

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

JACOB REINKRAUT, on behalf of himself and
all others similarly situated,

Plaintiff,

vs.

JOHNSON & JOHNSON CONSUMER, INC.
and KENVUE, INC.,

Defendants.

Docket No.:

**CLASS ACTION COMPLAINT
AND DEMAND FOR JURY TRIAL**

Plaintiff Jacob Reinkraut (“Plaintiff”), on behalf of himself and all others similarly situated, by and through his undersigned counsel, brings this lawsuit against Defendants Johnson & Johnson, Inc. (“JJCI”) and Kenvue, Inc. (“Kenvue”) (together, “Defendants”). Plaintiff alleges as follows based on personal knowledge concerning all facts related to himself and based on the investigation of his counsel, and information and belief concerning all other matters:

NATURE OF THE CASE

1. Plaintiff brings this case on behalf of a national class of all persons who purchased orally-administered Sudafed PE, an over-the-counter cold medication manufactured, marketed, labeled, distributed, and sold by Defendants that contains phenylephrine—an ingredient that supposedly acts as nasal decongestant but, in reality, does nothing.

2. Phenylephrine and pseudoephedrine are the two most common decongestants contained in over-the-counter cold medication. Pseudoephedrine is effective but subject to restriction due to its use as an ingredient in illegal methamphetamine. Phenylephrine, on the other hand, is not effective when orally ingested but is freely available because it is not subject to those same restrictions.

3. Since at least 2007, reliable scientific data has conclusively demonstrated phenylephrine is not an effective decongestant when orally ingested and, in fact, fares no better than placebos to reduce nasal congestion. In 2007, the FDA—through its Nonprescription Drugs Advisory Committee (“NDAC”)—met to discuss scientific data submitted in a petition that Public Citizen had filed on February 1, 2007 showing that “orally administered [phenylephrine] is not effective at monographed doses.” Since that time, numerous scientific studies have further confirmed Public Citizen’s findings and that orally ingested phenylephrine cannot effectively relieve nasal congestion. In September 2023, based on the scientific consensus undercutting the efficacy of phenylephrine, NDAC voted unanimously—16-0— that oral phenylephrine including Sudafed PE is ineffective to treat nasal congestion.

4. Defendants understood that phenylephrine was ineffective in at least as early as 2007 because, upon information and belief, they reviewed Public Citizen’s petition to the FDA as well as the systematic review and meta-analysis (and underlying data and studies) included in Public Citizen’s petition which predated the February 2007 submission (in some instances by decades). Defendants further reviewed subsequent studies and data from 2007 to 2016 further confirming phenylephrine’s inefficacy when compared to a placebo.

5. Despite Defendants’ knowledge that phenylephrine was ineffective as a nasal decongestant, Defendants failed to disclose to consumers or any wholesalers or retailers in the chain of distribution that phenylephrine was an ineffective decongestant and, in turn, that Sudafed PE was useless. Instead, Defendants expressly misrepresented and misled consumers, wholesalers, and retailers by touting Sudafed PE as a “Nasal Decongestant” that could be used to “temporarily relieve[] sinus congestion and pressure” and “temporarily relieve[] nasal decongestion due to the common cold, hay fever or other upper respiratory allergies[.]”

6. Defendants misrepresented the truth and omitted material information they had a duty to disclose to Plaintiff and other consumers to maximize their profits and to delay the massive costs of immediately ceasing and/or recalling ineffective Sudafed PE. Defendants sold \$1.8 billion in over-the-counter cold medication, including Sudafed PE, in 2022 alone.

7. Defendants sold ineffective Sudafed PE at the expense of their trusting customers who unwittingly purchased Sudafed PE believing it could relieve nasal congestion based on Defendants' misrepresentations and omissions. Consumers, like Plaintiff, depended on Defendants to disclose the truth about Sudafed PE but were, instead, presented with false, misleading, or incomplete representations and omissions regarding the uses and benefits of the Sudafed PE and suffered damages as a result.

8. During the Class Period (2017 to the present),¹ Plaintiff and Class members purchased Sudafed PE even though, by that time, Defendants fully understood that phenylephrine did not reduce nasal congestion. During the Class Period, Plaintiff purchased Sudafed PE in New Jersey on multiple occasions at Walgreens and CVS. Plaintiff purchased Sudafed PE after reviewing product labeling and based on Defendants' labeling misrepresentations and omissions that Sudafed PE could be used as a nasal decongestant. Plaintiff purchased and used the Sudafed PE without any knowledge that phenylephrine could not be used as an effective treatment of nasal decongestant. Plaintiff would not have purchased Sudafed PE had he known that it could not be used to treat nasal congestion.

9. As detailed below, Plaintiff brings express and implied warranty, fraudulent concealment, consumer protection, and unjust enrichment claims arising from Defendants' unfair

¹ The "Class Period" is the applicable statute of limitations for the claims brought by Plaintiff.

and deceptive business practices in knowingly placing ineffective Sudafed PE into the stream of commerce. Plaintiff seeks on behalf of himself and the Class (defined below) damages and/or restitution for Defendants' unlawful conduct.

PARTIES

10. Plaintiff is, and was at all relevant times, a resident of Bergen County, New Jersey and a citizen of New Jersey. Plaintiff reviewed the labeling and used Sudafed PE as directed on the instructions without any knowledge that Sudafed PE was ineffective as a treatment for nasal decongestion because it contained phenylephrine. Plaintiff would not have purchased Sudafed PE—or would have paid far less for Sudafed PE—had he known that phenylephrine is ineffective to treat nasal decongestion.

11. Defendant JJCI is a Delaware corporation that has its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Prior to February 2022 (when JJCI spun-off Kenvue), JJCI manufactured, marketed, designed, promoted, and/or distributed Sudafed PE containing ineffective phenylephrine in New Jersey and, from there, throughout the United States. Upon information and belief, JJCI directed the sale of Sudafed PE through McNeil Consumer Healthcare, a division of McNeil-PPC, Inc., another Johnson & Johnson affiliated corporation.

12. Defendant Kenvue is a Delaware corporation that was formerly the consumer healthcare division of JJCI prior to the February 2022 spin-off and has its principal place of business located at 99 Grandview Rd, Skillman, NJ 08558. Upon information and belief, JJCI currently maintains a 10% stake in Kenvue.

13. Upon information and belief, all assets and liabilities associated with the Sudafed PE that had been manufactured, marketed, and/or sold by JJCI prior to the February 2022 spin-off

are now owned by Kenvue as successor-in-interest, because: (1) Kenvue expressly or impliedly assumed JJCI's liabilities; (2) and/or Kenvue's business is a mere continuation of JJCI's business. Kenvue manufactures, markets, designs, promotes, and/or distributes the Sudafed PE containing ineffective phenylephrine in New Jersey and, from there, throughout the United States.

14. From their New Jersey headquarters, Defendants' management oversaw the production, distribution, and sale of Sudafed PE throughout the United States. Defendants' sales and marketing leadership, as well as their accounting, financial, and legal departments, are all based in in New Jersey headquarters in this District. Furthermore, upon information and belief, Defendants' marketing, marketing analysis, sales and financial documents, and relevant financial accounts were created and are located at their New Jersey headquarters and in this District.

15. Upon information and belief, Defendants created and/or authorized the false and misleading representations and omissions from New Jersey. Defendants and their management—from their New Jersey headquarters—collaborated in developing, manufacturing, and distributing Sudafed PE.

16. Defendants' substantial participation in designing, manufacturing, distributing, marketing, and selling the Products from New Jersey, including their New Jersey headquarters, means New Jersey has the greatest interest in the subject matter of this lawsuit.

JURISDICTION AND VENUE

17. This Court has original jurisdiction over this case under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2). Minimal diversity exists between members of the Class (defined below) and Defendants; the amount in controversy in this action exceeds \$5,000,000, exclusive of interest and costs; and there are more than 100 members in the proposed Class.

18. This Court has general personal jurisdiction over this case because Defendants expressly consented to general jurisdiction in New Jersey and/or because New Jersey is JJCI's and Kenvue's principal place of business. Alternatively, the Court has specific personal jurisdiction to adjudicate Plaintiff's claims because the claims arise from conduct Defendants purposefully directed to New Jersey. Defendants—through their management, employees, and agents—directed the production, distribution, promotion, and sale of the Sudafed PE through New Jersey headquarters, and Plaintiff purchased and used Sudafed PE in New Jersey. Those actions render the Court's exercise of jurisdiction over Defendants appropriate under traditional notions of fair play and substantial justice.

19. Venue is proper in this District pursuant to 28 U.S.C. § 1391. A substantial portion of the events or omissions giving rise to Plaintiff's claims occurred in this District (including Plaintiff's purchase and use of Sudafed PE), and Defendants regularly conduct business and are subject to personal jurisdiction in this District.

20. All conditions precedent to this action have occurred, been performed, or have been waived.

FACTUAL ALLEGATIONS

A. Defendants, the Products, and Misrepresentations and Omissions

21. At least as early as the Class Period (approximately 2017), Defendants manufactured, distributed, marketed, and sold Sudafed PE throughout the United States at premium prices based on a widespread advertising campaign highlighting Sudafed PE's ability to act as a decongestant.

22. Defendants sold Sudafed PE directly, through major online third-party retailers including Amazon.com, and in physical retail stores, including Walgreens and Target.

26. Those misrepresentations—given phenylephrine’s demonstrated and conclusive inefficacy as a decongestant—are widely echoed on Defendants’ website and third-party retailer websites. For example, Sudafed’s official website lists the same uses as the rear label and states:

- SUDAFED PE® Sinus Congestion provides maximum-strength sinus pressure and nasal congestion relief with a non-drowsy formula that contains phenylephrine HCl as a nasal decongestant.
 - relieves sinus congestion and pressure
 - contains decongestant phenylephrine HCl
 - non-drowsy formula decongestant tablets[.]²

27. At least as early as the beginning of the Class Period (2017), Defendants’ representations were false and/or misleading as incomplete or only partially true. Contrary to Defendants’ representations, the Sudafed PE could not be used as a decongestant because—as detailed further below—its active ingredient phenylephrine was ineffective as a decongestant when orally ingested.

28. At least as early as the beginning of the Class Period (2017), Defendants failed to disclose on Sudafed PE packaging and labeling (including in the ingredients section) or otherwise that Sudafed PE could not be used as a decongestant and/or that phenylephrine was an ineffective decongestant when administered orally despite knowing that information since at least 2007 and despite a duty to disclose that information based on their misleading partial representations and superior knowledge, among other reasons (as detail below in Section D).

B. Contrary to Defendants’ Misrepresentations, Phenylephrine Cannot Be Used as a Decongestant When Ingested Orally

29. Despite what Defendants state on labeling and in other promotional materials, scientific research—unknown to Plaintiff and the Class—has demonstrated since at least 2007 that phenylephrine cannot be used as a decongestant when ingested orally, that is, phenylephrine when

² <https://www.sudafed.com/products/sudafed-pe-sinus-congestion>.

taken orally fares no better than a placebo according to overwhelming scientific research.

30. The scientific data undercutting phenylephrine's efficacy when orally ingested dates to the early 1990s, when Dr. Leslie Hendeles noted in a medical journal that orally ingested phenylephrine could not reduce nasal congestion because it was destroyed in the stomach before it could reach the bloodstream.

31. A 2006 study published in the *Journal of Allergy and Clinical Immunology*, stated, "Phenylephrine...is unlikely to provide relief of nasal congestion. It has poor oral bioavailability because of extensive first-pass metabolism in the gut and liver . . . Moreover, in a randomized, double blind, placebo-controlled, crossover study of 3 oral decongestants in 20 patients with chronic nasal stuffiness, phenylephrine was no more effective than placebo in reducing nasal airway resistance."³

32. In 2007, based on accumulating scientific evidence, Public Citizen submitted a petition to the FDA demonstrating the inefficacy of orally ingested phenylephrine based on a reliable systematic review and meta-analysis. Public Citizen requested that the FDA re-evaluate the safety and efficacy of phenylephrine as a decongestant. Despite the petition, the FDA concluded that orally ingested phenylephrine was safe and effective (a determination that the FDA later recognized was deeply flawed and based on flawed data).

33. In 2009, a double-blind study concluded that phenylephrine was not statistically significant from a placebo in the mean change in subjective nasal congestion scores whereas pseudoephedrine, a positive control in the study, decreased congestion significantly greater than

³ Leslie Hendeles PharmD and Randy Hatton, Pharm D, *Oral phenylephrine: An ineffective replacement for pseudoephedrine?*, 118 *J. Allergy and Clinical Immunology* 1 (May 1, 2006).

placebo and phenylephrine.⁴ In 2009, another study also reported similar findings between phenylephrine and a placebo with respect to decreased nasal congestion scores.⁵

34. Likewise, in 2015, in a double-blind dose response study conducted by Meltzer, et al., where participants were given various commercially over-the-counter oral phenylephrine tablets and placebos, the authors unequivocally “failed to identify a dose for [phenylephrine]...that was significantly more effective than placebo in relieving nasal congestion”⁶ Upon information and belief, the commercially available phenylephrine tablets were Sudafed PE tablets sold by Defendants.

35. In 2015, in a study researching the efficacy of orally ingested phenylephrine, the authors also reported a lack of local decongestion effect of phenylephrine, finding that doses up to three times the labeled OTC dose for oral phenylephrine are unlikely to be effective.⁷

36. In 2016, another study published by Meltzer, et al., concluded—based on a double-blind placebo study—that phenylephrine “taken orally every 12 hours for 7 days is not more efficacious than placebo in relieving nasal congestion.”⁸

⁴ 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*.

⁵ 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*.

⁶ Meltzer et al., *Oral Phenylephrine HCl for Nasal Congestion in Seasonal Allergic Rhinitis: A randomized, Open-label, Placebo-controlled Study*, 3 *J. Allergy Clin. Immunol Pract.*

⁷ 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.*

⁸ 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*.

37. On September 12, 2023, the FDA NDAC panel voted unanimously against current scientific data supporting the clinical effectiveness of 10 mg oral phenylephrine as a nasal decongestant in the second portion of a 2-day meeting, i.e. the exact dosage and means that Sudafed PE is administered.

38. In doing so, NDAC conducted a re-analysis of the studies and data underlying its prior 2007 finding that phenylephrine was a safe and effective decongestant and determined that that finding was based on problematic data and studies supported by unreliable methodology and conclusions:

When 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 a similar study design and methodology.

Id.

C. Defendants Knew That the Phenylephrine Was Ineffective But Nevertheless Continued to Misrepresent and Omit Material Information While Selling Useless Sudafed PE During the Class Period

39. The cumulative impact of phenylephrine research means that phenylephrine's inefficacy was well established as early as 2006, with additional research since then consistently confirming phenylephrine's inefficacy. Even if Defendants could feign ignorance of phenylephrine's inefficacy for some time after the 2006 research and Public Citizen's 2007 FDA petition, by the end of 2016 and well-before the beginning of the Class Period (2017), it

was crystal-clear based on repeated, reliable studies that phenylephrine was ineffective. As a result, Defendants continued to expressly misrepresent the benefits of Sudafed PE on labeling and in other marketing and omitted material information they had a duty to disclose during the Class Period, which is when Plaintiff and the Class purchased Sudafed PE.

40. Plaintiff and the consuming public, on the other hand, had no actual or constructive knowledge of phenylephrine's inefficacy and, in turn, the inefficacy of Sudafed PE and had no reason or duty to independently investigate phenylephrine's efficacy at least until the FDA's September 2023 vote and media coverage of NDAC's decision. Instead, Plaintiff and the Class rightly relied on Defendants' representations, superior knowledge, and sophistication.

41. From at least the beginning of the Class Period (2017), Defendants had a duty to disclose to consumers, including Plaintiff, that phenylephrine did not treat nasal congestion. Plaintiffs had no reasonable access to this information, including through inspection or other means and relied on Defendants to make prompt and complete disclosure regarding product efficacy.

42. During the Class Period, Defendants possessed superior knowledge, not discoverable by Plaintiff, regarding phenylephrine's inefficacy and, in turn, Sudafed PE's inefficacy to treat nasal decongestion. During the Class Period, Defendants knew that Plaintiff and other consumers were purchasing the Sudafed PE based on Defendants' misrepresentation that Sudafed PE treated nasal congestion due on the inclusion of phenylephrine. Defendants had a duty to disclose their superior knowledge to Plaintiff but did not disclose that information to wrongly protect their business.

43. During the Class Period, Defendants made incomplete and false representations that required a corrective and complete disclosure regarding phenylephrine's efficacy. Among

other things, Defendants misrepresented on Sudafed PE labeling, packaging, and in other promotional materials that the Products could be used to “[t]emporarily relieve[] nasal congestion due to the common cold, hay fever or other upper respiratory allergies.” However, Defendants failed to disclose that, by at least 2017, scientific research had conclusively demonstrated that phenylephrine could not be used to treat nasal decongestion.

44. During the Class Period, Defendants actively concealed the fact that phenylephrine was ineffective, rendering Sudafed PE worthless. Defendants have long understood that orally ingested phenylephrine does not relieve nasal decongestion. To the extent Defendants had any doubts regarding whether phenylephrine was effective, Defendants could not have reasonably believed phenylephrine was effective by the end of 2016 after numerous clinical studies demonstrated that orally ingested phenylephrine—including Defendants’ own Sudafed PE—did not reduce nasal decongestion when compared with placebo pills.

45. Defendants knew that if they disclosed that Sudafed PE did not relieve nasal decongestion, Plaintiff and Class members would not have purchased or used Sudafed PE. To selfishly protect their business, Defendants were motivated to conceal the true facts regarding Sudafed PE’s efficacy on product packaging and in other promotional mediums. Defendants’ misrepresentations and omissions were not motivated simply to earn profit but to avoid a massive sea change in their over-the-counter drug portfolio, as the revelation of the truth would eliminate Sudafed PE and many other products containing phenylephrine and would reduce revenues by hundreds of millions of dollar or more.

46. Defendants’ misrepresentations and omissions were material because consumers are highly concerned with product efficacy and safety.

D. Plaintiff Purchased Sudafed PE During the Class Period Based on Defendants' Labeling Misrepresentations and Omissions

47. Between 2017 and 2023 Plaintiff purchased packages of Sudafed PE at Walgreens and CVS. Plaintiff purchased Sudafed PE from these retail stores in New Jersey and paid approximately \$12-\$14 for each package of Sudafed PE.

48. Prior to purchasing Sudafed PE, Plaintiff reviewed and relied on the product labeling, including front labeling stating "Phenylephrine HCl, Nasal Decongestant" and the rear labeling stating that Sudafed PE "[t]emporarily relieves" sinus congestion, pressure, and nasal congestion.

49. The Sudafed purchased by Plaintiff did not disclose that phenylephrine does not temporarily relieve nasal decongestion or that clinical studies and overwhelming reliable scientific evidence demonstrated the phenylephrine did not temporarily relieve nasal decongestion, material information that would have greatly impacted Plaintiff's purchasing decision.

50. Plaintiff used the Sudafed PE as directed on the instructions between 2017 and 2023 without any knowledge that the phenylephrine does not reduce nasal decongestion.

51. Plaintiff would not have purchased Sudafed PE had he known that phenylephrine could not temporarily relieve nasal decongestion.

E. Tolling of the Statute of Limitations and Estoppel

52. Any applicable statutes of limitation have been tolled by Defendants knowing and active concealment of the existence of the true nature and inefficacy of phenylephrine. Through no fault or lack of diligence, Plaintiff and Class members were deceived regarding the Sudafed PE's ineffectiveness and could not reasonably discover that fact until media coverage of NDAC's unanimous finding in September 2023 that orally ingested phenylephrine cannot relieve nasal congestion.

53. At all times, Defendants were and are under a continuous duty to disclose to Plaintiff and Class members the true standard, quality, character, nature, and grade of the Sudafed PE. Instead, Defendants made misrepresentations and omitted disclosure of Sudafed PE's inefficacy. Defendants actively concealed the true standard, quality, character, nature, and grade of the Sudafed PE and omitted material information about the quality, reliability, and characteristics of Sudafed PE. Plaintiff and Class members reasonably relied on Defendants' knowledge and concealment of the facts alleged herein.

54. For these reasons, all applicable statutes of limitation have been tolled based on the discovery rule and Defendants' fraudulent concealment; further, Defendants are estopped from relying on any statutes of limitations in defense of this action.

CLASS ACTION ALLEGATIONS

55. Plaintiff seeks to represent and certify the following class:

All United States residents who purchased orally-administered Sudafed PE during the Class Period (the "Class").

The Class excludes any judge or magistrate assigned to this case, Defendants, Defendants' officers, directors, legal representatives, successors, and assigns, and any entity in which Defendants have a controlling interest.

56. Numerosity: This proposed class action involves hundreds of millions or more in sales of Sudafed PE, and the Class includes hundreds of thousands, but far more likely millions, of purchasers. As a result, the Class is so numerous that joinder of all members is impracticable.

57. Typicality: Plaintiff's claims are typical of those belonging to every member of the Class. Plaintiff and every member of the Class purchased Sudafed PE after being exposed to Defendants' misrepresentations and/or without material information only Defendants knew

regarding Sudafed PE, but which Defendants withheld from consumers, including Plaintiff and the Class.

58. Adequacy: Plaintiff will fairly and adequately protect the interests of the Class, and Plaintiff has retained counsel experienced in complex class action litigation. Plaintiff and his chosen counsel have no interests adverse to those of the Class that he seeks to represent.

A. Rule 23(b)(2)

59. This action is appropriate as a class action pursuant to Rule 23(b)(2) because Defendants have acted in a manner generally applicable to the Class by designing, manufacturing, distributing, and selling ineffective and worthless Sudafed PE.

B. Rule 23(b)(3)

60. Common questions of law and fact exist as to every member of the Class and predominate over any questions solely affecting individual members of the Class, including:

- a) Whether the phenylephrine can temporarily relieve nasal congestion;
- b) Whether Defendants knew that phenylephrine and, in turn, Sudafed PE could not temporarily relieve nasal decongestion and Sudafed PE could not temporarily relieve nasal decongestion;
- c) Whether Defendants had a duty to disclose that Sudafed PE could not temporarily relieve nasal decongestion;
- d) Whether Defendants breached Sudafed PE's express and implied warranties;
- e) Whether Defendants violated the New Jersey Consumer Fraud Act;
- f) Whether Defendants were unjustly enriched because of their misrepresentations and omissions concerning Sudafed PE's supposed ability to temporarily relieve nasal decongestion; and
- g) Whether Plaintiff and the Class are entitled to damages and restitution.

61. A class action is also superior to other available means for the fair and efficient adjudication of this controversy for other reasons. The injuries suffered by individual members of

the Class, though important to them, are relatively small compared to the burden and expense of individual prosecution needed to address Defendants' misconduct. Individualized litigation presents a potential for inconsistent or contradictory judgments. In contrast, a class action presents far fewer management difficulties; allows the hearing of claims that might otherwise go unaddressed; and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court.

62. The proposed Class is defined by objective criteria so that it is administratively feasible for the Court to determine whether a particular individual is a member. Individual class members can be identified through affidavits and/or reference to documents in Defendants' possession, custody, or control without resort to a mini-hearing on the merits.

63. Plaintiff cannot be certain of the form and manner of proposed notice to members of the Class until the Class is finally defined and discovery is completed regarding the identity of members of the Class. Plaintiff anticipates, however, that notice by mail will be given to members of the Class who can be identified specifically. In addition, notice may be published in appropriate publications, on the internet, in press releases, and in similar communications in a way that is targeted to reach members of the Class. The cost of notice, after class certification, trial, or settlement before trial, should be borne by Defendants.

64. Plaintiff reserves the right to modify or amend the definition of the proposed Class at any time before the Class is certified by the Court.

FIRST CLAIM FOR RELIEF
VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT

65. Plaintiff re-alleges and incorporates the allegations made elsewhere in the Complaint as if set forth fully herein.

66. Plaintiff brings this claim on behalf of himself and on behalf of the Class.

67. The New Jersey Consumer Fraud Act (“NJCFA”) declares it to be an unlawful practice for “any person” to use an “unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of any material fact . . . in connection with the sale or advertisement of any merchandise.” N.J.S.A. 56:8-2.

68. The legislature intended the NJCFA to be “one of the strongest consumer protection laws in the nation.” *Cox v. Sears Roebuck & Co.*, 138 N.J. 2, 15, 647 A.2d 454, 460 (1994). The NJCFA is considered “remedial legislation,” and courts therefore construe its prohibitions “liberally to accomplish its broad purpose of safeguarding the public.” *Lee v. Carter-Reed Co.*, 203 N.J. 496, 522, 4 A.3d 561, 577 (2010).

69. The NJCFA broadly defines “person” to “include any natural person or his legal representative, partnership, corporation, company, trust, business entity or association.” N.J.S.A. 56:8-1(d). Here, Defendants are “person(s)” under the NJCFA.

70. The NJCFA broadly defines “merchandise” as “any objects, wares, goods, commodities, services, or anything offered, directly or indirectly to the public for sale.” N.J.S.A. 56:8-1(c). Here, Defendants offered the Sudafed PE products, constituting “merchandise” under the NJCFA, to the public for sale.

71. Defendants’ conduct in misrepresenting the benefits of Sudafed PE and/or omitting material information from Sudafed PE’s labels regarding efficacy and other marketing materials constitutes the act, use and employment of deception, fraud, false pretenses, false promises, misrepresentation, and unfair practices in the conduct of Defendants’ trade or commerce.

72. Defendants also knowingly concealed, suppressed, and consciously omitted material facts to Plaintiff and other members of the Class, knowing that consumers would rely on the advertisements, packaging, and Defendants' uniform representations to purchase Sudafed PE.

73. Defendants intended that Plaintiff and the Class rely on their continuing deception by purchasing Sudafed PE, unaware of the material facts and omissions described above. Defendants knew that their customers would continue to rely on Defendants' representations and omissions that phenylephrine and Sudafed PE were effective. This conduct constitutes consumer fraud within the meaning of the NJCFA.

74. Defendants' sale of ineffective and misbranded Sudafed PE, and the material non-disclosures set forth above, constitutes an unconscionable commercial practice, deception, fraud, false promise, misrepresentation and/or omission of material facts as to the nature of the goods, in violation of the NJCFA.

75. There is a causal relationship between Defendants' unlawful conduct and Plaintiff's and the Class's losses. Plaintiff and other members of the Class purchased Sudafed PE based on Defendants' false representation that Sudafed PE could relieve nasal congestion and Plaintiff and the Class did not know that phenylephrine was scientifically proven to be ineffective in temporarily relieving nasal congestion. Had Plaintiff, the Class, and the consuming public known that Sudafed PE did not relieve nasal congestion, they would not have purchased Sudafed PE.

76. Defendants' unconscionable commercial practices, along with their misrepresentations and omissions, make Defendants liable to Plaintiff and other class members under N.J.S.A. 56:8-2.11 and N.J.S.A. 56:8-2.12, which provide that "[a]ny person violating the provisions of the within act shall be liable for a refund of all moneys acquired by means of any

practice declared to be unlawful.” Defendants are further liable to Plaintiff and other class members for treble damages, attorneys’ fees, and costs under N.J.S.A. 56:8-19.

SECOND CLAIM FOR RELIEF
BREACH OF EXPRESS WARRANTY

77. Plaintiff re-alleges and incorporates the allegations made elsewhere in the Complaint as if set forth fully herein.

78. Plaintiff brings this claim on behalf of himself and on behalf of the Class.

79. During the Class Period, as set forth in Section A above, Defendants made representations to the public, including to Plaintiff and the Class, by advertising, packaging, labeling, ingredient lists and other means, that Sudafed PE could be used to treat nasal congestion. Those promises and related promises became part of the basis of the bargain between the parties and thus constituted express warranties.

80. Thereon, Defendants sold the goods to Plaintiff and the Class, who bought the goods from Defendants. Plaintiff reviewed and relied on Defendants’ labeling, representations, and warranties when purchasing and using the Products, including Defendants’ warranties on the product labeling about “Phenylephrine HCl, Nasal Decongestant” and on the rear labeling stating that Sudafed PE “[t]emporarily relieves” sinus congestion, pressure, and nasal congestion.

81. However, Defendants breached the express warranty in that Sudafed PE could not temporarily relieve nasal decongestion. As a result of this breach, Plaintiff and the Class in fact did not receive goods as expressly warranted by Defendants.

82. At least as early as the beginning of the Class Period, Defendants were on notice of their warranty breaches through interactions with regulatory agencies including the FDA; clinical studies dismissing the link between phenylephrine and nasal decongestion relief; and from other external and internal sources. Thus, Plaintiff was not required to provide Defendants with notice

of their warranty breaches to the extent Defendants were acting as manufacturers of Sudafed PE; based on futility; and/or because Defendants were on notice of their breaches from other sources (as alleged above).

83. Privity is not required between Plaintiff and Defendants because: (1) Defendants' warranties were included in public advertising and sales literature; (2) Plaintiff reviewed and relied on Defendants' labeling and ingredient lists warranting that Sudafed PE "[t]emporarily relieves" sinus congestion, pressure, and nasal congestion; and/or (3) Sudafed PE was consumer merchandise, were sealed, and were meant for human consumption. Moreover, Plaintiff was the known end purchaser of the Products; the Products' implied warranties were intended for Plaintiff's immediate benefit; and Plaintiff was the intended third-party beneficiary of the warranties between Defendants and the retailers who ultimately sold the Products to Plaintiff. Defendants' retailers were not intended to be the ultimate consumers of Sudafed PE and have no rights under the warranty agreements. As a result, Defendants have a duty to compensate Plaintiff and the Class for the warranty breaches.

THIRD CLAIM FOR RELIEF
BREACH OF IMPLIED WARRANTY

84. Plaintiff re-alleges and incorporates the allegations made elsewhere in the Complaint as if set forth fully herein.

85. Plaintiff brings this claim on behalf of himself and on behalf of the Class.

86. Defendants are merchants and were at all relevant times involved in manufacturing, distributing, warranting, and/or selling Sudafed PE.

87. Sudafed PE constitutes "goods" under the relevant laws, and Defendants knew or had reason to know of the specific use for which the Sudafed PE, as goods, were purchased.

88. The implied warranty of merchantability included with the sale of the Sudafed PE means that Defendants guaranteed that Sudafed PE would be fit for the ordinary purposes for which nasal decongestants are used and sold, conformed to labeling representations, and were not otherwise injurious to consumers. The implied warranty of merchantability is part of the basis for the benefit of the bargain between Defendants, and Plaintiff and members of the Class.

89. Defendants breached the implied warranty of merchantability because Sudafed PE is not fit for its ordinary purpose of temporary relief of nasal congestion and did not conform to labeling representations.

90. Had Plaintiff, Class Members, and the consuming public known that Sudafed was ineffective and did not relieve nasal congestion, they would not have purchased Sudafed PE.

91. As a direct and proximate result of the foregoing, Plaintiff and members of the Class suffered and continue to suffer financial damage and injury, and are entitled to all damages, in addition to costs, interest and fees, including attorneys' fees, as allowed by law.

FOURTH CLAIM FOR RELIEF
FRAUDULENT MISREPRESENTATION/CONCEALMENT

92. Plaintiff re-alleges and incorporates the allegations made elsewhere in the Complaint as if set forth fully herein.

93. Plaintiff brings this claim on behalf of himself and on behalf of the Class.

94. During the Class Period, Defendants made material representations to the public, including Plaintiff and the Class, by their advertising, packaging, labeling, and other means, that Sudafed PE could temporarily relieve nasal decongestion because it contained phenylephrine.

95. Defendants' representations were untrue or misleading because Sudafed PE could not relieve nasal congestion and phenylephrine has been scientifically proven as ineffective in relieving sinus congestion.

96. Defendants made these misrepresentations with actual knowledge of their falsity.

97. Defendants made the misrepresentations herein alleged with the intention of inducing the public to purchase Sudafed PE.

98. Plaintiff, the Class, and the consuming public saw, believed, and reasonably relied on Defendants' advertising, labeling, and packaging when purchasing the Products.

99. As a proximate result of Defendants' misrepresentations, Plaintiff and the Class were induced to spend an amount to be determined at trial on the Products.

100. Moreover, during the Class Period (2017 to the present), Defendants knew that Sudafed PE could not relieve nasal congestion based on clinical studies and other extensive scientific research.

101. During the Class Period (2017 to the present), Defendants had a duty to disclose that information: (a) to correct prior representations that were factually incorrect; (b) due to their exclusive and superior knowledge regarding Sudafed's inefficacy; (c) to make partial representations regarding Sudafed PE's inefficacy not misleading; and (d) due to Defendants' active concealment of Sudafed's inefficacy.

102. Plaintiff and the Class had no actual or constructive knowledge that Sudafed PE could not temporarily relieve sinus congestion because phenylephrine is ineffective when ingested orally. Moreover, Plaintiff and the Class had no duty to investigate Sudafed PE's effectiveness.

103. Defendants intended to deceive Plaintiff and the Class by concealing the foregoing facts to: (a) maintain the status quo; (b) prevent the collapse of a highly material portion of their over-the-counter drug portfolio (phenylephrine drugs) worth hundreds of millions of dollars or more; (c) maximize profits despite Sudafed PE's ineffectiveness; and (d) to avoid a recall and tens of millions of dollars or more in costs and liability.

104. Had Plaintiff and the Class known the truth, they would not have purchased the Sudafed PE.

105. Defendants' concealment was a substantial factor in causing Plaintiff's and Class's harm.

FOURTH CLAIM FOR RELIEF
UNJUST ENRICHMENT

106. Plaintiff re-alleges and incorporates the allegations made elsewhere in the Complaint as if set forth fully herein.

107. Plaintiff brings this claim on behalf of himself and on behalf of the Class.

108. Plaintiff and the other members of the Class conferred benefits on Defendants in the form of monies paid to purchase Defendants' ineffective and worthless Sudafed PE.

109. Defendants voluntarily accepted and retained this benefit.

110. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for ineffective and worthless Sudafed PE, it would be unjust and inequitable for Defendants to retain the benefit without paying the value thereof.

111. Defendants received benefits in the form of revenues from purchases of the ineffective Sudafed PE to the detriment of Plaintiff and the other members of the Class because Plaintiff, and members of the Class, purchased ineffective and worthless products that were not what they bargained for.

112. Defendants have been unjustly enriched in retaining the revenues derived from the purchases of Sudafed PE by Plaintiff and the other members of the Class. Retention of those monies under these circumstances is unjust and inequitable because Defendants' labeling and advertising of the Sudafed PE was misleading to consumers, which caused injuries to Plaintiff and

members of the Class, because they would have not purchased Sudafed PE had they known the true facts.

113. Because Defendants' retention of the non-gratuitous benefits conferred on them by Plaintiff and members of the Class is unjust and inequitable, Defendants must pay restitution to Plaintiff and members of the Class for Defendants' unjust enrichment, as ordered by the Court.

JURY DEMAND

WHEREFORE, Plaintiff, on behalf of himself and the Class, prays for relief as follows:

- a) An Order certifying this action to proceed on behalf of the Class and appointing Plaintiff and the counsel listed below to represent the Class;
- b) An Order awarding Plaintiff and Class members compensatory, actual, statutory, punitive or exemplary damages, restitution, and/or disgorgement along with such other equitable relief as the Court deems proper;
- c) An Order awarding Plaintiff attorneys' fees and other costs; and
- d) An Order awarding such other and further relief as may be just and proper, including pre-judgment and post-judgment interest on the above amounts.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b), Plaintiff and the Class demand a trial by jury.

Dated: September 18, 2023

SQUITIERI & FEARON, LLP

By: /s/ Stephen J. Fearon, Jr.
Stephen J. Fearon, Jr.
Paul Sweeny
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Attorneys for Plaintiff and the Proposed Class

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
JACOB REINKRAUT
(b) County of Residence of First Listed Plaintiff Bergen
(c) Attorneys (Firm Name, Address, and Telephone Number)
Squitieri & Fearon, LLP, 305 Broadway, 7th Floor, New York, NY 10007; (212) 421-6492

DEFENDANTS
JOHNSON & JOHNSON CONSUMER, INC., and KENVUE, INC.,
County of Residence of First Listed Defendant Middlesex
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
2 U.S. Government Defendant
3 Federal Question
XX Diversity
Class Action Fairness Act

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
PTF DEF
Citizen of This State XX 1
Citizen of Another State 2 2
Citizen or Subject of a Foreign Country 3 3

IV. NATURE OF SUIT (Place an "X" in One Box Only) Click here for: Nature of Suit Code Descriptions.

Table with columns: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, INTELLECTUAL PROPERTY RIGHTS, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

V. ORIGIN (Place an "X" in One Box Only)
X 1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from Another District
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)(2)
Brief description of cause:
Class action stemming from defective sinus medication

VII. REQUESTED IN COMPLAINT:
[X] CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: [X] Yes [] No

VIII. RELATED CASE(S) IF ANY (See instructions):
JUDGE Kevin McNulty DOCKET NUMBER 23-20370

DATE 9/18/2023 SIGNATURE OF ATTORNEY OF RECORD [Signature]

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.

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

_____ District of _____

_____)	
<i>Plaintiff</i>)	
)	
v.)	Civil Action No.
)	
_____)	
<i>Defendant</i>)	

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

A lawsuit has been filed against you.

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

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

CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. _____

PROOF OF SERVICE

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

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

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

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

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

I returned the summons unexecuted because _____; or

Other *(specify)*: _____

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

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

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc: