

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

LORISA PINEDA, individually and on behalf of
all others similarly situated,

Plaintiff,

v.

LAKE CONSUMER PRODUCTS, INC..

Defendant

Case No. 24-cv-1074

Jury Trial Demanded

Class Action Complaint

AMENDED CLASS ACTION COMPLAINT

COMES NOW, Plaintiff, Lorisa Pineda, individually and on behalf of all others similarly situated, who files this amended class action complaint against the below-referenced Defendant and alleges and avers as follows.

I. INTRODUCTION

1. This case arises from contaminated and wrongly manufactured shampoo products containing benzene that were designed, manufactured, marketed, distributed, packaged, and/or sold by Defendant (identified and defined *infra*) in the United States. The specific coal tar shampoo products are the MG217 or brand name such as MG217 Psoriasis Extra Strength, MG217 Psoriasis Medicated Conditioning 3% Coal Tar Shampoo, and MG217 Dandruff Therapeutic Shampoo (collectively, the “Coal Tar Shampoo Products”). These Coal Tar Shampoo Products are not merchantable and are not of the quality represented by Defendant named herein.

2. Defendant’s Coal Tar Shampoo Products contain dangerously high, undisclosed levels of benzene, a hazardous genotoxic substance. These dangerously high levels of benzene are

not disclosed by Defendant and were only discovered very recently by testing of Defendant's Coal Tar Shampoo Products.

3. Defendant sought to profit at consumers' expense by wrongly manufacturing, labelling, and selling Coal Tar Shampoo Products that contained undisclosed, dangerous levels of benzene. Benzene is typically used in the manufacture of gasoline and other industry chemicals or textiles. Because of its health effects, in 2011 the United States Environmental Protection introduced regulations that lowered benzene content in gasoline.¹ Meanwhile, Plaintiff and other class members directly and unknowingly purchased Defendant's Coal Tar Shampoo Products to apply to treat their scalps when the products contained undisclosed levels of benzene impurities.

4. The United States Food & Drug Administration ("FDA") has stated that benzene should not be present in any drug product (including an over-the-counter product such as Defendant's Coal Tar Shampoo Products), unless benzene is "unavoidable." But benzene *is* avoidable in the manufacture of shampoos and other products like Defendant's Coal Tar Shampoo Products. Well-known methods, dating back years, exist to process or refine coal tar in such a way as to eliminate the presence of benzene entirely, or at least greatly reduce benzene levels.

5. Defendant did not employ appropriate manufacturing steps, consistent with the FDA's current Good Manufacturing Practices ("cGMPs"), to properly test the Coal Tar Shampoo Products to detect or prevent the high levels of benzene present in them, and to remediate same by applying appropriate manufacturing practices to reduce or eliminate the benzene present.

6. Defendant's cGMP-related manufacturing failures render Defendant's Coal Tar Shampoo Products misbranded and adulterated under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, as well as analogous state statutes and regulations.

¹ EPA Gasoline Mobile Source Air Toxics, available at <https://www.epa.gov/gasoline-standards/gasoline-mobile-source-air-toxics>.

7. Defendant's Coal Tar Shampoo Products were further misbranded or adulterated because their promotional materials, product labels, and other disclosures neither identified benzene nor the fact that the Products were not made in a cGMP-compliant manner.

8. Plaintiff brings this action for economic damages and injunctive relief on behalf of all persons who paid for Defendant's Coal Tar Shampoo Products wrongly manufactured, sold, labeled, marketed, and distributed in the United States. Defendant's Coal Tar Shampoo Products contained high levels of benzene. Defendant's Coal Tar Shampoo Products were of lesser quality and worthless (or certainly worth less) through unacceptable and undisclosed levels of benzene.

9. At all times during the period alleged herein, Defendant represented and warranted to consumers and others that its Coal Tar Shampoo Products were comprised of the materials disclosed on the products' labels, were properly manufactured in a cGMP-compliant manner, and were merchantable and fit for use. Yet, Defendant knowingly, fraudulently, and/or negligently manufactured, labeled, marketed, and/or sold its Coal Tar Shampoo Products that contained extremely high levels of the carcinogenic substance benzene. Defendant has been unjustly enriched through the sale of these knowingly adulterated and/or misbranded products. Defendant's conduct also constitutes actionable fraud, consumer fraud, negligence, and other violations of law as set forth herein.

II. PARTIES

10. Plaintiff Lorisa Pineda (nee Middlecamp) is a citizen of Pennsylvania. During the class period, Plaintiff paid money for one or more of Defendant's Coal Tar Shampoo Products. Specifically, Plaintiff purchased at least one or more Coal Tar Shampoo Products, manufactured and sold at retail to Plaintiff and other consumers as follows. Plaintiff regularly purchased the Coal Tar Shampoo Products since at least 2022, if not earlier. She purchased at least two bottles of

MG217 Psoriasis Medicated Conditioning 3% Coal Tar Shampoo in July 2022 and February 2023. Defendant expressly and impliedly warranted to Plaintiff that the Coal Tar Shampoo Products that Plaintiff purchased were merchantable, properly manufactured, not adulterated or misbranded, of the represented quality, and did not contain any undisclosed substances or risks. But in fact, Plaintiff purchased product that was not of the represented merchantability or quality. As discussed *infra*, the product Plaintiff purchased in February 2023 bears the same expiration date and lot number prefix digit as one of the products tested, the results of which showed high levels of benzene, and therefore the product purchased by Plaintiff contained benzene as well as set forth *infra*.

11. Plaintiff would not have paid money, or at least not the amounts she did pay, for Defendant's Coal Tar Shampoo Products but for Defendant's concealment of the benzene levels in those products, carried the undisclosed risk of potentially containing benzene impurities, and failure to properly manufacture and test the Coal Tar Shampoo Products. Further, Plaintiff used Defendant's Coal Tar Shampoo Products to treat her scalp, not knowing the products were contaminated with harmful levels of benzene. Plaintiff thus suffered cellular and genetic injury and suffered an increased risk that Plaintiff will develop further personal harm injury in the future as a result of such exposure.

12. Defendant Lake Consumer Products, Inc. ("Lake") is a Wisconsin corporation with its principal place of business in Jackson, Wisconsin. At all times material to this action, Lake has been engaged in the manufacture, sale, marketing, and/or distribution of adulterated and/or misbranded Coal Tar Shampoo Products in the United States.

13. Upon information and belief, one or more other entities manufactured, distributed, marketed, and/or sold Coal Tar Shampoo Products during the class period. The true names,

affiliations, and/or capacities of John Doe Defendant are not presently known. However, each John Doe proximately caused damages to Plaintiff and other class members as alleged herein, and each John Doe is liable to Plaintiff and other class members for the acts and omissions alleged below as well as the resulting damages. Plaintiff will amend the complaint to allege the true names and capacities of the John Does when evidence reveals their identities.

III. JURISDICTION AND VENUE

14. This Court has original jurisdiction pursuant to 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 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.

15. This Court has personal jurisdiction over Defendant pursuant to 28 U.S.C. § 1407, and because Defendant has sufficient minimum contacts in Pennsylvania, and because Defendant has otherwise intentionally availed itself of the markets within Pennsylvania through its business activities, such that the exercise of jurisdiction by this Court is proper and necessary. Further, Plaintiff resides and purchased product in Pennsylvania.

16. Venue is proper in this District because at least one plaintiff resides in this District, 28 U.S.C. § 1391(b)(1); “a substantial part of the events or omissions giving rise to the claim occurred” in this District, 28 U.S.C. § 1391(b)(2); and Defendant is subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

IV. FACTUAL ALLEGATIONS

A. Benzene Is a Harmful Substance

17. Benzene is used primarily as a solvent in the chemical and pharmaceutical

industries, as a starting material and intermediate in the synthesis of numerous chemicals, and in gasoline. The major United States source of benzene is petroleum. The health hazards of benzene have been recognized for over one hundred years.

18. According to the National Toxicology Program (“NTP”), benzene is “*known to be a human carcinogen* based on sufficient evidence of carcinogenicity from studies in humans.”² Benzene has also been “found to be carcinogenic to humans” by the International Agency for Research on Cancer (“IARC”). Benzene was “[f]irst evaluated by IARC in 1974 ... and was found to be carcinogenic to humans (Group 1), a finding that has stood since that time.”³ As noted by the IARC:

In the current evaluation, the Working Group again confirmed the carcinogenicity of benzene based on sufficient evidence of carcinogenicity in humans, sufficient evidence of carcinogenicity in experimental animals, and strong mechanistic evidence The Working Group affirmed the strong evidence that benzene is genotoxic, and found that it also exhibits many other key characteristics of carcinogens, including in exposed humans. In particular, benzene is metabolically activated to electrophilic metabolites; induces oxidative stress and associated oxidative damage to DNA; is genotoxic; alters DNA repair or causes genomic instability; is immunosuppressive; alters cell proliferation, cell death, or nutrient supply; and modulates receptor-mediated effects.⁴

Likewise, the Food and Drug Administration (“FDA”) recognizes that “[b]enzene is a carcinogen that can cause cancer in humans”⁵ and classifies benzene as a “Class 1” solvent that should be a “avoided.”⁶ FDA’s Guidance for Industry states that “Solvents in Class 1 ... should not be employed in the manufacture of drug substances, excipients, and drug products because of their unacceptable toxicities or deleterious environmental effect.”⁷ Benzene also is associated with

² <http://ntp.niehs.nih.gov/go/roc/content/profiles/benzene.pdf> (emphasis added).

³ Benzene / IARC Working Group on the Evaluation of Carcinogenic Risks to Humans (2017:Lyon, France), at p. 33.

⁴ *Id.* at 34.

⁵ <https://www.fda.gov/food/chemicals/questions-and-answers-occurrence-benzene-soft-drinks-and-other-beverages#q1>.

⁶ <https://www.fda.gov/media/71737/download>.

⁷ FDA Guidance for Industry, Q3C Impurities: Residual Solvents (6/30/2017), available at <https://www.fda.gov/media/71736/download>.

blood cancers such as leukemia.

19. Aside from carcinogenicity, benzene is associated with numerous side effects, including vomiting, stomach irritation, dizziness, sleepiness, convulsions, irregular heartbeat, tissue injury, bone marrow damage, decrease in red blood cells, anemia, irregular menstrual cycles, low fertility, and excess bleeding.

20. For instance, the Centers for Disease Control and Prevention (“CDC”) warns that “[b]enzene works by causing cells not to work correctly. For example, it can cause bone marrow not to produce enough red blood cells, which can lead to anemia. Also, it can damage the immune system by changing blood levels of antibodies and causing the loss of white blood cells.”⁸ The CDC also advises that “[d]irect exposure of the eyes, skin, or lungs to benzene can cause tissue injury and irritation.”⁹

B. cGMP Regulations

21. As OTC drug products regulated by the FDA, the Coal Tar Shampoo Products must be both safe and effective and are subject to federal current Good Manufacturing Practices (“cGMP”) regulations, and analogous states’ laws. These cGMP regulations require products like the Products to meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

22. The cGMPs establish “minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is

⁸ Centers for Disease Control and Prevention, Facts About Benzene, <https://emergency.cdc.gov/agent/benzene/basics/facts.asp>.

