IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

DANIEL HEAGHNEY, an individual, on behalf of himself and all others similarly situated,	)	
Plaintiffs,	)	Case No. _____
v.	)	
Johnson & Johnson Holdco (NA), Inc.; GlaxoSmithKline LLC; Reckitt Benckiser LLC; Bayer Healthcare LLC; The Procter & Gamble Company; Walmart, Inc.; Walgreen Co.; Target Corporation; CVS Pharmacy, Inc.; Dierbergs Markets, Inc.; Price Chopper Foods, Incorporated; Amazon.com, Inc.; Amazon.com Services LLC; DOES 1-20,	)	
Defendants.	)	

CLASS ACTION PETITION

COMES NOW Plaintiff Daniel Heaghney, by and through his undersigned counsel, and hereby brings this action on behalf of himself and all others similarly situated, and in support thereof, states:

INTRODUCTION

1. This is a class action for damages and injunctive relief related to Defendants' wrongdoing in connection with the marketing, manufacturing, distribution, and sale of over-the-counter cold medicines containing Phenylephrine.

2. Phenylephrine is a purported decongestant used in at least 250 different products, including Nyquil Severe Cold & Flu, Tylenol Cold & Flu Severe, Sudafed Sinus Congestion, Mucinex Sinus Max, and many others, as well as generic brands developed and sold by retailers like Walmart, Walgreens, Target, and CVS (the "Phenylephrine Products").

3. Defendants manufacture, test, promote, advertise, market, distribute and sell the Phenylephrine Products for the treatment of congestion and other associated cold and flu symptoms. Millions of Missourians, and hundreds of millions of Americans, purchase these products for help relieving congestion and other associated cold and flu symptoms because they are told by the above-captioned Defendants that they work for that purpose.

4. For years, Defendants have advertised and marketed the Phenylephrine Products to unsuspecting consumers despite knowing that phenylephrine is ineffective for the treatment of nasal congestion and the other cold and flu symptoms for which Defendants promote its use. On or about September 12, 2023, the Federal Drug Administration ("FDA"), after careful study and consideration, announced publicly that phenylephrine is *ineffective* as a treatment for such symptoms.

5. As a proximate result of Defendants' deceptive, fraudulent, unlawful, and/or unfair conduct, Plaintiff and all class members collectively suffered hundreds of millions of dollars in damages in reliance upon Defendants' knowingly false representations about the effectiveness of phenylephrine and the Phenylephrine Products.

6. Plaintiff and the Class members therefore demand judgment against Defendants and request, among other things, compensatory damages, punitive damages, attorneys' fees, costs, injunctive relief, and all other available remedies and damages allowed by law.

PARTIES

7. At all relevant times, Plaintiff Daniel Heaghney was and has been a resident of the City of St. Louis, State of Missouri.

8. On numerous occasions within the statutory time period, in reliance upon Defendants' intentionally false and fraudulent marketing, Plaintiff Heaghney purchased the

Phenylephrine Products, and each of them, within the State of Missouri for treatment of cold and flu symptoms.

9. Defendant Johnson & Johnson Holdco (NA), Inc., is a New Jersey corporation, with headquarters and a principal place of business in the State of New Jersey. Upon information and belief, Defendant Johnson & Johnson Holdco (NA), Inc., is a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation, with headquarters and a principal place of business in the State of New Jersey (collectively "J&J"). Upon information and belief, Johnson & Johnson Holdco (NA), Inc., was previously named Johnson & Johnson Consumer Inc. At all times relevant hereto, Defendant J&J was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the Phenylephrine Products, including but not limited to, Tylenol, Sudafed, and Benadryl.

10. Defendant GlaxoSmithKline LLC is a Delaware corporation with headquarters and a principal place of business in the State of Pennsylvania. Upon information and belief, GlaxoSmithKline LLC is a wholly owned subsidiary of GlaxoSmithKline PLC a public limited company organized under the laws of England and Wales (collectively "GSK"). At all times relevant hereto, Defendant GSK was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the Phenylephrine Products, including but not limited to, Robitussin, Theraflu, Contac, and Advil.

11. Defendant Reckitt Benckiser LLC is a Delaware limited liability corporation, with headquarters and a principal place of business in the State of New Jersey. Upon information and belief, Reckitt Benckiser LLC, is a wholly owned subsidiary of Reckitt Benckiser Group PLC, a public limited company organized under the laws of England and Wales (collectively "Reckitt"). At all times relevant hereto, Reckitt was engaged in the business of manufacturing, marketing,

testing, promoting, selling, and/or distributing certain of the Phenylephrine Products, including but not limited to, Mucinex.

12. Defendant Bayer Healthcare LLC is a Delaware limited liability corporation with headquarters and a principal place of business in the State of New Jersey. Upon information and belief, Bayer Healthcare LLC is a wholly owned subsidiary of Bayer Corporation, an Indiana corporation with a principal place of business in the State of Pennsylvania (collectively "Bayer"). At all times relevant hereto, Defendant Bayer was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the Phenylephrine Products, including but not limited to, Alka-Seltzer.

13. Defendant The Procter & Gamble Company ("Proctor") is an Ohio corporation with headquarters and principal place of business in the State of Ohio. At all times relevant hereto, Defendant Proctor was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the Phenylephrine Products, including but not limited to, Dayquil and NyQuil.

14. Defendant Walmart Inc. ("Walmart") is a Delaware corporation with headquarters and principal place of business in the State of Arkansas. At all times relevant hereto, Walmart was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the Phenylephrine Products.

15. Defendant Target Corporation ("Target") is a Minnesota corporation with headquarters and principal place of business in the State of Minnesota. At all times relevant hereto, Target was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the Phenylephrine Products.

16. Defendant CVS Pharmacy, Inc. ("CVS") is a Delaware corporation with headquarters and principal place of business in the State of Rhode Island. At all times relevant hereto, CVS was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the Phenylephrine Products.

17. Defendant Walgreen Co. ("Walgreens") is an Illinois corporation with headquarters and principal place of business in the State of Illinois. At all times relevant hereto, Walgreens was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the Phenylephrine Products.

18. Defendant Amazon.com, Inc. is a Delaware corporation with its principal place of business in the State of Washington and Amazon.com Services LLC is a Delaware Limited Liability Company with its principal place of business in the State of Washington (collectively "Amazon"). At all times relevant hereto, Amazon was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the Phenylephrine Products.

19. Defendant Dierbergs Markets, Inc. ("Dierbergs"), is a Missouri corporation with principal place of business in the State of Missouri. At all times relevant hereto, Dierbergs was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the Phenylephrine Products.

20. Defendant Price Chopper Foods, Incorporation ("Price Chopper"), is a Missouri corporation with its principal office located in the State of Arkansas. At all times relevant hereto, Price Chopper was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the Phenylephrine Products.

21. The true names and capacities of defendants Does 1 through 20 are currently unknown to Plaintiff who, therefore, sues these Defendants under these fictitious names. These

defendants are each directly and/or vicariously responsible, in some manner, for the harms alleged herein. If/when Plaintiff learns these Defendants' true names and capacities, Plaintiff will seek leave to amend this Petition accordingly.

22. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of Defendants DOES 1 through 20, inclusive, and each of them, are unknown to Plaintiff at this time, who therefore sues said Defendants by such fictitious names. Plaintiff is informed and believe, and thereon alleges, that each Defendant designated herein as a DOE caused injuries and damages proximately thereby to Plaintiff and the class as hereinafter allege; and that each DOE Defendant is liable to Plaintiff and the class for the acts and omissions alleged herein below, and the resulting injuries to Plaintiff and the class, and damages sustained by them. Plaintiff will amend this Petition to allege the true names and capacities of said DOE Defendants when ascertained.

JURISDICITON AND VENUE

23. This Court has jurisdiction over this matter because it is a civil matter in which more than $25,000.00 is in controversy.

24. Venue is proper in this Circuit because Plaintiff is a resident of the City of St. Louis, purchased the Phenylephrine Products in the City of St. Louis, and was first harmed by the Phenylephrine Products in the City of St. Louis.

GENERAL ALLEGATIONS

25. The main active ingredient in the Phenylephrine Products is phenylephrine hydrochloride, or "PE." In 1994, the FDA issued a final monograph establishing conditions under which OTC nasal decongestant drug products are generally recognized as safe and effective

("GRASE") and not misbranded. Phenylephrine is included in the final monograph as an OTC oral nasal decongestant.

26. Defendants marketed PE as an effective decongestant that should be used to relieve nasal congestion and sinus pressure associated with colds, allergies, and other respiratory conditions. According to Defendants, phenylephrine works by constricting blood vessels in the nasal passages, which reduces swelling and congestion.

27. However, Defendants knew that these representations concerning phenylephrine's efficacy at treating nasal congestion were false.

28. In 2007, the consumer advocacy group Public Citizen filed a petition with the U.S. Food and Drug Administration (FDA) regarding phenylephrine. The petition requested that the FDA re-evaluate the safety and efficacy of phenylephrine as a nasal decongestant and take regulatory action.

29. Defendants deceived Plaintiff and the public in general by making these intentional misrepresentations regarding the efficacy of phenylephrine and the Phenylephrine Products. Public Citizen expressed concerns that phenylephrine, the active ingredient in many OTC decongestant products, was not as effective as another decongestant called pseudoephedrine. The petition argued that the switch from pseudoephedrine to phenylephrine in many cold and allergy medications had not been supported by adequate scientific evidence demonstrating the latter's effectiveness in relieving nasal congestion.

30. Public Citizen also raised concerns about the potential side effects and safety of phenylephrine, suggesting that its use might lead to increased blood pressure in some individuals.

31. The FDA reviewed the concerns raised by the Public Citizen petition regarding the safety and efficacy of phenylephrine as a nasal decongestant. The FDA concluded that, based on

the available data at the time of its review in 2007, phenylephrine could be considered effective as a nasal decongestant when used at the recommended doses.

32. Thus, in 2007, the FDA concluded that orally administered PE was Generally Recognized as Safe and Effective (GRASE).

33. The FDA's GRASE determination allowed Defendants to market the Products as an OTC or "over-the-counter" medication. This was an important designation to Defendants as it allowed them to market the Products to consumers without requiring a doctor's prescription, making it more accessible for self-treatment, and allowing Defendants to make billions of dollars in OTC sales.

34. However, on September 11th and 12th, 2023, the FDA issued a new report detailing its updated review of the efficacy of phenylephrine, based on the studies it initially reviewed in 2007 and additional studies obtained since its initial review. A copy of the FDA's report is attached as Exhibit 1.

35. The FDA's 2023 findings are based on rigorous scientific research and evaluation. At its initial 2007 Nonprescription Drugs Advisory Committee ("NDAC") meeting and review, the FDA reviewed clinical effectiveness data for oral doses between 5mg and 40mg in a total of 14 studies, of which 7 reported positive measurable efficacy results.

36. During its initial 2007 Nonprescription Drugs Advisory Committee ("NDAC") meeting and review, the FDA reviewed clinical effectiveness data for oral doses between 5mg and 40mg in a total of 14 studies, of which 7 reported positive measurable efficacy results.

37. However, in its re-analysis of these studies in 2023, the FDA found significant problems with the 2007 studies:

> [w]hen considering the studies through a modern drug review lens, all of the studies (both positive and negative) were highly problematic in both design and

> methodology. All used a highly variable endpoint (NAR) to study a drug in the setting of a highly variable disease state (the common cold) that is no longer used as a primary endpoint to evaluate congestion in pivotal trials. Further, all the positive studies (and most of the negative studies) were unpublished and therefore never peer-reviewed. Six of the seven positive studies came from a single study center (funded by the manufacturer of Neo-Synephrine), were very small in size, and (except in one instance) the results could not be duplicated at two other study centers (also funded by the same manufacturer) that used as similar study design and methodology.

(Exhibit 1).

38. Thus, the FDA found that the original studies had data integrity issues and that the results of some 2007 studies could not be replicated in other studies at other locations.

39. Due to the flaws in methodology and design of the previous studies, the FDA now believes that the studies evaluated for the efficacy of phenylephrine in 2007 are "unacceptable as continued support for the efficacy of monographed doses or oral PE." Exhibit 1.

40. Since 2007, several additional large clinical trials have been conducted regarding the efficacy of phenylephrine, providing evidence of the absence of a decongestant effect from the OTC approved doses of 10 mg.[1] These studies show that the Phenylephrine Products are no more effective than placebo in decreasing nasal congestion and, thus, lack efficacy.

41. On September 12, 2023, an FDA panel unanimously declared that phenylephrine, the active ingredient in the Phenylephrine Products, is an ineffective decongestant.

[1] 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-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.

42. At least since 2018, if not earlier, Defendants knew or should have known that their marketing claims regarding the Phenylephrine Products' efficacy were false and misleading.

43. Plaintiff and the class members purchased the Phenylephrine Products in reliance on Defendants' false and deceptive marketing claims. Plaintiff and the class members acted as reasonable consumers in light of all the circumstances.

CLASS ACTION ALLEGATIONS

44. Pursuant to Rules 52.08(a), (b)(3), (b)(2), and (c)(4) of the Missouri Rules of Civil Procedure, Plaintiff brings this class action on his own behalf and on behalf of all other similarly situated consumers in the United States as members of the following proposed Missouri class, to be defined as follows:

a. During the fullest period allowed by law, all persons who, while a resident of Missouri, purchased any of the Phenylephrine Products at any location in Missouri, including without limitation any online purchase made from Missouri (the "Class").

b. Excluded from the class are assigned judges and members of their families within the first degree of consanguinity, Defendants, and their subsidiaries, affiliates, officers, and directors.

45. Like Plaintiff, all Class members purchased the Phenylephrine Products based on the misrepresentations that said products were effective in the treatment of congestion and other associated cold and flu symptoms, and that such understanding was reasonable and was a material basis for the decision to purchase the Phenylephrine Product, which Defendants intended to foster through its various marketing activities in connection with the sale of the Phenylephrine Products.

46. The proposed Class is so numerous that individual joinder of all its members is impracticable because members of the Class number in the tens or hundreds of thousands. The

precise number of Class members and their identities are unknown to Plaintiff at this time but are objectively ascertainable and will be determined through appropriate discovery.

47. Plaintiff and his counsel will fairly and adequately protect and represent the interests of each member of the class. Plaintiff has retained counsel experienced in complex litigation and class actions.

48. Plaintiff has no adverse or antagonistic interests to those of the Class, nor is Plaintiff subject to any unique defenses. Plaintiff's claim is typical of every member of the Class.

49. There are common questions of law and fact affecting Plaintiff and the Class members. These include, but are not limited to:

a. Whether Defendants marketed and advertised the Phenylephrine Products in a way that was false or misleading.

b. Whether by the misconduct set forth herein, Defendants have engaged and continue to engage in any unfair practice, deception, fraud, false pretense, false promise, misrepresentation, concealment, suppression, or omission of any material fact in connection with the sale or advertisement of the Phenylephrine Products in violation of RSMo. 407.020.

c. Whether Defendants' conduct constitutes violations of the laws asserted herein.

d. Whether Class members were harmed by Defendants' misconduct and, if so, to what extent.

e. Whether the Class is entitled to recover statutory attorney's fees.

f. Whether the Class is entitled to punitive damages (following motion practice consistent with RSMo. § 510.261).

g. Whether an injunction is necessary to prevent Defendants from continuing to market and sell the Phenylephrine Products that lack efficacy.

50. These common questions of law and/or fact predominate over any questions affecting only individual Class members.

51. A class action is superior to the other available methods for a fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by the Plaintiff and individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendants. It would thus be virtually impossible for Plaintiff and Class members, on an individual basis, to obtain meaningful and effective redress for the wrongs done to them. Further, it is desirable to concentrate the litigation of the Class members' claims in one forum, as it will conserve party and judicial resources and facilitate the consistency of adjudications. Plaintiff knows of no difficulty that would be encountered in the management of this case that would preclude its maintenance as a class action.

52. The Class also may be certified because Defendants have acted or refused to act on grounds applicable to the Class, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

53. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent Defendants from engaging in the acts described above, including continuing to market and sell Phenylephrine Products that lack efficacy, and requiring Defendants to provide a full refund of the purchase price of the Products to Plaintiff and the Class members.

COUNT I

Violation of the Missouri Merchandising Practices Act

Mo. Rev. Stat. §§ 407.010 *et seq.*

(On Behalf of the Plaintiff and the Class Against All Defendants)

54. Plaintiff incorporates by reference and realleges every allegation contained above as though fully set forth herein.

55. Plaintiff and the Class members defined herein are each a "person" as defined by RSMo. § 407.010(5). Likewise, each of the Defendants are a "person" as defined by RSMo. § 407.010(5).

56. Plaintiff and the Class members' purchases of the Phenylephrine Products were "sales" and occurred in connection with a "sale" as defined by RSMo. §§ 407.0410(6) and 407.020.

57. The Defendants made numerous "advertisements" as defined by RSMo. § 407.010(1) in print, radio, television, packaging, and other forms regarding the purported efficacy of the Phenylephrine Products for treating congestion.

58. The Defendants used "deception" as that term is defined by 15 CSR 60-9.020(1) in connection with the sale and advertisement of the Phenylephrine Products.

59. The Defendants committed "fraud" as that is defined by 15 CSR 60-9.050(1) in connection with the sale and advertisement of the Phenylephrine Products as the term "fraud" is defined by 15 CSR 60-9.040.

60. The Defendants used "false pretenses" in connection with the "sale" and "advertisement" of the Phenylephrine Products.

61. The Defendants made "false promises" as that term is defined by 15 CSR 60-9.060(1) in connection with the sale and advertisement of the Phenylephrine Products.

62. The Defendants made "misrepresentations" as that term is defined by 15 CSR 60-9.060(1) in connection with the sale and advertisement of the Phenylephrine Products.

63. The Defendants concealed, suppressed, and/or omitted material facts about the Phenylephrine Products in connection with their sale and advertisement under CSR 60-9.110.

64. The Defendants committed unfair practices under CSR 60-8.020 by engaging in practices that were unethical, oppressive or unscrupulous and which presented the risk of, or caused, substantial injury to Plaintiff and the Class members, who are Missouri consumers.

65. Plaintiff and the Class members acted as reasonable consumers would in light of all the circumstances.

66. Defendants' deception, fraud, false pretenses, false promises, misrepresentations, concealments, suppressions, omissions, and unfair practices would, and did, cause reasonable persons to enter into transactions to purchase the Phenylephrine Products, resulting in damage to Plaintiff and the Class members.

67. Damages can be proven with sufficiently definitive and objective evidence to allow the loss to be calculated within a reasonable degree of certainty. Defendants are in possession of documents and data relating to the sales of the Phenylephrine Products in Missouri. Plaintiff and the Class members have been damaged in the amount of the purchase price of the Phenylephrine Products they purchased.

68. As a direct and proximate result of Defendants' violations of RSMo. § 407.020, Plaintiff and the Class members have or will suffer ascertainable loss of money and/or property and seek relief pursuant to RSMo. § 407.025.

69. Under RSMo. § 407.025.2, Plaintiff and the Class seek their reasonable attorney's fees incurred in connection with this action.

WHEREFORE Plaintiff, individually, and on behalf of the proposed Class, prays the Court grant the following relief:

a. Enter an order certifying this action as a class action and appointing Daniel Heaghney as the representative of the Class.

b. Enter an order appointing Benjamin Schmickle, Sophie Zavaglia, and Benjamin McIntosh of SWMW Law, LLC, as counsel of the Class.

c. In the event the Class is certified, enter judgment in favor of Plaintiff and members of the Class in the sum of the purchase price of the Phenylephrine Products.

d. Enter judgment awarding class counsel reasonable attorney's fees and all expenses of this action to be paid by Defendant, and to require Defendant to pay the costs and expenses of class notice and administration.

e. Enter judgment awarding Plaintiff a reasonable service award for serving as the representatives of the classes.

f. Enter a judgment of permanent injunction against Defendants prohibiting Defendants from selling the Phenylephrine Products to Missouri consumers.

Respectfully Submitted,
SWMW LAW, LLC

By: ***/s/ Benjamin S. McIntosh***

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