

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

SANDRA YOUSEFZADEH, individually and
on behalf of all others similarly situated,

Plaintiff,

v.

JOHNSON & JOHNSON CONSUMER, INC.,

Defendant.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Sandra Yousefzadeh, individually and on behalf of all others similarly situated, for her Class Action Complaint against Defendant Johnson & Johnson Consumer, Inc. (“JJCI”), based upon personal knowledge as to her own actions and based upon the investigation of counsel with respect to all other matters, complains as follows:

I. INTRODUCTION

1. JJCI sold and marketed directly to Plaintiff and the Class an over-the counter medication known as Sudafed PE[®] (“Sudafed PE”) containing the active ingredient Phenylephrine (“PE”), which purports to act as an oral nasal decongestant.

2. JJCI markets Sudafed PE to consumers as an effective oral nasal decongestant through tens of millions of dollars in advertising annually.

3. A Food and Drug Administration Nonprescription Drugs Advisory Committee (NDAC) has concluded that PE is no more effective as an oral nasal decongestant than a placebo.

4. By purchasing Sudafed PE, Plaintiff and the Class did not receive a product that was effective at treating nasal congestion.

5. Plaintiff and the Class have been damaged by JJCI’s actions. Plaintiff brings this action under New York General Business Law §§ 349 and 350 and for unjust enrichment,

because Plaintiff and the Class members did not receive the benefit of the bargain and/or suffered out-of-pocket loss, and are entitled to recover compensatory damages, trebling where permitted and attorneys' fees and costs.

II. JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter presented by this Complaint because it is a class action arising under the Class Action Fairness Act of 2005 ("CAFA"), Pub. L. No. 109-2, 119 Stat. 4 (2005), which explicitly provides for the original jurisdiction of the Federal Courts of any class action in which any member of the Class is a citizen of a State different from any Defendant, and in which the matter in controversy exceeds in the aggregate the sum of \$5,000,000.00, exclusive of interest and costs. Plaintiffs allege that the total claims of individual Class members in this action are in excess of \$5,000,000.00 in the aggregate, exclusive of interest and costs, as required by 28 U.S.C. §§ 1332(d)(2) and (6). Plaintiff is a citizen of New York, whereas JJCI is a citizen of New Jersey for purposes of diversity. Therefore, diversity of citizenship exists under CAFA as required by 28 U.S.C. § 1332(d)(2)(A). Furthermore, the total number of members of the proposed Class is greater than 100, pursuant to 28 U.S.C. § 1332(d)(5)(B).

7. Venue is appropriate in this District because plaintiff resides here and made her purchase of Sudafed here.

III. PARTIES

8. Plaintiff Sandra Yousefzadeh is a citizen and resident of the State of New York. Plaintiff purchased two packages of 24 tablets of Sudafed from Amazon.com Services LLC ("Amazon") on August 23, 2023, for \$6.97 per package. Plaintiff purchased Sudafed based on

JJCI's representation that Sudafed PE was, in fact, an effective nasal decongestant. Plaintiff was actually deceived, and damaged by JJCI's misrepresentations.

9. Defendant JJCI is a New Jersey corporation with its principal place of business in Skillman, New Jersey. On information and belief, JJCI is a wholly owned subsidiary of Johnson & Johnson, and JJCI's McNeil Consumer Healthcare Division is responsible for all aspects of making and selling Sudafed products, including research and development, quality control, supply chain management, medical affairs, product packaging, product marketing (including labeling), and regulatory/compliance functions.

10. On information and belief, non-party Amazon is JJCI's agent for direct sales by JJCI to consumers via the Amazon website.

IV. FACTS

A. Background on Over-the-Counter Nasal Decongestant Medications

11. Over-the-counter nasal decongestants are advertised as providing temporary relief of nasal congestion and pressure associated with a common cold, flu, sinus infection and allergies. Over-the-counter nasal decongestants generally use one of two active ingredients recognized as safe and effective for temporary relief of nasal congestion: pseudoephedrine and PE.

12. The Combat Methamphetamine Epidemic Act of 2005 ("CMEA") banned over-the-counter sales of cold medicines that contain pseudoephedrine, which is commonly used to make methamphetamine. The sale of cold medicine containing pseudoephedrine is limited to behind the counter. The amount of pseudoephedrine that an individual can purchase each month is limited and individuals are required to present photo identification to purchase products

containing pseudoephedrine. In addition, stores are required to keep personal information about purchasers for at least two years.

13. Because the CMEA, by design, made the purchase of cold medicines containing pseudoephedrine inconvenient and time consuming, consumer health manufacturers began offering cold medicines which contained an alternative active ingredient for the temporary relief of nasal congestion that could still be purchased over-the-counter, that active ingredient is PE. PE cannot be used to make methamphetamine.

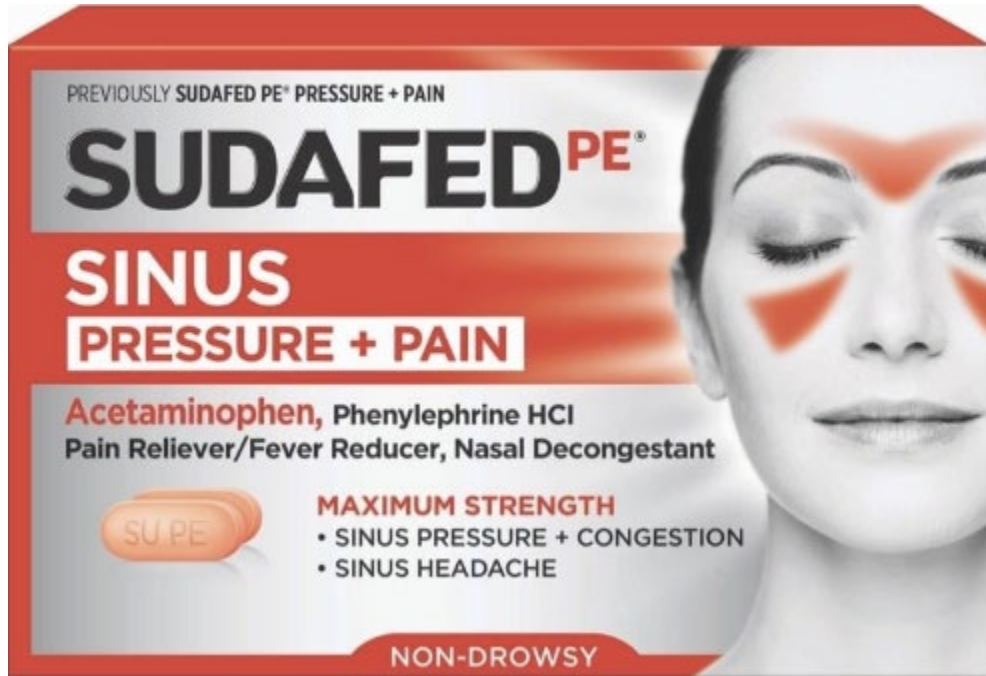
14. Prior to the passage of the CMEA, JJCI's most popular, market leading decongestant products, which contained pseudoephedrine were sold under the "Sudafed" brand.

B. JJCI Distributes, Markets and Sells Its Sudafed PE Products Containing Phenylephrine.

15. Following the effective date of the CMEA, consumer healthcare manufacturers, including JJCI switched their distributing, marketing and sale efforts to decongestant products that contained PE. JJCI's Sudafed PE products all contain PE as the active ingredient for the temporary relief of nasal congestion.

16. Apart from the names themselves, which described a particular type of nasal congestion or combination of nasal congestion and other symptoms the product is intended to treat, JJCI's packaging for its Sudafed PE products trumpeted their effectiveness against nasal congestion. For example, the packaging for "Sudafed PE Sinus Pressure + Pain" product advertises that it contains "Phenylephrine HCl" and indicates that the product is a "Pain Reliever/Fever Reducer, Nasal Decongestant." Moreover, the packaging represents that it is "MAXIMUM STRENGTH" for

- SINUS PRESSURE + CONGESTION
- SINUS HEADACHE



17. Here, JJCI intended that consumers rely on the packaging to mean, of course, that Sudafed PE Sinus Pressure + Pain would be safe and effective as a nasal decongestant and that it would provide “MAXIMUM STRENGTH” relief of “Sinus Pressure + Congestion” as well as “Sinus Headache.” In fact, as set forth below, the active ingredient in Sudafed PE Sinus Pressure + Pain” is no more effective as a nasal decongestant than a placebo.

C. JJCI Deceived Plaintiff and the Class Because Sudafed PE Products Do Not Contain an Active Ingredient that is Effective as a Nasal Decongestant.

18. As early as 2007, the FDA’s Nonprescription Drugs Advisory Committee (NDAC) met to discuss scientific data submitted in a citizen’s petition on February 1, 2007, that showed that “orally administered PE is not effective at the monographed dosages.”

19. Following a long-running review of the evidence, and multiple studies, the FDA reviewers announced as background for a meeting of the NDAC held on September 11-12, 2023 that: "we have now come to the initial conclusion that orally administered PE [phenylephrine] *is*

not effective as a nasal decongestant at the monographed dosage (10 mg of PE hydrochloride every 4 hours) as well as at doses up to 40 mg (dosed every 4 hours).” (emphasis added)

D. Plaintiff and the Class Were Damaged.

20. Because Sudafed PE products do not contain an active ingredient that is effective as a nasal decongestant, Plaintiff, as well as the Class she seeks to represent, suffered economic damages as a result of purchasing Sudafed PE products in order to obtain temporary relief from nasal congestion.

V. CLASS ACTION ALLEGATIONS

21. Class Definition: Plaintiff brings this action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of herself and a Class defined as follows:

All persons that purchased Sudafed PE products within the state of New York for personal, family or household uses.

Excluded from the Class are Defendant, any entity in which Defendant has a controlling interest and Defendant’s legal representatives, predecessors, successors, assigns, and employees. Also excluded from the Class is any judge, justice or judicial officer presiding over this matter and the members of their immediate families and judicial staff.

22. Numerosity: The proposed Class is so numerous that individual joinder of all members is impracticable.

23. Common Questions of Law and Fact Predominate: There are many questions of law and fact common to Plaintiff and the Class, and those questions substantially predominate over any questions that may affect individual Class members. Some of the common legal and factual questions include:

- a. Whether JJCI ‘s act, practice or advertisement was consumer-oriented;

- b. Whether JJCI's conduct constituted an act, practice, or advertisement that was misleading in a material respect;
- c. Whether the Class was thereby injured;
- d. Whether Defendant violated the common law of unjust enrichment; and
- e. The nature and extent of damages and other remedies to which the Class may be entitled.

24. Defendant engaged in a common course of conduct giving rise to the legal rights sought to be enforced by the Class members. Similar or identical statutory and common law violations and deceptive business practices are involved. Individual questions, if any, do not predominate over the numerous common questions.

25. The injuries sustained by the Class members flow, in each instance, from a common nucleus of operative facts—Defendant's misconduct. In each case Defendant marketed and sold Sudafed PE by misleading and deceiving Plaintiff and the Class that the active ingredient in the product was effective in providing temporary relief of nasal congestion.

26. The Class members have been damaged by Defendant's misconduct. The Class members would not have purchased Sudafed PE products in the absence of Defendant's marketing campaigns and deceptive scheme.

27. Plaintiff's claims are typical of the claims of the other Class members. Plaintiff purchased Sudafed PE products and was actually deceived.

28. Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff is familiar with the basic facts that form the bases of the Class members' claims. Plaintiff's interests do not conflict with the interests of the other Class members that she seeks to represent.

29. Plaintiff has retained counsel competent and experienced in Class action litigation and intends to prosecute this action vigorously. Plaintiff's counsel has successfully prosecuted complex Class actions, including consumer protection Class actions. Plaintiff and Plaintiff's counsel will fairly and adequately protect the interests of the Class members.

30. The class action device is superior to other available means for the fair and efficient adjudication of the claims of Plaintiff and the Class members. The relief sought by each individual member of the Class is small given the burden and expense of individual prosecution of the potentially extensive litigation necessitated by the conduct of Defendant. Furthermore, it would be virtually impossible for the Class members to seek redress on an individual basis. Even if the Class members themselves could afford such individual litigation, the court system could not.

31. Individual litigation of the legal and factual issues raised by the conduct of Defendant would increase delay and expense to all parties and to the court system. The Class action device presents far fewer management difficulties and provides the benefits of a single, uniform adjudication, economies of scale and comprehensive supervision by a single court. Given the similar nature of the Class members' claims and the absence of material differences in the state statutes and common laws upon which the Class members' claims are based, a nationwide Class will be easily managed by the Court and the parties.

VI. CAUSES OF ACTION

COUNT I

VIOLATIONS OF NEW YORK GENERAL BUSINESS LAW SECTIONS 349 and 350

32. Plaintiff incorporates by reference the preceding paragraphs.

33. Pursuant to GBL§ 349, it is unlawful to engage in any deceptive acts or practices in the conduct of any business, trade, or commerce in this State.

34. As set forth more fully above, Defendant engaged in deceptive business practices in violation of GBL § 349.

35. As set forth more fully above, Defendant's act, practice, and advertisement was consumer-oriented.

36. Defendant's deceptive business practice is the marketing, advertising, distribution, and sale of an over-the-counter nasal decongestant that is no more effective at treatment of nasal congestion than a placebo.

37. Plaintiff and the Class would not have purchased Sudafed PE products had they known they were not effective at providing temporary relief of nasal congestion.

38. At minimum, Plaintiff and the Class would not have purchased Sudafed PE products had they not seen the product packaging that promised relief from nasal congestion.

39. Where Defendant's Sudafed PE product is combined with another active ingredient, such as acetaminophen for pain relief, Plaintiff and the Class would not have paid the premium Defendant charged for the additional active PE ingredient in Sudafed PE, when generic acetaminophen sells for as little as \$0.02 per tablet.

40. Pursuant to GBL §§ 349(b) and 350-d, Plaintiff seeks injunctive relief, restitution, damages, and penalties.

COUNT II

UNJUST ENRICHMENT

41. Plaintiff re-alleges the preceding paragraphs as if fully set forth herein and, to the extent necessary, pleads this cause of action in the alternative.

42. Defendant received and retained wrongful benefits from Plaintiff and the Class in the form of revenue derived from the sale of Sudafed PE within the State.

43. As a result of Defendant's wrongful conduct as alleged herein, Defendant has been unjustly enriched at the expense of, and to the detriment of, Plaintiff and the Class.

44. Defendant's unjust enrichment is traceable to and resulted directly and proximately from the conduct alleged herein.

45. It is inequitable for Defendant to be permitted to retain the benefits it received, and is still receiving, without justification, from the sale of Sudafed PE within the State. Defendant's retention of such funds under circumstances making it inequitable to do so constitutes unjust enrichment.

46. The financial benefits derived by Defendant within the State rightfully belong to Plaintiff and the members of the Class. Defendant should be compelled to disgorge in a common fund for the benefit of Plaintiff and Members of the Class all wrongful and inequitable proceeds received from them. A constructive trust should be imposed upon all wrongful or inequitable sums received by Defendants traceable to Plaintiff and the member so the Class.

47. Plaintiff and the Class have no adequate remedy at law.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff and the Class members request that the Court enter an order or judgment against Defendant including the following:

- a. Certification of the action as a Class Action pursuant to Rule 23(b)(3) of the
- b. Federal Rules of Civil Procedure, and appointment of Plaintiffs as Class Representatives and their counsel of record as Class Counsel;
- c. Damages in the amount of monies paid for Sudafed PE products;

- d. Actual damages, statutory damages, punitive or treble damages, and such other relief as provided by the statutes cited herein;
- e. Pre-judgment and post-judgment interest on such monetary relief;
- f. Other appropriate injunctive relief;
- g. The costs of bringing this suit, including reasonable attorneys' fees; and
- h. All other relief to which Plaintiff and members of the Class may be entitled at law or in equity.

JURY DEMAND

Plaintiff hereby demands trial by jury on his own behalf and on behalf of Class members.

Dated: September 13, 2023

Respectfully submitted,

s/Darren T. Kaplan

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(212) 999-7370
dkaplan@kaplangore.com

Attorneys for Plaintiff

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

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

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

DEFENDANTS

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, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 4 Diversity (Indicate Citizenship of Parties in Item III)

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

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

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, 1 1, 2 2, 3 3, 4 4, 5 5, 6 6

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

Table with columns: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes categories like Personal Injury, Labor, and Property Rights.

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, 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):

Brief description of cause:

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 DOCKET NUMBER

DATE SIGNATURE OF ATTORNEY OF RECORD

Darren Kaplan

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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

UNITED STATES DISTRICT COURT

for the

Eastern District of New York

SANDRA YOUSEFZADEH, individually and on behalf of all others similarly situated,

Plaintiff(s)

v.

JOHNSON & JOHNSON CONSUMER, INC.,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address)

Johnson & Johnson Consumer, Inc.
199 Grandview Rd.
Skillman, NJ 08558

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:

Darren T. Kaplan
KAPLAN GORE LLP
1979 Marcus Ave., Suite 201
Lake Success, NY 11042
(212) 999-7370
dkaplan@kaplangore.com

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.

DOUGLAS C. PALMER
CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

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 \$ _____ 0.00 _____ .

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

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc: