UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

CHIOMA OZUZU, individually, and on behalf of all others similarly situated, Plaintiff, v. KENVUE INC., MCNEIL CONSUMER HEALTHCARE, and RECKITT BENCKISER, LLC Defendants.	Civil Action No.: 1:23-cv-7395 **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Chioma Ozuzu ("Plaintiff"), individually, and on behalf of all others similarly situated, by and through undersigned counsel, hereby submits the following Class Action Complaint and Demand for Jury Trial against Defendants Kenvue Inc.[1], McNeil Consumer Healthcare; and Reckitt Benckiser LLC ("Defendants") and alleges the following upon information and belief:

NATURE OF THE ACTION

1. This proposed Class Action is brought by Plaintiff, and all others similarly situated, against Defendants for multiple causes of action.

2. Plaintiff, and others similarly situated, purchased the following over-the-counter ("OTC") decongestant products ("PE Drugs") containing the active ingredient phenylephrine:

- Tylenol Cold & Flu Severe (Kenvue/McNeil);
- Mucinex Sinus Max (Reckitt)

3. PE Drugs are manufactured and sold by Defendants.

[1] Kenvue, founded in February 2022, previously served as the Consumer Healthcare division of Johnson & Johnson. On information and belief, all assets and liabilities associated with the PE Drugs that had been manufactured, marketed and/or sold by Johnson & Johnson are now owned by Kenvue.

4. PE Drugs were recently found by the Food and Drug Administration ("FDA") to lack efficacy.

5. At all pertinent times for this action, Defendants represented and warranted to consumers that PE Drugs were effective for treating the indications identified and were properly branded. Specifically, Defendants represented that PE Drugs were merchantable and fit for their ordinary uses (e.g., effectively treating nasal congestion).

6. Unfortunately for Plaintiff and the putative class members, Defendants willfully ignored scientific and industry knowledge concerning the lack of effectiveness of PE Drugs for treating the indications identified, and performed inadequate testing and quality oversight of the PE Drugs ascertain the true efficacy of PE Drugs for treating the indications identified (mainly, nasal congestion).

7. At no point in time did Defendants disclose the PE Drugs' lack of efficacy to the Plaintiff, nor the putative class members.

8. PE Drugs were advertised as efficacious. If Plaintiff and the putative class members had known that PE Drugs were not efficacious prior to their purchases of PE Drugs, they would not have purchased PE Drugs.

9. As a result of Defendants' mislabeling, Plaintiff and the putative class members suffered economic harm and damage. Plaintiff and the putative class members now seek injunctive relief against Defendants and restitution for the full purchase price of PE Drugs.

THE PARTIES

PARTY PLAINTIFF

10. At all relevant times and currently, Plaintiff has been a United States citizen, residing and domiciled in Kings County, New York and is thus a citizen of the State of New York.

11. Plaintiff purchased PE Drugs in Kings County, New York.

PARTY DEFENDANTS

12. Defendant Kenvue Inc. is an American consumer health company, and formerly the consumer healthcare division of Johnson & Johnson. Kenvue is headquartered in Skillman, New Jersey. It wholly owns Defendant McNeil Consumer Healthcare. On information and belief, all assets and liabilities associated with the PE Drugs that had been manufactured, marketed, and/or sold by Johnson & Johnson are now owned by Defendant Kenvue.

13. Defendant McNeil Consumer Healthcare is wholly owned by Defendant Kenvue, with headquarters in Fort Washington, Pennsylvania. McNeil manufactures and markets numerous PE Drugs, including but not limited to Tylenol Cold & Flu Severe, purported decongestants each containing phenylephrine.

14. Defendant Reckitt Benckiser LLC ("Reckitt") is a Delaware limited liability corporation with its headquarters and principal place of business located in Parsippany, New Jersey. Reckitt is a wholly-owned subsidiary of Reckitt Benckiser Group PLC, a public limited company registered in England and Wales. Among other PE Drugs, Reckitt manufactures and markets Mucinex products containing phenylephrine and purporting to act as decongestants.

JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(d) because the amount in controversy for both the Nationwide Class and the New

York Sub-class (as defined below) exceeds $5,000,000.00 exclusive of interest and costs, there are more than one-hundred (100) members of each putative class, and minimal diversity exists because a significant portion of the putative class members are citizens of a state different from the citizenship of Defendants.

16. This Court has personal jurisdiction over both Defendants because a substantial part of the events and conduct giving rise to the claims herein occurred in this State. Defendants have marketed, promoted, distributed, and sold PE Drugs in New York and Defendants have sufficient minimum contacts with this State and/or sufficiently avail themselves of the markets in this State through promotion, sales, distribution, and marketing within this State to render the exercise of jurisdiction by this Court permissible.

17. Furthermore, venue is proper in this Court pursuant to 28 U.S.C. § 1391(a)(1), because a substantial part of the events giving rise to this action occurred in this District and because Defendants transact substantial business generally in this District, in accordance with 18 U.S.C. § 1965(a).

INTRODUCTION

18. The main active ingredient in PE Drugs is Phenylephrine ("PE").

19. PE Drugs are purchased OTC.

20. In 1994, the FDA issued its final monograph ("Final Monograph") establishing conditions under which OTC nasal decongestant products are considered safe and effective (generally regarded as safe and effective or "GRASE") and not misbranded.

21. PE is included in the 1994 Final Monograph as an OTC nasal decongestant.

22. PE Drugs at issue in this case fall within two categories:

i. Phenylephrine hydrochloride; and

ii. Phenylephrine bitartrate.

23. The Federal Register, dated August 23, 1994, on page 433861 under Section III, first allowed Phenylephrine hydrochloride to be sold. Twelve years later, Phenylephrine bitartrate was included in the Federal Register on August 1, 2006 at page 833852.

24. According to Defendants, PE constricts the blood vessels in the nasal passages.

25. Defendants made claims in their marketing materials on the efficacy of PE Drugs.

26. In 2007, Public Citizen, a consumer advocacy group, filed a petition with the FDA regarding PE. The petition was based on a letter written by two University of Florida Professors, published in the *Journal of Allergy and Clinical Immunology* entitled: "Oral phenylephrine: An ineffective replacement for pseudoephedrine?"

27. The authors of the petition argued that PE was not as effective as pseudoephedrine, another decongestant.

28. The petition requested that the FDA reevaluate the dosage of PE and that approval for children under twelve years of age be withdrawn.

29. The FDA reviewed the request and stated that based on available data at the time of the 2007 review, PE could be considered effective as a nasal decongestant when used at recommended doses.

30. Importantly, at this time in 2007, nine of the twelve committee members voted that "new studies on response to higher doses were required."

31. In 2015, another Citizens Petition was filed. This time, the petition asked the FDA "to remove oral phenylephrine from the Final Monograph for OTC nasal decongestant products."

32. Importantly, the 2015 Citizen Petition was supported by the American Academy of Allergy, Asthma & Immunology.

33. Upon information and belief, neither Defendant conducted any additional testing to ascertain the effectiveness of the respective PE Drugs in treating nasal congestion. Had they done so, the data would have led to the same conclusion reached by an FDA advisory panel on September 12, 2023: PE has no efficacy in treating nasal congestion.

34. 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. In pertinent part, the Advisory Panel concluded: "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 doses up to 40 mg (dosed every 4 hours)."

35. The Panel also found that the initial findings which supported the use of PE, and to have inconsistent results, filled with data integrity issues and did not meet today's design standards.

36. The members of the panel voted unanimously (16-0) that PE was ineffective, which would allow PE Drugs to be pulled from the market.

37. Since 2007, several additional large clinical trials have been conducted regarding the efficacy of phenylephrine. Those studies provide the evidence of the absence of a decongestant effect from the OTC approved doses of 10 mg.[2]

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

38. For example, Horak *et al* (2009) found that PE was 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.

39. Day *et al* (2009) similarly reported no difference between PE and placebo with respect to decreased nasal congestion scores.

40. Gelotte and Zimmerman (2015) likewise reported a long of decongestion effect of PE, finding that doses up to three times the labeled OTC for oral phenylephrine are unlikely to be effective as a nasal decongestant.

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

42. On September 12, 2023, an FDA panel unanimously declared that phenylephrine, the active ingredient in the PE Drugs, is an ineffective decongestant.

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

44. In 2018, however, the FDA issued new guidance for industry as it related to the use of nasal congestion symptom scores to evaluate congestion.[3] Simply put, NAR was no longer used as a primary endpoint to evaluate congestion in studies.

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label, placebo-controlled study, J Allergy Clin Immunol Pract, 3(5):702-708; Meltzer, EO, PH Ratner, and T McGraw, 2016, Phenylephrine hydrochloride modified-release tablets for nasal congestion: a randomized, placebo-controlled trial in allergic rhinitis patients, Ann Allergy Asthma Immunol, 116(1):66-71.

[3] *See* https://www fda.gov/files/drugs/published/Allergic-Rhinitis--Developing-Drug-Products-for-Treatment-

45. Based on the FDA's new 2018 guidance, Defendants knew or should have known that their marketing claims regarding PE Drugs' efficacy were false and misleading.

46. In 2018, the primary endpoint for evaluating the efficacy of PE Drugs changed from the FDA's 2007 meeting, which meant the data under which PE Drugs were approved as GRASE no longer supported efficacy. There have been no published studies since the FDA's revised 2007 guidance for industry was released that demonstrated the effectiveness of oral phenylephrine as a decongestant. Accordingly, Defendants should have known since at least 2018 that their marketing claims regarding the PE Drugs' efficacy were false and misleading.

47. Plaintiff and the putative class members purchased the PE Drugs in reliance on Defendants' false and deceptive marketing claims.

48. As a result of Defendants' false and deceptive marketing, Plaintiff and the putative class members suffered economic damages, including the cost of purchasing PE Drugs.

EQUITABLE TOLLING OF STATUTES OF LIMITATIONS, CONCEALMENT, AND ESTOPPEL

49. Each purchase of PE Drugs constitutes a separate act that triggers anew the relevant statute of limitations.

50. Additionally, any applicable statutes of limitation have been tolled by (1) the delayed discovery doctrine, as Plaintiff and the putative class members (defined below) did not and could not — through no fault or lack of diligence — reasonably have discovered Defendants' conduct alleged herein until shortly before the filing of this Complaint; and (2) the fraudulent concealment doctrine due to Defendants' knowing, purposeful, and active concealment and denial of all facts alleged herein including but not limited to lack of efficacy concerning PE Drugs.

Guidance-for-Industry.pdf

51. Defendants had exclusive knowledge that its PE Drugs were not efficacious and deceptively marketed PE Drugs to Plaintiffs and the class.

52. Under the circumstances, Defendants had a duty to disclose the nature, significance, and consequences of the PE Drugs' lack of efficacy. Accordingly, Defendants are estopped from relying upon any statute of limitations.

CLASS ALLEGATIONS

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

Nationwide Class Action

> All consumers who purchased Tylenol Cold & Flu, and/or Mucinex Sinus Max Congestion Products in the United States of America and its territories from September 13, 2018 to the present (the "Class" and/or "Class Members") for personal use or consumption.

New York Sub-Class

> All consumers who purchased Tylenol Cold & Flu and/or Mucinex Sinus Max Congestion Products in the State of New York from September 13, 2018 to the present ("the Sub-Class" and/or "Sub-Class Members") for personal use or consumption.

54. Excluded from proposed classes are the Defendants, any entity or entities in which Defendants have a controlling interest, Defendants' officers, directors, legal representatives, successors, subsidiaries, and assigns.

55. Also excluded from the Nationwide Class and New York Sub-Class are any judicial officer presiding over this matter, members of their immediate family, and members of their judicial staff.

56. The members of the Class and Sub-Class are so numerous that joinder of all members of the Class and Sub-Class is impracticable. Plaintiff is informed and believes that the proposed Class and Sub-Class contains thousands of purchasers of Defendants' PE Drugs who have been damaged by Defendants' conduct as alleged herein. The precise number of class members is unknown to Plaintiff currently.

57. Plaintiff's claims are typical to those of all Class and Sub-Class members because members of the Class and Sub-Class are similarly injured through Defendants' uniform misconduct described above and were subject to Defendants' deceptive marketing claims that accompanied PE Drugs. Plaintiff is advancing the same claims and legal theories on behalf of herself and all members of the Class and Sub-Class.

58. Plaintiff's claims raise questions of law and fact common to all members of the Class and Sub-Class, and they predominate over any questions affecting only individual class members. These common legal and factual questions include, but are not limited to:

a. Whether Defendants' PE Drugs contain phenylephrine;

b. Whether Defendants' marketing statements are false, misleading, or objectively reasonably likely to deceive;

c. Whether the alleged conduct constitutes violations of the laws asserted;

d. Whether Defendants' alleged conduct violates public policy;

e. Whether Defendants engaged in false or misleading advertising;

f. Whether Defendants were unjustly enriched as a result of its labeling, marketing, advertising and/or selling of PE Drugs;

g. Whether Plaintiff and the Class Members and Sub-Class Members are entitled to damages and/or restitution and the proper measure of that loss; and

h. Whether an injunction is necessary to prevent Defendants from continuing to market and sell their PE Drugs that lack efficacy.

59. Plaintiff is an adequate representative of the members of the proposed Class and Sub-Class because her interests do not conflict with the interests of the members of the proposed Class and Sub-Class she seeks to represent; she is represented by experienced and able counsel who have litigated numerous other fraud, negligence, complex litigation, and mass tort and class actions, and intend to prosecute this action vigorously for the benefit of the entire proposed Class and Sub-Class; and she and her counsel will fairly and adequately protect the interest of the members of the proposed Class and Sub-Class.

60. Furthermore, a class action is superior to other available methods for the adjudication of this litigation since individual litigation of the claims of Plaintiff and the members of the proposed Class and Sub-Class is impracticable. It would be unduly burdensome to the courts in which the many thousands of individual actions would proceed. Also, individual litigations would present a potential for inconsistent or contradictory judgments, and inevitably increase the delay and expense to all parties and the courts in resolving the legal and factual issues of these cases.

61. By contrast, the class action, as a device for the adjudication of the claims asserted herein, presents far fewer managerial difficulties while providing the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

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

63. Unless a class is certified, Defendants will retain monies received as a result of their conduct that were taken from Plaintiff both sets of putative class members. Unless a class-wide injunction is issued, Defendants will continue to commit the violations alleged and the members of the Class and Sub-Class and the general public will continue to be misled. Indeed, to this day, Defendants continue to market and sell PE Drugs that were determined to lack efficacy by a unanimous FDA Panel.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES

64. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

65. Plaintiff, and each member of the Class and Sub-Class, formed a contract with each Defendant at the time Plaintiff and the other Class Members and Sub-Class Members purchased the PE Drugs. The terms of the contract include the promises and affirmations of fact made by Defendant on the PE Drugs' packaging and through marketing and advertising, including that the PE Drugs would be effective for the indications provided. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Sub-Class and Defendants.

66. Each Defendant expressly warranted that its PE Drugs were fit for ordinary use and effective for the indications listed and were merchantable and not misbranded.

67. Each Defendant sold PE Drugs that they expressly warranted to be effective at treating the indications identified and were not misbranded.

68. At all times relevant all fifty states and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code: 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.

69. Each Defendant knew or should have known that its PE Drugs were being manufactured and sold for the intended purpose of human consumption for treating the

indications identified (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their PE Drugs were of merchantable quality and fit for that purpose.

70. Each Defendant breached its express warranty because each Defendant's PE Drugs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

71. Each Defendant's express warranties were reflected in each PE Drug's product labeling (e.g., label, instructions, packaging) and promotion and marketing material, all of which uniformly identified PE as an active ingredient for effective treatment of the indications identified, principally nasal decongestion. Each Defendant's product labeling and other materials had to be truthful, accurate, and non-deceptive. But this was not the case, insofar as each Defendant's product labeling and other materials did not disclose that PE is not effective for the indications identified, principally nasal congestion.

72. Each Defendant's PE Drugs did not fulfill their intended purpose. Plaintiff and other Class Members and Sub-Class Members bargained for an adequately made, adequately labeled product, that performed as warranted. But each Defendant's PE Drugs were not adequately made, were not adequately labeled, and did not perform as warranted.

73. Plaintiff and other Class Members and Sub-Class Members purchased the PE Drugs in reliance upon Defendants' skill and judgment and the express warranties made.

74. Plaintiff and other Class Members and Sub-Class Members were reasonably expected purchasers who would use, consumer or be affected by (or whose insureds would use, consumer or be affected by) the misbranded, not effective PE Drugs marketed by each Defendant.

75. The PE Drugs were not altered by Plaintiff or Class members and/or Sub-Class members.

76. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members and Sub-Class Members have been injured and suffered damages, in that Defendants' PE Drugs they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

SECOND CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

77. Plaintiff re-alleges and incorporates the preceding paragraphs as if full set forth herein.

78. Plaintiff, and each member of the Class and Sub-Class formed a contract with each Defendant at the time Plaintiff and the other Class and Sub-Class members purchased the PE Drugs. The terms of the contract include the promises and affirmations of fact made by Defendants on the PE Drugs' packaging and through marketing and advertising, including that the products would be effective for the indications provided. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Sub-Class and Defendants.

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

80. Each Defendant was a merchant within the meaning of the above statutes.

81. Each Defendant's PE Drugs constituted "goods" or the equivalent within the meaning of the above statutes. Each Defendant placed their PE Drugs in sealed packaging or other closed containers and placed them on the market.

82. Each Defendant impliedly warranted that its PE Drugs were fit for ordinary use and effective for the indications listed and were merchantable and not misbranded.

83. Each Defendant sold PE Drugs that they impliedly warranted to be effective at treating the indications identified and were not misbranded.

84. Each Defendant knew or should have known that its PE Drugs were being manufactured and sold for the intended purpose of human consumption for treating the indications identified (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their PE Drugs were of merchantable quality and fit for that purpose.

85. Each Defendant breached its implied warranty because each Defendant's PE

Drugs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

86. Plaintiff and other Class and Sub-Class members purchased the PE Drugs in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

87. Each Defendant's PE Drugs did not fulfill their intended purpose. Plaintiff and other Class and Sub-Class Members bargained for an adequately made, adequately labeled product, that performed as warranted. But each Defendant's PE Drugs were not adequately made, were not adequately labeled, and did not perform as warranted.

88. Each Defendant's implied warranties were reflected in each PE Drug's product labeling (e.g., label, instructions, packaging) and promotion and marketing material, all of which uniformly identified PE as an active ingredient for effective treatment of the indications identified, principally nasal decongestion. Each Defendant's product labeling and other materials had to be truthful, accurate, and non-deceptive. But this was not the case, insofar as each Defendant's product labeling and other materials did not disclose that PE is not effective for the indications identified, principally nasal congestion.

89. Each Defendant's PE Drugs did not fulfill their intended purpose. Plaintiff and other Class and Sub-Class Members bargained for an adequately made, adequately labeled product, that performed as warranted. But each Defendant's PE Drugs were not adequately made, were not adequately labeled, and did not perform as warranted.

90. Plaintiff and other Class and Sub-Class Members purchased the PE Drugs in reliance upon Defendants' skill and judgment and the express warranties made.

91. Plaintiff and other Class and Sub-Class Members were reasonably expected

purchasers who would use, consumer or be affected by (or whose insureds would use, consumer or be affected by) the misbranded, not effective PE Drugs marketed by each Defendant.

92. Plaintiff and each other Class and Sub-Class Member were the intended third-party beneficiary recipients of all arrangements Defendants had with downstream resellers of Defendants' PE Drugs. Plaintiffs and each other Class and Sub-Class Member were those whose benefit any promises, affirmations, or warranties were made by Defendants concerning the PE Drugs, as they were the intended end purchasers and end users (or, in the case of entities, their insureds were the intended end users) of Defendants' PE Drugs, which Defendants knew by virtue of its position as manufacturer and seller of the PE Drugs.

93. The PE Drugs were not altered by Plaintiff or Class and/or Sub-Class Members.

94. As a direct and proximate result of each Defendants' breach of implied warranty, Plaintiff and other Class and Sub-Class Members have been injured and suffered damages, in that Defendants' PE Drugs they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

THIRD CAUSE OF ACTION
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, *ET SEQ.*

95. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

96. Each Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

97. Plaintiff and other Class and Sub-Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

98. Each Defendant expressly or impliedly warranted their PE Drugs as alleged in the First and Second Causes of Action.

99. Under 15 U.S.C. § 2310(d)(1), Plaintiff and other Class and Sub-Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiff sues pursuant to this section to recover money damages and for legal and equitable relief on behalf of herself and the Class and Sub-Class Members.

100. Each Defendant has not acted on the opportunity to cure its failure with respect to its warranted PE Drugs.

101. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiff and the Class and Sub-Class Members are entitled to receive an award of attorneys' fees and expenses and pray for the same.

FOURTH CAUSE OF ACTION
FRAUD (AFFIRMATIVE MISRREPRESENATION AND OMISSION)

102. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

103. Each Defendant affirmatively misrepresented material facts including, inter alia, that their PE Drugs were effective at treating the indications identified and/or were not misbranded.

104. Each Defendant omitted material facts including, inter alia, that their PE Drugs were not effective at treating the indications identifies and/or were misbranded.

105. Each Defendant's actions had the effect of fraudulently inducing customers to pay in whole or in part for each Defendant's PE Drugs – products which each Defendant knew or should have known were not effective at treating the indications identified and/or were misbranded. Plaintiff and other Class and Sub-Class Members would not have purchased Defendants' PE Drugs had they known the truth. Indeed, Plaintiff and other Class and Sub-Class Members could not have paid for Defendants' PE Drugs had they known the truth because Defendants' PE Drugs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiff and Class and Sub-Class Members based on each Defendants' fraudulent misrepresentations and omissions.

106. Each Defendant knew or should have known about the effectiveness and branding status of its PE Drugs as a result of industry and regulatory guidance dating back years.

107. Each Defendant knowingly, or at least recklessly, represented that its PE Drugs were effective in treating the indications identified and not misbranded, when that was not the

case. Rather, each Defendant knew or recklessly disregarded industry and regulatory guidance that was available to each Defendant.

108. Each Defendant knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

109. Each Defendant also knew, or had reason to know, that their misrepresentations and omissions would induce Plaintiff and the Class and Sub-Class Members to pay for some or all of the cost of Defendants' PE Drugs.