⁹ *Id.*; *see also*, e.g., National Institute for Occupational Safety and Health (NIOSH), Benzene, <https://www.cdc.gov/niosh/npg/npgd0049.html>.

represented to possess.” 21 C.F.R. § 210.1(a). In other words, manufacturers and sellers, like Defendant, at all phases of the design, manufacture, and distribution chain are bound by these requirements.

23. Any drug product 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.

24. FDA regulations require a drug product manufacturer to have “written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.” 21 C.F.R. § 211.100.

25. A drug product manufacturer’s “[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity.” 21 C.F.R. § 211.160.

26. “Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays” and a “statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested.” 21 C.F.R. § 211.194(a)(6).

27. Given the long history and widespread use of similar products without any benzene contamination, the use of benzene in the Coal Tar Shampoo Products is not “unavoidable,” and *any* level of benzene in the Coal Tar Shampoo Products is therefore unacceptable.

28. Defendant could have avoided any potential for benzene contamination in the Products by changing the manufacturing process or raw ingredients, and the Products could have been sold with absolutely no benzene in them.

29. The mere presence of benzene—which, upon information and belief, resulted from Defendant’s failure to comply with cGMPs—renders the Coal Tar Shampoo Products both adulterated and misbranded under the FDCA. The Coal Tar Shampoo Products are adulterated because they are “drug[s] and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.” 21 U.S.C. § 351(a)(1).

30. The Products are misbranded because their labeling is “false” and “misleading” because it does not disclose the presence of benzene. 21 U.S.C. § 352(a)(1).

31. A product that is “adulterated” or “misbranded” cannot legally be manufactured, advertised, distributed, or sold. 21 U.S.C. § 331(a). Adulterated and misbranded products thus have no economic value and are legally worthless; at a minimum (and alternatively), such products are worth lesser amounts than what Plaintiff and other class members paid for them.

32. FDA regulations also require, among other things, that a product be “manufactured in compliance with current good manufacturing practices, as established by parts 210 and 211,” *see* 21 C.F.R. § 330.1(a), and that the product “contains suitable inactive ingredients which are safe in amounts administered[,]” 21 C.F.R. § 330.1(e).¹⁰

¹⁰ “An inactive ingredient is any component of a drug product other than the active ingredient.” *See* FDA, *Inactive Ingredients in Approved Drug Products: Frequently Asked Questions*, at <https://www.fda.gov/drugs/drug-approvals-and-databases/inactive-ingredients-approved-drug-products-search-frequently-asked-questions>.

33. Plaintiffs reference federal law herein not in any attempt to enforce it, but to demonstrate that their state-law tort claims do not impose any additional obligations on Defendant, beyond what was already required of them under federal law.

B. Benzene Contamination in Defendant's Coal Tar Shampoo Products

34. The composition and properties of a coal tar depend primarily on the temperature of the carbonization and to a lesser extent on the nature (source) of the coal used as feedstock.

35. In general, coal tars are complex combinations of hydrocarbons, phenols, and heterocyclic oxygen, sulfur, and nitrogen compounds. Over 400 compounds have been identified in coal tars, and as many as 10,000 may actually be present.

36. Benzene is a substance found in, and that may be removed through refinement from, coal tar.

37. A manufacturer such as Defendant has an obligation to reduce or eliminate benzene from its Coal Tar Shampoo Products.

38. A manufacturer such as Defendant also has an obligation to test its Coal Tar Shampoo Products for undisclosed and/or potentially harmful substances, such as benzene.

39. Defendant did not properly manufacture its Coal Tar Shampoo Products to reduce or eliminate benzene or properly test and monitor its Coal Tar Shampoo Products for the presence of benzene.

40. Defendant never disclosed that any of its Coal Tar Shampoo Products contained any amount of benzene or posed any health risks associated with benzene.

41. However, Defendant's Coal Tar Shampoo Products did in fact contain benzene.

42. In February 2024, an independent analytical laboratory tested six samples of the Coal Tar Shampoo Products, two samples apiece for MG217 Psoriasis Extra Strength, MG217

Psoriasis Medicated Conditioning 3% Coal Tar Shampoo, and MG217 Dandruff Therapeutic Shampoo.

43. One of the samples of the MG217 Psoriasis 3% Coal Tar Shampoo tested bore the same expiration date – 9/2025 – as a bottle that Plaintiff had purchased. This same tested sample also bears the same two initial digits in its lot number – “92” – as the same bottle that Plaintiff purchased. That is, one of the samples tested bears the exact same expiration date and lot number prefix digits as one bottle purchased by Plaintiff. This same sample was found to contain benzene at a level of 9.64ppm. This is many times higher than the 2ppm limit the FDA has established when benzene is “unavoidable,” but here benzene is avoidable and should have not been present at all.

44. The other five samples tested contained benzene at levels of 5.64ppm, 6.04ppm, 7.56ppm, 9.21ppm, and 10.30ppm.

45. Manufacturing processes for OTC drugs, including the Coal Tar Shampoo Products, are required by cGMP regulations to follow the same steps and procedures for every production run, to ensure that each product meet the same specifications for identity, strength, quality, and purity. In other words, the manufacturing process must yield products that are virtually identical compositionally to assure they are safe, effective, not adulterated, and not misbranded.

46. Moreover, all of the Coal Tar Shampoo Products contain the exact same, singular active ingredient (coal tar) derived the exact same way (“from Coal Tar Topical Solution, USP 20%”). All of the Coal Tar Shampoo Products contain the exact same active ingredient, that adheres to the same standardized United States Pharmacopoeia (“USP”) formula (which does not include any tolerance limit for benzene, meaning it should not be present).

47. That 100% of the samples tested contained high levels of benzene strongly and

plausibly suggests that Defendant's manufacturing process was systematically flawed, inasmuch as the same repeated flaw (benzene) was found in every sample tested.

48. Between one sample bearing the same expiration date and lot number prefix digits as a product purchased by Plaintiff, and the uniform presence of benzene as a result of a common-by-design manufacturing process that uses the exact same singular active ingredient that adheres to the same specification across all products, it is plausible (and indeed, likely) that every Coal Tar Shampoo Product contained benzene due to Defendant's systematic cGMP failures to test, identify, and remove benzene. At a minimum, Defendant's inability to assure consumers that benzene is not present in a particular bottle is itself a deviation from cGMP and renders all Coal Tar Shampoo Products unmerchantable and unfit for use. No reasonable consumer would knowingly buy a product for which the manufacturer cannot vouch for the product's identity, strength, quality, and purity. Indeed, such a product would be considered adulterated or misbranded and illegal to sell.

49. Again, there should not be any benzene in Coal Tar Shampoo Products. The FDA re-affirmed recently: "Under section 501(a)(2)(b) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), a drug that is not manufactured, processed, packed, or held in conformity with current good manufacturing practice to assure that the drug meets requirements for safety, and quality and purity characteristics, which it purports or is represented to possess, is considered adulterated. ***Manufacturers should not use benzene in the manufacture of drugs.***"¹¹ By comparison, other firms recently recalled various sunscreen products for containing benzene levels up to 2ppm. The levels in Coal Tar Shampoo Products is at least the same, if not greater.

¹¹ Reformulating Drug Products that Contain Carbomers Manufactured with Benzene, Guidance for Industry (December 2023), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reformulating-drug-products-contain-carbomers-manufactured-benzene> (emphasis added).

C. Fraudulent Concealment, Tolling, and Continuing Violations

50. Plaintiff's and other class members' causes of action could not and did not accrue prior to the filing of this complaint because Defendant actively concealed and did not reveal the presence of benzene in Coal Tar Shampoo Products.

51. Plaintiff and other class members exercised reasonable diligence but could not discover Defendant's wrongful conduct earlier.

52. For instance, Defendant did not reveal to the public that its Coal Tar Shampoo Products contained benzene, or the levels of benzene present, or the insufficient manufacturing processes Defendant utilized to manufacture the Coal Tar Shampoo Products.

53. To the contrary, each Defendant continued to represent and warrant that the Coal Tar Shampoo Products were merchantable, fit for intended purpose, and of the quality and composition as marketed.

54. 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 other class members into believing that the prices paid for Coal Tar Shampoo Products were appropriate despite their exercise of reasonable and ordinary diligence.

55. Alternatively, any statute of limitation or prescriptive period is equitably tolled on account of fraudulent concealment. Defendant affirmatively concealed from Plaintiff and other class members its unlawful conduct. Defendant affirmatively strove to avoid disclosing its knowledge or the true nature of its Coal Tar Shampoo Products.

56. As a result of Defendant's affirmative and other acts of concealment, any applicable

statute of limitations affecting the rights of Plaintiff or 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.

57. Defendant's wrongful conduct and obfuscation thereof constitutes continuing violations for purposes of any limitations period.

V. CLASS ACTION ALLEGATIONS

58. Plaintiff brings this action both individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3) against Defendant on Plaintiff's own behalf and on behalf of the Class(es) defined below, to the extent class members from these jurisdictions can be grouped together for purposes of class treatment:

All individuals and entities in the United States and its territories and possessions who, within the applicable limitation periods to the present, paid any amount of money for Coal Tar Shampoo Products (intended for personal use) that were manufactured, distributed, or sold by Defendant.

59. Plaintiff also alleges the following Subclass:

All individuals and entities in Pennsylvania and its territories and possessions who, within the applicable limitation periods to the present, paid any amount of money for a Coal Tar Shampoo Product (intended for personal use) that were manufactured, distributed, or sold by Defendant.

60. Excluded from the Class(es) are: (a) any judge or magistrate presiding over this action, and members of their families; (b) Defendant and its employees, officers, directors, and agents; (c) Defendant's legal representatives, assigns, and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

61. Plaintiff reserves the right to narrow or expand the foregoing class definitions, or to create or modify subclasses as the Court deems necessary.

62. Plaintiff meets the prerequisites of Rule 23(a) to bring this action on behalf of the Class(es).

63. **Numerosity:** While the exact number of class members cannot be determined without discovery, they are believed to consist of potentially millions of consumers nationwide. The Class(es) are therefore so numerous that joinder of all members is impracticable.

64. **Commonality:** Common questions of law and fact exist as to all class members, including, but not limited to:

- a. Whether Defendant made express or implied warranties to Plaintiff and other class members regarding its Coal Tar Shampoo Products;
- b. Whether Defendant's Coal Tar Shampoo Products contained undisclosed benzene impurities and the levels of such impurities;
- c. Whether Defendant violated standards relating to the manufacture or testing of its Coal Tar Shampoo Products;
- d. Whether Defendant falsely claimed that its Coal Tar Shampoo Products were merchantable, fit for intended purposes, and otherwise of the quality and composition represented;
- e. Whether Defendant affirmatively or negligently misrepresented or omitted facts regarding its manufacture, sale, or testing of its Coal Tar Shampoo Products;
- f. Whether Plaintiff and other class members have been economically, or are at greater risk of bodily injury in the future, as a result of Defendant's unlawful conduct, and the amount of their damages;

- g. Whether a common damages model can calculate damages on a class-wide basis;
- h. When Plaintiff's and other class members' causes of action accrued; and
- i. Whether Defendant fraudulently concealed Plaintiff's and other class members' causes of action.

65. **Typicality:** Plaintiff's claims are typical of other class members' claims. Plaintiff and other 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.

66. **Adequacy of Representation:** Plaintiff is committed to pursuing this action and has retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation. Accordingly, Plaintiff and Plaintiff's counsel will fairly and adequately protect the interests of other 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 conflict with other class members and will fairly and adequately represent the interests of class members.

67. The elements of Rule 23(b)(2) are met. Defendant has acted on grounds that apply generally to all class members so that preliminary and/or final injunctive relief and corresponding declaratory relief are appropriate respecting the Class(es) as a whole.

68. The requirements of Rule 23(b)(3) are met. The common questions of law and fact enumerated above predominate over the questions affecting only individual class members, and a class action is the superior method for fair and efficient adjudication of the controversy. Although many other class members have claims against 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 plaintiffs. 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.

VI. CAUSES OF ACTION

A. Count I - Breach of Express Warranty Against Defendant

69. Plaintiff alleges this claim for relief on behalf of herself and all similarly situated class members, both those in Pennsylvania and those in other states the laws of which do not conflict with Pennsylvania law.

70. Plaintiff incorporates the allegations above as though fully set forth herein.

71. Plaintiff and each other class member as set forth in this subsection formed a contract with Defendant at the time they purchased Coal Tar Shampoo Products. The terms of the contract included the promises and affirmations of fact made by Defendant on the Coal Tar Shampoo Products' packaging and through marketing and advertising, including that the products would be of the quality and character as represented. 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 class members and Defendant.

72. Defendant expressly warranted that its Coal Tar Shampoo Products were fit for ordinary use, were safe and effective for their intended use, were manufactured in a cGMP-

compliant manner, were not adulterated or misbranded, and did not contain any undisclosed impurities, substances, or risks.

73. Defendant sold Coal Tar Shampoo Products that it expressly warranted were manufactured and tested properly and did not contain any undisclosed impurities, substances, or risks. This includes statements in the product labeling and packaging that described the product as safe and effective without disclosing the presence or levels of benzene.

74. Defendant's Coal Tar Shampoo Products did not conform to its express representations and warranties because the product was not manufactured, tested, or marketed properly to account for undisclosed impurities, substances, or risks. Defendant also touted using the Coal Tar Shampoo Products at least twice a week for "best results," when in fact using the products in such manner compounded the risks of exposure to undisclosed benzene.

75. At all times relevant times, Pennsylvania and all other states had codified and adopted the provisions of the Uniform Commercial Code governing the warranty of merchantability and fitness for ordinary purpose.

76. At the time Defendant marketed and sold its Coal Tar Shampoo Products, Defendant recognized the purposes for which the products would be used and expressly warranted the products were manufactured properly, tested properly, and did not contain any undisclosed impurities, substances, or risks. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiff and every other class member.

77. Defendant breached its express warranties with respect to its Coal Tar Shampoo Products as they were not of merchantable quality, were not fit for their ordinary purpose, and contained undisclosed impurities, substances, or risks.

78. Plaintiff and each other class member would not have purchased the Coal Tar

Shampoo Products had they known these drugs contained undisclosed benzene impurities, carried the undisclosed risk of potentially containing benzene impurities, or that the products did not have the represented safety and efficacy profile. Or, alternatively, Plaintiff and each other class member would have paid less for the Coal Tar Shampoo Products.

79. Direct privity exists between Defendant and Plaintiff and each other class member. Alternatively, direct privity is not required between Defendant and Plaintiff and each other class member because, among other things, Defendant is a manufacturer and made direct statements about the safety of its products and intended its statements and affirmations to flow to Plaintiff and to each other class member.

80. As a direct and proximate result of Defendant's breach of warranty, Plaintiff and each other class member have been injured and suffered damages in the amount of the purchase price of their medications, the purchase price of any replacement medications, and any consequential damages resulting from the purchases, in that the Coal Tar Shampoo Products they purchased were so inherently flawed, unfit, or unmerchantable as to have no market value.

81. Although Plaintiff does not seek to recover for physical injuries, Defendant's Coal Tar Shampoo Products carried undisclosed risks and resulted in physical impact to Plaintiff and other class members, including unbargained for, undisclosed sub-cellular or structural impact on Plaintiff's and each other class member's bodies.

82. Pre-suit notice is not required, but even if it is, such notice was provided to Defendant.

B. Count II - Breach of Implied Warranty Against Defendant

83. Plaintiff alleges this claim for relief on behalf of himself and all similarly situated class members, both those in Pennsylvania and those in other states, the laws of which do not

conflict with Pennsylvania law.

84. Plaintiff incorporates the allegations above as though fully set forth herein.

85. Plaintiff and each other class member formed a contract with Defendant at the time they purchased the Coal Tar Shampoo Products. The terms of the contract include the promises and affirmations of fact made by Defendant on the Coal Tar Shampoo Products' packaging and through marketing and advertising, including that the product would be of the quality and character as represented. 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 class members and Defendant.

86. Defendant impliedly warranted that its Coal Tar Shampoo Products were fit for ordinary use, were safe and effective for intended use, were manufactured in a cGMP-compliant manner, were not adulterated or misbranded, and did not contain any undisclosed impurities, substances, or risks. This includes statements in the product labeling and packaging that described the product as safe and effective without disclosing the presence or levels of benzene.

87. At the time Defendant marketed and sold its Coal Tar Shampoo Products, Defendant recognized the purposes for which the products would be used and impliedly warranted the products were manufactured properly, tested properly, and did not contain any undisclosed impurities, substances, or risks. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiff and every other class member.

88. At all times relevant times, Pennsylvania and all other states had codified and adopted the provisions of the Uniform Commercial Code governing the warranty of merchantability and fitness for ordinary purpose.

89. Defendant was a merchant within the meaning of the above statute.

90. Defendant's Coal Tar Shampoo Products constituted goods or products within the meaning of the products to which implied warranty attaches.

91. Defendant was obligated to provide Plaintiff and each other class member as set forth in this subsection reasonably fit Coal Tar Shampoo Products for the purpose for which the product was sold and to conform to the standards of the trade in which Defendant is involved such that the product was of fit and merchantability quality.

92. Defendant knew or should have known that its Coal Tar Shampoo Products were being manufactured and sold for the intended purpose and impliedly warranted that its Coal Tar Shampoo Products were of merchantable quality and fit for that purpose.

93. Defendant breached its implied warranty because its Coal Tar Shampoo Products were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

94. Plaintiff and each other class member would not have purchased the Coal Tar Shampoo Products had they known these products carried undisclosed risks, or, alternatively, would not have purchased them on the same terms (e.g., purchased them for substantially less).

95. To the extent applicable, direct privity is not required between Defendant and Plaintiff or other class members because, among other things, Defendant is a manufacturer and made direct statements about the safety of its products and intended its statements and affirmations to flow to Plaintiff and other class members. Further, Plaintiff and each other class member were intended third-party beneficiaries to the extent Defendant made any warranty or representation to a reseller who in turn resold Coal Tar Shampoo Products to consumers.

96. As a direct and proximate result of Defendant's breach of warranty, Plaintiff and each other class member have been injured and suffered damages in the amount of the purchase

price of the Coal Tar Shampoo Products, in that the Coal Tar Shampoo Products they purchased were so inherently flawed, unfit, or unmerchantable as to have no market value.

97. Although Plaintiff does not seek to recover for physical injuries, Defendant's Coal Tar Shampoo Products carried undisclosed risks and resulted in physical impact to Plaintiff and other class members, including unbargained for, undisclosed sub-cellular or structural impact on Plaintiff's and each other class member's bodies.

98. Pre-suit notice is not required, but even if it is, such notice was provided to each Defendant.

C. Count III - Fraud (Affirmative Misrepresentation, Omission, and Concealment) Against Defendant

99. Plaintiff alleges this claim for relief on behalf of himself and of all similarly situated class members, both those in Pennsylvania and those in other states, the laws of which do not conflict with Pennsylvania law.

100. Plaintiff incorporates the allegations above as though fully set forth herein.

101. Defendant affirmatively misrepresented material facts including, *inter alia*, that its Coal Tar Shampoo Products were not manufactured properly, were not tested properly, and contained any undisclosed impurities, substances, or risks.

102. Defendant omitted material facts including, *inter alia*, that its Coal Tar Shampoo Products were not manufactured properly, were not tested properly, and contained any undisclosed impurities, substances, or risks. This includes statements in the product labeling and packaging that described the product as safe and effective without disclosing the presence or levels of benzene. Defendant's action had the effect of fraudulently inducing customers to pay in whole or in part for Defendant's Coal Tar Shampoo Products – products which it knew or should have known did not comply with the applicable standards and contained undisclosed benzene

impurities.

103. Plaintiff and each other class member would not have purchased the Coal Tar Shampoo Products had they known these drugs contained undisclosed benzene impurities carried the undisclosed risk of potentially containing benzene impurities, or that the products did not have the represented safety and efficacy profile. Or, alternatively, Plaintiff and each other class member would have paid less for the Coal Tar Shampoo Products.

104. Defendant knew, or reasonably should have known, that its misrepresentations were materially false or misleading or that the omission of material facts rendered such misrepresentations false or misleading.

105. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce the Class(es) to pay for some or all of the cost of its Coal Tar Shampoo Products.

106. Defendant's misrepresentations and omissions were material.

107. Defendant actively concealed its misrepresentations and omissions from the Class(es), government regulators, and the public.

108. To the extent applicable, Defendant intended its misrepresentations and omissions to induce Plaintiff, and each other class member as set forth in this sub-section, to pay for its Coal Tar Shampoo Products.

109. But for these misrepresentations and omissions, Plaintiff and each other class member as set forth in this sub-section, would not have paid for Defendant's Coal Tar Shampoo Products. Or, alternatively, Plaintiff and each other class member would have paid less for the Coal Tar Shampoo Products.

110. Defendant's conduct alleged herein demonstrates its intent to deceive Plaintiff and

other class members. Defendant, *inter alia*, intentionally omitted material facts and made affirmative misrepresentations described herein about the Coal Tar Shampoo Products which it knew were false or inaccurate.

111. To the extent applicable, Plaintiff and each other class member as set forth in this sub-section, were justified in relying on Defendant's misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated to each Class(es) member, including through product labeling or other statements by Defendant. No reasonable consumer would have paid what they did for Defendant's Coal Tar Shampoo Products but for its unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

112. Although Plaintiff does not seek to recover for physical injuries, Defendant's Coal Tar Shampoo Products carried undisclosed risks and resulted in physical impact to Plaintiff and other class members, including unbargained for, undisclosed sub-cellular or structural impact on Plaintiff's and each other class member's body.

113. Plaintiff and each other class member as set forth in this sub-section were damaged by reason of Defendant's misrepresentations and omissions alleged herein.

D. Count IV - Negligent Misrepresentation and Omission

114. Plaintiff alleges this claim for relief on behalf of herself and all similarly situated class members, both those in Pennsylvania and those in other states, the laws of which do not conflict with Pennsylvania law.

115. Plaintiff incorporates the allegations above as though fully set forth herein.

116. Defendant had or undertook a duty to accurately and truthfully represent the quality, nature, and characteristics of its Coal Tar Shampoo Products.

117. Defendant failed to exercise ordinary care in making or representing statements (or

in failing to disclose facts) concerning the quality, nature, and characteristics of its Coal Tar Shampoo Products.

118. Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its Coal Tar Shampoo Products. This includes statements in the product labeling and packaging that described the product as safe and effective without disclosing the presence or levels of benzene or that the products were not manufactured in a cGMP-compliant manner, were adulterated, and/or were misbranded. Defendant's action had the effect of fraudulently inducing customers to pay in whole or in part for Defendant's Coal Tar Shampoo Products – products which it knew or should have known did not comply with the applicable standards and contained undisclosed benzene impurities.

119. Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading or that the omission of material facts rendered such representations false or misleading. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Plaintiff and each other class member as set forth in this sub-section, to make purchases of Defendant's Coal Tar Shampoo Products.

120. As a direct and proximate result of Defendant's acts and omissions described herein, Plaintiff and each other class member as set forth in this sub-section have suffered harm and will continue to do so.

121. Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiff's and other class members' paying for Coal Tar Shampoo Products.

122. Defendant intended its misrepresentations or omissions to induce Plaintiff and each other class member as set forth in this sub-section to make purchases of Coal Tar Shampoo Products, or had reckless disregard for same.

123. But for these misrepresentations (or omissions), Plaintiff and each other class member as set forth in this sub-section would not have made purchases of Defendant's Coal Tar Shampoo Products. Or, alternatively Plaintiff and each other class member would have paid less for Coal Tar Shampoo Products.

124. Defendant's conduct alleged herein demonstrates its intent to deceive Plaintiff and other class members. Defendant, *inter alia*, intentionally omitted material facts and made affirmative misrepresentations described herein about the Coal Tar Shampoo Products which it knew were false or inaccurate.

125. Plaintiff and each other class member as set forth in this sub-section were justified in relying on Defendant's misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, and/or the same or substantively identical omissions were not communicated to each purchaser.

126. Defendant owed a special duty to Plaintiff and each other class member on account of the special relationship that existed between Defendant, as a seller of a product to be applied to the human body. On account of the known or knowable application and use of the Coal Tar Shampoo Products, and Defendant's superior knowledge and position as manufacturer, distributor, and seller of the Coal Tar Shampoo Products, Defendant had a special duty to disclose risks to consumers such as Plaintiff and other class members.

127. Although Plaintiff does not seek to recover for physical injuries, Defendant's Coal Tar Shampoo Products carried undisclosed risks and resulted in physical impact to Plaintiff and other class members, including unbargained for, undisclosed sub-cellular or structural impact on Plaintiff's and each other class member's body.

128. Plaintiff and each other class member as set forth in this sub-section were damaged

by reason of Defendant's misrepresentation or omissions alleged herein.

E. Count V - Violation of Consumer Protection Law

129. Plaintiff alleges this claim for relief on behalf of herself and all similarly situated class members, both those in Pennsylvania and those in other states, the laws of which do not conflict with Pennsylvania law.

130. Plaintiff incorporates the allegations above as though fully set forth herein.

131. Defendant has violated the consumer protection statutes as follows:

- a. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;
- b. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;
- c. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;
- d. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;
- e. Defendant 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. Defendant violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;
- g. Defendant violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*;
- h. Defendant engaged in unfair competition or unfair or deceptive acts or

practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

- i. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;
- j. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;
- k. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;
- l. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;
- m. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;
- n. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;
- o. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;
- p. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;
- q. Defendant 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. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;
- s. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

- t. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;
- u. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;
- v. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;
- w. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;
- x. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;
- y. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;
- z. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;
- aa. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;
- bb. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Mo. Rev. Stat. § 407.0 10, *et seq.*;
- cc. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;
- dd. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;
- ee. Defendant engaged in unfair competition or unfair or deceptive acts or

practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

- ff. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;
- gg. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;
- hh. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;
- ii. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;
- jj. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;
- kk. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;
- ll. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*
- mm. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;
- nn. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;
- oo. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;
- pp. Defendant 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. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;
- rr. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;
- ss. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;
- tt. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;
- uu. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;
- vv. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;
- ww. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;
- xx. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;
- yy. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;
- zz. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;
- aaa. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and
- bbb. Defendant 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.

132. Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

133. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the state statutes by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Coal Tar Shampoo Products, including that: such products were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, that the products were not manufactured in a cGMP-compliant manner, were adulterated, were misbranded, and/or contained levels of benzene that rendered them unsafe and unfit.

134. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding the Coal Tar Shampoo Products, as detailed above, Defendant engaged in one or more unlawful practices in violation of the above state statutes. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of the Coal Tar Shampoo Products were disseminated to Plaintiff and each other class member as set forth in this sub-section in a uniform manner. Defendant sold Coal Tar Shampoo Products that it expressly warranted were manufactured and tested properly and did not contain any undisclosed impurities, substances, or risks. This includes statements in the product labeling and packaging that described the product as safe and effective without disclosing the presence or levels of benzene.

135. Defendant's conduct as alleged herein constitutes unfair, deceptive, misleading, or otherwise actionable practices as to Defendant's conduct concerning the ingredients and safety profile for the Coal Tar Shampoo Products. Defendant promised a safe and effective product, but

the products were not as promised because their actual safety profile was not the same as that represented and bargained for.

136. To the extent applicable, Defendant knew, intended, or should have known that its 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 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.

137. Defendant engaged in unlawful conduct by deliberately and knowingly engaging in misleading, deceptive, and false statements regarding the Coal Tar Shampoo Products in the course of Defendant's business. Specifically, Defendant represented that the Coal Tar Shampoo Products were safe and effective and did not carry any undisclosed risks. But this was not the case, as the products carried health risks that were not disclosed. Defendant also did not disclose the cGMP deviations concerning the products' manufacture and testing. Defendant made these misrepresentations, or omitted material information, in its marketing the Coal Tar Shampoo Products, and in the Products' packaging, labeling, and instructions.

138. The existence of undisclosed risks would have been material to Plaintiff and other class members.

139. Plaintiff and other class members suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's concealment, misrepresentations, and/or failure to disclose material information in that Plaintiff and other class members would not have purchased the Coal Tar Shampoo Products, or, alternatively, would not have purchased on the same terms (e.g., purchased them for substantially less), had they known the truth.

140. Although Plaintiff does not seek to recover for physical injuries, the Coal Tar

Shampoo Products carried undisclosed risks and resulted in physical impact to Plaintiff and other class members, including unbargained for, undisclosed sub-cellular or structural impact on Plaintiff's and each other class member's body.

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

F. Count VI - Negligence

142. Plaintiff alleges this claim for relief on behalf of herself and all similarly situated class members, both those in Pennsylvania and those in other states,, the laws of which do not conflict with Pennsylvania law.

143. Plaintiff incorporates the allegations above as though fully set forth herein.

144. Defendant owed a duty to Plaintiff and each other class member to ensure its Coal Tar Shampoo Products were safe and effective, were manufactured properly, were tested properly, and did not contain any undisclosed impurities, substances, or risks.

145. Defendant owed a duty to Plaintiff and each other class member because the latter were foreseeable, reasonable, and probably users of Coal Tar Shampoo Products, and victims of Defendant's deceptive and wrongful conduct. Defendant knew, or should have known, that its Coal Tar Shampoo Products were not safe and effective, were not manufactured properly, were not tested properly, and contained undisclosed risks.

146. Defendant inadequately oversaw its own manufacture, distribution, marketing, and sale of its Coal Tar Shampoo Products, resulting in the Coal Tar Shampoo Products being sold to consumers without disclosure of the true character of the product.

147. Defendant maintained or should have maintained a special relationship with Plaintiff and each other class member, who were anticipated or intended direct and intended third-

party beneficiaries, as it was obligated to ensure that its Coal Tar Shampoo Products were safe and effective, were manufactured properly, were tested properly, and did not contain any undisclosed risks.

148. Defendant also owed a duty to Plaintiff and other class members under the cGMP obligations under federal and analogous state law, insofar as Defendant had a duty to manufacture a cGMP-compliant, non-adulterated, non-misbranded product.

149. Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and each other class member.

150. Defendant breached duties owed to Plaintiff and each other class member by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiff and each other class member.

151. Although Plaintiff does not seek to recover for physical injuries, the Coal Tar Shampoo Products carried undisclosed risks and resulted in physical impact to Plaintiff and other class members, including unbargained for, undisclosed sub-cellular or structural impact on Plaintiff's and each other class member's body

152. As a direct and proximate result of Defendant's negligent conduct, Plaintiff and each other class member suffered injury and are entitled to damages in an amount to be proven at trial.

G. Count VII – Unjust Enrichment

153. Plaintiff alleges this claim for relief on behalf of herself and all similarly situated class members, both those in Pennsylvania and those in other states, the laws of which do not conflict with Pennsylvania law.

154. Plaintiff incorporates the allegations above as though fully set forth herein.

155. Defendant was unjustly enriched at the expense of Plaintiff and each other class member by virtue of their paying for Defendant's Coal Tar Shampoo Products. Plaintiff and each other class member conferred a direct benefit on Defendant by purchasing Defendant's Coal Tar Shampoo Products either directly from Defendant or through a reseller.

156. Defendant profited immensely from selling the Coal Tar Shampoo Products that carried undisclosed risks, that were not manufactured properly, and that were not tested properly.

157. Plaintiff and each other class member were unjustly deprived of money obtained by Defendant as a result of the improper amounts paid for Coal Tar Shampoo Products. It would be inequitable and unconscionable for Defendant to retain the profit, benefit, and other compensation obtained from Plaintiff and each other class member as a result of Defendant's wrongful conduct alleged.

158. In the alternative to the other causes of actions alleged herein, Plaintiff and each other class member have no adequate remedy at law.

159. Although Plaintiff does not seek to recover for physical injuries, Coal Tar Shampoo Products carried undisclosed risks and resulted in physical impact to Plaintiff and other class members, including unbargained for, undisclosed sub-cellular or structural impact on Plaintiff's and each other class member's body.

160. Plaintiff and each other class member are entitled to seek and do seek restitution from Defendant as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendant by virtue of its wrongful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following judgment:

A. An order certifying this action as a class action;

B. An order appointing Plaintiff as Class Representatives and appointing undersigned counsel as Class Counsel to represent the Class;

C. A declaration that Defendant is liable pursuant to 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 Defendant described herein;

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 or reimbursed for the Coal Tar Shampoo Products and Defendant's ill-gotten gains;

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 requests a trial by jury on all causes of action so triable.

Dated: December 20, 2024

/s/ Ruben Honik

Ruben Honik

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