UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

CASE NO.

HECTOR VALDES, on behalf of himself
and all others similarly situated,

Plaintiffs,

v.

MCNEIL CONSUMER HEALTHCARE,
PROCTER & GAMBLE COMPANY,
GLAXOSMITHKLINE LLC, and KENVUE, INC.,

Defendants.

CLASS ACTION COMPLAINT

Plaintiff Hector Valdes ("Plaintiff"), individually and on behalf of all others similarly situated, upon personal knowledge as to himself and his own acts, and as to all other matters upon information and belief, based upon the investigation made by the undersigned attorneys, allege as follows:

INTRODUCTION

1. Plaintiff seeks damages and equitable relief, individually and on behalf of all other Class members, for Defendants' sales of products to be taken orally containing phenylephrine, a compound that purportedly acts as a decongestant, but that Defendants have long known does not. Defendants sold these phenylephrine-containing "decongestants" anyway, generating billions of dollars in sales in the last year alone.

2. Phenylephrine is one of two compounds found in nasal decongestants administered orally and offered for sale on store shelves. The other compound is pseudoephedrine. While pseudoephedrine is effective as a decongestant, purchasing pseudoephedrine is often inconvenient

for a consumer because pseudoephedrine has been used as an ingredient in illicit methamphetamine laboratories, products containing it are usually placed behind store counters or in locked cabinets, and purchasers are sometimes forced to leave personal information every time they purchase it or are otherwise limited in the number of pseudoephedrine-containing medications they can buy. Consumers are naturally attracted to a decongestant that could be purchased without inconvenience.

3. By contrast, phenylephrine-containing products have no such restrictions and are not subject to an inconvenient buying process. Phenylephrine is found in many popular over-the-counter oral medications that purportedly act as decongestants—the "Decongestant Products"—including such popular products produced by Defendants as Tylenol Sinus + Headache (Kenvue[1]/McNeil); Theraflu (GlaxoSmithKline); Nyquil Severe Cold & Flu + Congestion (Procter & Gamble Company); and DayQuil Cold and Flu (Procter & Gamble Company).

4. Last year alone, nearly $1.8 billion in sales of phenylephrine-containing "decongestants" were made in the United States across more than 250 products, accounting for approximately 80% of the market for over-the-counter decongestants.

5. Unknown to the public, but known to the manufacturers in this lucrative market, phenylephrine taken orally is ineffective. It provides no relief for congestion, and is no better than a placebo, like a sugar pill, as a decongestant when taken orally.

6. Since at least 2007, scientific studies using modern testing methodologies and rigors have, time and again, shown that phenylephrine taken orally is ineffective. However, rather

[1]As noted below, Kenvue is a company, founded in February 2022, that prior to a spin-off had served as the Consumer Healthcare division of Johnson & Johnson. On information and belief, all assets and liabilities associated with the Decongestant Products that had been manufactured, marketed, and/or sold by Johnson & Johnson are now owned by Kenvue.

than acknowledge the truth of these studies, manufacturers, like Defendants, have continued to market and sell their products with phenylephrine as an effective decongestant medicine.

7. As one pharmacist who led the examination of the efficacy of phenylephrine summarized it, "if you have a stuffy nose and you take this medicine, you will still have a stuffy nose."

8. This fact did not stand in the way of Defendants continuing to sell phenylephrine products and charging a premium price for those ineffective products.

9. Had Plaintiff known that the phenylephrine-containing products were entirely ineffective as a nasal decongestant, he would not have purchased them, or would have paid substantially less for them.

10. Accordingly, Plaintiff, on behalf of himself and all other purchasers of Defendants' phenylephrine products, seek to hold Defendants accountable for their deceptions, breaches of warranties, and violations of consumer protection statutes. Defendants knew these products were ineffectual yet marketed and sold them anyway.

PARTIES

11. Plaintiff Valdes is a resident and citizen of Miami Springs, Florida. In early 2023, Plaintiff purchased Tylenol Sinus + Headache, a product manufactured by Defendants Kenvue/McNeil and containing phenylephrine for purported decongestant relief.

12. Plaintiff has also in the past purchased other Decongestant Products in the past year, including NyQuil Severe Cold & Flu (Procter & Gamble), DayQuil Cold & Flu (Procter & Gamble), and Theraflu ExpressMax Severe Cold & Cough (GlaxoSmithKline). All of Plaintiff's relevant purchases were in Miami-Dade County, Florida.

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

14. Defendant McNeil Consumer Healthcare is wholly owned by Defendant Kenvue, with headquarters in Fort Washington, Pennsylvania. McNeil manufactures and markets numerous Decongestant Products, including but not limited to Tylenol Sinus + Headache, a purported decongestant containing phenylephrine.

15. Defendant GlaxoSmithKline, LLC is a Delaware corporation with its headquarters and principal place of business in Philadelphia, Pennsylvania. GlaxoSmithKline is a wholly-owned subsidiary of GlaxoSmithKline PLC, a public limited company registered in England and Wales. GlaxoSmithKline is a biopharmaceutical company that, among other Decongestant Products, manufactures and markets Theraflu.

16. Defendant Procter & Gamble Company is an American multinational consumer goods corporation headquartered in Cincinnati, Ohio. Among other Decongestant Products, Procter & Gamble manufactures and markets Nyquil and DayQuil.

JURISDICTION & VENUE

17. This Court has subject matter jurisdiction pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because at least one Class member is of diverse citizenship from one defendant, there are more than 100 Class members nationwide, and the aggregate amount in controversy exceeds $5,000,000. This Court also has supplemental jurisdiction over the state law

claims because those claims are integrally related to the federal claims and form part of the same case and controversy under 28 U.S.C. § 1367.

18. This Court has personal jurisdiction over Defendants by virtue of their transacting and doing business in this District, including Miami-Dade County. Defendants have each purposefully availed themselves of the benefits and protections of the Southern District of Florida by continuously and systematically conducting substantial business in Florida. Each of the Defendants markets and distributes its products in Florida.

19. Venue is proper pursuant to 28 U.S.C. § 1391(a) & (b) because a substantial part of the events or omissions giving rise to the claims occurred in this District – specifically in Miami-Dade County. Defendants maintain key business operations in this District, and market and sell their products, including Decongestant Products, in this District.

FACTUAL ALLEGATIONS

The Market for Decongestants

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

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

22. Pseudoephedrine-based products are useful as decongestants. However, due to the misuse of pseudoephedrine as a base for the production of illegal methamphetamines, since 2006 federal law has made products containing pseudoephedrine, while available "over the counter" in the sense that they can, for the most part, be bought without a doctor's prescription, inconvenient to buy. The products are usually behind a pharmacy counter in locked containers, consumers are

limited in the amount that they can purchase, and purchasers are often required to provide personal identification and other information to track the amount of the substance being purchased.

23. Accordingly, the best-selling products in the decongestant market have been those that use phenylephrine, which account for approximately 80% of the market for over-the-counter decongestants. In the last year alone, nearly $1.8 billion of phenylephrine-based purported decongestants were sold.

The Truth About Phenylephrine

24. The problem—until recently unknown to the public, but well-known to Defendants—is that phenylephrine does not work when taken orally. While sold as a decongestant, it provides no better relief than a placebo.

25. Scientists have long reported that phenylephrine is ineffective. As Leslie Hendeles, PharmD and Randy Hatton, PharmD succinctly stated in the Journal of Allergy and Clinical Immunology in May 2006, "Phenylephrine ... is unlikely to provide relief of nasal congestion. It has poor oral bioavailability because of extensive first-pass metabolism in the gut and liver ... Moreover, in a randomized, double blind, placebo-controlled, crossover study of 3 oral decongestants in 20 patients with chronic nasal stuffiness, phenylephrine was no more effective than placebo in reducing nasal airway resistance."[2]

26. Scientific studies using modern testing methodologies (using good clinical practices) and rigors have, time and again, shown that phenylephrine is ineffective. On September 11 and September 12, 2023, the FDA held a non-prescription Drug Advisory Committee Meeting

[2] Leslie Handeles PharmD and Randy Hatton, Pharm D, Oral phenylephrine: *An ineffective replacement for pseudoephedrine?*, 118 J. Allergy and Clinical Immunology 1 (May 1, 2006), citing Bickerman HA. *Physiologic and pharmacologic studies on nasal airway resistance,* Presented at a conference sponsored by the Scientific Development Committee of the Proprietary Association. Washington, DC. December 8, 1971, available at https://www.jacionline.org/article/S0091-6749(06)00633-6/fulltext#bib5.

to discuss the efficacy of oral phenylephrine as a nasal decongestant. The Advisory Committee explained that multiple studies have shown phenylephrine is no better than a placebo.

27. For example, the committee described a study conducted by Johnson and Johnson from 2017 to 2018 to evaluate an oral phenylephrine product (Defendant Kenvue was until this year part of Johnson & Johnson). As explained by the panel, the trial "suggest[ed] no beneficial effect [of phenylephrine] when compared with placebo."[3]

28. This was hardly surprising. In 2015, Meltzer, et al., conducted a dose-response study relating to the treatment of nasal congestion. The study subjects were given various combinations of commercially available oral phenylephrine tablets and a placebo. The "commercially available" tablet was reported in an editorial published in the same journal as the study to have been Johnson and Johnson's (now Kenvue's) Sudafed PE.[4] The results of the study were unequivocal. As the authors put it, "we failed to identify a dose for [phenylephrine] ... that was significantly more effective than placebo in relieving nasal congestion."[5]

29. Nevertheless, Johnson & Johnson—and now freshly spun-off Kenvue—through its subsidiary Defendant McNeil continued to manufacture and sell its phenylephrine products, including Sudafed PE and Tylenol Sinus + Headache.

30. Defendants, as manufacturers of the phenylephrine-based products, were each aware of the studies suggesting that phenylephrine is ineffective as a nasal decongestant.

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[3] *See* NDAC Briefing Document: Oral Phenylephrine in the CCABA Monograph at 52, available at https://www.fda.gov/media/171915/download.

[4] Hatton and Hendeles, *Over the Counter Oral Phenylephrine: A Placebo for Nasal Congesion*, J. Allergy Clin. Immunol Prac. (Sept/Oct. 2015).

[5] Meltzer, et al., *Oral Phenylephrine HCI for Nasal Congestion in Seasonal Allergic Rhinitis: A randomized, Open-label, Placebo-controlled Study*, 3 J. Allergy Clin. Immunol Pract 6 (Sept/Oct 2015). Available at https://www.jaci-inpractice.org/action/showPdf?pii=S2213-2198%2815%2900252-4.

31. As one pharmacist who led the examination of the efficacy of phenylephrine summarized it, "if you have a stuffy nose and you take this medicine, you will still have a stuffy nose."

TOLLING OF ALL APPLICABLE STATUTES OF LIMITATIONS

Discovery Rule Tolling

32. Plaintiff and the other Class members had no way of knowing about Defendants' deception concerning their Decongestant Products. As consumers, they reasonably believed that the products offered for sale as decongestants were capable of acting as decongestants.

33. Within the time period of any applicable statutes of limitations, Plaintiff and the other Class members could not have discovered through the exercise of reasonable diligence that Defendants' Decongestant Products were ineffective.

34. Plaintiff and the other Class members did not discover and did not know facts that would have caused a reasonable person to suspect that Defendants did not report information within their knowledge about the ineffectiveness of their Decongestant Products; nor would a reasonable and diligent investigation have disclosed that Defendants concealed such information about the products' efficacy, which was only known by Plaintiff and the other Class members after the FDA decision in September 2023.

35. For these reasons, all applicable statutes of limitations have been tolled by operation of the discovery rule for the claims asserted herein.

Fraudulent Concealment Tolling

36. All applicable statutes of limitation have also been tolled by Defendants' knowing and active fraudulent concealment and denial of the facts alleged herein throughout the time-period relevant to this action.

37. Rather than disclose the truth about their Decongestant Products, Defendants falsely represented these products as ones that would relieve congestion.

Estoppel

38. Defendants were under a continuing duty to disclose to Plaintiff and the other Class members the true character, quality, and nature of their Decongestant Products.

39. Defendants knowingly, affirmatively, and actively concealed the true nature, quality, and character of their Decongestant Products.

40. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

CLASS ALLEGATIONS

41. Plaintiff brings this action pursuant to Rules 23(a), 23(b)(2), 23(b)(3), and 23(c)(4) of the Federal Rules of Civil Procedure on behalf of himself and all others similarly situated.

42. Plaintiff seeks to represent the following Classes:

All persons who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant McNeill Consumer Healthcare/Kenvue (the "Kenvue Nationwide Class").

All persons who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant McNeill Consumer Healthcare/Kenvue in the State of Florida (the "Kenvue Florida Class").

All persons who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant GlaxoSmithKline (the "GSK Nationwide Class").

All persons who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant GlaxoSmithKline in the State of Florida (the "GSK Florida Class").

All persons who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Procter & Gamble (the "Procter & Gamble Nationwide Class").

All persons who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendant Procter & Gamble in the State of Florida (the "Procter & Gamble Florida Class").

43. Excluded from the Classes are the Defendants, and any of the Defendants' members, affiliates, parents, subsidiaries, officers, directors, employees, successors, or assigns; the judicial officers, and their immediate family members; and the Court staff assigned to this case. Plaintiff reserves the right to modify or amend the Class definition, as appropriate, during the course of this litigation.

44. This action has been brought and may properly be maintained on behalf of the Classes proposed herein under the criteria of Rule 23 of the Federal Rules of Civil Procedure.

45. Certification of Plaintiff's claims for classwide treatment is appropriate because Plaintiff can prove the elements of his claims using the same evidence as would be used to prove those elements in individual actions alleging the same claims.

46. *Numerosity*: Rule 23(a)(1): The members of the Classes are so numerous and geographically dispersed that individual joinder of all Class members is impracticable. Plaintiff is informed and believes that there are hundreds of thousands of members of the Classes based on the size of the market for decongestant products and Defendants' share of that market, but the precise number of Class members is unknown to Plaintiff.

47. *Commonality and Predominance*: Rule 23(a)(2) and (b)(3): This action involves common questions of law and fact which predominate over any questions affecting individual Class members, including, without limitation:

a. When Defendants knew that phenylephrine was ineffective as a decongestant;

b. Whether Defendants sold Decongestant Products as effective;

c. What measures Defendants took to conceal the true nature of their Decongestant Products;

d. Defendants' duty to disclose the true nature of their Decongestant Products;

e. Whether Plaintiff and the other Class members overpaid for Defendants' Decongestant Products; and

f. Whether Plaintiff and the other Class members are entitled to equitable and injunctive relief.

48. *Typicality*: Rule 23(a)(3): Plaintiff's claims are typical of the other Class members' claims because, among other things, all Class members were comparably injured through Defendants' wrongful conduct as described above. Plaintiff suffered damages as a direct proximate result of the same wrongful practices in which Defendants engaged.

49. *Adequacy*: Rule 23(a)(4): Plaintiff is an adequate Class Representatives because his interests do not conflict with the interests of the other members of the Classes he seeks to represent; Plaintiff has retained counsel competent and experienced in complex class action litigation; and Plaintiff intends to prosecute this action vigorously. Plaintiff and his counsel will fairly and adequately protect the Class's interests.

50. *Declaratory Relief*: Federal Rule of Civil Procedure 23(b)(2): Defendants have acted or refused to act on grounds generally applicable to Plaintiff and the other members of the Classes, thereby making declaratory relief appropriate, with respect to each Class as a whole.

51. *Superiority*: Federal Rule of Civil Procedure 23(b)(3): A class action is superior to any other available means for the fair and efficient adjudication of this controversy and no unusual difficulties are likely to be encountered in managing this class action. The damages or other financial detriment suffered by Plaintiff and the other Class members are relatively small compared to the burden and expense that would be required to individually litigate their claims against Defendants, so it would be impracticable for the members of the Classes to individually seek redress for Defendants' wrongful conduct. Even if Class members could afford individual

litigation, such litigation creates a potential for inconsistent or contradictory judgments. It increases the delay and expense to all parties and the court system. By contrast, a class action is suited and intended to manage such difficulties and provide the benefits of uniform and common adjudication, economy of scale, and comprehensive supervision.

CLAIMS FOR RELIEF

COUNT ONE
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(All Defendants)

52. Plaintiff repeats and realleges the allegations contained in Paragraphs 1-51, as if fully set forth herein.

53. Plaintiff brings this claim on behalf of the Nationwide Classes or, in the alternative, the State Classes (the "Class," for purposes of this Count).

54. 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.[6]

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

[6] *See* e.g., 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.

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

57. Defendants were obligated to provide Plaintiff and the other Class members Decongestant Products that were of merchantable quality, were reasonably fit for the purpose for which they were sold, and conformed to the standards of the trade.

58. Defendants impliedly warranted that the Decongestant Products were of merchantable quality and fit for that purpose.

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

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

COUNT TWO
FRAUD BY OMISSION OR CONCEALMENT
(All Defendants)

61. Plaintiff repeats and realleges the allegations contained in Paragraphs 1-51, as if fully set forth herein.

62. Plaintiff brings this claim on behalf of the Nationwide Classes or, in the alternative, the State Classes (the "Class," for purposes of this Count).

63. Defendants intentionally and knowingly falsely concealed, suppressed and/or omitted material facts including as to the standard, quality, or grade of the Decongestant Products. Due to their fraudulent conduct, Plaintiff and the other Class members have suffered actual damages.

64. Defendants knew that phenylephrine is ineffective when consumed orally.

65. Defendants were obligated to inform Plaintiff and the other members of the Class of the effectiveness of phenylephrine due to their exclusive and superior knowledge of the

Decongestant Products. Plaintiff and other Class members also expressly reposed trust and confidence in Defendants because the nature of their dealings as a healthcare entity and with Plaintiff and other members of the Class as their consumers.

66. Plaintiff and the other Class members would not have purchased the Decongestant Products but for Defendants' omissions and concealment of material facts regarding the nature and quality of the Decongestant Products and existence of the Decongestant Products, or would have paid less for the Decongestant Products.

67. Defendants knew their concealment and suppression of material facts was false and misleading and knew the effect of concealing those material facts.

68. Defendants acted with malice, oppression, and fraud.

69. Plaintiff and the other Class members reasonably relied on Defendants' knowing, affirmative, and active false concealment and omissions. As a direct and proximate result of Defendants' omissions and active concealment of material facts regarding the Decongestant Products, Plaintiff and the other Class members have suffered actual damages in an amount to be determined at trial.

COUNT THREE
UNJUST ENRICHMENT
(All Defendants)

70. Plaintiff repeats and realleges the allegations contained in Paragraphs 1-51, as if fully set forth herein.

71. Plaintiff brings this claim on behalf of the nationwide Class or, in the alternative, the State Classes (the "Class," for purposes of this Count).

72. There are no material differences in the elements of the unjust enrichment cause of action in the various states. In all states, the focus of an unjust enrichment claim is whether the

defendant was unjustly enriched. At the core of each state's law are two fundamental elements – the defendant received a benefit from the plaintiff and it would be inequitable for the defendant to retain that benefit without compensating the plaintiff. The focus of the inquiry is the same in each state. Since there is no material conflict relating to the elements of unjust enrichment between the different jurisdictions from which class members will be drawn, Florida law applies to those claims.

73. Defendants' efforts include, but are not limited to, providing point-of-sale materials and coupons to entice Plaintiff and the other Class members to purchase Decongestant Products.

74. It would be inequitable for Defendants to insulate themselves from liability on this unjust enrichment claim by asserting that retail sales by their retailers cuts off any relationship between the Plaintiff and the Classes and Defendants because Plaintiff and the other Class members cannot seek a remedy directly from Defendants' retailers based on Defendants' sale of the Decongestant Products.

75. Plaintiff and all other Class members conferred a benefit on Defendants by purchasing Decongestant Products.

76. Defendants have been unjustly enriched in retaining the revenues derived from Class members' purchases of Decongestant Products, which retention under these circumstances is unjust and inequitable because Defendants misrepresented that Decongestant Products were effective for providing congestion relief when in fact they were not, which caused injuries to Plaintiff and all Class members because they paid a price premium due to Defendants' deception.

77. Because Defendants' retention of the non-gratuitous benefit conferred on it by Plaintiff and all Class members is unjust and inequitable, Defendants must pay restitution to Plaintiff and the Class members for their unjust enrichment, as ordered by the Court.

COUNT FOUR
Violation of Fla Stat. §501.204(1)
(All Defendants)

78. Plaintiff repeats and reallege the allegations contained in Paragraphs 1-51, as if fully set forth herein.

79. Plaintiff brings this claim on behalf of themselves and the Florida Classes (the "Class," for purposes of this Count) and against Defendants.

80. FDUTPA prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair and deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. §501.204(1).

81. In construing FDUTPA, "due consideration and great weight shall be given to the interpretation of the Federal Trade Commission and the federal courts relating to s. 5(a)(1) of the Federal Trade Commission Act, 15 U.S.C. s. 45(a)(1) as of July 1, 2017." Fla. Stat. §501.204(2).

82. Plaintiff and the Florida Class members are "[c]onsumers" and "[i]nterested part[ies] or person[s]" as defined by FDUTPA. Fla. Stat. §501.203(6)-(7).

83. Defendants' actions set forth herein occurred while engaging in "[t]rade or commerce" as defined by FDUTPA. Fla. Stat. §501.203(8).

84. Defendants' conduct, as set forth herein, constitutes unfair methods of competition, unconscionable acts or practices, or unfair or deceptive acts or practices under FDUTPA.

85. As alleged in more detail herein, at the time Defendants advertised and sold the Decongestant Products, they knew that the Decongestant Products did not work.

86. Plaintiff and the other Florida Class members were therefore induced to purchase the Decongestant Products under false pretenses.

87. Plaintiff and the other Florida Class members had no way of knowing that the Decongestant Products did not work.

88. Defendants knowingly and intentionally manufactured and sold the Decongestant Products with the intent to mislead reasonable consumers, including Plaintiff and the other Florida Class members.

89. Defendants knew or should have known that their conduct violated FDUTPA.

90. Defendants owed Plaintiff and the other Florida Class members a duty to disclose the true nature of their Decongestant Products, because Defendants:

(a) possessed exclusive knowledge that they were manufacturing, selling, and distributing products throughout the United States that did not perform as advertised; and/or

(b) intentionally concealed the foregoing from Plaintiff and the other Florida Class members.

91. Defendants' unfair, unconscionable, or deceptive acts or practices were likely to, and did in fact, deceive ordinary, reasonable consumers, including the Florida Class members, about the quality and efficacy of the Decongestant Products, and the true value of the Decongestant Products.

92. Defendants' violations present a continuing risk to the Florida Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

93. Defendants had an ongoing duty to all their customers to refrain from unfair, unconscionable, and deceptive acts and practices under FDUTPA.

94. All purchasers of the Decongestant Products suffered ascertainable loss and actual damages as a result of Defendants' deceptive, unconscionable, and unfair acts and practices made in the course of Defendants engaging in trade or commerce through loss of money or property at the time of purchase in form of the full or partial retail price paid for the Decongestant Products.

95. As a direct and proximate result of Defendants' violations of FDUTPA, Plaintiff and the Florida Class members have suffered injury-in-fact and/or actual damages.

96. As a result of the foregoing willful, knowing, and wrongful conduct of Defendants, Plaintiff and the Florida Class members have been damaged in an amount to be proven at trial, and seek all just and proper remedies, including, but not limited to, actual damages, reasonable attorneys' fees and costs, an Order enjoining Defendants' deceptive and unfair conduct, and all other appropriate relief available under FDUTPA.

97. Plaintiff, individually and on behalf of the Florida Classes, seeks monetary damages, costs, attorneys' fees, and such other and further relief provided by law and equity.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the other Class members, respectfully request that the Court enter judgement in their favor and against Defendants, as follows:

1. Certification of the proposed Classes with Plaintiff as class representative;

2. Appointment of Plaintiff's counsel as Class Counsel;

3. Injunctive relief, including, but not limited to:

   a. Requiring Defendants to make full disclosure of the efficacy of their Decongestant Products;

   b. Disgorgement of their profits from the sales of their Decongestant Products;

c. Damages, including punitive damages, costs, and disgorgement in an amount to be determined at trial;

d. An order requiring Defendants to pay both pre- and post-judgment interest on all amounts awarded;

e. An award of costs and attorneys' fees; and

f. Such other further relief as may be appropriate.

Dated this 13th day of October, 2023.

Respectfully submitted,

BUCKNER + MILES
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JS 44 (Rev. 04/21) FLSD Revised 12/02/2022

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.)* **NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.**

I. (a) PLAINTIFFS

Hector Valdes

DEFENDANTS

McNeil Consumer Healthcare, et. al.

(b) County of Residence of First Listed Plaintiff Miami-Dade
(EXCEPT IN U.S. PLAINTIFF CASES)

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

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

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

David M. Buckner, Esq., Buckner + Miles, 2020 Salzedo Street, Suite 3

Attorneys *(If Known)*

(d) Check County Where Action Arose: ■ MIAMI- DADE ☐ MONROE ☐ BROWARD ☐ PALM BEACH ☐ MARTIN ☐ ST. LUCIE ☐ INDIAN RIVER ☐ OKEECHOBEE ☐ HIGHLANDS

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 (Excl. 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 - Med. 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

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

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

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 (TCPA)
☐ 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

IMMIGRATION
☐ 462 Naturalization Application
☐ 465 Other Immigration Actions

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

■ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Re-filed **(See VI below)** ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district *(specify)* ☐ 6 Multidistrict Litigation Transfer ☐ 7 Appeal to District Judge from Magistrate Judgment ☐ 8 Multidistrict Litigation – Direct File ☐ 9 Remanded from Appellate Court

VI. RELATED/ RE-FILED CASE(S)

(See instructions): a) Re-filed Case ☐YES ☒ NO b) Related Cases ☐YES ■ NO

JUDGE: **DOCKET NUMBER:**

VII. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing and Write a Brief Statement of Cause ***(Do not cite jurisdictional statutes unless diversity)***:

28 U.S.C. § 1332(d)

LENGTH OF TRIAL via days estimated (for both sides to try entire case)

VIII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ■ Yes ☐ No

ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE

DATE: 10/13/2023

SIGNATURE OF ATTORNEY OF RECORD: s/David M. Buckner

FOR OFFICE USE ONLY : RECEIPT # **AMOUNT** IFP JUDGE MAG JUDGE

s/David M.

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence**. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked. Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Refiled (3) Attach copy of Order for Dismissal of Previous case. Also complete VI.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

Remanded from Appellate Court. (8) Check this box if remanded from Appellate Court.

VI. Related/Refiled Cases. This section of the JS 44 is used to reference related pending cases or re-filed cases. Insert the docket numbers and the corresponding judges name for such cases.

VII. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**. Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VIII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

Date and Attorney Signature. Date and sign the civil cover sheet.