UNITED STATES DISTRICT COURT EASTERN DISTRICT OF LOUISIANA

ROBERT FICHERA,	individually, and	on behalf
of all others similarly	situated,	

Case No. _____

Plaintiff,

v.

THE PROCTER & GAMBLE COMPANY, ASSOCIATED WHOLESALE GROCERS, INC., and VALU MERCHANDIERS CO.,

Defendants

CLASS ACTION COMPLAINT

JURY DEMAND

Plaintiff ROBERT FICHERA ("Plaintiff"), by and through the undersigned counsel, brings this action individually and on behalf of all others similarly situated, to seek economic damages for those who paid for or made reimbursements for oral phenylephrine ("PE") as nasal decongestant drugs ("PE drugs") that were illegally and willfully manufactured, distributed, and/or introduced into the market by Defendants The Procter & Gamble Company ("P&G") and by Defendants Associated Wholesale Grocers, Inc. and its subsidiary Value Merchandisers Co. (collectively, "AWG").

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INTRODUCTION

- 1. This case arises from the putative class members' purchase of ineffective and worthless (or, certainly worth less) over-the-counter drugs that were designed, manufactured, marketed, distributed, packaged, and/or ultimately sold by P&G and AWG in the United States that contained phenylephrine ("PE"). Such products for P&G include but are not limited to: DayQuil Severe and NyQuil Severe Cold & Flu. Such products for AWG include but are not limited to: Best Choice Maximum Strength Mucus Relief Sinus Pressure & Pain. All of Defendants' PE-containing products are referred to as "PE Drugs" herein.
- 2. Defendants' PE Drugs are marketed by each Defendant as effective for treating indications identified, most often nasal congestion.
- 3. On September 12, 2023, an FDA advisory panel unanimously voted 16-0 that PE is *not* effective for treating nasal congestion.¹
- 4. As stated by the panel, PE is "not effective as a nasal decongestant." Thus, it recommends avoiding unnecessary costs or delays in care by "taking a drug that has no benefit."
- 5. Thus, Defendants' PE drugs are non-merchantable, not fit for ordinary purpose, and are not effective for treating the indications identified, and were misbranded as a result.
- 6. At all pertinent times for this action, each Defendant represented and warranted to consumers that its PE Drugs were effective for treating the indications identified and were properly branded. Specifically, each Defendant represented and warranted that its PE Drugs were

¹https://www.nytimes.com/2023/09/12/health/cold-medicine-decongestant-fda.html#:~:text=%2C%E2%80%9D%20he%20said.-

<u>The%20F.D.A.,drug%20that%20has%20no%20benefit.%E2%80%9D</u> (last accessed Sept. 12, 2023).

² *Id*.

merchantable and fit for their ordinary uses (e.g., effectively treating nasal congestion).

- 7. However, each Defendant willfully ignored scientific and industry knowledge concerning the lack of effectiveness of PE Drugs for treating the indications identified, and performed inadequate testing and quality oversight of their respective PE Drugs to ascertain properly the true efficacy of their PE Drugs for treating the indications identified (principally, nasal decongestion).
- 8. Defendants' PE Drugs were not effective for treating the indications identified and/or were misbranded (and thereby rendered worthless, or certainly worth less).
- 9. Plaintiff brings this action to recover for the economic and related equitable or injunctive relief for himself and all other persons similarly situated who purchased Defendants' PE Drugs. Each putative class member paid for Defendants' PE Drugs, but those products were not effective for treating the indications identified and/or were misbranded, and they were not fit for ordinary purpose and were not merchantable. As a result of each Defendant's misconduct, each putative class member was damaged. Each Defendant's conduct as alleged herein constitutes breach of express and implied warranties and breach of warranty under the Magnuson Moss Warranty Act, fraud (affirmative and omission), negligent misrepresentation or omission, negligence and negligence per se, breach of consumer protection laws, and unjust enrichment.

PARTIES

A. Plaintiff

10. Plaintiff Robert Fichera is a citizen and resident of Louisiana. During the class period, Plaintiff Fichera paid money for Defendants' PE Drugs. Plaintiff purchased at least one of Defendant P&G's PE Drugs (specifically, a combination package of DayQuil Severe Cold & Flu and NyQuil Severe Cold & Flu), and at least one of Defendant AWG's PE Drugs (specifically,

Best Choice Maximum Strength Mucus Relief Sinus Pressure & Pain) within the applicable limitations periods. Each Defendant expressly and impliedly warranted to Plaintiff (either directly or indirectly by adopting warranties that were passed along to and incorporated further downstream) that their respective PE Drugs were effective at treating the indication identified and were not misbranded. He was exposed to the product packaging and labeling at the time of each purchase, which represented and warranted the product was effective for treating the indications identified, principally nasal congestion. But in fact, Plaintiff bought PE Drugs made by each Defendant that were not effective at treating the indications identified. Had Plaintiff known this, he would not have paid for Defendants' PE Drugs. Likewise, had each Defendant's deceptions been made known earlier, Plaintiff would not have paid for each Defendants' PE Drugs.

B. Defendants

- 11. Defendant The Procter & Gamble Company ("P&G") is an Ohio corporation with its principal place of business and headquarters located at One Procter & Gamble Plaza in Cincinnati, Ohio. At all times material to this case, P&G has been engaged in the manufacturing, sale, and/or distribution of misbranded and ineffective PE Drugs in the United States.
- 12. Defendant Associated Wholesale Grocers, Inc. is a Kansas corporation with its principal place of business at 5000 Kansas Ave., Kansas City, Kansas. Defendant Valu Merchandisers Co. is a Kansas corporation with its principal place of business at 4800 Campbell Drive, Fort Scott, Kansas, and is a wholly owned subsidiary of Associated Wholesale Grocers, Inc. Collectively, both of these Defendants are referred to as "AWG" herein. At all times material to this case, AWG has been engaged in the manufacturing, sale, and/or distribution of misbranded and ineffective PE Drugs in the United States.

JURISDICTION AND VENUE

- 13. This Court has original jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of each Defendant, (b) the amount in controversy exceeds \$5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.
- 14. This Court has personal jurisdiction over Defendants because each Defendant has sufficient minimum contacts in this state, and because each Defendant has otherwise intentionally availed itself of the markets within this state through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.
- 15. Venue is proper in this District because the claims alleged in this action accrued in this District and each Defendant regularly transacts its affairs in this District.
- 16. Each Defendant is subject to the personal jurisdiction of this Court because the Defendants conduct business within this state, maintain and carry out continuous and systematic contacts within this state and this judicial District, regularly transact business within this state and this judicial District, and regularly avail themselves of the benefits of their presence in this state and this judicial District.

FACTUAL ALLEGATIONS

A. History of PE Drugs

17. Phenylephrine ("PE") is a specific alpha-1 adrenergic receptor agonist that works by temporarily constricting blood vessels. By contrast, pseudoephedrine ("PSE") is a relatively less selective agonist that acts on both alpha and beta-adrenergic receptors. The literature reports

that PSE is more lipophilic than PE and thus is more accessible to the central nervous system by crossing the blood-brain barrier (Gheorghiev et al. 2018). The vasoconstriction effect of PSE is likely contributed to by an indirect action via release of norepinephrine in synaptic nerve terminals (Gorodetsky 2014).

- 18. The FM for OTC nasal decongestant drug products, issued in 1994, classified the PEH as a GRASE nasal decongestant when administered orally (immediate-release [IR] formulations) or intranasally (M012.80, previously 21 CFR 341.80). The PEB, an IR effervescent tablet for oral administration, was added to the monograph in 2006, based on pharmacokinetic (PK) data demonstrating that it has similar bioavailability to PEH.
 - 19. The PE drugs at issue in this case fall within two categories:
 - a. Phenylephrine hydrochloride
 - b. Phenylephrine bitartrate
- 20. The Federal Register, dated August 23, 1994 on page 433861 under section III, first allowed Phenylephrine hydrochloride to be sold: "Based on the available evidence, the agency is issuing a final monograph establishing conditions under which OTC nasal decongestant drug products are generally recognized as safe and effective and not misbranded. Specifically, the following ingredients are included in the final monograph as OTC oral nasal decongestants: Phenylephrine hydrochloride, pseudoephedrine hydrochloride, and pseudoephedrine sulfate." ³
- 21. Subsequently, Phenylephrine bitartrate was included in the Federal Register on August 1, 2006 on page 833582: "The Food and Drug Administration (FDA) is issuing a final rule to amend the final monograph (FM) for over-the-counter (OTC) nasal decongestant drug products

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^{3 &}lt;u>https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf.</u>

(drug products used to relieve nasal congestion due to a cold, hay fever, or other upper respiratory allergies) to add phenylephrine bitartrate (PEB), both individually and in combination drug products in an effervescent dosage form, as generally recognized as safe and effective (GRASE)."⁴

22. As a result of the market withdrawal and restrictions on the sale of other α -adrenergic agonists in the early and mid-2000s, Pfizer, Inc, introduced a replacement product (Sudafed-PE) that contained PE. Other manufacturers, including Defendants in this case, similarly followed suit by releasing products containing PE.

B. Questions Surrounding the Efficacy of PE Drugs

- 23. Phenylephrine is an over-the-counter (OTC) ingredient marketed in both single ingredient and combination products.⁴ It has been available in the United States more than 75 years and globally (e.g., Canada, Australia, UK).
- 24. PE has largely been approved for the temporary relief of nasal congestion due to the common cold, hay fever, or other respiratory allergies, or allergic rhinitis under the cough, cold, allergy, bronchodilator, and anti-asthmatic drug products monograph ("final monograph" or "CCABADP").
- 25. On May 1, 2006, two professors at the University of Florida, Dr. Leslie Hendeles, PharmD Professor, Pharmacy and Pediatrics, and Dr. Randy Hatton, PharmD FCCP BCPS Clinical Professor, Department of Pharmacotherapy and Translational Research College of Pharmacy published a letter in Journal of Allergy and Clinical Immunology titled: Oral phenylephrine: An

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^{4 &}lt;u>https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf.</u>

ineffective replacement for pseudoephedrine?⁵ The letter questions the effectiveness of PE for nasal congestion based upon the results of multiple double blind, placebo-controlled studies, that show PE was no more effective than placebo in reducing nasal airway resistance. Moreover, the letter notes that the studies relied on by the FDA to approve PE were unpublished, manufacturer-sponsored studies conducted by commercial testing laboratories.

- 26. On February 1, 2007, three professors from the University of Florida, Leslie Hendeles (PharmD, Professor, Department of Pharmacy and Pediatrics), Randy C. Hatton (PharmD FCCP BCPS, Co-Director, Drug Information and Pharmacy Resource Center, College of Pharmacy Clinical Professor) and Almut G. Winterstein (PhD, Assistant Professor, Department of Pharmacy Healthcare Administration) filed a Citizens Petition with the FDA concerning PE Drugs.⁶
- 27. Specifically, the Petition requested the dosage of oral phenylephrine (PE) be reevaluated and that approval for use in children under twelve years old be withdrawn. The Petition further stated that there was no data on the safety of PE in children under twelve years old. 8
- 28. As a result of the 2007 Citizens Petition, the FDA's Nonprescription Drugs Advisory Committee met on December 14, 2007 and concluded that the products could continue to be sold, but 9 of 12 of the committee members voted that "new studies on response to higher doses were required". Further, a member of the Division of Nonprescription Drug Products expressed a preference for subjective symptom scores over objective measurement of nasal airway

⁵ https://www.jacionline.org/article/S0091-6749(06)00633-6/fulltext.

⁶ https://www.regulations.gov/docket/FDA-2007-P-0108/document.

⁷ https://www.regulations.gov/docket/FDA-2007-P-0108/document.

⁸ https://www.regulations.gov/docket/FDA-2007-P-0108/document.

resistance to support the use of PE for temporary relief of nasal congestion.9

- 29. Schering-Plough Pharmaceuticals responded to the recommendations of the Committee and the Division by conducting a multicenter, phase 2, parallel trial among 539 adults with seasonal allergic rhinitis. The results of the study revealed no significant differences between placebo and active treatment groups. ¹⁰
- 30. Another manufacturer, McNeil Consumer Healthcare, conducted a pharmacokinetic, safety and cardiovascular tolerability study of PE. Similarly, this study revealed no difference in safety endpoints between placebo and 10, 20 and 30 mg of PE even though systemic exposure increased disproportionately with dose. According to the petitioners, "This is noteworthy since both the relief of congestion and systemic endpoints such as change in blood pressure and pulse are mediated by alpha adrenergic stimulation. The absence of a significant effect on the latter at the higher doses suggest that the concentrations reached are not sufficient to stimulate alpha adrenergic receptors." ¹¹
- 31. On November 4, 2015, yet another Citizens Petition was filed by two professors at the University of Florida, Dr. Leslie Hendeles, PharmD Professor, Pharmacy and Pediatrics, and Dr. Randy Hatton, PharmD FCCP BCPS Clinical Professor, Department of Pharmacotherapy and Translational Research College of Pharmacy. The petition asked the FDA "to remove oral phenylephrine from the Final Monograph for OTC nasal decongestant products." Specifically, the petition asked the FDA to remove Phenylephrine and to remove phenylephrine bitartrate (PEB),

⁹ <u>https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf.</u>

¹⁰ https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf.

https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf.

"both individually and in combination drug products in an effervescent dosage form." 12

- 32. According to the 2015 Citizens Petition, "Two additional studies published in 2009 provide further evidence of the absence of a decongestant effect from the FDA-approved nonprescription dose of 10 mg. Horak et al conducted a 3-way crossover, placebo-controlled study of the nasal decongestant effect of single doses of PE 12 mg, pseudoephedrine 60 mg or placebo among 39 grass-sensitive adults exposed to grass pollen in the Vienna Challenge Chamber. PE was not significantly different from 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 PE.
- 33. The 2015 Citizens Petition was further supported by the American Academy of Allergy, Asthma & Immunology. 13
- 34. On information and belief, at this time, each Defendant did not do additional testing and quality oversight of their respective PE Drugs to ascertain the true effectiveness for treating nasal congestion, or deliberately suppressed or avoid doing so. Had they done so and/or disclosed the results, the data would lead to the same inexorable conclusion reached on September 12, 2023 by an FDA Advisory Panel: PE is not effective for treating nasal congestion at all.

C. The FDA Advisory Panel's Unanimous Vote

35. On September 12, 2023, the FDA Advisory Panel on the Division of

^{12 &}lt;u>https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf.</u>

¹³ https://college.acaai.org/wp-content/uploads/2022/05/oral-phenylephrine-final-statement-in-support-of-citizens-petition-05-4-22.pdf.

Nonprescription Drugs recommended that PE Drugs not be sold due to lack of efficacy. 14

36. In the FDA's Briefing Document regarding the hearing that took place on September 11-12, 2023, the FDA notes that it has been reviewing the clinical studies on the efficacy of PE since the 2007 Citizens Petition.¹⁵

37. The Advisory Panel concluded,

In accordance with the effectiveness standard for determining that a category of over-the-counter (OTC) drugs is generally recognized as safe and effective that is set forth in 21 CFR § 330.10(a)(4)(ii), which defines effectiveness as: "a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed", we have now come to the initial conclusion that orally administered PE 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). ¹⁶

38. The Advisory Panel met for two days on September 11-12, 2023. During this meeting, FDA scientists presented the results of five studies conducted over the past two decades on the effectiveness of oral phenylephrine. All the studies concluded that the decongestant was no more effective than a placebo. The Advisory Panel further reevaluated the initial findings which supported PE Drugs' use and found that the results were inconsistent, did not meet modern study design standards and further that these studies may have data integrity issues:¹⁷

"In conclusion, we do believe that the original studies were methodologically unsound and do not match today's standard. By contrast, we believe the new data are credible and do not provide evidence that oral phenylephrine is effective as a nasal decongestant," said Dr. Peter Starke, an FDA official who led the review of

¹⁴ https://www.fda.gov/media/171915/download.

¹⁵ https://www.fda.gov/media/171915/download.

¹⁶ https://www.fda.gov/media/171915/download.

https://www.nbcnews.com/health/health-news/fda-panel-says-common-counter-decongestant-phneylephrine-doesnt-work-rcna104424.

phenylephrine. 18

- 39. At the conclusion of the meetings, members voted unanimously (16-0) that PE drugs were ineffective, paving the way for the drugs to be removed from the market.
- 40. Following this vote by the Advisory Panel, the FDA will now need to decide whether PE Drugs can still be sold and whether drugs should lose their designation as Generally Recognized as Safe and Effective (GRASE).

D. Misbranded Drugs Are Illegal to Sell

- 41. Any drug not manufactured in accordance with cGMPs is deemed "adulterated" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.
 - 42. A drug is misbranded:
 - a. "If its labeling is false or misleading in any particular", 19;
 - b. "If any word, statement, or other information required ... to appear on the label or labeling is not prominently placed thereon...in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use"²⁰;
 - c. If the labeling does not contain, among other things, "the proportion of each active ingredient" 21;

https://www.nbcnews.com/health/health-news/fda-panel-says-common-counter-decongestant-phneylephrine-doesnt-work-rcna104424.

¹⁹ 21 U.S.C. § 352(a)(1).

²⁰ 21 U.S.C. § 352(c).

²¹ 21 U.S.C. § 352(e)(1)(A)(ii).

- d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings ... against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users"²²;
- e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein"²³
- f. "if it is an imitation of another drug"²⁴;
- g. "if it is offered for sale under the name of another drug"²⁵;
- h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof", 26;
- i. If the drug is advertised incorrectly in any manner²⁷; and/or
- j. If the drug's "packaging or labeling is in violation of an applicable regulation." ²⁸
- 43. The manufacture and sale of any misbranded drug is prohibited under federal law.²⁹
- 44. The introduction into commerce of any misbranded drug is also prohibited.³⁰
- 45. Similarly, the receipt in interstate commerce of any misbranded or misbranded drug

²² 21 U.S.C. § 352(f).

²³ 21 U.S.C. § 352(g).

²⁴ 21 U.S.C. § 352(i)(2).

²⁵ 21 U.S.C. § 352(i)(3).

²⁶ 21 U.S.C. § 352(j).

²⁷ 21 U.S.C. § 352(n).

²⁸ 21 U.S.C. § 352(p).

²⁹ 21 U.S.C. § 331(g).

³⁰ 21 U.S.C. § 331(a).

is also unlawful.³¹

46. As articulated in this Complaint, Defendant's sale of PE Drugs that were not effective for treating the indications identified were misbranded in violation of the above-cited reasons.

47. Plaintiff's reference federal law in this Complaint not in any attempt to enforce it, but to demonstrate that their state-law tort claims do not impose any additional obligations on any Defendant, beyond what is already required of them under federal law.

i. Defendant Made False Statements in the Labeling

- 48. A manufacturer must give adequate directions for the use of a pharmaceutical drug so that a "layman can use a drug safely and for the purposes for which it is intended," and conform to requirements governing the appearance of the label. 33
- 49. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,³⁴ and therefore broadly includes nearly every form of promotional activity, including not only "package inserts" but also advertising.
- 50. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising." ³⁵
- 51. Because the labels on Defendants' PE drugs indicate that PE can be used to treat nasal congestion, the subject drugs were misbranded.

³¹ 21 U.S.C. § 331(c).

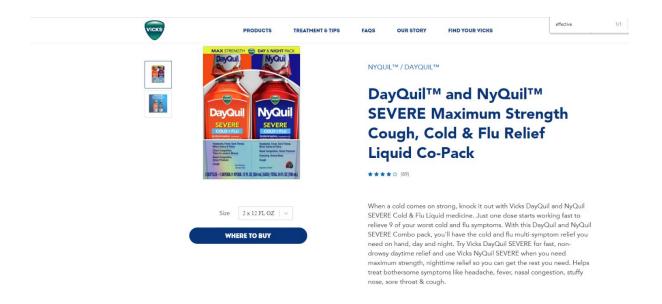
³² 21 C.F.R. § 201.5.

³³ 21 C.F.R. § 801.15.

³⁴ *Id.* 65 Fed. Reg. 14286 (March 16, 2000).

³⁵ U.S. v. Research Labs., 126 F.2d 42, 45 (9th Cir. 1942).

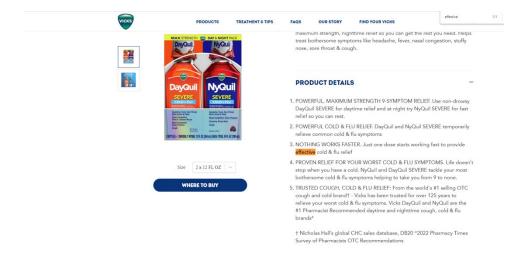
- 52. It is unlawful to introduce a misbranded drug into interstate commerce.³⁶ Thus, the PE Drugs ingested by Plaintiff were unlawfully distributed and sold.
 - ii. Each Defendant's Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their VCDs
- 53. Each Defendant made and breached express and implied warranties and made affirmative misrepresentations and omissions to consumers about their PE Drugs.
- 54. P&G, for instance, touted its PE Drugs as effective for treating nasal congestion. Its website states:



55. P&G further emphasized its drugs' effectiveness (see highlighting below):

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³⁶ 21 U.S.C. § 331(a).



56. Each of P&G's PE Drugs contained PE as advertised active ingredient supposedly effective at treating nasal congestion:



- 57. P&G's representations on its website, product packaging, product label, and other advertisements and promotions, were false and misleading. Contrary to P&G's statements, and undisclosed by P&G, PE was not effective at all for treating nasal congestion. P&G knew, or should have known, this.
- 58. Similarly, Defendant AWG paraded its own PE Drugs' effectiveness at treating nasal congestion. All of AWG's PE Drugs contained PE, as advertised, as a purportedly effective treatment for nasal congestion:



- 59. AWG "proudly" distributed its PE Drugs, emphasizing "consistent quality" that "you can trust," and compared the effectiveness and benefits of its PE Drugs to other competing PE Drugs.³⁷
- 60. AWG's representations on its website, product packaging, product label, and other advertisements and promotions, were false and misleading. Contrary to AWG's statements, and undisclosed by AWG, PE was not effective at all for treating nasal congestion. AWG knew, or should have known, this.
- 61. At all times, P&G and AWG, each separately, warranted that their respective PE Drugs were effective for treating the indications identified (namely, nasal decongestion), and warranted the products were merchantable and fit for purpose.

iii. Fraudulent Concealment and Tolling

62. Plaintiff's and Class Members' causes of action accrued on the date the FDA announced that PE was not effective at treating the indications identified in Defendants' PE Drug labeling and packaging, that is, September 12, 2023.

³⁷ https://bestchoicebrand.com/product/0007003865045/#company.

- 63. Alternatively, any statute of limitation or prescriptive period is equitably tolled on because of fraudulent concealment. Each Defendant affirmatively concealed from Plaintiff and other Class Members its unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of the ineffectiveness of their respective PE Drugs for treating the indications identified, and/or that such products were misbranded.
- 64. For instance, no Defendant revealed to the public that their PE Drugs were *not* effective at treating the indications identified, or that in fact PE was not effective at all to treat same (principally, nasal decongestion), despite reasons to believe the contrary due to their superior knowledge and position and the manufacturer or seller of their respective PE Drugs.
- 65. To the contrary, each Defendant continued to represent and warrant that its respective PE Drugs were effective for treating the indications identified, principally nasal decongestion.
- 66. Because of this, Plaintiff and other Class Members did not discover, nor could they have discovered through reasonable and ordinarily diligence, Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendant's false and misleading explanations, or obfuscations, lulled Plaintiff and Class Members into believing that the prices paid for their PE Drugs were appropriate for what they believed to be non-misbranded drugs despite their exercise of reasonable and ordinary diligence.
- 67. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiff and other Class Members has been tolled. Plaintiff and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiff was unable to discover, and could not have discovered, the unlawful conduct

alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

CLASS ACTION ALLEGATIONS

68. Plaintiff seeks to represent a Nationwide Class pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) as defined below:

National Class: All individuals and entities in the United States and its territories and possessions who paid any amount of money for any Defendant's PE Drugs (intended for personal or household use).

Louisiana Subclass: All individuals and entities in Louisiana who paid any amount of money for any Defendant's PE Drugs (intended for personal or household use).

- 69. Plaintiff alleges additional sub-classes for all Class Members in each State, territory, or possession or combination(s) of States, territories, or possessions to the extent class members from these jurisdictions can be grouped together for purposes of class treatment who, paid any amount of money for PE Drugs (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant (collectively, the "Subclasses").
- 70. Collectively, the foregoing Nationwide Class and the Subclasses are referred to as the "Class."
- 71. Excluded from the Class are: (a) any judge or magistrate presiding over this action, and members of their families; (b) Defendants and affiliated entities, and their employees, officers, directors, and agents; (c) Defendants' legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.
- 72. Plaintiff reserves the right to narrow or expand the foregoing class definition, or to create or modify subclasses as the Court deems necessary.

- 73. Plaintiff meets the prerequisites of Rule 23(a) to bring this action on behalf of the Class.
- 74. **Numerosity**: While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially millions of PE Drug purchasers nationwide. The Class Members are therefore so numerous that joinder of all members is impracticable.
- 75. Existence and predominance of common questions of law and fact: Common questions of law and fact exist as to all Class and Subclass Members and predominate over any questions affecting on individual Class and Subclass members. These common legal and factual questions include, but are not limited to, the following:
 - a. Whether each Defendant made express or implied warranties that their respective PE
 Drugs were effective for treating the indications identified (principally, nasal decongestion);
 - b. Whether each Defendant's PE Drugs were not effective for treating the indications identified (principally, nasal decongestion);
 - c. Whether each Defendant knew or should have known the truth about the effectiveness or lack thereof for their respective PE Drugs;
 - d. Whether Plaintiff and other Class Members have been injured as a result of each
 Defendant's unlawful conduct, and the amount of their damages;
 - e. Whether a common damages model can calculate damages on a class-wide basis;
 - f. When Plaintiff's and Class Members' causes of action accrued; and
 - g. Whether each Defendant fraudulently concealed Plaintiff's and Class Members' causes of action.

- 76. **Typicality**: Plaintiff's claims are typical of Class Members' claims. Plaintiff and Class Members all suffered the same type of economic harm. Plaintiff has substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as the claims of all other Class Members.
- Adequacy of Representation: Plaintiff is committed to pursuing this action and have retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation. Accordingly, Plaintiff and their counsel will fairly and adequately protect the interests of Class Members. Plaintiff's claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiff has no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.
- 78. The elements of Rule 23(b)(2) are met. Defendant has acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.
- 79. **Superiority**: A class action is superior to all other available means for the fair and efficient adjudication of this controversy. Although many other Class Members have claims against each Defendant, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues would not be efficient, timely or proper. Judicial resources would be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiff. Plaintiff's counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions,

and federal court litigation, foresee little difficulty in the management of this case as a class action.

CAUSES OF ACTION

FIRST COUNT BREACH OF EXPRESS WARRANTIES

- 80. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.
- 81. Plaintiff, and each member of the Class, formed a contract with each Defendant at the time Plaintiff and the other Class Members purchased the PE Drugs. The terms of the contract include the promises and affirmations of fact made by Defendant on the PE Drugs' packaging and through marketing and advertising, including that the product would be effective for the indications provided. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Defendants.
- 82. Each Defendant expressly warranted that its PE Drugs were fit for ordinary use and effective for the indications listed and were merchantable and not misbranded.
- 83. Each Defendant sold PE Drugs that they expressly warranted to be effective at treating the indications identified and were not misbranded.
- 84. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. §

- 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313; and Wyo. Stat. § 34.1-2-313.
- 85. Each Defendant knew or should have known that its PE Drugs were being manufactured and sold for the intended purpose of human consumption for treating the indications identified (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their PE Drugs were of merchantable quality and fit for that purpose.
- 86. Each Defendant breached its express warranty because each Defendant's PE Drugs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.
- 87. Each Defendant's express warranties were reflected in each PE Drug's product labeling (e.g., label, instructions, packaging) and promotion and marketing material, all of which uniformly identified PE as an active ingredient for effective treatment of the indications identified, principally nasal decongestion. Each Defendant's product labeling and other materials had to be truthful, accurate, and non-deceptive. But this was not the case, insofar as each Defendant's

product labeling and other materials did not disclose that PE is not effective for the indications identified, principally nasal congestion.

- 88. Each Defendant's PE Drugs did not fulfill their intended purpose. Plaintiff and other Class Members bargained for an adequately made, adequately labeled product, that performed as warranted. But each Defendant's PE Drugs were not adequately made, were not adequately labeled, and did not perform as warranted.
- 89. Plaintiff and other Class Members purchased the PE Drugs in reliance upon Defendant's skill and judgment and the express warranties made.
- 90. Plaintiff and other Class Members were reasonably expected purchasers who would use, consumer or be affected by (or whose insureds would use, consumer or be affected by) the misbranded, not effective PE Drugs marketed by each Defendant.
 - 91. The PE Drugs were not altered by Plaintiff or Class members.
- 92. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendant's PE Drugs they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.
- 93. To the extent applicable, pre-suit notice and/or a demand letter was sent to each Defendant prior to the filing of the Complaint.

SECOND COUNT BREACH OF IMPLIED WARRANTIES

- 94. Plaintiff re-alleges and incorporates the preceding paragraphs as if full set forth herein.
 - 95. Plaintiff, and each member of the Class, formed a contract with each Defendant at

the time Plaintiff and the other Class Members purchased the PE Drugs. The terms of the contract include the promises and affirmations of fact made by Defendant on the PE Drugs' packaging and through marketing and advertising, including that the product would be effective for the indications provided. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Defendants.

96. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 III. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Art. 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. §

- 402.314; and Wyo. Stat. § 34.1-2-314.
 - 97. Each Defendant was a merchant within the meaning of the above statutes.
- 98. Each Defendant's PE Drugs constituted "goods" or the equivalent within the meaning of the above statutes. Each Defendant placed their PE Drugs in sealed packaging or other closed containers and placed them on the market.
- 99. Each Defendant impliedly warranted that its PE Drugs were fit for ordinary use and effective for the indications listed and were merchantable and not misbranded.
- 100. Each Defendant sold PE Drugs that they impliedly warranted to be effective at treating the indications identified and were not misbranded.
- 101. Each Defendant knew or should have known that its PE Drugs were being manufactured and sold for the intended purpose of human consumption for treating the indications identified (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their PE Drugs were of merchantable quality and fit for that purpose.
- 102. Each Defendant breached its implied warranty because each Defendant's PE Drugs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.
- 103. Plaintiff and other Class Members purchased the PE Drugs in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.
- 104. Each Defendant's PE Drugs did not fulfill their intended purpose. Plaintiff and other Class Members bargained for an adequately made, adequately labeled product, that performed as warranted. But each Defendant's PE Drugs were not adequately made, were not adequately labeled, and did not perform as warranted.
 - 105. Each Defendant's implied warranties were reflected in each PE Drug's product

labeling (e.g., label, instructions, packaging) and promotion and marketing material, all of which uniformly identified PE as an active ingredient for effective treatment of the indications identified, principally nasal decongestion. Each Defendant's product labeling and other materials had to be truthful, accurate, and non-deceptive. But this was not the case, insofar as each Defendant's product labeling and other materials did not disclose that PE is not effective for the indications identified, principally nasal congestion.

- 106. Each Defendant's PE Drugs did not fulfill their intended purpose. Plaintiff and other Class Members bargained for an adequately made, adequately labeled product, that performed as warranted. But each Defendant's PE Drugs were not adequately made, were not adequately labeled, and did not perform as warranted.
- 107. Plaintiff and other Class Members purchased the PE Drugs in reliance upon Defendant's skill and judgment and the express warranties made.
- 108. Plaintiff and other Class Members were reasonably expected purchasers who would use, consumer or be affected by (or whose insureds would use, consumer or be affected by) the misbranded, not effective PE Drugs marketed by each Defendant.
- 109. Plaintiff and other Class Members were the intended third-party beneficiary recipients of all arrangements Defendant had with downstream resellers of Defendant's PE Drugs. Plaintiffs and other Class Members were those whose benefit any promises, affirmations, or warranties were made by Defendant concerning the PE Drugs, as they were the intended end purchasers and end users (or, in the case of entities, their insureds were the intended end users) of Defendant's PE Drugs, which Defendant knew by virtue of its position as manufacturer and seller of the PE Drugs.
 - 110. The PE Drugs were not altered by Plaintiff or Class members.

- 111. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendant's PE Drugs they purchased were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.
- 112. To the extent applicable, pre-suit notice and/or a demand letter was sent to each Defendant prior to the filing of the Complaint.

THIRD COUNT MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, ET SEQ.

- 113. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.
- 114. Each Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.
- 115. Plaintiff and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.
- 116. Each Defendant expressly or impliedly warranted their PE Drugs as alleged in the First and Second Causes of Action.
- 117. Under 15 U.S.C. § 2310(d)(1), Plaintiff and other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiff sues pursuant to this section to recover money damages and for legal and equitable relief on behalf of itself and the Class Members.
 - 118. Each Defendant has not acted on the opportunity to cure its failure with respect to

its warranted PE Drugs.

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

FRAUD (AFFIRMATIVE MISRREPRESENATION AND OMISSION)

- 120. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.
- 121. Each Defendant affirmatively misrepresented material facts including, inter alia, that their PE Drugs were effective at treating the indications identified and/or were not misbranded.
- 122. Each Defendant omitted material facts including, inter alia, that their PE Drugs were not effective at treating the indications identifies and/or were misbranded.
- in whole or in part for each Defendant's PE Drugs products which each Defendant knew or should have known were not effective at treating the indications identified and/or were misbranded. Plaintiff and other Class Members would not have purchased Defendants' PE Drugs had they known the truth. Indeed, Plaintiff and other Class Members could not have paid for Defendants' PE Drugs had they known the truth because Defendants' PE Drugs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs and Class Members based on each Defendants' fraudulent misrepresentations and omissions.
- 124. Each Defendant knew or should have known about the effectiveness and branding status of its PE Drugs as a result of industry and regulatory guidance dating back years.
- 125. Each Defendant knowingly, or at least recklessly, represented that its PE Drugs were effective in treating the indications identified and not misbranded, when that was not the

case. Rather, each Defendant knew or recklessly disregarded industry and regulatory guidance that was available to each Defendant.

- 126. Each Defendant knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.
- 127. Each Defendant also knew, or had reason to know, that their misrepresentations and omissions would induce Class Members to pay for some or all of the cost of Defendant's PE Drugs.
 - 128. Each Defendant's misrepresentations and omissions were material.
- 129. Each Defendant's actively concealed their misrepresentations and omissions from the Class, government regulators, and the public.
- 130. To the extent applicable, each Defendant intended their misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for each Defendant's PE Drugs.
- 131. But for these misrepresentations and omissions, Plaintiff and other Class Members would not have paid for each Defendant's PE Drugs.
- 132. To the extent applicable, Plaintiff and other Class Members were justified in relying on each Defendant's misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated, to each Class Member, including through product labeling and other statements by each Defendant. No reasonable consumer would have paid what they did for Defendants' PE Drugs but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.
- 133. Plaintiff and other Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

FIFTH COUNT NEGLIGENT MISREPRESENTATION AND OMISSION

- 134. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.
- 135. Each Defendant had or undertook a duty to represent the effectiveness of its PE Drugs accurately and truthfully.
- 136. Each Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the effectiveness of its PE Drugs.
- 137. Each Defendant negligently misrepresented or omitted facts regarding the effectiveness of its PE Drugs.
- 138. Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).
- 139. Each Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Each Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class Members to make purchases of each Defendant's PE Drugs.
- 140. Each Defendant had a duty to exercise reasonable care in the manufacture, quality control, and distribution of PE Drugs. Each Defendant's failure to exercise this duty, in spite of knowing or recklessly disregarding the effectiveness of its PE Drugs, meant Defendants could not assure that their PE Drugs were of as represented effectiveness.
 - 141. As a direct and proximate result of Defendants' acts and omissions described

herein, Plaintiffs and other Class Members have suffered harm, and will continue to do so.

- 142. Each Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for PE Drugs.
- 143. Each Defendant intended its misrepresentations or omissions to induce Plaintiff and Class Members to make purchases of PE Drugs, or had reckless disregard for same.
- 144. But for these misrepresentations (or omissions), Plaintiff and other Class Members would not have made purchases of Defendants' PE Drugs.
- 145. Plaintiff and other Class Members were justified in relying on Defendants' misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, and/or the same or substantively identical omissions were not communicated, to each Class Member.
- 146. Plaintiff and other Class Members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

SIXTH COUNT VIOLATION OF STATE CONSUMER PROTECTION LAWS

- 147. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.
 - 148. Each Defendant has violated the consumer protection statutes as follows:
 - a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;
 - b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;
 - c. Defendants have engaged in unfair competition or unfair or deceptive acts

- or practices in violation of Arizona Rev. Stat. § 44-1522, et seq.;
- d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, et seq.;
- e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, et seq.;
- f. Defendants have violated the California Consumers Legal Remedies Act,Cal. Civ. Code §§ 1750, et seq.;
- g. Defendants have violated the California False Advertising Law, Cal. Bus.& Prof. Code §§ 17500, et seq.
- h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, et seq.;
- i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;
- j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;
- k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;
- Defendant have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.;
- m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;
- n. Defendants have engaged in unfair competition or unfair or deceptive acts

- or practices in violation of Haw. Rev. Stat. § 480, et seq.;
- o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, et seq.;
- p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, et seq.;
- q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;
- r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, et seq.;
- s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, et seq.;
- t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;
- u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, et seq.;
- v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, et seq.;
- w. Defendant have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;
- x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;
- y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

- z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, et seq.;
- aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;
- bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mo. Rev. Stat. § 407.0 10, *et seq.*;
- cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, et seq.;
- dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, et seq.;
- ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, et seq.;
- ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;
- gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, et seq.;
- hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, et seq.;
- ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, et seq.;
- jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, et seq.;
- kk. Defendants have engaged in unfair competition or unfair or deceptive acts

- or practices in violation of N.D. Cent. Code § 51-15-01, et seq.;
- ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq*.
- mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, et seq.;
- nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, et seq.;
- oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, et seq.;
- pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;
- qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;
- rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;
- ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;
- tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, et seq.;
- uu. Defendant have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, et seq.;
- vv. Defendant have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, et seq.;

- ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;
- xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, et seq.;

 Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, et seq.;
- yy. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, et seq.;
- zz. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and
- aaa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.
- 149. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.
- 150. Each Plaintiff and other Class Member is a consumer or person aggrieved by Defendant's misconduct within the meaning of the above statutes.
- 151. Each Defendant's conduct as alleged herein constitutes unfair, deceptive, misleading, or otherwise actionable practices as to each Defendant's conduct concerning the purported effectiveness of its PE Drugs for treating the indications identified.
- 152. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of each

Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and other Class Members have suffered damages—an ascertainable loss—in an amount to be proved at trial.

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

<u>SEVENTH COUNT</u> UNJUST ENRICHMENT

- 154. Plaintiff re-alleges and incorporates the preceding paragraphs as if full set forth herein.
- 155. As alleged herein, each Defendant was unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendant's PE Drugs.
- 156. Each Defendant profited immensely from the sale of their products in the United States for human consumption. On top of that, because each Defendant's PE Drugs were misbranded, their distribution and sale in the United States was illegal.
- 157. Plaintiff and other Class Members were unjustly deprived of money obtained by each Defendant as a result of the improper amounts paid for Defendant's PE Drugs. It would be inequitable and unconscionable for each Defendant to retain the profit, benefit, and other compensation obtained from Plaintiff and other Class Members as a result of their wrongful conduct alleged in this Complaint. There is no adequate remedy at law for Plaintiff and other Class Members.
- 158. Plaintiff and other Class Members are entitled to seek and do seek restitution from each Defendant as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by each Defendant by virtue of its wrongful conduct.

EIGHTH COUNT NEGLIGENCE

- 159. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.
- 160. Each Defendant owed a duty to Plaintiff and the Class to use and exercise reasonable and due care in the manufacturing and sale of its PE Drugs.
- 161. Each Defendant owed a duty to Plaintiff and the Class to ensure that the PE Drugs it sold in the United States were effective for the indications identified and not misbranded.
- 162. Each Defendant owed a duty of care to Plaintiff and the Class because they were the foreseeable, reasonable, and probable user of PE Drugs and victim of Defendant's fraudulent and deceptive activities. Each Defendant knew, or should have known, that its PE Drugs were not effective for treating the indications identified and were misbranded, and each was in the best position to uncover and remedy these shortcomings.
- 163. Each Defendant failed to do this. Defendant inadequately oversaw the research, development, testing and sale of its own PE Drugs. Each Defendant knew that ignoring the research, development and testing issues surrounding its PE Drugs would damage Plaintiffs and the Class and increase its own profits.
- 164. Each Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its PE Drugs were effective to treat the indications identified and not misbranded.
- 165. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its PE Drugs.

- 166. Each Defendant breached duties owed to Plaintiff and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiff and the Class.
- 167. As a direct and proximate result of each Defendant's negligent conduct, Plaintiff and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

NINTH COUNT NEGLIGENCE PER SE

- 168. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.
- 169. Each Defendant owed a duty to Plaintiff and the Class to use and exercise reasonable and due care in the manufacturing and sale of its PE Drugs.
- 170. Each Defendant owed a duty to Plaintiff and the Class to ensure that the PE Drugs it sold in the United States were effective at treating the indications identified and were not misbranded.
- 171. Each Defendant owed a duty to Plaintiff and the Class because each state, territory, and possession has adopted/or adheres to federal standards, including but not limited to the following parallel state statutes:
 - Alabama Code §§ 20-1-24 and -27(1);
 - Alaska Statutes § 17.20.290(a)(1);
 - Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
 - Arkansas Code § 20-56-215(1);
 - California Health and Safety Code §§ 111295 and 111400;
 - Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
 - Title 16, Delaware Code §§ 3302 and 3303(2);

- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);
- Montana Code §§ § 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

- 172. Each Defendant failed to comply with federal standards, including branding standards.
- 173. As a result of each Defendant's failures to do so, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class.
- 174. As a direct and proximate result of each Defendant's negligent conduct, Plaintiff and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

PRAYER FOR RELIEF

For these reasons, Plaintiff prays for the following judgment:

- A. An order certifying this action as a class action;
- B. An order appointing Plaintiff as Class Representative, and appointing undersigned counsel as Class Counsel to represent the Class;
- C. A declaration that each Defendant is liable under each and every one of the above-enumerated causes of action;
- D. An order awarding appropriate preliminary and/or final injunctive relief against the conduct of each Defendant described above;
- E. Payment to Plaintiff and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid for the PE Drugs; the costs to replace or return PE Drugs; and/or the increases in the amounts paid for non-misbranded substitute products;
- F. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law and/or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

- G. An award of statutory penalties to the extent available;
- H. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and
- I. Such other and further relief as this Court may deem just, equitable, or proper.

JURY DEMAND

Plaintiff respectfully request a trial by jury on all causes of action so triable.

Dated: September 13, 2023

Respectfully Submitted,

/s/ Conlee S. Whiteley
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Kanner & Whiteley, L.L.C.
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New Orleans, LA 70130
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1515 Market Street, Suite 1100
Philadelphia, PA 19102
Tel: 267-435-1300

Attorneys for Plaintiff

JS 44 (Rev. 10/20)

Case 2:23-cv-05274-JT WIND COOPERSTHEEF Filed 09/13/23 Page 1 of 2

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			DEFENDANT	DEFENDANTS				
(b) County of Residence of First Listed Plaintiff (EXCEPT IN U.S. PLAINTIFF CASES)			NOTE: IN LAND	County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF				
(c) Attorneys (Firm Name, Address, and Telephone Number)				THE TRACT OF LAND INVOLVED. Attorneys (If Known)				
II. BASIS OF JURISD	_	One Box Only)	III. CITIZENSHIP OF (For Diversity Cases Onl	y)		Place an "X" in on the control of the Place an "X" in the Pox for I was a second of the Place and the Place and the Place and Table 1997.	Defendant))
Plaintiff	1 U.S. Government 3 Federal Question Plaintiff (U.S. Government Not a Party)		Citizen of This State	PTF DEF 1 1 1	Incorporated <i>or</i> Pri of Business In T		PTF	DEF 4
2 U.S. Government Defendant	4 Diversity (Indicate Citizenship	o of Parties in Item III)	Citizen of Another State	2 2	Incorporated and P of Business In A		5	5
W. MATHER OF CHA			Citizen or Subject of a Foreign Country	3 3	Foreign Nation		<u> </u>	6
IV. NATURE OF SUIT			EODEFITUDE/DENALTS		e for: Nature of S			
110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excludes Veterans) 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise	PERSONAL INJURY 310 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Federal Employers' Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle 355 Motor Vehicle Product Liability 360 Other Personal Injury 362 Personal Injury - Medical Malpractice 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	PERSONAL INJURY 365 Personal Injury - Product Liability 367 Health Care/ Pharmaceutical Personal Injury Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPERT 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage Product Liability PRISONER PETITIONS Habeas Corpus: 463 Alien Detainee 510 Motions to Vacate Sentence 530 General 535 Death Penalty Other: 540 Mandamus & Other 550 Civil Rights 555 Prison Condition 560 Civil Detainee -	of Property 21 USC 88 690 Other Ty LABOR 710 Fair Labor Standards Act 720 Labor/Management Relations 740 Railway Labor Act 751 Family and Medical Leave Act 790 Other Labor Litigation 791 Employee Retirement Income Security Act IMMIGRATION 462 Naturalization Applicat	422 Ap	NKRUPTCY Opeal 28 USC 158 thdrawal USC 157 IRTY RIGHTS pyrights tent - Abbreviated w Drug Application ademark fend Trade Secrets t of 2016 AL SECURITY A (1395ff) ack Lung (923) WC/DIWW (405(g)) ID Title XVI II (405(g)) AL TAX SUITS Exes (U.S. Plaintiff Defendant) S—Third Party 5 USC 7609	375 False C 376 Qui Ta 3729(a 400 State R 410 Antitru 430 Banks : 450 Comme 460 Deport 470 Racket Corrupt 480 Consur (15 US 485 Telephe Protect 490 Cable/S 850 Securit Exchat 890 Other S 891 Agricul 893 Environ Act 896 Arbitra 899 Admin Act/Rei	m (31 USC b)) teapportion tea	t t CC onment ting onced and actions t to r 1692) umer onodities/ Actions s Matters rmation
V. ORIGIN (Place an "X" in	n One Box Only)	Conditions of Confinement						
☐ 1 Original ☐ 2 Removed from Proceeding State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District ☐ 6 Multidistrict ☐ 8 Multidistrict ☐ 6 Litigation - Litigation - Litigation - Direct File								
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):								
VI. CAUSE OF ACTION Brief description of cause:								
VII. REQUESTED IN CHECK IF THIS IS A CLASS ACTION DEMAND \$ CHECK YES only if demanded in complaint: UNDER RULE 23, F.R.Cv.P. JURY DEMAND: Yes No								
VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE DOCKET NUMBER								
DATE		SIGNATURE OF ATTO	ORNEY OF RECORD					
FOR OFFICE USE ONLY								
	MOUNT	APPLYING IFP	JUDGE		MAG. JUD	OGE		

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 statue.

- 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:

110 110 (Rev. 00/12) Buillions in a civil rector	
	S DISTRICT COURT
	for the
Di	istrict of
Plaintiff(s) V. Defendant(s))))) Civil Action No.)))
Desendant(s)	,
SUMMONS IN	N 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 are the United States or a United States agency, or an office	you (not counting the day you received it) — or 60 days if you cer or employee of the United States described in Fed. R. Civ. aswer to the attached complaint or a motion under Rule 12 of ion must be served on the plaintiff or plaintiff's attorney,
If you fail to respond, judgment by default will be You also must file your answer or motion with the court.	e entered against you for the relief demanded in the complaint.
	CLERK OF COURT

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 (no	ame of individual and title, if an	ıy)			
was rec	ceived by me on (date)		·			
	☐ I personally serve	d the summons on the ind	ividual at (place)			
			on (date)	; or		
	☐ I left the summons	s at the individual's reside	ence or usual place of abode with (name)			
	, a person of suitable age and discretion who resides th					
	on (date), and mailed a copy to the individual's last known address; or					
	☐ I served the summ	nons on (name of individual)		, who is		
	designated by law to	accept service of process	s on behalf of (name of organization)			
			on (date)	; or		
	☐ I returned the sum	mons unexecuted because	e	; 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:

Date:

AO 440 (Rev. 00/12) Summons in a Civil Action	
	S DISTRICT COURT for the
D	vistrict of
Plaintiff(s)))))
v.	Civil Action No.
))))
Defendant(s)	,)
SUMMONS II	N A CIVIL ACTION
To: (Defendant's name and address)	
are the United States or a United States agency, or an off	you (not counting the day you received it) — or 60 days if you ficer or employee of the United States described in Fed. R. Civ.
	enswer to the attached complaint or a motion under Rule 12 of tion must be served on the plaintiff or plaintiff's attorney,
If you fail to respond, judgment by default will be You also must file your answer or motion with the court.	be entered against you for the relief demanded in the complaint.
	CLERK OF COURT

Signature of Clerk or Deputy Clerk

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

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	☐ I personally serve	d the summons on the ind	ividual at (place)			
			on (date)	; or		
	☐ I left the summons	s at the individual's reside	ence or usual place of abode with (name)			
	, a person of suitable age and discretion who resides th					
	on (date), and mailed a copy to the individual's last known address; or					
	☐ I served the summ	nons on (name of individual)		, who is		
	designated by law to	accept service of process	s on behalf of (name of organization)			
			on (date)	; or		
	☐ I returned the sum	mons unexecuted because	e	; 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:

Date:

110 110 (Rev. 00/12) Buillions in a civil rector	
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	for the
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Plaintiff(s) V. Defendant(s))))) Civil Action No.)))
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To: (Defendant's name and address)	
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Within 21 days after service of this summons on are the United States or a United States agency, or an office	you (not counting the day you received it) — or 60 days if you cer or employee of the United States described in Fed. R. Civ. aswer to the attached complaint or a motion under Rule 12 of ion must be served on the plaintiff or plaintiff's attorney,
If you fail to respond, judgment by default will be You also must file your answer or motion with the court.	e entered against you for the relief demanded in the complaint.
	CLERK OF COURT

Signature of Clerk or Deputy Clerk

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

Civil Action No.

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			on (date)				
	☐ I left the summons	at the individual's residence or	r 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 summo	ons on (name of individual)			, who is		
	designated by law to a	accept service of process on be	chalf of (name of organization)				
			on (date)	; or			
	☐ I returned the sumn	nons 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	on is true.				
Date:							
			Server's signature				
			Printed name and title				
			Server's address				

Additional information regarding attempted service, etc: