

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

[REDACTED],  
Plaintiff,  
  
v.  
  
L'ORÉAL USA, INC., L'ORÉAL USA  
PRODUCTS, INC., SOFT SHEEN-  
CARSON, LLC, SOFT SHEEN/CARSON,  
INC., and SOFT SHEEN/CARSON (W.I.),  
INC.  
  
Defendants.

Case Number:

**COMPLAINT**  
**AND DEMAND**  
**FOR JURY TRIAL**

Plaintiff [REDACTED], by her attorneys, [REDACTED], on behalf of herself individually, 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, [REDACTED], who was injured as a result of her use of certain of Defendants' Products, including, but not limited to, Dark & Lovely and Optimum ("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 had not been properly tested and/or were not safe for their indicated use.

5. Defendants negligently misrepresented and/or fraudulently represented to Plaintiff [REDACTED] and/or the public in general that their Products had been tested and were found to be safe for their indicated use despite their knowledge to the contrary.

6. Defendants concealed their knowledge of the Products' defects from Plaintiff [REDACTED] and/or the public in general.

7. Defendants' representations and/or omissions were done with the intent of defrauding and deceiving Plaintiff [REDACTED] and/or the public in general, and were made with the intent of inducing the public in general to purchase Defendants' Products for chemically straightening and/or relaxing hair, all of which evinced a callous, reckless, willful, depraved indifferent to health, safety, and welfare of the Plaintiff.

8. Defendants negligently and improperly failed to perform sufficient tests, if any, on the Products, forcing Plaintiff [REDACTED] to rely on inaccurate safety and risk information relating to the Products.

9. As a result of the foregoing acts and omissions of Defendants, the Plaintiff was and still is caused to suffer serious and dangerous side effects including, inter alia, uterine fibroids requiring a partial hysterectomy, as well as other severe and personal injuries which are permanent and lasting in are, 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.

10. Plaintiff [REDACTED] 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.

11. Consequently, Plaintiff [REDACTED] seeks compensatory damages as a result of her use of Defendants' Products, which has caused her to suffer from uterine fibroids requiring a partial hysterectomy, 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 developing any of the above named health consequences.

**PARTY PLAINTIFF**

12. Plaintiff, [REDACTED], is a citizen of the United States of America, and is a citizen of the State of Arizona.

13. Plaintiff, [REDACTED], was born on October 5, 1978.

14. Plaintiff, [REDACTED], first began using Defendants' Products in or about 1992, and frequently used Defendants' Products at all relevant times, including up to the time of her diagnosis with and treatment for uterine fibroids.

15. Plaintiff [REDACTED] used Defendants' Products by applying them to her scalp and/or by having a professional at a hair salon apply Defendants' Products, exactly as instructed by Defendants.

16. Plaintiff [REDACTED] would keep the Products on her hair for the time allotted in the instructions.

17. There was never any indication, on the Products' packaging or otherwise, that this normal use could and would cause her to develop uterine fibroids requiring a partial hysterectomy.

18. As a result of using Defendants' Products, Plaintiff [REDACTED] was caused to suffer from uterine fibroids requiring a partial hysterectomy in or about January 2021, and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

19. The injuries and damages sustained by Plaintiff [REDACTED] were caused by Defendants' Products.

**PARTY DEFENDANTS**

20. 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. L'OREAL USA, INC. is a wholly owned subsidiary of L'OREAL S.A., a corporation having its headquarters and principal place of business in France.

21. 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. L'OREAL USA PRODUCTS, INC. is a wholly owned subsidiary of Defendant L'OREAL USA, INC.

22. 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. Plaintiff alleges that SOFT SHEEN-CARSON, LLC's members and sole interested parties are L'ORÉAL S.A., a global corporation having its headquarters and principal place of business in France; and Defendant L'ORÉAL USA,

INC., incorporated in Delaware with its principal place of business and headquarters at 575 Fifth Avenue, New York, New York 10017.

23. 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.

24. Defendant CARSON (W.I.), INC., D/B/A SOFT SHEEN (“SOFTSHEEN-CARSON (W.I.), INC.”), is a Delaware corporation and process may be served upon its registered agent, Corporate Services Company 251 Little Falls Drive, Wilmington, Delaware 19808. SOFTSHEEN-CARSON (W.I.), INC. is a wholly-owned subsidiary of Defendant L’OREAL USA, INC.

25. 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 such products into interstate commerce within the United States with knowledge and intent that such products be sold in the States of New York and Arizona.

26. Upon information and belief, Defendants transacted and conducted business in the States of New York and Arizona.

27. Upon information and belief, Defendants derived substantial revenue from goods and products sold and/or used in the States of New York and Arizona.

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

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

30. 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. Dark & Lovely; and
- b. Optimum.

31. Defendants' defective Products were placed into the stream of commerce and used by the Plaintiff from approximately 1992 and at all relevant times, including up to the time of her diagnosis with and treatment for uterine fibroids.

### **FACTUAL BACKGROUND**

#### **A. Chemical Hair Straighteners and Relaxers**

32. Black people make up approximately 13% of the U.S. population, but by one estimate, African American spending accounts for as much as 22% of the \$42 billion-a-year personal care products market, suggesting that they buy and use more of such products – including those with potentially harmful ingredients– than Americans as a whole.<sup>1</sup>

33. In an analysis of ingredients in 1,177 beauty and personal care products marketed to Black women, about one in twelve (12) was ranked highly hazardous on the scoring system of EWG's Skin Deep® Cosmetics Database, a free online resource for finding less-hazardous

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<sup>1</sup> Thandisizwe Chimurenga, *How Toxic is Black Hair Care?*, New America Media, Feb. 2, 2012, [americamedia.org/2012/02/skin-deep-in-more-ways-than-one.php](http://americamedia.org/2012/02/skin-deep-in-more-ways-than-one.php); *Personal Care Products Manufacturing Industry Profile*, Dun & Bradstreet First Research, August 2016, [www.firstresearch.com/Industry-Research/Personal-Care-Products-Manufacturing.html](http://www.firstresearch.com/Industry-Research/Personal-Care-Products-Manufacturing.html) (This report uses "Black" to describe not only people who identify as African-American, but Black people in the U.S. who come from the Caribbean or other areas. "African-American" is used only when a cited source specifies that term).

alternatives to personal care products. The worst-scoring products marketed to Black women were hair relaxers, and hair colors and bleaching products. Each of these categories had an average product score indicating high potential hazard.<sup>2</sup>

34. In the U.S. alone, Black consumers spend over \$1 trillion each year, with a significant amount of that spending toward hair care products.<sup>3</sup>

35. In 2020, the global Black Hair care market was estimated at \$2.5 billion, with the hair relaxer market alone estimated at \$718 million in 2021, with the expectation of growth to \$854 million annually by 2028.<sup>4</sup>

### **1. Defendants' Marketing Efforts**

36. In 1971, Dark and Lovely manufactured the first lye relaxer. The formula consisted of sodium hydroxide, water, petroleum jelly, mineral oils, and emulsifiers.<sup>5</sup>

37. 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.<sup>6</sup> 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.<sup>7</sup>

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<sup>2</sup> Environmental Working Group. *Big Market for Black Cosmetics, but Less-Hazardous Choices Limited*. Available at: <https://www.ewg.org/research/big-market-black-cosmetics-less-hazardous-choices-limited>.

<sup>3</sup> Wright, Bruce C.T. *Black Buying Power By The Numbers: History In The Making*. Available at: <https://newsone.com/3901998/black-buying-power-by-numbers-history-making/>.

<sup>4</sup> Prinzi, Lucia. *Hair Facts: 50 Impressive Black Hair Industry Statistics*. <https://www.allthingshair.com/en-us/all-things-natural-hair/black-hair-industry-statistics/>

<sup>5</sup> Cicely A. Richard, *This History of Hair Relaxers*, September 29, 2017 <https://classroom.synonym.com/the-history-of-hair-relaxers-12078983.html>.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

38. Over time, Soft & Beautiful and other chemical relaxer manufacturers developed herbal and botanical hair relaxer formulas.<sup>8</sup>

39. 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.<sup>9</sup>

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



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<sup>8</sup> *Id.*

<sup>9</sup> *Id.*





## 2. Chemical Relaxer Use

41. 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.

42. 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.

43. 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.

44. 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.

45. 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.<sup>10</sup>

46. In the 1990s, the first relaxer product for young Black girls, Just for Me™, hit the market with a catchy advertising jingle that captured consumer attention.<sup>11</sup> It soon became one of the most popular straightening treatments, touting a no-lye formula designed to be gentler for children’s sensitive scalps.

47. 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.

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<sup>10</sup> Patrick Obukowcho, *Hair Relaxers: Science, Design, and Application* 27 (2018).

<sup>11</sup> Dana Oliver, *The ‘90s Just For Me Hair Relaxer Commercial Song Is Stuck In Our Heads*, HuffPost, Feb., 1, 2014. [https://www.huffpost.com/entry/just-for-me-hair-relaxer-commercial-song\\_n\\_4689981](https://www.huffpost.com/entry/just-for-me-hair-relaxer-commercial-song_n_4689981)

## **B. Regulatory Framework**

48. 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”).

49. The FD&C Act expressly prohibits the marketing of “adulterated” or “misbranded” cosmetics in interstate commerce.

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

51. 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.

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

53. 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.<sup>12</sup>

54. 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

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<sup>12</sup> Food and Drug Administration Cosmetic Act § 602 (1938).

cosmetic harmful when used as intended.<sup>13</sup> An example is methylene chloride because it causes cancer in animals and is likely to be harmful to human health, too.<sup>14</sup>

55. 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.<sup>15</sup> 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.<sup>16</sup>

56. 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.

57. 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

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<sup>13</sup> *Prohibited & Restricted Ingredients in Cosmetics*, U.S. Food and Drug Administration, <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics>

<sup>14</sup> 21 Code of Federal Regulations § 700.19.

<sup>15</sup> § 87 FR 31080

<sup>16</sup> *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>

additional toxicological and other tests that are appropriate in light of such existing data and information.<sup>17</sup>

58. 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.<sup>18</sup>

59. 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.

60. 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

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<sup>17</sup> *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated*, U.S. Food and Drug Administration, Mar., 3, 2005, <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated>

<sup>18</sup> *Id.*

dangerous harms associated with their products when used as intended, particularly in women of color.

### C. Components of Chemical Hair Straighteners and/or Relaxers

61. 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 and uterine fibroids. 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.<sup>19</sup>

62. 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<sup>20</sup> (“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

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<sup>19</sup> 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.

<sup>20</sup> Also known as Bis(2-ethylhexyl) phthalate.

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 additive estrogenic activity.”<sup>21</sup>

63. Regarding parabens and phthalates, a recent study stated that, “Accumulating evidence from experimental and animal studies supports the carcinogenic potential of these chemicals.”<sup>22</sup> 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.<sup>23</sup> They have also been detected in human breast tumors.<sup>24</sup> Additionally, studies have shown higher urinary levels of certain phthalates and parabens in U.S. Black women compared to

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<sup>21</sup> 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.

<sup>22</sup> 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.

<sup>23</sup> 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](https://doi.org/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](https://doi.org/10.1007/s11356-019-06228-1).

<sup>24</sup> 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.

U.S. White women.<sup>25</sup> Black individuals in the U.S. have also been found to have higher concentrations of certain parabens than White individuals.<sup>26</sup>

64. 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 endometrial cancer development and progression.<sup>27</sup> Urine levels of BPA have also been positively associated with the prevalence of uterine fibroids.<sup>28</sup> Black individuals in the U.S. have also been found to have higher concentrations of BPA than White individuals.<sup>29</sup>

65. Further, studies have associated cyclosiloxanes with neoplastic responses, which can lead to tumor growth, in the uterus of rats.<sup>30</sup>

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<sup>25</sup> 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.

<sup>26</sup> 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>.

<sup>27</sup> 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.

<sup>28</sup> Wise, L.A. et al. *Epidemiology of Uterine Fibroids – From Menarche to Menopause*. Clin Obstet Gynecol. 2016;59(1):2-24. doi:10.1097/GRF.0000000000000164

<sup>29</sup> 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>.

<sup>30</sup> Dekant W, et al. *Biological relevance of effects following chronic administration of octamethylcyclotetrasiloxane (D4) in Fischer 344 rats*. Toxicol Lett. 2017;279:42-53.



66. Finally, diethanolamine, metals, and formaldehyde have all been considered carcinogenic.<sup>31</sup>

### 1. Endocrine-Disrupting Chemicals

67. The endocrine system is indispensable for life and influences nearly every cell, organ, and processes within the body.<sup>32</sup> 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.<sup>33</sup>

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doi:[10.1016/j.toxlet.2017.01.010](https://doi.org/10.1016/j.toxlet.2017.01.010).; Jean PA, et al. *Chronic toxicity and oncogenicity of decamethylcyclotetrasiloxane in the Fischer 344 Rat*. Regul Toxicol Pharmacol. 2016;

74:S57-S66. doi:[10.1016/j.yrtph.2015.06.014](https://doi.org/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](https://doi.org/10.1016/j.toxlet.2017.06.003).

<sup>31</sup> 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](https://doi.org/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](https://doi.org/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.

<sup>32</sup> *Endocrine System: The Endocrine System Includes The Thyroid, Adrenals, and the Pituitary Gland*, Science Direct, <https://www.sciencedirect.com/topics/psychology/endocrine-system>

<sup>33</sup> *Endocrine Disruption*, United States Environmental Protection Agency, Mar., 7, 2022, <https://www.epa.gov/endocrine-disruption/what-endocrine-system>

68. 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.<sup>34</sup>

69. Hormones, such as estrogen, testosterone, progesterone, and androgen, are chemical signals that control or regulate critical biological processes.<sup>35</sup>

70. 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.<sup>36</sup>

71. 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.<sup>37</sup>

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

73. EDCs can act directly on hormone receptors as mimics or antagonists, or on proteins that control hormone delivery.<sup>38</sup>

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<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup>*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>

<sup>38</sup> 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/>

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

75. 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.

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

77. 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.<sup>39</sup>

78. 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.<sup>40</sup> Specifically, EDCs have the potential to cause formation of several hormone-dependent cancers, including breast and ovarian cancers.<sup>41</sup>

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<sup>39</sup> 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>

<sup>40</sup> *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>

<sup>41</sup> 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 mesenchymal transition process*. Mol Cell Endocrinol 2017;457:103-113, doi:10.1016/j.mce.2016.12.026.

79. 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.

80. 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.<sup>42</sup>

81. 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."<sup>43</sup>

82. 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**

83. 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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<sup>42</sup> 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/>.

<sup>43</sup> 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.

84. 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.

85. At all relevant times herein, phthalates were used in Defendants’ products.

86. Phthalates are chemicals used to improve the stability and retention of fragrances and to help topical products stick to and penetrate skin and hair.<sup>44</sup>

87. Phthalates are known EDCs which interfere with natural hormone production and degradation and are detrimental to human health.<sup>45</sup>

88. 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.

89. 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.<sup>46</sup>

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<sup>44</sup> Olivia Koski & Sheila Hu, *Fighting Phthalates*, National Resources Defense Council, April 20, 2022, <https://www.nrdc.org/stories/fighting-phthalates>

<sup>45</sup> 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/>

<sup>46</sup> *Id.*

90. Defendants' products referenced herein contain phthalates, including Di-2-ethylhexylphthalate.

91. 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.

92. 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.

93. Since 1999, the Centers for Disease Control ("CDC") have found phthalates in individuals studied for chemical exposure.<sup>47</sup>

### 1. Di-2-ethylhexylphthalate

94. Di-2-ethylhexylphthalate<sup>48</sup> ("DEHP") is a highly toxic manufactured chemical,<sup>49</sup> classified by the International Agency for Research on Cancer ("IARC") as possibly carcinogenic to humans,<sup>50</sup> that is not found naturally in the environment.<sup>51</sup>

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<sup>47</sup> *Biomarker Groups*, National Report on Human Exposure to Environmental Chemicals, Center for Disease Control, [https://www.cdc.gov/exposurereport/pdf/Biomarker\\_Groups\\_Infographic-508.pdf](https://www.cdc.gov/exposurereport/pdf/Biomarker_Groups_Infographic-508.pdf)

<sup>48</sup> Also known as Bis(2-ethylhexyl) phthalate.

<sup>49</sup> 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>.

<sup>50</sup> IARC Monographs – 101: Di(2-Ethylhexyl) Phthalate. Available at: <https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono101-006.pdf>.

<sup>51</sup> *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

95. DEHP belongs to the family of chemicals called phthalates<sup>52</sup> and can be found in hair relaxers.<sup>53</sup>

96. DEHP was first used in 1949 in United States and has been the most abundantly used phthalate derivative in the Twentieth century.<sup>54</sup>

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.<sup>55</sup>

98. Humans are exposed to DEHP through ingestion, inhalation, and dermal exposure for their lifetimes, including intrauterine life.<sup>56</sup>

99. The Agency for Toxic Substances and Disease Registry (“ATSDR”) estimates that the range of daily human exposure to DEHP is 3–30 µg/kg/day.<sup>57</sup>

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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”).

<sup>52</sup> *Di(2-ethylhexyl) phthalate (DEHP)*, Proposition 65, California. Gov, <https://www.p65warnings.ca.gov/fact-sheets/di2-ethylhexylphthalate-dehp>

<sup>53</sup> 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.

<sup>54</sup> Pinar Erkekoglu & Belma Kocer-Gumusel, *Environmental Effects of Endocrine-Disrupting Chemicals: A Special Focus on Phthalates and Bisphenol A*, Environmental Health Risk, June 16, 2016, <https://www.intechopen.com/chapters/50234>

<sup>55</sup> 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>

<sup>56</sup> 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/>

<sup>57</sup> Hannon, Patrick et. al., *Daily Exposure to Di(2-ethylhexyl) Phthalate Alters Estrous Cyclicity and Accelerates Primordial Follicle Recruitment Potentially Via Dysregulation of the Phosphatidylinositol 3-Kinase Signaling Pathway in Adult Mice*, Biology of Reproduction Volume 90, Issue 6, June 2014, 136, 1–11 <https://academic.oup.com/biolreprod/article/90/6/136,%201-11/2514356>

100. The no-observed-adverse-effect level for DEHP to humans is 4.8 mg/kg bodyweight/day and the tolerated daily intake (TDI) is 48 µg/kg bodyweight.<sup>58</sup>

<b>Endpoint</b>	<b>Cancer (NSRL)</b>		<b>Developmental and Reproductive Toxicity (MADL)</b>	
	<b>Oral</b>	<b>Inhalation</b>	<b>Oral</b>	<b>Inhalation</b>
<b>DEHP</b>	310 µg/day	N.C.	410 µg/day	N.C.

Source: OEHHA's safe harbor levels for TDCIPP, DBP, DEHP, benzene, and formaldehyde. N.C. = not calculated by OEHHA as of August 2020.<sup>59</sup>

101. 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)phthalate (MEOHP).<sup>60</sup>

<sup>58</sup> Yufei Wang & Haifeng Qian, *Phthalates and Their Impacts on Human Health*, Healthcare (Basel) 9(5):603, May 18, 2021, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8157593/>

<sup>59</sup> Aalekhya Reddam & David Volz, *Inhalation of two Prop 65-listed Chemicals Within Vehicles May Be Associated with Increased Cancer Risk*, Environment International Volume 149, April 2021, <https://www.sciencedirect.com/science/article/pii/S016041202100026X>

<sup>60</sup> 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://bmstructbiol.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)).



102. DEHP and its metabolites are implicated in reproductive tract abnormalities, including cancer and infertility, as well as potential teratogenic effects.<sup>61</sup> Specifically, DEHP is considered carcinogenic in animals.<sup>62</sup>

103. 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.<sup>63</sup>

104. 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 descent 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.

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<sup>61</sup> 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/>.

<sup>62</sup> 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.

<sup>63</sup> *Chapter 2: Health Effects*, Toxicological profile for Di(2-ethylhexyl) phthalate (DEHP) (2001), <https://www.atsdr.cdc.gov/ToxProfiles/tp9-c2.pdf>

105. The global consumption of DEHP was estimated at 3.07 million tons (Global demand for plasticizers continues to rise). The estimated global market of phthalates in 2020 is expected to reach 10 billion USD and would still be widely used in plasticizers.<sup>64</sup>

106. Human epidemiological studies have shown a significant association between phthalates exposures and adverse reproductive outcomes in both women and men.<sup>65</sup>

107. Evidence found that DEHP was significantly related to insulin resistance and higher systolic blood pressure and the reproduction system problems, including earlier menopause, low birth weight, pregnancy loss, and preterm birth.<sup>66</sup>

108. 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.<sup>67</sup>

109. 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.<sup>68</sup>

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<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> 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>

<sup>67</sup> *Id.*

<sup>68</sup> Consumer Product Safety Improvement Act of 2008, H.R. 4040, 110<sup>th</sup> Cong. (2008), <https://www.congress.gov/110/plaws/publ314/PLAW-110publ314.pdf>

## ii. Parabens

110. Parabens are used as preservative and antibacterial agents in personal care products, and have estrogenic and anti-androgenic activity.<sup>69</sup>

111. Hair products used by Black women, including chemical straighteners/relaxers, are more likely to contain parabens, which affect estrogenic pathways.<sup>70</sup>

112. 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.<sup>71</sup> In addition, one study indicated that Black children in the U.S. have five times the urinary paraben levels of White children.<sup>72</sup>

113. Parabens have been associated with uterine fibroid tumors, premature puberty, and endocrine disruption.<sup>73</sup>

114. In one study, parabens were found in breast tumor tissue at levels similar to those shown to induce uterine growth in rodents.<sup>74</sup>

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<sup>69</sup> 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>.

<sup>70</sup> Zota A.R., et al. *The environmental injustice of beauty: framing chemical exposures from beauty products as a health disparities concern*. *Am. J. Obst. & Gyn.* Oct. 2017.

<sup>71</sup> 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.

<sup>72</sup> 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].

<sup>73</sup> 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.

<sup>74</sup> 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.

## 2. Formaldehyde

115. Formaldehyde is a naturally occurring, organic, reactive, volatile, colorless gas detectable in air, drinking water, and foods.<sup>75</sup>

116. 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 the International Agency for Research on Cancer ("IARC").<sup>76</sup>

117. 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."<sup>77</sup>

118. 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 application.<sup>78</sup>

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

#### **a. Uterine Cancer**

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

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<sup>75</sup> 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.

<sup>76</sup> *Id.*

<sup>77</sup> 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/>

<sup>78</sup> 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.

120. Uterine cancer<sup>79</sup> accounts for approximately 3% of all new cancer cases.<sup>80</sup>

121. 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.<sup>81</sup>

122. In addition, Black women with uterine cancer carry a poorer prognosis as compared to White women.<sup>82</sup>

123. 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.<sup>83</sup>

124. 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.<sup>84</sup>

125. 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.<sup>85</sup>

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<sup>79</sup> Uterine cancer includes endometrial carcinoma as well as uterine sarcoma, among other less common types.

<sup>80</sup> *Cancer Stat Facts: Uterine Cancer*, National Cancer Institute, <https://seer.cancer.gov/statfacts/html/corp.html>

<sup>81</sup> *Id.*; *Key Statistics for Endometrial Cancer*, American Cancer Society, <https://www.cancer.org/cancer/endometrial-cancer/about/key-statistics.html>.

<sup>82</sup> Joel Sorosky, *Endometrial Cancer*, *Obstetrics & Gynecology* Volume 120, 383-97, Aug. 2012, <https://pubmed.ncbi.nlm.nih.gov/22825101/>

<sup>83</sup> *Id.*

<sup>84</sup> 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>

<sup>85</sup> Clarke M.A., et al. *Hysterectomy-Corrected Uterine Corpus Cancer Incidence Trends and*

126. 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<sup>86</sup> 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.<sup>87</sup>

127. 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.<sup>88</sup>

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*Differences in Relative Survival Reveal Racial Disparities and Rising Rates of Nonendometrioid Cancers.* J. Clin. Oncol. 2019;37:1895-1908.

<sup>86</sup> Uterine cancer cases were defined as women who reported a diagnosis of endometrial cancer, uterine sarcoma, or other types of cancer in the uterus after enrollment.

<sup>87</sup> 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/>

<sup>88</sup> *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.

128. 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%.<sup>89</sup>

129. 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).<sup>90</sup>

130. 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.<sup>91</sup>

**b. Breast Cancer**

131. Breast cancer is associated with phthalate metabolites found in hair care products.

132. In Black women, breast cancer is diagnosed earlier and tends to be more aggressive, resulting in Black women having the highest rates of death due to this disease than any other ethnic/racial group.

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<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> 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.

133. The role of environmental exposure to estrogen and EDCs has been studied for good reason. A growing body of evidence links: (1) environmental estrogen and EDC exposures to breast cancer risk, (2) the presence of such chemicals in personal care products, including hair products, and (3) the use of certain hair products with potential breast cancer risk in African Americans.<sup>92</sup>

134. Numerous, biologically plausible mechanisms have been published in the peer-reviewed medical and scientific literature that support a causal link between hair straighteners and reproductive and/or endocrine-related tumors.

- a. Hormonal imbalances and over-activation of the estrogen, progesterone, and epidermal receptors are associated with development and progression of breast cancer.<sup>93</sup>
- b. Studies have shown that increased breast cancer mortality, poor prognosis, and the recurrence of breast cancer are associated with the higher urinary concentrations of DEHP and its metabolite, MEHP.<sup>94</sup> Studies have also shown that exposure to DEHP increases invasive properties of breast cells.<sup>95</sup>

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<sup>92</sup> Laura Stiel, et al., *A Review of Hair Product Use on Breast Cancer Risk in African American Women*, *Cancer Medicine*, 5(3):597-604, March 2016, <https://pubmed.ncbi.nlm.nih.gov/26773423/>

<sup>93</sup> *Hormone Action in the Mammary Gland*, Cold Spring Harbor Perspectives in Biology, 2(12), December 2010, <https://pubmed.ncbi.nlm.nih.gov/20739412/> ; Suzanne Fenton & Linda Birnbaum, *Timing of Environmental Exposures as a Critical Element in Breast Cancer Risk*, *The Journal of Clinical Endocrinology & Metabolism*, Volume 100, Issue 9, 3245–3250, Sept., 1, 2015, <https://academic.oup.com/jcem/article/100/9/3245/2836022>

<sup>94</sup> Tsung-Hua Hsieh, et al., *DEHP Mediates Drug Resistance by Directly Targeting AhR in Human Breast Cancer*, *Biomedicine & Pharmacotherapy*, Volume 145, 112400, Nov., 18, 2021, <https://pubmed.ncbi.nlm.nih.gov/34801851/>

<sup>95</sup> Belinda Crobeddu, et al., *Di(2-ethylhexyl) Phthalate (DEHP) Increases Proliferation of Epithelial Breast Cancer Cells Through Progesterone Receptor Dysregulation*, *Environmental Research*, Volume 172, 165-173, June 2019,



- c. Hormone receptor-negative breast cancer means that cancer cells do not grow in response to the hormones estrogen or progesterone.<sup>96</sup> Receptors are proteins on certain tumor cells that hormones stick to, allowing cancer cells to grow and multiply.
- d. Progesterone is essential for the mammary gland development and has a proliferative effect on epithelial cells.<sup>97</sup> Disruption of the progesterone pathway is known to be a risk factor for breast cancer.<sup>98</sup> Two progesterone receptors are expressed at similar levels in the mammary gland, PR-A and PR-B.<sup>99</sup>
- e. The progesterone receptor gene is an estrogen-regulated gene.<sup>100</sup>
- f. T-47D cells are cancer cells isolated from breast cancer patients and contain the receptors involved in hormone-dependent breast cancer, estrogen, and progesterone receptors.
- g. DEHP and its metabolite, MEHP, increase cell proliferation of T-47D cancerous cells.<sup>101</sup> DEHP and MEHP induce progesterone receptor stimuli,

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<https://www.sciencedirect.com/science/article/abs/pii/S0013935119301653?via%3Dihub#bib82>

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> P.A. Mote, et al., *Loss of Co-ordinate Expression of Progesterone Receptors A and B is an Early Event in Breast Carcinogenesis*, *Breast Cancer Research and Treatment*, 72, 163-172, 2002, <https://link.springer.com/article/10.1023/A:1014820500738#citeas>

<sup>100</sup> Mariana Brandao, et al., *Molecular Biology of Breast Cancer*, *Essential Concepts in Molecular Pathology, Progesterone Receptor*, 2020, <https://www.sciencedirect.com/topics/medicine-and-dentistry/progesterone-receptor>

<sup>101</sup> Bélinda Crobeddu, et al., *Di(2-ethylhexyl) Phthalate (DEHP) Increases Proliferation of Epithelial Breast Cancer Cells Through Progesterone Receptor Dysregulation*, *Environmental Research*, Volume 172, 165-173, June 2019,

resulting in increased progesterone receptor levels and T-47D cell proliferation.<sup>102</sup>

- h. Importantly, when progesterone receptors are purposefully inhibited by administration of a pharmacologic antagonist competitor of the progesterone receptor, it decreases the proliferation of T-47D induced by DEHP and MEHP.<sup>103</sup> Thus, exposure to DEHP and its metabolite increases proliferation of breast cancer cells by activating the progesterone receptor.<sup>104</sup>
- i. Estrogen receptor  $\alpha$  drives more than 70% of breast cancers.<sup>105</sup>
- j. Estrogen receptor-negative breast cancers are a group of tumors with poor prognosis and fewer cancer prevention and treatment strategies compared to estrogen-positive tumors.<sup>106</sup>
- k. DEHP metabolites were associated with increased risk of breast cancer as well as uterine leiomyoma due to the EDC's influence on estrogen receptors.<sup>107</sup>

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<https://www.sciencedirect.com/science/article/abs/pii/S0013935119301653?via%3Dihub#bib82>

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> David G. Hicks M.D. & Susan C. Lester MD, PhD, *Hormone Receptors (ER/PR)*, Diagnostic Pathology: Breast, Progesterone Receptor, 2016, <https://www.sciencedirect.com/topics/medicine-and-dentistry/progesterone-receptor>

<sup>106</sup> Thomas C Putti, et al., *Estrogen Receptor-Negative Breast Carcinomas: A Review of Morphology and Immunophenotypical Analysis*, *Modern Pathology*, 18, 26–35, Aug., 27, 2004, <https://www.nature.com/articles/3800255>

<sup>107</sup> Zhiqin Fu, et al., *Association Between Urinary Phthalate Metabolites and Risk of Breast Cancer and Uterine Leiomyoma*, *Reproductive Toxicology*, 74: 134-142, Sept., 23, 2017, <https://pubmed.ncbi.nlm.nih.gov/28951174/>

- l. Aromatase and estrogen receptor  $\alpha$  are two key proteins for the proliferation of endocrine-responsive and endocrine-resistant breast cancers.<sup>108</sup>
- m. Aromatase is an enzyme involved in the conversion of androgen, such as testosterone, to estrogen, such as  $17\beta$ -estradiol. It is also a very effective therapeutic target for the treatment of endocrine-responsive breast cancer.<sup>109</sup>
- n. The aryl hydrocarbon receptor (AhR) can form an estrogen receptor  $\alpha$  complex, which activates the receptor's response even in the absence of estrogen.<sup>110</sup>
- o. AhR plays an important role in estrogen receptor-negative breast cancer, including the regulation of tumor growth, metastasis,<sup>111</sup> and drug resistance.<sup>112</sup>
- p. AhR functions as a receptor for EDC phthalates and causes drug inactivation. Overexpression of AhR affects cell proliferation and motility and is associated with a poor prognosis in human cancer.<sup>113</sup>

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<sup>108</sup> Hei Jason Chan, et al., *Structural and Functional Characterization of Aromatase, Estrogen Receptor, and Their Genes in Endocrine-Responsive and -Resistant Breast Cancer Cells*, *The Journal of Steroid Biochemistry and Molecular Biology*, Volume 161, 73-83, July 2016, <https://www.sciencedirect.com/science/article/abs/pii/S0960076015300303>

<sup>109</sup> *Id.*

<sup>110</sup> *Aromatic Hydrocarbon Receptor*, *Comprehensive Toxicology*, 2010, <https://www.sciencedirect.com/topics/medicine-and-dentistry/aromatic-hydrocarbon-receptor>.

<sup>111</sup> The spread of cancer cells from the place where they first formed to another part of the body.

<sup>112</sup> Tsung-Hua Hsieh, et al., *DEHP mediates drug resistance by directly targeting AhR in human breast cancer*, *Biomedicine & Pharmacotherapy*, Volume 145, Jan. 2022, <https://www.sciencedirect.com/science/article/pii/S0753332221011860?via%3Dihub>.

<sup>113</sup> *Id.*

- q. CYP450 is a group of enzymes involved in the estrogen pathway and are considered important candidate genes for the susceptibility to breast carcinoma.<sup>114</sup>
- r. CYP1A1 is a CYP450 enzyme examined extensively for its capacity to activate compounds with carcinogenic properties.<sup>115</sup> Continuous exposure to inhalation chemicals and environmental carcinogens is assumed to increase the level of CYP1A1 through the AhR.<sup>116</sup> CYP1A1 is a known significant risk factor for breast carcinoma.<sup>117</sup>
- s. CYP1B1 is another CYP450 enzyme involved in the metabolism of potential carcinogens.<sup>118</sup> CYP1B1 expression has been shown to be higher in tumors compared to normal tissues, especially in hormone-related cancers including breast, ovary, and prostate tumors.<sup>119</sup>
- t. A recent study provided a clinical outcome demonstrating that DEHP directly binds to AhR and induces downstream CYP1A1 and CYP1B1 expression

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<sup>114</sup> Balraj Mittal, et al., *Chapter 4 – Cytochrome P450 in Chapter Susceptibility and Treatment*, *Advances in Clinical Chemistry*, Volume 71, 77-139, 2015, <https://www.sciencedirect.com/science/article/abs/pii/S0065242315000517>.

<sup>115</sup> Vasilis Androutsopoulos, et al., *Cytochrome P450 CYP1A1: Wider Roles in Cancer Progression and Prevention*, *BMC Cancer*, Volume 9, June 16, 2009. <https://bmccancer.biomedcentral.com/articles/10.1186/1471-2407-9-187>.

<sup>116</sup> *Id.*

<sup>117</sup> Tsung-Hua Hsieh, et al., *DEHP mediates drug resistance by directly targeting AhR in human breast cancer*, *Biomedicine & Pharmacotherapy*, Volume 145, Jan. 2022, <https://www.sciencedirect.com/science/article/pii/S0753332221011860?via%3Dihub>.

<sup>118</sup> Yeo-Jung Kwon, et al., *Enhances Cell Proliferation and Metastasis through Induction of EMT and Activation of Wnt/ $\beta$ -Catenin Signaling via Sp1 Upregulation*, *PLoS One*, 11(3), March 16, 2016, <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0151598>

<sup>119</sup> *Id.*

through the genomic AhR pathway. This study thus revealed new evidence by which DEHP and AhR are co-involved in breast cancer drug resistance.<sup>120</sup>

- u. This same study also evaluated DEHP metabolites in the urine of approximately 500 breast cancer patients and demonstrated that the metabolite concentration was significantly higher in the recurrent breast cancer group compared with non-recurrent patients.<sup>121</sup>
- v. Urinary concentrations of mono-ethyl phthalate have been positively associated with breast cancer risk, as well as the number of personal care products used, and the use of hair products, among other personal care products, has been significantly associated with urinary phthalate concentration.

135. Studies published in peer reviewed scientific journals have shown a positive correlation between increased breast cancer risk and adolescent use of hair products that modify hair texture, specifically hair straighteners, perms, and hair dye in Black women in the U.S.<sup>122</sup> The frequency of use is associated with a higher risk of premenopausal breast cancer.

136. The use of straighteners in the year prior to baseline was associated with an 18% higher risk of breast cancer.<sup>123</sup> In the Women's Circle of Health Study (WCHS), a case-control study of women in New York, use of relaxers before age 12 and between the ages of 13–19 years

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<sup>120</sup> Tsung-Hua Hsieh, et al., *DEHP mediates drug resistance by directly targeting AhR in human breast cancer*, *Biomedicine & Pharmacotherapy*, Volume 145, Jan. 2022, <https://www.sciencedirect.com/science/article/pii/S0753332221011860?via%3Dihub>.

<sup>121</sup> *Id.*

<sup>122</sup> Alexander J. White et al., *Adolescent use of hair dyes, straighteners and perms in relation to breast cancer risk*, *Int'l J. of Cancer*, Vol. 148(9):2255-2263 (2021), <https://pubmed.ncbi.nlm.nih.gov/33252833/>.

<sup>123</sup> *Id.*

was positively associated with Endocrine Receptive breast cancer among African-American women; which is consistent with our finding of a suggestive higher risk for Endocrine Receptive tumors.<sup>124</sup>

137. In the Ghana Breast Health study, use of relaxers was associated with a higher risk overall and risk was elevated regardless of age of first use, including in the youngest age category (<21 years).<sup>125</sup>

138. A recent study, published in the *Carcinogenesis Journal* by Oxford University, concluded that Black women who used lye-based relaxers at least seven times a year for over 15 years or more had around a 30% increased risk of developing breast cancer, compared with those who used it less frequently.<sup>126</sup>

139. The US-based researchers examined data from Boston University's Black Women's Health Study, which assessed the medical diagnoses of 50,000 African American women over a 25-year time period plus variable factors that could impact upon their wellbeing. Between 1997 and 2017, some 95% reported using lye-based relaxers and 2,311 developed breast cancers.<sup>127</sup>

140. Another recent publication from the researchers of the Sister Study found that use of chemical hair straighteners in the year prior to enrollment was associated with an 18% increased

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<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

<sup>126</sup> Patricia F. Coogan et al., *Hair product use and breast cancer incidence in the Black Women's Health Study*, *Carcinogenesis*, Vol. 42, Issue 7 (July 2021) 924–930, <https://doi.org/10.1093/carcin/bgab041>.

<sup>127</sup> Wise, L. A., Palmer, J. R., Reich, D., Cozier, Y. C., & Rosenberg, L. (2012). Hair Relaxer Use and Risk of Uterine Leiomyomata in African-American Women. *American Journal of Epidemiology*, 175(5), 432–440. <https://doi.org/10.1093/aje/kwr351>.

risk of breast cancer, with an even higher risk associated with frequent use. Further, “women who used straighteners at least every 5-8 weeks had a 31% higher breast cancer risk.”<sup>128</sup>

### c. Ovarian Cancer

141. 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.<sup>129</sup>

142. While overall rates of ovarian cancer have declined in the U.S., which has been attributed to increased exposure to oral contraceptives, Black women have the poorest survival rate at every stage and across subtypes.<sup>130</sup>

143. 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).<sup>131</sup>

144. 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

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<sup>128</sup> 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.

<sup>129</sup> *Cancer Stat Facts: Ovarian Cancer*, National Cancer Institute, <https://seer.cancer.gov/statfacts/html/ovary.html>.

<sup>130</sup> 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.

<sup>131</sup> White A.J., et al. *Use of hair products in relation to ovarian cancer risk*. *Carcinogenesis* 2021;42(9):1189-1195.

of these products, the impact of these results is more relevant for African American/Black women.”<sup>132</sup>

#### **d. Uterine Fibroids**

145. Uterine fibroids,<sup>133</sup> or uterine leiomyomata, are associated with phthalate metabolites and BPA found in hair care products.<sup>134</sup>

146. Although typically benign, uterine fibroids can cause significant health issues such as excessive menstrual bleeding and pelvic pain, which can significantly affect a woman’s quality of life, and may require invasive surgery.<sup>135</sup> It has been estimated that uterine fibroids account for approximately 30% of all hysterectomies performed on women aged 18-44 years,<sup>136</sup> and are the leading indication for hysterectomy in the U.S.<sup>137</sup>

147. Black women have a higher prevalence of uterine fibroids and tumors than any other ethnicity/racial group.<sup>138</sup> Specifically, Black women have a two to three times greater incidence of uterine fibroids than White women at all ages, and lower mean ages at first diagnosis and hysterectomy. The authors of one study noted that environmental factors, which would include

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<sup>132</sup> *Id.*

<sup>133</sup> Uterine fibroids are smooth muscle tumors that typically develop during reproductive years.

<sup>134</sup> Wise, L.A. et al. *Epidemiology of Uterine Fibroids – From Menarche to Menopause*. Clin Obstet Gynecol. 2016;59(1):2-24. doi:10.1097/GRF.0000000000000164

<sup>135</sup> Wise, L.A. et al. *Epidemiology of Uterine Fibroids – From Menarche to Menopause*. Clin Obstet Gynecol. 2016;59(1):2-24.

<sup>136</sup> *Id.*

<sup>137</sup> *Study of Environment, Lifestyle & Fibroids (SELF)*, National Institute of Environmental Health Sciences, <https://www.niehs.nih.gov/research/atniehs/labs/epi/studies/self/index.cfm>

<sup>138</sup> Wise L. A., et al. *Hair Relaxer Use and Risk of Uterine Leiomyomata in African-American Women*. American Journal of Epidemiology. 2012;175(5):432–440. <https://doi.org/10.1093/aje/kwr351>.



exposure to EDCs, cannot be ruled out as a possible explanation for this difference.<sup>139</sup> Another study indicated that EDC exposure may contribute to fibroid risk and progression.<sup>140</sup>

148. It has been estimated that more than 80% of Black women will develop uterine fibroids, with 20% requiring a hysterectomy.<sup>141</sup>

149. A 2012 study in the *American Journal of Epidemiology* associated fibroid risk with the use of hair relaxers. In the Black Women’s Health Study, the authors assessed hair relaxer use in relation to uterine leiomyomata incidence. In 1997, participants reported on hair relaxer use (*i.e.*, age at first use, frequency, duration, number of burns, and type of formulation). From 1997 to 2009, 23,580 premenopausal women were followed for incident uterine leiomyomata. The authors noted that the incidence of uterine leiomyomata was two to three times higher in US Black women than in US white women, with the lifetime risk estimated to be 80% in US Black women. The study showed positive trends for frequency of use, duration of use, and number of burns: “Among long-term users ( $\geq 10$  years), the incidence rate ratios for frequency of use categories 3-4, 5-6, and  $\geq 7$  versus 1-2 times/year were 1.04 [...], 1.12 [...], and 1.15 [...], respectively.”<sup>142</sup>

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<sup>139</sup> Wise, L.A. et al. *Epidemiology of Uterine Fibroids – From Menarche to Menopause*. Clin Obstet Gynecol. 2016;59(1):2-24.

<sup>139</sup> *Study of Environment, Lifestyle & Fibroids (SELF)*, National Institute of Environmental Health Sciences, <https://www.niehs.nih.gov/research/atniehs/labs/epi/studies/self/index.cfm>

<sup>139</sup> Wise L. A., et al. *Hair Relaxer Use and Risk of Uterine Leiomyomata in African-American Women*. American Journal of Epidemiology. 2012;175(5):432–440. <https://doi.org/10.1093/aje/kwr351>.

<sup>139</sup> Obstet Gynecol. 2016;59(1):2-24. doi:10.1097/GRF.000000000000164.

<sup>140</sup> Bariani M. V., et al. *The role of endocrine-disrupting chemicals in uterine fibroid pathogenesis*. Curr Opin Endocrinol Diabetes Obes 2020;27:380-387, doi:10.1097/MED.0000000000000578.

<sup>141</sup> Study of Environment, Lifestyle & Fibroids, <https://www.detroitself.org/About>.

<sup>142</sup> Wise L. A., et al. *Hair Relaxer Use and Risk of Uterine Leiomyomata in African-American Women*. American Journal of Epidemiology. 2012;175(5):432–440.

150. Shirley McDonald of the Hair and Scalp Clinic says, “We now know that many hair products contain chemicals that are considered carcinogenic and/or hormone disrupters, leading to increased risk of medical issues such as fibroids (non-cancerous tumors that grow in the uterus, potentially damaging fertility and leading to a host of other complications). Trichologists see lots of conditions that are likely to be triggered by hair products, particularly central centrifugal cicatricial alopecia, a type of permanent hair loss to the crown area of the scalp.”<sup>143</sup>

151. One study examined the association between exposure to phthalates and measures of uterine fibroid burden, namely fibroid diameter and uterine volume. Associations between uterine volume and certain phthalate metabolites were most pronounced: the sum of DEHP increased volume risk by 33% and the sum of androgenic phthalates increased risk by 27%. The researchers concluded that, “Exposure to some phthalate biomarkers was positively associated with uterine volume, which further supports the hypothesis that phthalates exposures may be associated with fibroid outcomes.”<sup>144</sup>

152. In the FORGE study, researchers found that exposure to some phthalates was associated with microRNA expression, an epigenetic modification, in uterine fibroids. They also found that some of those associations varied by race/ethnicity.<sup>145</sup>

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<https://doi.org/10.1093/aje/kwr351>.

