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

ANDREA WILSON, on behalf of herself and all others similarly situated,

Docket No.:

Plaintiff,

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

VS.

JOHNSON & JOHNSON CONSUMER, INC.; GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US) d/b/a HALEON; PROCTER & GAMBLE COMPANY; and RB HEALTH (US) LLC,

Defendants.

Plaintiff Andrea Wilson ("Plaintiff"), on behalf of herself and all others similarly situated, by and through his undersigned counsel, brings this lawsuit against Defendants Johnson & Johnson Consumer, Inc. ("JJCI"); GlaxoSmithKline Consumer Healthcare Holdings (US) d/b/a Haleon ("GSK"); Procter & Gamble Company ("P&G"); and RB Health (US), LLC ("RB Health") (collectively, "Defendants"). Plaintiff alleges as follows based on personal knowledge concerning all facts related to herself and based on the investigation of her 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 over-the-counter medications manufactured, marketed, labeled, distributed, and sold by Defendants that contained phenylephrine—an ingredient that supposedly acts as nasal decongestant but, in reality, does nothing (the "Nasal Decongestants").
- 2. Plaintiff purchased the following Nasal Decongestants during the applicable statute of limitations for her claims, that is, between 2017 and 2023 (the "Class Period):

- Children's Dimetapp Nighttime Cold & Congestion ("Children's Dimetapp"), manufactured by GSK;
- Dayquil Severe-Cold & Flu ("Dayquil Severe"), manufactured by P&G;
- Maximum Strength Mucinex Fast-Max Cold & Flu ("Maximum Strength Mucinex"), manufactured by RB Health;
- Mucinex Children's Multi-Symptom Cold, manufactured by RB Health ("Mucinex Children's"); and
- Sudafed PE Sinus Pressure + Pain ("Sudafed PE"), manufactured by JJCI.
- 3. Phenylephrine and pseudoephedrine are the two most common active ingredients contained in over-the-counter cold medications purporting to treat nasal congestion, including the Nasal Decongestants. 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.
- 4. 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 the Nasal Decongestants are ineffective to treat nasal congestion.
- 5. Defendants understood that phenylephrine was ineffective in at least 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 also reviewed subsequent studies and data from 2007 to 2016 further confirming phenylephrine's inefficacy when compared to a placebo.

- 6. 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 the Nasal Decongestants were useless. Instead, Defendants expressly misrepresented and misled consumers, wholesalers, and retailers by claiming that the Nasal Decongestants could be used to treat sinus congestion.
- 7. 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 the ineffective Nasal Decongestants. Defendants and their competitors sold \$1.8 billion in over-the-counter cold medications purporting to treat nasal congestion, including the Nasal Decongestants, in 2022 alone.
- 8. Defendants sold ineffective Nasal Decongestants at the expense of their trusting customers who unwittingly purchased the Nasal Decongestants believing they could relieve nasal congestion based on Defendants' misrepresentations and omissions. Consumers, like Plaintiff, depended on Defendants to disclose the truth about the Nasal Decongestants but were, instead, presented with false, misleading, or incomplete representations and omissions regarding the uses and benefits of the Nasal Decongestants and suffered damages as a result.
- 9. During the Class Period (at least 2017 to the present), Plaintiff and other consumers purchased the Nasal Decongestants even though, by that time, Defendants fully

understood that phenylephrine did not reduce nasal congestion. During the Class Period, Plaintiff purchased the Nasal Decongestants on multiple occasions at various retailers including Target, Walmart, and Walgreens. Plaintiff purchased the Nasal Decongestants after reviewing product labeling and other advertising (including television commercials) and based on Defendants' misrepresentations and omissions that the Nasal Decongestants could be used to treat nasal congestion. Plaintiff purchased and used the Nasal Decongestants without any knowledge that phenylephrine could not be used as an effective treatment for nasal congestion. Plaintiff would not have purchased the Nasal Decongestants had she known that they could not be used to treat nasal congestion, or she would have paid far less for the Nasal Decongestants.

10. As detailed below, Plaintiff brings express and implied warranty, fraudulent concealment, consumer protection, and unjust enrichment claims arising from Defendants' unfair and deceptive business practices in knowingly placing ineffective Nasal Decongestants into the stream of commerce. Plaintiff seeks on behalf of herself and the Class (defined below) damages and/or restitution for Defendants' unlawful conduct.

PARTIES

Plaintiff

11. Plaintiff is, and was at all relevant times, a resident of Idaho, and a citizen of Idaho. Plaintiff reviewed the labeling and other advertising (including television commercials) and used the Nasal Decongestants as directed on the instructions without any knowledge that the Nasal Decongestants were ineffective as a treatment for nasal congestion because they contained phenylephrine. Plaintiff would not have purchased the Nasal Decongestants—or would have paid far less for the Nasal Decongestants—had she known that phenylephrine is ineffective to treat nasal congestion.

Defendants

- 12. Defendant JJCI is a Delaware corporation that has its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. JJCI manufactured, marketed, designed, promoted, and/or distributed Sudafed PE containing ineffective phenylephrine in New Jersey and, from there, throughout the United States.
- 13. Defendant GSK is a Delaware limited liability company that has its principal place of business located at 2929 Walnut Street, Suite 1700, Philadelphia, Pennsylvania. Upon information and belief, GSK is a wholly-owned subsidiary of GlaxoSmithKline PLC, a public limited company registered in England and Wales. Among other Nasal Decongestants, GSK manufactured, marketed, designed, promoted, and/or distributed Children's Dimetapp throughout New Jersey and is registered to do business in New Jersey.
- 14. Defendant P&G is an Ohio corporation that has its principal place of business located at One Procter & Gamble Plaza, Cincinnati, Ohio 45202. Among other Nasal Decongestants, P&G manufactured, marketed, designed, promoted, and/or distributed Dayquil Severe throughout New Jersey and is registered to do business in New Jersey.
- 15. Defendant RB Health is a Delaware limited liability company with its headquarters and principal place of business located at 399 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, RB Health is a wholly-owned subsidiary of Reckitt Benckiser Group PLC, a public limited company registered in England and Wales. RB Health manufactured, marketed, designed, promoted, and/or distributed Mucinex products, including Maximum Strength Mucinex and Mucinex Children's, containing ineffective phenylephrine in New Jersey and, from there, throughout the United States.

- 16. From their New Jersey headquarters, Defendants JJCI and RB Health's management oversaw the production, distribution, and sale of certain Nasal Decongestants throughout the United States. Defendants JJCI and RB Health's sales and marketing leadership, as well as their accounting, financial, and legal departments, are all based in and have their New Jersey headquarters in this District. Furthermore, upon information and belief, Defendants JJCI and RB Health's 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.
- 17. Upon information and belief, Defendants JJCI and RB Health created and/or authorized the false and misleading representations and omissions from New Jersey. Defendants JJCI and RB Health and their management—from their New Jersey headquarters—collaborated in developing, manufacturing, and distributing the Nasal Decongestants.
- 18. Defendants GSK and P&G marketed, promoted, and/or distributed millions of dollars of Nasal Decongestants in New Jersey; are registered to do business in New Jersey; and have offices in New Jersey.
- 19. Defendants' substantial participation in designing, manufacturing, distributing, marketing, and selling the Nasal Decongestants from New Jersey, including Defendants JJCI and RB Health's New Jersey headquarters, means Defendants are each essentially at home in New Jersey, and New Jersey has the greatest interest in the subject matter of this lawsuit.

JURISDICTION AND VENUE

20. 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. Plaintiff is a citizen of Idaho, and Defendants are citizens of states other

than Idaho. 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.

- 21. This Court has general personal jurisdiction over this case because Defendants each expressly consented to general jurisdiction in New Jersey and/or because New Jersey is Defendants' principal place of business and/or Defendants are essentially at home in New Jersey. Alternatively, the Court has specific personal jurisdiction to adjudicate Plaintiff's claims against Defendants because the claims arise from conduct Defendants each purposefully directed to New Jersey. Defendants manufactured, marketed, designed, promoted, and/or distributed the Nasal Decongestants in and throughout New Jersey, and their actions render the Court's exercise of jurisdiction appropriate under traditional notions of fair play and substantial justice.
- 22. 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 the marketing and sale of the Nasal Decongestants), and Defendants regularly conduct business and are subject to personal jurisdiction in this District.
- 23. All conditions precedent to this action have occurred, been performed, or have been waived.

FACTUAL ALLEGATIONS

A. Nasal Decongestant Misrepresentations and Omissions

24. At least as early as 2017, Defendants manufactured, distributed, marketed, and sold the Nasal Decongestants throughout the United States at premium prices based on a widespread advertising campaign highlighting the Nasal Decongestants' ability to provide nasal decongestion.

25. Defendants sold the Nasal Decongestants directly, through major online third-party retailers including Amazon.com, and in physical retail stores, including Target, Walgreens, and Walmart.

Children's Dimetapp

- 26. At least as early as the beginning of the Class Period (approximately 2017) and continuing to the present, on front and rear product labeling and in advertising, GSK touted Children's Dimetapp's efficacy as a decongestant due to the presence of phenylephrine.
- 27. On the front label, GSK states among other things: "Phenylephrine HCI (Nasal Decongestant)" and "Relieves + comforts: √ Stuffy, runny nose."
- 28. On the rear label, GSK again touts Children's Dimetapp's efficacy as a decongestant due to inclusion of phenylephrine, stating among other things:
 - Active Ingredient (in each tablet) Purpose "Phenylephrine HCI USP 5mgNasal decongestant
 - "Uses
 - o temporarily relieves these symptoms occurring with a cold, hay fever, or other upper respiratory allergies:
 - nasal congestion
- 29. Those misrepresentations are widely echoed on GSK's website and third-party retailer websites. For example, Children's Dimetapp's official website states:
 - There's nothing worse than watching your little one struggle to sleep when they're sick. All you want is to wave a magic wand and help them feel better again. Enter Dimetapp Nighttime Cold & Congestion: it's fast-acting and made to soothe the bothersome symptoms that cause kids to toss and turn at night, helping to quiet coughs and ease runny noses. Shut eye, here you come.
 - Helps relieve your child's: √ Stuffy, runny nose" ¹

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https://www.dimetapp.com/products/dimetapp-nighttime-cold-congestion/

30. GSK also broadly disseminated the misrepresentation that Children's Dimetapp could relieve nasal congestion in television and internet commercials, in print advertisements, and through other promotional channels. For instance, in one commercial for Children's Dimetapp, GSK describes Children's Dimetapp as "the new look! of kids' cold relief" and the phrase "defeats cold symptoms" underscores Children's Dimetapp's packaging:



Dayquil Severe

- 31. At least as early as the beginning of the Class Period (approximately 2017) and continuing to the present, on the front and rear product labeling and advertising, P&G touted Dayquil Severe's efficacy as a decongestant due to the presence of phenylephrine.
- 32. On the front label, P&G states among other things: "Phenylephrine HCI" and "Nasal Decongestion & Sinus Pressure."

- 33. On the rear label, P&G again touts Dayquil Severe's efficacy as a decongestant due to inclusion of phenylephrine, stating among other things:
 - Active Ingredient (in each tablet) Purpose "Phenylephrine HCI 5mgNasal decongestant
 - "Uses
 - o temporarily relieves these common cold/flu symptoms:
 - nasal congestion
 - sinus congestion & pressure
 - reduces swelling of nasal passages
 - temporarily restores freer breathing through the nose
 - promotes nasal and/or sinus drainage
- 34. Those misrepresentations are widely echoed on P&G's website and third-party retailer websites. For example, Dayquil Severe's official website states:
 - Vaporize your cold with Vicks DayQuil VapoCOOL SEVERE Cold & Flu + Congestion Caplets. Experience the powerful, cooling rush of Vicks Vapors and daytime relief that ripples through your senses. Just one dose starts working fast to relieve 9 of your worst cold and flu symptoms. Vicks DayQuil VapoCOOL provides fast, powerful, maximum strength 9-symptom relief you can feel. Helps treat coughing, stuffy nose, minor body pain, chest congestion, sinus congestion, sinus pressure, sore throat, headache, and fever. Use when you need fast, non-drowsy daytime relief for your cold symptoms.²
- 35. P&G also broadly disseminated the misrepresentation that Dayquil Severe could relieve nasal congestion in television and internet commercials, in print advertisements, and through other promotional channels. For instance, in one commercial for Dayquil Severe, a series of purported Dayquil Severe users provide testimonials attesting to Dayquil Severe's ability to relieve nasal congestion, including statements such as "it takes care of all of that sinus build up," and "the pressure was gone:"

https://vicks.com/en-us/shop-products/dayquil/dayquil-severe-vapocool-daytime-cough-cold-and-flu-relief-caplets-24ct.



Maximum Strength Mucinex

- 36. At least as early as the beginning of the Class Period (approximately 2017) and continuing to the present, on front and rear product labeling and in advertising, RB Health touted Maximum Strength Mucinex's efficacy as a decongestant due to the presence of phenylephrine.
- 37. On the front label, RB Health states among other things: "All In One* Nasal Decongestion Sinus Decongestion Sinus Pressure" and "Phenylephrine HCI 5 Nasal Decongestant."
- 38. On the rear label, RB Health again touts Maximum Strength Mucinex's efficacy as a decongestant due to inclusion of phenylephrine, stating (among other things):
 - Active Ingredient (in each tablet) Purpose "Phenylephrine HCI 5mgNasal decongestant
 - "Uses
 - Temporarily relieves these common cold and flu symptoms:
 - sinus congestion and pressure
- 39. Those misrepresentations are widely echoed on RB Health's website and third-party retailer websites. For example, Maximum Strength Mucinex's official website states:
 - Sometimes, when you're sick, you're really sick. 1 dose of this Maximum Strength formula provides relief from 9 symptoms so you can get on with your day.
 - Nasal Congestion³

https://www.mucinex.com/products/mucinex-fast-max-max-strength-severe-cold-liquid-gels-16ct-flow-through

40. RB Health also broadly disseminated the misrepresentation that Maximum Strength Mucinex could relieve nasal congestion in television and internet commercials, in print advertisements, and through other promotional channels. For instance, in one commercial for Maximum Strength Mucinex, a narrator states "Mucinex Cold & Flu All In One Fights Nine" and lists "Sinus Congestion" and "Sinus Pressure" as two of the nine symptoms:



Mucinex Children's

- 41. At least as early as the beginning of the Class Period (approximately 2017) and continuing to the present, on the front and rear product labeling and in advertising, RB Health touted Mucinex Children's efficacy as a decongestant due to the presence of phenylephrine.
- 42. On the front label, RB Health states among other things: "Relieves Stuffy Nose" and "Phenylephrine HCI 2.5 Nasal Decongestant."
- 43. On the rear label, RB Health again touts Mucinex Children's efficacy as a decongestant due to inclusion of phenylephrine, stating (among other things):
 - Active Ingredient (in each tablet) Purpose "Phenylephrine HCI 2,5 mgNasal decongestant

- "Uses
 - o Temporarily relieves:
 - nasal decongestion due to cold
 - stuffy nose
- 44. Those misrepresentations are widely echoed on RB Health's website and third-party retailer websites. For example, Mucinex Children's official website states:
 - Mucinex Children's Multi-Symptom Cold Liquid. A stuffy nose, cough, and chest congestions all adds up to one unhappy camper. Get them relief with this multisymptom medicine.
 - Relieves the following symptoms
 - Nasal Congestion⁴
- 45. RB Health also broadly disseminated the misrepresentation that Mucinex Children's could relieve nasal congestion in television and internet commercials, in print advertisements, and through other promotional channels. For instance, in one commercial for Mucinex Children's, a narrator states "fast acting Mucinex multi-symptom cold breaks up mucus and relieves your child's worst cold symptoms" and lists "Stuffy Nose" as one of the symptoms:



⁴ https://www.mucinex.com/products/mucinex-childrens-multi-symptom-liquid-cold-very-berry

Sudafed PE

- 46. At least as early as the beginning of the Class Period (approximately 2017) and continuing to the present, on front and rear product labeling and in advertising, JJCI touted Sudafed PE's efficacy as a decongestant due to the presence of phenylephrine.
 - 47. On the front label, JJCSI states:
 - "Phenylephrine, HCI, Nasal Decongestant;"
 - "Maximum Strength
 - Sinus Pressure + Sinus Congestion"
- 48. On the rear label, JJCI touts Sudafed PE's efficacy as a decongestant due to inclusion of phenylephrine, stating (among other things):
 - Active Ingredient (in each tablet) Purpose "Phenylephrine HCI 5mgNasal decongestant
 - "Uses
 - o temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
 - sinus congestion and pressure
 - o headache
 - o minor aches and pains
 - o nasal congestion
 - o promotes sinus drainage
 - o temporarily reduces fever[.]
- 49. Those misrepresentations are widely echoed on JJCI's website and third-party retailer websites. For example, Sudafed PE's official website lists the same uses as the rear label and states:
 - Non-drowsy tablets for temporary relief of sinus congestion and pressure with pain, plus headaches. Formulated with acetaminophen for pain relief and phenylephrine HCI as a decongestant.
 - o Sinus pressure and pain relief
 - o Acetaminophen and phenylephrine HCI
 - o Non-drowsy decongestant formula ⁵
 - Uses

https://sudafed.com/products/sudafed-pe-sinus-pressure-pain.

- sinus congestion and pressure
- headache
- o minor aches and pains
- nasal congestion
- o promotes sinus drainage
- o temporarily reduces fever[.]
- 50. JJCI also broadly disseminated the misrepresentation that Sudafed PE could relieve nasal congestion in television and internet commercials, in print advertisements, and through other promotional channels. For instance, in one commercial for Sudafed PE, a narrator states "Sudafed gives you maximum strength sinus pressure and pain relief, so you feel free, liberated, released, decongested, open for business. Powerful sinus relief from the #1 pharmacist recommended brand. Sudafed Open up:"



Defendants Generally

- 51. 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 Nasal Decongestants could not be used as decongestants because—as detailed further below—their active ingredient, phenylephrine, was ineffective as a decongestant when orally ingested.
- 52. At least as early as the beginning of the Class Period (2017), Defendants failed to disclose on the Nasal Decongestants' packaging and labeling (including in the ingredients section) or otherwise that the Nasal Decongestants could not be used as decongestants 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 C).

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

- 53. 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 taken orally fares no better than a placebo according to overwhelming scientific research.
- 54. 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.
- 55. 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."
 - 56. In 2007, based on accumulating scientific evidence, Public Citizen submitted a

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

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).

- 57. 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 placebo and phenylephrine.⁷ In 2009, another study also reported similar findings between phenylephrine and a placebo with respect to decreased nasal congestion scores.⁸
- 58. 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[.]" Upon information and belief, the commercially available phenylephrine tablets were Sudafed PE tablets sold by JJCI.
- 59. 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

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.

⁸ 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.

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

three times the labeled OTC dose for oral phenylephrine are unlikely to be effective. 10

- 60. 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."¹¹.
- 61. 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 the Nasal Decongestants are administered.
- 62. 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

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.

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.

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 Continued to Misrepresent and Omit Material Information While Selling Useless Nasal Decongestants During the Class Period
- 63. 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 Nasal Decongestants in marketing and omitted material information they had a duty to disclose during the Class Period, which is when Plaintiff and the Class purchased the Nasal Decongestants.
- 64. 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 the Nasal Decongestants 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 and omissions, superior knowledge, and sophistication.
- 65. 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.

- 66. During the Class Period, Defendants possessed superior knowledge, not discoverable by Plaintiff, regarding phenylephrine's inefficacy and, in turn, the Nasal Decongestants' inefficacy to treat nasal congestion. During the Class Period, Defendants knew that Plaintiff and other consumers were purchasing the Nasal Decongestants based on Defendants' misrepresentation that the Nasal Decongestants containing phenylephrine treated nasal congestion. Defendants had a duty to disclose their superior knowledge to Plaintiff but did not disclose that information to wrongly protect their business.
- 67. 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 the Nasal Decongestants' benefits on labeling, packaging, and in other promotional materials, including that the Nasal Decongestants could relieve nasal congestion. However, Defendants failed to disclose that, by at least 2017, scientific research had conclusively demonstrated that phenylephrine could not be used to treat nasal congestion.
- 68. During the Class Period, Defendants actively concealed the fact that phenylephrine was ineffective, rendering the Nasal Decongestants worthless. Defendants have long understood that orally ingested phenylephrine does not relieve nasal congestion. 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 did not reduce nasal congestion when compared with placebo pills.
 - 69. Defendants knew that if they disclosed that the Nasal Decongestants did not relieve

nasal congestion, Plaintiff and Class members would not have purchased or used the Nasal Decongestants. To selfishly protect their business, Defendants were motivated to conceal the true facts regarding the Nasal Decongestants' 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 or materially alter the Nasal Decongestants and many other products containing phenylephrine and would reduce revenues by hundreds of millions of dollars or more.

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

D. Plaintiff Purchased Nasal Decongestants During the Class Period Based on Defendants' Misrepresentations and Omissions

- 71. Between 2017 and 2023, Plaintiff purchased packages of Nasal Decongestants from retail stores, including Target, Walgreens, and Walmart. Plaintiff purchased the Nasal Decongestants from these retail stores in Idaho and paid approximately \$9 for Children's Dimetapp; \$17 for Dayquil Severe; \$10 for each package of Mucinex Children's Multi-Symptom Cold; \$14 for Maximum Strength Mucinex; and \$8 for Sudafed PE Sinus Pressure & Pain.
- 72. Prior to purchasing the Nasal Decongestants, Plaintiff reviewed and relied on the product labeling, as well as Defendants' widespread television commercials. Plaintiff also relied on Defendants' omissions of material information regarding phenylephrine's efficacy.
- 73. Defendants did not disclose, and the Nasal Decongestants purchased by Plaintiff did not disclose, that phenylephrine does not temporarily relieve nasal congestion or that clinical studies and overwhelming reliable scientific evidence demonstrated the phenylephrine did not temporarily relieve nasal congestion, material information that would have greatly impacted Plaintiff's purchasing decision.

- 74. Plaintiff used the Nasal Decongestants as directed on the instructions between 2017 and 2023 without any knowledge that phenylephrine does not reduce nasal congestion.
- 75. Plaintiff would not have purchased the Nasal Decongestants—or would have paid a far lower price than she did—had she known that phenylephrine could not temporarily relieve nasal congestion.

E. Tolling of the Statute of Limitations and Estoppel

- 76. 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 Nasal Decongestants' 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.
- 77. 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 Nasal Decongestants. Instead, Defendants made misrepresentations and omitted disclosure of the Nasal Decongestants' inefficacy. Defendants actively concealed the true standard, quality, character, nature, and grade of the Nasal Decongestants and omitted material information about the quality, reliability, and characteristics of the Nasal Decongestants. Plaintiff and Class members reasonably relied on Defendants' knowledge and concealment of the facts alleged herein.
- 78. 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

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

All United States residents who purchased orally-administered Nasal Decongestants 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.

- 80. <u>Numerosity</u>: This proposed class action involves hundreds of millions of dollars or more in sales of Nasal Decongestants, 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.
- 81. <u>Typicality</u>: Plaintiff's claims are typical of those belonging to every member of the Class. Plaintiff and every member of the Class purchased Nasal Decongestants after being exposed to Defendants' misrepresentations and/or without material information only Defendants knew regarding the Nasal Decongestants, but which Defendants withheld from consumers, including Plaintiff and the Class.
- 82. <u>Adequacy:</u> Plaintiff will fairly and adequately protect the interests of the Class, and Plaintiff has retained counsel experienced in complex class action litigation. Plaintiff and her chosen counsel have no interests adverse to those of the Class that she seeks to represent.

A. Rule 23(b)(2)

83. 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 Nasal Decongestants.

B. Rule 23(b)(3)

- 84. 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 Defendants knew that phenylephrine and, in turn, the Nasal Decongestants could not temporarily relieve nasal congestion and the Nasal Decongestants could not temporarily relieve nasal congestion;
 - b) Whether Defendants had a duty to disclose that the Nasal Decongestants could not temporarily relieve nasal congestion;
 - c) Whether Defendants breached the Nasal Decongestants' express and implied warranties;
 - d) Whether Defendants JJCI and RB Health violated the New Jersey Consumer Fraud Act;
 - e) Whether Defendants were unjustly enriched because of their misrepresentations and omissions concerning the Nasal Decongestants' supposed ability to temporarily relieve nasal congestion; and
 - f) Whether Plaintiff and the Class are entitled to damages and restitution.
- 85. 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.
- 86. 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.

- 87. 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.
- 88. 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

- 89. Plaintiff re-alleges and incorporates the allegations made elsewhere in the Complaint as if set forth fully herein.
- 90. Plaintiff brings this claim on behalf of herself and on behalf of the Class against Defendants JJCI and RB Health.
- 91. 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.
- 92. 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).

- 93. 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 JJCI and RB Health are "person(s)" under the NJCFA.
- 94. 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 JJCI and RB Health offered the Nasal Decongestants for sale, constituting "merchandise" under the NJCFA, to the public for sale.
- 95. Defendants' conduct in misrepresenting the benefits of the Nasal Decongestants and/or omitting material information from the Nasal Decongestants labels and other advertising 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.
- 96. Defendants JJCI and RB Health 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 the Nasal Decongestants.
- 97. Defendants JJCI and RB Health intended that Plaintiff and the Class rely on their continuing deception by purchasing the Nasal Decongestants, unaware of the material facts and omissions described above. Defendants knew that its customers would continue to rely on Defendants' representations and omissions that phenylephrine and the Nasal Decongestants were effective. This conduct constitutes consumer fraud within the meaning of the NJCFA.
- 98. Defendants' sale of ineffective and misbranded Nasal Decongestants, 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.

- 99. 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 the Nasal Decongestants based on Defendants' false representation that the Nasal Decongestants 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 the Nasal Decongestants did not relieve nasal congestion, they would not have purchased the Nasal Decongestants.
- 100. Defendants' unconscionable commercial practices, along with their misrepresentations and omissions, make Defendants JJCI and RB Health 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 JJCI and RB Health 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

- 101. Plaintiff re-alleges and incorporates the allegations made elsewhere in the Complaint as if set forth fully herein.
- 102. Plaintiff brings this claim on behalf of herself and on behalf of the Class against Defendants.
- 103. 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 the Nasal Decongestants 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.

- 104. 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 that the Nasal Decongestants could relieve nasal congestion.
- 105. However, Defendants breached the express warranty in that the Nasal Decongestants could not temporarily relieve nasal congestion. As a result of this breach, Plaintiff and the Class in fact did not receive goods as expressly warranted by Defendants.
- 106. At least as early as the beginning of the Class Period, Defendants were on notice of its warranty breaches through interactions with regulatory agencies including the FDA; clinical studies dismissing the link between phenylephrine and nasal congestion relief; and from other external and internal sources. Thus, Plaintiff was not required to provide Defendants with notice of its warranty breaches to the extent Defendants were acting as manufacturers of the Nasal Decongestants; based on futility; and/or because Defendants were on notice of their breaches from other sources (as alleged above).
- 107. 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 advertising warranting that the Nasal Decongestants temporarily relieves sinus congestion; and/or (3) the Nasal Decongestants were consumer merchandise, were sealed, and were meant for human consumption. Moreover, Plaintiff was the known end purchaser of the Nasal Decongestants; the Nasal Decongestants' 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 Nasal Decongestants to Plaintiff. Defendants' retailers were not intended to be the ultimate consumers of the Nasal Decongestants 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

- 108. Plaintiff re-alleges and incorporates the allegations made elsewhere in the Complaint as if set forth fully herein.
- 109. Plaintiff brings this claim on behalf of herself and on behalf of the Class against Defendants.
- 110. Defendants are merchants and were at all relevant times involved in manufacturing, distributing, warranting, and/or selling the Nasal Decongestants.
- 111. The Nasal Decongestants constitute "goods" under the relevant law, and Defendants knew or had reason to know of the specific use for which the Nasal Decongestants, as goods, were purchased.
- 112. The implied warranty of merchantability included with the sale of the Nasal Decongestants means that Defendants guaranteed that the Nasal Decongestants 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.

- 113. Defendants breached the implied warranty of merchantability because the Nasal Decongestants is not fit for its ordinary purpose of temporary relief of nasal congestion and did not conform to labeling representations.
- 114. Had Plaintiff, Class Members, and the consuming public known that the Nasal Decongestants were ineffective and did relieve nasal congestion, they would not have purchased the Nasal Decongestants.
- 115. 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

- 116. Plaintiff re-alleges and incorporates the allegations made elsewhere in the Complaint as if set forth fully herein.
- 117. Plaintiff brings this claim on behalf of herself and on behalf of the Class against Defendants.
- 118. 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 the Nasal Decongestants could temporarily relieve nasal congestion because it contained phenylephrine.
- 119. Defendants' representations were untrue or misleading because the Nasal Decongestants could not relieve nasal congestion and phenylephrine has been scientifically proven as ineffective in relieving sinus congestion.
 - 120. Defendants made these misrepresentations with actual knowledge of their falsity.

- 121. Defendants made the misrepresentations herein alleged with the intention of inducing the public to purchase the Nasal Decongestants.
- 122. Plaintiff, the Class, and the consuming public saw, believed, and reasonably relied on Defendants' advertising, labeling, and packaging when purchasing the Nasal Decongestants.
- 123. 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.
- 124. Moreover, during the Class Period (2017 to the present), Defendants knew that the Nasal Decongestants could not relieve nasal congestion based on clinical studies and other extensive scientific research.
- 125. 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 the Nasal Decongestants' inefficacy; (c) to make partial representations regarding the Nasal Decongestants' inefficacy not misleading; and (d) due to Defendants' active concealment of the Nasal Decongestants' inefficacy.
- 126. Plaintiff and the Class had no actual or constructive knowledge that the Nasal Decongestants could not temporarily relieve sinus congestion because phenylephrine is ineffective when ingested orally. Moreover, Plaintiff and the Class had no duty to investigate the Nasal Decongestants' effectiveness.
- 127. 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 the Nasal Decongestants' ineffectiveness; and (d) to avoid a recall and tens of millions of dollars or more in costs and liability.

- 128. Had Plaintiff and the Class known the truth, they would not have purchased the Nasal Decongestants.
- 129. Defendants' concealment was a substantial factor in causing Plaintiff's and Class's harm.

FOURTH CLAIM FOR RELIEF UNJUST ENRICHMENT

- 130. Plaintiff re-alleges and incorporates the allegations made elsewhere in the Complaint as if set forth fully herein.
- 131. Plaintiff brings this claim on behalf of herself and on behalf of the Class against Defendants.
- 132. Plaintiff and the other members of the Class conferred benefits on Defendants in the form of monies paid to purchase Defendants' ineffective and worthless Nasal Decongestants.
 - 133. Defendants voluntarily accepted and retained this benefit.
- 134. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for ineffective and worthless Nasal Decongestants, it would be unjust and inequitable for Defendants to retain the benefit without paying the value thereof.
- 135. Defendants received benefits in the form of revenues from purchases of the ineffective the Nasal Decongestants 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.
- 136. Defendants have been unjustly enriched in retaining the revenues derived from the purchases of Nasal Decongestants 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 Nasal Decongestants was misleading to consumers, which caused injuries

to Plaintiff and members of the Class, because they would have not purchased the Nasal Decongestants had they known the true facts.

137. 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 herself 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: October 18, 2023

SQUITIERI & FEARON, LLP

By: /s/ Stephen J. Fearon, Jr.
Stephen J. Fearon, Jr.
Paul Sweeny
305 Broadway, 7th Floor
New York, New York 10007
P: (212) 421-6492
F. (212) 421-6553
stephen@sfclasslaw.com
paul@sfclasslaw.com

Attorneys for Plaintiff and the Proposed Class

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m OV}$ Fig. \$10(19/23) Page 1 of 2 PageID: 34

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.)

purpose of initiating the civil d	ocket sheet. (SEE INSTRUC	TIONS ON NEXT PAGE C	OF THIS FO	DRM.)						
I. (a) PLAINTIFFS				DEFENDAN	TS					
Andrea Wilson				Johnson & Johnson Consumer, Inc., et al.						
(b) County of Residence of First Listed Plaintiff (EXCEPT IN U.S. PLAINTIFF CASES)				County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.						
(c) Attorneys (Firm Name, Squitieri & Fearon	•	*	or,	Attorneys (If Kno		Em D II	TOE VED.			
New York, New Y	ork 10007; (212)	421-6492								
II. BASIS OF JURISD	ICTION (Place an "X" in o	One Box Only)		FIZENSHIP OF (For Diversity Cases O		NCIPA		Place an "X" in and One Box for		
1 U.S. Government Plaintiff	_ `		Citize	n of This State	PTF 1	DEF 1	Incorporated <i>or</i> Pri of Business In T		PTF 4	DEF
2 U.S. Government Defendant	Diversity (Indicate Citizenshi	p of Parties in Item III)	Citize	n of Another State	X 2	_ 2	Incorporated and P of Business In A		5	5
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IV. NATURE OF SUIT	Γ (Place an "X" in One Box On	ly)			C1	ick here	for: Nature of S	uit Code De	scription	<u>1S</u> .
CONTRACT	TO	RTS	FO	RFEITURE/PENALT	ГҮ	BAN	KRUPTCY	ОТНЕБ	R STATUT	ES
110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgmen 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excludes Veterans) 153 Recovery of Overpayment	PERSONAL INJURY 310 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Federal Employers' Liability 340 Marine 345 Marine Product Liability	PERSONAL INJURY 365 Personal Injury - Product Liability 367 Health Care/ Pharmaceutical Personal Injury Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPER	[] 69 FY []	5 Drug Related Seizure of Property 21 USC 8 0 Other	881	423 Witi 28 INTE PROPE 820 Cop 830 Pate 835 Pate Nev 840 Trace	thdrawal 376 Qui 3729 ELLECTUAL 400 State 410 Anti 430 Banl 430 Banl 450 Com 460 Deput 470 Rack Corr fend Trade Secrets 480 Cons		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	
of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise	350 Motor Vehicle 355 Motor Vehicle Product Liability 360 Other Personal Injury 362 Personal Injury - Medical Malpractice	370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage 385 Property Damage Product Liability	72 74 75	0 Fair Labor Standards Act 0 Labor/Management Relations 0 Railway Labor Act 1 Family and Medical Leave Act		Act of 2016 485 SOCIAL SECURITY 861 HIA (1395ff) 490 862 Black Lung (923) 850 863 DIWC/DIWW (405(g)) 864 SSID Title XVI 890		485 Telepl Protect 490 Cable. 850 Securi Excha 890 Other		
REAL PROPERTY 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability 290 All Other Real Property	CIVIL RIGHTS 440 Other Civil Rights 441 Voting 442 Employment 443 Housing/ Accommodations 445 Amer. w/Disabilities - Employment 446 Amer. w/Disabilities - Other 448 Education	PRISONER PETITION Habeas Corpus: 463 Alien Detainee 510 Motions to Vacate Sentence 530 General 535 Death Penalty Other: 540 Mandamus & Othe 550 Civil Rights 555 Prison Condition 560 Civil Detainee - Conditions of Confinement	79	0 Other Labor Litigation 1 Employee Retirement Income Security Act IMMIGRATION 2 Naturalization Applic 5 Other Immigration Actions		FEDERA 870 Tax or I 871 IRS	(405(g)) AL TAX SUITS es (U.S. Plaintiff Defendant) — Third Party USC 7609	891 Agricultural Acts 893 Environmental Matte 895 Freedom of Informat Plaintiff Act t) 896 Arbitration Party 899 Administrative Proce		fatters mation rocedure ppeal of
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VII. REQUESTED IN COMPLAINT:		IS A CLASS ACTION		EMAND \$		С	HECK YES only i	if demanded i X Yes	n complai	
VIII. RELATED CASI IF ANY	(See instructions):	_{JUDGE} Kevir	n McN	ulty		_DOCK		23-2037(23-2044		
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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.

Date:

AO 440 (Rev. 12/09) Summons in a Civil Action	
United S	TATES DISTRICT COURT
	District of
Plaintiff V. Defendant))) (Civil Action No.)))
SUM	MONS IN A CIVIL ACTION
To: (Defendant's name and address)	
are the United States or a United States agency, P. 12 (a)(2) or (3) — you must serve on the plai	nmons on you (not counting the day you received it) — or 60 days if you or an officer or employee of the United States described in Fed. R. Civ. Intiff an answer to the attached complaint or a motion under Rule 12 of over or motion must be served on the plaintiff or plaintiff's attorney,
If you fail to respond, judgment by defa You also must file your answer or motion with	nult will be entered against you for the relief demanded in the complaint. the court.

CLERK OF COURT

Signature of Clerk or Deputy Clerk

SCHEDULE A

JOHNSON & JOHNSON CONSUMER, INC. One Johnson & Johnson Plaza New Brunswick, New Jersey 08933

GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US) d/b/a HALEON
2929 Walnut Street, Suite 1700
Philadelphia, Pennsylvania.

PROCTER & GAMBLE COMPANY One Procter & Gamble Plaza Cincinnati, Ohio 45202

RB HEALTH (US) LLC 399 Interpace Parkway Parsippany, New Jersey 07054 AO 440 (Rev. 12/09) 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 (nan	me of individual and title, if any)								
was re	ceived by me on (date)									
	☐ I personally served	the summons on the individu	aal at (place)							
	-		on (date)	; or						
	☐ I left the summons	at the individual's residence of	or usual place of abode with (name)							
	, a person of suitable age and discretion who resides there,									
	on (date)	on (date), and mailed a copy to the individual's last known address; or								
	☐ I served the summe	ons on (name of individual)		, who is						
	designated by law to accept service of process on behalf of (name of organization)									
		on (date)								
	☐ I returned the sum	mons unexecuted because		; or						
	☐ Other (<i>specify</i>):									
	My fees are \$	for travel and \$	for services, for a total of \$							
	I declare under penalty of perjury that this information is true.									
Date:			g , , ,							
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			Printed name and title							
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Additional information regarding attempted service, etc: