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10	CENTRAL DISTR	ICT OF CALIFORNIA						
11	WESTER	WESTERN DIVISION						
12	ALAN MONTENEGRO on behalf of	Civil Action No.: 2:24-cv-1876						
13	himself, and all others similarly situated, and the general public,	CLASS ACTION COMPLAINT						
14	and the general patents,							
15	Plaintiff,	CONSUMER FRAUD, BREACH OF EXPRESS & IMPLIED						
16	V.	WARRANTIES, AND UNJUST						
17		ENRICHMENT						
18	CVS PHARMACY, INC., CVS HEALTH CORPORATION, and DOES 1 to 50,							
19	Inclusive,	DEMAND FOR JURY TRIAL						
20	Defendants.							
21	Defendants.							
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CLASS ACTION COMPLAINT

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¹ Food and Drug Administration, *Q3C – Tables and List Guidance for Industry* (2017), https://www.fda.gov/media/71737/download.

² 21 U.S.C. § 351(a)(2011); see also § 351(b)-(d) (noting that a lack of purity or mixture with another substance also renders drug adulterated).

³ 21 U.S.C. § 331(a)(2010).

("Class Action") against Defendant, alleging the following upon Plaintiff's personal knowledge, or where Plaintiff lacks personal knowledge, upon information and belief, including the investigation of counsel.

I. <u>INTRODUCTION</u>

Plaintiff, ALAN MONTENEGRO, on behalf of himself, the putative National

and State Subclasses defined below, and the public, brings this Class Action Complaint

- 1. This is a consumer fraud Class Action to redress the economic harms caused by Defendant's sale of benzoyl peroxide acne treatment drug products ("BPO Products") without warning consumers the BPO Products contain unsafe levels of the potent human carcinogen benzene, and that the BPO Products were at risk of degrading further into benzene under normal use, handling, and storage conditions.
- 2. The BPO Products are "drugs" used to treat acne vulgaris ("acne"), formulated with a chemical called benzoyl peroxide ("BPO"), along with other inactive ingredients, to make acne treatment creams, washes, scrubs, and bars. Before being sold to the public, the Products must be made in conformity with current good manufacturing practices and must conform to quality, safety, and purity specifications. Defendant's Products did not.
- 3. BPO Products should not contain benzene, nor degrade into benzene, except under extraordinary circumstances.¹ 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.² Under the FDA Act it is a crime to introduce or deliver "into interstate commerce any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." If benzene is found in any on-market or post-market

Product, the drug manufacture must contact the FDA to initiate a voluntary recall.⁴

- Throughout this Complaint, references to federal law and FDA regulation 4. are merely to provide context and are not intended to raise a federal question of law. All claims alleged herein arise out of violations of state law, which in no way conflict, interfere with, or impose obligations that are materially different than those imposed by federal law.
- The BPO Products marketed and sold to Plaintiff, the Class, Subclasses, 5. and the public by the Defendant decomposed into benzene rendering them materially different than advertised, i.e., by containing unsafe levels of benzene. Benzene is a known human carcinogen. Studies dating to the 1800s have led to a consensus within the medical and scientific communities that benzene exposure, even in low amounts, increases the risk of blood cancers and other adverse effects.
- In 2023, Valisure, LLC,⁵ an independent, accredited laboratory that has 6. developed analytical methods to test drugs and consumer products for public safety, tested a representative sample of BPO and non-BPO products and found the BPO Products had dangerous levels of benzene, many multiple times higher than allowed in

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benzene-explainer-wellness/index.html.

⁴ Food and Drug Administration. (Dec. 22, 2022). FDA Alerts Drug Manufacturers to the Risk of Benzene in Certain Drugs, https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alertsdrug-manufacturers-risk-benzene-contamination-certain drugs (last visited Feb. 9, 2024). ⁵ Valisure is an independent third-party analytical laboratory that is accredited to International

Organization for Standardization ("ISO/IEC") 17025:2017 standards for chemical testing (PJLA Accreditation Number 94238). In response to rising concerns about drug shortages, generics, and 21 overseas manufacturing, Valisure developed and validated methods to test medications and consumer

products distributed in the United States. Valisure has tested a variety of drug and consumer healthcare products for benzene including sunscreens, antiperspirants, body sprays, hand sanitizers, and dry shampoos for benzene. Valisure's testing results submitted to the FDA in its Citizen's

Petitions, were widely publicized in the media leading to numerous recalls of contaminated consumer products. See Valisure Citizen's Petition on Benzoyl Peroxide (March 4, 2024), pp. 6-7, see also

Valisure Detects Benzene in Sunscreen, https://www.valisure.com/valisure-newsroom/valisuredetects-benzene-in-sunscreen; Bruce Y. Lee, Forbes, FDA: P&G Recalls Antiperspirant Sprays Due

To Cancer Risk Of Benzene (Nov. 24, 2021), https://www.forbes.com/sites/brucelee/2021/11/24/fdapg-recalls-antiperspirants-body-sprays-due-to-cancer-risk-of-benzene/?sh=69cf13c24f32; see also

Sandee LaMotte, CNN, Antiperspirant recall: What the finding of a cancer-causing chemical means for you (Dec. 1, 2021), https://www.cnn.com/2021/12/01/health/deodorants-antiperspirants-recall-

any regulated drug.⁶ Using industry standard gas chromatography and detection by mass spectrometry ("GC-MS") instrumentation, with selected ion flow tube mass spectrometry ("SIFT-MS") for detection of benzene released into the air around certain BPO Products, the Products were incubated to temperatures common during consumer use, handling, and storage and then sampled for benzene.⁷ Levels as high as 1600 ppm were found in common BPO Products.⁸ Unexpectedly, researchers found that benzene was released into the surrounding air even when the BPO Products' packaging was closed raising concern for even more inhalation exposures—a particularly pernicious form of exposure to benzene.⁹ For the non-BPO products tested, benzene was not present, or at trace levels below 2 ppm.¹⁰ Valisure filed a FDA Citizen's Petition on March 4, 2024 demanding an immediate BPO product recall.¹¹ The Petition is pending.¹²

- 7. The high levels of benzene led Valisure to conduct a stability study on a diverse market sweep of BPO Products and formulations, which led to their finding that all on market BPO Products appear to be fundamentally unstable and form unacceptably high levels of benzene.¹³
- 8. Although the BPO Products have been found to have benzene, Defendant never listed benzene among the ingredients anywhere on the Products, labels, containers, or in the advertising or on its websites. Defendant warned no one the Products had benzene or were at risk of benzene contamination.

22 6 Valisure FDA Citizen's Petition on Benzoyl Peroxide (March 6, 2024).

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 $23 \| {}^{8}Id. \text{ at p.17.}$

 $^{^{7}}$ Id.

 $_{14}$ | 9 *Id.* at p. 23.

¹⁰ *Id.* at p. 15 ("76 non-BPO products had no detectable benzene or values below 0.1ppm. 6 non-BPO products contained traces of benzene below 2 ppm, which could be due to various inactive ingredients used in consumer products that have been theorized to contain trace benzene"); see also Valisure,

LLC, https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide (last visited March 6, 2024).

¹¹ Valisure BPO Citizen's Petition (March 4, 2024).

¹² Valisure's Petition was still pending as of this Class Action's filing.

¹³ *Id.* at 25.

9. Defendant knew or should have known the BPO Products contain and/or degraded into benzene when exposed to expected consumer use, handling, and storage conditions. BPO is known, within the scientific community (but not amoung consumers) to degrade into benzene according to the mechanism below:¹⁴

- 10. Defendant misled Plaintiff, the Class, Subclasses, and the public by representing the BPO Products only had the ingredients listed, and not benzene. Defendant misled Plaintiff, the Class, Subclasses, and the public by representing the BPO Products were safe while concealing material health and safety information known to them, e.g., the BPO Products degraded to benzene, or were contaminated with benzene. Defendant misled Plaintiff, the Class, Subclasses, and the public by giving the BPO Products long expiration dates of 2-3 years, affirming the BPO Products were safe for use for years when Defendant knew or should have known the BPO Products degraded much sooner to benzene under normal and expected consumer use, handling, and storage conditions.
 - 11. Defendant's statements and omissions of material health and safety

¹⁴ The disposition of benzoyl peroxide to form benzene. Benzoyl peroxide is known to thermally decompose to form two molecules of benzoyloxy radicals that can further decompose to benzoic acid or phenyl radicals with liberation of carbon dioxide. The phenyl radicals can then produce benzene. *See* Shang-Hao Liu, et al, *Thermal hazard evaluation of the autocatalytic reaction of benzoyl peroxide using DSC and TAM III*, THERMOCHIMICA ACTA, Volume 605, Pages 68-76, , (2015), ISSN 0040-603, https://www.sciencedirect.com/science/article/pii/S004060311500057X.

- information unreasonably placed Plaintiff, the Class, the Subclasses, and the public at risk of exposure to benzene without their knowledge and consent. Defendant's statements to Plaintiff, the Class, Subclasses, and the public about the Products were false, misleading, unsubstantiated, and blatantly deceptive.
- 12. As a result of the consumer deception, the Plaintiff, the Class, Subclasses, and the public were economically harmed, as they purchased a product that they otherwise would have never purchased. They were also physically harmed by being exposed to a known human carcinogen.
- 13. This Class Action is necessary to redress the economic harms caused to Plaintiff and the Class who bought the Products believing them to be safe and only containing the ingredients on the BPO Products' labels, containers, in advertising, and on Defendant's websites. This Class Action is further necessary to expose Defendant's ongoing consumer fraud and to enjoin Defendant from continuing its misconduct and deception to protect the public.
- 14. Plaintiff brings this Class Action individually, and on behalf of those similarly situated, and seeks to represent a National Class of consumers and State Subclasses of consumers from California, Connecticut, Hawaii, Illinois, Maryland, Missouri, Massachusetts, Nevada, New York, Ohio, Pennsylvania, Rhode Island, and Washington (defined *infra*). Plaintiff seeks damages, reasonable attorneys' fees and costs, interest, restitution, other equitable relief, including an injunction and disgorgement of all benefits and profits Defendant received from misconduct.

II. THE PARTIES

15. Plaintiff Alan Montenegro is a California resident, located in Los Angeles County who bought BPO Products including, but not limited to, Clearasil Stubborn Acne Control 5 in 1 Spot Treatment Cream, CVS Health Acne Treatment Cream, CVS Health Acne Control Cleanser, and Neutrogena Rapid Clear Stubborn Acne Spot Gel from 2017 to 2021. Plaintiff has suffered economic damages and a result of Defendant's violations of the state laws alleged herein. Plaintiff would never have

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purchased Defendant's BPO Products had Defendant warned about the presence of benzene or that the Products could degrade into benzene.

- Defendant CVS Pharmacy, Inc. is a citizen of Rhode Island with its principal place of business at 1 CVS Drive, Woonsocket, Rhode Island. CVS Pharmacy, Inc. is a subsidiary of Defendant CVS Health Corporation (collectively "CVS"). CVS sells BPO Products under the brand name CVS Health. CVS's Products include, inter alia: (1) CVS Health Acne Treatment Cream and (2) CVS Health Acne Control Cleanser. At all relevant times, CVS conducted business and derived substantial revenue from its manufacturing, advertising, marketing, distributing, and selling of the Products within the State of California.
- Defendant CVS Health Corporation is a citizen of Delaware with its principal place of business at 1 CVS Drive, Woonsocket, Rhode Island. CVS Health Corporation together with its subsidiaries (collectively "CVS") sells BPO Products under the brand name CVS Health. CVS's Products include, inter alia: (1) CVS Health Acne Treatment Cream and (2) CVS Health Acne Control Cleanser. At all relevant times, CVS conducted business and derived substantial revenue from its manufacturing, advertising, marketing, distributing, and selling of the Products within the State of California.
- 18. The term "Defendant" refers to each individual Defendant during the period it was responsible for manufacturing, distributing, advertising, labeling, and selling the BPO Products.
- Defendant and its agents promoted, marketed, and sold the Products in California and in this District. The unfair, unlawful, deceptive, and misleading advertising, and labeling of the Products were prepared and/or approved by Defendant and its agents and were disseminated by Defendant and its agents through labeling and advertising containing the misrepresentations alleged and disseminated uniformly through advertising, packaging, containers, and via websites and social media.

III. JURISDICTION AND VENUE

- 20. This Court has jurisdiction over this matter because the amount in controversy exceeds \$5 million satisfying 28 U.S.C. § 1332(d)(2) for subject matter jurisdiction. This Court has supplemental jurisdiction over any state law claims under 28 U.S.C. § 1367.
- 21. Venue is proper in the Central District of California under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims occurred in this District.
- 22. This Court has personal jurisdiction over the Defendant because Defendant transact business in California, including in this District, have substantial aggregate contacts with the State of California, including in this District, engaged in misconduct that has and had a direct, substantial, reasonably foreseeable, and intended effect of injuring people in this District, and Defendant purposely availed themselves of the benefits of doing business in the State of California, and in this District. This Court also has personal jurisdiction over each Defendant under 18 U.S.C. § 1965.

IV. GENERAL ALLEGATIONS

- 23. Fifty million Americans suffer from acne annually. ¹⁵ Acne is the most common skin condition in the United States with a prevalence among adolescents of almost 95 percent. ¹⁶ Acne can begin as early as age seven and, for some, can persist through adulthood and into ages 50s and 60s. ¹⁷ Millions of acne sufferers seek treatment every year making it a billion-dollar industry and a key business segment for Defendant, who are among America's most prominent companies.
- 24. Some of Defendant's most profitable acne treatment products contain BPO. To make the finished BPO Products, BPO, a dry white powder, is mixed with other ingredients to create topical drug creams, cleansers, scrubs, and washes for use on the

¹⁵ American Association of Dermatology, https://www.aad.org/media (visited October 24, 2023).

¹⁶ JL Burton et al., *The prevalence of acne vulgaris in adolescence*, BR J

DERMATOL,(1971);85(2):119–126.

face and body. BPO is formulated into these Products at concentrations up to 10%.

A. DEFENDANT ARE AMONG AMERICA'S TOP FORTUNE 50 COMPANIES

- 25. Defendant dominate the drug and consumer health care products' markets year after year and are among the U.S. stock market's coveted "blue chip" and Fortune 50 companies. At the end of fiscal year 2022, CVS ranked sixth among America's Fortune 50 companies.
- 26. Defendant's Products are widely marketed, available, sold, and used by children, teenagers, and adults throughout the United States and the world. The acne treatment industry is a highly competitive billion-dollar market. To remain relevant and top of mind, Defendant spend millions of dollars every year promoting the Products directly to consumers, including teenagers. Defendant make promises to consumers to influence their purchasing decisions such as affirming the Products are tested, backed by science, and approved by dermatologists. Defendant tells consumers they should buy its Products because Defendant are the market leaders, are acne experts, and who care about consumers, the environment, and only sell safe and tested Products.
- 27. CVS dominates the retail pharmacy market with over 9,000 retail locations, 1,100 walk-in medical clinics, a leading pharmacy benefits manager with over 110 million plan members and a dedicated senior pharmacy care business serving more than one million patients per year. CVS also serves about 35 million people through traditional, voluntary, and consumer-directed health insurance products and related services. CVS reported a revenue of 88.9 billion dollars for fiscal year 2023. CVS's proprietary brands, including CVS Health, account for over 20% of its front store sales. CVS

¹⁸ CVS Health Corporation (December 31, 2022). *Form 10-K 2022*. Retrieved from SEC EDGAR website http://www.sec.gov/edgar.shtm.

¹⁹ Press Release. CVS Health Corporation. (August 2, 2023). CVS Beats on Earnings and Revenue as the Company Slashes Costs, https://www.cnbc.com/2023/08/02/cvs-health-cvs-q2-2023-earnings.html (visited October 27, 2023).

²⁰ See CVS. Form 10-K 2022.

B. DEFENDANT DID NOT COMPLY WITH FDA'S TESTING REQUIREMENTS BEFORE SELLING THE PRODUCTS TO THE PUBLIC

- 28. Despite Defendant's positions as market leaders who affirm its commitment to safety, research, and development, Defendant did not adequately test its Products before selling them to Plaintiff, the Classes, and the public. Defendant's Products are "drugs" regulated by the FDA. As with any regulated drug, Defendant must follow current good manufacturing practices ("CGMPs"), have scientifically sound specifications, and must have test procedures and processes to ensure the drug's components (active and inactive ingredients), and finished products are safe. Both raw ingredient materials and finished batches must be tested before released to the public to confirm they meet specifications for identity, strength, quality, and purity. If testing results of the raw materials or finished product do not conform with the specifications, the product cannot be sold to the public. Defendant must also re-test any Products subject to deterioration. Any Products not made in conformity with the CMGPs is considered "adulterated" under 501(a)(2)(B) of the Food, Drug, and Cosmetic Act. Cannot be sold to the public of the Food, Drug, and Cosmetic Act.
- 29. Defendant must also do stability testing to understand the "shelf life" of the Products and to assign an expiration date. It is well known that certain chemical ingredients can degrade or change because of environmental, and storage conditions such as light, moisture, temperature, and humidity, or because of the passage of time. The stability testing should cover all expected distributor and consumer storage, handling, and use conditions and must be done using "reliable, meaningful, and specific

²¹ 21 C.F.R. § 211.84 (1978); see also 21 C.F.R. § 211.160 (1978).

²² 21 C.F.R. § 211.160(b)(1)(1978).

²³ 21 C.F.R. § 225.1 (1976). Under 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act a drug is considered "adulterated" (poorer in quality by adding another substance) if 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 CGMP; see also Food and Drug Administration, Facts About the Current Good Manufacturing Practices (CGMP);

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmp (last visited Feb. 11, 2024).

test methods."²⁴ If stability testing finds a drug product is not stable under expected

storage or use conditions, degrades, or create toxic byproducts, the product cannot be

products are safe for public use. These are the minimum requirements. Because the

manufacturers, the public, and concerned citizens to report unsafe drugs. The FDA

when exposed to heat. Defendant knew that, because of the chemical nature of the

would degrade when exposed to heat from normal distributor and consumer use,

active and inactive ingredients, including BPO, the BPO Products were not stable and

time. This process was first reported in the scientific literature as early as 1936.26 BPO

32. It is well known that BPO degrades to benzene when exposed to heat over

DEFENDANT KNEW, OR SHOULD HAVE KNOWN, THE PRODUCTS DEGRADE TO BENZENE WHEN EXPOSED TO

Defendant knew, or should have known, the Products degrade to benzene

drug manufacturers are largely self-regulated, the FDA must rely on drug

cannot force a drug manufacturer to recall a contaminated drug.²⁵

degrades into benzene according to the mechanism below.²⁷

The CGMPs and stability test requirements are there to ensure drug

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sold to the public.

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C.

HEAT

handling, and storage conditions.

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²⁵ Food and Drug Administration, *Facts About the Current Good Manufacturing Practices (CGMP);* https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmp (last visited Feb. 11, 2024).

²⁶ 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 (last visited Feb. 5, 2024).

²⁷ Benzoyl peroxide is known to thermally decompose to form two molecules of benzoyloxy radicals that can further decompose to benzoic acid or phenyl radicals with liberation of carbon dioxide. The phenyl radicals can then produce benzene. *See* Shang-Hao Liu et al.,, *Thermal hazard evaluation of the autocatalytic reaction of benzoyl peroxide using DSC and TAM III*, THERMOCHIMICA ACTA, Volume 605, (2015), Pages 68-76, ISSN 0040-6031,

https://www.sciencedirect.com/science/article/pii/S004060311500057X (last visited Feb. 5, 2024).

²⁴ 21 CFR 211.166.

Free radica	al and heat
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	2
Benzoyl peroxide	Benzoic acid
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	- + CO ₂
Benzoic acid	Benzene

- 33. The degradation of BPO to benzene was known or should have been known to the Defendant, who promote themselves as expending substantial sums of money and resources to science and research. Defendant marketed themselves as world class drug and healthcare companies Defendant employed high-level scientists, chemists, and researchers to formulate its drug products for public use. Defendant with these resources and expertise were aware of the well-known chemical processes that degrade BPO Products into benzene when exposed to common and expected use, handling, and storage conditions.
- 34. Defendant further knew or should have known that specific ingredients derived from hydrocarbons increased the risk the BPO Products would yield benzene.²⁸ At-risk ingredients include carbomers, mineral spirits, and other petroleum derived substances. These ingredients are red flags for risk of benzene contamination. The FDA published guidance in 2022 urging the industry to reformulate drug products at risk of benzene contamination.²⁹ The FDA's alert highlighted ingredients made from hydrocarbons, including carbomers (thickening agents), urging drug manufacturers to test products containing them for benzene contamination.³⁰ Many of the Defendant's

²⁸ Food and Drug Administration. (Dec. 22, 2022). FDA Alerts Drug Manufacturers to the Risk of Benzene in Certain Drugs.

²⁹ Food and Drug Administration. *Reformulating Drug Products That Contain Carbomers Manufactured With Benzene* (December 27, 2023), https://www.fda.gov/regulatory-information/search-fda-guidance- documents/reformulating-drug-products-contain-carbomers-manufactured-benzene.

³⁰ *Id; see also* December 22, 2022 FDA Alert at 1.

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Products contain hydrocarbons and carbomers but none have been recalled due to benzene contamination.

- Defendant knew or should have known through its own research, development, investigations, and marketing whether the BPO Products were chemically and physically stable. Defendant were required not only to adequately test the BPO Products for safety and stability before selling them to the public, but also to monitor its internal practices, processes, and specifications to make sure they kept pace with science and emerging methodologies. Defendant knew or should have known from expiration and stability studies examining the "shelf life" of the BPO Products, the chemical changes took place because of normal and expected environmental, use, and storage conditions.
- 36. Defendant knew or should have known the BPO Products would be handled, used, and stored by distributors, sellers, and consumers under various temperatures that affect chemical stability. Defendant knew or should have known the BPO Products would travel by commercial carriers and distributors in varying storage conditions and would be stored by consumers in handbags, backpacks, bathrooms, showers, lockers, and in vehicles during warm months where the BPO Products would be exposed to heat. Defendant knew or should have known consumers would apply the benzene contaminated BPO Products to their faces and bodies and would also use the BPO Products in heated showers as scrubs and washes. Defendant knew or should have known the BPO Products would be used and applied to the skin at normal body temperatures, and elevated temperatures following showers or baths, after physical activity, and after the BPO Products sat in warm temperatures or hot vehicles.
- These storage, use, and handling conditions were known or should have been known to Defendant before the BPO Products were marketed and sold to Plaintiff and the Class members. Defendant knew or should have known the BPO Products degrade to benzene under these conditions exposing consumers to benzene. Defendant further knew or should have known that, because of the known degradation of BPO to

benzene, its BPO Products were contaminated with benzene by the time they reached consumers, but they sold them to Plaintiff, the Class, and the public anyway, without warning of the risk of exposure. Moreover, the 2–3-year shelf life printed on the BPO Products told consumers they were safe for use for years, when they were not. 4

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D. DEFENDANT KNEW OR SHOULD HAVE KNOWN BENZENE WAS FOUND IN OTHER CONSUMER PRODUCTS BUT DID NOT TEST THE BPO PRODUCTS

Defendant were aware or should have been aware of benzene 38. contamination in other on-market drug and healthcare products when they marketed and sold the BPO Products to Plaintiff, the Class and the public but did not test the BPO Products for benzene contamination. 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.31

Ε. DEFENDANT IGNORED FDA'S BENZENE ALERT TO TEST ITS **PRODUCTS**

In 2022, the FDA issued a safety alert warning drug manufacturers of the risk of benzene contamination in certain drug products and drug components. The FDA reiterated the risk benzene exposure poses to public health and the drug manufacturers' obligations to test drug products under the U.S. Code of Federal Regulations, Title 21:

> FDA reminds manufacturers they are required to establish scientifically sound and appropriate specifications and test procedures to assure drug components (active and inactive ingredients) and finished drug products conform to appropriate quality specifications (21 C.F.R. 211.84, 21 C.F.R. 211.160). This includes testing of raw materials and finished batches (21 C.F.R. 211.165) prior to release to ensure they meet appropriate

³¹ Valisure Citizen Petition on Benzene in Sunscreen and After-sun Care Products, May 24, 2021.

specifications for identity, strength, quality, and purity.³²

- 40. The FDA warned drug manufacturers that any drug products or components at risk of benzene contamination should be tested, and any batches with benzene above 2 ppm should not be released to the public.³³ The FDA further warned that, if any drug or drug component was subject to deterioration, drug manufacturers must have re-testing procedures in place to ensure continued purity and stability. The FDA recommended risk assessments to evaluate the possibility of benzene contamination in the drug products or components.³⁴ If any drug product in circulation was found to have benzene over 2ppm, the FDA directed that drug manufacturers contact the FDA to discuss a voluntarily recall.³⁵
- 41. To date, none of the Defendant's Products have been recalled due to benzene contamination.

F. TESTING FOUND COMMON BPO PRODUCTS CONTAIN DANGEROUS LEVELS OF BENZENE IN EXCESS OF REGULATORY LIMITS

42. Testing by Valisure in 2023 found common acne treatment products formulated with BPO are not only contaminated with benzene but have levels dangerous to public health. Valisure is an accredited independent laboratory who has developed validated analytical methods³⁶ to test drugs and consumer products to address rising concerns about public safety. Valisure has tested a wide variety of drugs and products for benzene including sunscreens, antiperspirants, hand sanitizers, and dry shampoos. Their work has led to widely publicized product recalls protecting the public

³² Federal Drug Administration. (Dec. 22, 2022). FDA Alerts Drug Manufacturers to the Risk of Benzene in Certain Drugs, 1.

 $^{26 \}parallel ^{33} Id., 3.$

 $^{27 \}begin{vmatrix} 34 & Id. \\ 35 & Id. \end{vmatrix}$

³⁵ *Id.*, 2.

³⁶ Valisure's test methods largely mirror those utilized by FDA's own "Drug Quality Sampling and Testing" ("DQST") Program. Valisure FDA Citizen's Petition at 4.

from dangerous and carcinogenic consumer products.³⁷

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- In 2023, Valisure tested 175 finished acne treatment products to determine whether any had benzene. Of the 175 products tested, 99 were formulated with BPO, 58 had active ingredients (either individually or in combination) of salicylic acid, sulfur, adapalene, azelaic acid, niacinamide and zinc, and 18 had no drug ingredients.³⁸ 83 of the BPO Products were purchased over the counter from major retailers and 16 were prescription products purchased from licensed wholesalers.³⁹ The BPO Products included popular BPO Products: Proactiv 2.5% BPO Cream, Target Up & Up 2.5% BPO Cream, Equate Beauty 10% BPO Cream, Equate BPO Cleanser, Neutrogena 10% BPO Cleanser, Clearasil 10% BPO Cream, CVS Health 10% BPO Face Wash, Walgreens 10% BPO Cream, La Roche Posay BPO Cream, and Clean & Clear 10% BPO Lotion.
 - Valisure used three incubation temperatures to evaluate the effects of

15 ³⁷ See Valisure May 24, 2021 Citizen Petition on Benzene in Sunscreen and After-sun Care Products, https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-sunscreen); Valisure's 16 Citizen Petition on Hand Sanitizer Products Containing Benzene Contamination (filed March 24, 2021), https://www.regulations.gov/document/FDA-2021-P-0338-0001), Valisure's Citizen Petition 17

on Benzene in Sunscreen and After-sun Care Products (filed May 24, 2021), https://www.regulations.gov/document/FDA-2021-P-0497-0001), Valisure's Citizen Petition on

18 Benzene in Body Spray Products (filed November 3, 2021,

19 https://www.regulations.gov/document/FDA-2021-P-1193-0001), Valisure's Citizen Petition on Benzene in Dry Shampoo Products (filed October 31, 2022), 20

https://www.regulations.gov/document/FDA-2022-P-2707-0001) see also CNET, Dry Shampoo 21

Recall: What Is Benzene and Which Brands Are Affected https://www.cnet.com/health/personalcare/dry-shampoo-recall-what-is-benzene-and-which-brands-are-affected/ (identifying 19 types of dry

22 shampoo have been recalled due to benzene content); Ryan Basen, Medpage Today, After Valisure Petition, Ol' Dirty Benzene Forces Another Recall (November 30, 2021),

23 https://www.medpagetoday.com/special-reports/exclusives/95929 ("After Valisure Petition, Ol' Dirty

Benzene Forces Another Recall"); Bruce Y. Lee, Forbes, FDA: P&G Recalls Antiperspirant Sprays Due To Cancer Risk Of Benzene (Nov. 24, 2021),

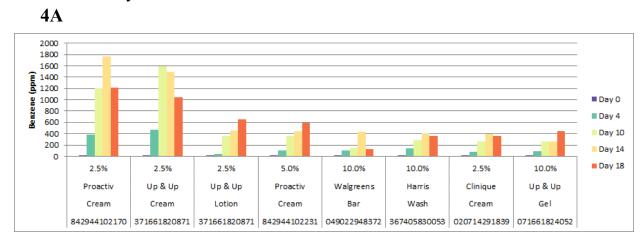
https://www.forbes.com/sites/brucelee/2021/11/24/fda-pg-recalls-antiperspirants-body-sprays-due-to-25 cancer-risk-of-benzene/?sh=69cf13c24f32; see also Sandee LaMotte, CNN, Antiperspirant recall:

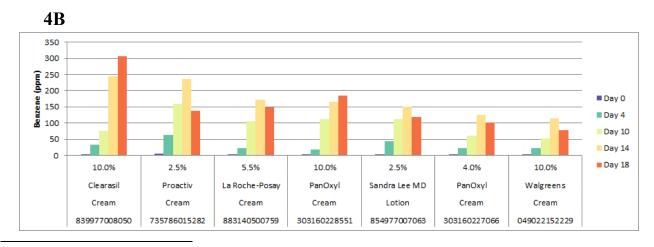
26 What the finding of a cancer-causing chemical means for you (Dec. 1, 2021),

https://www.cnn.com/2021/12/01/health/deodorants-antiperspirants-recall-benzene-explainer-27 wellness/index.html.

³⁸ See Valisure Citizen's Petition on Benzoyl Peroxide (March 4, 2024). ³⁹ *Id*.

common distributor and consumer use, handling, and storage conditions on benzene formation. 37°C/98.6°F was used for human body temperature, 50°C/122°F was used to evaluate shelf-life performance as an accelerated stability testing temperature used by the pharmaceutical industry, ⁴⁰ and 70°C/158°F to model storage in a hot vehicle. ⁴¹ The BPO Products were incubated at 37°C for four weeks and 50°C for three weeks and benzene concentration was measured at certain time intervals using GC-MS. Benzene findings were plotted in real time and reported in parts per million ("ppm"). The results below were submitted to the FDA in Valisure's March 5, 2024 Citizen's Petition on Benzoyl Peroxide.



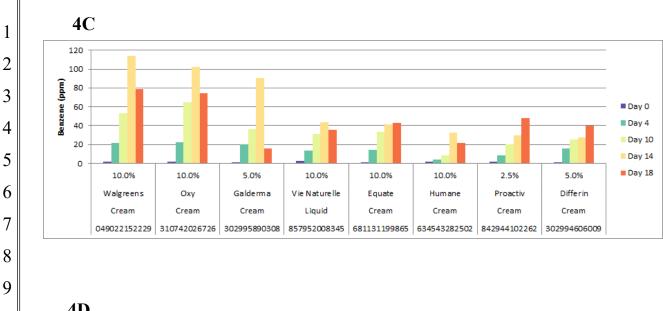


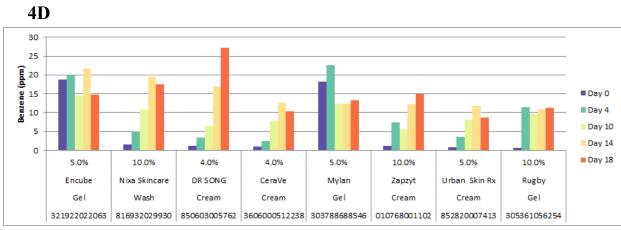
⁴⁰ Ghimire, Prakash et al., *Guidelines on Stability Studies of Pharmaceutical Products and Shelf Life Estimation*. INTERNATIONAL JOURNAL OF ADVANCES IN PHARMACY AND BIOTECHNOLOGY, (2020). 06. 15-23. 10.38111/ijapb.20200601004.

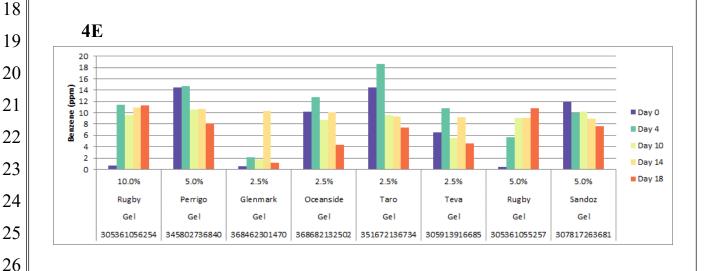
⁴¹ Grundstein A, Meentemeyer V, Dowd J. *Maximum vehicle cabin temperatures under different meteorological conditions*. Int J Biometeorol. 2009 May;53(3):255-61. doi: 10.1007/s00484-009-0211-x. Epub 2009 Feb 21. PMID: 19234721.

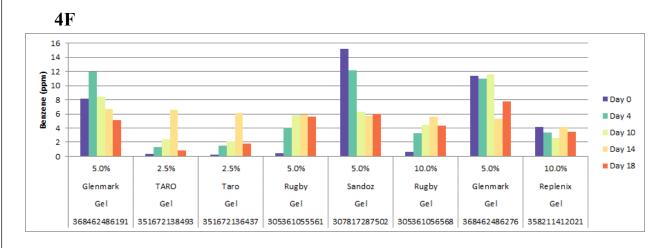
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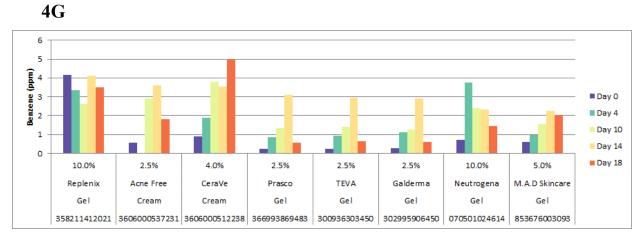
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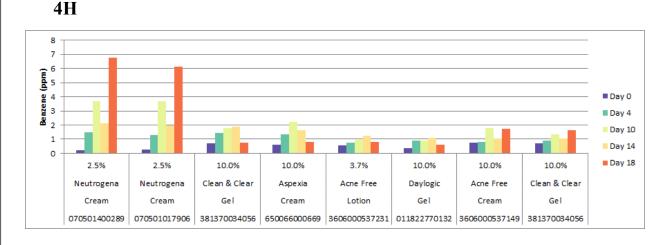












45. Valisure found the BPO formulated products were not chemically stable and yielded benzene at levels well over 2 ppm, the maximum amount allowed in any U.S. regulated drug. Some of the benzene levels were many times higher than 2 ppm reaching as high as 1700 ppm for Proactiv's 2.5% BPO Cream and 1600 ppm for

- Target's Up & Up 2.5% BPO Cream. 42 The concentration of BPO in the product did not influence the benzene levels, e.g., Target's Up & Up BPO Lotion and Proactiv's 10% BPO Cream yielded similar benzene results in the range of 600 ppm. Unexpectedly, Valisure found that benzene vapors leaked from some of the tested products' packaging contaminating the surrounding air even when the packaging was closed raising concern for additional inhalation exposures. 43
- 46. Valisure concluded that all on-market BPO acne formulations are fundamentally unstable and form unacceptably high levels of benzene under normal use, handling, and storage temperatures, but no such evidence was observed for acne treatment products not formulated with BPO.⁴⁴ The finding that additional benzene leaked into the surrounding air from the products' containers means the total consumer benzene exposure would be even more dangerous than the levels reported.
- 47. Valisure filed a Citizen's Petition on Benzoyl Peroxide on March 5, 2024⁴⁵ with the FDA requesting the FDA Commissioner to immediately demand a recall of all Products formulated with BPO and further to require that drug manufacturers do independent chemical verification.
 - G. DEFENDANT EXPOSED PLAINTIFF, THE CLASS, AND THE PUBLIC TO BENZENE, A KNOWN HUMAN CARCINOGEN, WITHOUT THEIR KNOWLEDGE
- 48. Although benzene has been found in the BPO Products and released into the surrounding air from the packaging, Defendant did not list benzene among the Products' ingredients, on the Products' label or container, or anywhere in its advertising or on its websites. Defendant did not (and still do not) warn that the Products contain benzene, are at risk of benzene contamination, or that the product could cause consumers to be exposed to benzene even when sealed.

 $^{27 \}Big|_{43}^{42} Id.$

⁴³ *Id*.

^{| &}lt;sup>44</sup> Id.

⁴⁵ As of the date of filing this Class Action, Valisure's FDA Petition is still pending.

- 50. Benzene has no known safe level of exposure.⁴⁷ Benzene causes central nervous system depression and destroys bone marrow, leading to injury in the hematopoietic system.⁴⁸ The International Agency for Research on Cancer ("IARC") classifies benzene as a "Group 1 Carcinogen" that causes cancer in humans, including acute myelogenous leukemia ("AML").⁴⁹ AML is the signature disease for benzene exposure with rates of AML particularly high in studies of workers exposed to benzene.⁵⁰
 - 51. Benzene exposure is cumulative and additive. There is no safe level of

19 46 See Hamilton A., Benzene (benzol) poisoning, ARCH PATHOL, (1931):434-54, 601-37; Hunter

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FT, Chronic exposure to benzene (benzol). Part 2: The clinical effects. J. IND. HYG TOXICOL, (1939):21 (8) 331-54; Mallory TB, et al., Chronic exposure to benzene (benzol). Part 3: The pathological results. J. IND. HYG TOXICOL, (1939):21 (8) 355-93; Erf LA, Rhoads CP., The hematological effects of benzene (benzol) poisoning. J. IND. HYG TOXICOL, (1939):21 421-35;

American Petroleum Institute, *API Toxicological Review: Benzene*, NEW YORK, (1948); Infante PF, Rinsky RA, Wagoner JK, et al., *Leukemia in benzene workers*, LANCET, (1977);2 (8028): 76-78.

⁴⁷ Harrison R, Saborit, J., *WHO Guidelines for Indoor Air Quality – Selected Pollutants, (2010); see also* Smith, Martyn T. (2010). Advances in Understanding Benzene Health Effects and Susceptibility. *Annual Review of Public Health., (2010)* Vol. 31:133-148.

⁴⁸ FDA Toxicological Data for Class 1 Solvents, Appendix 4, *Benzene*, https://www.fda.gov/media/71738/download.

⁴⁹ International Agency for Research on Cancer. *Benzene, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 120,* LYON, France: World Health Organization, (2018).

⁵⁰ American Cancer Association, *Benzene and Cancer Risk*, https://www.cancer.org/cancer/risk-prevention/chemicals/benzene.html (last visited October 20, 2023).

exposure to benzene, and all exposures constitute some risk in a linear, if not supralinear, and additive fashion."⁵¹

- 52. The Agency for Toxic Substances and Disease Registry's ("ATSDR") "Tox Facts" for benzene warns that people can be exposed to benzene vapors from benzene-containing products and that benzene harms the blood marrow, causing leukemia and anemia, and affects the immune system leaving victims vulnerable to infection.⁵²
- 53. According to the FDA, benzene in small amounts over long periods of time can decrease the formation of blood cells and long-term exposure through inhalation, oral intake, and skin absorption may result in cancers such as leukemia and other blood disorders.⁵³
- 54. Benzene is a major industrial chemical made from coal and oil that is heavily regulated by the EPA as an important environmental pollutant that negatively affects the soil, air, and groundwater. Waste and air emissions containing benzene are considered hazardous waste. The coal, oil, paint, and chemical industries are heavily regulated due to the emission of carcinogens including benzene from refining and other industries processes involving benzene and benzene byproducts, which can end up in the air, water, and food supply.
- 55. Benzene is heavily regulated to protect public health and should not be in drug products, especially ones such as acne treatment that are used daily by children and teenagers for many years. The FDA drug guidelines specify that benzene must not be used to make drugs products because of the unacceptable toxicity and deleterious environmental effects.⁵⁴ The FDA allows one limited exception where the use of

⁵¹ Smith, Martyn T., *Annual Review of Public Health*, ADVANCES IN UNDERSTANDING BENZENE HEALTH EFFECTS AND SUSCEPTIBILITY *(*2010) Vol. 31:133-148.

⁵² Agency for Toxic Substances and Disease Registry, *Benzene – Tox Facts*, CAS # 71-43-2.

⁵³ Federal Drug Administration. (June 9, 2022). *Frequently Asked Questions*: https://www.fda.gov/drugs/drug-safety-and-availability/frequently-asked-questions-benzene-contamination-drugs.

⁵⁴ Food and Drug Administration, *Q3C – Tables and Lists Guidance for Industry*, https://www.fda.gov/media/71737/download (last visited September 26, 2023).

benzene in a drug product is unavoidable to produce a drug product with a significant therapeutic advance. In that instance, benzene must be restricted to 2 parts per million (ppm).⁵⁵ Defendant's BPO Products do not meet this rare exception.

- 56. Benzene is heavily regulated in the workplace. The U.S. Occupational Safety and Health Administration ("OSHA") set an eight-hour exposure standard of 1 ppm.⁵⁶ The National Institute for Occupational Safety and Health ("NIOSH") established a recommended exposure level (REL) of 0.1 ppm (15-minute ceiling limit). Subsequent exposure studies known as the "China studies" confirmed cancer at levels below 1 ppm.⁵⁷ The benzene levels created from Defendant's BPO Products are many times higher than the levels reported in these worker studies and the acceptable limits set by regulators.
- 57. Benzene can also pass from the mother's blood to a developing fetus causing the baby to be exposed to benzene.⁵⁸ Animal studies have shown low birth weights, delayed bone formation, and damage to the bone marrow of developing offspring when pregnant animals breathed benzene.⁵⁹
- 58. Plaintiff, the Class, and Subclasses were exposed to benzene from the BPO Products by inhalation and dermal absorption. Benzene can be absorbed into the body via inhalation, skin absorption, ingestion, and/or eye contact. ⁶⁰ Plaintiff, the Class, and Subclasses applied the BPO Products to areas of the skin including the face, neck, chest, and back one to three times per day and used the BPO Products as washes or scrubs in heated showers. Plaintiff, the Class, and Subclasses were also exposed to

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⁵⁵ *Id*.

^{23 | &}lt;sup>10.</sup> OSHA. Occupational exposure to benzene: Final rule. Fed. Reg. 1987;52-34460-578.

⁵⁷ See Lan Q, Zhang L et al., Hematotoxicity in Workers Exposed to Low Levels of Benzene, SCIENCE, (December 3, 2004); Costa-Amaral I, V. B. L., Environmental Assessment and Evaluation of

Oxidative Stress and Genotoxicity Biomarkers Related to Chronic Occupational Exposure to Benzene, INT J ENVIRON RES PUBLIC HEALTH, (2019) Jun; 16(12): 2240.

^{26 | 58} *Id*.

 $^{27 \}Big|_{60}^{59} \frac{Ia}{60}$

⁶⁰ Centers for Disease Control and Prevention, *The National Institute for Occupational Safety and Health Pocket Guide to Chemical Hazards, Benzene Exposure Limits*, https://www.cdc.gov/niosh/npg/npgd0049.html.

benzene leaked from contaminated BPO Products.

DEFENDANT MARKETED THEMSELVES AS EXPERTS BUT Η. CONCEALED FROM PLAINTIFF AND THE CLASS ITS FAILURE TO TEST THE PRODUCTS FOR SAFETY

- Defendant's BPO Products degrade to benzene, during normal and expected handling, use, or storage but Defendant did not warn Plaintiff, the Class, the Subclasses, and the public about benzene contamination or the health risks of exposure. Instead, Defendant made broad sweeping claims that the BPO Products were safe, researched, tested, validated, backed by science, and approved by dermatologists.
- 60. CVS promised Plaintiff, the Class, and Subclasses that dermatologists were involved in the Products' review and "also participated directly in the research behind a product or oversaw testing."61 CVS affirmed its CVS Health Products and other national brand BPO Products made by other Defendant were "dermatologist-tested and reviewed by a qualified dermatologist before release."62
- Defendant's misrepresentations and omissions misled Plaintiff, the Class, the Subclasses, and the public regarding the safety, stability, and quality of the BPO Products. Defendant's broad claims of safety in its marketing, social media, and on websites gave Plaintiff, the Class, the Subclasses, and the public a false sense of safety leading them to believe the BPO Products were safe. Defendant made these statements uniformly to Plaintiff, the Class, the Subclasses, and the public, while shirking its responsibility to do adequate and meaningful testing before selling them to the public. Defendant's statements and affirmations to Plaintiff, the Class, the Subclasses, and the public were false, misleading, unsubstantiated, and blatantly deceptive. ///

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⁶¹ CVS, Dermatologist Recommended Skin Products, CVS Pharmacy, https://www.cvs.com/shop/beauty/skin-care/dermatologist-tested-skin-care (last visited October 17, 2023). ⁶² *Id*.

2.1

I. DEFENDANT DID NOT WARN PLAINTIFF AND THE CLASS THE PRODUCTS WERE AT RISK OF BENZENE CONTAMINATION

- 62. Defendant represented to the Plaintiff, the Class, the Subclasses, and the public, that each of its BPO Products had only the ingredients listed on the Product label, package, container, and company website. Defendant did not identify benzene anywhere on the Product label, container, advertising, or packaging, and benzene is not mentioned or discussed on Defendant's website where Product information is found.
- 63. Defendant's statements about the BPO Products' ingredients were false, deceptive, and misleading. Defendant's statements were meant to convey to consumers the Products were safe and did not contain contaminants or carcinogens such as benzene. Defendant made these statements to the Plaintiff, the Class, and the Subclasses, and omitted benzene from all advertising, labeling, and packaging when they knew or should have known the statements were false, misleading, and deceptive. Reasonable consumers, relying on Defendant's statements about the Products reasonably believed the Products were safe and did not contain benzene. Reasonable consumers reasonably believed Defendant, one of the largest pharmacy retailers in America, would provide correct and truthful information about its drug products.

J. DEFENDANT DIRECTLY MARKETED TO CHILDREN AND TEENAGERS

- 64. Defendant's BPO Products are widely used by children and teenagers as a standalone treatment or in combination with other BPO Products. Defendant knew that adolescents were the largest users with users as young as 7-10 years old. Defendant knew that some consumers would use the BPO Products for many years starting in their teens. There is no cure for acne. Defendant knew that consumers with chronic acne would use its BPO Products several times a day throughout their lifetime exposing themselves to Defendant's Products countless times.
- 65. Defendant marketed and sold the BPO Products directly to children and teenagers when they knew or should have known the BPO Products degraded to

benzene under normal use and storage conditions. Defendant's marketing of BPO Products to children and teenagers without mentioning benzene, the risk of benzene exposure, or lack of testing for benzene was egregious, deceptive, and dangerous.

V. PUNITIVE DAMAGES ALLEGATIONS

- 66. Defendant's conduct was done with malice and reckless disregard for human life. Defendant knew the BPO Products degraded to benzene when exposed to heat under normal consumer use, handling, and storage conditions. Defendant further knew that benzene is a known human carcinogen that is not supposed to be in the BPO Products due to the grave risk of harm to consumers. Defendant disregarded this information and the known risks of benzene exposure and deliberately omitted benzene from the list of ingredients, the Products' labels, and its social media and websites where information about the Products can be found. Defendant consciously and deliberately crafted the BPO Products' marketing, labels, packaging, containers, and warnings intending to mislead consumers and lead them to believe the BPO Products were safe and carcinogen-free.
- 67. Defendant marketed itself as an leading pharmaceutical retailer and merchandiser skilled in selling safe and reliable drug products while at the same time withholding material health and safety information Defendant knew was essential to informed consumer decision making. Defendant knew that, by its conduct, it was robbing Plaintiff, the Class, the Subclasses, and the public of their right to choose safe products.
- 68. Defendant was on notice of benzene findings in its own and other consumer and drug products leading to widely publicized recalls. Defendant was on notice of the FDA's concerns of benzene contamination in drug and consumer products including its own products and received the FDA's 2022 directive to test Products for benzene contamination. Defendant disregarded these notices and continued to market and sell the BPO Products without testing them for benzene.
 - 69. Defendant knew its decisions and chosen course of conduct was risky and

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would cause consumers such as the Plaintiff, the Class, and Subclasses to be exposed to benzene. Defendant's conduct was not by accident, but was deliberate, calculated, and informed. Defendant knew they could sell more BPO Products and earn more money by concealing material human health and safety information. Defendant further knew that testing the BPO Products for benzene would yield findings of benzene requiring recalls and/or a shutdown of production causing significant losses of income. Defendant's goals were met not only because of its false and deceptive advertising, labeling, and packaging, but through a comprehensive scheme of aggressive marketing and image branding leading consumers to believe they were acne treatment experts dedicated to drug research, development, and safety and using only the safest ingredients and formulations that would remain pure and stable until the designated end. Defendant's conduct and concealment of material health information was done to further its own monetary gain and with conscious disregard of the Plaintiff, the Class, and the public's right to choose safe products. Defendant's conduct was intentional, calculated, blatantly deceptive, unscrupulous, and offensive to consumer health and public policy. To redress the harm caused by Defendant's conduct, Plaintiff, on behalf of the Class, and the Subclasses seek punitive damages against the Defendant.

VI. PLAINTIFF SPECIFIC ALLEGATIONS

70. Plaintiff Alan Montenegro is a Los Angeles County, California resident who places a high priority on health and safety, and on the adverse health consequences of exposure to carcinogens such as benzene. In shopping for drug products for his skin and face, Plaintiff Alan Montenegro was particularly concerned about the product being cost effective, that the BPO Product received positive reviews from verified buyers, and the before and after images for use of the Product. Plaintiff recalls seeing online advertisements by Defendant before purchasing them in the store. Based on the statements made by Defendant, their widely recognized name, and lack of information that the BPO Products contained carcinogens such as benzene, Plaintiff believed the Products were safe to put on his skin. Defendant's representations and omissions of

human health and safety information were material to Plaintiff.

- 71. Plaintiff Montenegro bought Clearasil Stubborn Acne Control 5 in 1 Spot Treatment Cream, CVS Health Acne Treatment Cream, CVS Health Acne Control Cleanser, and Neutrogena Rapid Clear Stubborn Acne Spot Gel and used it from 2017 to 2021 in hopes of creating a daily skin routine and getting rid of acne spots and blemishes. Plaintiff was unaware when he bought the BPO Product that it was contaminated with benzene or that it could degrade to benzene. Had Defendant been truthful and told Plaintiff he would be exposed to benzene and/or be at increased risk of cancer, he would not have purchased Clearasil Stubborn Acne Control 5 in 1 Spot Treatment Cream, CVS Health Acne Treatment Cream, CVS Health Acne Control Cleanser, and Neutrogena Rapid Clear Stubborn Acne Spot Gel.
- 72. Plaintiff Montenegro suffered an ascertainable economic loss because of Defendant's statements and misrepresentations in that he bought the BPO Products he would not have bought but for Defendant's statements and misrepresentations.

VII. CLASS ACTION ALLEGATIONS

- 73. Plaintiff brings this case on behalf of himself, and all others similarly situated as a Class Action under Rule 23 of the Federal Rules of Civil Procedure. Plaintiff seeks to represent a National Class of consumers who bought the Products, and State Subclasses of consumers from the states identified below. Excluded from this Class are Defendant, its employees, co-conspirators, officers, directors, legal representatives, heirs, successors, and affiliated companies; Class counsel and their employees; and judicial officers and their immediate families as court staff assigned to the case.
- 74. The Class does not seek damages for physical injuries, although Plaintiff was physically harmed by being exposed to benzene.
- 75. The Class will include a National Class to include all persons who bought for use, and not resale, the Products within the United States.
 - 76. The State Subclasses will include all persons who bought for use, and not

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27 28 throughout the United States, and there are tens of thousands of Subclass members in each of the listed states, making the Class and state Subclasses so numerous and geographically dispersed that joinder of all members is inconvenient and impracticable.

- resale, the Products within California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Ohio, Pennsylvania, Rhode Island, and Washington.
- 77. This action has been brought and may be properly maintained as a Class Action under Rule 23 of the Federal Rules of Civil Procedure because there is a welldefined community of interest and the proposed Class meets the class action requirements under Rule 23 of numerosity, commonality, typicality, and adequacy of representation.
- Defendant engaged in a common course of conduct giving rise to the legal rights sought to be enforced by Plaintiff, on behalf of himself, and the other Class members. Similar or identical statutory and common law violations, business practices, and injuries are involved.

Numerosity. Plaintiff believes there are millions of Class members

- **Commonality.** There are questions of law and fact common to all Class and Subclass members that predominate over questions which affect only individual Class members. All Class and Subclass members were deceived and misled by Defendant through the same advertising, online representations, labeling, and packaging, which do not mention benzene and misrepresent the characteristics, ingredients, and safety of the BPO Products. All Class and Subclass members bought Defendant's BPO Products and have suffered an economic loss because of Defendant's deceptions and omissions. Thus, there is a well-defined community of interest in the questions of law and facts common to all Class and Subclass members. Other common questions of law and fact in this dispute include, without limitation:
 - a. Whether Defendant's BPO Products degrade to benzene under common distributor and consumer handling, use, and storage conditions.

- q. Whether Defendant's conduct violated Pennsylvania consumer protection laws.
- r. Whether Defendant's conduct violated Rhode Island consumer protection laws.
- s. Whether Defendant's conduct violated Washington's consumer protection laws.
- t. Whether Defendant breached the express and implied warranties they made about the BPO Products.
- u. Whether Defendant was unjustly enriched by the Plaintiff, the proposed Class, and Subclasses members' purchase of the BPO Products.
- v. Whether the Plaintiff, the proposed Class, and Subclasses have been injured and if so, what is the proper measure of damages.
- w. Whether the Plaintiff, the proposed Class, and Subclasses have the right to economic damages including compensatory, exemplary, and statutory remedies for Defendant's misconduct.
- x. Whether the Plaintiff, the proposed Class, and Subclasses have the right to injunctive, declaratory, or other equitable relief and attorneys' fees.
- 81. **Typicality.** Plaintiff's claims are typical of the claims of the Class and Subclasses because the claims arise from the same course of misconduct by Defendant, *i.e.*, Defendant's false and misleading advertising and its failure to disclosure benzene in the Products. The Plaintiff, and all Class and Subclass members were all exposed to the same uniform and consistent advertising, labeling, and packaging statements Defendant made about the Products. Because of the Defendant's misconduct, Plaintiff, like all Class members, was damaged and has incurred economic loss because of buying the Products believed to be safe. The claims of the Plaintiff are typical of Class members.
- 82. **Adequacy.** The Plaintiff will fairly and adequately represent and protect the interests of all Class and Subclass members. Plaintiff has no interests antagonistic to

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the Class or Subclass members. Plaintiff hired attorneys experienced in the prosecution of consumer Class Actions and Plaintiff intends to prosecute this action vigorously. Plaintiff anticipates no difficulty in the management of this litigation as a Class Action.

Finally, this Class Action is proper under Rule 23(b) because, under these facts, a Class Action is superior to other methods and is the most efficient method for the fair and efficient adjudication of the dispute. The Class and Subclass members have all suffered economic damages because of Defendant's deceptive trade practices, false advertising, and omissions of material health and safety information. Because of the nature of the individual Class and Subclass members' claims and the cost of the Products, few, if any individuals, would seek legal redress against Defendant because the costs of litigation would far exceed any potential economic recovery. Absent a Class Action, individuals will continue to suffer economic losses for which they would have no remedy, and Defendant will unjustly continue its misconduct with no accountability while retaining the profits of its ill-gotten gains. Even if separate cases could be brought by individuals, the resulting multiplicity of lawsuits would cause undue hardship, burden, and expense for the Court and the litigants, as well as create a risk of inconsistent rulings across the country, which might be dispositive of the interests of individuals who are not parties. A Class Action furthers the important public interest of containing legal expenses, efficiently resolving many claims with common facts in a single forum simultaneously, and without unnecessary duplication of effort and drain on critical judicial resources. The Class Action method presents far fewer management difficulties than individual cases filed nationwide and provides the benefit of comprehensive supervision by a single court.

VIII. CAUSES OF ACTION

- A. VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW BUS. & PROF. CODE § 17200 et seq., on Behalf of the Nationwide Class and California Subclass
- 84. Plaintiff realleges and incorporates all other paragraphs in this Class Action

Complaint and further alleges:

- 85. Plaintiff brings this cause of action on behalf of himself, and all members of the Nationwide Class, and the California Subclass, all of whom are similarly situated consumers.
- 86. California's Unfair Competition Law, CAL. BUS. & PROF. CODE § 17200, et seq., prohibits "unlawful, unfair, or fraudulent business act or practices" and "unfair, deceptive, untrue or misleading advertising." Defendant misrepresented its Products in advertising, labels, and containers and misled Plaintiff, the Class and Subclass, and the public about the ingredients, characteristics, purity, quality, approval, and safety of the Products. Defendant led Plaintiff, the Class, and Subclass, and the public to believe the Products were safe.
- 87. Defendant's advertising, online representations, labeling, and packaging of the Products were misleading, fraudulent, and deceptive. Defendant knew through the Products' development, formulation, research, and pre-sale safety and stability testing, the Products were not chemically and physically stable when exposed to common temperature conditions. Defendant knew or should have known the Products formulated benzene under normal and expected consumer use, handling, and storage conditions, and that consumers would be exposed to benzene. Defendant were specifically reminded by the FDA of its obligation to ensure the safety and quality of its Products, including testing them for benzene before selling them to the public, but shirked its duties and continued to market and sell the Products without substantiating safety, or warning Plaintiff, the Class, and the public about benzene.
- 88. Defendant omitted material health and safety information, *e.g.*, benzene, from the Products' advertising, label, container, and warnings. Defendant did not tell Plaintiff and the Class members they would be exposed to benzene, a human carcinogen, during normal and expected handling, use and storage of the Products, even with the Products' container closed.
 - 89. Defendant's acts and omissions were likely to deceive reasonable

consumers and the public. Reasonable consumers expect to be told about all ingredients in Products. Reasonable consumers further expect that carcinogens in the Products be disclosed. Reasonable consumers further expect that on market drugs to be free of carcinogens, unless told otherwise. Benzene in a widely marketed drug product used by children, teens, and the public is material health information reasonable consumers expect to be told.

- 90. Had Defendant been truthful in its advertising, labeling, packaging, and online statements about benzene in the Products, or the risk of contamination, and the risk of cancer, Plaintiff and the Class members would not have bought the Products.
- 91. Defendant's acts, omissions, and concealment of material health and safety information are ongoing and continuing to cause harm. Defendant continues to market, advertise, and sell the Products to the public without telling the public about benzene in the Products, or the risk of contamination, and the risk of cancer. Defendant continues to market themselves as responsible drug manufacturers and sellers who sell safe products when they have not tested the Products for benzene or quantified the levels of benzene formed in the Products during normal and expected storage conditions.
- 92. Defendant engaged in these deceptive practices for significant financial gain, which is unfair, unreasonably dangerous to Plaintiff, the Class, and California Subclass members, and not outweighed by any benefit. Omitting and concealing material human health and safety information such as benzene in the Product and the consumers' risk of cancer from the Products is unethical, unscrupulous, and offensive. Defendant does not have to sell acne Products with BPO. Some of the Defendant sell equally effective acne drug products that do not contain BPO.
- 93. Plaintiff, on behalf of himself, and all members of the Nationwide Class, and the California Subclass suffered ascertainable economic losses because of Defendant's misconduct because he bought the Products, he otherwise would not have bought but for Defendant's misrepresentations and affirmations of safety.
 - 94. Because of Defendant's misconduct, Plaintiff, on behalf of himself, the

Class and Subclass members, seek recovery of their economic damages, attorneys' fees, restitution, and all other relief allowable under CAL. BUS. & PROF. CODE § 17200, et seq., including an injunction to enjoin Defendant from continuing its fraudulent and deceptive business practices. The damages sought are ascertainable, uniform to the Class and can be measured and returned to the Class members.

B. <u>VIOLATION OF CALIFORNIA'S CONSUMER LEGAL</u> <u>REMEDIES ACT, CAL. Civ. Code § 1750, et seq.</u>, on Behalf of the Nationwide Class and California Subclass

- 95. Plaintiff realleges and incorporates all other paragraphs in this Complaint and further alleges:
- 96. Plaintiff brings this cause of action on behalf of himself, and all Class California Subclass members, all of whom are similarly situated consumers within the meaning of CAL. CIV. CODE § 1781.
- 97. Defendant's acts and omissions violated California's Consumer Legal Remedies Act, CAL. CIV. CODE § 1750, *et seq.*, enacted to protect consumers from being victimized and deceived by advertisers, distributors, and sellers like the Defendant. Other Defendant regularly transact business in California, including in this District, and have engaged in misconduct that has and had a direct, substantial, foreseeable, and intended effect of injuring people in California generally, and in this District.
- 98. California's Consumer Legal Remedies Act, CAL. CIV. CODE § 1750, *et seq. prohibits* unfair methods of competition and unfair or deceptive acts or practices in connection with the sale of consumer goods. Defendant violated several prohibitions of CIV. CODE § 1750(a).
- 99. Defendant violated CAL. CIV. CODE § 1750(a)(2) by representing the source, sponsorship, and approval, of the Products, *e.g.*, the Products were backed by sound scientific principles, that Defendant met its obligations to conduct adequate and meaningful quality and safety testing before selling the Products to the public, and

represented the Products only contained the ingredients listed, and were free of carcinogens.

- 100. Defendant violated CAL. CIV. CODE § 1750(a)(3) by representing the affiliation, connection, or association with, or certification by, another *e.g.*, the Products were approved by dermatologists and manufactured in conformity with current good manufacturing practices.
- 101. Defendant violated CAL. CIV. CODE § 1750 (a)(4) by using deceptive representations, *e.g.*, the Products were safe, validated, and supported by the latest research, and free of carcinogens such as benzene.
- 102. Defendant violated CAL. CIV. CODE § 1750(a)(5) by representing the Products have characteristics, ingredients, uses, or benefits, which they do not, *e.g.*, misleading Plaintiff and the Class members the Products only contained the listed ingredients, did not contain benzene, and did not increase the risk of the consumers' risk of cancer.
- 103. Defendant violated CAL. CIV. CODE § 1750(a)(6) by representing the Products were not deteriorated unreasonably or altered *e.g.*, the Products were pure and had not degraded or formed benzene.
- 104. Defendant violated CAL. CIV. CODE § 1750(a)(7) by representing the Products were pure and of a particular standard or quality, when they are not.
- 105. Defendant violated CAL. CIV. CODE § 1750(a)(9) by advertising the Products with the intent not to sell them as advertised, *e.g.*, the Products were of pure quality, safe, made in conformity with current good manufacturing practices, and not adulterated.
- 106. Had Defendant been truthful in its advertising, labeling, packaging, warnings, and online statements about benzene in the Products and the risk of cancer, Plaintiff and the Class members would not have bought the Products. Benzene, a human carcinogen, in a widely marketed and available consumer drug product, is material health and safety information Defendant knew Plaintiff, the Class members,

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and the public would want to know. The Defendant's omission of this material information was common to all Class and Subclass members and made to all Class and Subclass members uniformly through common advertising, online representations, labeling, and packaging.

- 107. Defendant's acts, omissions, and concealment of material health and safety information are ongoing and continuing to cause harm. Defendant continues to market, advertise, and sell the Products to the public without telling the public about benzene in the Products and the risk of cancer. Defendant continues to market themselves as responsible drug manufacturers and sellers who sell safe products when they have not quantified the levels of benzene in and created in the Products during normal and expected storage conditions.
- 108. Defendant engaged in these deceptive practices for significant financial gain, which is unfair, unreasonably dangerous to Plaintiff, the Class and Subclass members, and not outweighed by any benefit. Omitting and concealing material human health and safety information such as the consumers' risk of cancer from exposure to the Products is unethical, unscrupulous, and offensive. Defendant does not have to sell acne Products with BPO. Some of the Defendant sell equally effective acne drug products that do not contain BPO.
- 109. Plaintiff, on behalf of himself, and all Class California Subclass members suffered ascertainable economic losses because of Defendant's misconduct because he bought the Products, he otherwise would not have but for Defendant's misrepresentations.
- 110. Because of Defendant's misconduct, Plaintiff, on behalf of himself and the Class and Subclass members, seeks recovery of their economic damages, attorneys' fees, punitive damages, restitution, and all other relief allowable under CAL. CIV. CODE § 1750, et seq., including an injunction to enjoin Defendant from continuing its fraudulent business practices. The damages sought are ascertainable, uniform to the Class and Subclass and can be measured and returned to the Class and Subclass

members.

C. <u>FALSE ADVERTISING UNDER VARIOUS STATE STATUTES</u>, on Behalf of the California, Hawaii, and New York Subclasses

- 111. Plaintiff realleges and incorporates all other paragraphs in this Complaint and further alleges:
- 112. Plaintiff brings this cause of action on behalf of himself, and all members of the National Class and the California, Hawaii, and New York Subclasses, all of whom are similarly situated consumers.
- 113. Defendant develops, research, manufactures, tests, markets and sell the BPO Products throughout the United States. Defendant knew through the Products' development, formulation, and testing, the Products are not chemically stable when exposed to certain expected and normal environmental and storage conditions and can form benzene, as a toxic byproduct. Despite this knowledge, Defendant did not mention benzene in the Products' advertising, ingredient list, label, container, or warnings. Defendant did not tell Plaintiff, the Class, and Subclass members they would be exposed to benzene, a human carcinogen, during normal and expected handling, use and storage of the Products, even with the Products' containers closed.
- 114. Benzene, a human carcinogen, in a widely marketed and available consumer drug product, is material health and safety information Defendant knew Plaintiff, the Class, and Subclass members, and the public would want to know. Defendant not only omitted this material human health and safety information from advertising, online representations, blogs, labeling, packaging, and warnings, but Defendant aggressively marketed themselves as drug experts, innovators, researchers, market leaders, and companies committed to consumer safety who devote substantial resources to drug research and development. Defendant's affirmations of safety and responsibility misled Plaintiff, and the Class members, leading them to believe the Products were tested, verified, and safe. Defendant further marketed the Products touting the approval of dermatologists, who likely were not aware of the presence of

benzene in the Products and of Defendant refusal to conduct adequate and meaningful testing before marketing and selling the Products to the public and following the FDA's 2022 alert to specifically look for benzene.

115. Defendant's acts and omissions constitute false advertising. Defendant advertised the Products with the intent not to sell them as advertised. Reasonable consumers, including Plaintiff and the Class and Subclass members, exposed to Defendant advertising would believe the Products were safe, verified, and free of benzene.

Advertising Law, Bus. & Prof. Code § 17500 et seq., which prohibits Defendant from disseminating statements "which are untrue or misleading, and which are known, or which by the exercise of reasonable care should be known, to be untrue or misleading." Defendant knew or should have known the Products formed benzene under normal, handling, use, and storage conditions but did not disclose this to Plaintiff and the Class and Subclass members. Defendant knew through the Products' development, formulation, research, and testing, the Products were not chemically stable when exposed to certain normal and expected environmental conditions. Defendant knew Plaintiff, the Class and Subclass members, and consumers would be exposed to benzene in the Products, even with the Products' original packaging closed.

117. Defendant's false and misleading advertising violated Hawaii's False Advertising Law, HI REV. STAT. § 708-871. Defendant knowingly or recklessly made false and misleading statements in the Products' advertising to the public. 63 Defendant further advertised the Products with the intent not to sell them as advertised and

⁶³ HI REV STAT § 708-871, False Advertising: (1) A person commits the offense of false advertising if, in connection with the promotion of the sale of property or services, the person knowingly or recklessly makes or causes to be made a false or misleading statement in any advertisement addressed to the public or to a substantial number of persons. (2) "Misleading statement" includes an offer to sell property or services if the offeror does not intend to sell or provide the advertised property or services: (a) At the price equal to or lower than the price offered; or (b) In a quantity sufficient to meet the reasonably- expected public demand unless quantity is specifically stated in the advertisement; or (c) At all.

misrepresented the ingredients, quality, purity, safety, and character of the Products.

118. Defendant's false and misleading advertising violated New York's General

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Business Law § 350 et seq. ("GBL § 350"), which prohibits "[f]alse advertising in the misconduct of any business, trade or commerce or in the furnishing of any service" in

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New York. Under GBL § 350, "false advertising" includes "advertising, including

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labeling, of a commodity . . . if such advertising is misleading in a material respect."

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Defendant violated GBL § 350 by advertising and selling the Products without

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disclosing material health and safety information, *e.g.*, benzene and the consumers risk of cancer from benzene. Defendant's false and misleading advertising was directed at

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consumers, the New York Subclass members, and the public, and caused consumer

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injury and harm to the public interest.

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119. Had Defendant been truthful in its advertising, online representations, labeling, and packaging about benzene, Plaintiff, the Class, and Subclass members

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would not have bought the Products.

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Subclasses suffered ascertainable economic losses because of Defendant's misconduct

120. Plaintiff on behalf of himself, California, Hawaii, and New York

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because they bought the Products, they otherwise would not have but for Defendant's

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material misrepresentations.

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Class and Subclass members, seek recovery of their economic damages, attorneys' fees,

121. Because of Defendant's misconduct, Plaintiff, on behalf of himself, and the

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injunction to enjoin Defendant from continuing its fraudulent business practices. The

punitive damages, restitution, and all other relief allowable by law, including an

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damages sought are ascertainable, uniform to the Class and Subclasses and can be

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measured and returned to the Class and Subclass members.

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D.

<u>DECEPTIVE TRADE PRACTICES UNDER VARIOUS STATE</u>
<u>STATUTES</u>, on Behalf of the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses

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122. Plaintiff realleges and incorporates all other paragraphs in this Complaint

- 123. Plaintiff brings this cause of action on behalf of himself, and all members of the National Class and California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses, all of whom are similarly situated consumers.
- 124. Defendant's acts and omissions constitute deceptive business practices in violation of state deceptive trade practices laws.
- 125. Defendant represented the BPO Products had characteristics, uses, and benefits, they did not, *e.g.*, Defendant represented the BPO Products were pure, of good quality, safe, and only contained the ingredients disclosed.
- 126. Defendant represented the BPO Products were not deteriorated or altered, when they knew, or should have known, the BPO Products degraded to benzene under normal and expected use, handling, and storage conditions.
- 127. Defendant represented the BPO Products contained only the ingredients listed on Defendant's websites, advertising, labels, and containers. Defendant did not disclose to Plaintiff, the Class and Subclass members, and the public the BPO Products were at risk of benzene contamination.
- 128. Defendant advertised the BPO Products with the intent not to sell them as advertised.
- 129. Defendant's acts and omissions violated Connecticut Unfair Trade Practices Act, Conn. Gen Stat. Ann., § 42-110, et seq., which broadly prohibits Defendant from engaging in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce such as those committed by Defendant and alleged in this Class Action.
- 130. Defendant's acts and omissions violated Hawaii's Uniform Deceptive Trade Practice Act, HAW. REV. STAT. §481-A3 because Defendant: (1) caused the likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of the Products; (2) represented the Products had characteristics,

ingredients, or benefits, they did not; (3) represented the Products were not deteriorated or altered, when they were; (4) represented the Products were of a particular standard or quality when they were not; and (5) advertised the Products with the intent not to sell them as advertised.

- 131. Defendant's acts and omissions violated Illinois' Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 *et seq*. Defendant's used deception, fraud, false pretense, false promises, and omitted material health and safety information about the Products' degradation to benzene, and/or contamination with benzene, which Defendant intended the Illinois Subclass members to rely upon.
- 132. Defendant's acts and omissions violated Maryland's Unfair or Deceptive Trade Practices Act, MD. Com. Code, Title 13, Subtitle 3, §13-301 because Defendant: (1) represented the Products had characteristics, ingredients, uses, and benefits, they did not; (2) represented the Products were not deteriorated or altered, when they were; (3) represented the Products were of a particular standard or quality, when they were not. Defendant's representations about the Products' ingredients, and omission of benzene were misleading, deceptive, incomplete, and not truthful in violation of Maryland's Unfair or Deceptive Trade Practices Act.
- 133. Defendant's acts and omissions violated Massachusetts consumer protection law, MASS. GEN. LAWS ANN. Ch. 93A, § 1 *et seq.*, which broadly prohibits unfair and deceptive trade practices such as those committed by Defendant and alleged in this Class Action.
- 134. Defendant's acts and omissions violated the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407, et seq., which prohibits the use of deception, fraud, misrepresentations, or unfair practices by a business, e.g., marketing Products as safe, approved, tested, and only containing the listed ingredients. Missouri's law further prohibits the suppression or omission of material facts such as the Products' degradation to benzene.
 - 135. Defendant's acts and omissions violated N.Y. GEN. Bus. LAW § 349, which

- prohibits Defendant from engaging in deceptive, unfair, and misleading acts and practices such as those committed by Defendant and alleged in this Class Action.

 Defendant's misrepresentations and omissions caused consumer injury and harm to the public interests of protecting public health and the public's right to know about any harmful constituents in the Products.
- 136. Defendant's acts and omissions violate Nevada Deceptive Trade Practice Act, Nev. Rev. Statutes, Title 52, Chapter 598 *et seq*. which prohibits Defendant from making false statements about its Products and advertising the Products without the intent to sell them as advertised.
- 137. Defendant's acts and omissions acts and omissions violated Ohio's Consumer Sales Practices Act, OHIO REV. CODE ANN. § 1345.01, et seq. which prohibits sales practices that are deceptive, unfair, or unconscionable, and Ohio's Deceptive Trade Practices Act, OHIO REV. CODE ANN.§ 4165 et seq.
- 138. Defendant's acts and omissions violated Pennsylvania's Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§201-1 *et seq.* because Defendant: (1) caused the likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of the Products; (2) used deceptive representations about the Products; (3) represented the Products had characteristics, ingredients, or benefits, they did not; (3) represented the Products were not deteriorated or altered, when they were; (4) represented the Products were particular standard or quality when they are not; and (5) advertised the Products with the intent not to sell them as advertised.
- 139. Defendant's acts and omissions violated Rhode Island's Deceptive Trade Practices Act, R.I. GEN. LAWS § 6- 13.1- 5.2(B), *et seq.* because Defendant: (1) caused likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of the Products; (2) used deceptive representations in connection with the Products; (3) represented the Products had sponsorship, approval, characteristics, ingredients, uses, benefits, they did not; (4) represented the Products were not

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⁶⁴ Under § 19.86.090, Washington consumers harmed by such practices may recover actual damages, the costs of the suit, including reasonable attorney's fees, and the court may, in its discretion, increase the award of damages to an amount up to three times the actual damages sustained.

deteriorated or altered, when they were; (5) represented the Products were of a particular standard, quality, or grade, when they were not; and (6) advertised the Products with the intent not to sell them as advertised.

- 140. Defendant's acts and omissions violated Washington's Consumer Protection Act, WASH. REV. CODE § 19.86.010, et seq., which broadly prohibits Defendant from engaging in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce. 64 Defendant's concealment of material health and safety information about the Products, which they knew or should have known, was injurious to the public interests of protecting public health and the public's right to know about any harmful constituents in the Products. Defendant's conduct caused harm to the Plaintiff, the Washington subclass members, and members of the public who bought the Products without knowing they degraded to benzene. Defendant's conduct has the capacity to cause harm to other persons who buy the Products.
- 141. Had Defendant been truthful in its advertising, labeling, and packaging of the Products and not omitted material health and safety information about benzene in and formed from the Products, Plaintiff, the Class, and Subclass members would not have bought the Products.
- 142. Defendant's acts and omissions and violations of the state consumer protection statutes are ongoing and continuing to cause harm.
- 143. Plaintiff on behalf of himself, California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses suffered an ascertainable economic loss because of Defendant's misconduct because they bought the Products, they would not have bought but for Defendant's misrepresentations.

144. Because of Defendant's misconduct, Plaintiff, on behalf of himself, and the Class and Subclass members, seek recovery of their economic damages, attorneys' fees, punitive damages, and all other relief allowable under the law. The damages sought are ascertainable, uniform to the Class and can be measured and returned to the Class members.

- E. <u>BREACH OF EXPRESS WARRANTY</u>, on Behalf of the Nationwide Class and on Behalf of the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses
- 145. Plaintiff realleges and incorporates all other paragraphs in this Complaint and further alleges:
- 146. Plaintiff brings this cause of action on behalf of himself, and all members of the National Class and the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses, all of whom are similarly situated consumers.
- 147. The Uniform Commercial Code § 2-313 provides that an affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the promise. Defendant advertised and sold the Products as safe, pure, of good quality, and only containing the listed ingredients. Defendant's advertising, labels, containers, packaging, advertising, and online statements did not mention benzene, leading consumers to believe the Products were safe for their ordinary use. Defendant's affirmations were uniformly made to Plaintiff and the Class members by Defendant in the Products' advertising, labeling, packaging, and online statements and were part of the basis of the bargain between Defendant, the Plaintiff, the Class and Subclass members.
- 148. Defendant's affirmations and promises are unlawful. When Defendant marketed, distributed, and sold the Products, Defendant knew, or should have known, the Products degraded to benzene under normal and expected use, handling, and storage

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27 28 conditions. Defendant knew, or should have known, the Products formed benzene and therefore did not conform to Defendant's express representations and warranties to consumers. Plaintiff, the Class, and Subclass members purchased the Products in reasonable reliance on Defendant's statements.

- 149. Because of Defendant's misconduct, Plaintiff, on behalf of himself, the Class and Subclass members, seek recovery of their economic damages, attorneys' fees, punitive damages, restitution, and all other relief allowable by law, including an injunction to enjoin Defendant from continuing its fraudulent business practices. The damages sought are ascertainable, uniform to the Class and Subclasses and can be measured and returned to the Class and Subclass members.
 - F. BREACH OF IMPLIED WARRANTY, on Behalf of the Nationwide Class and on Behalf of the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses
- 150. Plaintiff realleges and incorporates all other paragraphs in this Complaint and further alleges:
- 151. Plaintiff brings this cause of action on behalf of himself, and all members of the National Class and the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses, all of whom are similarly situated consumers.
- 152. Defendant, as sellers of the Products, also made implied warranties including warranting the Products were of the same quality and purity represented on the labels, in advertising, and on Defendant's websites, were fit for the ordinary purpose of the Products and conformed to the promises made on the containers, labels, advertising, and websites that all ingredients were listed, and all warnings given.
- 153. Defendant advertised its Products as safe, when they knew, or should have known, the Products degraded to benzene. Defendant did not list benzene as an ingredient or contaminant anywhere on the Products or advertising. The Products are not of the quality and purity represented by Defendant because the Products degrade to

benzene under normal use, handling, and storage conditions.

- 154. Defendant did not tell Plaintiff or the Class or Subclass members the Products were not fit for their ordinary use because the Products, as advertised and sold by Defendant, degraded to benzene under normal and expected handling, use, and storage.
- 155. Defendant's affirmations that the Products were safe for use were uniformly made to the Plaintiff and the Class members in the Products' advertising, labeling, and packaging, and on Defendant's websites, which were part of the basis of the bargain.
- 156. Plaintiff, the Class, and Subclass members purchased the Products in reasonable reliance on Defendant's statements, affirmations, and omissions of material health and safety information.
 - 157. Defendant's acts and omissions are ongoing and continuing to cause harm.
- 158. Because of Defendant's misconduct, Plaintiff, on behalf of himself, the Class and Subclass members, seek recovery of their actual damages, injunctive relief, attorneys' fees, punitive damages, and all other relief allowable under the law. The damages sought are uniform to the Class and Subclasses and the actual damages can be measured and returned to consumers who bought Defendant's Products.
 - G. <u>UNJUST ENRICHMENT</u>, on Behalf of the Nationwide Class and State on Behalf of the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses
- 159. Plaintiff realleges and incorporates all other paragraphs in this Complaint and further alleges:
- 160. Plaintiff brings this cause of action on behalf of himself, and all members of the National Class and the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses, all of whom are similarly situated consumers.
 - 161. Defendant have unjustly profited from its deceptive business practices and

kept the profits from Plaintiff and the Class and Subclass members who purchased the Products.

- 162. Defendant requested and received a measurable economic benefit at the expense of Plaintiff, the Class, and Subclass members as payment for the Products. Defendant accepted the economic benefits from Plaintiff, the Class, and Subclass members knowing the economic benefit received was based on deception and omission of material human health and safety information.
- 163. There is no utility in Defendant's misconduct and Defendant's enrichment from the misconduct is unjust, inequitable, unconscionable, and against the strong public policy to protect consumers against fraud.
- 164. Because of Defendant's misconduct, Plaintiff, on behalf of himself, the Class and Subclass members, and the public seeks recovery of their actual damages, disgorgement of profits, injunctive relief, attorneys' fees, punitive damages, and all other relief allowable under the law. The damages sought are uniform to the Class and Subclasses and the actual damages can be measured and returned to consumers who bought Defendant's Products.

IX. PRAYER FOR RELIEF

- 165. WHEREFORE, Plaintiff pray for judgment against Defendant:
- 166. That the Court determine this action may be maintained as a Class Action under Rule 23(a) and (b)(1), (2) and (3) of the Federal Rules of Civil Procedure:
 - a. That Defendant's misconduct be adjudged to have violated the state consumer protection laws identified herein;
 - b. That injunctive and declaratory relief be awarded against Defendant, including but not limited to an order prohibiting Defendant from engaging in the alleged misconduct;
 - c. That Defendant be ordered to disgorge profits and revenues derived from its course of misconduct and that such unjust enrichment be restored to the class and or distributed cy pres as the Court shall deem just and equitable;

1	d. That Plaintiff recover all compensatory damages and other damages
2	sustained by Plaintiff;
3	e. That Plaintiff recover punitive damages as allowed by law;
4	f. That Plaintiff recover all statutory damages as allowed by law;
5	g. That Plaintiff recover their attorneys' fees and all costs of suit;
6	h. That Plaintiff recover all Statutory pre-judgment and post-judgment intere
7	on any amounts; and
8	i. That all further relief as this Court may deem just and proper be granted.
9	X. <u>DEMAND FOR JURY TRIAL</u>
10	167. Demand is made for a jury trial.
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12	Respectfully submitted, Dated: March 7, 2024 WISNER BAUM LLP
13	
14	By: <u>/s/ R. Brent. Wisner</u> R. Brent Wisner, Esq.
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