UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CASE NO. 24-cv-3998

LATIFAH ABEDNEGO, individually and on behalf of all others similarly situated, Plaintiff, v. L'OREAL USA, INC., Defendant.	CLASS ACTION **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiff, Latifah Abednego ("Plaintiff"), individually, on behalf of herself, and on behalf of all others similarly situated, by and through her attorneys, brings this class action complaint against Defendant, L'Oreal USA, Inc. ("Defendant"), and alleges the following upon information and belief, except for those allegations pertaining to Plaintiff, which are based on personal knowledge:

NATURE OF THE ACTION

1. This is a class action lawsuit regarding Defendant's manufacturing, distribution, advertising, marketing, and sale of CeraVe branded benzoyl peroxide ("BPO") acne treatment products (the "BPO Products"[1]) that contain dangerously high levels of benzene, a carcinogenic impurity that has been linked to leukemia and other cancers.

2. The presence of benzene in the BPO Products renders them adulterated, misbranded, and illegal to sell under federal and state law.

[1] The BPO Products refer to CeraVe Acne Foam Cream Cleanser with 4% BPO and CeraVe Acne Foaming Cream Wash with 10% BPO.

3. Prior to placing the BPO Products into the stream of commerce and into the hands of consumers to use on their skin, Defendant knew or should have known that the BPO Products contained benzene, but misrepresented, omitted, and concealed this fact to consumers, including Plaintiff and Class members, by not including benzene on the BPO Products' labels or otherwise warning about its presence.

4. Plaintiff and Class members reasonably relied on Defendant's representations that the BPO Products were safe, unadulterated, and free of any carcinogens that are not listed on the label.

5. Plaintiff and Class members purchased the BPO Products, which contain harmful levels of benzene.

6. The BPO Products are worthless because they contain benzene, a known human carcinogen that is an avoidable ingredient in the BPO Products' manufacturing process. Indeed, the presence of benzene renders the BPO Products adulterated, misbranded, and illegal to sell.

7. Defendant is therefore liable to Plaintiff and Class members for misrepresenting and/or failing to disclose or warn that the BPO Products contain benzene or degrade and form benzene over a short period of time.

PARTIES

8. Plaintiff Abednego is a resident and citizen of West Palm Beach, Florida. Plaintiff Abednego purchased Defendant's BPO Products several times from Walgreens, Publix, and Target stores located in West Palm Beach, Florida over a period of at least one year. The last time Plaintiff Abednego purchased one of the BPO Products for personal or household use was in approximately March 2024, when she purchased CeraVe Acne Foaming Cream Wash with 10% BPO at a Walgreens store located in West Palm Beach, Florida.

9. When purchasing the BPO Products, Plaintiff Abednego reviewed the accompanying labels and disclosures and understood them as representations by Defendant that the BPO Products were properly manufactured, free from defects, and safe for their intended use. Plaintiff Abednego relied on these representations when deciding to purchase the BPO Products, and these representations were part of the basis of the bargain. Had Defendant not made the false, misleading, and deceptive representations and omissions regarding the BPO Products containing benzene or that the BPO Products would degrade into benzene in a short period of time under reasonable conditions, Plaintiff Abednego would not have purchased the BPO Products. The BPO Products Plaintiff Abednego purchased were worthless because they contained the known carcinogen benzene. Accordingly, Plaintiff Abednego was injured in fact and lost money as a result of Defendant's improper conduct.

10. Defendant is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware with its principal place of business located in New York, New York. Defendant markets, sells, and distributes the BPO Products at issue in Florida, New York, and throughout the United States. The BPO Products, including those purchased by Plaintiff and Class members, are available for sale on Defendant's website, www.cerave.com, on third party websites (e.g., www.amazon.com), and are sold by various retailers, including Target, Ulta Beauty, CVS Pharmacy, Publix, and Walgreens, both online and in their brick-and-mortar stores throughout the United States. Defendant authorized the false, misleading, and deceptive marketing, advertising, distribution, and sale of the BPO Products.

JURISDICTION AND VENUE

11. This Court has subject-matter jurisdiction pursuant to the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d) because (1) the matter in controversy exceeds the sum or value of

$5,000,000, exclusive of interest and costs, (2) the action is a class action, (3) there are members of the Class who are diverse from Defendant, including Plaintiff and (4) there are more than 100 Class members. This Court has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367 because they form part of the same case or controversy as the claims within the Court's original jurisdiction.

12. This Court has personal jurisdiction over Defendant because Defendant resides and operates in this District.

13. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(1) because Defendant resides in this District.

FACTUAL ALLEGATIONS

A. CeraVe

14. Defendant manufacturers, markets, distributes, and sells various skin care products, including CeraVe Acne Foam Cream Cleanser with 4% BPO and CeraVe Acne Foaming Cream Wash with 10% BPO.

15. Benzoyl peroxide is an active ingredient in all the BPO Products.

16. All of Defendant's BPO Products are manufactured in the same manner.

17. All lots of Defendants' BPO Products systematically degrade to form benzene. As noted below, this is supported by testing of 66 acne treatment products containing benzoyl peroxide, all of which tested positive for benzene at various levels ranging from 2,000 ppm to 1.8 ppm. Defendant's BPO Products, in particular, were tested and found to contain benzene at levels ranging from 5 ppm to over 12 ppm.

18. The rates of degradation and benzene impurities in the BPO Products occur at a systematic rate.

B. Evidence of Benzene's Danger

19. 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.

20. "Human exposure to benzene has been associated with a range of acute and long-term adverse health effects and diseases, including cancer and haematological effects."[2]

21. A toxicity assessment by the Centers for Disease Control and Prevention has shown benzene can harm the central nervous system and may affect reproductive organs.[3]

22. According to the World Health Organization, "Benzene is a genotoxic carcinogen in humans and no safe level of exposure can be recommended."[4]

23. According to the National Cancer Institute, "[e]xposure to benzene increases the risk of developing leukemia and other blood disorders."[5]

24. According to the National Toxicology Program, benzene is "known to be a human carcinogen based on sufficient evidence of carcinogenicity from studies in humans."[6]

25. 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."[7] As noted by the IARC:

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[2] https://www.who.int/publications/i/item/WHO-CED-PHE-EPE-19.4.2.
[3] https://www.atsdr.cdc.gov/toxprofiles/tp3.pdf.
[4] WHO Guidelines for Indoor Air Quality: Selected Pollutants (2010).
[5] https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/benzene.
[6] http://ntp.niehs.nih.gov/go/roc/content/profiles/benzene.pdf (emphasis in original).
[7] Benzene / IARC Working Group on the Evaluation of Carcinogenic Risks to Humans (2017: Lyon, France), at p. 33.

> 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.[8]

26. The U.S. Food and Drug Administration ("FDA") also recognizes that "[b]enzene is a carcinogen that can cause cancer in humans"[9] and classifies benzene as a "Class 1" solvent that should be "avoided" in drug manufacturing.[10] FDA guidance provides: "Solvents in Class 1 [e.g. benzene] should not be employed in the manufacture of drug substances, excipients, and drug products because of [its] unacceptable toxicity."[11]

27. "Even in trace amounts, benzene is known to pose a health risk from exposure routes that include inhalation, ingestion, dermal absorption, and skin or eye contact."[12]

28. In July 2021, the FDA conducted a "Health Hazard Evaluation" on "Multiple Aerosol Sunscreen Products" manufactured by Johnson & Johnson.[13] The evaluation was requested following testing which showed benzene levels ranging "from 11.2 to 23.6 ppm" in Johnson & Johnson's aerosol sunscreen products. Specifically, the agency requested "an evaluation of the likelihood and risks associated with using aerosol sunscreens that contain

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[8] *Id*. at 34.
[9] https://www.fda.gov/food/chemicals/questions-and-answers-occurrence-benzene-soft-drinks-and-other-beverages#q1.
[10] https://www.fda.gov/media/71737/download.
[11] *Id.*
[12] Hudspeth, A., et al., Independent Sun Care Product Screening for Benzene Contamination, Environmental Health Perspectives, 130:3, Online Publication 29 March 2022.
[13] https://article.images.consumerreports.org/prod/content/dam/CRO-Images-2021/Health/12Dec/FDA_Benzene_in_Sunscreen_Assessment.

benzene 11.2 to 23.6 ppm," which "levels exceed the guideline value provided by ICH [Q3C][14] and USP[15]" limits, states the report. The FDA report concluded that serious adverse effects, including potential for "life-threatening" issues or "permanent impairment of a body function" were "likely to occur" at exposure levels within that range. In addition, the report stated that "individuals with altered skin absorption (i.e., infants, elderly, broken skin) and individuals who are exposed to benzene from other sources (e.g. smokers or occupational/environmental exposure) may be at greater risk."

29. On December 27, 2023, in response to reports of benzene contamination in various drug products, the FDA issued an "Alert," advising manufacturers that "If any drug products batches with benzene above 2 ppm are already in distribution, the manufacturer should contact FDA to discuss the voluntary initiation of a recall…."[16]

30. Direct benzene exposure through the skin is particularly concerning, because "[d]irect exposure of the eyes, skin, or lungs to benzene can cause tissue injury and irritation."[17] Accordingly, The National Institute for Occupational Safety and Health ("NIOSH") recommends protective equipment be worn by workers exposed or expecting to be exposed to benzene at

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[14] The term "ICH" refers to The International Conference on Harmonization (ICH) Q3C Impurities: Residual Solvents guidance (December 1997), at https://www.fda.gov/media/71736/download?attachment.

[15] The term "USP" refers to United States Pharmacopeia (USP) Residual Solvents, at https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalChapter467Current.pdf.

[16] https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs.

[17] *Facts About Benzene,* CENTERS FOR DISEASE CONTROL AND PREVENTION, https://emergency.cdc.gov/agent/benzene/basics/facts.asp.

concentrations of 0.1 ppm and defines "inhalation, skin absorption, ingestion, skin and/or eye contact" as exposure routes or paths.[18]

31. As with other topically applied products, such as sunscreen, the application of acne products specifically increases the absorption rate of benzene through the skin, thereby increasing the risk of harm.[19]

C. Discovery of Benzene in the BPO Products

32. Due to the substantial harm to humans caused by exposure to chemicals such as benzene, companies have been founded with the specific goal of preventing defective products containing said harmful chemicals from reaching consumers. Valisure "is a pioneering technology company at the forefront of addressing a critical gap in the healthcare supply chain through independent quality assurance.[20] Its mission is "to help ensure the safety, quality, and consistency of medications and supplements in the market."[21]

33. In terms of accreditation and registration, "Valisure operates an analytical laboratory that is accredited under International Organization for Standardization ('ISO/IEC') 17025:2017 standards for chemical testing (PJLA Accreditation Number 94238)," and it "is registered with the Drug Enforcement Administration (License # RV0484814)."[22]

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[18] *NIOSH Pocket Guide to Chemical Hazards - Benzene*, THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH), https://www.cdc.gov/niosh/npg/npgd0049.html.
[19] *Valisure Detects Benzene in Sunscreen*, VALISURE BLOG (May 25, 2021), https://www.valisure.com/blog/valisure-news/valisure-detects-benzene-in-sunscreen/.
[20] https://www.valisure.com/about.
[21] *Valisure Citizen Petition on Benzene in Benzoyl Peroxide Drug Products* (March 5, 2024), chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://assets-global.website-files.com/6215052733f8bb8fea016220/65e8560962ed23f744902a7b_Valisure%20Citizen%20Petition%20on%20Benzene%20in%20Benzoyl%20Peroxide%20Drug%20Products.pdf ("*Valisure Citizen Petition*") at 5.
[22] *Id.*

34. Valisure has tested for specific chemical qualities in numerous types of products, such as N-Nitrosodimethylamine in ranitidine and metformin and benzene in hand sanitizers and sun care products. Each time, Valisure's detection of benzene and other carcinogens has been independently confirmed by the industry and led to recalls by manufacturers over the subject products.

35. On March 5, 2024, Valisure reported its testing results for benzene in various types of BPO drug products, mostly utilizing gas chromatography and detection by mass spectrometry ("GC-MS") instrumentation that allows mass spectral separation and utilizing selected ion chromatograms, along with Selected Ion Flow Tube-Mass Spectrometry ("SIFT-MS") for detection of benzene released into the air around certain BPO products. Valisure also used other orthogonal approaches for confirmation of a few select products.[23]

36. GC-MS "is generally considered one of the most accurate analyses available."[24] Indeed, the FDA used the same method to test for impurities like benzene in hand sanitizers.[25]

37. "The GC-MS method described in [Valisure's] petition utilized body temperature (37°C) for oven incubation. 40°C has been previously used for benzene analysis from liquid pharmaceuticals and beverages, and reduced false positive results compared with higher-temperature incubation."[26]

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[23] *Id.* at 10.
[24] *GC/MS Analysis*, Element, https://www.element.com/materials-testing-services/chemical-analysis-labs/gcms-analysis-laboratories.
[25] *Direct Injection Gas Chromatography Mass Spectrometry (GC-MS) Method for the Detection of Listed Impurities in Hand Sanitizers*, FDA (Aug. 24, 2020), https://www.fda.gov/media/141501/download.
[26] *Valisure Citizen Petition* at 10-11 (citations omitted).

38. Valisure analyzed 66 different BPO containing drug products incubated at 50°C[27] for 18 days, including Defendant's CeraVe Acne Foam Cream Cleanser with 4% BPO, for the presence of benzene.[28]

39. Defendant's tested BPO Product contained high levels of benzene, ranging from 5 ppm to over 12 ppm.[29]

40. "The current data on BPO degrading into high levels of benzene is extremely concerning given its prominent use in skin care, and this study should serve as another wake-up call for improved manufacturing and quality control of consumer healthcare products."[30]

41. The BPO Products are not designed to contain benzene, and no amount of benzene is acceptable in acne treatment products such as the BPO Products manufactured, distributed, and sold by Defendant. Further, although Defendant lists the ingredients on the BPO Products' labels, Defendant failed to disclose on the BPO Products' labeling or anywhere in Defendant's marketing that the BPO Product contains benzene.

42. Despite its knowledge that the BPO Products contain benzene, Defendant has failed to issue a voluntary recall of the BPO Products.

D. Benzene Renders the BPO Product Adulterated, Misbranded, and Illegal to Sell

43. The BPO Products are "drugs" used to treat acne (i.e., *acne vulgaris*), formulated with a chemical called benzoyl peroxide, along with other inactive ingredients, to make acne

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[27] "50°C (122°F) is not only a reasonable temperature that 'the product may be exposed to during distribution and handling by consumers' but is an accepted incubation temperature used by the pharmaceutical industry for performing accelerated stability studies with a duration of at least 3 months." *Id.* at 18-19 (citations omitted).
[28] *Id.* at 15-16.
[29] *Id.* at 17-18.
[30] *Id.* at 29 (citing Email from Dr. Christopher Bunick, MD, PhD, Associate Professor of Dermatology at Yale University, New Haven, CT.).

treatment creams, washes, scrubs, and bars. Before being sold to the public, the BPO Products must be made in conformity with current good manufacturing practices and must conform to quality, safety, and purity specifications.

44. As drugs regulated by the FDA, the BPO Products are prohibited from being adulterated or misbranded.

45. A drug is "adulterated" if it consists in whole or in part of any filthy, putrid, or decomposed substance, is impure, or mixed with another substance.[31]

46. A drug is deemed misbranded if its labeling is false or misleading in any particular and/or if it is dangerous to health when used in the manner recommended or suggested in the labeling thereof.[32]

47. FDA guidance permits up to 2 ppm benzene in a product if its use in the manufacturing process is "unavoidable."[33]

48. The FDA has announced recalls of various products contaminated with benzene, including certain hand sanitizers and sunscreens.[34]

49. As set forth above, Defendant's BPO Products contain levels of benzene above 2 ppm.

50. Defendant could have avoided any potential for benzene contamination in the BPO Products by changing the manufacturing process or raw ingredients, and the BPO Products could have been sold with absolutely no benzene in them. Specifically, BPO as a raw material is known

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[31] *See* 21 U.S.C. § 351(a); *see also* § 351(b)-(d) (noting that a lack of purity or mixture with another substance also renders drug adulterated).
[32] *See* 21 U.S.C. § 352(a)(1), (j).
[33] *Valisure Citizen Petition* at 6 (citing Food and Drug Administration, Q3C – *Tables and List Guidance for Industry* (2017) (https://www.fda.gov/media/71737/download)).
[34] *See Valisure Citizen Petition* at 7 (citations omitted).

to be thermally stable at purities as high as 75% up to temperatures of 98°C.[35] Valisure also evaluated pure BPO reference powder in its GC-MS analytical system and found no evidence of the instability and formation of benzene seen in formulated final products of BPO containing acne treatments.[36] Thus, if BPO is inherently stable as a pure, crystalline powder, a reformulated product that focuses on substantially reducing or entirely preventing the degradation of BPO into benzene could potentially be developed.[37]

51. The mere presence of benzene renders the BPO Products both adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act ("FDCA").

52. A product that is "adulterated" or "misbranded" cannot legally be manufactured, advertised, distributed, or sold.[38] Thus, adulterated and misbranded products like the BPO Products have no economic value and are legally worthless.

53. The manufacture and introduction into commerce of any misbranded or adulterated drug is also prohibited under the Florida Drug and Cosmetic Act.[39]

54. The definition of "adulterated" as defined by the Florida Drug and Cosmetic Act mirrors the FDA definition, defining an adulterated drug as one that, for example, "consists in whole or in part of any filthy, putrid, or decomposed substance," "has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health," "is a drug and the methods used in…its manufacture, processing, packing, or

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[35] *Valisure Citizens Petition* at 25 (citation omitted).
[36] *Id.*
[37] *See id.* at 25-26.
[38] *See* 21 U.S.C. § 331(a).
[39] *See* § 499.005(1), Fla. Stat. ("It is unlawful for a person to perform or cause the performance of any of the following acts in this state: (1) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.").

holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practices to assure that the drug meets the requirements of this part and that the drug has the identity and strength, and meets the standard of quality and purity, which it purports or is represented to possess," or "is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which could render the contents injurious to health."[40]

55. Similarly, a drug is misbranded "[i]f its labeling is in any way false or misleading."[41]

56. In fact, under Florida law, drugs are required to satisfy the requirements of the Federal FDCA (21 U.S.C. Sec. 301, *et seq.*).[42]

57. Further, it is unlawful for any person to disseminate any false or misleading advertisement of a drug under Florida law.[43]

58. As alleged herein, Defendant has violated the FDCA; the Florida Drug and Cosmetic Act; and Florida's Deceptive and Unfair Trade Practices Act. Defendant engaged in fraudulent, unfair, deceptive, misleading, and/or unlawful conduct stemming from its misrepresentations and omissions regarding benzene in the BPO Products.

59. If Defendant had disclosed to Plaintiff and putative Class members that the BPO Products contained or would degrade into benzene, and thus risked benzene exposure during use of the BPO Products, Plaintiff and putative Class members would not have purchased the BPO Products.

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[40] *See* § 499.006(1)-(4), Fla. Stat.
[41] *See* § 499.007(1), Fla. Stat.
[42] *See* § 499.002(1)(b), Fla. Stat.
[43] § 499.005(5), Fla. Stat.

60. As manufacturers, distributors, and sellers of acne treatment products, Defendant had and has a duty to ensure that their BPO Products did not and do not contain excessive (or any) level of benzene, including through regular testing, especially before injecting the BPO Products into the stream of commerce for consumers to use on their skin. But based on Valisure's testing results set forth above, Defendant made no reasonable effort to test its BPO Products for benzene. Defendant also had a duty to disclosed to Plaintiff in its advertising and marketing that its BPO Products contained or would degrade into benzene; yet Defendant failed to disclose to Plaintiff in any advertising or marketing that its BPO Products contained or would degrade into benzene, let alone at levels that are many multiples of the emergency, interim limit set by the FDA. To the contrary, Defendant represented the BPO Products were of merchantable quality, complied with federal and state law, and did not contain carcinogens or other impurities such as benzene.

E. Defendant's Knowledge, Misrepresentations, Omissions, and Concealment of Material Facts Deceived Plaintiff and Reasonable Consumers

61. It is well known that BPO degrades to benzene when exposed to heat over time. This process was first reported in scientific literature as early as 1936.[44]

62. The issue of BPO decomposition into benzene has been previously identified and acted upon in industries other than in the acne treatment product industry.

63. For example, at least one patent application was filed by the chemical company Akzo Nobel N.V. in 1997 which "relates to a method for reducing the rate of free benzene and/or

[44] H. Erlenmeyer and W. Schoenauer, *Über die thermische Zersetzung von Di-acyl-peroxyden,* HELU. CHIM. ACTA, 19, 338 (1936), https://onlinelibrary.wiley.com/doi/10.1002/hlca.19360190153.

benzene derivative formation in BPO formulations based on organic plasticizers, such as pastes, emulsions, suspensions, dispersions and the like."[45]

64. In the polymer manufacturing industry, BPO's decomposition into benzene has been studied and concern was raised specifically regarding the carcinogenic implications of the presence of benzene. In 1994, a paper was published[46] by researchers at Denmark's Department of Environmental Chemistry titled "Formation of benzene by hardeners containing benzoyl peroxide and phthalates" and stated:

> Recently, during the investigation of benzene residues in chemical products (Rastogi 1993a),[47] it was observed that the benzene content in benzoyl peroxide containing hardeners of two component repair-sets (fillers, elastomers) were >2 % (w/w) [20,000 ppm]. Benzene is carcinogenic (IARC 1982), and its use in consumer and industrial products is generally avoided.

65. The study continues with heating of various BPO-containing products at 34°C, 50°C and 80°C finding substantial benzene formation at elevated temperatures, even exceeding levels found in this Petition. Furthermore, similar to Valisure's results, Rastogi finds that only formulations of BPO are unstable, while BPO alone is relatively stable:

> Even heating of BPO-phthalate mixtures at 50°C produced significant amounts of benzene (approximately 0.3% [3,000 ppm]), while no benzene production was detected when benzoyl peroxide was heated alone at this temperature (Table 2).[48]

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[45] Borys F. SchafranBryce Milleville (1997). "Reduction of benzene formation in dibenzoyl peroxide formulations." Akzo Nobel N.V. Worldwide application, WO1997032845A1. (https://patents.google.com/patent/WO1997032845A1/en)

[46] Rastogi SC. Formation of benzene by hardeners containing benzoyl peroxide and phthalates. *Bull Environ Contam Toxicol*. 1994 Nov;53(5):747-52. doi: 10.1007/BF00196949. PMID: 7833612.

[47] Rastogi, S.C. Residues of benzene in chemical products. Bull. Environ. Contam. Toxicol. 50, 794-797 (1993). https://doi.org/10.1007/BF00209940.

[48] *Id.*

66. The referenced 1993 Rastogi article above, titled "Residues of Benzene in Chemical Products," has also been flagged by the US EPA as part of its Health & Environmental Research Online ("HERO") system.[49]

67. Chemical evidence of carcinogenicity has been reported since at least 1981.[50] Multiple studies in the 1980s were conducted using animal models that suggested carcinogenic potential of benzoyl peroxide, including the use of commercial drug formulations of BPO like that of PanOxyl Gel, another acne treatment product.[51]

68. In 1991, FDA posted an amendment to the monograph for OTC topical acne drug products because, "the agency became aware of a 1981 study by Slage, et al. ([FDA] Ref. 1) that raised a safety concern regarding benzoyl peroxide as a tumor promoter in mice and a 1984 study by Kurokawa, et al. ([FDA] Ref. 2) that reported benzoyl peroxide to have tumor initiation

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[49] US Environmental Protection Agency. Health & Environmental Research Online (HERO). "Residues of Benzene in Chemical Products." HERO ID 2894703 (http://hero.epa.gov/hero/index.cfm/reference/details/reference__id/2894703).

[50] Slaga TJ, Klein-Szanto AJ, Triplett LL, Yotti LP, Trosko KE. Skin tumor-promoting activity of benzoyl peroxide, a widely used free radical-generating compound. Science. 1981 Aug 28;213(4511):1023-5. doi: 10.1126/science.6791284. PMID: 6791284.

[51] Kurokawa Y, Takamura N, Matsushima Y, Imazawa T, Hayashi Y. *Studies on the promoting and complete carcinogenic activities of some oxidizing chemicals in skin carcinogenesis.* Cancer Lett. 1984 Oct;24(3):299-304. doi: 10.1016/0304-3835(84)90026-0. PMID: 6437666; Pelling JC, Fischer SM, Neades R, Strawhecker J, Schweickert L. *Elevated expression and point mutation of the Ha-ras proto-oncogene in mouse skin tumors promoted by benzoyl peroxide and other promoting agents*. Carcinogenesis. 1987 Oct;8(10):1481-4. doi: 10.1093/carcin/8.10.1481. PMID: 3115617; 81 O'Connell JF, Klein-Szanto AJ, DiGiovanni DM, Fries JW, Slaga TJ. *Enhanced malignant progression of mouse skin tumors by the free-radical generator benzoyl peroxide.* Cancer Res. 1986 Jun;46(6):2863-5. PMID: 3084079; 82 Iversen OH. *Carcinogenesis studies with benzoyl peroxide (Panoxyl gel 5%)*. J Invest Dermatol. 1986 Apr;86(4):442-8. doi: 10.1111/1523-1747.ep12285787. PMID: 3091706.

potential," leading FDA to determine that "further study is necessary to adequately assess the tumorigenic potential of benzoyl peroxide."[52]

69. By 2010, FDA published a final monograph on benzoyl peroxide along with summarizing results from further studies on the potential carcinogenicity of benzoyl peroxide and actions of the FDA Advisory Committee. This final monograph stated, "The Committee recommended, by a four-to-three vote (with one abstention), that the known safety data regarding the tumor promoting potential of benzoyl peroxide should be communicated to consumers. Because this data was inconclusive, the Committee unanimously agreed that the word, ''cancer'' should not be included in the labeling of acne drug products containing benzoyl peroxide. The Committee was concerned that the word ''cancer'' would cause consumers to avoid using these products (even though the data were inconclusive)."[53]

70. In 2020, the FDA started working with companies to identify benzene in products, which resulted in product recalls of hand sanitizers, sunscreens, and deodorants. In 2021, an independent chemical analysis by Valisure of hundreds of sunscreens and after-sun care products from 69 brands found 27 percent of the batches had significant levels of benzene above the FDA 2 ppm limit.[54]

71. By 2021, Defendant was well aware of benzene contamination issues in its BPO Products and in products of its competitors.

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[52] Food and Drug Administration. *Proposed Rule: Reclassifies benzoyl peroxide from GRASE to Category III.* (August 7, 1991) Federal Register, 56FR37622. pp 37622 - 37635 (https://cdn.loc.gov/service/ll/fedreg/fr056/fr056152/fr056152.pdf#page=178).
[53] Food and Drug Administration. Final Monograph. (March 4, 2010) Federal Register, 75FR9767. (https://www.gpo.gov/fdsys/pkg/FR-2010-03-04/pdf/2010-4424.pdf).
[54] Valisure Citizen Petition on Benzene in Sunscreen and After-sun Care Products, May 24, 2021.

72. Further, Defendant, which markets itself as a merchandiser of quality acne treatment products and employed high-level scientists, chemists, and researchers to formulate and/or decide which drug products to label and sell for public use, was aware of the well-known chemical processes that degrade their BPO Products into benzene when exposed to commonly used temperatures and conditions.

73. Defendant, a large, sophisticated corporation in the business of manufacturing, distributing, and selling products containing BPO, knew or should have known the BPO Products were contaminated with excess levels of benzene and that testing the BPO Products for benzene was necessary to protect Plaintiff and putative class members from harmful levels of benzene exposure.

74. Defendant's use of BPO put it on notice of the excessive levels of benzene in the BPO Products.

75. Notwithstanding this knowledge, Defendant failed to appropriately and adequately test its BPO Products for the presence of benzene to protect Plaintiff and Class members from dangerous levels of benzene exposure.

76. Defendant sold, and continues to sell, BPO Products during the class period despite Defendant's knowledge of the risk of benzene contamination.

77. Benzene is not listed on the BPO Products' labels as an ingredient, nor is there any warning about the inclusion (or even potential inclusion) of benzene in the BPO Products.

78. Plaintiff has standing to represent members of the putative Class because there is sufficient similarity between the specific products purchased by Plaintiff and the other BPO Products not purchased by Plaintiff. Specifically, each and every one of the BPO Products (i) are marketed in substantially the same way—as an acne treatment—and (ii) fail to include labeling

indicating to consumers that the BPO Products contain benzene or degrade into benzene. Accordingly, the misleading effect of all the BPO Products' labels are substantially the same.

79. Defendant has engaged in deceptive, untrue, and misleading advertising by making representations by failing to warn about the potential presence of benzene in the BPO Products, and nothing on the BPO Products' labels otherwise insinuate, state, or warn that the BPO Products contain or will degrade into benzene.

80. As alleged, the presence of benzene in the BPO Products renders the BPO Products misbranded and adulterated and therefore illegal and unfit for sale in trade or commerce. Plaintiff would not have purchased the BPO Products had they been truthfully and accurately labeled.

81. Had Defendant adequately tested its BPO Products for benzene and other carcinogens and impurities, it would have discovered its BPO Products contained benzene – even at levels above the FDA's limit (to the extent even applicable), making the BPO Products illegal to distribute, market, and sell.

82. Accordingly, Defendant knowingly, recklessly, or at least negligently, introduced a contaminated, adulterated, and misbranded BPO Products containing or that would degrade into dangerous amounts of benzene into the U.S. market.

83. Defendant's concealment was material and intentional because people are concerned with what is in the products that they are putting onto and into their bodies. Consumers such as Plaintiff and Class members make purchasing decisions based on the representations made on the BPO Products' labeling, including the ingredients listed.

F. Injuries to Plaintiff and Class Members

84. When Plaintiff purchased Defendant's BPO Products, Plaintiff did not know, and had no reason to know, that Defendant's BPO Products contained or would degrade into the

harmful carcinogen benzene. Not only would Plaintiff not have purchased Defendant's BPO Products had they known the Products contained or would degrade into benzene, but they would also not have been capable of purchasing them if Defendant had done as the law required and tested the BPO Products for benzene and other carcinogens and impurities.

85. Consumers lack the ability to test or independently ascertain or verify whether a product contains unsafe substances, such as benzene, especially at the point of sale, and therefore must rely on Defendant to truthfully and honestly report what the BPO Products contain on the BPO Products' packaging or labels.

86. Further, given Defendant's position as a leader in the pharmaceutical, health, and beauty market, Plaintiff and reasonable consumers trusted and relied on Defendant's representations and omissions regarding the presence of benzene in the BPO Products.

87. Yet, when consumers look at the BPO Products' packaging, there is no mention of benzene. It is not listed in the ingredients section, nor is there any warning about the inclusion (or even potential inclusion) of benzene in the BPO Products. This leads reasonable consumers to believe the BPO Products do not contain benzene. Indeed, these expectations are reasonable because if the BPO Products are manufactured and tested properly, benzene will not be present in the Products.

88. No reasonable consumer would have paid any amount for products that contain or will degrade into benzene, a known carcinogen and reproductive toxin, much less above the limits set by the FDA.

89. Thus, if Plaintiff and Class members had been informed that Defendant's BPO Products contained or would degrade into benzene, they would not have purchased or used the BPO Products, making such omitted facts material to them.

90. Defendant's false, misleading, omissions, and deceptive misrepresentations regarding the presence of benzene in the BPO Products are likely to continue to deceive and mislead reasonable consumers and the public, as it has already deceived and misled Plaintiff and the Class members.

91. Plaintiff and Class members bargained for products free of contaminants and dangerous substances. Plaintiff and Class members were injured by the full purchase price of the BPO Products because the BPO Products are worthless, as they are adulterated and contain harmful levels of benzene and Defendant failed to warn consumers of this fact. Such illegally sold products are worthless and have no value.

92. As alleged above, Plaintiff and Class members' BPO Products contained benzene.

93. Plaintiff and Class members are further entitled to statutory and punitive damages, attorneys' fees and costs, and any further relief this Court deems just and proper.

94. All conditions precedent to the prosecution of this action have occurred, and/or have been performed, excused, or otherwise waived.

CLASS ALLEGATIONS

95. Plaintiff, individually and on behalf of all others similarly situated, brings this class action pursuant to Fed. R. Civ. P. 23.

96. Plaintiff seeks to represent a class defined as:

> All persons who purchased the BPO Products in the United States for personal or household use within any applicable limitations period ("Nationwide Class").

97. In the alternative, Plaintiff also seeks to represent a subclass defined as:

> All persons who purchased the BPO Products in Florida for personal or household use within any applicable limitations period ("Florida Subclass").

98. Plaintiff also seeks to represent a subclass defined as:

> All persons who purchased one or more of Defendant's BPO Products in the States of California, Florida, Illinois, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, or Washington for personal or household use within any applicable limitations period ("Consumer Fraud Multi-State Subclass").[55]

99. Excluded from the Class and Subclasses are: (1) any Judge or Magistrate presiding over this action and any members of their families; (2) Defendant, Defendant's subsidiaries, parents, successors, predecessors, and any entities in which Defendant or its parents and any entities in which Defendant has a controlling interest and its current or former employees, officers, and directors; and (3) individuals who allege personal bodily injury resulting from the use of the BPO Products.

100. Plaintiff reserves the right to modify, change, or expand the definitions of the Class based upon discovery and further investigation.

101. *Numerosity*: The Class is so numerous that joinder of all members is impracticable. The Class likely contains hundreds of thousands of members based on publicly available data. The Class is ascertainable by records in Defendant's possession.

102. *Commonality*: Questions of law or fact common to the Class include, without limitation:

a. Whether the BPO Products contain benzene;

b. Whether a reasonable consumer would consider the presence of benzene in the BPO Products to be material;

[55] While discovery may alter the following, the states in the Consumer Fraud Multi-State Subclass are limited to those states with similar consumer fraud laws under the facts of this case: California (Cal. Bus. & Prof. Code § 17200, *et seq.*); Florida (Fla. Stat. § 501.201, *et seq.*); Illinois (815 Ill. Comp. Stat. 505/1, *et seq.*); Massachusetts (Mass. Gen. Laws Ch. 93A, *et seq.*); Michigan (Mich. Comp. Laws § 445.901, *et seq.*); Minnesota (Minn. Stat. § 325F.67, *et seq.*); Missouri (Mo. Rev. Stat. § 407.010, *et seq.*); New Jersey (N.J. Stat. § 56:8-1, *et seq.*); New York (N.Y. Gen. Bus. Law §§ 349 and 350); and Washington (Wash. Rev. Code § 19.86.010, *et seq.*).

c. Whether Defendant had a duty to ensure that their BPO Products did not and do not contain excessive (or any) level of benzene, including through regular testing, especially before injecting the BPO Products into the stream of commerce for consumers to use on their skin;

d. Whether Defendant had a duty to disclosed to Plaintiff in its advertising and marketing that its BPO Products contained or would degrade into benzene;

e. Whether Defendant knew or should have known that the BPO Products contain or will degrade into benzene;

f. Whether Defendant misrepresented the BPO Products contain or will degrade into benzene;

g. Whether Defendant failed to disclose that the BPO Products contain or will degrade into benzene;

h. Whether Defendant concealed that the BPO Products contain or will degrade into benzene;

i. Whether Defendant engaged in unfair or deceptive trade practices;

j. Whether Defendant violated the state consumer protection statutes alleged herein;

k. Whether Defendant was unjustly enriched;

l. Whether Defendant acted negligently; and

m. Whether Plaintiff and Class members are entitled to damages.

103. *Typicality*: Plaintiff's claims are typical of the claims of Class members. Plaintiff and Class members were injured and suffered damages in substantially the same manner, have the same claims against Defendant relating to the same course of conduct, and are entitled to relief under the same legal theories.

104. *Adequacy*: Plaintiff will fairly and adequately protect the interests of the Class and has no interests antagonistic to those of the Class. Plaintiff has retained counsel experienced in the prosecution of complex class actions, including actions with issues, claims, and defenses similar to the present case. Counsel intends to vigorously prosecute this action.

105. *Predominance and superiority*: Questions of law or fact common to Class members predominate over any questions affecting individual members. A class action is superior to other available methods for the fair and efficient adjudication of this case because individual joinder of all Class members is impracticable and the amount at issue for each Class member would not justify the cost of litigating individual claims. Should individual Class members be required to bring separate actions, this Court would be confronted with a multiplicity of lawsuits burdening the court system while also creating the risk of inconsistent rulings and contradictory judgments. In contrast to proceeding on a case-by-case basis, in which inconsistent results will magnify the delay and expense to all parties and the court system, this class action presents far fewer management difficulties while providing unitary adjudication, economies of scale and comprehensive supervision by a single court. Plaintiff is unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

106. Accordingly, this class action may be maintained pursuant to Fed. R. Civ. P. 23(b)(3).

CAUSES OF ACTION

COUNT I
VIOLATION OF STATE CONSUMER FRAUD ACTS
(On behalf of Plaintiff and the Consumer Fraud Multi-State Subclass)

107. Plaintiff re-alleges and incorporates by reference all preceding factual allegations in paragraphs 1 through 106 above as though set forth fully herein.

108. Plaintiff brings this Count on behalf of herself and the Consumer Fraud Multi-State Subclass against Defendant.

109. The Consumer Fraud Acts of the states in the Consumer Fraud Multi-State Subclass prohibit the use of unfair or deceptive business practices in the conduct of trade or commerce.

110. Plaintiff and the other Members of the Consumer Fraud Multi-State Subclass have standing to pursue a cause of action for violation of the Consumer Fraud Acts of the states in the Consumer Fraud Multi-State Subclass because Plaintiff and Members of the Consumer Fraud Multi-State Subclass have suffered an injury in fact and lost money as a result of Defendant's actions set forth herein.

111. Defendant engaged in unfair and/or deceptive conduct by making material misrepresentations and omissions regarding the presence of benzene in the BPO Products, as discussed herein.

112. Defendant intended that Plaintiff and each of the other Members of the Consumer Fraud Multi-State Subclass would rely upon its unfair and deceptive conduct and a reasonable person would in fact be misled by this deceptive conduct described above.

113. Given Defendant's position in the acne treatment market as an industry leader, Plaintiff and reasonable consumers trusted and relied on Defendant's representations and omissions regarding the presence of benzene in the BPO Products.

114. As a result of Defendant's use or employment of unfair or deceptive acts or business practices, Plaintiff and each of the other Members of the Consumer Fraud Multi-State Subclass have sustained damages in an amount to be proven at trial.

115. In addition, Defendant's conduct showed malice, motive, and the reckless disregard of the truth such that an award of punitive damages is appropriate.

COUNT II
VIOLATION OF THE FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT, FLA. STAT. §§ 501.201 *et seq.*
(On behalf of Plaintiff and the Florida Subclass)

119. Plaintiff re-alleges and incorporates by reference all preceding factual allegations in paragraphs 1 through 106 above as though set forth fully herein.

120. Plaintiff brings this claim individually and on behalf of the Florida Subclass pursuant to section 501.211, Florida Statutes.

121. The Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") makes unlawful "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.204(1).

122. Plaintiff and the Florida Subclass members are "consumers" within the meaning of section 501.203(7), Florida Statutes.

123. Defendant is engaged in the practice of manufacturing, marketing, distributing, selling, and otherwise placing into the stream of commerce the BPO Products, which constitutes trade and commerce as defined by section 501.203(8), Florida Statutes, and is therefore subject to FDUPTA.

124. As alleged herein, Plaintiff has suffered injury in fact and lost money as a result of Defendant's conduct because she purchased BPO Products from Defendant in reliance on Defendant's representation that the ingredients in its BPO Products were safe and effective and

were not adulterated with benzene, a known human carcinogen.

125. As alleged herein, Defendant's actions are deceptive and in clear violation of FDUTPA, entitling Plaintiff and the Class to damages and relief under sections 501.201-213, Florida Statutes.

126. Defendant has engaged, and continues to engage, in conduct that is likely to deceive members of the public. This conduct includes representing in its labels that its BPO Products contain only the ingredients listed in the label, which is untrue, and failing to make any mention that the BPO Products are adulterated with benzene, a known human carcinogen.

127. By committing the acts alleged above, Defendant has engaged in unconscionable, deceptive, or unfair acts or practices, which constitute unfair competition within the meaning of FDUTPA. Specifically, Defendant engaged in unfair practices by selling products contaminated with benzene, which are adulterated and illegal to sell.

128. Defendant's conduct is substantially injurious to consumers. Consumers are purchasing and using Defendant's BPO Products without knowledge that the BPO Products contain or will degrade into a human carcinogen. This conduct has caused, and continues to cause, substantial injury to consumers because consumers would not have paid for BPO Products containing benzene but for Defendant's false labeling, advertising, and promotion. Thus, Plaintiff and the Florida Subclass have been "aggrieved" (i.e., lost money) as required for FDUTPA standing, and such an injury is not outweighed by any countervailing benefits to consumers or competition.

129. Indeed, no benefit to consumers or competition results from Defendant's conduct. Since consumers reasonably rely on Defendant's labeling of the ingredients and other information disclosing what is contained in the BPO Products and injury resulting from ordinary use,

consumers could not have reasonably avoided such injury.

130. Further, Defendant's conduct is ongoing and continuing, such that prospective injunctive relief is necessary. Plaintiff desires to purchase Defendant's BPO Products in the future if she can be assured that the BPO Products are unadulterated and meet the advertising claims. Absent injunctive relief, Defendant may continue to advertise, promote, and sell adulterated BPO Products that deceive the public regarding their ingredients, contents and/or safety. Plaintiff is thus likely to be again wronged in a similar way. For example, if Plaintiff or the Florida Subclass members encounter Defendant's BPO Products in the future and there is a risk those products still contain benzene, Plaintiff or Florida Subclass members may mistakenly rely on the BPO Product's label to believe that Defendant's eliminated benzene when they did not.

131. Plaintiff and Florida Subclass members are entitled to recover their reasonable attorney's fees pursuant to section 501.2105, Florida Statutes.

132. Moreover, Plaintiff and the Florida Subclass seek an order enjoining Defendant from continuing to conduct business through fraudulent or unlawful acts and practices and to commence a corrective advertising campaign. Defendant's conduct is ongoing and continuing, such that prospective injunctive relief is necessary.

133. On behalf of Plaintiff and the Florida Subclass, Plaintiff also seeks an order entitling her and the Class to recover all monies spent on Defendant's BPO Products, which were acquired through acts of fraudulent, unfair, or unlawful competition.

134. In addition, the measure of restitution should be a full refund of the purchase price, since the BPO Products are worthless. But for Defendant's misrepresentations and omissions, Plaintiff and Class members would have paid nothing for BPO Products containing benzene. Indeed, there is no discernible "market" for an acne treatment product that is adulterated with a

known human carcinogen. As a result, Defendant's BPO Products are rendered valueless.

COUNT III
UNJUST ENRICHMENT
(On behalf of Plaintiff and the Nationwide Class)

174. Plaintiff re-alleges and incorporates by reference all preceding factual allegations in paragraphs 1 through 106 above as though set forth fully herein.

175. Plaintiff brings this cause of action on behalf of herself and the Nationwide Class against Defendant.

176. This claim is brought under the laws of the state of New York.

177. Defendant's conduct violated, *inter alia*, state and federal law by manufacturing, advertising, marketing, and selling the BPO Products while misrepresenting and omitting material facts.

178. Defendant's unlawful conduct allowed Defendant to knowingly realize substantial revenues from selling the BPO Products at the expense of, and to the detriment or impoverishment of Plaintiff and Class members and to Defendant's benefit and enrichment. Defendant has thereby violated fundamental principles of justice, equity, and good conscience.

179. Plaintiff and Class members conferred significant financial benefits and paid substantial compensation to Defendant for the BPO Products, which was not as Defendant represented them to be.

180. Defendant knowingly received and enjoyed the benefits conferred on it by Plaintiff and Class members.

181. It is inequitable for Defendant to retain the benefits conferred by Plaintiff and Class members' overpayments.

182. Plaintiff and Class members seek establishment of a constructive trust from which

Plaintiff and Class members may seek restitution.

COUNT IV
NEGLIGENT MISREPRESENTATION/OMISSION
(On behalf of Plaintiff and the Nationwide Class)

183. Plaintiff re-alleges and incorporates by reference all preceding factual allegations in paragraphs 1 through 106 above as though set forth fully herein.

184. This claim is brought under the laws of the state of New York.

185. Through its labeling and advertising, Defendant made representations of material fact to Plaintiff and the Class members concerning the content of its BPO Products.

186. Defendant has a duty to provide accurate information to consumers with respect to the contents of its BPO Products as detailed above.

187. Defendant failed to fulfill its duty to accurately disclose, through its labeling, advertising or otherwise, that its BPO Products contain or will degrade into benzene.

188. Additionally, Defendant has a duty to not make false representations with respect to its BPO Products.

189. Defendant failed to fulfill this duty when it made false representations regarding the quality and safety of the BPO Products as detailed above.

190. Defendant made these misrepresentations, which it believed to be true, but were in fact false.

191. For the reasons set forth above, Defendant knew or should have known about the quality and safety of the BPO Products, including that they contain or will degrade into benzene.

192. Such failures to disclose on the part of Defendant amount to negligent omission and the representations regarding the quality and safety of the BPO Products amount to negligent misrepresentation.

193. Defendant intended Plaintiff to rely on the misrepresentations.

194. Plaintiff and the other members of the Class reasonably relied upon such representations and omissions to their detriment.

195. By reason thereof, Plaintiff and the other Class members have suffered damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually on behalf of herself and on behalf of all others similarly situated, prays for relief and judgment against Defendant as follows:

a. Certifying the Class pursuant to Rule 23 of the Federal Rules of Civil Procedure, appointing Plaintiff as representative of the Class and Subclasses, and designating Plaintiff's counsel as Class Counsel;

b. Awarding Plaintiff and Class members compensatory damages, in an amount to be determined at trial;

c. Awarding Plaintiff and Class members appropriate relief, including but not limited to actual damages;

d. For restitution and disgorgement of profits;

e. Awarding Plaintiff and Class members reasonable attorneys' fees and costs as allowable by law;

f. Awarding pre-judgment and post-judgment interest;

g. For punitive damages; and

h. Granting any other relief as this Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury of all claims so triable.

Dated: May 24, 2024

Respectfully submitted,

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