UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

ROCHELLE CORONADO, as putative personal representative of GAIL HAMILTON,

Plaintiff,

v.

L'ORÉAL USA, INC.,

and

L'ORÉAL USA PRODUCTS, INC.,

and

SOFT SHEEN-CARSON, LLC,

and

SOFT SHEEN/CARSON, INC.,

and

SOFT SHEEN/CARSON (W.I.), INC.,

and

STRENGTH OF NATURE, LLC,

and

GODREJ CONSUMER PRODUCTS LTD.,

and

GODREJ SON HOLDINGS, INC.,

Defendants.

CIVIL ACTION NO.:

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff ROCHELLE CORONADO, as putative personal representative of GAIL HAMILTON, by her attorneys, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

NATURE OF THE CASE

2. This action is brought by Plaintiff, Rochelle Coronado, as putative personal representative of Gail Hamilton, who was injured as a result of her use of certain of Defendants' Products, including, but not limited to Mizani, TCB, and TCB Naturals ("Products"), to chemically straighten or relax her hair.

3. Defendants were responsible for the design, research, manufacture, testing, advertisement, labeling, promotion, marketing, sale, and/or distribution of Defendants' Products.

4. At all relevant times, Defendants knew or should have known that their Products were not safe for their intended use, and had not been properly tested.

5. Defendants concealed their knowledge of the Products' defects from Plaintiff and/or the public in general.

6. Defendants negligently misrepresented and/or fraudulently represented to Plaintiff and/or the public in general that their Products had been properly tested and were found to be safe for their intended use despite their knowledge to the contrary.

7. Defendants' representations and/or omissions were done with the intent of defrauding and deceiving Plaintiff, and the public in general, and were made with the intent of

inducing consumers to purchase Defendants' Products for chemically straightening and/or relaxing hair, all of which evinced a callous, reckless, willful, depraved indifference to health, safety, and welfare of the Plaintiff.

8. Defendants negligently and improperly failed to inform consumers about the harmful nature of their products, the harmful components of their products, and the likelihood that consumers would suffer severe physical harm from using their products.

9. Defendants negligently and improperly failed to perform sufficient tests on the Products, and provided inaccurate safety and risk information relating to Plaintiff.

10. As a result of the foregoing acts and omissions of Defendants, the Plaintiff suffered serious and dangerous side effects including, inter alia, ovarian cancer, as well as other severe and personal injuries which were permanent and lasting to include, physical pain and mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring, and/or medications, and fear of developing any of the above named health consequences.

11. Plaintiff has sustained the above health consequences due to her use of Defendants' Products, and Defendants' actions and/or omissions were a direct and proximate cause of her health consequences.

12. Consequently, Plaintiff seeks compensatory damages as a result of her use of Defendants' Products, which has caused her to suffer from ovarian cancer, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTY PLAINTIFF

13. Plaintiff, Rochelle Coronado, is a citizen of the United States of America, and is a citizen of the State of Florida. Plaintiff's address is 587 Horseman Drive, Oviedo, Florida 32765.

14. Plaintiff, Rochelle Coronado is the putative Personal Representative of the Estate of Gail Hamilton, who was injured as a result of her use of certain of Defendants' Products. Gail Hamilton was a citizen of Florida at the time of her death.

15. Potential beneficiaries of a recovery for wrongful death of Gail Hamilton, and their relationship to the deceased, are identified as follows:

a. The Estate of Gail Hamilton c/o Rochelle Coronado, as Putative Personal Representative of the Estate of Gail Hamilton;

b. Pamela Hamilton-Stubbs, half sibling and survivor of Gail Hamilton pursuant to the Florida Wrongful Death Act.

c. Carl Hamilton, half sibling and survivor of Gail Hamilton pursuant to the Florida Wrongful Death Act.

d. Michael Hamilton, half sibling and survivor of Gail Hamilton pursuant to the Florida Wrongful Death Act.

e. Debbie Waters, half sibling and survivor of Gail Hamilton pursuant to the Florida Wrongful Death Act.

16. Plaintiff first began using Defendants' Products approximately in the late 1980s, and frequently used Defendants' Products at all relevant times, including up to and through the time of her diagnosis with and treatment for ovarian cancer.

17. Plaintiff used Defendants' Products by applying them to her scalp, exactly as instructed by Defendants.

18. Plaintiff would keep the Products on her hair for the time allotted in the

instructions.

19. There was never any indication, on the Products' packaging or otherwise, that this normal use could and would cause her to develop ovarian cancer.

20. As a result of using Defendants' Products, Plaintiff suffered from ovarian cancer on or about May 3, 2016 and sustained severe and permanent personal injuries, pain, suffering, and emotional distress.

21. The injuries and damages sustained by Plaintiff were caused by Defendants' Products.

PARTY DEFENDANTS

22. Defendant L'ORÉAL USA, INC. is incorporated in Delaware with its principal place of business and headquarters located at 575 Fifth Avenue, New York, New York 10017, and process may be served upon its registered agent, Corporation Service Company, 80 State Street, Albany, New York 12207.

23. Defendant L'ORÉAL USA PRODUCTS, INC. is incorporated in Delaware with its principal place of business and headquarters located at 10 Hudson Yards, 347 10th Avenue, New York, New York 10001, and process may be served upon its registered agent, Corporation Service Company, 80 State Street, Albany, New York 12207.

24. Defendant SOFT SHEEN-CARSON, LLC, is a limited liability company organized in New York with its principal place of business and headquarters located at 80 State St., Albany, New York 12207, and process may be served upon its registered agent, Corporation Service Company, 80 State Street, Albany, New York 12207. Plaintiffs allege that SOFT SHEEN-CARSON, LLC's members and sole interested parties are L'ORÉAL S.A., a corporation having its headquarters and principal place of business in France; and L'ORÉAL USA, INC., incorporated in Delaware with its principal place of business and headquarters at 575 Fifth Avenue, New York,

New York 10017.

25. Defendant CARSON, INC., D/B/A SOFT SHEEN, is a corporation with its principal place of business and headquarters located at 2870 Peachtree Rd., Suite. 464, Atlanta, Georgia 40405, and process may be served upon its registered agent, Justin Hill, 2870 Peachtree Rd., Suite 464, Atlanta, Georgia 40405.

26. Defendant CARSON (W.I.), INC., D/B/A SOFT SHEEN, is a Delaware corporation and process may be served upon its registered agent, Corporate Services Company 251 Little Falls Drive, Wilmington, Delaware 19808.

27. Defendant STRENGTH OF NATURE, LLC is a corporation with its principal place of business and headquarters located at 64 Ross Road, Savannah, Georgia 31405, and process may be served upon its registered agent, Karen Sood, 6355 Peachtree Dunwoody Rd., Atlanta, Georgia 30328. Upon information and belief, Plaintiffs allege in good faith STRENGTH OF NATURE, LLC's members, Mario M. De La Guardia, Jr., is domiciled in Florida and is a citizen of Florida, having his true, fixed, and permanent home and principal establishment in the State of Florida; and Jack Wardlaw is domiciled in Georgia and is a citizen of Georgia having his true, fixed, and permanent home and principal establishment in the State of Georgia.

28. Defendant GODREJ CONSUMER PRODUCTS LTD. is a global corporation with its principal place of business located at Godrej One, 4th Floor, Pirojshanagar, Eastern Express Highway, Vikhroli (East), Mumbai 400 079, India. The company's website references Defendant STRENGTH OF NATURE as its base of operations in the U.S., which is located at 64 Ross Road, Savannah, Georgia, and process may be served upon its registered agent, Karen Sood, 6355 Peachtree Dunwoody Road, Atlanta, Georgia 30328.

29. Defendant GODREJ SON HOLDINGS, INC. is a corporation with its principal place of business and headquarters located at 64 Ross Road, Savannah, Georgia 31405, and process

may be served upon its registered agent, Corporation Service Company, 2 Sun Court, Suite 400, Peachtree Corners, Georgia 30092.

30. Upon information and belief, at all pertinent times, all Defendants were engaged in the research, development, manufacture, design, testing, sale, and marketing of the Products, and introduced them into interstate commerce within the United States with knowledge and intent that such products be sold in the State of Florida.

31. Upon information and belief, Defendants transacted and conducted business in the State of Florida.

32. Upon information and belief, Defendants derived substantial revenue from goods and products sold and/or used in the State of Florida.

33. Upon information and belief, Defendants expected or should have expected their acts to have consequences within the State of Florida, and derived substantial revenue from interstate commerce within the United States, and the State of Florida, more particularly.

34. Plaintiff purchased Defendants' products in the State of Florida, and the damages sustained by Plaintiff as alleged herein occurred within the State of Florida.

35. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective Products, including but not limited to:

a. Mizani;

b. TCB; and

c. TCB Naturals.

36. Defendants' defective Products were placed into the stream of commerce and used by the Plaintiff from approximately in the late 1980s and at all relevant times, including up to and through the time of her diagnosis with and treatment for ovarian cancer.

FACTUAL BACKGROUND

1. Defendants' Marketing Efforts

37. In 1971, Dark and Lovely manufactured its first lye relaxer. The formula consisted of sodium hydroxide, water, petroleum jelly, mineral oils, and emulsifiers.[1]

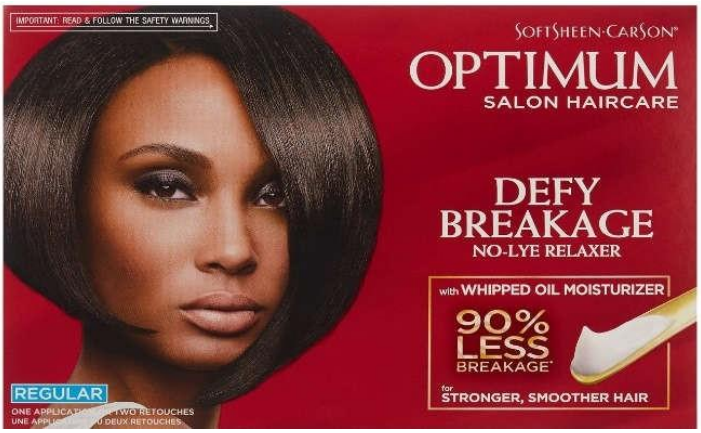
38. In the 1970s, lye relaxer users and manufacturers noticed that the lye formula stripped proteins from the hair strand, resulting in the hair thinning and breaking.[2] As a result, Johnson and Johnson marketed the first "gentle" hair relaxer in 1981, which used milder chemicals such as potassium hydroxide and lithium hydroxide.[3]

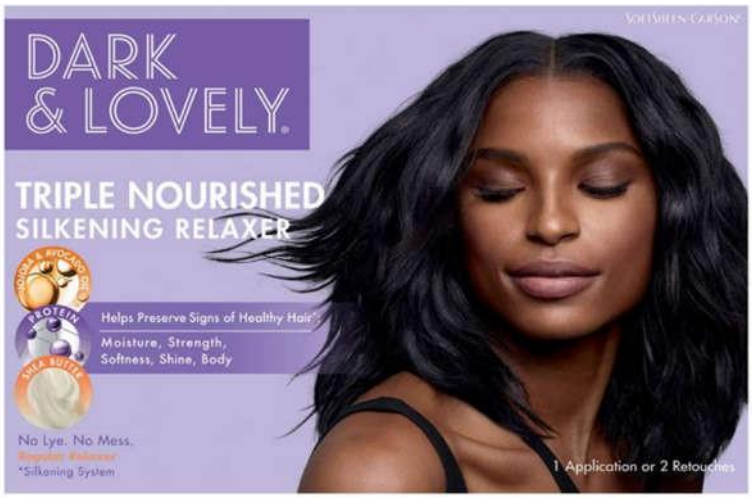
39. Over time, Soft & Beautiful and other chemical relaxer manufacturers developed herbal and botanical hair relaxer formulas.[4]

40. Today, Defendants market their hair relaxer products to African American customers across the United States, and the world, reinforcing the same historical Eurocentric standards of beauty. Defendants' marketing scheme relies heavily on branding and slogans that reinforce straight hair as the standard.[5]

41. The L'ORÉAL and SOFT SHEEN Defendants depict a Black woman with straight hair on each of their Dark and Lovely and Optimum brands of relaxer product.

[1] Cicely A. Richard, *This History of Hair Relaxers*, September 29, 2017 https://classroom.synonym.com/the-history-of-hair-relaxers-12078983.html.
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] *Id.*





2. Chemical Relaxer Use

42. Hair relaxers are classified as creams or lotions which are specifically marketed to Black and Brown women to "tame" their ethnic hair by making it smoother, straighter, and easier to manage on a daily basis.

43. Hair relaxing, or lanthionization, can be performed by a professional cosmetologist in a salon or barbershop, or at home with at-home relaxer kits designed for individual use. These home kits are sold in grocery, drug, and beauty supply stores in urban and rural cities throughout the United States.

44. Relaxers are applied to the base of the hair shaft and left in place for a "cooking" interval, during which the relaxer alters the hair's texture by purposefully damaging the hair's natural protein structure. The effect of this protein damage straightens and smooths the hair. After

a period of weeks (4 – 8 weeks on average), depending on the hair's natural growth rate, the treated portion of the hair grows away from the scalp as new growth sprouts from the roots, requiring additional relaxer treatment to smooth the roots. These additional treatments are colloquially referred to in the community as "re-touches", resulting in women relaxing their new growth every four to eight weeks on average, usually for decades.

45. During applications, chemicals from hair relaxer kits enter the body through dermal openings in the user's scalp and hands, and are also inhaled by the user.

46. Hair relaxers can, and often do, cause burns and lesions in the scalp, facilitating entry of hair relaxer constituents into the body. The main ingredient of ''lye'' relaxers is sodium hydroxide; no-lye relaxers contain calcium hydroxide and guanidine carbonate; and ''thio'' relaxers contain thioglycolic acid salts. No-lye relaxers are advertised to cause fewer scalp lesions and burns than lye relaxers, but there is little evidence to support this claim.

47. In some studies, up to 90% of Black and Brown women have used hair relaxants and straighteners, which is more commonplace for these women than for any other race. Hair products such as relaxers contain hormonally active and carcinogenic compounds, such as phthalates, known to cause endocrine disruption, which are not required to be listed separately as ingredients and are often broadly lumped into the "fragrance" or "perfume" categories. Relaxer habits usually begin in formative childhood years, and adolescence is likely a period of enhanced susceptibility to debilitating conditions resulting from exposure to these chemicals.[6]

48. Once relaxer use begins in childhood, it usually becomes a lifetime habit. The frequency of scalp burns with relaxer application can increase the risk of permanent and debilitating diseases associated with long-term exposure to endocrine-disrupting chemicals.

A. Regulatory Framework

[6] Patrick Obukowcho, Hair Relaxers: Science, Design, and Application 27 (2018).

49. The law does not require cosmetic products and ingredients, other than color additives, to have FDA approval before they go to market. But there are laws and regulations that apply to cosmetics placed into the market. The two most important laws pertaining to cosmetics marketed in the United States are the Federal Food Drug and Cosmetic Act ("FD&C Act") and the Fair Packaging and Labeling Act ("FPLA").

50. The FD&C Act expressly prohibits the marketing of "adulterated" or "misbranded" cosmetics in interstate commerce.

51. Adulteration refers to a violation involving product composition whether it results from ingredients, contaminants, processing, packaging, shipping, or handling.

52. Under the FD&C Act a cosmetic is adulterated if: 1) it bears or contains any poisonous or deleterious substance causing injury to the product user and 2) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

53. Misbranding refers to violations involving improperly labeled or deceptively packaged products.

54. Under the FD&C Act, a cosmetic is misbranded if 1) labeling is false or misleading, 2) the label does not include all required information, 3) required information is not prominent and conspicuous, 4) the packaging and labeling is in violation of an applicable regulation issued pursuant to section 3 and 4 of the Poison Prevention Packaging Act of 1970.[7]

55. Under U.S. law, cosmetic manufacturers are not required to submit their safety data to the FDA. However, it is against the law to put an ingredient in a cosmetic that makes the

[7] Food and Drug Administration Cosmetic Act § 602 (1938).

cosmetic harmful when used as intended.[8] An example is methylene chloride because it causes cancer in animals and is likely to be harmful to human health, too.[9]

56. On May 19, 2022, the FDA issued a rule to amend its food additive regulations to no longer provide for most previously-authorized phthalates to be used as food additives because these uses have been abandoned by industry.[10] The FDA revoked authorizations for the food contact use of 23 phthalates and two other substances used as plasticizers, adhesives, defoaming agents, lubricants, resins, and slimicides.[11]

57. Companies and/or individuals who manufacture or market cosmetics have a legal responsibility and duty to ensure the safety of their own products. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients, and the law also does not require cosmetic companies to share their safety information with the FDA.

58. The FDA has consistently advised manufacturers to use whatever testing is necessary to ensure the safety of products and ingredients, which may be substantiated through (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic and (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information.[12]

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[8] *Prohibited & Restricted Ingredients in Cosmetics*, U.S. Food and Drug Administration, https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics

[9] 21 Code of Federal Regulations § 700.19.

[10] § 87 FR 31080

[11] *Phthalates in Food Packages and Food Contact Applications*, U.S. Food and Drug Administration, https://www.fda.gov/food/food-ingredients-packaging/phthalates-food- packaging-and-food-contact-applications

[12] *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated*, U.S. Food and Drug Administration, Mar., 3, 2005,

59. Except for color additives and ingredients prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that (1) the ingredient and the finished cosmetic are safe under labeled or customary conditions of use, (2) the product is properly labeled, and (3) the use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws the FDA enforces.[13]

60. With respect to whether the product is properly labeled, Title 21 of the Code of Federal Regulations defines the establishment of warning statements related to cosmetic products. Section 740.1 states that "[t]he label of a cosmetic product ***shall*** bear a warning statement whenever necessary or appropriate to prevent a health hazard that ***may*** be associated with the product." (emphasis added). This warning directive directly correlates with the broad authority of manufacturers over their own cosmetic products to ensure that products are safe under labeled or customary conditions of use, properly labeled, and not adulterated or misbranded under FDA laws.

61. In short, under the current regulatory framework in the United States, it is incumbent upon the manufacturers of cosmetic products, and them alone, to assess the safety and risks of their products, and to warn consumers anytime a health hazard may be associated with their products. Here, a wealth of peer-reviewed, scientific information is available regarding long-term use of hair relaxers, straighteners and hair dyes as containing certain endocrine-disrupting chemicals, which should have alerted manufacturers of these products to the specific and dangerous harms associated with their products when used as intended, particularly in women of color.

B. Components of Chemical Hair Straighteners and/or Relaxers

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https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated

[13] *Id.*

62. Recent studies investigating the potential link between various adverse health effects in women, including cancer, and the use of chemical hair straighteners and/or relaxers have implicated certain frequent chemical components of chemical hair straighteners as possible contributors to adverse health effects in women, including, but not limited to, increased cancer incidence. These constituents include phthalates, parabens, bisphenol A ("BPA"), cyclosiloxanes, diethanolamine (all of which are considered endocrine disrupting chemicals ("EDCs"), discussed in further detail below), metals, and formaldehyde.[14]

63. One study examining the chemical components of hair products used by Black women found that hair relaxers for children contained five chemicals that were either regulated by California's Proposition 65 or prohibited by EU cosmetics regulations (including the phthalate Di-2-ethylhexylphthalate[15] ("DEHP") and BPA) due to their associations with reproductive toxicity and cancer, and were not generally listed on the product labels. Specifically, 84% of the chemicals detected in the study were not listed on the label. The researchers noted: "Mixtures of chemicals may act additively through a common biological pathway or affect multiple carcinogenic mechanisms, resulting in a greater effect than each chemical in isolation. Low-dose mixtures of phthalates, parabens…and other common chemicals exhibit additive anti-androgenic activity and

[14] Chang C-J, et al. *Use of Straighteners and Other Hair Products and Incidence Uterine Cancer*. JNCI J Natl Cancer Inst. 2022:00(0). Available at: https://doi.org/10.1093/jnci/djac165.; White A.J., et al. *Use of hair products in relation to ovarian cancer risk*. Carcinogenesis 2021;42(9):1189-1195. Available at: https://doi.org/10.1093/carcin/bgab056; Coogan P.F., et al. *Hair product use and breast cancer incidence in the Black Women's Health Study*. Carcinogenesis 2021;42(7):924-930. DOI:10.1093/carcin/bgab041; Gaston S.A., et al. *Chemical/Straightening and Other Hair Product Usage during Childhood, Adolescence, and Adulthood among African-American Women: Potential Implications for Health*. J. Expo. Sci. Environ. Epidemiol. 2020;30(1):86-96. doi:10.1038/s41370-019-0186-6; Zota A.R., Shamasunder B. *The environmental injustice of beauty: framing chemical exposures from beauty products as a health disparities concern*. Am. J. Obstet. Oct. 2017;418-422.

[15] Also known as Bis(2-ethylhexyl) phthalate.

additive estrogenic activity."[16]

64. Regarding parabens and phthalates, a recent study stated that, "Accumulating evidence from experimental and animal studies supports the carcinogenic potential of these chemicals."[17] Previous studies have shown higher levels of parabens (in endometrial tissues) and phthalates (in urine) in participants diagnosed with endometrial cancer than those who were cancer-free.[18] They have also been detected in human breast tumors.[19] Additionally, studies have shown higher urinary levels of certain phthalates and parabens in U.S. Black women compared to U.S. White women.[20] Black individuals in the U.S. have also been found to have higher concentrations of certain parabens than White individuals.[21]

65. Other studies have indicated a link between altered estrous cycle and uterine pathology in rats with chronic exposure to low-dose BPA, an adverse effect associated with

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[16] Helm J.S., et al. *Measurement of endocrine disrupting and asthma-associated chemicals in hair products used by Black women*. Environ. Research 2018;165:448-458.

[17] Coogan P.F., et al. Hair product use and breast cancer incidence in the Black Women's Health Study. Carcinogenesis 2021;42(7):924-930. DOI:10.1093/carcin/bgab041.

[18] Sarink D, et al. *BPA, parabens, and phthalates in relation to endometrial cancer risk: a case-control study nested in the multiethnic cohort*. Environ Health Perspect. 2021;129(5):57702.doi:10.1289/EHP8998.; Dogan S, et al. *Traces of intact paraben molecules in endometrial carcinoma*. Environ Sci Pollut Res Int. 2019;26(30):31158-31165. doi: 10.1007/s11356-019-06228-1.

[19] Darbre P.D., et al. *Concentrations of parabens in human breast tumours*. J. Appl. Toxicol. 2004;24:5–13; Barr L., et al. *Measurement of paraben concentrations in human breast tissue at serial locations across the breast from axilla to sternum*. J. Appl. Toxicol. 2012;32:219–232.

[20] Helm J.S., et al. *Measurement of endocrine disrupting and asthma-associated chemicals in hair products used by Black women*. Environ. Research 2018;165:448-458; James-Todd T.M., et al. *Racial and ethnic variations in phthalate metabolite concentration changes across full- term pregnancies*. J. Expo. Sci. Environ. Epidemiol. 2017;27:160–166; Varshavsky J.R., et al. *A novel method for calculating potency weighted cumulative phthalates exposure with implications for identifying racial/ethnic disparities among U.S. reproductive-aged women in NHANES 2001-2012*. Environ. Sci. Technol. 2016;50:10616–10624; Nguyen V.K., et al. *A comprehensive analysis of racial disparities in chemical biomarker concentrations in United States women, 1999-2014*. Environ. Int. 2020;137:105496.

[21] US Centers for Disease Control and Prevention. Fourth national report on human exposure to environmental chemicals: updated tables, Volume 1. US Department of Health and Human Services; 2019. Available at: https://stacks.cdc.gov/view/cdc/75822.

endometrial cancer development and progression.[22] Urine levels of BPA have also been positively associated with the prevalence of uterine fibroids.[23] Black individuals in the U.S. have also been found to have higher concentrations of BPA than White individuals.[24]

66. Further, studies have associated cyclosiloxanes with neoplastic responses, which can lead to tumor growth, in the uterus of rats.[25]

67. Finally, diethanolamine, metals, and formaldehyde have all been considered carcinogenic.[26]

1. Endocrine-Disrupting Chemicals

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[22] Leung YK, et al. *Low-dose bisphenol a in a rat model of endometrial cancer: a CLARITY- BPA study*. Environ Health Perspect. 2020;128(12):127005.doi:10.1289/EHP6875; Mallozzi M, et al. *Endocrine disrupting chemicals and endometrial cancer: an overview of recent laboratory evidence and epidemiological studies*. Int J Environ Res Public Health. 2017;14(3): 334.doi:10.3390/ijerph14030334.

[23] Wise, L.A. et al. *Epidemiolgoy of Uterine Fibroids – From Menarche to Menopause*. Clin Obstet Gynecol. 2016;59(1):2-24. doi:10.1097/GRF.0000000000000164

[24] US Centers for Disease Control and Prevention. Fourth national report on human exposure to environmental chemicals: updated tables, Volume 1. US Department of Health and Human Services; 2019. Available at: https://stacks.cdc.gov/view/cdc/75822.

[25] Dekant W, et al. *Biological relevance of effects following chronic administration of octamethylcyclotetrasiloxane (D4) in Fischer 344 rats*. Toxicol Lett. 2017;279:42-53. doi:10.1016/j.toxlet.2017.01.010.; Jean PA, et al. *Chronic toxicity and oncogenicity of decamethylcyclopentasiloxane in the Fischer 344 Rat*. Regul Toxicol Pharmacol. 2016;

74:S57-S66. doi:10.1016/j.yrtph.2015.06.014.; Jean PA, Plotzke KP. *Chronic toxicity and oncogenicity of octamethylcyclotetrasiloxane (D4) in the Fischer 344 rat*. Toxicol Lett. 2017;279:75-97. doi:10.1016/j.toxlet.2017.06.003.

[26] Mallozzi M, et al. *Endocrine disrupting chemicals and endometrial cancer: an overview of recent laboratory evidence and epidemiological studies*. Int J Environ Res Public Health. 2017;14(3):334.doi:10.3390/ijerph14030334; International Agency for Research on Cancer (IARC). *Chemical Agents and Related Occupations*. Vol 100F. Lyon, France: IARC Monographs on the Evaluation of Carcinogenic Risks to Humans; 2012.; Aglan MA, Mansour GN. *Hair straightening products and the risk of occupational formaldehyde exposure in hairstylists*. Drug Chem Toxicol. 2020;43(5):488-495. doi:10.1080/01480545.2018.1508215; International Agency for Research on Cancer (IARC). *Arsenic, Metals, Fibres and Dusts*. Vol 100 C. Lyon, France: IARC Working Group on the Evaluation of Carcinogenic Risks to Humans; 2012; International Agency for Research on Cancer (IARC). *Some Chemicals Present in Industrial and Consumer Products, Food and Drinking-Water*. Vol 101. Lyon, France: IARC Monographs on the Evaluation of Carcinogenic Risks to Humans; 2013.

68. The endocrine system is indispensable for life and influences nearly every cell, organ, and processes within the body.[27] The endocrine system regulates all biological processes in the body from conception through adulthood, including the development of the brain and nervous system, the growth and function of the reproductive system, as well as the metabolism and blood sugar levels.[28]

69. The endocrine system is a tightly regulated system made up of glands that produce and release precise amounts of hormones that bind to receptors located on specific target cells throughout the body.[29]

70. Hormones, such as estrogen, testosterone, progesterone, and androgen, are chemical signals that control or regulate critical biological processes.[30]

71. When a hormone binds to a target cell's receptor, the receptor carries out the hormone's instructions, the stimulus, and either switches on or switches off specific biological processes in cells, tissues, and organs.[31]

72. The precise functioning of the endocrine system is vital to maintain hormonal homeostasis, the body's natural hormonal production and degradation. A slight variation in hormone levels can lead to significant adverse-health effects, including reproductive impairment and infertility, cancer, cognitive deficits, immune disorders, and metabolic syndrome.[32]

73. EDCs are chemicals, or chemical mixtures, that interfere with the normal activity of the endocrine system.

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[27] *Endocrine System: The Endocrine System Includes The Thyroid, Adrenals, and the Pituitary Gland*, Science Direct, https://www.sciencedirect.com/topics/psychology/endocrine-system

[28] *Endocrine Disruption*, United States Environmental Protection Agency, Mar., 7, 2022, https://www.epa.gov/endocrine-disruption/what-endocrine-system

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*; Michele La Merrill, et al., *Consensus on the Key Characteristics of Endocrine-Disrupting Chemicals as a Basis for Hazard Identification*, Nature Reviews Endocrinol, Nov., 12, 2019, https://www.nature.com/articles/s41574-019-0273-8

74. EDCs can act directly on hormone receptors as mimics or antagonists, or on proteins that control hormone delivery.[33]

75. EDCs disrupt the endocrine system and interfere with the body's hormonal homeostasis in various ways.

76. EDCs can cause the body to operate as if there were a proliferation of a hormone and thus over-respond to the stimulus or respond when it was not supposed to by mimicking a natural hormone.

77. EDCs can increase or decrease the levels of the body's hormones by affecting the production, degradation, and storage of hormones.

78. EDCs can block the hormone's stimulus through inducing epigenetic changes, modifications to DNA that regulate whether genes are turned on or off or altering the structure of target cells' receptors.[34]

79. EDCs are linked to numerous adverse human health outcomes including endometriosis, impaired sperm quality, abnormalities in reproductive organs, various cancers, altered nervous system and immune function, respiratory problems, metabolic issues, diabetes, obesity, cardiovascular problems, growth, neurological and learning disabilities.[35] Specifically, EDCs have the potential to cause formation of several hormone-dependent cancers, including breast and ovarian cancers.[36]

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[33] Evanthia Diamanti-Kandarakis, et al., *Endocrine-Disrupting Chemicals: An Endocrine Society Scientific Statement*, Endocrine Reviews, June 30, 2009, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2726844/

[34] Luis Daniel Martínez-Razo, et al., *The impact of Di-(2-ethylhexyl) Phthalate and Mono(2- ethylhexyl) Phthalate in placental development, function, and pathophysiology*, Environment International, January 2021, https://www.sciencedirect.com/science/article/pii/S0160412020321838?via%3Dihub

[35] Endocrine Disrupting Chemicals (EDCs), Endocrine Society, Jan., 24, 2022, https://www.endocrine.org/patient-engagement/endocrine-library/edcs#:~:text=EDCs%20can%20disrupt%20many%20different,%2C%20certain%20cancers%2C%20respiratory%20problems%2C

[36] Lee H. M., et al. *Diverse pathways of epithelial mesenchymal transition related with cancer progression and metastasis and potential effects of endocrine disrupting chemicals on epithelial*

80. EDCs that mimic the effects of estrogen in the body may contribute to disease risk because exposure to estrogen, endogenously and exogenously, is associated with breast cancer, and a woman's lifetime risk of developing the disease increases with greater duration and cumulative exposure.

81. Indeed, numerous studies spanning more than two decades have demonstrated the adverse impact EDCs, including Di-2-ethylhexylphthalate, may have on the male and female reproductive systems such as inducing endometriosis, abnormal reproductive tract formation, decreased sperm counts and viability, pregnancy loss, and abnormal puberty onset.[37]

82. Black women of reproductive age tend to have higher biomarkers of exposure to EDCs. One study stated: "EDCs are an understudied potential contributor to racial disparities in women's health outcomes despite higher chemical exposures among Black women resulting from historical and contemporary structural oppression."[38]

83. Natural and synthetic EDCs are present in hair products under the guise of "fragrance" and "perfumes," and thus enter the body when these products are exogenously applied to the hair and scalp. Studies exploring this issue have thus far classified EDCs as estrogens, phthalates, and parabens.

i. Phthalates

84. Phthalates are used in a variety of cosmetics and personal care products. Phthalates are chemical compounds developed in the last century that are used to make plastics more durable.

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mesenchymal transition process. Mol Cell Endocrinol 2017;457:103-113, doi:10.1016/j.mce.2016.12.026.

[37] Hee-Su Kim, et al., *Hershberger Assays for Di-2-ethylhexyl Phthalate and Its Substitute Candidates*, Dev Reproduction, Mar., 22, 2018, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915764/.

[38] Wesselink A.K., et al. Urinary concentrations of phenols, parabens, and triclocarban in relation to uterine leiomyomata incidence and growth. Fertility and Sterility 2021;116(6):1590-1600. https://doi.org/10.1016/j.fertnstert.2021.07.003.

These colorless, odorless, oily liquids also referred to as "plasticizers" based on their most common uses.

85. Phthalates also function as solvents and stabilizers in perfumes and other fragrance preparations. Cosmetics that may contain phthalates include nail polishes, hair sprays, aftershave lotions, cleansers, and shampoos.

86. At all relevant times herein, phthalates were contained in Defendants' products that were used by Plaintiff.

87. Phthalates are chemicals used to improve the stability and retention of fragrances and to help topical products stick to and penetrate skin and hair.[39]

88. Phthalates are known EDCs which interfere with natural hormone production and degradation and are detrimental to human health.[40]

89. Phthalates are commonly used by cosmetics and hair care product manufacturers to make fragrances and colors last longer, and to make hair more flexible after product is applied, among other uses.

90. Phthalates can be found in most products that have contact with plastics during producing, packaging, or delivering. Despite the short half-lives in tissues, chronic exposure to phthalates will adversely influence the endocrine system and functioning of multiple organs, which has negative long-term impacts on the success of pregnancy, child growth and development, and reproductive systems in both young children and adolescents. Several countries have established restrictions and regulations on some types of phthalates.[41]

91. Plaintiff used defendants' products referenced herein that contain phthalates,

[39] Olivia Koski & Sheila Hu, Fighting Phthalates, National Resources Defense Council, April 20, 2022, https://www.nrdc.org/stories/fighting-phthalates
[40] Yufei Wang & Haifeng Qian, *Phthalates and Their Impacts on Human Health*, Healthcare
[41] *Id*.

including Di-2- ethylhexylphthalate.

92. Under the authority of the Fair Packaging and Labeling Act ("FPLA"), the FDA requires an ingredient declaration on cosmetic products sold at the retail level to consumers.

93. However, the regulations do not require the listing of the individual fragrance or flavor, or their specific ingredients meaning phthalates evade listing when combined with a fragrance. As a result, a consumer, including Plaintiff, was not able to determine from the ingredient declaration on the label if phthalates were present in a fragrance used in the herein referenced hair products used by the Plaintiff and placed into the stream of commerce by Defendants.

94. Since 1999, the Centers for Disease Control ("CDC") have found phthalates in individuals studied for chemical exposure.[42]

1. Di-2-ethylhexylphthalate

95. Di-2-ethylhexylphthalate[43] ("DEHP") is a highly toxic manufactured chemical,[44] classified by the International Agency for Research on Cancer ("IARC") as possibly carcinogenic to humans,[45] that is not found naturally in the environment.[46]

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[42] *Biomarker Groups*, National Report on Human Exposure to Enviornemntal Chemicals, Center for Disease Control, https://www.cdc.gov/exposurereport/pdf/Biomarker_Groups_Infographic-508.pdf

[43] Also known as Bis(2-ethylhexyl) phthalate.

[44] Sai Rowdhwal & Jiaxiang Chen, *Toxic Effects of Di-2-ethylhexyl Phthalate: An Overview*, Biomed Research International, Feb., 22, 2018 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5842715/#:~:text=DEHP%20is%20noncovalently%20bound%20to,and%20plastic%20waste%20disposal%20sites.

[45] IARC Monographs – 101: Di(2-Ethylhexyl) Phthalate. Available at: https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono101-006.pdf.

[46] *Toxicological Profile for Di(2-Ethylhexyl) Phthalate (DEHP)*, U.S. Dept of Health and Human Services, January 2022, https://www.atsdr.cdc.gov/ToxProfiles/tp9.pdf (DEHP is listed as hazardous pollutants under the Clean Air Act.; DEHP is on the Proposition 65 list "because it can cause cancer and birth defects or other reproductive harm").

96. DEHP belongs to the family of chemicals called phthalates[47] and can be found in hair relaxers.[48]

97. DEHP does not covalently bind to its parent material. Non-covalent bonds are weak and, as a result, DEHP readily leaches into the environment increasing human exposure.[49]

98. Humans are exposed to DEHP through ingestion, inhalation, and dermal exposure for their lifetimes, including intrauterine life.[50]

99. When DEHP enters the human body, it breaks down into specific metabolites. The toxicity of DEHP is mainly attributed to its unique metabolites which include the primary metabolite, mono-(2-ethylhexyl)phthalate (MEHP), and secondary metabolites, mono-(2-ethyl-5-hydroxyhexyl)phthalate (MEHHP), and mono-(2-ethyl-5-oxohexyl)phthlate (MEOHP).[51]

100. DEHP and its metabolites are implicated in reproductive tract abnormalities,

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[47] *Di(2-ethylhexyl) phthalate (DEHP)*, Proposition 65, California. Gov, https://www.p65warnings.ca.gov/fact-sheets/di2-ethylhexylphthalate-dehp

[48] Helm J.S., et al. *Measurement of endocrine disrupting and asthma-associated chemicals in hair products used by Black women*. Environ. Research 2018;165:448-458.

[49] Katelyn H. Wong & Timur Durrani, *Exposures to Endocrine Disrupting Chemicals in Consumer Products – A Guide for Pediatricians*, Current Problems in Pediatric and Adolescent Health Care, Science Direct, May 2017, https://www.sciencedirect.com/science/article/pii/S1538544217300822?via%3Dihub

[50] Schmidt, Juliane-Susanne, et al., *Effects of Di(2-ethylhexyl) Phthalate (DEHP) on Female Fertility and Adipogenesis in C3H/N Mice*, Environmental Health Perspective, May 15, 2012, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3440070/

[51] Saab, Yolande, et. al., *Risk Assessment of Phthalates and Their Metabolites in Hospitalized Patients: A Focus on Di- and Mono-(2-ethylhexyl) Phthalates Exposure from Intravenous Plastic Bags*. Toxics, 10(7), 357, https://pubmed.ncbi.nlm.nih.gov/35878262/; Ishtaf Sheikh, et. at., *Endocrine disruption: In silico perspectives of interactions of di-(2-ethylhexyl)phthalate and its five major metabolites with progesterone receptor*. BMC Structural Biology Volume 16, Suppl 1, 16, Sept., 30, 2016, https://bmcstructbiol.biomedcentral.com/articles/10.1186/s12900-016- 0066-4 (Other secondary metabolites include mono(2-ethyl-5-carboxypentyl)phthalate (5-cx- MEPP) and mono[2-(carboxymethyl)hexyl]phthalate (2-cx-MMHP)).

including cancer and infertility, as well as potential teratogenic effects.[52] Specifically, DEHP is considered carcinogenic in animals.[53]

101. Most of the available studies on the health effects of DEHP in laboratory animals used oral administration, with a few inhalation studies and only two dermal exposure studies identified.[54]

102. The results of the selected animal studies, along with limited human data, suggest potential associations between DEHP exposure and the following health outcomes:

a) **Reproductive effects.** Epidemiological studies suggest a potential association between DEHP exposure and decreased serum testosterone and altered sperm parameters in males. Available studies on fertility effects in humans do not indicate an association between DEHP exposure and infertility. In animals, the available oral and inhalation studies provide evidence that the male reproductive system, particularly the testes, is susceptible to DEHP toxicity. Evidence from animal studies indicates decreased male and female fertility at high oral doses.

b) **Developmental effects.** Epidemiological studies suggest a potential association between reduced AGD and testicular decent in male infants and prenatal DEHP exposure. In addition, human epidemiological studies provide mixed results for potential relationships between exposure to DEHP and preterm birth, early puberty, and delayed mental and psychomotor development in children. Studies in animals indicate that altered glucose homeostasis and the development of the reproductive system following early life exposure is a particularly sensitive target of DEHP toxicity.

103. Human epidemiological studies have shown a significant association between phthalates exposures and adverse reproductive outcomes in both women and men.[55]

104. Evidence found that DEHP was significantly related to insulin resistance and

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[52] Richardson, Kadeem et. al., *Di(2-ethylhexyl) Phthalate (DEHP) Alters Proliferation and Uterine Gland Numbers in the Uterine of Adult Exposed Mice*, Reproductive Toxicology, 77, 70- 79, https://pubmed.ncbi.nlm.nih.gov/29458081/; Yufei Wang & Haifeng Qian, *Phthalates and Their Impacts on Human Health*, Healthcare (Basel) 9, 603, May 9, 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8157593/.

[53] Helm J.S., et al. *Measurement of endocrine disrupting and asthma-associated chemicals in hair products used by Black women*. Environ. Research 2018;165:448-458.

[54] *Chapter 2: Health Effects*, Toxicological profile for Di(2-ethylhexyl) phthalate (DEHP) (2001), https://www.atsdr.cdc.gov/ToxProfiles/tp9-c2.pdf

[55] *Id*.

higher systolic blood pressure and the reproduction system problems, including earlier menopause, low birth weight, pregnancy loss, and preterm birth.[56]

105. When it comes to the impacts on children, epidemiological studies about phthalates' toxicity focused on pregnancy outcomes, genital development, semen quality, precocious puberty, thyroid function, respiratory symptoms, and neurodevelopment.[57]

106. Since the turn of the century, restrictions on phthalates have been proposed in many Asian and western countries. In 2008, the US Congress announced the Consumer Protection Safety Act (CPSA) that permanently banned the products, especially children's toys and childcare articles, containing DEHP, DBP, and BBP at levels >0.1% by weight.[58]

ii. Parabens

107. Parabens are used as preservative and antibacterial agents in personal care products, and have estrogenic and anti-androgenic activity.[59]

108. Hair products used by Black women, including chemical straighteners/relaxers, are more likely to contain parabens, which affect estrogenic pathways.[60]

109. The prevalence of these compounds in such products is consistent with corresponding higher levels found in biomonitoring samples of Black women as compared with White women.[61] In addition, one study indicated that Black children in the U.S. have five times

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[56] N.M. Grindler, et al., *Exposure to Phthalate, an Endocrine Disrupting Chemical, Alters the First Trimester Placental Methylome and Transcriptome in Women*, Scientific Reports Volume 8, April 17, 2018, https://doi.org/10.1038/s41598-018-24505-w

[57] *Id*.

[58] Consumer Product Safety Improvement Act of 2008, H.R. 4040, 110th Cong. (2008), https: //www.congress.gov/110/plaws/publ314/PLAW-110publ314.pdf

[59] Harley KG, et al. *Reducing phthalate, paraben, and phenol exposure from personal care products in adolescent girls: findings from the HERMOSA Intervention Study*. Environ Health Perspect 2016;124:1600–1607; http://dx.doi. org/10.1289/ehp.1510514.

[60] Zota A.R., et al. *The environmental injustice of beauty: framing chemical exposures from beauty products as a health disparities concern*. Am. J. Obest. & Gyn. Oct. 2017.

[61] Helm J.S., et al. *Measurement of endocrine disrupting and asthma-associated chemicals in hair products used by Black women*. Environ. Research 2018;165:448-458.

the urinary paraben levels of White children.[62]

110. Parabens have been associated with uterine fibroid tumors, premature puberty, and endocrine disruption.[63]

111. In one study, parabens were found in breast tumor tissue at levels similar to those shown to induce uterine growth in rodents.[64]

2. Formaldehyde

112. Formaldehyde is a naturally occurring, organic, reactive, volatile, colorless gas detectable in air, drinking water, and foods.[65]

113. Formaldehyde has been classified as a known human carcinogen by both the U.S. Department of Health and Human Services' National Toxicology Program ("NTP") and IARC.[66]

114. Specifically, in 2005, IARC published its conclusions regarding formaldehyde: "After a thorough discussion of the epidemiologic, experimental, and other relevant data, the working group concluded that formaldehyde is carcinogenic to humans, based on sufficient evidence in humans and in experimental animals."[67]

115. Formaldehyde is a common ingredient in chemical hair straighteners, even in those labeled as "formaldehyde-free," released into the air when the product is heated during

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[62] Calafat A.M., et al. *Urinary concentrations of four parabens in the U.S. population: NHANES 2005–2006*. Environ Health Perspect. 2010;118:679–685. [PubMed: 20056562].

[63] Helm J.S., et al. *Measurement of endocrine disrupting and asthma-associated chemicals in hair products used by Black women*. Environ. Research 2018;165:448-458.

[64] Myers S.L., et al. *Estrogenic and anti-estrogenic activity of off-the-shelf hair and skin care products*. J. Expo. Sci. Environ. Epidemiol. 2015;25(3):271-277. doi:10.1038/jes.2014.32.

[65] Pierce J.S., et al. *Characterization of Formaldehyde Exposure Resulting from the Use of Four Professional Hair Straightening Products*. J. Occ. and Environ. Hygiene 2011;8:686-699.

[66] *Id*.

[67] Cogliano V.J., et al. *Meeting Report: Summary of* IARC Monographs *on Formaldehyde, 2-Butoxyethanol, and 1*-tert-*Butoxy-2Propanol*. Environ. Health Perspect. 2005;113:1205–1208. doi:10.1289/ehp.7542 available via http://dx.doi.org/

application.[68]

C. Injuries Associated with Exposure to Chemical Hair Straighteners/Relaxers and/or Endocrine Disrupting Chemicals

a. Uterine Cancer

116. Uterine cancer is associated with phthalate metabolites found in hair care products.

117. Uterine cancer[69] accounts for approximately 3% of all new cancer cases.[70]

118. There are an estimated almost 66,000 new cases of uterine cancer in 2022 in the USA alone, out of which more than 90% is of endometrial origin. It is commonly diagnosed in the seventh decade, with the median age being 63 years.[71]

119. In addition, Black women with uterine cancer carry a poorer prognosis as compared to White women.[72]

120. Though death rates from other cancers in women have declined in recent years, death rates for uterine cancer have increased by more than 100% in the last 20 years.[73]

121. Indeed, new cases of uterine cancer have increased by 0.6% per year from 2010 to 2019, and death rates have risen an average of 1.6% per year over 2011 to 2020.[74]

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[68] Pierce J.S., et al. *Characterization of Formaldehyde Exposure Resulting from the Use of Four Professional Hair Straightening Products*. J. Occ. and Environ. Hygiene 2011;8:686-699.

[69] Uterine cancer includes endometrial carcinoma as well as uterine sarcoma, among other less common types.

[70] *Cancer Stat Facts: Uterine Cancer*, National Cancer Institute, https://seer.cancer.gov/statfacts/html/corp.html

[71] *Id*.; *Key Statistics for Endometrial Cancer*, American Cancer Society, https://www.cancer.org/cancer/endometrial-cancer/about/key-statistics.html.

[72] Joel Sorosky, *Endometrial Cancer*, Obstetrics & Gynecology Volume 120, 383-97, Aug. 2012, https://pubmed.ncbi.nlm.nih.gov/22825101/

[73] *Id*.

[74] Jack J. Lee, *Rising Endometrial Cancer Rate Spur New Approaches to Prevention*, National Cancer Institute: Division of Cancer Prevention, June 28, 2022, https://prevention.cancer.gov/news-and-events/blog/rising-endometrial-cancer

122. One study conducted by the National Cancer Institute (NCI) found that uterine cancer incidence rates increased by about 1% per year from 2003 to 2015, with a more rapid increase among women of other racial/ethnic groups than among White women. Uterine cancer incidence rates for Black women in particular have been higher than that of White women since 2007, and were consistently higher from 2011 through 2015.[75]

123. Recent findings from the Sister Study – a large, diverse, ongoing prospective cohort study conducted by the National Institute of Environmental Health Sciences (NIEHS), one of the National Institutes of Health (NIH), to investigate risk factors for breast cancer and other health conditions – show that women who used chemical hair straighteners and/or relaxers had a higher risk of uterine cancer[83] than those who did not. Importantly, the researchers found no such association with other hair products used by those women, including hair dye, bleach, highlights, or perms.[76]

124. The NIEHS study followed 33,947 US women aged 35-74 for almost 11 years. During follow-up, there were 378 cases of uterine cancer, 262 of which were confirmed through medical records and used for the analysis. The researchers concluded that women who reported frequent use of hair straightening products (i.e., more than four times in the previous year) were more than twice as likely to develop uterine cancer compared to those who did not use the products.[77]

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[75] Clarke M.A., et al. *Hysterectomy-Corrected Uterine Corpus Cancer Incidence Trends and Differences in Relative Survival Reveal Racial Disparities and Rising Rates of Nonendometrioid Cancers*. J. Clin. Oncol. 2019;37:1895-1908.

[76] Che-Jung Chang, et al., *Use of Straighteners and Other Hair Products and Incident Uterine Cancer*, Journal of the National Cancer Institute, Oct., 17, 2022, https://pubmed.ncbi.nlm.nih.gov/36245087/

[77] *Id.* Specifically, in ever vs. never users the HR = 1.80 [1.12-2.88]; for frequent vs. never users the HR = 2.55 [1.46-4.45]. The researchers estimated that 1.64% of women who did not use the products would develop uterine cancer by age 70, compared to 2.82% of ever users and 4.05% of frequent users.

125. The study found that an estimated 1.64% of women who never used chemical hair straighteners or relaxers would go on to develop uterine cancer by the age of 70; but for frequent users, that risk more than doubles, increasing to 4.05%.[78]

126. Approximately 60% of the women in the NIEHS study who used straighteners/relaxers identified as Black women. While the study did not show a difference in uterine cancer incidence based on race, the researchers stated that Black women may experience greater adverse health effects based on higher reported prevalence and frequency of use, younger age of initiating use, and harsher chemicals (i.e., higher concentrations of EDCs and other chemicals being regulated or banned).[79]

127. These recent findings are consistent with earlier studies showing an increase in hormone-related cancers in women with use of straighteners, including breast and ovarian cancer. The NIH Sister Study researchers previously found that permanent hair dye and straighteners might increase breast and ovarian cancer risk. [80]

b. Ovarian Cancer

128. Ovarian cancer is rare, making up approximately 1% of new cancer cases, with almost 20,000 new cases estimated in 2022. Approximately 1.1% of all women will be diagnosed with ovarian cancer. Of the 10.6 per 100,000 women per year who will be diagnosed with ovarian cancer, the death rate is 6.3 per 100,000 women – a 49.7% survival rate. [81]

129. While overall rates of ovarian cancer have declined in the U.S., which has been

[78] *Id.*
[79] *Id.*
[80] Eberle C.E., et al. *Hair dye and chemical straightener use and breast cancer risk in a large US population of black and white women*. Int. J. Cancer. 2020;147:383-391; White A.J., et al. *Use of hair products in relation to ovarian cancer risk*. Carcinogenesis 2021;42(9):1189-1195.
[81] *Cancer Stat Facts: Ovarian Cancer*, National Cancer Institute, https://seer.cancer.gov/statfacts/html/ovary.html.

attributed to increased exposure to oral contraceptives, Black women have the poorest survival rate at every stage and across subtypes.[82]

130. Another recent publication from the researchers of the Sister Study found the risk of ovarian cancer approximately doubled with frequent use (defined as greater than four times per year) of chemical hair straighteners/relaxers in the previous year as opposed to never use (HR = 2.19). [83]

131. While the study was not powered to detect differences based on race/ethnicity, among Black women the hazard ratios were elevated for ever use of straighteners (HR = 1.28) or perms (HR = 1.80). Further, the researchers noted that "given the much higher prevalence of use of these products, the impact of these results is more relevant for African American/Black women."[84]

132. As Putative Personal Representative of the Estate of Gail Hamilton, Rochelle Coronado seeks all damages available under Florida's Wrongful Death Act, and/or all damages available through Survival actions under Fl. St. 46.021.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
FLORIDA PRODUCTS LIABILITY ACT
(DEFECTIVE DESIGN AND FAILURE TO WARN)

133. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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[82] Park H.K., et al. *Recent Trends in Ovarian Cancer Incidence and Relative Survival in the United States by Race/Ethnicity and Histologic Subtypes*. Cancer Epidemiol. Biomarkers Prev. 2017;26(10):1511-1518. doi: 10.1158/1055-9965.EPI-17-0290.

[83] White A.J., et al. *Use of hair products in relation to ovarian cancer risk*. Carcinogenesis 2021;42(9):1189-1195.

[84] *Id*.

134. The Defendants are manufacturers, as defined in Fla. Stat. § 768.81(1)(d), and/or distributors that, at all times herein mentioned, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Products as hereinabove described that were used by the Plaintiff.

135. Defendants' actions, as identified herein, violated statutes, ordinance and/or rules and regulations.

136. That the Products were expected to and did reach the usual consumers, handlers, and persons coming into contact with said Product without substantial change in the condition in which they were produced, manufactured, sold, distributed, and/or marketed by the Defendants.

137. At those times, the Products were in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff.

138. At those times, given their increased safety risks, the Products were not fit for the ordinary purpose for which they were intended – chemically straightening and/or relaxing hair.

139. At those times, given their increased safety risks, the Products did not meet the reasonable expectations of an ordinary consumer, particularly, the Plaintiff.

140. The Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturer and/or suppliers, the foreseeable risks of ovarian cancer exceeded the benefits associated with the design or formulation of the Products.

141. The Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants manufacturers and/or suppliers, they were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect.

142. The Products designed, researched, manufactured, tested, advertised, promoted,

marketed, sold, and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants manufacturers and/or suppliers, Defendants knew or should have known that the design of the Products posed a substantial likelihood of harm (i.e., ovarian cancer) to Plaintiff and other users of the Products.

143. The Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective in design and/or formulation, in that, upon information and belief, when they left the hands of the Defendant manufacturers and/or suppliers, a safer feasible alternative design existed that was capable of preventing Plaintiff's injuries and damages – an alternative design that was and is in the exclusive possession, custody, and control of Defendants.

144. Upon information and belief, at all relevant times and at the time the Products left the Defendants' control, the Products were unreasonably dangerous in design because there existed a feasible, safer alternative design for the Products, the utility of which outweighed the utility of the design that was actually being used for the Products.

145. Upon information and belief, the safer, feasible, alternative design for the Products was a hair straightening treatment that did not contain endocrine disrupting chemicals and/or formaldehyde.

146. At all times herein mentioned, the Products were in a defective condition and unsafe, and Defendants knew or had reason to know that said Products were defective and unsafe, especially when used in the form and manner as provided by the Defendants.

147. Defendants knew, or should have known, that at all times herein mentioned their Products were in a defective condition and were and are inherently dangerous and unsafe.

148. At the time of the Plaintiff's use of the Products, the Products were being used for the purposes and in a manner normally intended, namely for straightening/relaxing

hair.

149. Defendants with this knowledge voluntarily designed their Products in a dangerous condition for use by the public, and in particular the Plaintiff.

150. Defendants had a duty to create Products that were not unreasonably dangerous for their normal, intended use.

151. Defendants breached this duty by creating Products unreasonably dangerous for their normal, intended use.

152. The Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached Plaintiff in the same defective and unreasonably dangerous condition in which the Defendants' Products were designed.

153. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective Products which created an unreasonable risk to the health of consumers and to the Plaintiff, in particular, and Defendants are therefore strictly liable under the Florida Products Liability Act for the injuries sustained by the Plaintiff.

154. The Plaintiff could not by the exercise of reasonable care have discovered the Products' defects herein mentioned and perceived their danger.

155. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, testing, marketing, supplying, promotion, advertising, sale and/or distribution of the Products into the stream of commerce, including a duty to assure the Products would not cause harm to users, such as the Plaintiff, to suffer unreasonable and dangerous side effects, such as ovarian cancer.

156. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, testing, marketing, supplying, promotion, advertising, sale and/or distribution of the Products into interstate commerce in that Defendants knew or should have known that using

the Products placed users at risk of developing serious and dangerous side effects, particularly ovarian cancer, and that the Products had not been sufficiently and/or adequately tested, yet they placed the Products into the steam of commerce anyway without adequate warnings.

157. The Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate warnings or instructions as the Defendants knew or should have known that the Products created a risk of serious and dangerous side effects including ovarian cancer, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

158. The Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

159. The Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including ovarian cancer, as well as other severe and permanent health consequences from the Products, they failed to provide adequate warnings to users or consumers of the Products, and continued to improperly advertise, market and/or promote their Products.

160. The Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate warnings, inadequate testing and/or inadequate post-marketing surveillance, in that, when they left the hands of the Defendants' manufacturers and/or suppliers, they were unreasonably dangerous, and more dangerous than an ordinary consumer would expect.

161. The packaging and/or labeling for the Products were inadequate because they did

not warn and/or adequately warn of the increased risk of ovarian cancer associated with the Products.

162. The packaging and/or labeling for the Products were inadequate because they did not warn and/or adequately warn that the Products had not been sufficiently and/or adequately tested for safety risks, including ovarian cancer.

163. Communications made by Defendants to Plaintiff and/or the public generally were inadequate because Defendants failed to warn and/or adequately warn them of the increased risk of ovarian cancer associated with the Products.

164. Communications made by Defendants to Plaintiff and/or the public generally were inadequate because Defendants failed to warn and/or adequately warn them that the Products had not been sufficiently and/or adequately tested for safety risks, including the risk of ovarian cancer.

165. Had Plaintiff been warned of the increased risk of ovarian cancer associated with the Products, she would not have used the Products and/or suffered ovarian cancer.

166. Had Plaintiff been warned that the Products had not been sufficiently and/or adequately tested for safety risks, including ovarian cancer, she would not have used the Products and/or suffered ovarian cancer.

167. By reason of the foregoing, Defendants have become liable in tort to the Plaintiffs under the Florida Products Liability Act for designing, marketing, promoting, distribution, and selling of the defective Products.

168. Defendants' defective design of and inadequate warnings relating to the Products were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

169. Said defects in Defendants' Products were a substantial factor in causing Plaintiff's injuries.

170. Said defects in Defendants' Products were the direct and proximate cause of Plaintiff's injuries.

171. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including ovarian cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

172. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

SECOND CAUSE OF ACTION
AS AGAINST DEFENDANTS
FLORIDA PRODUCTS LIABILITY
ACT
(FAILURE TO CONFORM TO REPRESENTATIONS)

173. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

174. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed and/or have acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Products as hereinabove described that was used by Plaintiff.

175. At all relevant times, Defendants reasonably anticipated and expected that individuals such as the Plaintiff would use or be affected by the Products.

176. In or about the late 1980s, when Plaintiff began using the Products and throughout her use of the Products, Defendants represented to her, by way of the Products' packaging and/or labeling, that the Products were safe to use for chemically straightening/relaxing hair.

177. As a result of Defendants' representations to her, Plaintiff was induced to use the Products from approximately the late 1980s at all relevant times, including up to and through the time of her diagnosis with and treatment for ovarian cancer.

178. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as the Plaintiff, would use the Products based upon their express warranties.

179. At all relevant times, Defendants knew or should have known that the Products were unreasonably dangerous because of their increased risk of ovarian cancer, especially when used in the form and manner as provided by Defendants.

180. At all relevant times, Defendants knew or should have known that the Products were unreasonably dangerous because their safety risks outweighed any cosmetic benefit they may have.

181. At all relevant times, Defendants knew or should have known that the Products had not been sufficiently and/or adequately tested for safety.

182. The unreasonably dangerous characteristics of the Products were beyond that which would be contemplated by the ordinary user such as Plaintiff, with the ordinary knowledge common to the community.

183. At the time the Products left the Defendants' control, the Products did not conform to Defendants' representations because the Products were not safe to use to chemically straighten/relax hair.

184. At the time the Products left the Defendants' control, the Products did not conform to Defendants' representations because the cosmetic benefits of the Products did not

outweigh any the dangers and/or risks associated with the Products.

185. The representations made by Defendants regarding the safety of the Products were made with the intent to induce Plaintiff to use the Products.

186. Defendants knew and/or should have known that by making the representations to Plaintiff it would be the natural tendency of Plaintiff to use the Products.

187. Plaintiff, as well as members of the public generally, relied on the representations of the Defendants herein.

188. The representations made by Defendants regarding the safety of the Products induced Plaintiff to use the Products.

189. Had Defendants not made these representations, Plaintiff would not have used the Products.

190. Plaintiff's injuries and damages were directly caused by the Products' failure to conform to Defendants' representations regarding the safety of the Products.

191. Said defects in Defendants' Products were the direct and proximate cause of Plaintiff's injuries.

192. Plaintiff's injuries and damages arose from a reasonably anticipated use of the Products by Plaintiff.

193. Accordingly, Defendants are liable under the Florida Products Liability Act to Plaintiff because the Products failed to conform to Defendants' representations.

194. As a result of the foregoing, Plaintiff was caused to suffer serious and dangerous side effects including ovarian cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

195. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of the Products.

196. As a result of the foregoing, the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

THIRD CAUSE OF ACTION
AS AGAINST DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

197. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

198. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed and/or have acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Products as hereinabove described that were used by Plaintiff.

199. At all relevant times, Defendants reasonably anticipated and expected that individuals such as the Plaintiff would use or be affected by the Products.

200. Upon information and belief, at all relevant times, Defendants expressly warranted to Plaintiff that the Products were safe to use for chemically straightening/relaxing hair.

201. Upon information and belief, at all relevant times, Defendants expressly warranted to Plaintiff that the cosmetic benefit of the Products outweighed any potential

dangers and/or risks.

202. Upon information and belief, at all relevant times, the aforementioned express warranties were made to Plaintiff by way of the Products' packaging and/or labeling.

203. In or about the late 1980s, Plaintiff began using the Products for chemically straightening/relaxing her hair.

204. In or about the late 1980s, Plaintiff purchased the Products for use believing they were safe and effective for their intended use – chemically straightening/relaxing hair.

205. Upon information and belief, Plaintiff obtained the information regarding the side effects of the Products from the packaging and/or labeling of the Products.

206. Upon information and belief, in or about the late 1980s, when Plaintiff began using the Products and throughout her use of the Products, Defendants expressly warranted to her, by way of the Products' packaging and/or labeling, that the Products were safe and effective to use for chemically straightening/relaxing hair.

207. As a result of Defendants' express warranties to her, Plaintiff was induced to use the Products from approximately the late 1980s, up to and through the time of her diagnosis with and treatment for ovarian cancer.

208. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as the Plaintiff, would use the Products based upon their express warranties.

209. At all relevant times, Defendants knew or should have known that the Products were unreasonably dangerous because of their increased risk of ovarian cancer, especially when the Products were used in the form and manner as provided by Defendants.

210. At all relevant times, Defendants knew or should have known that the Products were unreasonably dangerous because their safety risks outweighed any cosmetic benefit they may have.

211. At all relevant times, Defendants knew or should have known that the Products had not been sufficiently and/or adequately tested for safety.

212. The unreasonably dangerous characteristics of the Products were beyond that which would be contemplated by the ordinary user such as Plaintiff, with the ordinary knowledge common to the community as to the Products' characteristics.

213. At the time the Products left the Defendants' control, the Products did not conform to Defendants' express warranties because the Products were not safe to use to chemically straighten/relax hair.

214. At the time the Products left the Defendants' control, the Products did not conform to Defendants' express warranties because the cosmetic benefit of the Products does not outweigh any of the dangers and/or risks associated with them.

215. The express warranties made by Defendants regarding the safety of the Products were made with the intent to induce Plaintiff to use the Products.

216. Defendants knew and/or should have known that by making the express warranties to Plaintiff, it would be the natural tendency of Plaintiff to use the Products.

217. Plaintiff, as well as members of the general public, relied on the express warranties of the Defendants herein.

218. The express warranties made by Defendants regarding the safety of the Products induced Plaintiff to use the Products.

219. Had Defendants not made these express warranties, Plaintiff would not have used the Products.

220. Plaintiff's injuries and damages were directly and proximately caused by Defendants' breach of the aforementioned express warranties.

221. Plaintiff's injuries and damages arose from a reasonably anticipated use of the

product by Plaintiff.

222. Accordingly, Defendants are therefore to Plaintiffs for their breaches of the aforementioned express warranties.

223. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous side effects including ovarian cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

224. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Products.

225. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services

FOURTH CAUSE OF ACTION
AS AGAINST DEFENDANTS
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY)

226. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

227. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed and/or have acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed and distributed the Products as hereinabove described that was used by Plaintiff.

228. At the time Defendants marketed, sold, and distributed the Products for use by Plaintiff, Defendants knew of the use for which the Products were intended and impliedly warranted the Products to be of merchantable quality and safe and fit for ordinary use.

229. At all relevant times, Defendants reasonably anticipated and expected that individuals such as the Plaintiff would use or be affected by the Products.

230. At all relevant times, Defendants impliedly warranted to Plaintiff and the public generally that the Products were of merchantable quality and safe and fit for ordinary use in that they were safe to use to chemically straighten/relax hair.

231. At all relevant times, Defendants impliedly warranted to Plaintiff and the public generally that the Products were of merchantable quality and safe and fit for ordinary use in that they were effective to use to chemically straighten/relax hair.

232. At all relevant times, Defendants impliedly warranted to Plaintiff and the public generally that the Products were of merchantable quality and safe and fit for ordinary use in that the cosmetic benefit of the Products outweighed any potential dangers and/or risks

233. At all relevant times, Defendants knew or should have known that the Products were unreasonably dangerous because of their increased risk of ovarian cancer, especially when used in the form and manner as provided by Defendants.

234. At all relevant times, Defendants knew or should have known that the Products were unreasonably dangerous because their safety risks outweighed any cosmetic benefit they may have.

235. The unreasonably dangerous characteristics of the Products were beyond that which would be contemplated by the ordinary user such as Plaintiff, with the ordinary knowledge common to the community as to the Products' characteristics.

236. At all relevant times and at the time the Products left the Defendants' control, the

implied warranties made by Defendants were false, misleading, and inaccurate because the Products were not safe to use to chemically straighten/relax hair in that they carried an increased risk of ovarian cancer.

237. At all relevant times and at the time the Products left the Defendants' control, the implied warranties made by Defendants were false, misleading, and inaccurate because the cosmetic benefit of the Products did not outweigh any the dangers and/or risks associated with them.

238. Plaintiff did rely on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to the Products.

239. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the Products were of merchantable quality and safe and fit for their intended use.

240. As a result of Plaintiff's reasonable reliance upon Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to the Products, she used the Products.

241. The Products were injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the Products and materials were expected to and did reach users, handlers, and persons coming into contact with said Products without substantial change in the condition in which they were sold.

242. Defendants herein breached the aforesaid implied warranties, as their Products were not merchantable nor fit for their intended purposes and uses in that they had not been properly or sufficiently tested for risks, they were associated with an increased risk of ovarian cancer, and/or any cosmetic benefits the Products were outweighed by their risks, particularly their increased risk of ovarian cancer.

243. Plaintiff's injuries and damages were directly and proximately caused by

Defendants' breach of the aforementioned implied warranties.

244. Plaintiff's injuries and damages arose from a customary, usual, reasonably foreseeable use of the Products by Plaintiff.

245. Defendants are therefore liable to Plaintiff for their breaches of the implied warranty of merchantability.

246. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous side effects including ovarian cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

247. As a result of the foregoing acts and omissions the Plaintiff required more health care and services and did incur medical, health, incidental, and related expenses.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiffs for past and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages as allowed for by law for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings;

5. Pre- and post-judgment interest;

6. Trial by Jury; and

7. Such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury of all claims asserted in this Complaint.

Respectfully submitted,

Dated: February 1, 2023

/s/ George G. Triantis

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