142. Defendants knew that the PE Drugs could not conform to their representations because PE is ineffective in treating nasal congestion.

143. Defendants mispresented, concealed, and omitted material information concerning the effectiveness of PE.

144. The facts mispresented, concealed, and omitted by Defendants are material because a reasonable consumer would have considered them to be important in deciding whether to purchase the PE Drugs or pay a lower price.

145. Defendants mispresented, concealed, and omitted material information concerning the effectiveness of the PE Drugs in order to induce Plaintiffs and Class Members to purchase the PE Drugs at a substantially higher price than what they would have paid.

146. Defendants failed to exercise reasonable care in misrepresenting, concealing, and omitting material information concerning the effectiveness of the PE Drugs, thereby breaching their duties to Plaintiffs and Class Members.

147. Plaintiffs and Class Members reasonably and justifiably relied on Defendants' representations and advertisements when purchasing the PE Drugs.

148. Plaintiffs and Class Members would not have purchased the PE Drugs if they knew that PE was not effective in treating nasal congestion, or they would have only paid substantially less.

149. As a direct and proximate result of Defendants' conduct, Plaintiffs and Class Members have been injured and sustained damages.

COUNT VII
NEGLIGENCE PER SE
(on behalf of the Class)

150. All preceding paragraphs are hereby incorporated by reference as though fully set forth herein.

151. Defendants had a duty to Plaintiffs and Class Members to accurately represent the effectiveness of the PE Drugs in treating nasal congestion.

152. Defendants' duties arise out of, *inter alia*, the following state statutes enforcing the efficacy and branding of drugs:

a. Alabama Code §§ 20-1-24 and -27(1);

b. Alaska Statutes § 17.20.290(a)(1);

c. Arizona Statutes §§ 32-1965(1), (2) and -1966(3);

d. Arkansas Code § 20-56-215(1);

e. California Health and Safety Code §§ 111295 and 111400;

f. Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);

g. Title 16, Delaware Code §§ 3302 and 3303(2);

h. District of Columbia Code § 48-702(2);

i. Florida Statutes §§ 499.005(1) and .006(3);

j. Georgia Code § 26-3-3(1);

k. Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);

l. Idaho Code § 37-115(a);

m. Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);

n. Iowa Code §§ 126.3(1) and .9(1)(c);

o. Kentucky Statutes § 217.175(1);

p. Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);

q. Massachusetts General Laws chapter 94 §§ 186 and 190;

r. Minnesota Statutes §§ 151.34(1) and .35(1);

s. Missouri Statutes § 196.015(1);

t. Montana Code §§ § 50-31-305(3) and -501(1);

u. Nebraska Revised Statutes §§ 71-2461(2) and -2481;

v. Nevada Statutes § 585.520(1);

w. New Hampshire Revised Statutes §§ 146:1(I) and :4(V);

x. New Mexico Statutes §§ 26-1-3(A) and -10(A);

y. New York Education Law § 6811;

z. North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);

aa. Ohio Code § 3715.52(A)(1);

bb. Oklahoma Statutes title 63 § 1-1402(a);

cc. Title 35, Pennsylvania Statutes § 780-113(a)(1);

dd. Title 21, Rhode Island General Laws § 21-3-3(1);

ee. South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);

ff. South Dakota Code §§ 39-15-3 and -10;

gg. Title 18, Vermont Statutes § 4052(1);

hh. Virginia Code § 54.1-3457(1);

ii. West Virginia Code §§ 16-7-1 and -2(a)(3); and

jj. Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

153. Defendants violated these statutes by representing to Plaintiffs and Class Members that the PE Drugs were effective for treating nasal congestion and were not misbranded.

154. As a direct and proximate result of Defendants' conduct, Plaintiffs and Class Members have been injured and sustained damages.

COUNT VIII
UNJUST ENRICHMENT
(on behalf of the Class)

155. All preceding paragraphs are hereby incorporated by reference as though fully set forth herein.

156. Defendants represented to Plaintiffs and Class Members that the PE Drugs were effective in treating nasal congestion.

157. The PE Drugs fail to conform to Defendants' representations and were therefore of a substantially lesser quality and value than Defendants represented.

158. Defendants knew or should have known that the PE Drugs could not conform to their representations.

159. Defendants mispresented, concealed, and omitted material information concerning the effectiveness of PE.

160. The facts mispresented, concealed, and omitted by Defendants are material because a reasonable consumer would have considered them to be important in deciding whether to purchase the PE Drugs or pay a lower price.

161. Defendants mispresented, concealed, and omitted material information concerning the effectiveness of the PE Drugs in order to induce Plaintiffs and Class Members to purchase the PE Drugs at a substantially higher price than what they would have paid.

162. Plaintiffs and Class Members reasonably and justifiably relied on Defendants' representations and advertisements when purchasing the PE Drugs.

163. Plaintiffs and Class Members would not have purchased the PE Drugs if they knew that PE was not effective in treating nasal congestion, or they would have only paid substantially less.

164. Plaintiffs and Class Members conferred substantial benefits on Defendants by purchasing misbranded and ineffective PE Drugs at a premium without receiving a product that conformed to Defendants' representations.

165. Defendants knowingly and willingly accepted and enjoyed these benefits.

166. Defendants' retention of these benefits would be inequitable.

167. As a direct and proximate result of Defendants' conduct, Plaintiffs and Class Members have been injured and sustained damages.

COUNT IX
VIOLATIONS OF STATE CONSUMER PROTECTION LAWS
(on behalf of the Class)

168. All preceding paragraphs are hereby incorporated by reference as though fully set forth herein.

169. Defendants represented to Plaintiffs and Class Members that the PE Drugs were effective for treating nasal congestion and were not misbranded.

170. The PE Drugs are unable to treat nasal congestion as Defendants represented and are therefore of a substantially lesser quality and value than Defendants represented.

171. Defendants knew that the PE Drugs could not conform to their representations because PE is ineffective in treating nasal congestion.

172. Defendants mispresented, concealed, and omitted material information concerning the effectiveness of PE.

173. The facts mispresented, concealed, and omitted by Defendants are material because a reasonable consumer would have considered them to be important in deciding whether to purchase the PE Drugs or pay a lower price.

174. Defendants mispresented, concealed, and omitted material information concerning the effectiveness of the PE Drugs in order to induce Plaintiffs and Class Members to purchase the PE Drugs at a substantially higher price than what they would have paid.

175. Plaintiffs and Class Members reasonably and justifiably relied on Defendants' representations and advertisements when purchasing the PE Drugs.

176. Plaintiffs and Class Members would not have purchased the PE Drugs if they knew that PE was not effective in treating nasal congestion, or they would have only paid substantially less.

177. Defendants' conduct violates state consumer protection statutes as follows:

a. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendants violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

f. Defendants violated the California Consumers Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.*;

g. Defendants violated the California False Advertising Law, Cal. Bus. & Prof. Code § 17500, *et seq.*;

h. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

i. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

j. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq*.;

k. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq*.;

l. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq*.;

m. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

n. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq*.;

o. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq*.;

p. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS 505/1, *et seq.*;

q. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

r. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

s. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

t. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

u. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

v. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

w. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

x. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

y. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

z. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

aa. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

bb. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Mo. Rev. Stat. § 407.0 10, *et seq*.;

cc. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

dd. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

ee. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

ff. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

gg. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

hh. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

ii. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

jj. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

kk. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

ll. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

mm. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

nn. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

oo. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

pp. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

qq. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

rr. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

ss. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

tt. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

uu. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

vv. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

ww. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

xx. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

yy. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

zz. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

aaa. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

bbb. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

178. As a direct and proximate result of Defendants' conduct, Plaintiffs and Class Members have been injured and sustained damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment as follows:

a. An order certifying this action as a class action;

b. An order appointing Plaintiff as Class Representatives, and appointing undersigned counsel as Class Counsel to represent the Class;

c. A declaration that Defendants are liable under each and every one of the above-enumerated causes of action;

d. An order awarding compensatory damages, restitution, or refund of all funds acquired by Defendants from Plaintiffs and Class Members as a result of Defendants' unlawful conduct as described above, including actual, statutory, and punitive damages to the extent permitted by law in an amount to be proven at trial;

e. An order awarding appropriate preliminary and final injunctive relief against the conduct of Defendants as described above;

f. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

g. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

h. Such other and further relief as this Court may deem just, equitable, or proper.

JURY DEMAND

Plaintiffs demand trial by jury.

Dated: September 28, 2023

Respectfully submitted,

/s/ Michael M. Weinkowitz

Charles E. Schaffer

Michael M. Weinkowitz
Nicholas J. Elia
LEVIN SEDRAN & BERMAN
510 Walnut Street, Suite 500
Philadelphia, PA 19106
Tel: (215) 592-1500
cschaffer@lfsblaw.com
mweinkowitz@lfsblaw.com
nelia@lfsblaw.com

D. Aaron Rihn
ROBERT PEIRCE & ASSOCIATES
707 Grant Street, Suite 125
Pittsburgh, PA 15219
Tel: (844) 383-0565
arihn@peircelaw.com

JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 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 by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Millard Adkins, et al.

(b) County of Residence of First Listed Plaintiff Marion County, VA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Michael M. Weinkowitz, Charles E. Schaffer, Nicholas J. Elia
Levin Sedran & Berman LLP
510 Walnut Street, Suite 500 Philadelphia, PA 19106
(215)592-1500

DEFENDANTS

Reckitt Benckiser Pharnaceuticals Inc., et al

County of Residence of First Listed Defendant Morris County, NJ
(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)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 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

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

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

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

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 and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 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

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

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

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

INTELLECTUAL 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

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:
Violations of state consumer protection and common laws for unlawful sale of consumer product.

VII. REQUESTED IN COMPLAINT:

☑ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Kevin McNulty DOCKET NUMBER 2:23-cv-20370-KM-JSA

DATE
September 28, 2023

SIGNATURE OF ATTORNEY OF RECORD
/s/ Michael M. Weinkowitz

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____