110. Each Defendant's misrepresentations and omissions were material.

111. Each Defendant's actively concealed their misrepresentations and omissions from Plaintiff, the Class and Sub-Class Members, government regulators, and the public.

112. To the extent applicable, each Defendant intended their misrepresentations and omissions to induce Plaintiff and other Class and Sub-Class Members to pay for each Defendant's PE Drugs.

113. But for these misrepresentations and omissions, Plaintiff, and other Class and Sub-Class Members would not have paid for each Defendant's PE Drugs.

114. To the extent applicable, Plaintiff and other Class and Sub-Class Members were justified in relying on each Defendant's misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated, to each Class and Sub-Class Member, including through product labeling and other statements by each Defendant. No reasonable consumer would have paid what they did for Defendants' PE Drugs but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

115. Plaintiff and other Class and Sub-Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION AND OMISSION

116. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

117. Each Defendant had or undertook a duty to represent to the effectiveness of its PE Drugs accurately and truthfully.

118. Each Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the effectiveness of its PE Drugs.

119. Each Defendant negligently misrepresented or omitted facts regarding the effectiveness of its PE Drugs.

120. Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

121. Each Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Each Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Plaintiff and the Class Members and/or Sub-Class Members to make purchases of each Defendant's PE Drugs.

122. Each Defendant had a duty to exercise reasonable care in the manufacture, quality control, and distribution of PE Drugs. Each Defendant's failure to exercise this duty, despite knowing or recklessly disregarding the effectiveness of its PE Drugs, meant Defendants could not assure that its PE Drugs were of as represented effectiveness.

123. As a direct and proximate result of Defendants' acts and omissions described herein, Plaintiffs and other Class and Sub-Class Members have suffered harm, and will continue to do so.

124. Each Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class and Members' paying for PE Drugs.

125. Each Defendant intended its misrepresentations or omissions to induce Plaintiff and the Class and Sub-Class Members to make purchases of PE Drugs, or had reckless disregard for same.

126. But for these misrepresentations (or omissions), Plaintiff and other Class and Sub-Class Members would not have made purchases of Defendants' PE Drugs.

127. Plaintiff and other Class and Sub-Class Members were justified in relying on Defendants' misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, and/or the same or substantively identical omissions were not communicated, to Plaintiff or each Class or Sub-Class Member.

128. Plaintiff and other Class and Sub-Class Members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

SIXTH CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION LAWS

129. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

130. Each Defendant violated the 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. Defendant 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. Defendant 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 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. Defendant 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 Vernon's 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. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

ee. Defendant 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.Y. Gen. Bus. Law § 350, et seq.;

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

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

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

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

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

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

qq. 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.*;

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

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

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

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

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

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

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

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

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

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

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

ccc. 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.

131. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

132. Each Plaintiff and other Class Member and/or Sub-Class Member is a consumer or person aggrieved by Defendants' misconduct within the meaning of the above statutes.

133. Each Defendant's conduct as alleged herein constitutes unfair, deceptive, misleading, or otherwise actionable practices as to each Defendant's conduct concerning the purported effectiveness of its PE Drugs for treating the indications identified.

134. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of each Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiff, and other Class Members and/or Sub-Class Members have suffered damages– an ascertainable loss – in an amount to be proved at trial.

SEVENTH CAUSE OF ACTION
UNJUST ENRICHMENT

135. Plaintiff re-alleges and incorporates the preceding paragraphs as if full set forth herein.

136. As alleged herein, each Defendant was unjustly enriched at the expense of Plaintiffs and other Class and Sub-Class Members by virtue of the latter's paying for Defendants' PE Drugs.

137. Each Defendant profited immensely from introducing a carcinogen into the United States for human consumption. On top of that, because each Defendant's PE Drugs were misbranded, their distribution and sale in the United States was illegal.

138. Plaintiff and other Class and Sub-Class Members were unjustly deprived of money obtained by each Defendant as a result of the improper amounts paid for Defendants' PE Drugs. It would be inequitable and unconscionable for each Defendant to retain the profit, benefit,

and other compensation obtained from Plaintiff and other Class Members and/or Sub-Class Members as a result of their wrongful conduct alleged in this Class Action Complaint. There is no adequate remedy at law for Plaintiff and other Class and Sub-Class Members.

139. Plaintiff and other Class Members and/or Sub-Class Members are entitled to seek and do seek restitution from each Defendant as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by each Defendant by virtue of its wrongful conduct.

EIGHTH CAUSE OF ACTION
NEGLIGENCE

140. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

141. Each Defendant owed a duty to Plaintiff and the Class and Sub-Class Members to use and exercise reasonable and due care in the manufacturing and sale of its PE Drugs.

142. Each Defendant owed a duty to Plaintiff and the Class and Sub-Class Members to ensure that the PE Drugs it sold in the United States were effective for the indications identified and not misbranded.

143. Each Defendant owed a duty of care to Plaintiff and the Class and Sub-Class Members because they were the foreseeable, reasonable, and probable users of PE Drugs and victim of Defendants' fraudulent and deceptive activities. Each Defendant knew, or should have known, that its PE Drugs were not effective for treating the indications identified and were misbranded, and each was in the best position to uncover and remedy these shortcomings.

144. Each Defendant failed to do this. Defendants inadequately oversaw the manufacture and sale of its own PE Drugs. Each Defendant knew that ignoring the manufacturing

issues surrounding its PE Drugs would damage Plaintiff and the Class and Sub-Class Members and increase its own profits.

145. Each Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its PE Drugs were effective to treat the indications identified and not misbranded.

146. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class and Sub-Class Members. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its PE Drugs.

147. Each Defendant breached duties owed to Plaintiff and the Class and Sub-Class Members by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiff and the Class and Sub-Class Members.

148. As a direct and proximate result of each Defendants' negligent conduct, Plaintiff and the Class and Sub-Class Members have suffered injury and are entitled to damages in an amount to be proven at trial.

NINTH CAUSE OF ACTION
NEGLIGENCE *PER SE*

149. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

150. Each Defendant owed a duty to Plaintiff and the Class and Sub-Class Members to use and exercise reasonable and due care in the manufacturing and sale of its PE Drugs.

151. Each Defendant owed a duty to Plaintiff and the Class and Sub-Class Members to ensure that the PE Drugs it sold in the United States were effective at treating the indications identified and were not misbranded.

152. Each Defendant owed a duty to Plaintiff and the Class and Sub-Class Members because each state, territory, and possession has adopted/or adheres to federal standards, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);
- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);

- Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);
- Montana Code §§ § 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

153. Each Defendant failed to comply with federal standards, including branding standards.

154. As a result of each Defendant's failures to do so, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class and Sub-Class Members.

155. As a direct and proximate result of each Defendant's negligent conduct, Plaintiff and the Class and Sub-Class Members have suffered injury and are entitled to damages in an amount to be proven at trial.

PRAYER FOR RELIEF

For these reasons, Plaintiff prays for the following judgment:

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

B. An order appointing Plaintiff as Class Representative, and appointing undersigned counsel as Class Counsel to represent both Classes;

C. A declaration that each Defendant is liable under each and every one of the above-enumerated causes of action;

D. An order awarding appropriate preliminary and/or final injunctive relief against the conduct of each Defendant described above;

E. Payment to Plaintiff and Class Members and Sub-Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid or reimbursed for the PE Drugs; the costs to replace or return PE Drugs; and/or the increases in the amounts paid for non-misbranded substitute products;

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

G. An award of statutory penalties to the extent available;

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

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

JURY DEMAND

Plaintiff respectfully request a trial by jury on all causes of action so triable.

Dated: October 3, 2023

Respectfully Submitted,

PARKER WAICHMAN LLP

/s/ Raymond S. Silverman
Raymond S. Silverman
Melanie H. Muhlstock
Jason S. Goldstein
6 Harbor Park Drive
Port Washington, NY 11050
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JS 44 (Rev 4-29-21)

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

Chioma Ozuzu, individually, and on behalf of all others

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

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

Parker Waichman LLP, 6 Harbor Park Drive, Port Washington, NY 11050, 516-466-6500

DEFENDANTS

Kenvue, Inc., McNeil Consumer Healthcare, and Reckitt

County of Residence of First Listed Defendant Somerset, 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)*

Does this action include a motion for temporary restraining order or order to show cause? Yes ☐ No ☑"

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

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

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

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

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

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

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

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

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

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

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced 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

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. § 1391 (a) and (b)

Brief description of cause:
Class Ac ion Fairness Act, 28 U.S.C. § 1332(d)(2)

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 5,000,000.00+

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

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

JUDGE _____ DOCKET NUMBER _____

DATE
October 3, 2023

SIGNATURE OF ATTORNEY OF RECORD
/s/Raymond C. Silverman

FOR OFFICE USE ONLY

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

CERTIFICATION OF ARBITRATION ELIGIBILITY

Local Arbitration Rule 83.7 provides that with certain exceptions, actions seeking money damages only in an amount not in excess of $150,000, exclusive of interest and costs, are eligible for compulsory arbitration. The amount of damages is presumed to be below the threshold amount unless a certification to the contrary is filed.

Case is Eligible for Arbitration ☐

I, Raymond C. Silverman, counsel for Plaintiffs, do hereby certify that the above captioned civil action is ineligible for compulsory arbitration for the following reason(s):

☑ monetary damages sought are in excess of $150,000, exclusive of interest and costs,

☐ the complaint seeks injunctive relief,

☐ the matter is otherwise ineligible for the following reason

DISCLOSURE STATEMENT - FEDERAL RULES CIVIL PROCEDURE 7.1

Identify any parent corporation and any publicly held corporation that owns 10% or more or its stocks:

RELATED CASE STATEMENT (Section VIII on the Front of this Form)

Please list all cases that are arguably related pursuant to Division of Business Rule 50.3.1 in Section VIII on the front of this form. Rule 50.3.1 (a) provides that "A civil case is "related" to another civil case for purposes of this guideline when, because of the similarity of facts and legal issues or because the cases arise from the same transactions or events, a substantial saving of judicial resources is likely to result from assigning both cases to the same judge and magistrate judge." Rule 50.3.1 (b) provides that " A civil case shall not be deemed "related" to another civil case merely because the civil case: (A) involves identical legal issues, or (B) involves the same parties." Rule 50.3.1 (c) further provides that "Presumptively, and subject to the power of a judge to determine otherwise pursuant to paragraph (d), civil cases shall not be deemed to be "related" unless both cases are still pending before the court."

NY-E DIVISION OF BUSINESS RULE 1(c)

1.) Is the civil action being filed in the Eastern District removed from a New York State Court located in Nassau or Suffolk County? ☐ Yes ☑ No

2.) If you answered "no" above:

a) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in Nassau or Suffolk County? ☐ Yes ☑ No

b) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in the Eastern District? ☑ Yes ☐ No

c) If this is a Fair Debt Collection Practice Act case, specify the County in which the offending communication was received:

If your answer to question 2 (b) is "No," does the defendant (or a majority of the defendants, if there is more than one) reside in Nassau or Suffolk County, or, in an interpleader action, does the claimant (or a majority of the claimants, if there is more than one) reside in Nassau or Suffolk County? ☐ Yes ☑ No

(Note: A corporation shall be considered a resident of the County in which it has the most significant contacts).

BAR ADMISSION

I am currently admitted in the Eastern District of New York and currently a member in good standing of the bar of this court.

☑ Yes ☐ No

Are you currently the subject of any disciplinary action (s) in this or any other state or federal court?

☐ Yes (If yes, please explain ☑ No

I certify the accuracy of all information provided above.

Signature: /s/ Raymond C. Silverman

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of New York

Chioma Ozuzu, individually, and on behalf of all others similarly situated

Plaintiff(s)

v.

Kenvue Inc., McNeil Consumer Healthcare, and Reckitt Benckiser, LLC

Defendant(s)

Civil Action No. 1:23-cv-7395

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Kenvue Inc. c/o C T Corporation System
28 Liberty Street
New York, NY 10005

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Raymond C. Silverman, Esq.
Parker Waichman LLP
6 Harbor Park Drive
Port Washington, NY 11050

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:23-cv-7395

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of New York

Chioma Ozuzu, individually, and on behalf of all others similarly situated

Plaintiff(s)

v.

Kenvue Inc., McNeil Consumer Healthcare, and Reckitt Benckiser, LLC

Defendant(s)

Civil Action No. 1:23-cv-7395

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* McNeil Consumer Healthcare
7050 Camp Hill Road
Fort Washington, PA 19034

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Raymond C. Silverman, Esq.
Parker Waichman LLP
6 Harbor Park Drive
Port Washington, NY 11050

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CLERK OF COURT

Date: _____

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Signature of Clerk or Deputy Clerk

Civil Action No. 1:23-cv-7395

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This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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v.

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Defendant(s)

Civil Action No. 1:23-cv-7395

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* McNeil Consumer Healthcare c/o Secretary of State of the State of New York
99 Washington Avenue, 6th Floor
Albany, NY 12231

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Raymond C. Silverman, Esq.
Parker Waichman LLP
6 Harbor Park Drive
Port Washington, NY 11050

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

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Signature of Clerk or Deputy Clerk

Civil Action No. 1:23-cv-7395

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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Plaintiff(s)

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Defendant(s)

Civil Action No. 1:23-cv-7395

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Reckitt Benckiser LLC c/o Corporation Service Company
80 State Street
Albany, NY 12207

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Raymond C. Silverman, Esq.
Parker Waichman LLP
6 Harbor Park Drive
Port Washington, NY 11050

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Signature of Clerk or Deputy Clerk

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

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I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

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Printed name and title

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Additional information regarding attempted service, etc: