**UNITED STATES DISTRICT COURT**

**EASTERN DISTRICT OF PENNSYLVANIA**

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| **MICHELE KASPARIE and KIMBERLY JAMES, individually and on behalf of all others similarly situated,** | **Case No.** |
| **Plaintiffs** | **CLASS ACTION COMPLAINT** |
| **v.** | |
| **Bayer Healthcare LLC, GlaxoSmithKline LLC, Kenvue Inc., McNeil Consumer Healthcare, Procter & Gamble Company, Target Corporation, and Walmart Inc.,** | **DEMAND FOR JURY TRIAL** |
| **Defendants.** | |

Plaintiffs Michelle Kasparie ("Kasparie") and Kimberly James ("James") (collectively "Plaintiffs"), individually and on behalf of all similarly situated persons who purchased over-the-counter oral decongestant products, allege the following based upon personal knowledge as to themselves and their own acts, and as to all other matters upon information and belief, based upon the investigation of counsel, and further believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery:

## I. INTRODUCTION

1. Oral decongestant products, sold online and over-the-counter in retail stores, have been relied upon by consumers for many years as an expedient way to treat nasal decongestion, without the need or hassle involved in securing a doctor's prescription.

2. One primary active ingredient that has been used by manufactures of such over-the-counter oral decongestants is "phenylephrine."

3. Drug companies and Defendants named herein began increasingly relying upon phenylephrine after concerns were voiced in 2006 about the use of pseudoephedrine – an

acknowledged effective active ingredient to treat nasal decongestion – as a basis for the manufacture of illegal methamphetamine products.

4. The sale of oral decongestant products using phenylephrine has sky-rocketed with sales of over $1.8 billion in the United States in 2022 alone.

5. Members of the consumer public, including Plaintiffs named herein and the putative Class Members for whom this suit is brought, purchased these oral decongestant products, often at a premium price, and were unaware of a hidden undisclosed adverse truth. Specifically, that **Phenylephrine** is **not effective** in treating and alleviating nasal decongestion when taken orally. Simply put – it does not work as an decongestant.

6. On September 12, 2023, an FDA advisory panel confirmed that phenylephrine, when taken orally, is not effective. Meanwhile, Defendants and drug companies comprising the oral decongestant industry, knew and certainly had reason to know, at all times material that their oral decongestant products, more fully identified and discussed below, were no more effective than a placebo such as a sugar pill.

7. Hence, while consumers have been duped for many years by "taking a drug that has no benefit" (according to an FDA advisory panel), the oral decongestant products industry – comprised chiefly of Defendants named herein – has profited handsomely, much to the detriment, harm, and economic injury of Plaintiffs and putative Class Members.

8. Had Plaintiffs known that these oral decongestant products containing phenylephrine as their active ingredient were simply ineffective as a nasal congestion when taken orally, they would not have purchased them, or certainly would have paid substantially less for them, if anything.

9. Accordingly, Plaintiffs, on behalf of themselves and all other purchasers of Defendants' phenylephrine based oral decongestant products, hereby seek to hold the Defendants herein – all primary players in the oral decongestant products industry – accountable for their deceptions, breaches of warranties, and violations of relevant state or federal consumer protection statutes.

## II. PARTIES

### A. Plaintiffs

10. Plaintiff **Kimberly James** is, and at all times relevant was, a citizen of Florida, residing in Tampa. Plaintiff James buys over the counter medicines containing Phenylephrine on a periodic basis and has done so for years to treat colds and provide relief from congestion. For example, in January 2023, Plaintiff James purchased Nyquil Severe Cold and Flu and Dayquil Honey, both containing phenylephrine, for nasal congestion relief, at a Walgreens in Tampa, Florida. In June 2023, Plaintiff James purchased Sudafed PE containing phenylephrine, for congestion relief, at a Walgreens located in Tamp, Florida. In addition, Plaintiff James has purchased Benadryl Allergy Plus Congestion, containing phenylephrine, for congestion relief.

11. None of these orally ingested products was effective in relieving nasal congestion. Had Defendants disclosed that phenylephrine is not effective in relieving congestion, Plaintiff James would not have purchased the products to orally remedy her nasal congestion.

12. Plaintiff **Michelle Kasparie** is, and at all times relevant was, a citizen of Illinois, residing in Liberty. Plaintiff Kasparie buys over the counter cold medicines containing Phenylephrine on a periodic basis and has done so for years to treat colds and provide relief from congestion. For example, In October 2022, Plaintiff Kasparie purchased Sudafed PE containing phenylephrine, for congestion relief, at Walmart. In September 2022, Plaintiff Kasparie purchased Alka-Seltzer Plus Severe Cold and Cough decongestant containing phenylephrine and Advil Multi-Symptom Cold & Flu decongestant containing phenylephrine from Target.com. Similarly, in or about October 2021, Plaintiff Kasparie purchased Equate Sudaphedrine PE decongestant containing phenylephrine, for congestion relief, at Walmart. Plaintiff Kasparie made her Walmart purchases at Walmart stores in Quincy, Illinois and Hannibal, Missouri.

13. None of these orally ingested products was effective in relieving nasal congestion. Had Defendants disclosed that phenylephrine is not effective in relieving congestion, Plaintiff Kasparie would not have purchased the products to remedy her nasal congestion.

**B. Defendants**

14. Defendant **Procter & Gamble Company** ("P&G") is an Ohio corporation with its principal place of business and headquarters located at One Procter & Gamble Plaza in Cincinnati, Ohio. At all times material to this case, P&G has been engaged in the manufacturing, sale, and distribution of misbranded and ineffective congestion products in the United States, including Sudafed, Tylenol, and Benadryl.

15. Defendant **GlaxoSmithKline LLC** ("GSK") 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 oral decongestant Products, manufactures and markets Advil and Theraflu.

16. Defendant **Bayer Healthcare LLC** ("Bayer") 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 Commonwealth of Pennsylvania (collectively "Bayer"). At all times relevant to this complaint, Defendant Bayer was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the oral decongestant products, including but not limited to, Alka-Seltzer.

17. Defendant **Sanofi-Aventis U.S. LLC** ("Sanofi") is a Delaware limited liability corporation with headquarters and a principal place of business in the State of New Jersey. Upon information and belief, Sanofi- Aventis U.S. LLC is a wholly owned subsidiary of Sanofi S.A, a company organized under the laws of France (collectively "Sanofi"). At all times relevant to this complaint, Defendant Sanofi was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the oral decongestant products, including but not limited to, Allegra.

18. Defendant **Walmart Inc.** ("Walmart") is a Delaware corporation with headquarters and principal place of business in the State of Arkansas. At all times relevant to this complaint,

Walmart was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the oral decongestant products.

19. Defendant **Target Corporation** ("Target") is a Minnesota corporation with headquarters and principal place of business in the State of Minnesota. At all times relevant to this complaint, Target was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the oral decongestant products.

20. 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 to this complaint, CVS was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the oral decongestant products.

21. Defendant **Walgreen Co.** ("Walgreens") is an Illinois corporation with headquarters and principal place of business in the State of Illinois. At all times relevant to this complaint, Walgreens was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the oral decongestant products.

22. Defendant **Rite Aid Corporation** ("Rite Aid") is a Delaware corporation with its principal place of business in Camp Hill, Pennsylvania. At all times relevant to this complaint, Rite Aid was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing certain of the oral decongestant products.

23. Defendant **McNeil Consumer Healthcare** ("McNeil") is a Pennsylvania corporation with its principal place of business and headquarters located at 7050 Camp Hill Road, Fort Washington, Pennsylvania. At all times material to this case, McNeil has been engaged in the manufacturing, sale, and distribution of misbranded and ineffective oral decongestant products in the United States, including Sudafed, Tylenol, and Benadryl.

24. Defendant **Johnson & Johnson Consumer Inc.**, a McNeil Consumer Healthcare Division, ("J&J") is a New Jersey corporation with its headquarters and principal place of business at 199 Grandview Road, Skillman, New Jersey, 08558. J&J manufactures, markets, advertises,

labels, distributes, and sells oral decongestant products, Sudafed PE and Benadryl Allergy Plus Congestion.

25. 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 oral decongestant products, Reckitt manufacturers and markets Mucinex products containing phenylephrine and purporting to act as decongestants.

26. Defendant **Kenvue Inc.** ("Kenvue") 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 oral decongestant products that had been manufactured, marketed, and/or sold by Johnson & Johnson are now owned by Defendant Kenvue.

## III. JURISDICTION AND VENUE

27. 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.

28. This Court has personal jurisdiction over Defendants by virtue of their transacting and doing business in this District. Defendants have each purposefully availed themselves of the benefits and protections of the Eastern District of Pennsylvania by continuously and systematically conducting substantial business in Pennsylvania. Each of the Defendants markets and distributes its products in the Eastern District of Pennsylvania.

29. The Court additionally and independently has personal jurisdiction over Defendant GlaxoSmithKline LLC because it operates from headquarters in Philadelphia Pennsylvania and

Defendant McNeil Consumer Healthcare because it operates from headquarters in Fort Washington, Pennsylvania.

30. 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. Defendants maintain key business operations in this district, and market and sell their products, including oral decongestant products, as discussed below, in this District.

## IV. SUBSTANTIVE ALLEGATIONS

### Oral Decongestant Products Based on Phenylephrine Are Not Effective in Alleviating Nasal Decongestion

31. Oral decongestant products have typically relied on one of two active ingredients – pseudoephedrine or phenylephrine – to alleviate congestion.

32. However, after a concern was raised that pseudoephedrine-based products used as the active ingredient in oral decongestants was being misused as a base for the production of illegal methamphetamines since 2006, federal law thereafter made products containing pseudoephedrine inconvenient to purchase "over-the-counter."

33. As a consequence, the second major ingredient used to provide relief from nasal congestion – phenylephrine – increasingly became the most widely used active ingredient in oral decongestants, ultimately accounting for approximately 80% of the market for over-the-counter decongestants in the United States.

34. The market for phenylephrine based on oral decongestants is worth billions and includes over 250 such products. Annual sales of phenylephrine-based oral decongestants sold in the United States in 2022 alone accounted for approximately $1.8 billion in sales – a huge market.

35. Defendants have routinely and consistently marketed their products containing phenylephrine as an effective oral decongestant that should be used to alleviate nasal decongestion and sinus pressure associated with colds, allergies, and other respiratory conditions.

36. Phenylephrine purportedly works as an oral medication by constricting blood vessels in the nasal passages, thereby reducing swelling and congestion. In contrast to pseudoephedrine – which has proven to be effective as a decongestant – phenylephrine containing products have no restrictions and are not subject to an inconvenient purchasing process because consumers are readily able to buy those oral decongestants over-the-counter. Pseudoephedrine based decongestants are far more difficult to purchase because of their potential for misuse as a base for methamphetamine production, and are thereby a far less attractive option for consumers in order to treat nasal congestion.

37. However, phenylephrine, when taken orally, is ineffective. It does not provide relief from congestion and has now been shown to be no better than taking a placebo when it is taken orally. Manufactures have been aware of the ineffectiveness of phenylephrine for a number of years and at lease since no later than 2018.

38. Phenylephrine is found in many popular over-the-counter oral medications that purportedly act as a decongestant. The more popular over-the-counter oral decongestant products using phenylephrine – the supposedly active ingredient that the FDA regulatory panel has found ineffective when taken orally – include:

- Mucinex Sinus Max (Reckitt)
- Sudafed PE (Kenvue/McNeil)
- Tylenol Cold & Flu Severe (Kenvue/McNeil)
- Benadryl Allergy Plus (Kenvue/McNeil)
- Theraflu Severe Cold Relief (GlaxoSmithKline)
- Vicks Nyquil Severe Cold & Flu (Procter & Gamble)
- Vicks Nyquil Sinex (Procter & Gamble)
- Sinus PE Non-Drowsy Congestion Relief Tablets (Target)
- Wal-Phed PE Nasal Decongestant Tablets (Walgreens)
- Wal-Phed PE Sinus Congestion Day & Night Tablets (Walgreens)
- Nasal Decongestant PE Tablets (CVS)
- 12 Hour Nasal Decongestant Tablets (CVS)

39. The foregoing identified over-the-counter products and all oral decongestant products manufactured and sold by the Defendants are collectively referred to herein as the "Oral Decongestant Products" or "Defendants' Products."

40. By way of background, commencing in approximately 2007, scientific studies were surfacing showing that phenylephrine, when taken orally, was not effective. In 2018, the FDA issued new guidance for the industry relating to the use of nasal decongestant symptom scores to evaluate congestion, thereby undermining the primary end-point to evaluate congestion in studies that had been done previously. Defendants knew this. Given the FDA's new 2018 guidance, the Defendants certainly knew or should have known by then, at the very latest, that their marketing claims and representations regarding the Oral Decongestant Products' efficacy were false and misleading.

41. Still, Defendants continued to market and sell their phenylephrine based Oral Decongestant Products as effective decongestants, while even charging a premium price for such ineffective products. Thereby simultaneously taking advantage of the controversy over pseudoephedrine and the fact that Defendants could more readily sell their phenylephrine containing products over-the-counter, without requiring a doctor's prescription.

42. Defendants represented and warranted at all times material that their Oral Decongestant Products were effective for treating the indications identified and were properly branded – representing and warranting that such Oral Decongestant Products were merchantable and fit for their particular use, *i.e.*, effectively treating nasal decongestion orally.

43. On September 12, 2023, after an analysis of prior studies, the FDA found significant problems with phenylephrine after which a FDA advisory panel unanimously voted 16-0 that phenylephrine is not effective for treating nasal decongestant when taken orally, and

recommending that consumers avoid unnecessary cost or delays in care by **"taking a drug that has no benefit."**

44. Plaintiffs are informed and believe and thereupon allege that, at all times material, each of the Defendants named herein willfully ignored the scientific and industry knowledge concerning the lack of effectiveness of phenylephrine for treating nasal decongestion when taken orally, and either performed or were aware of the fact that testing and quality oversight was inadequate to support the efficacy of phenylephrine as the active ingredient for orally treating nasal decongestant.

45. Defendants knew or should have known that the primary end-point for evaluating the efficacy of the Oral Decongestant Products had changed significantly, and that previous data therefore did not support efficacy. They knew or should have known by at least 2018, and certainly sooner, that their marketing claims regarding their Oral Decongestant Products' efficacy were simply false and misleading.

46. Defendants' Oral Decongestant Products were never and currently are not merchantable, are not fit for their ordinary purpose, and are not effective for orally treating the indications regarding nasal decongestion and as such have been and are misbranded.

47. Had Plaintiffs known that the phenylephrine containing Oral Decongestion Products were entirely ineffective as a nasal decongestant when taken orally, they would not have purchased them, or would have paid substantially less for them.

48. Accordingly, Plaintiffs, on behalf of themselves and all other purchasers of Defendants Products, seeks to hold Defendants accountable for their deceptions, breaches of warranties, and violations of consumer protection statutes, arising from the fact that they sold products that they knew and should have known were ineffectual, but nevertheless continued to

market and sell anyway, at a premium price, directly and proximately causing Plaintiffs and Class Members damages, as more fully discussed below.

***Plaintiffs and Class Members Have Suffered Injury***

49. As alleged above, the Oral Decongestant Products active ingredient, phenylephrine, does not have the ability to alleviate nasal congestion, when taken orally, despite Defendants marketing and related representations that such products alleviate nasal congestion.

50. The Oral Decongestant Products' packaging and representations and omissions lead reasonable consumers to believe that they had the ability to alleviate nasal congestion orally.

51. Plaintiffs did not know, and had no reason to know upon purchase, that Defendants' Oral Decongestant Products were ineffective to alleviate nasal congestion. Not only would Plaintiffs not have purchased the Oral Decongestant Products had Plaintiffs known that they did not have the ability to alleviate nasal congestion, Plaintiffs would also not have been capable of purchasing them if Defendants had done as the law required and tested said products for their ability to alleviate nasal congestion when taken orally.

52. Consumers must depend on Defendants to truthfully and honestly represent and disclose on their packaging, labels, and marketing what their Oral Decongestant Products can do, as consumers lack the ability to test or independently ascertain or verify whether a product possesses the ability, quality, and characteristics that it purports to possess, especially at the point of sale.

53. Defendants are leaders in the nasal decongestion health and medication market. Reasonable consumers trusted their advertising and representations and did not know the adverse truth Defendants concealed or omitted regarding the ability of the Oral Decongestant Products to alleviate nasal congestion.

54. Defendants' false, misleading, and deceptive misrepresentations, and material omissions, regarding the Oral Decongestant Products' ability to alleviate nasal congestion, are likely to continue to deceive and mislead reasonable consumers and the public, as it has already deceived and misled Plaintiffs and Class Members.

55. No reasonable consumer would have paid any amount for Oral Decongestant Products that do not have the ability to alleviate nasal congestion even though they are marketed to consumers as having the ability to alleviate nasal congestion.

56. Plaintiffs and Class members bargained for a product that has the ability to alleviate nasal congestion when taken orally. If Plaintiffs and Class members had been informed that Defendants' Oral Decongestant Products do not have the ability to alleviate nasal congestion, they would not have purchased or used them, or would have paid significantly less for them as such omitted facts are material to their purchase decisions.

57. Plaintiffs and Class members were injured and suffered damages for which they are entitled to be compensated, having paid the full purchase price of Defendants' Products, because the Oral Decongestant Products are worthless and have no value, as they do not have the ability to alleviate nasal congestion when taken orally. Defendants knowingly failed to warn consumers of, or disclose to them, this material fact.

58. Plaintiffs and Class members are further entitled to statutory and punitive damages, attorneys' fees and costs, and any further relief this Court deems just and proper.

## V. TOLLING

59. Any applicable statute of limitations has been tolled by the "delayed discovery" rule. Plaintiffs did not know (and had no way of knowing) at the time of purchase that the Oral Decongestant Products were ineffective to treat nasal congestion because their active ingredient – phenylephrine – was ineffective when taken orally. Defendants did not warn or inform Plaintiffs

and Class Members of this material fact, which was hidden from Plaintiffs and Class Members. Defendants were obliged to disclose the conduct complained of herein, purposely did not do so, and are thereby estopped from relying upon or asserting any statute of limitations in an effort to bar any claim herein.

## VI. CLASS ACTION ALLEGATIONS

60. Plaintiffs bring this action individually and as a representative of all those similarly situated, pursuant to Fed. R. Civ. P. 23, on behalf of themselves and the members of the following proposed nationwide class ("Nationwide Class"):

> **During the fullest period allowed by law, all persons who purchased one or more of the Oral Decongestant Products in the United States within the applicable statute of limitations.**

61. Plaintiff James brings this action individually and as a representative of all those similarly situated, pursuant to Fed. R. Civ. P. 23, on behalf of herself and the members of the following subclass ("Florida Subclass"):

> **During the fullest period allowed by law, all persons who purchased one or more of the Oral Decongestant Products in the State of Florida within the applicable statute of limitations.**

62. Plaintiff Kasparie brings this action individually and as a representative of all those similarly situated, pursuant to Fed. R. Civ. P. 23, on behalf of herself and the members of the following subclass ("Illinois Subclass"):

> **During the fullest period allowed by law, all persons who purchased one or more of the Oral Decongestant Products in the State of Illinois within the applicable statute of limitations.**

63. The foregoing Nationwide and Florida and Illinois Subclasses are sometimes collectively referred to herein as "Class" or "Class Members."

64. Specifically excluded from these definitions are: (1) Defendants, any entity in which Defendants have a controlling interest, and their legal representatives, officers, directors,

employees, assigns and successors; (2) the Judge to whom this case is assigned and any member of the Judge's staff or immediate family; and (3) Class Counsel. Plaintiffs reserve the right to amend the Class definition as necessary.

65. **Numerosity**: The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class Members is presently unknown, it likely consists of at least many thousands of people collectively in the state Subclasses and Nationwide. The number of Class Members can be determined by sales information and other records. Moreover, joinder of all potential Class Members is not practicable given their numbers and geographic diversity. The Class is readily identifiable from information and records in the possession of Defendants.

66. **Typicality**: The claims of the representative Plaintiffs are typical in that Plaintiffs, like all Class Members, were similarly impacted by Defendants' conduct with respect to the marketing and sale of the Oral Decongestant Products that were ineffective when taken orally as they used phenylephrine as their active ingredient. Plaintiffs and Class Members purchased said products at premium prices, and said products were valueless as an oral decongestant remedy. In addition, Defendants' misconduct is common to all putative Class Members because Defendants have engaged in systematic deceptive and fraudulent behavior that was deliberate and results in the same injury to all Class Members.

67. **Commonality**: Common questions of law and fact exist as to all Class Members. These questions predominate over questions that may affect only individual Class Members because Defendants have acted on grounds generally applicable to the Class. Such common legal or factual questions include, *inter alia*:

a. Whether the Oral Decongestant Products are ineffective;

b. Whether Defendants knew or reasonably should have known about the ineffectiveness of the Oral Decongestant Products prior to selling or distributing them to Plaintiffs and putative Class Members;

c. Whether Defendants concealed from and/or failed to disclose to Plaintiffs and putative Class Members the truth about the Oral Decongestant Products lack of efficacy;

d. Whether Defendants' conduct was done knowingly;

e. Whether Defendants breached the implied warranty of merchantability;

f. Whether Defendants breached express warranties relating to said products;

g. Whether Defendants should be ordered to disgorge all or part of the ill-gotten profits they received from the sale of the Oral Decongestant Products;

h. Whether Plaintiffs and putative Class Members are entitled to damages, including compensatory, exemplary, and statutory damages, and the amount of such damages;

i. Whether Plaintiffs and putative Class Members either paid a premium for the said products that they would not have paid but for Defendants' false representations or would not have purchased them at all;

j. Whether Plaintiffs and putative Class Members are entitled to injunctive, declaratory, or other equitable relief; and

k. Whether Defendants engaged in unfair, unconscionable, or deceptive trade practices by selling and/or marketing the ineffective Oral Decongestant Products.

68. **Adequate Representation**: Plaintiffs will fairly and adequately protect the interests of putative Class Members. They have no interests antagonistic to those of Class Members. Plaintiffs have retained attorneys experienced in the prosecution of class actions, including consumer product cases, and Plaintiffs intend to prosecute this action vigorously.

69. **Injunctive/Declaratory Relief**: The elements of Rule 23(b)(2) are met. Defendants will continue to commit the unlawful practices alleged herein, and Plaintiffs and Class Members will continue to be deceived by Defendants misrepresentations and omissions and unknowingly be exposed to damage on account thereof. Defendants have acted and refused to act on grounds that apply generally to the Class, such that final injunctive relief, public injunctive

relief, and corresponding declaratory relief are appropriate respecting the Class as a whole. Injunctive relief is necessary in this action.

70. **Predominance and Superiority**: Plaintiffs and Class Members have all suffered and will continue to suffer risk of harm and damages as a result of Defendants unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the controversy. The likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues is not efficient, timely, or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of many thousands of claimants in one suit would be impractical or impossible. Individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiffs.

71. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

## COUNT I
## Breach of Express Warranties

72. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

73. Plaintiffs bring this claim on behalf of the Nationwide Class or, in the alternative, their respective State Subclasses (collectively the "Class" for purposes of this Count).

74. Plaintiffs, and each member of the Class, formed a contract with each Defendant at the time each Plaintiffs and Class Member purchased the Oral Decongestant Products. The terms of the contract include the promises and affirmations of fact made by Defendants on Defendants' Products' packaging and through marketing and advertising, including that the product 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 Plaintiffs and the members of the Class and the respective Defendants whose products they purchased.

75. Each of the Defendants expressly warranted that its respective Oral Decongestant Product was fit for ordinary use and effective for the indications listed and were merchantable and not misbranded.

76. Defendants sold Oral Decongestant Products that they expressly warranted were effective at treating the indications identified and were not misbranded.

77. 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.

78. Defendants knew or should have known that their Oral Decongestant Products 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 products were of merchantable quality and fit for that purpose.

79. Defendants breached their express warranty because each of their respective Oral Decongestant Products 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.

80. Defendants' express warranties were reflected in each of their Oral Decongestant Products' labeling (*e.g.*, label, instructions, packaging) and promotion and marketing material, all of which uniformly included and/or identified as an active ingredient for effective treatment of the indications identified, principally nasal decongestion, when taken orally. Each of the Defendants' product labeling and other materials were required to be truthful, accurate, and non-deceptive. Despite this, each of the Defendants' Oral Decongestant Products labeling and other materials failed to and did not disclose that phenylephrine is not effective for the indications identified, principally nasal congestion when taken orally.

81. Each of Defendants' Oral Decongestant Products did not fulfill their intended purpose. Plaintiffs and other Class Members bargained for an adequately made, adequately labeled product that performed as warranted. But each of Defendants' Oral Decongestant Products were not adequately made, were not adequately labeled, and did not perform as warranted.

82. Plaintiffs and other Class Members purchased the Oral Decongestant Products in reliance upon Defendants' skill and judgment and the express warranties made associated with their respective products.

83. Plaintiffs and other Class Members were reasonably foreseeable purchasers who would use, and consumers who would be affected, by the misbranded, ineffective Oral Decongestant Products marketed and sold by Defendants.

84. The Oral Decongestant Products were not altered by Plaintiffs or Class members. As a direct and proximate result of each Defendants' breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' Oral Decongestant Products they purchased were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

85. To the extent applicable, pre-suit notice and/or a demand letter was sent to each Defendant prior to the filing of the Complaint.

**COUNT II**

**Breach of Implied Warranties**

86. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

87. Plaintiffs bring this claim on behalf of the Nationwide Class or, in the alternative, their respective State Subclasses (collectively the "Class" for purposes of this Count).

88. Plaintiffs, and each member of the Class, formed a contract with Defendants at the time Plaintiffs and the other Class Members purchased their respective Oral Decongestant Products. The terms of the contract include the promises and affirmations of fact made by Defendants on their products – packaging and through marketing and advertising, including that the product would be effective for the indications provided. This labeling, marketing, and advertising constitute, at a minimum, implied warranties of their respective products fitness and merchantability, and became part of the basis of the bargain, between Plaintiffs and the members of the Class and Defendants.

89. 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 particular 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.

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

91. Each of the Defendants respective Oral Decongestant Products constituted "goods" or the equivalent within the meaning of the above statutes. Each of the Defendants placed their Oral Decongestant Products in sealed packaging or other closed containers and placed them on the market and in the stream of commerce in this District and across the United Stated.

92. Each of the Defendants impliedly warranted that its respective Oral Decongestant Products were fit for ordinary use and effective for the indications listed and were merchantable and not misbranded.

93. Each of the Defendants sold their respective Oral Decongestant Products that they impliedly warranted to be effective at treating the indications identified and were not misbranded.

94. Each of the Defendants knew or should have known that their respective Oral Decongestant Products 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.

95. Defendants breached their implied warranties because the Oral Decongestant Products 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.

96. Plaintiffs and other Class members purchased the Oral Decongestant Products in reliance upon Defendants' skill and judgment and the implied warranties of their fitness for the particular purpose.

97. Defendants' Oral Decongestant Products did not fulfill their intended purpose were not adequately made, were not adequately labeled, and did not perform as warranted. Plaintiffs and other Class Members bargained for an adequately made, adequately labeled product, that performed as warranted, which the products were not.

98. Defendants' implied warranties were reflected in each of their respective Oral Decongestant Products labeling (*e.g.*, label, instructions, packaging) and promotion and marketing material, all of which uniformly utilized phenylephrine as an active ingredient for the treatment of the indications identified, principally nasal decongestion, which product labeling and other materials was required to be truthful, accurate, and non-deceptive. Defendants' Products labeling and other materials did not disclose that phenylephrine is not effective for the indications identified, principally nasal congestion when taken orally.

99. Plaintiffs and the other Class Members were reasonably expected purchasers who would use, consumer or be affected by the misbranded, ineffective Oral Decongestant Products marketed and sold by Defendants.

100. Plaintiffs and the other Class Member were the intended third-party beneficiary recipients of all arrangements Defendant had with downstream resellers of Defendants' Products.

101. Plaintiffs and the other Class Member were those for whose benefit any promises, affirmations, or warranties were made by Defendants concerning the oral decongestant products, as they were the intended end purchasers and end users of Defendants' Products, which Defendants knew by virtue of their position as manufacturers and sellers.

102. The oral decongestant products were not altered by Plaintiffs or Class members. As a direct and proximate result of Defendants breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that they purchased Defendants'

Products that were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

103. To the extent applicable, pre-suit notice and/or a demand letter was sent to each Defendant prior to the filing of the Complaint.

**COUNT III**
**Violation of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et Seq*.**

104. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

105. Plaintiffs bring this claim on behalf of the Nationwide Class or, in the alternative, their respective State Subclasses (collectively the "Class" for purposes of this Count).

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

107. Plaintiffs and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

108. Defendants expressly or impliedly warranted their Oral Decongestant Products as alleged in the foregoing causes of action.

109. Under 15 U.S.C. § 2310(d)(1), Plaintiffs and other 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). Plaintiffs sue pursuant to this section to recover money damages and for legal and equitable relief on behalf of themselves and the Class Members.

110. Defendants has not cured their failure with respect to their warranted Oral Decongestant Products.

111. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiffs are entitled to receive an award of attorneys' fees and expenses.

**COUNT IV**
**Fraud By Omission or Concealment**

112. Plaintiffs repeat and incorporate the preceding paragraphs, as if fully set forth herein.

113. Plaintiffs bring this claim on behalf of the Nationwide Class or, in the alternative, the State Classes (collectively, the "Class," for purposes of this Count).

114. Defendants intentionally and knowingly falsely concealed, suppressed and/or omitted material facts including as to the standard, quality, or grade of the Oral Decongestant Products.

115. Defendants knew that phenylephrine is ineffective at safe dosages when consumed orally.

116. Defendants were obligated to inform Plaintiffs and the other members of the Class of the lack of effectiveness of phenylephrine due to their exclusive and superior knowledge of the Oral Decongestant Products. Plaintiffs and other Class members also expressly reposed a trust and confidence in Defendants because the nature of their dealings as a healthcare entity and with Plaintiffs and other members of the Class as their consumers.

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

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

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

120. Plaintiffs and the other Class Members were deceived by 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 Oral Decongestant

Products, Plaintiffs and the other Class members have suffered actual damages in an amount to be determined at trial.

**COUNT V**
**Negligent Misrepresentation and Omission**

121. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

122. Plaintiffs bring this claim on behalf of the Nationwide Class or, in the alternative, their respective State Subclasses (collectively, the Class for purposes of this Count).

123. Defendants had or undertook a duty to represent to the effectiveness of their Oral Decongestant Products accurately and truthfully.

124. Defendants failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the effectiveness of their Oral Decongestant Products.

125. Defendants negligently misrepresented or omitted facts regarding the effectiveness of their Oral Decongestant Products.

126. Defendants' statements were false at the time the misrepresentations or material omissions were made or occurred.

127. Defendants knew, and, upon the exercise of reasonable diligence, reasonably should have known, that their representations regarding their Oral Decongestant Products were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Class Members to make purchases of each Defendants' Oral Decongestant Products.

128. Defendants had a duty to exercise reasonable care in the manufacture, quality control, distribution, and marketing of their Oral Decongestant products. Their failure to exercise this duty, in spite of knowing or recklessly disregarding the lack of effectiveness of Defendants' Products meant that they could not assure such Products were effective.

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

130. Defendants' misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for the Oral Decongestant Products.

131. Defendants intended their misrepresentations or omissions to induce Plaintiffs and Class Members to make purchases of said Products or had reckless disregard for same.

132. But for these misrepresentations (or omissions), Plaintiffs and other Class Members would not have made purchases of Defendants' said Products.

133. Plaintiffs and other 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 each Class Member.

134. Plaintiffs and other Class Members were damaged by reason of each Defendants' misrepresentations or omissions alleged herein.

## COUNT VI
## Negligence

135. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

136. Plaintiffs bring this claim on behalf of the Nationwide Class or, in the alternative, their respective State Subclasses (collectively, the Class for purposes of this Count).

137. Defendants owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing and sale of their Oral Decongestant Products.

138. Defendants owed a duty to Plaintiffs and the Class to ensure that their Oral Decongestant Products sold in the United States were effective for the indications identified and not misbranded.

139. Defendants owed a duty of care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable user of PE Drugs and victim of Defendants' fraudulent and deceptive activities. Defendants knew, or in the exercise of reasonable care should have known, that their Oral Decongestant Products were not effective for treating the indications identified and were misbranded.

140. Defendants failed to remedy the defect of their Oral Decongestant Products, or otherwise adequately and timely alert Plaintiffs and Class Members to this. Each of the Defendants inadequately oversaw the manufacture and sale of its own Oral Decongestant Products and knew that ignoring the manufacturing issues surrounding them would damage Plaintiffs and the Class, while increasing their own profits.

141. Defendants maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that their respective Oral Decongestant Products were effective to treat the indications identified and not misbranded.

142. Defendants' own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of their PE Drugs.

143. Each Defendant breached duties owed to Plaintiffs and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiffs and the Class.

144. As a direct and proximate result of each Defendants' negligence, Plaintiffs and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

## COUNT VII
## Negligence *Per Se*

145. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

146. Plaintiffs bring this claim on behalf of the Nationwide Class or, in the alternative, their respective State Subclasses (collectively, the Class for purposes of this Count).

147. Defendants owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing, marketing, and sale of their respective Oral Decongestant Products.

148. Defendants owed a duty to Plaintiffs and the Class to ensure that their respective Oral Decongestant Products sold in the United States were effective at treating the indications identified and were not misbranded or misrepresented.

149. Each Defendant owed a duty to Plaintiffs and the Class 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.

150. Defendants failed to comply with federal standards, including branding standards. As a result of the Defendants' failure to do so, their actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

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

## COUNT VIII

## Unjust Enrichment

152. Plaintiffs repeat and incorporate the preceding paragraphs, as if fully set forth herein.

153. Plaintiffs bring this claim on behalf of the Nationwide Class or, in the alternative, the State Classes (collectively, the "Class," for purposes of this Count).

154. 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, the law of the forum applies to those claims.

155. Defendants' efforts include, but are not limited to, providing point-of-sale materials and coupons to entice Plaintiffs and the other Class Members to purchase their Oral Decongestant Products.

156. Plaintiffs and all other Class members conferred a benefit on Defendants by purchasing their Oral Decongestant Products.

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

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

## COUNT IX
## Violation of State Consumer Protection Laws

159. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

160. Defendants violated the following consumer protection statutes with respect to the respective Florida and Illinois Subclasses as follows:

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

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

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

161. Defendants' conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

162. Plaintiffs and the Class Members are consumers or persons aggrieved by Defendants' misconduct within the meaning of the above statutes.

163. Defendants' conduct as alleged herein constitutes unfair, deceptive, misleading, or otherwise actionable practices with respect to the purported effectiveness of their respective Oral Decongestant products taken orally for treating the indications identified.

164. To the extent applicable, Defendants 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 Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages– an ascertainable loss – in an amount to be proved at trial.

165. To the extent applicable, pre-suit notice and/or a demand letter was sent to each Defendant prior to the filing of the Complaint.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Class, pray for relief and judgment against Defendants as follows:

A. certifying the Class pursuant to Rule 23 of the Federal Rules of Civil Procedure, appointing Plaintiffs as representatives of the Class, and designating Plaintiffs' counsel as Class Counsel;

B. declaring that Defendants' conduct violates the laws referenced herein;

C. finding in favor of Plaintiffs and the Class on all counts asserted herein;

D. awarding Plaintiffs and the Class compensatory damages and actual damages, trebled, in an amount exceeding $5,000,000, to be determined by proof;

E. awarding Plaintiffs and the Class appropriate relief, including actual, nominal and statutory damages;

F. awarding Plaintiffs and the Class punitive damages;

G. awarding Plaintiffs and the Class civil penalties;

H. granting Plaintiffs and the Class declaratory and equitable relief, including restitution and disgorgement;

I. enjoining Defendants from continuing to engage in the wrongful acts and practices alleged herein;

J. awarding Plaintiffs and the Class the costs of prosecuting this action, including expert witness fees;

K. awarding Plaintiffs and the Class reasonable attorneys' fees and costs as allowable by law;

L. awarding pre-judgment and post-judgment interest; and

M. granting any other relief as this Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: September 27, 2023

Respectfully submitted

/s/ Jeffrey A. Barrack

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*Attorneys for Plaintiffs and the Putative Nationwide Class, Florida Class and Illinois Class*

*Application for Admission *Pro Hac Vice* to be filed

JS 44 (Rev. 04/21)

# CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

## I. (a) PLAINTIFFS

Michele Kasparie and Kimberly James

**(b)** County of Residence of First Listed Plaintiff _____
*(EXCEPT IN U.S. PLAINTIFF CASES)*

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

Jeffrey A. Barrack, Barrack, Rodos & Bacine, 3300 Two Commerce Square, 2001 Market Street, Philadelphia, PA 19103 (215) 963-0600

## DEFENDANTS

Bayer Healthcare LLC, et al.

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.

Attorneys *(If Known)*

## II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

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

*(For Diversity Cases Only)*

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

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

Click here for: Nature of Suit Code Descriptions.

**CONTRACT**
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

**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

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

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

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

**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. § 1332(d)

Brief description of cause:
Consumer class action arising from misleading marketing of nasal decongestants

## VII. REQUESTED IN COMPLAINT:

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

**DEMAND $**

CHECK YES only if demanded in complaint:

**JURY DEMAND:** ☒ Yes ☐ No

## VIII. RELATED CASE(S) IF ANY

*(See instructions):*

JUDGE Kai N. Scott DOCKET NUMBER 2:23cv3663 and MDL 23-3089

DATE 9/27/2023

SIGNATURE OF ATTORNEY OF RECORD /s/ Jeffrey A. Barrack

**FOR OFFICE USE ONLY**

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

# 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.Cv.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**; NOTE: 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.** 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.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
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 – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
**PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

**VI.** **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.

**VII.** **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 actual dollar amount 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.

**VIII.** **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

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