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NOTES

Cosmetic Crisis: The Obsolete Regulatory Framework of the Ever-Evolving Cosmetic Industry

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Cosmetics only first became regulated after a series of tragic events where users were seriously harmed from the use of cosmetic products. These tragic events prompted legislators to enact the Food, Drug, and Cosmetics Act of 1938. Before then, law makers feared that regulating the cosmetic industry would lower the tone of legislation because they considered the cosmetic industry to be inconsequential. At present, the regulatory system in place to protect vulnerable cosmetic consumers is nearly identical to when it was enacted over eighty-six years ago—even though the cosmetic market looks nothing like it did back then. The consumer base for cosmetics has expanded drastically, and consumers use more products daily. Further, scientific advancements now reveal the safety or danger of chemicals within the products. Given the multitude of studies indicating the presence of dangerous chemicals latent in cosmetics, the regulatory system requires modernization. Unfortunately, legislators consistently fail to

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pass legislation to regulate the industry and protect cosmetic consumers. Do legislators still consider the cosmetic market too inconsequential to regulate? This Note advocates for stricter cosmetic regulations, discusses alternative means of regulation reform, and evaluates the likelihood of legislators enacting such reform.

INTRODUCTION

In the United States, the average woman applies twelve different cosmetic products each day.[1] In doing so, they apply approximately

[1] *Toxic Beauty: Are Your Personal Care Products Putting Your Health at Risk?*, HARV. HEALTH PUBL'G (Apr. 1, 2020), https://www.health.harvard.edu/womens-health/toxic-beauty; Sydney Lupkin, *Women Put an Average of 168 Chemicals on Their Bodies Each Day, Consumer Group Says*, ABC NEWS (Apr. 27, 2015, 2:26 PM), https://abcnews.go.com/Health/women-put-average-168-chemicals-bodies-day-consumer/story?id=30615324; Amy Westervelt, *Not So Pretty: Women Apply an Average of 168 Chemicals Every Day*, GUARDIAN

168 different chemicals to their body.[2] While women remain the predominant consumer of cosmetics,[3] men nonetheless apply roughly eighty-five chemicals daily.[4] Additionally, recent trends reveal that individuals emerge into the cosmetic market at a younger age.[5] On average, teens use seventeen cosmetic products per day.[6] Viewed alone, these statistics do not raise a cause for concern. Yet, coupled with the multitude of studies indicating the presence of dangerous chemicals in cosmetic products, the rampant use of cosmetic products in the United States is alarming.[7] Even more alarming is the fact that federal regulations fail to adequately protect consumers from exposure to the harmful substances latent in cosmetics.[8]

The detrimental results of inadequate cosmetic regulation are blatant. One in five cosmetic products contain at least one ingredient linked to cancer.[9] More than fifty percent of cosmetics contain chemicals known to cause serious adverse health effects, including

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(Apr. 30, 2015, 12:20 PM), https://www.theguardian.com/lifeandstyle/2015/apr/30/fda-cosmetics-health-nih-epa-environmental-working-group.

[2] Lupkin, *supra* note 1.

[3] *Beauty Market Ruled By Female Millennials*, PYMNTS (Dec. 15, 2016), https://www.pymnts.com/news/retail/2016/beauty-market-ruled-by-female-millennials/.

[4] Lupkin, *supra* note 1.

[5] See *Experts Concerned About Factors Influencing Kids to Wear Makeup Younger*, WKTR, https://www.wtkr.com/2019/09/30/experts-concerned-about-factors-influencing-kids-to-wear-makeup-younger/ (Sept. 30, 2019, 9:49 PM) (reporting that individuals now begin using beauty products as preteens, as compared to early adulthood).

[6] Lupkin, *supra* note 1.

[7] *See, e.g.*, Mathew Daly, *Study: Half of US Cosmetics Contain Toxic Chemicals*, PHYS.ORG (June 15, 2021), https://phys.org/news/2021-06-cosmetics-toxic-chemicals.html; Biljana Kaličanin & Dragan Velimirović, *A Study of the Possible Harmful Effects of Cosmetic Beauty Products on Human Health*, 170 BIOLOGICAL TRACE ELEMENT RSCH. 476, 476–77, 483 (2016).

[8] *See* Michael Kwa et al., *Adverse Events Reported to the US Food and Drug Administration Events for Cosmetics and Personal Care Products* 177 JAMA INTERNAL MED. 1202, 1203 (2017); Linda S. Birnbaum, *FDA Fails to Protect Public From Health Risks Linked to Chemicals in Food, Cosmetics*, DEFENDER: CHILD.'S HEALTH DEF. NEWS & VIEWS (May 2, 2022), https://childrenshealthdefense.org/defender/fda-health-risks-chemicals-food-cosmetics/.

[9] Niha Naveed, *The Perils of Cosmetics*, 6 J. PHARM. SCI. & RSCH. 338, 338 (2014).

high cholesterol and weakened immune systems.[10] One study identified the presence of sixteen hormone-altering chemicals in teenagers, indicating that the harmful ingredients in cosmetic products entered their bodies.[11] While these findings are appalling, they are not surprising. Only a mere ten percent of the 10,500 chemicals found in cosmetic products have been evaluated for safety by the Food and Drug Administration ("FDA").[12]

Currently, the system in place for regulating cosmetics has been left largely unchanged for over eighty-six years.[13] The enactment of the Food, Drug, and Cosmetics Act of 1938 ("FDCA") marks the last significant shift in cosmetic regulation.[14] The FDCA has been widely criticized for the limited protections available to ensure the safety of cosmetics.[15] Many question the disparity between the comprehensive and stringent regulations in place for drugs and the minimal and permissive regulations for cosmetics.[16] Nonetheless, the FDCA was a major victory for cosmetic regulation because prior to its passage, there were no regulations to ensure the safety of cosmetics.[17] While this was a significant achievement at the time, the cosmetic market has evolved considerably since then. For example, the cosmetic market has grown and continues to grow exponentially.[18] Currently, the total annual sales of cosmetics surpass the total sales

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[10] Karen Shelby, *45% of People Worry About Toxic Makeup – Should You?*, ASBESTOS, https://www.asbestos.com/featured-stories/makeup-toxicity-survey/ (Sept. 13, 2021).

[11] Lupkin, *supra* note 1.

[12] Lisa M. Chan et al., *Female College Student Awareness of Exposures to Environmental Toxins in Personal Care Products and Their Effect on Preconception Health*, 63 WORKPLACE HEALTH & SAFETY 64, 64 (2015).

[13] Scott Faber, *80 Years Later, Cosmetics Chemicals Still Unregulated*, ENV'T WORKING GRP. (June 25, 2018), https://www.ewg.org/news-insights/news/80-years-later-cosmetics-chemicals-still-unregulated.

[14] *Id.*

[15] *See, e.g.*, Laura A. Heymann, *The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids*, 52 FOOD & DRUG L.J. 357, 363.

[16] *See id.* at 363–64.

[17] Amity Hartman, *FDA's Minimal Regulation of Cosmetics and the Daring Claims of Cosmetic Companies That Cause Consumers Economic Harm*, 36 W. ST. U. L. REV. 53, 56 (2019).

[18] *See* Jonas Sickler, *Beauty Industry: Cosmetic Market Share, Trends, and Statistics*, TERAKEET, https://terakeet.com/blog/beauty-industry/ (last visited Jan. 3, 2022).

generated shortly after the FDCA's passage by over 3,000 times.[19] The growth in sales is partly attributable to the more diverse consumer base for cosmetics, which now expands beyond the scope of adult women.[20] Even further, scientific advancements in cosmetic research altered the cosmetic market by providing data indicating the safety of certain substances.[21] Such changes necessitate contemporary and more stringent regulations crafted to ensure the safety of cosmetics and protect consumers.

Almost all efforts of modernizing cosmetic regulations to meet the safety needs of consumers and emulate the protections afforded in other countries have been unsuccessful.[22] Consequently, the safety of cosmetics has been largely left to industry self-regulation, consisting primarily of voluntary programs and blind trust in cosmetic brands to certify the safety of their own products.[23] Given that studies indicate that half of cosmetics contain chemicals linked to

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[19] *See id.*; Casey Mee Lee Daum, Self-Regulation in the Cosmetics Industry: A Necessary Reality or a Cosmetic Illusion? (May 2006) (Third Year Written Work Requirement, Harvard Law School), https://dash.harvard.edu/bitstream/handle/1/8965615/Daum06.html (citing Peter Barton Hutt, *A History of Government Regulation of Adulteration and Misbranding of Cosmetics*, *in* COSMETIC REGULATION IN A COMPETITIVE ENVIRONMENT 1 (Norman F. Estrin & James M. Akerson eds., 2000)). In 2020, cosmetics sales exceeded $480 billion. Sickler, *supra* note 18. In 1940, shortly following the FDCA's enactment, cosmetics sales reached $150 million. Daum, *supra* note 19.

[20] *See* Daum, *supra* note 19; Nia Warfield, *Men are a Multibillion Dollar Growth Opportunity for the Beauty Industry*, CNBC (May 20, 2019, 3:20 PM), https://www.cnbc.com/2019/05/17/men-are-a-multibillion-dollar-growth-opportunity-for-the-beauty-industry.html; Bridget March, *Do Girls Really Now Wear Makeup at 11-Years-Old?*, COSMOPOLITAN (Mar. 17, 2014), https://www.cosmopolitan.com/uk/beauty-hair/news/a25794/girls-start-wearing-makeup-aged-11/.

[21] *See* Liz Grubow & Elle Morris, *The Role of Science in Beauty*, GLOB. COSM. INDUS. (Mar. 9, 2012), https://www.gcimagazine.com/brands-products/color-cosmetics/article/21849701/the-role-of-science-in-beauty; Kaličanin & Velimirović, *supra* note 7, at 476–77.

[22] *See, e.g.*, 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, 245 (discussing cosmetic reform bills that have failed to be enacted).

[23] *See* Gabrielle Eriquez, *Makeup Call: How Cosmetic Product Use Affects Women Absent Federal Regulation*, 25 WM. & MARY J. RACE, GENDER, & SOC. JUST. 221, 231 (2019); *infra* Section II.A.

serious adverse health effects,[24] the current laissez-faire, self-regulation system is unequivocally insufficient and requires modification.[25] Recognizing the deficiencies in the current system and the gravity of the potential health consequences prompted lawmakers to introduce the Safer Beauty Bill Package of 2021 ("SBBP").[26] To date, the SBBP has only been introduced to the House of Representatives and referred to the House Committee on Energy and Commerce.[27] Despite previous failed efforts, passage of the SBBP, or at least part of the four standalone bills, seems hopeful.[28]

This Note argues that the SBBP's strict and extensive provisions tailored specifically to concerns unique to the cosmetic industry make it the optimal solution for repairing cosmetic regulations. There are, however, alternative solutions—namely, redefining the

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[24] Daly, *supra* note 7.

[25] *See infra* Section II.A.

[26] Press Release, United States Congresswoman: Jan Schakowsky, Schakowsky Announces The Safer Beauty Bill Package to Protect Consumers From Harmful Products in Cosmetics and Personal Care Products (July 29, 2021), https://schakowsky.house.gov/media/press-releases/schakowsky-announces-safer-beauty-bill-package-protect-consumers-harmful.

[27] *All Actions H.R. 5537 – 117th Congress (2021–2022): Bill History – Congressional Record References*, CONGRESS, https://www.congress.gov/bill/117th-congress/house-bill/5537/all-actions?q=%7B%22action-by%22%3A%22all%22%2C%22house-committees%22%3A%22all%22%7D (last visited Jan. 25, 2022); *All Actions H.R. 5538 – 117th Congress (2021–2022): Bill History – Congressional Record References*, CONGRESS, https://www.congress.gov/bill/117th-congress/house-bill/5538/actions?q=%7B%22search%22%3A%5B%22H.R.5538%22%2C%22H.R.5538%22%5D%7D&r=1&s=1 (last visited Jan. 25, 2022); *All Actions H.R. 5539 – 117th Congress (2021–2022): Bill History – Congressional Record References*, CONGRESS, https://www.congress.gov/bill/117th-congress/house-bill/5539?q=%7B%22search%22%3A%5B%22H.R.5539%22%2C%22H.R.5539%22%5D%7D&s=2&r=1 (last visited Jan. 25, 2022); *All Actions H.R. 5540 – 117th Congress (2021–2022): Bill History – Congressional Record References*, CONGRESS,https://www.congress.gov/bill/117th-congress/house-bill/5540/all-ations?q=%7B%22search%22%3A%5B%22H.R.5540%22%2C%22H.R.5540%22%5D%7D&s=3&r=1 (last visited Jan. 25, 2022). H.R. 5540, the Cosmetic Safety for Communities of Color and Professional Salon Workers Act of 2021, was also referred to the Committee on Education and Labor for consideration of the provisions that fall within that committee's jurisdiction.

[28] Alexandra B. Cunningham & Elizabeth Reese, *"Safer Beauty" Bill Package Targets PFAS, Phthalates, Formaldehyde, and Other Common Chemicals in Cosmetics*, 11 NAT'L L. REV., Oct. 26, 2021, at 4.

terms "drug" and "cosmetic" under the FDCA—that may also help remedy the flaws of the current system. This Note argues that while the passage of the SBBP would best meet the needs of the cosmetic industry, any change in the current regulation would be a critical step in the right direction. Part I describes the history of cosmetic regulation and details provisions within the FDCA, focusing on the distinction between cosmetic and drug regulation. Part II addresses the evolution of the cosmetic market and describes the current regulation of cosmetics. Part III discusses the most recent proposals to modify the regulatory system of cosmetics, evaluates the likelihood of Congress approving any changes, and provides alternative solutions to improve the current regulatory system.

I. HISTORY OF THE REGULATION OF COSMETICS

A. *Food and Drugs Act of 1906*

In 1906, Congress enacted the predecessor of today's cosmetic regulation act without mention of cosmetics.[29] This Act was the first comprehensive federal consumer protection law and its focus centered on the prevention of misbranded and adulterated food and drugs in interstate commerce.[30] Despite its shortcomings, the Food and Drugs Act of 1906 paved the way for the FDA's modern regulatory functions.[31] However, among its shortcomings, the Act excluded large areas of commerce.[32] Notably, the Act failed to include cosmetics within its regulatory scope.[33]

The Act's exclusion of cosmetics can largely be attributed to a few factors. First, cosmetic consumers were comprised mostly of women—women who were unable to vote and thus unable to enact legislative change.[34] In addition, women only first began serving in

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[29] Daum, *supra* note 19.

[30] *How did the Federal Food, Drug, and Cosmetic Act Come About?*, FDA, https://www.fda.gov/about-fda/fda-basics/how-did-federal-food-drug-and-cosmetic-act-come-about (Mar. 28, 2018).

[31] *FDA History*, FDA, https://www.fda.gov/about-fda/fda-history (June 29, 2018).

[32] *See* Daum, *supra* note 19.

[33] *Id.*

[34] *Id.*

Congress in 1917;[35] therefore, they were unable to influence legislation from within Congress before then. Second, legislators believed that "the beauty industry was considered so inconsequential that its inclusion would have lowered the tone of legislation."[36] Admittedly, in 1900, the cosmetic industry did not generate a considerable amount of sales.[37] Yet, shortly thereafter, the cosmetic industry boomed in response to evolving consumer preferences.[38] Due to the increasing demand for cosmetic products as women sought to experiment with make-up and skincare products, business models shifted: small, largely women-owned cosmetic businesses evolved into large scale, mass-produced, male-owned cosmetics businesses.[39] As a result, by 1915, the market for cosmetics amassed more than $50 million dollars in sales.[40]

Unfortunately, as the industry boomed with no formal federal regulatory structure in place for cosmetics, consumers were left unprotected from dangerous products.[41] These dangerous products included Lash Lure, an eyebrow and lash dye manufactured in 1933, advertised as the "new and improved mascara [that] will give [users] a radiating personality."[42] In spite of these grand claims, several

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[35] *I'm No Lady: I'm a Member of Congress: Women Pioneers on Capitol Hill, 1917–1934*, HISTORY, ART & ARCHIVES UNITED STATES HOUSE OF REPRESENTATIVES, https://history.house.gov/Exhibitions-andPublications/WIC/Historical-Essays/No-Lady/Introduction/ (last visited Jan. 25, 2022).

[36] Daum, *supra* note 19.

[37] *Id.* ("[A]ccording to manufacturing census data on toilet items, with which cosmetics were included . . . sales of cosmetics in 1900 stood at about $100,000.").

[38] *See id.*

[39] *Cosmetics and Personal Care Products in the Medicine and Science Collections: Make-up*, SMITHSONIAN, https://www.si.edu/spotlight/health-hygiene-and-beauty/make-up (last visited Dec. 22, 2021).

[40] Roseann B. Termini & Leah Tressler*, Analyzing the Laws, Regulations, and Policies Affecting FDA-Regulated Products: American Beauty: An Analytical View of the Past and Current Effectiveness of Cosmetic Safety Regulations and Future Direction*, 63 FOOD DRUG L.J. 257, 258 (2008).

[41] Marie Boyd, *Gender, Race & the Inadequate Regulation of Cosmetics*, 30 YALE J. L. & FEMINISM 275, 312–315 (2018).

[42] Alice T. Gasch, *Lash Lure and Paraphenylenediamine: Toxic Beauty Past and Present*, AM. ACAD. OF OPHTHALMOLOGY (Nov. 2, 2017), https://www.aao.org/senior-ophthalmologists/scope/article/lash-lure-paraphenylenediamine-toxic-beauty.

Lash Lure users suffered severe adverse reactions from the product.[43] One woman's use of the product caused burning and swelling immediately upon application, leaving her unable to open the affected eye.[44] Thereafter, she became ill and had a high fever.[45] Despite medical treatment, the woman died eight days after using the product.[46] Because of this fatality, other instances of severe allergic responses to Lash Lure, and growing evidence of the dangers posed by the product, doctors warned that the application of Lash Lure caused "disastrous effects" and stated that "some way should be found to prevent their use."[47]

Lash Lure was only one of many products that harmed innocent consumers prior to the enactment of the Food, Drug, and Cosmetics Act of 1938.[48] For example, Koremlu, a product containing thallium acetate, a chemical used as rat poison, was marketed to consumers as a "safe and permanent hair-removing cream."[49] Its dangerous side effects included hair loss outside of the application site, paralysis, and eye damage.[50] Following the numerous accounts of serious poisonings from the product's use, doctors referred to Koremlu as a "viciously dangerous depilatory."[51] Gouraud's Oriental Cream similarly marketed their skin cream as a safe product and promoted it as a "magic beautifier."[52] Again, these remarkable claims were in sharp contrast to the products true effects.[53] The cream contained toxic levels of mercury that resulted in dark rings around eyes and necks, bluish black gums, and loose teeth from mercury poisoning.[54]

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[43] S. B. Forbes & W. C. Blake, *Fatality Resulting From the Use of Lash-Lure on the Eyebrow and Eyelashes*, 103 JAMA 1441, 1441 (1934).

