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Dying to Be Fresh and Clean? Toxicants in Personal Care Products, the Impact on Cancer Risk, and Epigenetic Damage

Katherine Drabiak
University of South Florida, College of Public Health

ARTICLE

Dying to Be Fresh and Clean? Toxicants in Personal Care Products, the Impact on Cancer Risk, and Epigenetic Damage

KATHERINE DRABIAK*

The FDA does not conduct pre-market review of chemicals contained in cosmetics—which encompasses not only makeup but also numerous personal care products including shampoo, lotion, perfume, aftershave, and shaving cream. Every day, consumers use cosmetic products that contain a variety of synthetic ingredients, none of which the FDA has approved for safety but each of which are being ingested, absorbed, and inhaled into our bodies and accumulating in our tissue. Many of these products contain endocrine disrupting chemicals ("EDCs"), which emerging research links to an increased risk of cancer as well as immune and neurological dysfunction. This Article examines how the current risk-based regulatory system enables manufacturers to market products containing toxicants that cause preventable cancer while promising product safety. In addition to increasing cancer risk, EDCs have the potential to induce both epigenetic marks and transgenerational epigenetic damage, increasing the risk of cancer and widespread adverse health consequences for future generations never exposed to the toxicant. This Article asserts that we have an ethical duty to enact precautionary regulations governing cosmetics that would protect the integrity of the human genome against preventable, environmentally mediated damage.

* Katherine Drabiak, JD is an Assistant Professor in the College of Public Health at the University of South Florida HEALTH. She may be contacted at kdrabiak@health.usf.edu.

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I. INTRODUCTION

In 2016, a jury in St. Louis awarded an unprecedented $72 million verdict against consumer product giant Johnson & Johnson in a lawsuit over one of the most ubiquitous and recognizable

household products: Johnson's Baby Powder.[1] Class action plaintiffs in the lawsuit, *Hogans v. Johnson & Johnson*, asserted that Johnson & Johnson was aware of scientific evidence linking perineal use of the talc in Johnson's Baby Powder and Shower to Shower to an increased risk of ovarian cancer, but continued marketing its products as safe while actively working to expand its market.[2] *Hogans* raised media attention to a mistaken presumption made by the public: if a personal care product is on store shelves, it must be safe.[3] Contrary to popular belief, the FDA does not conduct pre-market review of chemicals contained in cosmetics—which encompasses not only makeup but also numerous personal care products like shampoo, lotion, perfume, aftershave, and shaving cream.[4] Every day, consumers use an average of twelve cosmetic products that contain a variety of synthetic ingredients, none of which the FDA has approved for safety but each of which is being ingested, inhaled, and absorbed into our bodies and accumulating in our tissue.[5]

Data from the National Biomonitoring Program administered by the Centers for Disease Control and Prevention has found more than 260 environmental chemicals in the human body, many of which are also found in the umbilical cord blood of newborns.[6]

1. Roni Caryn Rabin, *Lawsuits Over Baby Powder Raise Questions About Cancer Risk*, N.Y. TIMES (May 23, 2016, 3:41 PM), http://perma.cc/F7RW-F6X4; Jonathan Stempel, *J&J Must Pay $72 million for Cancer Death Linked to Talcum Powder*, REUTERS (Feb. 23, 2016, 11:54 AM), http://perma.cc/D7M4-QP3H.
2. Amended Complaint & Demand for Jury Trial at 48, Hogans v. Johnson & Johnson, No. 1422-CC09012 (C.C. Mo. June 23, 2014) [hereinafter Amended Complaint].
3. *See* Susan Berfield et al., *Johnson & Johnson Has a Baby Powder Problem*, BLOOMBERG (Mar. 31, 2016), https://perma.cc/5CTA-JKYS.
4. *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA Approved, But Are FDA Regulated*, FDA (last updated Nov. 15, 2016), https://perma.cc/9CCJ-UEVC [hereinafter *FDA Authority Over Cosmetics*].
5. SHARIMA RASANAYAGAM ET AL., CAMPAIGN FOR SAFE COSMETICS, ANTI-AGING SECRETS EXPOSED: CHEMICAL LINKED TO BREAST CANCER IN SKIN CARE 1, 7 (2015), https://perma.cc/LH9H-SGRC [hereinafter RASANAYAGAM ET AL.] (discussing statistics on consumer product use); HEATHER SARANTIS ET AL., CAMPAIGN FOR SAFE COSMETICS & ENVTL. WORKING GRP., NOT SO SEXY: THE HEALTH RISKS OF SECRET CHEMICALS IN FRAGRANCE 1, 6 (2010), https://perma.cc/W55Q-K9FB [hereinafter SARANTIS ET AL.] (discussing absorption).
6. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS (2009),

Scientists from the Halifax Project suggest that many of these synthetic chemicals contribute significantly to the rising rates of cancer in the past several decades.[7] Despite substantial media attention to heritable risk for cancer, only 5 to 10% of all cancer cases have a genetic basis.[8] In 2010, the President's Cancer Panel affirmed the substantial environmental contribution to cancer risk, asserting that cancer prevention efforts have been insufficient and that we should increase awareness of the true magnitude of preventable risk from environmental carcinogens in consumer products.[9]

Several stakeholders including corporate interests strategically exploit the current regulatory shortcomings governing cosmetics. To the public's detriment, these entities misrepresent the evidentiary standards set forth by the reigning risk-based approach to undermine scientific research demonstrating potential harm from toxicants in cosmetic products.[10] Scientists are learning that the toxicants contained in cosmetics can not only contribute to risk of cancer but also induce epigenetic marks that cause dysfunction across the genome.[11] Problematically, this damage affects

https://perma.cc/TGA6-AEF6 [hereinafter FOURTH NATIONAL REPORT]; CTRS. FOR DISEASE CONTROL & PREVENTION, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS, UPDATED TABLES (2015), https://perma.cc/VN3T-L2FS [hereinafter UPDATED TABLES].

7. CURT DELLAVALLE, ENVTL. WORKING GRP., RETHINKING CARCINOGENS: NEW VIEW OF CANCER DEVELOPMENT FOCUSES ON SUBTLE, COMBINED EFFECTS 3 (2015), https://perma.cc/9GN6-FC2Y [hereinafter DELLAVALLE].

8. *The Genetics of Cancer*, NATIONAL CANCER INSTITUTE, https://perma.cc/JE4R-868H (last updated May 1, 2017); Angelina Jolie, *My Medical Choice*, N.Y. TIMES (May 14, 2013), https://perma.cc/YQH3-2KNB; Angelina Jolie Pitt, *Diary of a Surgery*, N.Y. TIMES (Mar. 24, 2015), https://perma.cc/RDA6-DRE2.

9. SUZANNE H. REUBEN ET AL., PRESIDENT'S CANCER PANEL, U.S. DEP'T HEALTH & HUMAN SERVS., REDUCING ENVIRONMENTAL CANCER RISK: WHAT WE CAN DO NOW (2010), https://perma.cc/6VTX-AX2Q [hereinafter PRESIDENT'S CANCER PANEL].

10. *See infra* Part III.

11. Arline T. Geronimus, *Deep Integration: Letting the Epigenome Out of the Bottle Without Losing Sight of the Structural Origins of Population Health*, 103 AM. J. PUB. HEALTH S1, S56–63 (2013); Mark A. Rothstein et al., *The Ghost in Our Genes: Legal and Ethical Implications of Epigenetics*, 19 HEALTH MATRIX 1, 3–4 (2009); Mitchell S. Turker, *Banning Bisphenol A in the United States and Canada: Epigenetic Science, The Precautionary Principle, and a Missed Opportunity to Protect the Fetus*, 8 J. HEALTH & BIOMEDICAL L. 173, 175–78 (2012); Christopher J. Wiener,

not only the current generation but may imprint the legacy of toxicants into our descendants' genome, increasing their risk for cancer as well as endocrine, neurological, and reproductive impairment.[12] We have a duty to both present and future generations to mitigate preventable environmental contributors to cancer and advocate for a more stringent regulatory structure governing cosmetics.

II. DYING TO BE FRESH AND CLEAN: TOXIC INGREDIENTS IN COSMETICS AND RISK OF CANCER

A. *Hogans v. Johnson & Johnson*

Deane Berg of South Dakota had been using Johnson's Baby Powder in her perineal area for decades when she discovered she had ovarian cancer.[13] In 2013, Berg filed suit against Johnson & Johnson, alleging a causal connection between using Johnson's Baby Powder and her ovarian cancer.[14] At trial, Berg's attorneys introduced expert testimony from Dr. Daniel Cramer, who presented his independent research demonstrating a 33% increased risk of ovarian cancer for women who used talcum powder in the genital area.[15] Berg's attorneys also introduced evidence of talc's immunotoxic and immunosuppressive properties that could contribute to cancer-causing inflammation, which was bolstered by the pathologist's report finding talc particles embedded in Berg's ovarian tissue.[16] Accompanying his oral testimony, Dr. Cramer submitted into evidence a written report that summarized over

Transgenerational Tort Liability for Epigenetic Disease, 13 DEPAUL J. HEALTH CARE L. 319, 320–23 (2011).

12. David Crews & Andrea C. Gore, *Transgenerational Epigenetics: Current Controversies and Debates, in* TRANSGENERATIONAL EPIGENETICS 371, 377–79 (Trygve Tollefsbol ed., 2014); Matthew D. Anway et al., *Epigenetic Transgenerational Actions of Endocrine Disruptors and Male Fertility*, 308 SCIENCE 1466, 1466 (2005); Laura Rozek et al., *Epigenetics: Relevance and Implications for Public Health*, 35 ANN. REV. PUB. HEALTH 105, 107–10 (2014).
13. Rabin, *supra* note 1.
14. Berg v. Johnson & Johnson, 983 F. Supp. 2d 1151, 1154 (D.S.D. 2013).
15. *Id.* at 1155–56, 1160–61; Plaintiff's Expert Testimony Report by Dr. Daniel Cramer at 9, *Berg*, 983 F. Supp. 2d 1151 [hereinafter Cramer's Testimony].
16. *Berg*, F. Supp. 2d at 1155.

twenty additional studies demonstrating a significant increase in the risk of ovarian cancer associated with perineal talc use.[17] The jury found in Berg's favor, concluding that Johnson's Baby Powder was unreasonably dangerous and that Johnson & Johnson failed to warn of the dangers associated with its use.[18] Despite this conclusion, the jury elected not to award any damages to Berg.[19]

Three years later in the spring of 2016, America's most trusted brand was again under fire as media outlets, health groups, and environmental advocates began to question the talc used in Johnson's Baby Powder and Shower to Shower.[20] Like Berg, plaintiffs in *Hogans v. Johnson & Johnson* all used Johnson's Baby Powder or Shower to Shower for decades, all developed ovarian cancer, and, as a class, alleged a causal link between their use of these products and the development of their cancer.[21] For many women, including the 57 plaintiffs in *Hogans*, dusting talc in the genital area for feminine "freshness" was merely another part of their customary practice.[22] In advertising campaigns, Johnson & Johnson specifically marketed Johnson's Baby Powder to adult women through the tagline: "for you, use every day to help feel soft, fresh, and comfortable," while promising it is "clinically proven gentle and mild."[23] A surviving son of one of the plaintiffs who passed away from ovarian cancer expressed dismay: "It has to be safe. It's put on babies. It's been around forever. Why haven't we heard of any ill effects?"[24] This disbelief highlighted the massive disconnect between Johnson & Johnson's advertising promising product safety and its simultaneous strategizing to refute credible evidence linking product use to ovarian cancer.

Plaintiffs' exhibits also brought to the forefront the ethical issue of marketing a product that may increase risk of cancer to a market segment with pre-existing health disparities. Integration of Johnson's Baby Powder into women's daily routines is stratified

17. Cramer's Testimony, *supra* note 15, at 4.
18. Rabin, *supra* note 1.
19. *Id.*
20. STACY MALKAN, CAMPAIGN FOR SAFE COSMETICS, BABY'S TUB IS STILL TOXIC 4–5 (2011), https://perma.cc/4NG9-6RTA; Berfield et al., *supra* note 3; Rabin, *supra* note 1.
21. Amended Complaint, *supra* note 2, at 53.
22. *Id*. at 19–20, 48; Berfield et al., *supra* note 3; Rabin, *supra* note 1.
23. Amended Complaint, *supra* note 2, at 47–48.
24. Berfield et al., *supra* note 3.

by race: Johnson & Johnson's own marketing statistics demonstrate greater use among black and Hispanic women.[25] Internal memoranda demonstrated that Johnson & Johnson attempted to target this market segment with advertising campaigns in the 1990s designed to increase minority product uptake and counter negative publicity surrounding the link between talc use and cancer.[26] While this move capitalized on the minority market share, Plaintiffs attacked this strategy, alleging that Johnson & Johnson committed further ethical breaches by encouraging use of products containing toxicants that would increase existing health disparities[27] in ovarian cancer.[28]

According to Plaintiffs in *Hogans*, Johnson & Johnson acted to deliberately ensure the public would not become aware of adverse health risks.[29] Plaintiffs asserted that, not only did Johnson & Johnson manufacture an unreasonably dangerous product and fail to warn consumers of the increased risk of cancer, but the company procured and disseminated "false, misleading, and biased information regarding the safety" of talc to the public and regulatory bodies that rose to the level of civil conspiracy.[30] Through discovery, Plaintiffs' attorneys uncovered damaging memoranda between Johnson & Johnson and an independent toxicologist suggesting that Johnson & Johnson was aware of the risk of ovarian cancer from perineal talc use but deliberately attempted to

25. *Id.*
26. *Id*.
27. *See* Robert E. Bristow et al., *Disparities in Ovarian Cancer Care Quality and Survival According to Race and Socioeconomic Status*, 105 J. NAT'L CANCER INST. 823, 823 (2013); *Cancer Health Disparities Research*, NAT'L CANCER INST., https://perma.cc/3KXK-QGFU (last updated July 24, 2017); *see also* Kim Pearson, *Chemical Kids*, 24 TEXAS J. WOMEN, GENDER & L. 67, 85–86 (2014) (discussing educational and financial barriers stratified by race and class for parents attempting to select products that do not contain toxicants to use for their children); Rajiv Shah & Kelly E. Taylor, *Concealing Danger: How the Regulation of Cosmetics in the United States Puts Consumers at Risk*, 23 FORDHAM ENVTL. L. REV. 203, 211–14 (2012) (discussing racially stratified health risks of using hair relaxers containing toxicants).
28. Amended Complaint, *supra* note 2, at 8; Martha Neil, *St. Louis Jury Says J&J Must Pay $72M to Family to Dead Woman in Landmark Talcum Powder Cancer Case*, ABA JOURNAL (Feb. 23, 2016), https://perma.cc/34PJ-X9EN.
29. Amended Complaint, *supra* note 2, at 49.
30. *Id.* at 51, 58–61.

mischaracterize the conclusions of data by denying such risk.[31] In these memoranda, Johnson & Johnson's independent toxicologist warned the Manager of Preclinical Toxicology that Johnson & Johnson's assertion that lifetime exposure to talc by skin contact presents no significant risk of ovarian cancer is "outright false," and that the company's admission that although a weak association might exist, "studies are insufficient to demonstrate any real association," is inaccurate.[32] Perhaps most damning, this independent expert likened these blatant mischaracterizations to Big Tobacco denying the increased risk of lung cancer from smoking cigarettes.[33]

Despite the International Agency for Research on Cancer's ("IARC") 2006 classification of perineal talc use as possibly carcinogenic to humans,[34] Johnson & Johnson swiftly responded to defend its reputation.[35] Johnson & Johnson claimed that the jury verdict in *Hogans* "goes against decades of sound science"[36] and that "the safety of talc is based on a long history of safe use and more than 30 years of research."[37] Additional parties have filed lawsuits against Johnson & Johnson with similar claims while Johnson & Johnson continues to deny wrongdoing, referring to a 2014 FDA statement finding no conclusive evidence of a link between talc and increased risk of ovarian cancer.[38] This reference, however, perpetuates the misunderstanding of the current principles governing regulatory risk analysis of cosmetics; an agency statement of a lack of conclusive evidence does not equate to product safety.

31. *See id*. at 59.
32. Letter from Dr. Alfred P. Whener (Exhibit 20) at 1–2, Hogans v. Johnson & Johnson, No. 1422-CC09012 (C.C. Mo. June 23, 2014).
33. *Id.* at 2.
34. Amended Complaint, *supra* note 2, at 50 (citing International Agency for Research on Cancer, IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS: CARBON BLACK, TITANIUM DIOXIDE AND TALC, WORLD HEALTH ORG. 412 (2010)).
35. *See* Press Release, *The Facts About Talc Safety*, JOHNSON & JOHNSON (Feb. 24, 2016), https://perma.cc/29NB-AH54.
36. Associated Press, *Johnson & Johnson To Pay $72m In Case Linking Baby Powder to Ovarian Cancer*, GUARDIAN (Feb. 23 2016, 7:32 PM), https://perma.cc/ZTR6-TFKK.
37. *The Facts about Talc Safety*, *supra* note 35.
38. David Siegel, *Johnson & Johnson Rocked by $55M Verdict in Talcum Powder Cancer Trial*, COURTROOM VIEW NETWORK (May 2, 2016, 9:17 PM), https://perma.cc/75ZD-XNY3.

B. The Tip of the Iceberg: Toxicants in Cosmetics as Preventable Risk Factors for Cancer

1. Cancer as Public Health Concern

The lawsuits against Johnson & Johnson brought attention to more substantial issues: First, the routine cosmetic products we use every day are likely contributing to an increased risk for cancer that is otherwise preventable.[39] Second, it is probable that the public is unaware of FDA's lack of stringency pertaining to cosmetics and the risk of their toxic ingredients.[40] In the past several decades, we have witnessed a staggering increase in a variety of cancers, including childhood cancer, that correlates to the increase in synthetic chemicals like those in cosmetics.[41]

Cancer represents a significant public health issue: 41% of the U.S. population will be diagnosed with cancer at some point in their lives, and 21% will die from cancer.[42] Cancer is costly,[43] physically and emotionally devastating,[44] and current treatments can introduce secondary morbidities.[45] Contrary to the media focus on inherited mutations, only 5 to 10% of all cases of cancer are traced

39. *See* Song Wu et al., *Substantial Contribution of Extrinsic Risk Factors to Cancer Development,* 529 NATURE 43 (2016); MALKAN, *supra* note 20.

40. *See generally* Taylor Kraus, *Caring About Personal Care Products: Regulation in the United States, The European Union, and China in the Age of Global Consumption*, 33 WIS. INT'L L.J. 167, 177 (2015); Pearson, *supra* note 27; Valerie J. Watnick, *Our Toxins Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point*, 2004 UTAH L. REV. 1305, 1307 (2004) [hereinafter Watnick I]; Berfield et al., *supra* note 3.

41. SAMUEL S. EPSTEIN, NATIONAL CANCER INSTITUTE AND AMERICAN CANCER SOCIETY: CRIMINAL INDIFFERENCE TO CANCER PREVENTION AND CONFLICTS OF INTEREST 7 (2011); PRESIDENT'S CANCER PANEL, *supra* note 9, at 4–5; Janet Nudelman et al., *Policy and Research Recommendations Emerging from the Scientific Evidence Connecting Environmental Factors and Breast Cancer*, 15(1) INT'L J. ENVTL. & OCCUPATIONAL HEALTH 79, 79–80 (2009); Valerie J. Watnick, *The Missing Link: Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment*, 31 PACE ENVTL. L. REV. 595, 612–13 (2014) [hereinafter Watnick II].

42. PRESIDENT'S CANCER PANEL, *supra* note 9, at i.

43. *Annualized Mean Net Costs of Care*, NAT'L CANCER INST., https://perma.cc/4TBF-M3ZT.

44. *Feelings and Cancer*, NAT'L CANCER INST. (Dec. 2, 2014), https://perma.cc/PD42-UW66.

45. *Cancer Survivors: Late Effects of Cancer Treatment*, MAYO CLINIC, https://perma.cc/JJ5S-QUHU.

to inherited genetic mutations, whereas a substantial percentage of the remaining risk can be attributed to environmental and lifestyle factors.[46] In 2010, the President's Cancer Panel released its report, *Reducing Environmental Cancer Risk*, which called attention to the contribution of environmental toxicants to the development of cancer.[47] The President's Cancer Panel noted a variety of current shortcomings relating to toxicity testing and the ineffective regulation of toxicants. The Panel also observed that corporations have exploited the current risk-based regulatory approach that permits manufacturers to use toxicants in cosmetic products while placing the burden on the public and the corresponding regulatory agency to demonstrate conclusive harm.[48] These numerous deficiencies, according to the report, run contrary to a fundamental principle underlying public health policy: it is far more effective to prevent cancer than to treat it.[49]

2. Common Toxicants in Cosmetic Products

Toxicants in personal care products are numerous,[50] scientifically troubling,[51] and present in even the smallest of members of the population: neonates.[52] According to surveys conducted by the Campaign for Safe Cosmetics, a consumer advocacy organization, the average person uses 12 cosmetic products and will be exposed to 126 chemicals on a daily basis.[53] These chemicals are inhaled, ingested, and absorbed into the body.[54] Data from the National Biomonitoring Program conducted through the Centers for Disease

46. *The Genetics of Cancer*, NAT'L CANCER INST. (last updated May 1, 2017), https://perma.cc/LT95-LA3Q.
47. PRESIDENT'S CANCER PANEL, *supra* note 9.
48. *Id.* at ii–viii, 19, 99.
49. *Id.* at 97.
50. RASANAYAGAM ET AL., *supra* note 5, at 7.
51. *See* DELLAVALLE, *supra* note 7, at 6, 11.
52. *Id.* at 7; Philippa Darbre & Philip Harvey, *Parabens Can Enable Hallmarks and Characteristics of Cancer in Human Breast Epithelial Cells: A Review of the Literature With Reference to New Exposure Data and Regulatory Status*, 34 J. APPLIED TOXICOLOGY 925 (2014); Nudelman et al., *supra* note 41, at 80, 82, 88–89; Rachael Rawlins, *Teething on Toxicants: In Search of Regulatory Solutions for Toys and Cosmetics*, 20 FORDHAM ENVTL. L. REV. 1, 2, 4–6 (2009).
53. RASANAYAGAM ET AL., *supra* note 5, at 7. *See generally* SARANTIS ET AL., *supra* note 5.
54. SARANTIS ET AL., *supra* note 5, at 3, 6, 22.

Control and Prevention found more than 260 environmental chemicals present in the human body, many of which have also found their way to developing fetuses.[55] When pregnant women use cosmetic products, these toxicants seep into umbilical cord blood and across the placenta, pre-polluting society's youngest and most vulnerable.[56]

Scientific evidence has not only mounted against ingredients such as talc[57] but also against many others commonly found in cosmetics that belong to a class of chemicals scientists refer to as endocrine disrupting chemicals ("EDCs"). Such EDCs include parabens, a class of preservatives;[58] phthalates, a plasticizer;[59] and Perfluorooctanoic acid ("PFOA").[60] Scientists believe EDCs disrupt normal hormone activity by blocking or mimicking the effect of hormones, which alters the course of an organism's growth and development.[61] EDCs can mimic estrogen[62] and have been linked to the development of cancer.[63] Research has also demonstrated a link between EDCs and decreased sperm count; breast, testicular, and prostate cancer; and neurological disorders.[64]

55. *See* FOURTH NATIONAL REPORT, *supra* note 6; UPDATED TABLES, *supra* note 6.
56. DELLAVALLE, *supra* note 7; Darbre & Harvey, *supra* note 52; Nudelman et al., *supra* note 40, at 82–83, 88; Rawlins, *supra* note 52, at 2.
57. *See* Daniel W. Cramer et al., *Genital Talc Exposure and Risk of Ovarian Cancer*, 81 INT'L J. CANCER 351 (1999).
58. Shawn Pan et al., *Parabens and Human Epidermal Growth Factor Receptor Ligand Cross-Talk in Breast Cancer Cells*, 124(5) ENVTL. HEALTH PERSP. 563 (2016); Darbre & Harvey, *supra* note 52; Kraus, *supra* note 40, at 171–73; Watnick II, *supra* note 41, at 615–16.
59. LISA ARCHER ET AL., CAMPAIGN FOR SAFE COSMETICS, A LITTLE PRETTIER: COSMETIC COMPANIES DENY HEALTH PROBLEMS RELATED TO PHTHALATES, BUT ARE THEY SECRETLY REFORMULATING? 3 (2008), https://perma.cc/444U-63AU; JANE HOULIHAN ET AL., ENVTL. WORKING GROUP, NOT TOO PRETTY: PHTHALATES, BEAUTY PRODUCTS & THE FDA (2002), https://perma.cc/W264-W7P2; PRESIDENT'S CANCER PANEL, *supra* note 9, at 23, 38–40; SARANTIS ET AL., *supra* note 5; Kraus, *supra* note 40, at 171–73; Rawlins, *supra* note 52, at 4–5.
60. *See* RASANAYAGAM ET AL., *supra* note 5.
61. Watnick II, *supra* note 41, at 608.
62. PRESIDENT'S CANCER PANEL, *supra* note 9, at 2–3; Rawlins, *supra* note 52, at 4–5, 12–15; Watnick I, *supra* note 40, at 1307–10; Watnick II, supra note 41, at 606–09, 614–22.
63. PRESIDENT'S CANCER PANEL, *supra* note 9, at 3, 22, 38; *see* Watnick II, supra note 41, at 608–09, 612–22.
64. PRESIDENT'S CANCER PANEL, *supra* note 9, at 38; Watnick I, *supra* note 40, at 1308–09.

III. THE CURRENT RISK-BASED REGULATORY FRAMEWORK

A. Regulation of Cosmetics by the FDA

Contrary to common public opinion,[65] the FDA does not assess the safety of ingredients in cosmetics prior to their entry into the marketplace. Instead, regulatory policy pertaining to cosmetics follows a risk-based approach whereby the FDA presumes the product and all ingredients contained therein "safe" unless there is incontrovertible proof of harm.[66] In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act ("FDCA"), which granted the FDA the authority to regulate cosmetics.[67] Yet, current regulations are minimal, contain numerous loopholes, and lack authority for meaningful product oversight.

The FDCA defines "cosmetics" as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance."[68] This definition encompasses a lengthy list of personal care products such as makeup, shampoo, hairspray, aftershave, shaving cream, deodorant, lotion, baby products, and perfume.[69] Manufacturers have a responsibility to ensure the safety of their products, but the FDA does not require specific tests or data relating to product safety from manufacturers.[70] The FDA does not conduct any pre-market review of the final product or its ingredients to assess either short- or long-term adverse health effects, and there is no mandated prospective determination of safety before the product enters the market.[71]

65. *See* Berfield et al., *supra* note 3.
66. Carl Cranor, *Do You Want to Bet Your Children's Health on Post-Market Harm Principles?*, 19 VILL. ENVTL. L.J. 251, 275–76 (2008); S. Lochlann Jain, *Fear of Cancer*, 44 LOY. L.A. L. REV. 233, 239 (2010); Kraus, *supra* note 40, at 173–75; Rawlins, *supra* note 52, at 9–16.
67. *See* Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA") § 1, 21 U.S.C. § 301 (2012).
68. FDCA § 201(i).
69. *Id.* § 201.
70. Kraus, *supra* note 40, at 176–77; Rawlins, *supra* note 52, at 9–15; *FDA Authority Over Cosmetics*, *supra* note 4.
71. Kraus, *supra* note 40, at 176–77; Rawlins, *supra* note 52, at 9–15; Watnick II, *supra* note 41, at 601–03; *FDA Authority Over Cosmetics*, *supra* note 4.

Under the FDCA, manufacturers are prohibited from marketing adulterated or misbranded cosmetics.[72] The FDCA defines "adulteration" as "violations involving product composition" that include "ingredients, contaminants, [and] processing" that would result in the product containing a "poisonous or deleterious substance which may render it injurious to users . . . ."[73] Misbranding refers to violations for lack of accurate and proper labeling, which includes listing ingredients in a manner that is false or misleading, failing to list ingredients or material facts about the product, or failing to include warning statements.[74] Despite these requirements, legal scholars have noted the difficulty of determining what constitutes a product that would be injurious to users given manufacturers' vested financial interest in proclaiming the product's safety.[75] In theory, the provision pertaining to adulterated and misbranded cosmetics prevents manufacturers from marketing a cosmetic that is harmful to consumers when the consumer uses the product as intended.[76]

However, failing to define what constitutes "harmful" presents a substantial shortcoming. For toxicants that do not cause an immediate and severe reaction but rather subtle effects, latent harm, and increased risk of disease, the definition of an "adulterated" product becomes murkier—and, thus, warrants re-envisioning current limitations on the definition of "injurious." That is, if a cosmetic's ingredients cause serious latent harms such as the increased risk of cancer from EDCs, they should be prohibited under the adulteration provision—even if the cosmetic's ingredients would not cause immediate and visible injury. Re-envisioning the definition of "injurious" would also require a corresponding change in prohibitions against misbranding and require manufacturers to list harmful ingredients on labels or warn of such risks.

Currently, there are several mechanisms to track products and data, both through the FDA as well as the cosmetic industry's trade association, the Cosmetic Ingredient Review ("CIR") Panel.[77]

72. FDCA §§ 601–02.
73. *Id.* § 601.
74. *Id.* § 602.
75. Rawlins, *supra* note 52, at 9–15.
76. *Id.*; *FDA Authority Over Cosmetics*, *supra* note 4.
77. *Cosmetic Ingredient Review Expert Panel*, COSMETICS INFO, http://perma.cc/E75E-BALB [hereinafter *Cosmetic Ingredient Review*].

The FDA utilizes a system for manufacturers to register their products, but this registration is voluntary, rather than required.[78] Combining voluntary registration with a lack of pre-market review means manufacturers have little incentive to submit data to the FDA about their products' ingredients.[79] Manufacturers may also voluntarily submit their data to CIR, which can assess the safety of ingredients.[80] Recent estimates show only 11 to 13% of all ingredients in cosmetics have been subjected to CIR's analysis, and since CIR's inception in 1976, it has concluded lack of safety for only 11 out of the more than 10,000 chemicals currently used in cosmetics.[81] Finally, CIR is an industry-funded organization, which raises conflict of interest concerns relating to the potential for lack of impartial self-regulation.[82]

In addition to the shortage of data on product safety, the current system also lacks transparency relating to basic disclosure of product ingredients. The FDCA contains numerous loopholes that permit manufacturers to omit potentially harmful cosmetic ingredients from the product label.[83] Under the FDCA, manufacturers are not required to list the composition of ingredients under the headings "fragrance" or "flavor," although both may contain EDCs; manufacturers may claim such ingredients constitute a protected trade secret.[84] Thus, although EDCs may be present in products, they may not be listed on product labels. This leaves consumers unaware of many products' ingredients and the health risks of using those products.[85]

Two consumer advocacy groups, the Campaign for Safe Cosmetics and the Environmental Working Group, have conducted several independent investigations which found that the ingredient labels for many common products such as perfume, face cream, and lotion did not list phthalates despite their presence in 75% of

78. *FDA Authority Over Cosmetics*, *supra* note 4.
79. Shah & Taylor, *supra* note 27, at 225–27; Watnick II, *supra* note 41, at 604–06.
80. Rawlins, *supra* note 52, at 10–13; Watnick II, *supra* note 41, at 604–06, 622–26; *Cosmetic Ingredient Review*, *supra* note 77.
81. Watnick II, *supra* note 41, at 605–06.
82. *Id.*; Rawlins, *supra* note 52, at 11–12.
83. Rawlins, *supra* note 52, at 6–7, 10–13; Shah & Taylor, *supra* note 27, at 224–28.
84. Shah & Taylor, *supra* note 27, at 227–28.
85. RASANAYAGAM ET AL., *supra* note 5; SARANTIS ET AL., *supra* note 5.

the products tested.[86] Manufacturers may also decline to list an ingredient on a label if the ingredient is designated as a contaminant of another ingredient.[87] In one independent investigation, the Campaign for Safe Cosmetics tested products such as anti-aging face creams, makeup, and shaving cream—all of which contain Polytetrafluoroethylene ("PTFE"), which creates a sleek and smooth finish.[88] PFOA, a contaminant in PTFE linked to cancer, endocrine disruption, and reproductive harm, was not listed on the label for the products that contained it in these independent tests.[89] A product may also contain an ingredient that releases chemicals into the air during the normal course of use but that the manufacturer does not list on the label. In 2012, the media reported that Johnson & Johnson's "Johnson's Baby Shampoo" formulation contained quaternium-15—a preservative that releases formaldehyde which, in 2004, IARC determined is carcinogenic to humans.[90] Failing to fully and accurately disclose ingredients on the label makes it exceedingly difficult for consumers to buy products without harmful toxicants.

Even if consumers become aware of a product's adverse effects, the FDA has no authority to order a recall of the product.[91] If the FDA determines that a product is adulterated or misbranded, the FDA may issue a Warning Letter to the manufacturer indicating the manufacturer's regulatory noncompliance or request that the Department of Justice intervene.[92] Such an attempt to alert consumers, contact the Department of Justice to initiate a complaint against the manufacturer, and obtain a judicial ruling to remediate the danger constitutes a more challenging proposition. It also raises questions about the sufficiency of the FDA's ability to shield

86. HOULIHAN ET AL., *supra* note 59, at 1–2.
87. RASANAYAGAM ET AL., *supra* note 5, at 18.
88. *Id.* at 8, 10.
89. *Id.* at 8, 12.
90. MALKAN, *supra* note 20, at 4–10; Katie Thomas, *The 'No More Tears' Shampoo, Now With No Formaldehyde*, N.Y. TIMES (Jan. 17, 2014), https://perma.cc/T76B-TA9K; Press Release, International Agency on Cancer Research, IARC Classified Formaldehyde as Carcinogenic to Humans (June 15, 2004), https://perma.cc/RB3X-GCG9.
91. *FDA Authority Over Cosmetics*, *supra* note 4.
92. *Id.*; Letter from Michael Roosevelt, Acting Director, CFSAN Off. of Compliance, to Mike Brady, CEO, GIB, LLC dba Brazilian Blowout (Aug. 22, 2011), https://perma.cc/5WS9-MXUZ.

consumers from cosmetics with high levels of carcinogens that cause immediate adverse health reactions.

B. Limitations of the FDCA and Implications for Consumers

The impact of these ineffectual provisions became apparent several years ago when a new product called Brazilian Blowout inundated salons as a chemical treatment designed to straighten women's hair.[93] While women raved about their newly smooth hair, salon workers started to report serious physical reactions to the chemical straightening product in droves. Such reported reactions included burning throats, stinging eyes, blistering rashes, and breathing difficulty.[94] Despite Brazilian Blowout's manufacturer—GIB, LLC—explicitly advertising its product as "formaldehyde free," it contained a liquid form of formaldehyde called methylene glycol.[95] GIB argued in a subsequent lawsuit that methylene glycol did not equate to formaldehyde, even though the product released dangerously high levels of formaldehyde when used as intended.[96] Specifically, the Occupational Safety and Health Administration found that Brazilian Blowout products released approximately five times the acceptable workplace limit of formaldehyde.[97] An official with the California Department of Public Health confirmed that "[c]osmetic products that contain known human carcinogens or chemicals that impair human reproduction or development are marketed and sold without adequate safety tests

93. Jane Kay et al., *U.S. Government Has Little Authority to Stop Unsafe Cosmetics*, SCIENTIFIC AMERICAN (Oct. 18, 2012), http://perma.cc/WL4S-SSKY.

94. *Id*.

95. *Hair-Smoothing Products that Release Formaldehyde when Heated*, FDA, https://perma.cc/WD77-3RY3 (last updated Nov. 3, 2017); *Hair Smoothing Products that Could Release Formaldehyde*, OSHA, https://perma.cc/CU2Q-ZYRD.

96. Second Am. Compl. & Demand for Jury Trial, *In re* Brazilian Blowout Litig., No. 10-8452 JFW (C.D. Cal. Nov. 5, 2010); Consent Judgment, People v. GIB, No. RG10545880 (Cal. Super. Ct. Jan. 5, 2012); Press Release, Cal. Dep't of Justice Office of the Att'y Gen., Attorney General Kamala D. Harris Announces Settlement Requiring Honest Advertising Over Brazilian Blowout Products (Jan. 30, 2012), https://perma.cc/WQ3T-HH52 [hereinafter Attorney General Press Release on Brazilian Blowout].

97. Kay et al., *supra* note 93.

because the . . . law allows it."[98] Moreover, in referencing Brazilian Blowout, this official stated that "the levels of formaldehyde exceeded levels that would be of concern for causing cancers and short-term effects."[99]

Although the California Attorney General announced a settlement against the manufacturer, the terms of the settlement were primarily confined to re-labeling the product and modifying advertising to indicate the risk associated with use.[100] The product thus remained on the market—but merely with an updated label.[101] This raised the question of the label's sufficiency in protecting cosmetics consumers from dangerous levels of toxicants; they may continue to use the product without understanding either its warning label's implications or the level of associated risk.[102]

As the President's Cancer Panel observed, the current regulatory framework for cosmetics is both outdated and ineffective. The FDCA ultimately fails to ensure the safety of products that enter the marketplace, permits products with known carcinogens onto store shelves, and lacks the authority to remove products posing substantial risks.[103] Importantly, attempting to regulate the cosmetics industry product by product is piecemeal and inefficient. Legal and regulatory interventions should not be contingent upon public outcry when a product generates serious adverse health outcomes in its users.[104]

Augmenting these shortcomings associated with lack of required product review, FDA's risk-based framework equivocates potential risks in its consumer product information. For example, FDA's consumer information pertaining to EDCs such as phthalates states that "[i]t's not clear what effect, if any, phthalates have on human health," and that, "[a]t the present time, FDA does not have evidence that phthalates as used in cosmetics pose a safety risk."[105] Similarly, FDA's consumer

98. *U.S. Government Has Little Authority to Stop Unsafe Cosmetics*, SCIENTIFIC AMERICAN (Oct. 18, 2012), https://perma.cc/W454-RYWB.
99. *Id.*
100. Attorney General Press Release on Brazilian Blowout, *supra* note 96.
101. Amy Westervelt, *Brazilian Blowout Legally Labeled Carcinogenic . . . Will It Matter*?, FORBES (Jan. 30, 2012, 9:18 PM), https://perma.cc/P88Z-3ED5.
102. *Id.*
103. PRESIDENT'S CANCER PANEL, *supra* note 9, at i, ii, xiii, 2, 19, 99.
104. *See* Shah & Taylor, *supra* note 27, at 205, 207–08, 216, 220.
105. *Phthalates*, FDA, https://perma.cc/REF8-7HBH (last updated Oct. 5, 2016).

information page for parabens claims that the FDA "[does] not have information showing that parabens as they are used in cosmetics have an effect on human health."[106] Although such statements are aligned with the standards governing the current risk-based regulatory framework, it likely compounds the consumer's belief that these assertions equate to product safety.

C. Cultivating Consumer Confusion

Consumers who attempt to gain clarity about product risk or safety information from sources such as the manufacturer or CIR will encounter grossly inaccurate representations made on each's websites.[107] These descriptions do not merely reflect the risk-based framework but rather undermine and mischaracterize the available data and scientific consensus. Cosmetics giant Proctor & Gamble asserts that its products contain parabens and phthalates at levels well below safe ranges, that the body easily breaks down and eliminates these chemicals, and that these chemicals have been thoroughly studied and found to be safe.[108] Reports by the President's Cancer Panel, the Environmental Working Group, and the Campaign for Safe Cosmetics, as well as independent scientific research, contradict these inaccurate statements, finding instead a lack of safety and mounting cause for concern.[109] These statements also mischaracterize the U.S. regulatory risk-based system because the FDA has not made any safety determination but rather requires a high evidentiary bar demonstrating risk before declaring a product potentially harmful.[110]

106. *Parabens in Cosmetics*, FDA, https://perma.cc/MM6L-QNMK (last updated Oct. 5, 2016).

107. *About Us*, COSMETICS INFO, https://perma.cc/9KC5-SXDF; *Cosmetic Ingredient Review*, *supra* note 77; *How Cosmetics Are Regulated in the US*, COSMETICS INFO, https://perma.cc/PEH4-SKUG; *Parabens*, PROCTOR & GAMBLE, https://perma.cc/H35K-3FJN; *Phthalates*, PROCTOR & GAMBLE, https://perma.cc/X87R-UVYG.

108. *See* Parabens, *supra* note 107; Phthalates, *supra* note 107.

109. ARCHER ET AL., *supra* note 59; Crews & Gore, *supra* note 12; DELLAVALLE, *supra* note 7; HOULIHAN ET AL., *supra* note 59; PRESIDENT'S CANCER PANEL, *supra* note 9; RASANAYAGAM ET AL., *supra* note 5; SARANTIS ET AL., *supra* note 5; Anway et al., *supra* note 12; Darbre & Harvey, *supra* note 52; Rozek et al., *supra* note 12;.

110. Watnick I, *supra* note 40, at 1329–30; Cranor, supra note 66, at 281–82.

Similarly, the industry-funded CIR states that "[c]osmetic companies' strong commitment to safety has made cosmetic and personal care products among the safest product categories regulated by the FDA," and that manufacturers perform rigorous testing.[111] The CIR further claims that any adverse reactions are related to mere allergies or rashes and that the FDCA requires every cosmetic and its ingredients to be substantiated for safety before going to market.[112] CIR's statement alluding to testing impartiality and thoroughness could be misinterpreted as stringent safeguards against harmful products' entry into the market. Further, numerous legal scholars and consumer advocacy groups have called attention to the lack of rigor in product oversight for cosmetics and its resulting adverse health impact.[113]

Manufacturer defenses pertaining to the nature of their products closely track those employed by Big Tobacco several decades ago.[114] The documentary *The Human Experiment* discusses how public relations teams strategically manufacture doubt to undermine allegations within the scientific community about the true risk associated with product use.[115] Such methods include creating distraction, employing deception, using strategic marketing, and skewing science.[116] A variety of cosmetic manufacturers appear to employ this model. First, by donating to the American Cancer Society and strategically marketing their involvement in finding a "cure" for cancer, these corporations purposely distract from the policy paradox that the majority of cancer is caused by environmental toxicants like those found in the cosmetics these corporations manufacture.[117] Second, assertions by manufacturers such as Proctor & Gamble that parabens and phthalates are eliminated by the body and have been proven safe inaccurately—and

111. *How Cosmetics Are Regulated in the US*, *supra* note 107.
112. *About Us*, *supra* note 107; *Cosmetic Ingredient Review*, *supra* note 77; *How Cosmetics Are Regulated in the US*, *supra* note 107.
113. *See, e.g.*, Rawlins, *supra* note 52; sources cited *supra* note 109.
114. DEVRA DAVIS, THE SECRET HISTORY OF THE WAR ON CANCER 3, 9–12 (2007) (ebook); EPSTEIN, *supra* note 41, at 116–17, 118–32.
115. THE HUMAN EXPERIMENT (Area 23a 2013).
116. *Id.*
117. PINK RIBBONS, INC. (First Run Features 2011); *Poison Isn't Pretty*, BREAST CANCER ACTION, https://perma.cc/4YJG-3PM3; Karuna Jagger, *Why the American Cancer Society Must Take A Stronger Stand Against Cancer Prevention*, HUFFINGTON POST (Nov. 3, 2015, 9:39 AM), https://perma.cc/H7MS-H38P.

deceptively—skew the scientific consensus.[118] Public health scholars such as Devra, Davis, and Epstein have extensively researched and commented on this disconnect between public messaging employed by manufacturers who support research to cure cancer while "hiding or stifling evidence that their own products caused the disease."[119]

D. Conflicts of Interest and the American Cancer Society

Problematically, for consumers particularly motivated to investigate whether cosmetics increase their risk of preventable disease, turning to the American Cancer Society's ("ACS") consumer information echoes the deceptive industry tagline. Both Davis and Epstein have meticulously detailed the substantial funding the ACS receives from the very companies that manufacture products containing environmental toxicants, including Johnson & Johnson, Avon, and Revlon.[120] This creates immense conflicts of interest for the ACS when representing to the public the risk or safety of its donors' products.[121] On a consumer information web page on cosmetics, ACS asserts that there are gaps in scientific evidence of whether cosmetics can cause health problems because there have been no long-term studies, it is unclear what chemicals are absorbed into the body, and epidemiological studies using animal models may *inflate* actual risk.[122] The ACS also proclaims that "most scientists and regulatory agencies believe it is 'very unlikely' that cosmetic ingredients have serious health effects."[123] Each of these statements starkly contrasts the findings of the President's Cancer Panel, the Halifax Project, and independent scientific assessments. It is unacceptable that the ACS not only adopts the

118. *See Parabens*, *supra* note 106; *Phthalates*, *supra* note 105.
119. DAVIS, *supra* note 114, at 14.
120. EPSTEIN, *supra* note 41, at 116; *Acknowledging Corporate Support*, AMERICAN CANCER SOCIETY, https://perma.cc/VKJ2-87TV.
121. EPSTEIN, *supra* note 41, at 116; *Acknowledging Corporate Support*, supra note 120.
122. *Cosmetics*, AMERICAN CANCER SOCIETY, https://perma.cc/PAY3-5YWB (last updated May 28, 2014).
123. *Id.*

FDA's risk-based model that equivocates the potential for harm but further mischaracterizes the scientific consensus.[124]

E. Shortcomings of Risk-Based Approach and Adoption of Precautionary Approach

Rather than relying on an ineffective risk-based approach that requires definitive proof of harm, both the President's Cancer Panel and the United Nations General Assembly's Rio Declaration affirmed that federal regulations, where practicable, should follow the precautionary principle—for example, manufacturers should submit data to the appropriate regulatory agency for pre-market review and approval.[125] Instead of treating the American public as guinea pigs for determining the risks from toxicant exposures, if a toxicant raises a threat of harm to human health or the environment, the federal government should have a duty to enact precautionary measures to mitigate such harm.[126] As discussed below, scientific evidence affirms that EDCs pose a substantial threat to human health and that Congress should revise the FDCA to align with a precautionary model for cosmetics regulation.

IV. PROPERTIES OF EDCS

A. How EDCs Operate

The current risk-based model and extensive shortcomings in FDA regulations constitute an even greater concern when considering the impact of EDCs as a particular class of toxicants.[127] Implementing the precautionary principle becomes compelling considering that the President's Cancer Panel also confirmed what scientists are discovering: EDCs challenge several traditional

124. ARCHER ET AL., *supra* note 59; DELLAVALLE, *supra* note 7; HOULIHAN ET AL., *supra* note 59; PRESIDENT'S CANCER PANEL, *supra* note 9; RASANAYAGAM ET AL., *supra* note 5; SARANTIS ET AL., *supra* note 5.

125. Fazal Khan, *Preserving Human Potential as Freedom: A Framework for Regulating Epigenetic Harms*, 20 HEALTH MATRIX: J.L. MED. 260, 263, 300–01 (2012); PRESIDENT'S CANCER PANEL, *supra* note 9, at ii, xi, 16–17.

126. Khan, *supra* note 125, at 263.

127. PRESIDENT'S CANCER PANEL, *supra* note 9, at 38–40; Rawlins, *supra* note 52, at 3–6; Shah & Taylor, *supra* note 27, at 208–11; Watnick I, *supra* note 40, at 1307–10; Watnick II, supra note 41, at 606–10, 614–22.

notions of toxicity and risk.[128] Most chemicals adhere to a standardized risk assessment—toxicology tests that follow a traditional dose-response curve which assumes that a lower amount of the chemical results in a lower risk of harm.[129] EDCs, on the other hand, cause disruption at very low doses, including levels which scientists have not previously considered ecologically relevant.[130] Accordingly, traditional testing methods likely miss the risks present at lower doses, and presuming minimal disruption based on exposure data from higher doses is also an inaccurate assessment of risk.[131] Some experts theorize that there may be no threshold level of safety for EDCs but rather only varying scopes and severity of harm based on exposure.[132]

The President's Cancer Panel noted several additional limitations of current toxicity testing that pose concerns for EDCs based on how toxicants accumulate, interact synergistically, and the timing of exposure. EDCs constitute a distinct class of toxicants which defies risk parameters established for traditional toxicity testing.[133] Many EDCs accumulate in the body and are stored in fat tissue.[134] Each additional toxicant present in cosmetic products that we ingest, absorb, or inhale increases the amount of potential toxicants circulating or stored in the body at one time.[135] The average individual encounters numerous toxicants throughout the course of the day, exposing the individual to multiple sources of phthalates, parabens, and other EDCs at one time in addition to increasing the total amount of toxicants within the body.[136] Concurrent exposure can create a synergistic impact of each chemical; the interaction between toxicants can magnify the risks each poses alone.[137] Stored toxicants may also interact with new exposures

128. *See* PRESIDENT'S CANCER PANEL, *supra* note 9, at 38–39.
129. Crews & Gore, *supra* note 12, at 383.
130. Pan et al., *supra* note 58; Watnick I, *supra* note 40, at 1321–30.
131. PRESIDENT'S CANCER PANEL, *supra* note 9, at 38.
132. Watnick I, *supra* note 40, at 1322–27.
133. *See* PRESIDENT'S CANCER PANEL, *supra* note 9.
134. Nudelman et al., *supra* note 41, at 79.
135. PRESIDENT'S CANCER PANEL, *supra* note 9, at 2, 36; Cranor, *supra* note 66; Watnick II, *supra* note 41, at 620–21.
136. Watnick II, *supra* note 41, at 621.
137. Cranor, *supra* note 66, at 275–76; Nudelman et al., *supra* note 41, at 79–80; Rawlins, *supra* note 52, at 23; PRESIDENT'S CANCER PANEL, *supra* note 9, at 2, 11, 36.

such that both cumulative exposure and synergistic interaction shape the risk outcome.[138] The full impact of these potential risks are not only unknown, but they are also unregulated because the United States does not currently utilize any mechanism to measure the synergistic impact of toxicants or assess acceptable limits on combined exposures.[139]

B. The Hallmarks of Cancer

The effects of EDCs may be subtle and variable, impacting a number of functions from the endocrine system and neurological functioning to fertility and risk of cancer.[140] As with any chemical exposure, EDCs may influence individuals differently, increasing the unpredictability of reactions.[141] Research demonstrates that EDCs exert genotoxic effects and can cause chromosomal damage, thereby increasing subsequent risk of disease including cancer.[142]

A consortium of scientists working on the Halifax Project proposed a fundamental paradigm shift to assess the contribution of environmental toxicants to the development of cancer and address the impact of the sheer amount of toxicant exposure.[143] This consortium concluded that instead of searching for toxicants that constitute complete carcinogens, regulatory policy should assess whether chemicals induce what scientists call the "Hallmarks of Cancer."[144] This refers to how toxicants initiate a series of biological changes including triggering inflammation and genomic instability, undermining immune function, and interfering with stages of cell division, death, and reproduction—multiple steps which, when combined, constitute what is labelled cancer.[145]

Halifax Project scientists hypothesized that low doses of common chemicals can affect cancer-related mechanisms consumers

138. Cranor, *supra* note 66, at 275–76; Watnick I, *supra* note 40, at 1321, 23–24, 27–28.
139. Rawlins, *supra* note 52, at 3, 6; Watnick I, *supra* note 40, at 1321, 1324.
140. PRESIDENT'S CANCER PANEL, *supra* note 9, at 3, 38–40; Crews & Gore, *supra* note 12, at 379–80; Watnick I, *supra* note 40, at 1307–10, 1321.
141. Watnick I, *supra* note 40, at 1321–22, 25–26.
142. PRESIDENT'S CANCER PANEL, *supra* note 9, at 2–3; Cranor, *supra* note 66, at 256, 258; Darbre & Harvey, *supra* note 52.
143. DELLAVALLE, *supra* note 7, at 3, 5–6.
144. *Id.* at 13.
145. *Id.* at 3, 8, 11.

typically encounter in the environment.[146] They also proposed that even if the chemicals cannot induce carcinogenesis on their own, they can function through bioaccumulation and synergy to overwhelm the body's defenses and initiate the multi-step process.[147] As one biologist summarized, the combined effect of chemicals on the Hallmarks of Cancer "explains why no single chemical has been linked consistently with breast cancer causation and probably never will be."[148] This, in the biologist's view, "should not lead to a dismissal of any chemical as insignificant but more an appreciation of the complexity of . . . chemical mixtures."[149] Accordingly, we must assess the potential for each of these chemicals to initiate the Hallmarks of Cancer and envision risk within a cumulative and synergistic mindset.

C. Vulnerable Populations: Pregnant Women, Fetuses, and Children

Incorporating both the effects of EDCs and scientific knowledge of how toxicants affect us requires re-assessing risk—specifically as it pertains to vulnerable populations. Even if manufacturers conduct independent testing, reference doses to determine acceptable risk do not account for scaling to society's youngest.[150] Children are particularly vulnerable to toxicant exposure based on pediatric magnification[151]: their bodies are smaller, so the same dose of a toxicant is more concentrated in a child's body;[152] children are slower to detoxify from harmful exposures;[153] and they are less able to repair damage resulting from toxicant

146. DELLAVALLE, *supra* note 7, at 3; William H. Goodson III et al., *Assessing the Carcinogenic Potential of Low-Dose Exposures to Chemical Mixtures in the Environment: The Challenge Ahead*, 36 CARCINOGENESIS S254 (2015).
147. *Id.* at 5, 8, 12–13; PRESIDENT'S CANCER PANEL, *supra* note 9; Cranor, *supra* note 66, at 275–76; Darbre & Harvey, *supra* note 52.
148. Darbre & Harvey, *supra* note 52, at 935.
149. *Id.* at 936.
150. PRESIDENT'S CANCER PANEL, *supra* note 9, at 8.
151. *Id.* at vii, 8–9; Cranor, *supra* note 66, at 268–69.
152. Cranor, *supra* note 66, at 275.
153. PRESIDENT'S CANCER PANEL, *supra* note 9, at 5; Shah & Taylor, *supra* note 27, at 212.

exposure.[154] Thus, exposing children to the same level of toxicants as adults results in greater risk and impact.[155]

The impact of fetal exposure implicates each of the pediatric considerations, in addition to concerns about the timing of exposure during crucial stages of early development. Pregnant women pass along their body burden of toxicants to the developing fetus during gestation.[156] Scientists describe a period called the critical "window of vulnerability" or "window of susceptibility" during gestation and early infancy, during which exposure to toxicants can alter normal development and manifest in acute or long-term health effects.[157] The developing brain is more susceptible to injury because the blood-brain barrier that normally filters some toxicants has not developed.[158] During fetal development, the brain and fetal tissue undergo rapid maturation along a specific pathway.[159] Any exposure to toxicants during this crucial stage could halt or alter the normal course of neuronal development, proper fetal tissue differentiation, and the development of the immune system, leading to long-lasting—or even permanent—health issues.[160] This critical window of development requires heightening protection for pregnant women, developing fetuses, and infants in a manner proportionate to the increased risks they face.[161]

In many cases involving fetal development, there is a long latency period from the time of exposure to the onset of illness caused by the toxicant, and effects of fetal exposure may not only directly impact the individual but their offspring as well.[162] Perhaps the best-known example of this phenomenon is the case of Diethylstilbestrol ("DES"). From the 1950s to the 1970s, physicians treated

154. PRESIDENT'S CANCER PANEL, *supra* note 9, at 5; Cranor, *supra* note 66, at 262.
155. PRESIDENT'S CANCER PANEL, *supra* note 9, at iii, xix, 5, 8–9.
156. Cranor, *supra* note 66, at 258.
157. PRESIDENT'S CANCER PANEL, *supra* note 9, at vi, 2; Turker, *supra* note 11, at 193.
158. PRESIDENT'S CANCER PANEL, *supra* note 9, at 5; Cranor *supra* note 66, at 261–62.
159. Cranor, *supra* note 66, at 261–62.
160. *Id.* at 262–63.
161. PRESIDENT'S CANCER PANEL, *supra* note 9, at 2–5, 98; Turker, *supra* note 11, at 177–78; Watnick II, *supra* note 41, at 613.
162. PRESIDENT'S CANCER PANEL, *supra* note 9, at 2, 98; Cranor, *supra* note 66, at 253–65; Rothstein et al., *supra* note 11, at 6, 14–15, 21–22; Watnick I, supra note 40, at 1321, 1325; Wiener, *supra* note 11, at 322–23.

pregnant women with DES, a synthetic estrogen, for decades before discovering some of the daughters and granddaughters exposed to DES in utero developed rare and aggressive forms of vaginal and uterine cancer.[163] Accordingly, the effects of EDCs may not only be subtle and long-term but also multigenerational.[164]

V. THE IMPLICATION OF TOXICANTS IN COSMETICS FOR EPIGENETICS AND TRANSGENERATIONAL EPIGENETICS

A. How Toxicants Induce Epigenetic and Transgenerational Epigenetic Damage

The field of epigenetics offers insight on how toxicant exposure can alter our genome and act as a direct causal link to the subsequent onset of disease.[165] Environmental interaction with our genome occurs from numerous sources including diet, stress, and environmental toxicants.[166] Epigenetic changes occur above the genes either through methylation, altering histone proteins, or RNA interference, distorting how each gene is expressed.[167] Further, epigenetic alterations occur much more frequently than genotoxic mechanisms and affect several processes relating to growth, development, and risk for future disease.[168] Toxicants in cosmetic products can induce chemical DNA modifications, leaving marks that will affect whether and how the gene's sequence is expressed.[169] For example, epigenetic marks induced by environmental triggers such as EDCs may turn off tumor suppressor genes or turn on oncogenes, leading to cancer development in either case.[170]

163. Sindell v. Abbott Labs., 607 P.2d 924, 925–26 (Cal. 1980); Turker, *supra* note 11, at 190; Wiener, *supra* note 11, at 323–24.
164. Crews & Gore, *supra* note 12, at 377–79; Anway et al., *supra* note 12, at 1466–68; Watnick II, *supra* note 41, at 625; *see* Geronimus, *supra* note 11, at 59 (recognizing the plausibility of transgenerational inheritance of epigenetic modifications).
165. Geronimus, *supra* note 11, at 556–60; Turker, *supra* note 11, at 175–78; Wiener, *supra* note 11, at 320–23. *See generally* Rothstein et al., *supra* note 11.
166. Geronimus, *supra* note 11, at 556–57, 561.
167. Rothstein et al., *supra* note 11, at 6.
168. *Id.* at 3, 5, 9–12, 21.
169. *Id.* at 3, 6–7.
170. Shikar Sharma et al., *Epigenetics in Cancer*, 31 CARCINOGENESIS 27, 27, 30–31 (2010).

Exposure to adverse agents during critical periods of development enhances the potential for widespread and severe epigenetic damage.[171] If a fetus's developing epigenome is exposed to toxicants such as EDCs in utero that induce harmful epigenetic marks, this process could derail fetal development and prevent the affected cells from ever arriving at the intended optimal gene expression.[172] As a result, the fetus could face lifelong health damage such as increased risk of cancer, decreased fertility, neurological deficits, and immune dysfunction.[173]

Although some epigenetic changes are potentially reversible, identifying and attempting to correct epigenetic marks may be ineffective or cause off-target effects.[174] If epigenetic marks persist in the genome, they can be passed on to subsequent generations during fetal development.[175] Epigenetic marks may also be imprinted in the germline, which permanently re-programs future generations' epigenome.[176] At this point, removing the intervening toxicant will not restore the genome to its original state, and all subsequent generations will face a deficiently programmed genome that carries an increased risk for adverse health outcomes.[177] Thus, exposure to EDCs through daily and ongoing usage of cosmetic products not only increases the current population's risk for cancer and other health issues but can also induce germline transgenerational epigenetic damage, increasing future generations' cancer potential—even if never exposed to the same toxic products.

B. Legal and Policy Implications of Epigenetics and Transgenerational Epigenetics

The legal and policy implications of the true impact of our current risk-based framework for regulating toxicants in cosmetics

171. Rothstein et al., *supra* note 11, at 12–14, 21–22, 36 n.119.
172. *See* Crews & Gore, *supra* note 12, at 372; Turker, *supra* note 11, at 177–78.
173. *See* sources cited *supra* note 164.
174. *See* Rothstein et al., *supra* note 11, at 29–30.
175. Anway et al., *supra* note 12, at 1466; Crews & Gore, *supra* note 12, at 377, 379; Rozek et al., *supra* note 12, at 115.
176. Crews & Gore, *supra* note 12, at 377, 379; Anway et al., *supra* note 12, at 1467; Rozek et al., *supra* note 12.
177. Geronimus, *supra* note 11, at 556–57, 561.

are staggering and far reaching.[178] The existing regulatory framework permits manufacturers to use toxicants such as EDCs—which, as scientific research shows, causes epigenetic changes to the user and increases risk of serious, yet preventable, diseases like cancer. This framework also passes risk along to future generations through transmuting the genome, placing them at an increased risk of cancer and other disease. This regulatory passivity is simply untenable and unsustainable. Further, representations by manufacturers, CIR, and the ACS that mischaracterize the current state of research on EDCs are particularly egregious. These statements purposely—and falsely—assuage consumer concern about products that potentially induce irreversible, transgenerational epigenetic damage for the sake of financial gain.

C. An Ethical Duty to Protect the Genome

In 1998, the United Nations General Assembly referred to the human genome as the common "heritage of humanity."[179] Yet, EDCs and other toxicants in cosmetics that induce transgenerational damage to the genome limit one's health and future potential before birth—even if that person never used the product containing those toxicants.[180] Legal scholars such as Mark Rothstein and Christopher Wiener have recognized the formidable threat epigenetic damage poses to future generations' health and the importance of removing the threat.[181] This suggests that the damage is preventable—and that we thus have an ethical duty to protect the human genome from such risk. However, the current regulatory framework and misrepresentations by manufacturers, CIR, and the ACS refuting harm from toxicants are fundamentally incompatible with embracing current science to protect the human genome from preventable, environmentally mediated damage.

178. Khan, *supra* note 125, at 262.
179. G.A. Res. AIRES/53/152, Universal Declaration on the Human Genome and Human Rights, art. 1 (Dec. 9, 1998).
180. Khan, *supra* note 125, at 293.
181. Rothstein et al, *supra* note 11, at 48, 56–57; Wiener, *supra* note 11, at 330–32; *see also* Khan, *supra* note 125, at 262–63.

VI. SOLUTIONS FOR REFORM

Legal scholars and legislators have proposed several solutions to remediate the current shortcomings of the risk-based regulatory framework governing cosmetics, ranging from private litigation and state regulation to retail oversight and overhauling federal rules.

A. Private Litigation

Currently, courts will consider injury from environmental toxicants only when the plaintiff can satisfy the substantial factor test—that is, there is reasonable medical probability that the plaintiff's exposure to a toxicant is sufficient to cause the type of injury suffered.[182] Generally, courts will only permit recovery when the plaintiff can demonstrate that toxic exposure not only caused an increased risk of disease but also created a present physical injury.[183]

However, environmental toxicant jurisprudence offers a pathway to assess epigenetic risk and classify epigenetic marks as present physical injury where causation can be traced to cosmetic toxicant exposure.[184] In *Brafford v. Susquehanna Corp.*, a radiation exposure case, the court permitted plaintiffs' evidence that subcellular damage from radiation could be a cognizable injury, as this damage "operated to 'cock the trigger' of cancer in the future" and deprived plaintiffs "a degree of immunity which they had enjoyed prior to their exposure."[185] Similarly, in *Werlein v. United States*, where plaintiffs were exposed to contaminated water, the court considered subcellular damage as a present physical injury by acknowledging that the toxicant could induce chromosomal damage, which adversely affects cardiovascular and immune function.[186] Thus, the epigenetic marks induced by toxicant exposure *are* the present physical injury, and plaintiffs should not be required to

182. Karriann Laubach, *Epigenetics and Toxic Torts: How Epidemiological Evidence Informs Causation*, 73 WASH. & LEE L. REV. 1019, 1034–36 (2016).

183. *Id.* at 1022–23; Khan, *supra* note 125, at 230–83.

184. *See* Laubach, supra note 182; Khan, *supra* note 125, at 281–83.

185. Laubach, *supra* note 182, at 1047–48 (quoting Brafford v. Susquehanna Corp., 586 F. Supp. 14, 18 (D. Colo. 1984)).

186. *Id.* at 1048 (citing Werlein v. United States, 746 F. Supp. 887 (D. Minn. 1990)).

further demonstrate latent traditional notions of harm.[187] Accordingly, cosmetics that contain EDCs sufficient to cause epigenetic marks that magnify health risks of adverse health outcomes such as cancer should constitute an *ipso facto* cognizable injury. In addition to standalone claims for epigenetic damage, plaintiffs could introduce claims of added expenses relating to medical monitoring.[188]

Considering the outcome in *Hogans*, juries in jurisdictions that recognize subcellular injury could spark a product-by-product, litigation-initiated incentive for manufacturers to reduce the toxicants contained in their products. Despite the potential for spurring piecemeal positive changes, legal scholars have noted the inherent limits of using the tort law system to regulate environmental toxicants due to factors including: difficulties with demonstrating specific causation;[189] courts' desire to limit liability within immediate generations;[190] and the struggle of identifying the contributing source of a toxicant, particularly when multiple products contain the same ingredient.[191]

B. State Law

Some states, such as California, have enacted laws that impose requirements for products sold within the state containing toxicants.[192] In 2005, the California legislature passed the California Safe Cosmetics Act, which requires manufacturers to submit to the state information about their products that contain chemicals "known or reasonably anticipated to be a human carcinogen"[193] as

187. Khan, *supra* note 125, at 281–82. *See generally* Laubach, *supra* note 182.

188. *See* Khan, *supra* note 125, at 282; Laubach, *supra* note 182, at 1046, 1059–60.

189. *See* Laubach, *supra* note 182, at 1034–38; Wiener, *supra* note 11, at 330. *See generally* Steve C. Gold, *When Certainty Dissolved into Probability: A Legal Vision of Toxic Causation for the Post-Genomic Era*, 70 WASH. & LEE L. REV. 234, 244–51 (2013).

190. *See* Sindell v. Abbott Labs., 607 P.2d 924, 938, 942 (Cal. 1980) (Richardson, J., dissenting); Wiener, *supra* note 11, at 324–28.

191. Khan, *supra* note 125, at 278.

192. *See, e.g.*, California Safe Cosmetics Act, CAL. HEALTH & SAFETY CODE §§ 111791–111793.5; Safe Water and Toxic Enforcement Act of 1986, CAL. HEALTH & SAFETY CODE §§ 25249.5–25249.13.

193. California Safe Cosmetics Act § 2(b)(1), CAL. HEALTH & SAFETY CODE §§ 111791.5(b)(1). *See also* Public Health Service Act § 301(b)(4), 42 U.S.C. § 241 (2012).

well as ingredients that have some or clear evidence of adverse developmental or reproductive toxicity defined by the National Toxicology Program.[194] The Act also created a database run by the California Department of Public Health that provides this information to the public.[195]

California has also taken steps to increase manufacturer transparency at the point of purchase through Proposition 65.[196] Proposition 65 requires manufacturers to use a warning label on consumer products that are "known . . . to cause cancer or reproductive toxicity."[197] Although these two laws aim to increase oversight of toxic products and provide consumers with valuable information, federal law exempts categories of ingredients such as "fragrances" and ingredient formularies that the manufacturer designates as trade secrets, permitting the undisclosed presence of EDCs in products.[198] Additionally, California's laws lack the authority for pre-market review.[199] Finally, the inherent nature of state regulations means these requirements only pertain to California, which may create inconsistencies among the states.

C. Retail Regulation

In 2013, Walmart and Target announced sustainable product initiatives designed to prompt major manufacturers of consumer products—including cosmetics—to disclose product formulations, reduce priority defined toxic ingredients, and reformulate products with less toxic alternatives.[200] While a laudable effort, this retail

194. Rawlins, *supra* note 52, at 6–7; *California Safe Cosmetics Program*, CAL DEP'T PUB. HEALTH, https://perma.cc/GW2N-7LFJ (last updated July 7, 2017).

195. California Safe Cosmetics Act, CAL. HEALTH & SAFETY CODE §§ 111791–111793.5; Rawlins, *supra* note 52, at 6–7; *California Safe Cosmetics Program*, *supra* note 194. *See California Safe Cosmetics Program Product Database*, CAL. DEP'T PUB. HEALTH, https://perma.cc/YK3Y-GNX7.

196. Safe Water and Toxic Enforcement Act of 1986, CAL. HEALTH & SAFETY CODE §§ 25249.5–25249.13.

197. *Id.* § 25249.6.

198. 21 C.F.R. § 701.3 (2017); Fair Packaging and Labeling Act § 454(c)(3), 15 U.S.C. § 1454(c)(3) (2012).

199. California Safe Cosmetics Act § 1(d), CAL. HEALTH & SAFETY CODE § 111791.

200. *See Policy on Sustainable Chemistry in Consumables*, WALMART (last updated Feb. 21, 2014), https://perma.cc/UUU2-ZMAW; Melody M. Bomgardner, *Walmart and Target Take Aim At Hazardous Ingredients*, CHEMICAL & ENGINEERING NEWS (Feb. 17, 2014), https://perma.cc/QX6T-DJKT; Lauren

regulation still falls short, as demonstrated by the case of Bisphenol A ("BPA"), an EDC used as a plasticizer and in epoxy resin canned food lining.[201] In 2008, manufacturers began phasing out the use of BPA in selected consumer products with the presumption that alternative formulations would pose less risk to consumers.[202] However, many reformulated products contain Bisphenol S, which emerging research suggests also acts an EDC and poses similar risk concerns to BPA.[203] This example demonstrates a number of limitations with retailer regulation. For instance, manufacturers may simply replace toxicants with other chemicals with unknown risk profiles, or even other chemicals also linked to risk of adverse health concerns.[204] This leaves the toxic alternative in the marketplace for years until adequate proof of harm emerges.

D. Amending the FDCA

Despite the positive intentions of these solutions, each has significant shortcomings, and adequate reform requires uniform federal regulation for comprehensive and effective change. In 2015, Senator Dianne Feinstein introduced in Congress the Personal Care Products Safety Act, which would amend the FDCA to permit manufacturer registration and the FDA to slowly review priority-listed chemicals based on risk.[205] However, Senator Feinstein is not the first to introduce such legislation—and such previous attempts have failed repeatedly.[206] It is critical to develop a comprehensive regulatory framework that reviews risk assessment data

Coleman-Lochner & Shannon Pettypiece, *Target Expands List of Chemicals It Wants Out of Consumer Goods*, BLOOMBERG (Sept. 28, 2015, 12:01 AM), https://perma.cc/BUR8-RRES; Marc Gunther, *A Toxic Situation: Walmart and Target Take On Chemical Safety*, THE GUARDIAN (Dec. 17, 2013), https://perma.cc/YX5E-ZKBY.

201. *See generally Endocrine Disruptors*, NAT'L INST. ENVTL. HEALTH SCI.'S (Mar. 31, 2015), https://perma.cc/HNB9-BWVH.

202. BREAST CANCER FUND ET AL., BUYER BEWARE: TOXIC BPA AND REGRETTABLE SUBSTITUTES FOUND IN THE LININGS OF CANNED FOOD 7, 15–17 (2016), https://perma.cc/M5LG-U4HH; Jane Houlihan et al., *Timeline: BPA From Invention to Phase Out*, ENVTL. WORKING GRP. (Apr. 22, 2008), https://perma.cc/9GBM-NXG4.

203. Jenna Bilbrey, *BPA-Free Plastic Containers May Be Just as Hazardous*, SCIENTIFIC AMERICAN (Aug. 11, 2014), https://perma.cc/KB4C-H44F.

204. BREAST CANCER FUND ET AL., *supra* note 202, at 15–17.

205. *See* Personal Care Products Safety Act, S. 1014, 114th Cong. (2015).

206. Watnick II, *supra* note 41, at 643–49.

prior to a cosmetic product's marketing. It is equally as crucial that this framework recognize the potential of toxicants such as EDCs to induce subcellular injury in the form of epigenetic harm, both present and transgenerational. Reactionary policies that respond in a fragmented, chemical-by-chemical manner are inefficient and leave consumers exposed to demonstrated toxicants or equally harmful alternatives.

VII. CONCLUSION

Recent litigation against Johnson & Johnson over seemingly benign talc alerted the public to the unfortunate reality that the ingredients in cosmetic products we use daily are not FDA approved yet may expose us to adverse health risks. A growing body of research links cosmetic products containing potentially toxic ingredients—like talc and EDCs like parabens, phthalates, and PFOA—to an increased risk of cancer that is otherwise preventable. Although the FDA's risk-based approach prohibits manufacturers from placing adulterated or misbranded products in the stream of commerce, the FDCA does not require that the FDA assess the safety of the ingredients of cosmetics, and the FDA has no authority to recall demonstrably harmful cosmetics. Emerging scientific knowledge of how EDCs function fundamentally challenges traditional notions of what constitutes acceptable risk; EDCs cause harm at low doses, accumulate, interact synergistically, and disproportionately impact society's most vulnerable: pregnant women, fetuses, and children.

For the current generation, cancer rates will likely continue to increase unless we abandon our failed risk-based and reactionary regulatory approach in favor of a precautionary framework designed to critically examine the role of toxicants in the Hallmarks of Cancer. Most problematically, consumer exposure to EDCs in cosmetics may induce permanent, transgenerational epigenetic deficiencies that increase future cohorts' risks of cancer, fertility issues, neurological deficits, and immune dysfunction. It is imperative that we re-envision a comprehensive regulatory model that recognizes the dangers of failing to adopt the precautionary principle for ingredients in cosmetics.