<sup>143</sup> *There’s Hidden Danger in Black Hair Relaxers*, Houston Fibroids Blog (Oct. 19, 2022), <https://houstonfibroids.com/posts/fibroid-symptoms/warning-your-hair-products-could-be-hurting-you/>

<sup>144</sup> Zota A.R., et al., *Phthalates exposure and uterine fibroid burden among women undergoing surgical treatment for fibroids: a preliminary study*. *Fertil Steril* 2019;111(1):112-121, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6321778/>.

<sup>145</sup> Zota A.R., et al. *Phthalate Exposures and MicroRNA Expression in Uterine Fibroids: The FORGE Study*. *Epigenetics Insights* 2020;13:1-11.

**e. Endometriosis**

153. Endometriosis<sup>146</sup> is associated with phthalate metabolites found in hair care products.

154. In Black women in the USA, endometriosis is one of the common indications for major gynecological surgery and hysterectomy, and is associated with long hospital stays and high hospital charges.<sup>147</sup>

155. The function of the uterine lining, the endometrium, is based on cell-to-cell interactions under the instruction of steroid hormones.<sup>148</sup> Endometriosis, a common cause of female infertility, occurs almost exclusively in menstruating women of reproductive age and often results from disruptions of this well-balanced cellular equilibrium.<sup>149</sup>

156. It is estimated that 20-50% of women being treated for infertility have endometriosis.<sup>150</sup>

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<sup>146</sup> Endometriosis is a disease in which endometrial cells grow outside the uterus.

<sup>147</sup> M. C. Kyama, *The prevalence of endometriosis among African-American and African-indigenous women*. *Gynecologic and obstetric investigation*, Vol. 57(1) (2004), <https://pubmed.ncbi.nlm.nih.gov/14974452/>.

<sup>148</sup> L. Cobellis et al., *High plasma concentrations of di-(2-ethylhexyl)-phthalate in women with endometriosis*, *Human Reproduction*, Vol. 18, Issue 7 (2003), 1512–1515, <https://doi.org/10.1093/humrep/deg254>.

<sup>149</sup> D. L. Olive and L. B. Schwartz, *Endometriosis*, *The New England J. of Med.*, Vol. 328(24):1759-69 (1993), <https://pubmed.ncbi.nlm.nih.gov/8110213/>; K. G. Osteen and E. Sierra-Rivera, *Does disruption of immune and endocrine systems by environmental toxins contribute to development of endometriosis?*, *Seminars in Reproductive Endocrinology*, Vol. 15(3):301-8 (1997) <https://pubmed.ncbi.nlm.nih.gov/9383839/>.

<sup>150</sup> *Endometriosis*, World Health Organization (March 31, 2021), <https://www.who.int/news-room/fact-sheets/detail/endometriosis>.

157. Endometriosis is a painful, estrogen-dependent disease resulting from the growth of endometrial glands and stroma outside the uterus that causes a chronic inflammatory reaction.<sup>151</sup>

158. During the follicular phase of the menstrual cycle, estrogen, working through estrogen receptor  $\alpha$ <sup>152</sup>, induces growth of the endometrium.<sup>153</sup>

159. The developing fetus and the female reproductive tract are particularly susceptible to EDCs.<sup>154</sup> EDCs are known to interfere with hormonal homeostasis, leading to alteration of estrogen signaling.<sup>155</sup> Specifically, DEHP is known to cause enhanced-estrogenic activity.<sup>156</sup>

160. DEHP is a known estrogen receptor agonist that promotes cell proliferation.<sup>157</sup> An agonist is a chemical that activates a receptor to produce a biological response.

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<sup>151</sup> *Id.*

<sup>152</sup> Ilaria Paterni et al., *Estrogen receptors alpha (ER $\alpha$ ) and beta (ER $\beta$ ): subtype-selective ligands and clinical potential*, *Steroids*, Vol. 90:13-29 (2014), <https://pubmed.ncbi.nlm.nih.gov/24971815/>.

<sup>153</sup> Kun Yu et al., *Estrogen Receptor Function: Impact on the Human Endometrium*, *Frontiers in endocrinology*, Vol. 13 (2022), <https://pubmed.ncbi.nlm.nih.gov/35295981/>.

<sup>154</sup> Saniya Rattan et al., *Di(2-Ethylhexyl) Phthalate Exposure During Prenatal Development Causes Adverse Transgenerational Effects on Female Fertility in Mice*, *Toxicol Sci.*, Vol. 163(2) (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5974785/>.

<sup>155</sup> Xueping Chen et al., *Toxicity and Estrogenic Endocrine Disrupting Activity of Phthalates and Their Mixtures*, *Int'l J. Envntl. Res. and Pub. Health*, 1(3):3156-3168 (2014) <https://doi.org/10.3390/ijerph110303156>; Pablo A, Pérez et al., *The phthalate DEHP modulates the estrogen receptors  $\alpha$  and  $\beta$  increasing lactotroph cell population in female pituitary glands*, *Chemosphere*, Vol. 258:127304 (2020), <https://pubmed.ncbi.nlm.nih.gov/32559490/>.

<sup>156</sup> Chon-Kit Chou et al., *Reduced camptothecin sensitivity of estrogen receptor-positive human breast cancer cells following exposure to di(2-ethylhexyl)phthalate (DEHP) is associated with DNA methylation changes*, *Envntl. Toxicology*, Vol. 3, Issue 4 (2019), <https://doi.org/10.1002/tox.22694>.

<sup>157</sup> Juhye Kim, et al., *Chronic Low-Dose Nonylphenol or Di-(2-ethylhexyl) Phthalate has a Different Estrogen-like Response in Mouse Uterus*, *Development & reproduction*, Vol. 22(4):379-391 (2018), <https://pubmed.ncbi.nlm.nih.gov/30680337/>. (“In the present study, we could see that in vitro treatment with DEHP caused various biological changes of endometrial cells such as increased MMP-2 and -9 activities, increased cell invasion, increased Erk phosphorylation, and increased Pak4 expression. Taken these findings together with our previous in vitro study, we can propose that refluxed endometrial cells could not only survive in the pelvic

161. An experimental study supports the hypothesis that DEHP leads to changes in the endometrium, including increasing the viability, activity, proliferation, and migration of endometrial stromal cells, a precondition of endometriosis.<sup>158</sup>

162. Studies have shown that endometriotic women have significantly higher plasma DEHP concentrations than those without the disease.<sup>159</sup> A study that included a sample size of approximately 500 women living in various states observed that DEHP's metabolite, MEHP, was the only phthalate consistently associated with endometriosis.<sup>160</sup> Another study found high serum levels of DEHP in women diagnosed with endometriosis, with an increasing trend in advanced stages, which led the authors to suggest a role of phthalates in endometriosis etiology.<sup>161</sup>

163. One study also found a correlation between BPA serum levels and endometriosis.<sup>162</sup>

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cavity following retrograde menstruation, but also invade through mesothelial layer, develop vascular supplies, proliferate at ectopic location, and eventually establish endometriotic lesions through various biological alterations caused by exposure to high level of phthalate.”)

<sup>158</sup> *Id.*

<sup>159</sup> L. Cobellis et. al, *High plasma concentrations of di-(2-ethylhexyl)-phthalate in women with endometriosis*, Human Reproduction, Vol. 18, Issue 7 (July 1, 2013), 1512–1515, <https://doi.org/10.1093/humrep/deg254>. Concluded that 92.6% of women with endometriosis tested had detectable levels of DEHP and /or its metabolite, MEHP.

<sup>160</sup> Buck Louis G. M. et al., *Bisphenol A and phthalates and endometriosis: the Endometriosis: Natural History, Diagnosis and Outcomes Study*, Fertility and sterility, Vol. 100(1):162-9.e1-2 (2013), <https://pubmed.ncbi.nlm.nih.gov/23579005/>.

<sup>161</sup> Nazi S., et al. *Women diagnosed with endometriosis show high serum levels of diethyl hexyl phthalate*. J. Human Reproductive Sciences 2018;11(2):131-136.

<sup>162</sup> Cobellis, L. et al., 2009. *Measurement of bisphenol A and bisphenol B levels in human blood sera from healthy and endometriotic women*. Biomedical chromatography. 2009;23(11):1186–90.

**FIRST CAUSE OF ACTION  
AS AGAINST THE DEFENDANTS  
(NEGLIGENCE)**

164. Plaintiff repeats, reiterates, and realleges 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.

165. At all relevant times and at the time the Products left the Defendants' control, Defendants knew or should have known that their Products were not safe for human use because they caused unreasonably dangerous side effects, including, but not limited to, uterine fibroids.

166. At all relevant times and at the time the Products left the Defendants' control, Defendants knew or should have known that the safety risks of their Products (i.e., uterine fibroids) outweighed any benefits the Products may have.

167. At all relevant times and at the time the Products left the Defendants' control, Defendants knew or should have known that their Products had not been properly, adequately, or sufficiently tested for safety when they were in possession of information that signaled that the Products could cause uterine fibroids and/or the uterine fibroid risk needed further testing and studies prior to its introduction to the market.

168. At all relevant times and at the time the Products left the Defendants' control, Defendants knew or should have known that the Products were unreasonably dangerous because of inadequate warnings, because they did not adequately warn of its risks of uterine fibroids, especially when used in the form and manner as provided by Defendants.

169. At all relevant times and at the time the Products left the Defendants' control, Defendants knew or should have known that the Products were unreasonably dangerous because of their design defects, especially when used in the form and manner as provided by Defendants.

170. At all relevant times and at the time the Products left the Defendants' control, Defendants knew or should have known that the design of the Products posed a substantial likelihood of harm (i.e., uterine fibroids) to Plaintiff and other users of the Products.

171. At all relevant times and at the time the Products left the Defendants' control, Defendants knew or should have known that the Products were more dangerous than an ordinary user or consumer, such as Plaintiff [REDACTED], would expect.

172. At all relevant times and at the time the Products left the Defendants' control, the Products were more dangerous than an ordinary user or consumer, such as Plaintiff [REDACTED], would expect.

173. 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 that was capable of preventing Plaintiff [REDACTED]'s injuries and damages – an alternative design that was and is in the exclusive possession, custody, and control of Defendants.

174. 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 used for the Products.

175. 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.

176. Despite the fact that Defendants knew or should have known that the Products caused unreasonably dangerous side effects, Defendants continued to market, manufacture, distribute, and/or sell the Products to consumers, including the Plaintiff [REDACTED].

177. Despite the fact that Defendants knew or should have known that the Products caused unreasonably dangerous side effects, Defendants continued to market, distribute, and/or sell the Products to professional cosmetologists, including Plaintiff [REDACTED]'s professional cosmetologist(s).

178. Defendants knew or should have known that consumers such as the Plaintiff [REDACTED] would foreseeably suffer injury as a result of their failure to exercise ordinary care, as set forth herein.

179. At all relevant times, the Products were in an unsafe, defective, and inherently and unreasonably dangerous condition, which was dangerous to users, and in particular, the Plaintiff [REDACTED].

180. At all relevant 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.

181. At all relevant times, given their increased safety risks, the Products did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiff [REDACTED].



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

183. Defendants had a duty to warn Plaintiff [REDACTED], her professional cosmetologist(s), and/or the general public of all safety risks associated with the Products, including its increased risk of causing uterine fibroids.

184. Defendants had a duty to warn Plaintiff [REDACTED], her professional cosmetologist(s), and/or the general public that the Products had not been adequately and/or sufficiently tested regarding their safety.

185. Defendants had a duty to adequately and sufficiently test the Products.

186. Defendants had a duty to design the Products in a manner that was safe for their users.

187. Defendants breached their duties to Plaintiff [REDACTED] by failing to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the Products into interstate commerce in that Defendants knew or should have known that using the Products created a high risk of unreasonable, dangerous side effects, including uterine fibroids requiring a partial hysterectomy, 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 uterine fibroids that may require further surgical intervention.

188. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:
- a. Promoting, formulating, creating, and/or designing the Products without thoroughly testing them;
  - b. Promoting, formulating, creating, and/or designing the Products without adequately testing them;
  - c. Not conducting sufficient testing to determine whether the Products were safe for use in that Defendants herein knew or should have known that the Products were unsafe and unfit for use by reason of the dangers to their users;
  - d. Promoting, marketing, and/or selling the Products without making proper and sufficient tests to determine the dangers to their users;
  - e. Negligently failing to adequately and correctly warn the Plaintiff, her professional cosmetologist(s), and/or the public generally of the dangers of the Products, particularly their increased risk of causing uterine fibroids;
  - f. Failing to provide adequate instructions to Plaintiff and/or her professional cosmetologist(s) regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, the Products;
  - g. Failing to test the Products and/or failing to adequately, sufficiently, and properly test the Products;
  - h. Negligently advertising and recommending the use of the Products without sufficient knowledge as to their dangerous propensities;
  - i. Negligently representing that the Products were safe for use for their intended purpose, when, in fact, they were unsafe;
  - j. Negligently representing that the benefits of the Products outweigh their risks;
  - k. Negligently designing the Products in a manner which was dangerous to their users;
  - l. Concealing information concerning warnings from the Plaintiff and/or her professional cosmetologist(s) in knowing that the Products were unsafe, dangerous, and/or non-conforming with relevant regulations; and

- m. Improperly concealing and/or misrepresenting information from the Plaintiff, her professional cosmetologist(s), and/or the public generally, concerning the severity of risks and dangers of the Products.

189. Defendants under-reported, underestimated and downplayed the serious dangers of the Products.

190. Defendants were negligent in the designing, researching, supplying, promoting, packaging, distributing, testing, advertising, warning, marketing, and sale of the Products in that they:

- n. Failed to use due care in designing the Products so as to avoid the aforementioned risks to individuals when the Products were used for straightening/relaxing hair;
- o. Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects and risks associated with the use of the Products;
- p. Failed to warn Plaintiff and/or her professional cosmetologist(s) of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
- q. Failed to conduct adequate testing to determine the safety of the Products and particularly their propensity to cause uterine fibroids;
- r. Failed to warn Plaintiff and/or the public generally, prior to actively encouraging the sale of the Products, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and
- s. Were otherwise careless and/or negligent.

191. The packaging and/or labeling for the Products were inadequate because they did not warn of the increased risk of uterine fibroids associated with the Products.

192. The packaging and/or labeling for the Products were inadequate because they did not warn that the Products had not been adequately and/or sufficiently tested for safety.

193. Communications made by Defendants to Plaintiff [REDACTED] and/or her professional cosmetologist(s) were inadequate because Defendants failed to warn of the increased risk of uterine fibroids associated with the Products and/or that the Products had not been adequately and/or sufficiently tested for safety.

194. Upon information and belief, had Plaintiff's professional cosmetologist(s) been warned of the increased risk of uterine fibroids associated with the Products they would not have used the Products and/or would have provided Plaintiff with adequate warnings regarding the dangers of the Products so as to allow Plaintiff to make an informed decision regarding her use of the Products.

195. Upon information and belief, had Plaintiff's professional cosmetologist(s) been warned that the Products had not been sufficiently and/or adequately tested for safety, they would not have used the Products and/or would have provided Plaintiff with adequate warnings regarding the inadequate and/or inappropriate testing of the Products so as to allow Plaintiff to make an informed decision regarding her use of the Products.

196. Had Plaintiff been warned of the increased risk of uterine fibroids associated with the Products, she would not have used the Products and/or suffered uterine fibroids requiring a partial hysterectomy.

197. Had Plaintiff been warned of the inadequate and/or inappropriate testing of the Products, she would not have used the Products and/or suffered uterine fibroids requiring a partial hysterectomy.

198. Defendants' negligence in failing to warn Plaintiff and/or her professional cosmetologist(s) of the dangers associated with their Products was the contributing and/or

proximate cause of Plaintiff's injuries, harm, and economic loss which Plaintiff suffered and/or will continue to suffer.

199. Defendants' negligence in failing to sufficiently and/or adequately test the Products was the contributing and/or proximate cause of Plaintiff's injuries, harm, and economic loss which Plaintiff suffered and/or will continue to suffer.

200. Defendants' negligence in defectively designing the Products was the contributing and/or proximate cause of Plaintiff's injuries, harm, and economic loss which Plaintiff suffered and/or will continue to suffer.

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

202. Plaintiff [REDACTED]'s injuries and damages as a result of her use of the Products were foreseeable by Defendants.

203. As a result of the foregoing negligent acts and omissions, the Plaintiff [REDACTED] was caused to suffer serious and dangerous side effects including uterine fibroids requiring a partial hysterectomy, 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 uterine fibroids that may require further surgical intervention.

204. As a result of the foregoing negligent acts and omissions Plaintiff [REDACTED] requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff [REDACTED] is informed and

believes and further alleges that she will in the future be required to obtain further medical and/or hospital care, attention, and services.

205. By reason of the foregoing, Plaintiff [REDACTED] has been damaged as against the Defendants in excess of seventy-five thousand dollars (\$75,000.00).

**SECOND CAUSE OF ACTION  
AS AGAINST DEFENDANTS  
(STRICT PRODUCTS LIABILITY –  
DEFECTIVE DESIGN AND FAILURE TO WARN)**

206. Plaintiff repeats, reiterates, and realleges 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.

207. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Products as hereinabove described that was used by the Plaintiff [REDACTED].

208. 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 marketed by the Defendants.

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

210. 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.

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

212. 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 uterine fibroids exceeded the benefits associated with the design or formulation of the Products.

213. 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.

214. 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 (e.g., uterine fibroids) to Plaintiff and other users of the Products.

215. 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 [REDACTED]'s injuries and damages – an alternative design that was and is in the exclusive possession, custody, and control of Defendants.

216. 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.

217. 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.

218. 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.

219. 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.

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

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

[REDACTED].

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

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



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

225. 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 [REDACTED], in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff [REDACTED].

226. The Plaintiff [REDACTED] and/or her professional cosmetologist(s) could not, by the exercise of reasonable care, have discovered the Products' defects herein mentioned and perceived their danger.

227. 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 uterine fibroids, 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.

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

229. 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 uterine fibroids, as well as other severe and permanent health consequences from the Products, they failed to provide adequate warnings to users of the Products, and continued to improperly advertise, market and/or promote their Products.

230. 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.

231. The packaging and/or labeling for the Products were inadequate because they did not warn and/or adequately warn of the increased risk of uterine fibroids associated with the Products.

232. 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 uterine fibroids.

233. Communications made by Defendants to Plaintiff [REDACTED] and/or her professional cosmetologist(s) were inadequate because Defendants failed to warn and/or adequately warn them of the increased risk of uterine fibroids associated with the Products.

234. Communications made by Defendants to Plaintiff [REDACTED] and/or her professional cosmetologist(s) 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 uterine fibroids.

235. Upon information and belief, had Plaintiff's professional cosmetologist(s) been warned of the increased risk of uterine fibroids associated with the Products, they would not have used the Products and/or would have provided Plaintiff with adequate warnings regarding the dangers of the Products so as to allow Plaintiff to make an informed decision regarding her use of the Products.

236. Upon information and belief, had Plaintiff's professional cosmetologist(s) been warned that the Products had not been sufficiently and/or adequately tested for safety risks, including the risk of uterine fibroids, they would not have used the Products and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of the Products so as to allow Plaintiff to make an informed decision regarding her use of the Products.

237. Had Plaintiff been warned of the increased risk of uterine fibroids associated with the Products, she would not have used the Products and/or suffered uterine fibroids requiring a partial hysterectomy.

238. Had Plaintiff been warned that the Products had not been sufficiently and/or adequately tested for safety risks, including uterine fibroids, she would not have used the Products and/or suffered uterine fibroids requiring a partial hysterectomy.

239. By reason of the foregoing, Defendants have become strictly liable in tort to the Plaintiff [REDACTED] for the designing, marketing, promoting, distribution, and selling of a defective Products.

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

241. That said defects in Defendants' Products were a substantial factor in causing Plaintiff's injuries.

242. That said defects in Defendants' Products were the proximate cause of Plaintiff's injuries.

243. As a result of the foregoing acts and omissions, the Plaintiff [REDACTED] [REDACTED] was caused to suffer serious and dangerous side effects including uterine fibroids requiring a partial hysterectomy, 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 uterine fibroids.

244. As a result of the foregoing acts and omissions the Plaintiff [REDACTED] [REDACTED] requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff [REDACTED] is informed and believes and further alleges that she will in the future be required to obtain further medical and/or hospital care, attention, and services.

245. By reason of the foregoing, Plaintiff [REDACTED] has been damaged as against the Defendants in excess of seventy-five thousand dollars (\$75,000.00).

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

246. Plaintiff repeats, reiterates, and realleges 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.

247. 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 were used by Plaintiff [REDACTED] [REDACTED].

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

249. Upon information and belief, at all relevant times, Defendants expressly warranted to Plaintiff [REDACTED] and/or her professional cosmetologist(s) that the Products were safe to use for chemically straightening/relaxing hair.

250. Upon information and belief, at all relevant times, Defendants expressly warranted to Plaintiff [REDACTED] and/or her professional cosmetologist(s) that the cosmetic benefit of the Products outweighed any potential dangers and/or risks.

251. Upon information and belief, at all relevant times, the aforementioned express warranties were made to Plaintiff [REDACTED] and/or her professional cosmetologist(s) by way of direct-to-consumer marketing, advertisements, and/or the Products' packaging and/or labeling.

252. In or about 1992, Plaintiff [REDACTED] began using the Products for chemically straightening/relaxing her hair.

253. In or about 1992, Plaintiff [REDACTED] purchased for use and/or her professional cosmetologist(s) applied the Products believing they were safe for their intended use – chemically straightening/relaxing hair.

254. Upon information and belief, Plaintiff [REDACTED] and/or her professional cosmetologist(s) obtained the information regarding the side effects of the Products from direct-to-consumer marketing, advertising, and/or the packaging and/or labeling of the Products.

255. Upon information and belief, in or about 1992, when Plaintiff [REDACTED] began using the Products and throughout her use of the Products, Defendants expressly warranted to her and/or her professional cosmetologist(s), by way of direct-to-consumer marketing, advertising, and/or the Products' packaging and/or labeling, that the Products were safe to use for chemically straightening/relaxing hair.

256. As a result of Defendants' express warranties to her, Plaintiff [REDACTED] and/or her professional cosmetologist(s) were induced to use the Products from approximately 1992 up to the time of her diagnosis with and treatment for uterine fibroids.

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

258. At all relevant times, Defendants reasonably anticipated and expected that professional cosmetologist(s), such as Plaintiff [REDACTED]'s professional cosmetologist(s), would recommend and/or apply the Products based upon their express warranties.

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

260. 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.

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

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

263. The unreasonably dangerous characteristics of the Products were beyond that which would be contemplated by Plaintiff [REDACTED]'s professional cosmetologist(s), with the ordinary knowledge common to the community as to the Products' characteristics.

264. 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.

265. 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.

266. The express warranties made by Defendants regarding the safety of the Products were made with the intent to induce Plaintiff [REDACTED] to use the Products and/or her professional cosmetologist(s) to use/apply the Product.

267. Defendants knew and/or should have known that by making the express warranties to Plaintiff [REDACTED] and/or her professional cosmetologist(s), it

would be the natural tendency of Plaintiff to use the Products and/or her professional cosmetologist(s) to use/apply the Products.

268. Plaintiff [REDACTED] and her professional cosmetologist(s), as well as members of the general public, relied on the express warranties of the Defendants herein.

269. The express warranties made by Defendants regarding the safety of the Products induced Plaintiff [REDACTED] to use the Products and/or her professional cosmetologist(s) to use/apply the Products.

270. Had Defendants not made these express warranties, Plaintiff [REDACTED] would not have used the Products and/or, upon information and belief, her professional cosmetologist(s) would not have used/applied the Products.

271. Plaintiff [REDACTED]'s injuries and damages were directly caused by Defendants' breach of the aforementioned express warranties.

272. Plaintiff [REDACTED]'s injuries and damages arose from a reasonably anticipated use of the product by Plaintiff [REDACTED].

273. Accordingly, Defendants are liable as a result of their breach of express warranties to Plaintiff [REDACTED].

274. As a result of the foregoing breaches, Plaintiff [REDACTED] was caused to suffer serious and dangerous side effects including uterine fibroids requiring a partial hysterectomy, 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 uterine fibroids.



275. By reason of the foregoing, Plaintiff [REDACTED] 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.

276. As a result of the foregoing acts and omissions the Plaintiff [REDACTED] [REDACTED] required and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff [REDACTED] is informed and believes and further alleges that she will in the future be required to obtain further medical and/or hospital care, attention, and services.

277. By reason of the foregoing, Plaintiff [REDACTED] has been damaged as against the Defendants in excess of seventy-five thousand dollars (\$75,000.00).

**FOURTH CAUSE OF ACTION  
AS AGAINST DEFENDANTS  
(BREACH OF IMPLIED WARRANTIES)**

278. Plaintiff repeats, reiterates, and realleges 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.

279. 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 [REDACTED] [REDACTED].

280. At the time Defendants marketed, sold, and distributed the Products for use by Plaintiff [REDACTED], 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.

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

282. At all relevant times, Defendants reasonably anticipated and expected that professional cosmetologists, such as Plaintiff [REDACTED]'s professional cosmetologist(s), would recommend and/or use/apply the Products for chemically straightening/relaxing hair.

283. At all relevant times, Defendants impliedly warranted to Plaintiff [REDACTED], her professional cosmetologist(s), 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.

284. At all relevant times, Defendants impliedly warranted to Plaintiff [REDACTED], her professional cosmetologist(s), 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.

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

286. 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.

287. At all relevant times, Defendants knew or should have known that the Products had not been sufficiently and/or adequately tested for safety risks, including risk of uterine fibroids.

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

289. The unreasonably dangerous characteristics of the Products were beyond that which would be contemplated by professional cosmetologists, such as Plaintiff [REDACTED] [REDACTED]'s professional cosmetologist(s), with the ordinary knowledge common to the community as to the Products' characteristics.

290. 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 uterine fibroids.

291. 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.

292. 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 had not been sufficiently and/or adequately tested regarding their safety risks, including the risk of uterine fibroids.

293. Plaintiff [REDACTED] relied on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to the Products.

294. Plaintiff [REDACTED] 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.

295. Upon information and belief, Plaintiff [REDACTED]'s professional cosmetologist(s) relied on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to the Products.

296. Upon information and belief, Plaintiff [REDACTED]'s professional cosmetologist(s) 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.

297. As a result of Plaintiff [REDACTED]'s and/or her professional cosmetologist(s)'s reasonable reliance upon Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to the Products, Plaintiff [REDACTED] used the Products.

298. 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.

299. Defendants herein breached the aforesaid implied warranties, as their Products were not merchantable nor fit for their intended purposes and uses.

300. Plaintiff [REDACTED] would not have used the Products and/or, upon information and belief, her professional cosmetologist(s) would not have applied the Products, but for the aforesaid implied warranties.

301. Plaintiff [REDACTED]'s injuries and damages were directly caused by Defendants' breach of the aforementioned implied warranties.

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

303. As a result of the foregoing breaches, Plaintiff [REDACTED] was caused to suffer serious and dangerous side effects including uterine fibroids requiring a partial hysterectomy, 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 uterine fibroids that may require further surgical intervention.

304. As a result of the foregoing acts and omissions the Plaintiff [REDACTED] requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff [REDACTED] is informed and believes and further alleges that she will in the future be required to obtain further medical and/or hospital care, attention, and services.

305. By reason of the foregoing, Plaintiff [REDACTED] has been damaged as against the Defendants in excess of seventy-five thousand dollars (\$75,000.00).

**FIFTH CAUSE OF ACTION  
AS AGAINST DEFENDANTS  
(FRAUDULENT MISREPRESENTATION AND  
FRAUDULENT CONCEALMENT)**

306. Plaintiff repeats, reiterates, and realleges 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.

307. Prior to 1992, Defendants knew or should have known that the Products were not safe to use to chemically straighten/relax hair given their increased risk of uterine fibroids.

308. Nevertheless, in 1992, Defendants falsely represented in direct-to-consumer marketing, advertisements, and/or on the packaging and/or labeling of the Products that the Products were safe to use to chemically straighten/relax hair and concealed that the Products were associated with an increased risk of uterine fibroids.

309. Prior to 1992, Defendants knew or should have known that the cosmetic benefit of the Products did not outweigh the dangers and risks associated with the Products.

310. Nevertheless, in 1992, Defendants falsely represented in direct-to-consumer marketing, advertisements, and/or on the packaging and/or labeling of the Products that the cosmetic benefit of the Products outweighed the dangers and risks associated with the Products.

311. Prior to 1992, Defendants knew or should have known that the Products had not been adequately and/or sufficiently tested for safety.

312. Nevertheless, in 1992, Defendants falsely represented in direct-to-consumer marketing, advertisements, and/or on the packaging and/or labeling of the Products that the Products were safe to use to chemically straighten/relax hair and concealed that the Products had not been adequately and/or sufficiently tested for safety.

313. Defendants' fraudulent representations and/or concealments as identified herein were done with the intent of defrauding and deceiving consumers, including the Plaintiff [REDACTED], professional cosmetologists, and the public generally, which evinced a callous, reckless, willful, depraved indifference to the health, safety, and welfare of the Plaintiff [REDACTED].

314. Defendants' fraudulent representations and/or omissions as identified herein were done with the intent of inducing consumers, including the Plaintiff [REDACTED] [REDACTED], into using the Products to chemically straighten/relax hair, which evinced a callous, reckless, willful, depraved indifference to health, safety, and welfare of the Plaintiff [REDACTED].

315. Defendants' fraudulent representations and/or omissions as identified herein were done with the intent of inducing professional cosmetologists, including Plaintiff [REDACTED]'s professional cosmetologist(s), to recommend and/or use/apply the Products to chemically straighten/relax hair, which evinced a callous, reckless, willful, depraved indifference to health, safety, and welfare of the Plaintiff [REDACTED].

316. In or about 1992, Plaintiff [REDACTED] began using the Products to chemically straighten/relax her hair.

317. Upon information and belief, Plaintiff [REDACTED] and/or her professional cosmetologist(s) obtained the information regarding the side effects of the Products from direct-to-consumer marketing, advertisements, and/or the packaging and/or labeling of the Products.

318. Upon information and belief, Defendants represented to Plaintiff [REDACTED] [REDACTED] and/or her professional cosmetologist(s) by way of direct-to-consumer marketing,

advertisements, and/or the Products' packaging and/or labeling that the Products were safe to use for chemically straightening/relaxing hair in that they were not associated with an increased risk of uterine fibroids.

319. Upon information and belief, Defendants concealed from Plaintiff [REDACTED] and/or her professional cosmetologist(s) by way of direct-to-consumer marketing, advertisements, and/or the Products' packaging and/or labeling that the Products were associated with an increased risk of uterine fibroids.

320. Upon information and belief, Defendants concealed from Plaintiff [REDACTED] and/or her professional cosmetologist(s) by way of direct-to-consumer marketing, advertisements, and/or the Products' packaging and/or labeling that the Products had not been tested sufficiently and/or adequately for increased safety risks, including the risk of uterine fibroids.

321. In or about 1992, when Plaintiff [REDACTED] began using the Products and throughout her use of the Products, Defendants represented to her and/or her professional cosmetologist(s) by way of the direct-to-consumer marketing, advertisements, and/or Products' packaging and/or labeling that the Products were safe to use to chemically straighten/relax hair in that they were not associated with an increased risk of uterine fibroids.

322. In or about 1992, when Plaintiff [REDACTED] began using the Products and throughout her use of the Products, Defendants concealed from her and/or her professional cosmetologist(s) by way of direct-to-consumer marketing, advertisements, and/or the Products' packaging and/or labeling that the Products were associated with an increased risk of uterine fibroids.



323. In or about 1992, when Plaintiff [REDACTED] began using the Products and throughout her use of the Products, Defendants concealed from her and/or her professional cosmetologist(s) by way of direct-to-consumer marketing, advertisements, and/or the Products' packaging and/or labeling that the Products had not been tested sufficiently and/or adequately for increased safety risks, including uterine fibroids.

324. The aforementioned representations made in the direct-to-consumer marketing, advertisements, and/or packaging and/or labeling of the Products in or about 1992 were fraudulently made in that that Defendants concealed that the Products were associated with an increased risk of uterine fibroids despite their knowledge to the contrary.

325. The aforementioned representations made in the direct-to-consumer marketing, advertisements, and/or packaging and/or labeling of the Products in or about 1992 were fraudulently made in that Defendants concealed that the Products had not been adequately and/or sufficiently tested for safety, including the risk of uterine fibroids.

326. Upon information and belief, as a result of the direct-to-consumer marketing, advertisements, and/or packaging and/or labeling for the Products, in or about 1992, and particularly as a result of Defendants' fraudulent misrepresentation and concealments contained therein, Plaintiff [REDACTED] was induced to and did purchase the Products in 1992.

327. Upon information and belief, as a result of the direct-to-consumer marketing, advertisements, and/or packaging and/or labeling for the Products, in or about 1992, and particularly as a result of Defendants' fraudulent misrepresentation and concealments contained therein, Plaintiff [REDACTED]'s professional cosmetologist(s) was induced to and did recommend and/or apply the Products in 1992.

328. As a result of the direct-to-consumer marketing, advertisements, and/or packaging and/or labeling for the Products in or about 1992, and particularly as a result of Defendants' fraudulent misrepresentation and concealments contained therein, Plaintiff [REDACTED] was induced to and did use the Products between approximately 1992 up to the time of her diagnosis with and treatment for uterine fibroids.

329. Upon information and belief, had Plaintiff [REDACTED]'s professional cosmetologist(s) been told of the increased risk of uterine fibroids associated with the Products, they would not have recommended/applied the Products and/or would have provided Plaintiff with adequate warnings regarding the dangers of the Products so as to allow Plaintiff to make an informed decision regarding her use of the Products.

330. Upon information and belief, had Plaintiff [REDACTED]'s professional cosmetologist(s) been told that the cosmetic benefits of the Products, if any, were outweighed by their safety risks, particular the risk of uterine fibroids, they would not have recommended/applied the Products and/or would have provided Plaintiff with adequate information regarding the safety of the Products so as to allow Plaintiff to make an informed decision regarding her use of the Products.

331. Upon information and belief, had Plaintiff [REDACTED]'s professional cosmetologist(s) been told that the Products had not been sufficient and/or adequately tested for safety risks, including the risk of uterine fibroids, they would not have recommended/applied the Products and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of the Products so as to allow Plaintiff to make an informed decision regarding her use of the Products.

332. Had Plaintiff [REDACTED] been told of the increased risk of uterine fibroids associated with the Products, she would not have used the Products and/or suffered uterine fibroids requiring a partial hysterectomy.

333. Had Plaintiff [REDACTED] been told that the cosmetic benefits of the Products were outweighed by their safety risks, particularly the risk of uterine fibroids, she would not have used the Products and/or suffered uterine fibroids requiring a partial hysterectomy.

334. Had Plaintiff [REDACTED] been told of the lack of sufficient and/or appropriate testing of the Products for safety risks, including the risk of uterine fibroids, she would not have used the Products and/or suffered uterine fibroids requiring a partial hysterectomy.

335. Plaintiff [REDACTED] had no way to determine the truth behind Defendants' misrepresentations and concealments as identified herein, and her reliance upon Defendants' representations and concealments was reasonable.

336. Plaintiff [REDACTED]'s professional cosmetologist(s) had no way to determine the truth behind Defendants' misrepresentations and concealments as identified herein, and their reliance upon Defendants' representations and concealments was reasonable.

337. Defendants had sole access to material facts concerning the defective nature of the Products, and, particularly, their increased risk of uterine fibroids.

338. Defendants had sole access to material facts concerning the lack of adequate and appropriate testing regarding the safety of the Products.

339. At all relevant times, Defendants were under a duty to disclose to Plaintiff [REDACTED] and/or her professional cosmetologist(s) the defective nature of the Products, including but not limited to the heightened risk of uterine fibroids.

340. At all relevant times, Defendants were under a duty to disclose to Plaintiff [REDACTED] and/or her professional cosmetologists(s) that the risks of the Products outweighed any cosmetic benefit they may have.

341. At all relevant times, Defendants were under a duty to disclose to Plaintiff [REDACTED] and/or her professional cosmetologist(s) that the Products had not been adequately and/or sufficiently tested.

342. Defendants breached their duties to disclose the Products' serious safety risks to Plaintiff [REDACTED], her professional cosmetologist(s), and the public in general.

343. Defendants could have and should have revealed the truth behind the safety of the Products through various outlets, including direct-to-consumer marketing, advertisements, and/or the packaging and/or labeling for the Products.

344. Defendants' misrepresentations and concealments concerning the safety of the Products were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff [REDACTED], and her professional cosmetologist(s), into reliance, continued use of the Products, and actions thereon, and to cause them to purchase, recommend, and/or use the Products.

345. Defendants knew that Plaintiff [REDACTED] and her professional cosmetologist(s) had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding the Products, as set forth herein.

346. Plaintiff [REDACTED]'s injury and damages were proximately caused by Defendants' fraudulent misrepresentations and concealments as set forth herein.

347. Plaintiff [REDACTED]'s injury and damages were proximately caused by her reasonable reliance on Defendants' fraudulent misrepresentations and concealments as set forth herein.

348. Plaintiff [REDACTED]'s injury and damages were proximately caused by her professional cosmetologist(s)'s reasonable reliance on Defendants' fraudulent misrepresentations and concealments as set forth herein.

349. As a result of the foregoing acts and omissions, the Plaintiff [REDACTED] [REDACTED] was caused to suffer serious and dangerous side effects including uterine fibroids requiring a partial hysterectomy, 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 uterine fibroids that may require further surgical intervention.

350. As a result of the foregoing acts and omissions the Plaintiff [REDACTED] [REDACTED] requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff [REDACTED] is informed and believes and further alleges that she will in the future be required to obtain further medical and/or hospital care, attention, and services.

351. By reason of the foregoing, Plaintiff [REDACTED] has been damaged as against the Defendants in excess of seventy-five thousand dollars (\$75,000.00).

**SIXTH CAUSE OF ACTION  
AS AGAINST DEFENDANTS  
(NEGLIGENT MISREPRESENTATION)**

352. Plaintiff repeats, reiterates, and realleges 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.

353. Defendants had a duty to make honest and accurate representations to the Plaintiff, her professional cosmetologist(s), and the public in general regarding the safety of the Products.

354. At all relevant times, Defendants represented to Plaintiff [REDACTED], her professional cosmetologist(s), and the public in general that the Products were safe to use to chemically straighten/relax hair in that they did not cause an increased risk of uterine fibroids.

355. The aforementioned representations made by Defendants were, in fact, false because the Products were not safe to use to chemically straighten/relax hair given their increased risk of uterine fibroids.

356. When said representations were made by Defendants, they knew or should have known those representations to be false.

357. The representations made by Defendants were made to Plaintiff [REDACTED] between approximately 1992 up to the time of her diagnosis with and treatment for uterine fibroids through direct-to-consumer marketing, advertisements, and/or the packaging and/or labeling of the Products.

358. As a result of Defendants' representations through direct-to-consumer marketing, advertisements, and/or the packaging and/or labeling of the Products, Plaintiff [REDACTED]

██████████ was induced to want to use the Products and/or request the use of the Products through her professional cosmetologist(s).

359. Upon information and belief, Plaintiff ██████████'s professional cosmetologist(s) obtained the information regarding the side effects of the Products from direct-to-consumer marketing, advertisements, and/or the packaging and/or labeling of the Products.

360. Upon information and belief, Defendants represented to Plaintiff ██████████'s professional cosmetologist(s) by way of direct-to-consumer marketing, advertisements, and/or the packaging and/or labeling of the Products that the Products were safe to use for chemically straightening/relaxing hair.

361. In or about 1992, when Plaintiff ██████████ began using the Products and throughout her use of the Products, Defendants represented to her by way of direct-to-consumer marketing, advertisements, and/or the packaging and/or the Products' packaging and/or labeling that the Products were safe to use for chemically straightening/relaxing hair and were not associated with an increased risk of uterine fibroids.

362. When the aforementioned representations were made by Defendants, Defendants were aware of and/or should have been aware that their representations would induce Plaintiff ██████████ and/or her professional cosmetologist(s) to use and/or recommend and/or apply the Products.

363. When the aforementioned representations were made by Defendants, Defendants were aware of and/or should have been aware that the Products were to be used by Plaintiff ██████████ and/or recommended/applied by Plaintiff's professional cosmetologist(s) in reliance upon their representations regarding the safety of the Products.

364. At the time the aforementioned representations were made by Defendants and at the time Plaintiff [REDACTED] used the Products and her professional cosmetologist(s) recommended/applied the Products, Plaintiff [REDACTED] was unaware of the falsity of said representations and reasonably believed them to be true.

365. Upon information and belief, at the time the aforesaid representations were made by the Defendants and at the time Plaintiff [REDACTED] used the Products and/or her professional cosmetologist(s) recommended/applied the Products, her professional cosmetologist(s) were unaware of the falsity of said representations and reasonably believed them to be true.

366. In reasonable and foreseeable reliance upon said representations, the Plaintiff [REDACTED] was induced to and did use the Products.

367. Upon information and belief, in reasonable and foreseeable reliance upon said representations, the Plaintiff's professional cosmetologist(s) were induced to and did recommend and/or use/apply the Products.

368. Defendants failed to exercise ordinary care regarding their representations relating to the safety of the Products, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution into interstate commerce, in that Defendants negligently misrepresented the Products' safety and/or the weighing of risk between the safety of the Products.

369. Defendants breached their duty by misrepresenting the Products' serious safety risks to Plaintiff [REDACTED], her professional cosmetologist(s), and the public in general.



370. Upon information and belief, had Plaintiff's professional cosmetologist(s) known these representations regarding the safety of the Products to be false, they would not have recommended and/or used/applied the Products to Plaintiff [REDACTED].

371. Had Plaintiff known these representations regarding the safety of the Products to be false, she would not have used the Products.

372. Defendant's negligent misrepresentations proximately caused Plaintiff's injuries and damages as alleged herein.

373. As a result of their misrepresentations, the Plaintiff [REDACTED] was caused to suffer serious and dangerous side effects including uterine fibroids requiring a partial hysterectomy, 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 uterine fibroids that may require further surgical intervention.

374. As a result of the foregoing acts and omissions the Plaintiff [REDACTED] [REDACTED] requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff [REDACTED] is informed and believes and further alleges that she will in the future be required to obtain further medical and/or hospital care, attention, and services.

375. By reason of the foregoing, Plaintiff [REDACTED] has been damaged as against the Defendants in excess of seventy-five thousand dollars (\$75,000.00).

**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 Plaintiff for past and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by the Plaintiff [REDACTED], health care costs, medical monitoring, together with interest and costs as provided by law;

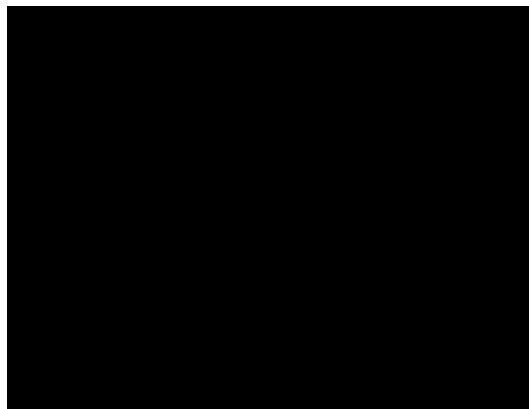
2. Punitive and/or exemplary damages as allowed for by law for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants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

3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings; and

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

Dated: December 22, 2022  
New York, New York

A large black rectangular redaction box covering the signature area of the attorneys for the plaintiff.

*Attorneys for the Plaintiff*

**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands a trial by jury as to all issues.