[44] *Id.*

[45] *Id.*

[46] *Id.* at 1442.

[47] *Id.*

[48] *See* Kat Eschner, *Three Horrifying Pre-FDA Cosmetics: From Mercury-Loaded Face Cream to Mascara that Left You Blind*, SMITHSONIAN MAG. (June 26, 2017), https://www.smithsonianmag.com/smart-news/three-horrifying-pre-fda-cosmetics-180963775/.

[49] *Id.*

[50] *Id.*

[51] *See* Louis Sattler, *Correspondence: Koremlu Cream—A Disclaimer*, 99 JAMA 1710, 1710–11 (1932).

[52] *See* Eschner, *supra* note 48.

[53] *See id.*

[54] *Id.*

As noted in the 1933 FDA Annual Report, "federal law was 'wholly without jurisdiction over cosmetics, except in those rare instances when the labeling bear[ed] medicinal claims.'"[55] Consequently, the aforementioned products and others which likewise produced hazardous effects, were left unchecked and readily available for use by vulnerable consumers.[56]

B. *Food, Drug and Cosmetics Act of 1938*

New regulation often follows critical events such as crises, tragedies, or scandals.[57] Cosmetic regulation is no exception. Legal scholars have noted that the tragedies resulting from the lack of cosmetic regulation, such as those described above, "provided the political impetus and momentum for legislative change in the form of increased federal regulation of cosmetic products."[58]

In 1938, Congress enacted the FDCA, expanding the FDA's jurisdiction to encompass cosmetic products[59] and prohibit the adulteration and misbranding of cosmetics.[60] A product may be considered adulterated, and thus prohibited from entering interstate commerce, if it (1) contains any substance which may cause injury to users if used as prescribed on the product's label or conditions of customary use;[61] (2) consists of any "filthy, putrid, or decomposed" substance;[62] (3) was prepared, packed, or held under unsanitary conditions whereby it may have become harmful to users;[63] (4) was contained in a poisonous or deleterious substance which may render the

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[55] Boyd, *supra* note 41, at 314 (citing CHARLES WESLEY DUNN, FEDERAL FOOD, DRUG AND COSMETIC ACT: A STATE OF ITS LEGISLATIVE RECORD 156 (1938) (reproducing 78 Cong. Rec. 8966–67 (May 16, 1934))).

[56] *See* Eschner, *supra* note 48.

[57] *See* Daniel Carpenter & Gisela Sin, *Policy Tragedy and the Emergence of Regulation: The Food, Drug, and Cosmetic Act of 1938*, 21 STUDIES IN AM. POL. DEV. 149, 149 (2007). This holds true beyond the context of cosmetics. *Id.* Tragedies such as the Union Carbides gas leak in Bhopal, India and birth defects from the use of the thalidomide sedative prompted regulation. *Id.*

[58] Daum, *supra* note 19.

[59] *Id.*

[60] 21 U.S.C. §§ 361, 362; *see also* Grace Wallack, *Rethinking FDA's Regulation of Cosmetics*, 56 HARV. J. ON LEGIS. 311, 313 (2019).

[61] 21 U.S.C. § 361(a). This provision explicitly states that it does not apply to coal-tar hair dye and details the regulation for such coal-tar hair dye products. *Id.*

[62] 21 U.S.C. § 361(b).

[63] 21 U.S.C. § 361(c).

contents injurious to health;[64] or (5) bears or contains a color additive which is deemed unsafe within the Act.[65]

To avoid misbranding, a cosmetic product's packaging must bear a label containing "the name and place of business of the manufacturer, packer, or distributor" and "an accurate statement of the quantity of the contents in terms of weight, measure or numerical count."[66] In addition, a cosmetic product may be deemed misbranded and thus prohibited from introduction into interstate commerce if (1) its labeling is false or misleading; (2) any information required to appear on the label is not prominently and conspicuously placed to render it likely to be read under customary conditions; and (3) its container is made, formed, or filled to be misleading.[67]

Given that there was no previous regulatory structure in place for cosmetics prior to this Act, the FDCA was regarded as a significant leap in the regulation of cosmetics.[68] Nonetheless, the mere classification of a product as a cosmetic as opposed to a drug subjects the product to far less stringent standards.[69]

1. CLASSIFICATION OF PRODUCTS: DRUGS OR COSMETICS OR BOTH

Whether a product is classified as a drug, cosmetic, or both, has a significant impact on the regulations the product is subject to and in turn, the protections afforded to consumers.[70] The FDCA defines cosmetics as

> (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced onto, or otherwise applied to the human body or any part thereof for cleansing,

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64 21 U.S.C. § 361(d).

65 21 U.S.C. § 361(e). This provision does not apply to hair dye. *Id.* The regulations of color additives, including which color additives are deemed unsafe under the FDCA, can be found at 21 U.S.C. § 379(e). *Id.* Notably, unlike cosmetics generally, color additives must be approved by the FDA for use in food, drugs, cosmetics, and medical devices. *See id.*; 21 U.S.C. § 379(e).

66 21 U.S.C. § 362(b). This provision also notes that reasonable variations and exceptions may be made by the Secretary for small packages.

67 21 U.S.C. § 362(a), (c)–(d).

68 Hartman, *supra* note 17, at 56.

69 *Id.* (citing Heymann, *supra* note 15, at 363).

70 *Id.* at 59–60.

> beautifying, promoting attractiveness, or altering appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.[71]

Products such as nail polish, lipstick, perfume, and hair dye are classified as cosmetics.[72] Drugs, on the other hand, include articles "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and articles intended to "affect the structure or any function of the body."[73] In addition, a product can meet the definition of both a cosmetic and a drug.[74] Such products are often referred to as "cosmeceuticals," though the Act makes no mention of this term.[75] For example, a foundation or setting powder with SPF protection and marketed for its sun-protection capabilities would fall into the category of both a cosmetic and a drug.[76]

The critical inquiry in classifying a product as a drug or cosmetic is determining the product's intended use.[77] The FDA provides some guidance for determining a product's intended use.[78] Although intended use may be established in various ways, the FDA provides three examples of how to determine intended use.[79] First, "[c]laims stated on the product labeling, in advertising, on the Internet, or in other promotional materials" may establish that the product is a drug or cosmetic.[80] Notably, the FDA specifies that claims made in a product's marketing may result in it being classified as one type of

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71 21 U.S.C. § 321(i).

72 *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, FDA, https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap#Cosmeceutical (Feb. 22, 2022).

73 21 U.S.C. § 321(g)(1).

74 *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, *supra* note 72 (noting that when a product is classified as both a drug and cosmetic, the product must therefore meet the requirements in place for both drugs and cosmetics).

75 *Id.*

76 *See id.*

77 *See* United States v. An Article of a Drug Consisting of 216 Individually Cartoned Bottles, More or Less, of an Article Labeled in part: Sudden Change, 409 F.2d 734, 741–42 (2d Cir. 1969).

78 *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, *supra* note 72.

79 *Id.*

80 *Id.*

product, despite the product being marketed under a different category.[81] A skin cream marketed as a cosmetic product, for instance, may nonetheless be deemed a drug if it contains claims such as reducing cellulite because affecting the structure of the human body is its intended use.[82] Second, consumer perception is another means of determining a product's intended use.[83] Specifically, a product's reputation, including a consumer's reason for purchasing the product and their expectation when using the product may also be indicative of the product's intended use.[84] Lastly, ingredients may "cause a product to be considered a drug because they have a well-known (to the public and the industry) therapeutic use, [such as] fluoride in toothpaste."[85]

In addition to the FDA's guidance, legal precedent has been instrumental in delineating the distinction between drugs and cosmetics—especially in light of the claims cosmetic brands make when marketing to consumers.[86] In *Sudden Change,* the Second Circuit recognized that consumers are constantly exposed to "puffing and extravagant claims" and thus, "even the 'ignorant, the unthinking and the credulous' [consumer] must be presumed able to discount their promises as typical of cosmetic advertising puffery."[87] Notwithstanding, the *Sudden Change* court pointed to the lotion at issue's labeling, which claimed that it gives "a face lift without surgery,"[88] and stated that such a claim "carr[ies] distinctively physiological connotations, suggesting, at least to the vulnerable consumer, that the product will 'affect the structure of the body' in some way other than merely temporarily altering the appearance."[89] In holding that the lotion was a drug and thus subject to the corresponding requirements, the court set out the following rule:

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81 *See id.*

82 *See id.*

83 *Id.*

84 *Id.*

85 *Id.*

86 Hartman, *supra* note 17, at 60; *see also* United States v. An Article of a Drug Consisting of 216 Individually Cartoned Bottles, More or Less, of an Article Labeled in part: Sudden Change, 409 F.2d 734, 739 (2d Cir. 1969).

87 *Sudden Change*, 409 F.2d at 741.

88 *Id.* (quotation marks omitted).

89 *Id.*

> [W]ith the exception of those claims which have become so associated with the familiar exaggerations of cosmetics advertising that virtually everyone can be presumed to be capable of discounting them as puffery, the question of whether a product is "intended to affect the structure of the body of man" is to be answered by considering, first, how the claim might by understood by the 'ignorant, unthinking or credulous' consumer, and second, whether the claim as so understood may fairly be said to constitute a representation that the product will affect the structure of the body in some medical—or drug type fashion, i.e., in some way other than merely "altering the appearance."[90]

Thereafter, other courts, including the Third Circuit in *Line Away*, applied the rule set forth above. The *Line Away* court explained that though "[s]ome 'puffery' may not amount to representation of a cosmetic as a drug, [] when 'puffery' contains [] strong therapeutic implications . . . , the dividing line [between a drug and cosmetic] has been crossed."[91] However, in *Magic Secret*, a case markedly similar to *Sudden Change* and *Line Away*, the court reached a different outcome when applying the *Sudden Change* standard.[92] In the court's view, claims such as a "'pure protein' which causes an 'astringent sensation'" do not rise to the level of exaggeration nor carry the same drug connotation as in *Line Away* or *Sudden Change*.[93] Consequently, the court held that Magic Secret, the product in question, was not intended to affect the structure

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[90] *Id.* at 741–42.

[91] United States v. An Article of Drug Consisting of 36 Boxes, More or Less, Each Containing One Bottle of An Article Labeled in Part "Line Away Temporary Wrinkle Smoother, Coty," 415 F.2d 369, 373 (3d Cir. 1969) (classifying a product with packaging stating "amazing protein lotion," "pharmaceutical laboratory," and "packaged under biologically aseptic conditions" as a drug).

[92] Hartman, *supra* note 17, at 61–62; *see generally* United States v. An Article of Drug Consisting of 47 Shipping Cartons, More or Less, Each Containing One Bottle of an Article Labeled in Part "Helene Curtis Magic Secret," 331 F. Supp. 912 (D. Md. 1971).

[93] *Magic Secret*, 331 F. Supp. at 917.

of the body and thus is not a drug under the FDCA.[94] The foregoing cases demonstrate the difficulties in classifying a product as either a drug or a cosmetic product.[95]

2. THE DISPARITY BETWEEN THE REGULATIONS OF COSMETICS AND DRUGS

A product's classification as either a drug or cosmetic has a profound impact on the regulations the product is subject to.[96] As stated above, the FDA has significantly greater authority over the regulation of drugs as opposed to cosmetics.[97] Given the disparity in regulations, cosmetic companies are incentivized to attempt having their product categorized as a cosmetic to avoid the stringent regulations required for drugs.[98]

One of the most significant hurdles a cosmetic company may avoid if not classified as a drug is premarket review.[99] Specifically, cosmetics, except those which contain color additives, do not require premarket approval by the FDA.[100] Drugs, in contrast, must undergo the premarket approval process.[101] This process is formally initiated when the drug is proposed to the FDA for sale and marketing in the United States.[102] Before submitting this proposal, however, the company must acquire data from clinical trials "to provide evidence of a drug's safety and effectiveness."[103] This requires the

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[94] *Id.*

[95] *See supra* notes 86–93 and accompanying text.

[96] *See Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, *supra* note 72 (describing the differing laws and regulations for cosmetics and drugs, such as good manufacturing practice requirements, registration requirements, and labeling requirements).

[97] Heymann, *supra* note 15, at 363 ("Drug regulation, [in] contrast [to cosmetics], is considerably more extensive, with much of the statutory subchapter devoted to safety.").

[98] *See* Hartman, *supra* note 17, at 60.

[99] *See* Heymann, *supra* note 15, at 363; *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, *supra* note 72.

[100] *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, *supra* note 72.

[101] *Id.*; *see also* 21 U.S.C. § 360.

[102] *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, *supra* note 72.; *see also* 21 U.S.C. § 360.

[103] AGATA DABROWSKA & SUSAN THAUL, CONG. RSCH. SERV. R41983, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS 4–5 (2018). With respect to safety, the FDA determines "the highest tolerable dose

company to file an investigational New Drug Application with the FDA and conduct several trial phases, typically with animals first, then followed by humans.[104] When submitting a New Drug Application, the company must include extensive amounts of information such as (1) the clinical trial results, (2) information about the manufacturing process, (3) quality control and assurance procedures, (4) production descriptions, including the chemical formula, specifications as to the intended purpose, and population of users, (5) labeling, and (6) a proposed Risk Evaluation and Mitigation Strategy.[105] The information is then utilized by the FDA's scientific and regulatory personnel to review the application.[106] Specifically, the FDA must consider:

> Whether the drug is safe and effective in its proposed use, and whether the benefits of the drug outweigh the risks[; w]hether the drug's proposed labeling (package insert) is appropriate, and what it should contain[; and w]hether the methods used to manufacture the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.[107]

An application will be approved only where there is "substantial evidence of drug safety and effectiveness."[108] In light of the FDA's extensive drug approval process,[109] one may question why cosmetic

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or the optimal dose of a drug needed to achieve the desired benefit." *Id.* The FDA looks to toxicity testing and studies to identity any potential adverse effects from the drug. Efficacy requires the FDA to discern whether use of the drug results in a health benefit "over a placebo or other intervention when tested in an ideal situation." *Id.* Lastly, as to effectiveness, the FDA considers how the drug works in a real-world situation. *Id.*

104 *Id.* at 4–5; 21 U.S.C. § 360.

105 DABROWSKA & THAUL *supra* note 103, at 5–6; 21 U.S.C. § 360.

106 DABROWSKA & THAUL *supra* note 103, at 6–8; 21 U.S.C. § 360.

107 DABROWSKA & THAUL *supra* note 103, at 6.

108 *Id.* at 6–8 (specifying that the "FDA has interpreted ['substantial evidence' of drug safety and effectiveness] to mean that the manufacturer must provide at least two adequate and well-controlled Phase III clinical studies, each providing convincing evidence of effectiveness"); 21 U.S.C. § 360.

109 *See* DABROWSKA & THAUL *supra* note 103, at 6; 21 U.S.C. § 360.

companies are not required to undergo any sort of premarket approval process. Instead, the FDA entrusts cosmetic manufacturers themselves with the responsibility of ensuring that their "products and ingredients are safe and properly labeled, in full compliance with the law."[110]

Additionally, the good manufacturing practice ("GMP") requirements differ between cosmetic products and drugs.[111] GMPs are minimum requirements designed to "assure proper design, monitoring, and control of manufacturing processes and facilities" for the purposes of ensuring the identity, strength, quality, and purity of products.[112] The FDA requires that drug manufacturers strictly adhere to the GMP requirements set forth for drugs.[113] In comparison, the FDA does not impose any GMP requirements for cosmetic manufacturers and solely provides GMP *guidelines*.[114]

Another aspect of FDA regulations that differs between cosmetics and drugs are the respective registration requirements.[115] In particular, cosmetic registration is voluntary whereas drug registration is compulsory.[116] Drug manufacturers must register their establishment with the FDA and must identify each drug manufactured at their establishment.[117] As to cosmetics, the FDA's voluntary reporting system, the Voluntary Cosmetic Registration Program

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[110] *See Voluntary Cosmetic Registration Program*, FDA, https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program (Mar. 29, 2022).

[111] *See Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, *supra* note 72.

[112] *Facts About the Current Good Manufacturing Practices* (CGMPs), FDA, https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps (June 1, 2021).

[113] *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, *supra* note 72; 21 C.F.R. §§ 210, 211.

[114] *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, *supra* note 72; *see generally Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist for Cosmetics*, FDA, https://www.fda.gov/cosmetics/cosmetics-guidance-documents/good-manufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics (Feb. 25, 2022).

[115] *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, *supra* note 72.

[116] *Id.*

[117] *Electronic Drug Registration and Listing System* (eDRLS), FDA, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/electronic-drug-registration-and-listing-system-edrls (Nov. 4, 2021); 21 C.F.R. § 207.

("VCRP"), allows for cosmetic manufacturers to register their manufacturing facilities and importantly, allows them to file a statement detailing the ingredient list for their product.[118] As a result, the VCRP aids the FDA in regulating cosmetics by providing the "best estimate of information available about cosmetic products and ingredients, their frequency of use, and businesses engaged in their manufacture and distribution."[119] Yet its ability to truly aid in regulating cosmetics and protecting consumers is severely hindered by the fact that the VCRP is merely voluntary.[120]

While the regulations afforded to cosmetics pale in comparison to drugs or other products protected under the FDCA, there are a few regulations in place to protect cosmetic consumers.[121] For instance, the FDA is authorized to *request* that a company recall a product.[122] The FDA cannot itself order a recall of a product;[123] however, it may monitor the progress of a recall and conduct audits to verify the recall's effectiveness.[124] Furthermore, depending on the severity and/or probability of a health hazard of a cosmetic product, the FDA can issue a press release to warn consumers about the hazard.[125]

The FDA's list of harmful ingredients barred or restricted from use in cosmetic products also serves to protect consumers.[126] For

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[118] *Voluntary Cosmetic Registration Program*, *supra* note 110; 21 C.F.R. §§ 710, 720.

[119] *Voluntary Cosmetic Registration Program*, *supra* note 110.

[120] Daum, *supra* note 19 (emphasizing the criticisms of the cosmetic industry's voluntary self-regulations as "ineffective and inadequate for the protection of consumer safety").

[121] *See generally FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated*, FDA, https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated (Mar. 2, 2022).

[122] *FDA Recall Policy for Cosmetics*, FDA, https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-recall-policy-cosmetics (Mar. 3, 2022).

[123] *Id.*

[124] *Id.*

[125] *Id.*; *see also Cosmetics Recalls & Alerts*, FDA, https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/cosmetics-recalls-alerts (Feb. 25, 2022).

[126] *See Prohibited & Restricted Ingredients in Cosmetics*, FDA, https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics (Feb. 25, 2022); 21 C.F.R. § 700. Despite these provisions, any use of harmful ingredients in cosmetic products would be illegal because it is

instance, the FDA prohibits the use of chloroform in cosmetic products and restricts the use of mercury compounds to limited trace amounts because such ingredients have the potential to cause harm when used.[127] However, critics of the United States's regulation of cosmetics often disapprove of the FDA's list of a mere eleven ingredients that are banned or restricted.[128] Prominently, the United States's list of eleven ingredients is in sharp contrast to the long list of restricted ingredients in other countries and regions.[129] The European Union, for example, prohibits or restricts more than 1,300 ingredients from use in cosmetics.[130]

Furthermore, under the FDCA, the FDA limits and proscribes specific limitations for use of color additives in cosmetic products.[131] Unlike cosmetics in general, color additives require premarket approval and are subject to more stringent regulations.[132] Specifically, the FDA must approve and certify all products containing color additives, among other requirements set forth by the FDA.[133] Overall, it appears that though cosmetics are afforded protections by the FDA,[134] those protections are minimal as compared to other products regulated under the FDCA and even as compared to cosmetic regulations in other countries.[135]

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against the law for a cosmetic manufacturer to use an ingredient in its product which, when used as intended, would make their product harmful. *See Prohibited & Restricted Ingredients in Cosmetics*, *supra* note 126.

[127] *Prohibited & Restricted Ingredients in Cosmetics*, *supra* note 126; 21 C.F.R. §§ 700.13, 700.18.

[128] Oliver Milman, *US Cosmetics are Full of Chemicals Banned by Europe – Why?*, GUARDIAN (May 22, 2019, 2:00 PM), https://www.theguardian.com/us-news/2019/may/22/chemicals-in-cosmetics-us-restricted-eu.

[129] *See, e.g.*, Cosmetic Products Regulation, Annex III – Restricted Substances, EUR. CHEMS. AGENCY, https://echa.europa.eu/cosmetics-restricted-substances (Jan. 3. 2022) (listing the ingredients prohibited for use in cosmetic products in the European Union).

[130] *Id.*; *see also* Milman, *supra* note 128.

[131] *Color Additives and Cosmetics: Fact Sheet*, FDA, https://www.fda.gov/industry/color-additives-specific-products/color-additives-and-cosmetics-fact-sheet (June 28, 2022).

[132] *See id.*

[133] *Color Additives and Cosmetics: Fact Sheet*, *supra* note 131.

[134] *See FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated*, *supra* note 121.

[135] *See supra* note 97 and accompanying text.

II. REGULATION OF TODAY'S COSMETIC MARKET

Since the FDCA's enactment in 1938, the cosmetic industry has significantly changed.[136] The revenue generated from this booming market has exploded[137] in response to an increasing demand from consumers.[138] Scientific advancements,[139] an expanding consumer base,[140] and evolving consumer preferences[141] transformed the cosmetic industry. Despite the growth of the industry, nearly no advancements occurred in the regulation of cosmetics.[142] Such lack of action by Congress leaves many concerned of the long-term effects of consumers that remain vulnerable to the hazardous chemicals in cosmetics.[143]

A. *What Has Changed Since the FDCA's Enactment?*

As an initial matter, the sheer size of the cosmetics industry and the corresponding revenue, is one of the most significant industry

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136 Faber, *supra* note 13.

137 *See* Sickler, *supra* note 18.

138 *Cosmetics Market Size to Hit USD 415.29 Billion by [2021-2028]; Rising Awareness Regarding Health, Hygiene, and Grooming to Augment Industry Growth, Says Fortune Business Insights*, GLOB. NEWSWIRE (Sept. 15, 2021, 4:36 PM), https://www.globenewswire.com/newsrelease/2021/09/15/2297232/0/en/Cosmetics-Market-Size-to-Hit-USD-415-29-Billion-by-2021-2028-Rising-Awareness-Regarding-Health-Hygiene-and-Grooming-to-Augment-Industry-Growth-Says-Fortune-Business-Insights.html.

139 *See* Andrea Rinaldi, *Healing Beauty: More Biotechnology Cosmetic Products that Claim Drug-Like Properties Reach the Market*, 9 EMBO REPS. 1073, 1073 (2008).

140 *See* Warfield, *supra* note 20; March, *supra* note 20.

141 *See* Saloni Patil, Sabrina Placeres, and Lauren Cosby, *The Beauty Trends that are Driving Change, Including Among Multicultural Consumers*, IRI WORLDWIDE, https://www.iriworldwide.com/en-us/insights/blog/the-beauty-trends-that-are-driving-change-including-among-multicultural-consumers (last visited Jan. 3, 2022); *How the Inclusive Beauty Movement is Redefining the Industry*, CBS INSIGHTS (June 23, 2021), https://www.cbinsights.com/research/what-is-inclusive-beauty/. Consumers are increasingly demanding products that are more tailored to them. *How the Inclusive Beauty Movement is Redefining the Industry*, *supra* note 141. Such demands include products tailored to men, gender-neutral beauty products, and products available in a wide array of skin tones. *Id.*

142 Faber, *supra* note 13.

143 *Id.*

changes since the FDCA's enactment.[144] In 1940, shortly after the FDCA was enacted, the cosmetic industry generated approximately $150 million in sales.[145] The total sales of cosmetics in 2020, in comparison, was approximately $483 billion.[146] The industry's annual growth rate is 4.5% and thus, it is projected that by 2025 the industry's total revenue will exceed $716 billion.[147] In light of the COVID-19 pandemic and lockdowns, online channels for cosmetic sales increased by 5.6% in 2020.[148]

A multitude of factors are responsible for the growth and overall evolution of the beauty industry.[149] Prominently, the consumers of cosmetic products now encompass more demographic groups.[150] In the beginning of the twentieth century, women were, by and large, the only consumers of cosmetics.[151] Presently, however, men are also part of the cosmetic market.[152] A study conducted in 2017 found that approximately two-thirds of the men surveyed use facial skin care products.[153]

Even further, minority demographic groups are responsible for a considerable share of the market's consumers—so much so that they are "driving personal care shares."[154] This is likely due to the increased demand and achievements in diversity and inclusion

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144 *See* Sickler, *supra* note 18.

145 Daum, *supra* note 19 (citing PETER BARTON HUTT, A HISTORY OF GOVERNMENT REGULATION OF ADULTERATION AND MISBRANDING OF COSMETICS, in COSMETIC REGULATION IN A COMPETITIVE ENVIRONMENT 1 (Norman F. Estrin & James M. Akerson eds., 2000)).

146 Sickler, *supra* note 18.

147 *Id.*

148 *Id.*

149 *Id.*

150 *See, e.g.*, Andria Cheng, *The Surprising Trend in Beauty? Skincare Sales Growing the Fastest Among Men's Grooming Products*, FORBES (June 15, 2018, 6:00 AM), https://www.forbes.com/sites/andriacheng/2018/06/15/the-gift-your-dad-really-wants-this-fathers-day-anti-aging-cream/?sh=6a2ad0c733ba.

151 Daum, *supra* note 19.

152 GWEN KAY, DYING TO BE BEAUTIFUL: THE FIGHT FOR SAFE COSMETICS 126 (2005); Cheng, *supra* note 150.

153 Cheng, *supra* note 150. The percentage increases to 87% when confined to men between the ages of 18 and 44. *Id.*

154 *Multicultural Consumers are Set to Drive Beauty Growth Amid Continued Category Shifts in 2021*, NIELSENIQ (Apr. 12, 2021), https://nielseniq.com/global/en/insights/analysis/2021/multicultural-consumers-are-set-to-drive-beauty-growth-amid-continued-category-shifts-in-2021/.

within the cosmetics market.[155] Makeup brands, such as Fenty Beauty, made it a foundational element of their business model to foster diversity and inclusion.[156] Fenty Beauty's first launch in 2017 included over forty foundation shades to provide a shade for a wide array of skin tones, generating $100 million in sales within their first month.[157] Other companies followed suit, resulting in a widespread trend of inclusivity in the cosmetics industry.[158] Thus, as more brands continue to cater to a wider variety of people, sales in cosmetics will likely continue to grow.[159]

Additionally, individuals are entering into the cosmetic market from a younger age.[160] In the past, many individuals began wearing cosmetic products in early adulthood, starting around seventeen years old.[161] Presently, however, individuals begin emerging into the market as preteens.[162] A study conducted by a marketing agency found that roughly eighty percent of those aged nine to eleven years old wear some form of beauty product.[163] Further, the study found that "[m]ore than half of 12- to 14-year-olds use mascara, eyeliner and eyebrow pencils, and 45% also use foundation and concealer products, which is basically a full face of makeup."[164] Technology and social media allows marketers to reach younger individuals and

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155 *See* Alison Bringé, *All Eyes On Beauty: Why Diversity and Inclusivity are Key in the Beauty Industry*, FORBES (May 28, 2021, 7:20 AM), https://www.forbes.com/sites/forbescommunicationscouncil/2021/05/28/all-eyes-on-beauty-why-diversity-and-inclusivity-are-key-in-the-beauty-industry/?sh=5bb8bc057a38.

156 *See* Funmi Fetto, *How Fenty Beauty Changed the State of Play in the Industry*, VOGUE (Apr. 6, 2020), https://www.vogue.co.uk/beauty/article/rihanna-fenty-beauty-diversity.

157 *Id.*

158 *Id.*

159 *See supra* note 147 and accompanying text.

160 *See Experts Concerned About Factors Influencing Kids to Wear Makeup Younger*, *supra* note 5.

161 *Id.*

162 *Id.*

163 *Id.*

164 *Id.*

likely is a driving force in this change.[165] Even beyond young consumers, individuals of all ages are being exposed to marketing of cosmetic products, like makeup and skincare, through social media.[166] Such exposure drives the market and has significantly benefitted cosmetic brands.[167]

Furthermore, scientific advancement in the industry is one of the most prominent changes impacting cosmetics.[168] These substantial scientific advancements may serve to propel companies to create safer cosmetic products.[169] Specifically, these advancements allow researchers to study scientific evidence and determine which ingredients are potential causes for concern.[170] For instance, scientific data allowed researchers to study the long term effects of formaldehyde, a product found in skincare products, and identify its potentially carcinogenic effect.[171] Indeed, molecular biologists recognize the rise in usage of biological and chemical science research to create more sophisticated cosmetic products that contain drug-like properties.[172] Importantly, despite acknowledging that consumers may be lured by irresistible product claims, they conclude that "the increasing use of scientific research in the development of new cosmetics should ultimately benefit the consumer, as it contributes to the next generation of safer and more efficient beauty products."[173]

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[165] *See Beauty is Child's Play: 80% of US Tweens Use Beauty and Personal Care Products*, MINTEL (July 28, 2016), https://www.mintel.com/press-centre/beauty-and-personal-care/beauty-is-childs-play-80-of-us-tweens-use-beauty-and-personal-care-products; Bin Shen & Kimberly Bissell, *Social Media, Social Me: A Content Analysis of Beauty Companies' Use of Facebook in Marketing and Branding*, 19 J. PROMOTIONAL MGMT. 629, 629–30 (2013) (discussing the use of social media in cosmetic marketing).

[166] Werner Geyser, *How Social Media is Shaping the Beauty Industry (+5 Social Media Strategies for Beauty Brands)*, INFLUENCER MKTG. HUB, https://influencermarketinghub.com/social-media-beauty-industry/ (Sept. 22, 2021).

[167] *See id.; Skincare Brands Are Using TikTok to Spark Growth in 2021*, GLOSSY (Aug. 4, 2021), https://www.glossy.co/sponsored/skincare-brands-are-using-tiktok-to-spark-growth-in-2021/.

[168] *See* Grubow & Morris, *supra* note 21.

[169] *See* Rinaldi, *supra* note 139, at 1077.

[170] *See* Molly Wanner & Neera Nathan, *Clean Cosmetics: The Science Behind the Trend*, HARV. HEALTH BLOG (Mar. 12, 2019), https://www.health.harvard.edu/blog/clean-cosmetics-the-science-behind-the-trend-2019030416066.

[171] *Id.*

[172] Rinaldi, *supra* note 139, at 1073.

[173] *Id.* at 1077.

In addition, scientific advancements serve to illuminate the pressing concerns over the dangers present in many products left on the market.[174] Studies show the alarming presence of toxic chemicals found in cosmetics.[175] For example, key findings from a 2017 report by the California Department of Health indicated that "[c]osmetic products in [thirteen] different categories of personal care, ranging from beauty products to shaving and baby care products, have been reported to contain ingredients that may cause cancer or reproductive developmental harm."[176] In addition, a study conducted in 2016 at the University of Notre Dame found that "[m]ore than half of the cosmetics sold in the United States . . . contain high levels of a toxic industrial compound linked to serious health conditions, including cancer and reduced birth weight."[177] Given these shocking findings and the commensurate danger posed to human health, the researchers conducting the study urged for better governmental oversight of toxic chemicals in cosmetics.[178]

Another study found that synthetic chemicals known as phthalates may contribute from 91,000 to 107,000 premature deaths annually among people between the age of 55 and 64.[179] In addition to premature death, phthalates are known to impact testosterone, which increases the likelihood of mortality, obesity, and diabetes.[180] This synthetic chemical is often an ingredient in cosmetics, such as shampoo, makeup, and perfume.[181]

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[174] *See, e.g.*, Westervelt, *supra* note 1.

[175] *See generally* Heather D. Whitehead et al., *Fluorinated Compounds in North American Cosmetics* 8 ENVIRON. SCI. TECHNOL. LETT. 538, 538 (2021).

[176] PAULA I. JOHNSON ET AL., COSMETICS CONTAINING INGREDIENTS LINKED TO CANCER OR REPRODUCTIVE HARM: DATA REPORTED TO THE CALIFORNIA SAFE COSMETICS PROGRAM 2009–2015 1–2 (Scott Cottingham et al. eds., 2016).

[177] Daly, *supra* note 7; *see also* Whitehead et al., *supra* note 175, at 538. The toxic compound referenced in this study are per- and polyfluoroalkyl substances ("PFAS"). Daly, *supra* note 7.

[178] Whitehead et al., *supra* note 175, at 542.

[179] Sandee LaMotte, *Synthetic Chemical in Consumer Products Linked to Early Death, Study Finds*, CNN (Oct. 12, 2021, 4:34 PM), https://www.cnn.com/2021/10/12/health/plastic-chemical-early-death-wellness/index.html.

[180] *Id.*; *see also* Milica Medic Stojanoska et al., *The Influence of Phthalates and bisphenol A on the Obesity Development and Glucose Metabolism Disorders*, 55 ENDOCRINE 666, 666–67 (2017).

[181] LaMotte, *supra* note 179.

Furthermore, while studies have long established the danger posed by lead exposure,[182] more recent studies have tested the quantity of lead present in cosmetic products.[183] One study analyzing cosmetic products found that the presence of lead, and other potentially toxic chemicals, can have an "adverse effect on human health due to their highly toxic lead contents which could cause cumulative toxic effects."[184]

Studies have also revealed that exposure to toxic chemicals in cosmetic products are largely concentrated within certain demographic groups.[185] A study published by the American Journal of Obstetrics & Gynecology reported that women between the ages of eighteen and thirty-four are more likely to be "heavy buyers" of cosmetics, and thus are increasingly exposed to the toxic chemicals found in such products.[186] Notably, the study found that low-income and racial/ethnic minority groups are more susceptible to the harmful chemicals found in cosmetic products due to their more frequent exposure to "multiple environmental and social risk factors and face poorer health outcomes."[187] The study also addressed workers in the beauty industry which is predominantly comprised of women of color and immigrant women, who, by the nature of their work, are highly exposed to cosmetic products.[188] Specifically, researchers noted that cosmetic workers "face occupational health hazards from chemicals in professional cosmetic products and ad-hoc workplace

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[182] *See Caution: Lead Paint Handle With Care*, U.S. DEPT. OF HOUS. & URB. DEV., https://permanent.fdlp.gov/LPS108997/LPS108997/www.hud.gov/offices/lead/library/outreach/Trades.pdf (last visited Jan. 3, 2022).

[183] *See* Kaličanin & Velimirović, *supra* note 7, at 476–77. Researchers determined that "[t]he content of toxic metal lead in the tested lipsticks ranged from 16.67 to 105.60 μg/g." *Id.* at 480. Based on these findings, they stated that, "[t]he lead content in lipstick samples analyzed in this study is high and above some internal standards, which prescribe a maximum level of 20 μg/g of this heavy metal in cosmetic products. According to these recommended values, it can be said that the lead contents in the lipstick samples tested in this study can be seen as toxic." *Id.* at 480.

[184] *Id.* at 483.

[185] *See* Ami R. Zota & Bhavna Shamasunder, *The Environmental Injustice of Beauty: Framing Chemical Exposures from Beauty Products as Health Disparities Concern*, 217 AM. J. OBSTETRICS & GYNECOLOGY 418, 418–19 (2017).

[186] *Id.* at 418.

[187] *Id.*

[188] *Id.*

safety standards."[189] In sum, scientific advancements in cosmetic research plainly reveal the presence of severe hazards latent in the products used by the masses.

In response to these alarming health concerns and in acknowledgement of the lack of congressional intervention, cosmetic brands and non-governmental organizations took the matter into their own hands by seeking to minimize potential detrimental health effects on cosmetic consumers.[190] An organization at the forefront of these efforts is the Personal Care Products Council ("PCPC"), formerly known as the Cosmetic, Toiletry and Fragrance Association ("CTFA").[191] The PCPC, a national trade association representing global cosmetics and personal care products companies,[192] sets out three main strategic priorities that guide its work: advocating for impact, fortifying partnerships, and strengthening trust.[193] One of the PCPC's chief successes is its establishment of the Cosmetic Ingredient Review ("CIR") program.[194] This program is conducted by an expert panel of scientists and physicians who examine and evaluate scientific data for ingredients used in cosmetics.[195] The mission of the panel is to "review[] and assess[] the safety of ingredients used in cosmetics in an open, unbiased, and expert manner, and publish[]

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189 *Id.*

190 *See, e.g.*, *Who We Are: Our Mission*, EWG, https://www.ewg.org/who-we-are/our-mission (last visited Jan. 3, 2022); *Our Mission: To Get Safer Products into the Hands of Everyone*, BEAUTYCOUNTER, https://www.beautycounter.com/our-story (last visited Jan. 3, 2022) (discussing EWG's initiative to inform consumers of product ingredients and their push for legislative change); *CTFA Changes Name to the Personal Care Products Council, Launches Consumer Information Website on Product Safety*, PERS. CARE PRODS. COUNCIL (Nov. 29, 2007), https://www.personalcarecouncil.org/news-release/ctfa-changes-name-to-the-personal-care-products-council-launches-consumer-information-web-site-on-product-safety/ (noting the PCPC's efforts to ensure the safety of cosmetic products by working directly with cosmetic companies).

191 *See* Hartman, *supra* note 17, at 60; *CTFA Changes Name to the Personal Care Products Council, Launches Consumer Information Website on Product Safety*, *supra* note 190.

192 *About PCPC,* PERS. CARE PRODS. COUNCIL, https://www.personalcarecouncil.org/about-us/ (last visited Jan. 3, 2022).

193 *Id.*

194 *See Expert Panel for Cosmetic Ingredient Safety*, PERS. CARE PRODS. COUNCIL, https://www.personalcarecouncil.org/science-safety/cosmetic-ingredient-review/ (last visited Jan. 3, 2022).

195 *Id.*

the results in the peer-reviewed literature."[196] The CIR program is widely regarded as successful given that its "member companies represent more than [ninety percent] of the [United States] beauty industry."[197] Nonetheless, critics are justified in questioning the true benefit of this program. First, the widespread acceptance of the CIR findings among cosmetic companies may likely result from the fact that there have been so few ingredients deemed unsafe for use in cosmetic products.[198] The CIR has consistently been unable to declare several ingredients unsafe because "many of the evaluations have led to the conclusion that there [is] not enough data to substantiate safety."[199] Second, with respect to informing consumers, the benefit of the CIR reviews are only beneficial to the extent that consumers know of the existence of these CIR report findings.[200] Finally, because of the PCPC's, and therefore the CIR's, relationship and financial interest with its member companies, there is a clear conflict of interest that undermines the integrity of the CIR's findings.[201]

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196 *Expert Panel for Cosmetic Ingredient Safety*, INGREDIENT SAFETY EXPERT PANEL, https://ingredientsafetyexpertpanel.org/ (last visited Jan. 3, 2022).

197 *About PCPC*, *supra* note 192.

198 *See* Hartman, *supra* note 17, at 64 n.131; *see generally Unsafe Ingredients: Quick Reference Table*, CIR, https://www.cir-safety.org/sites/default/files/Unsafe_Dec2014_posted031815.pdf (last visited Jan. 27, 2022). The CIR lists the following ingredients as unsafe: 4-Methoxy-m- Phenylenediamine, 4-Methoxy-m-Phenylenediamine HCl, 4-Methoxy-m-Phenylenediamine Sulfate, Chloroacetamide, Ethoxyethanol, Ethoxyethanol Acetate, Formaldehyde, HC Blue No. 1, Hydroquinone, Methylene Glycol, P-hydroxyanisole, and Pyrocatechol. *Unsafe Ingredients: Quick Reference Table*, *supra* note 198. The CIR provides qualifications for several of these ingredients, which, if followed, would render them "safe for use in cosmetics" by their standards. *Id.*

199 Hartman, *supra* note 17, at 64 (internal citations omitted).

200 *See id.* at 64 n.132.

201 *See Industry-Funded Cosmetics Safety Panel Fails to Protect Public Health and the Environment*, WOMEN'S VOICES FOR THE EARTH, https://www.womensvoices.org/industry-funded-cosmetics-safety-panel-fails-to-protect-public-health-and-the-environment/ (last visited Jan. 3, 2022); *Report Exposes Industry-Funded Cosmetics Ingredient Review (CIR) Panel's Failure to Protect the Public and Manufacturers*, WOMEN'S VOICES FOR THE EARTH, https://www.womensvoices.org/2018/04/24/report-exposes-industry-funded-cosmetics-ingredient-review-cir-panels-failure-protect-public-manufacturers/ (last visited Jan. 3, 2022).

In addition, smaller nonprofit organizations such as the Environmental Working Group ("EWG") similarly seek to protect public health against cosmetic companies and outdated legislation.[202] A significant focus of the EWG is to educate, inform, and empower consumers to use safer products.[203] The EWG's cosmetic database serves to meet this end by detailing information on cosmetic ingredients and providing a rating that indicates the relative level of concern posed by exposure to "known and suspected hazards linked to the ingredients" in a product.[204] Even further, the EWG now marks products with an "EWG VERIFIED" seal indicating that "the product meets EWG's strictest standards for transparency and health."[205] Critics of the EWG have recognized that despite the EWG's success in motivating clean beauty dialogue, "their method for assessing risk does not seem to be data driven."[206] Additionally, critics have noted that "[t]he EWG also profits from participating in affiliate programs where they receive a percentage of the sale when a consumer makes a purchase through their website, which may be a notable conflict of interest."[207] Notwithstanding, just the mere presence of the EWG's logo on products will hopefully prompt consumers to research their product's ingredients or realize that all products on the shelves before them are not created with equal safety standards.

Several cosmetic brands also seek to protect the health of their consumers by producing products free from hazardous ingredients.[208] For example, Beautycounter, a beauty brand devoted to providing safer products to consumers,[209] sets standards for creating their products that far exceed the FDA regulations and even exceed

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202 *See Who We Are: Our Mission*, *supra* note 190.

203 *See id.*

204 *Understanding Skin Deep Ratings*, EWG, ewg.org/skindeep/understanding_skin_deep_ratings/ (last visited Jan. 3, 2022).

205 *Id.*

206 Courtney B. Rubin & Bruce Brod, *Natural Does Not Mean Safe—The Dirt on Clean Beauty Products*, 155 JAMA DERMATOLOGY 1344, 1344–45 (2019).

207 *Id.*

208 *See* Brianna Lapolla, *25 Best Clean Beauty Brands to Know, Shop and Love*, PURE WOW (Jul. 8, 2021), https://www.purewow.com/beauty/best-clean-beauty-brands.

209 *Our Story*, BEAUTYCOUNTER, https://www.beautycounter.com/our-mission (last visited Jan. 3, 2022).

standards of other countries with more stringent regulations.[210] They bar the use of over 1,800 "questionable ingredients"[211] and screen all of their ingredients to ensure they do not cause harmful health effects, such as carcinogenicity, neurotoxicity, and developmental harm.[212] Furthermore, Beautycounter tests for trace contaminants, such as phthalates and heavy metals, that may unintentionally contaminate their product through sourcing and manufacturing.[213] The steps taken by this company to ensure product safety—steps not demanded by federal regulation, nor taken by thousands of other cosmetic companies—prompt "clean" skincare enthusiasts to regard their products as safer than a majority of products on the market.[214]

Similarly, Sephora, a cosmetics retailer with one of the largest market shares in the United States,[215] implemented "Clean at Sephora."[216] This program marks its products with a "Clean at Sephora" seal to indicate to its customers that the product was formulated without certain ingredients that are known or suspected to be potentially harmful to human health.[217] Such prohibited ingredients include phthalates, formaldehydes, and other potentially toxic ingredients.[218] Since the inception of this program, Sephora has con-

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[210] *Safety: Beautycounter's Blueprint for Clean*, BEAUTYCOUNTER, https://www.beautycounter.com/safety (last visited Jan. 3, 2022).

[211] *Id.*

[212] *#BetterBeauty: Setting the Highest Bar in Clean Beauty*, BEAUTYCOUNTER (Apr. 20, 2020), https://beautycounter.com/blog/better-beauty/setting-the-highest-bar-in-clean-beauty/.

[213] *Safety: Beautycounter's Blueprint for Clean*, *supra* note 210.

[214] *See An Unbiased Review of Beautycounter*, ANCESTRAL NUTRITION (May 23, 2018), https://ancestral-nutrition.com/an-unbiased-review-of-beautycounter/.

[215] *Beauty, Cosmetics & Fragrance Stores Industry in the US – Market Research Report*, IBIS WORLD, https://www.ibisworld.com/united-states/market-research-reports/beauty-cosmetics-fragrance-stores-industry/ (July 12, 2021).

[216] *See generally CLEAN at Sephora*, SEPHORA, https://www.sephora.com/beauty/clean-beauty-products?activeTab=cleanplusanim0721_cleanskincare_tab_UFE&gclid=Cj0KCQiAq7COBhC2ARIsANsPATFrojqfhYzvejcTw2eqal-1BB7v68Kw-XKBHq-E5MMh90rqraO6UzYaAvN6EALw_wcB (last visited Jan. 3, 2022).

[217] *Id.*

[218] *Id.*

tinued to expand the ingredient list to include more than fifty prohibited ingredients and implemented further requirements for products to be marked with the "Clean at Sephora" seal.[219]

Though retailers like Sephora, and brands like Beautycounter, take steps in the right direction to ensure cosmetic consumer safety, dermatologists caution that terms like "clean" and "natural" are merely marketing terms and do not ensure that a product is safer or more effective.[220] Indeed, an article published by JAMA Dermatology stated

> [m]isinformation may lead to higher rates of contact dermatitis, substantial financial investment into natural products encouraged by companies with a clear financial conflict of interest, and unnecessary avoidance of safe and necessary skin care ingredients . . . .[T]he FDA [should] consider defining *clean* and *natural* to prevent consumer misconceptions about what these terms mean. Finally, both consumers and physicians should demand that the clean beauty movement back up their claims with evidence.[221]

Ultimately, while the concerns of dermatologists and other critiques of the efforts described above are sound, these efforts far exceed any initiatives taken by Congress and, at minimum, spur important conversations about the safety of cosmetic products.

B. *What Has Remained the Same Since the FDCA's Enactment?*

Given all that has changed in the cosmetic industry, it is puzzling why new legislation has failed to arise.[222] Since the FDCA was

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[219] Leah Prinzivalli, *Sephora Just Expanded Its "Clean at Sephora" Program List of Banned Ingredients in Beauty Products*, ALLURE (July 15, 2019), https://www.allure.com/story/clean-at-sephora-category-filter-by-ingredient-expanded-list.

[220] Rubin & Brod, *supra* note 206, at 1345.

[221] *Id.*

[222] *See supra* note 9 and accompanying text.

signed into law—over eighty-six years ago—there has been no significant changes to the regulation of cosmetics.[223] As a result, the FDA regulations that once governed the cosmetic market of the early-to-mid twentieth century are primarily the same regulations that now control the safety of cosmetic products in a substantially larger market—with significantly more knowledge on the adverse health effects latent in these products.[224]

The three—and only—modifications made to cosmetic regulations since the passage of the FDCA concern color additives, labeling requirements, and nanotechnology.[225] First, as previously discussed, the FDA regulates color additives and such additives are subject to more stringent regulations than cosmetics generally.[226] This expansion of the FDA's regulatory authority is a result of the Color Additive Amendments of 1960,[227] which "defined 'color additive' and required that only color additives (except coal-tar hair dyes) listed as 'suitable and safe' for a given use could be used in foods, drugs, cosmetics, and medical devices."[228]

Second, with respect to labeling requirements, the FDCA aims "[t]o protect consumers from unsafe or *deceptively labeled or packaged products*."[229] In addition to the FDA's prohibition of cosmetic

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[223] *See* Press Release, United States Senator for California: Dianne Feinstein, 81 Years Since Last Update to Personal Care Products Law: Feinstein, Collins Bill Would Overhaul Decades-Old Rules to Protect Consumers, Regulate Personal Care Products Industry, FEINSTEIN.SENATE.GOV (June 25, 2019), https://www.feinstein.senate.gov/public/index.cfm/press-releases?ID=FEF521A8-9137-401C-950B-FDF7D5903339.

[224] *See* Faber, *supra* note 13.

[225] Emily Jones, *Stripped From Sunscreen, But Fine for Foundation: How the Regulatory Dichotomy of Topically Applied Skin Products Endangers Women*, 35 WIS. J.L. GENDER & SOC'Y 143, 147–48 (2020).

[226] *See Color Additive Laws, Regulations, and Guidance*, FDA, https://www.fda.gov/industry/color-additives/color-additive-laws-regulations-and-guidance (last visited Jan. 3, 2022) (stating that cosmetics are not subject to premarket approval, whereas the FDA mandates premarket approval of color additives).

[227] 21 C.F.R. § 70.

[228] Julie N. Barrows et al., *Color Additives History*, FDA, https://www.fda.gov/industry/color-additives/color-additives-history#authors (Nov. 3, 2017).

[229] *Cosmetics Labeling Guide*, FDA, https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/cosmetics-labeling-guide (Aug. 24, 2020) (emphasis added).

products that do not meet the label requirements set forth in § 602 of the FDCA, cosmetic labels are subject to the Fair Packaging and Label Act[230] ("FPLA"); this "ensure[s] that packages and their labels provide consumers with accurate information about the quantity of contents and facilitate value comparisons."[231] Prominently, in 1977, the FPLA required cosmetics to include the ingredients of their product.[232] A cosmetic product's ingredients—except flavor, fragrance, and trade secret ingredients—must be declared on the label in descending order of predominance.[233] The FPLA does, however, lay out a prominent limitation:

> Since the FPLA *applies only to consumer commodities* and their packages as defined in the Act, cosmetic ingredient declarations are required only on the label of the outer container of cosmetics customarily sold at retail or used in the performance of services conducted within the households. It *does not apply*, for example, to products used at professional establishments or samples distributed free of charge, unless such products are customarily also sold at retail, even if they were labeled "For professional use only."[234]

As a whole, this revision to the FDCA was successful in achieving transparency in cosmetic ingredients though limited to consumer commodities and ingredients that are not flavor, fragrance, or trade secret ingredients.[235]

Lastly, in 2012, Congress implemented its most recent amendment to the FDCA concerning nanotechnology.[236] Nanomaterials were first used in an anti-aging cream manufactured by Christian Dior, and since then, other cosmetic brands have followed suit by

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230 15 U.S.C. §§ 1451–60.

231 *Cosmetics Labeling Guide*, *supra* note 229.

232 *See Cosmetics Labeling Guide*, *supra* note 229; 21 C.F.R. § 701.3.

233 *Cosmetics Labeling Guide*, *supra* note 229.

234 *Id.* (emphasis added).

235 *See supra* notes 225–34 and accompanying text.

236 *See* Valerie J. Watnick, *The Missing Link: U.S. Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment*, 31 PACE ENVTL. L. REV. 595, 603–04 (2014).

gradually incorporating nanomaterials in their products.[237] Consequently, "[t]he World Health Organization (WHO), non-governmental organizations, political institutions and agencies have raised concerns about the safety of [nanomaterials] and their use in consumer goods."[238] The 2012 update allowed the FDA to further research nanomaterials in regulated products.[239] Notably, the impact of this update is minimal because the FDA merely "issued non-binding guidance on the use of nanomaterials in cosmetics" and "the scope of the guidance relies on the same safety considerations that were recommended prior to any revisions."[240]

The foregoing revisions illustrate the minimal changes that have taken place since the FDCA's enactment. Such minimal change, and the corresponding failure to protect consumers, may prompt consumers to vilify the FDA. In reality, the source of this lack of legislative modernization is Congress, who provides the FDA with the authority to carry out the regulations it enacts.[241] Indeed, the FDA itself "made clear that the agency lacks the necessary authority to ensure the safety of personal care products."[242]

Lawmakers throughout the United States consistently introduce bills to Congress to reform the antiquated cosmetic regulation system and better protect consumers.[243] None, thus far, have proven

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[237] Georgios Fytianos et al., *Nanomaterials in Cosmetics: Recent Updates*, 10 NANOMATERIALS, May 20, 2020, at 1–2 (identifying L'Oréal and Shiseido as other large cosmetic companies using nanomaterials in their products).

[238] *Id.* at 2.

[239] Jones, *supra* note 225, at 148.

[240] *Id.* at 148–49.

[241] *FDA's Legal Authority*, FDA, https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/fdas-legal-authority (Apr. 24, 2019).

[242] *See* Press Release, FDA Admits Lack of Authority to Ensure Safety of Personal Care Products, FEINSTEIN.HOUSE.GOV (Oct. 13, 2016), https://www.feinstein.senate.gov/public/index.cfm/2016/10/fda-admits-lack-of-authority-to-ensure-safety-of-personal-care-products.

[243] *See, e.g.*, Press Release, United States Congresswoman: Jan Schakowsky, Reps. Schakowsky, Markey, Baldwin Introduce Bill to Protect Consumers and Workers From Harmful Chemicals in Cosmetics, SCHAKOWSKY.HOUSE.GOV (June 24, 2021), https://schakowsky.house.gov/media/press-releases/reps-schakowsky-markey-baldwin-introduce-bill-protect-consumers-and-workers; Press Release, United States Senator for California: Dianne Feinstein, Senators introduce Bill to Strengthen Personal Care Product Oversight,

successful.[244] For example, the Safe Cosmetics Act of 2010 was introduced in the House of Representatives but stalled in committee.[245] This bill sought to amend the FDA by requiring annual cosmetic registration, permitting FDA recalls, and mandating adverse event reporting, among other requirements to better regulate cosmetics.[246] Interestingly, proposals in other areas of cosmetic regulation, such as efforts to ban testing on animals, have likewise been unsuccessful.[247]

So, why has the law remained stagnant with respect to cosmetic regulations, when other areas under the FDA's scope are subject to far more stringent regulations that are consistently updated? One potential justification is that the laws adhered to the sentiments of former FDA Commissioner Frank Young who stated in 1989, "[a]dverse reactions to cosmetics are [usually] of lesser consequence [and are] reported less frequently . . . risk to human health is usually less because of the nature of the customary cosmetic use and the substances used as cosmetic ingredients."[248] Additionally, the concern for the effect on smaller cosmetic businesses may have influenced Congress not to implement the increased regulations proposed in reform bills.[249] Indeed, trade organizations have opposed reform bills due to fear that registration, disclosure, and safety testing requirements would, for example, be "onerous" to small businesses.[250] Congress, however, could have provided for specific exceptions for smaller businesses or crafted the provisions to ameliorate the disproportionate effect stricter regulations may have on smaller businesses.

FEINSTEIN.SENATE.GOV (Apr. 20, 2015), https://www.feinstein.senate.gov/public/index.cfm/2015/4/feinstein-collins-introduce-bill-to-strengthen-oversight-of-personal-care-products.

244 *See, e.g.*, Shah & Taylor, *supra* note 22, at 245.

245 *Id.* at 242–45 (citing Safe Cosmetics Act of 2010, H.R. 5786, 111th Congress (2010)).

246 *Id.* at 242–43.

247 *See Cruelty in Animal Testing Laboratories*, PETA, https://www.peta.org/issues/animals-used-for-experimentation/cosmetic-household-products-animal-testing/ (last visited Jan. 3, 2022).

248 Termini & Tressler, *supra* note 40, at 272 n.129 (citing Letter of FDA Director of the Office of the Comm'r on Human Resources F. Young to Congressman R. Wyden, at 4 (July 5, 1989)).

249 *See* Shah & Taylor, *supra* note 22, at 244.

250 *Id.*

Further, repeated failed legislative efforts to strengthen cosmetic regulations also likely stem from (1) poor representation of women in positions that can affect change in regulating the industry and (2) the "hidden danger" of chemicals found in cosmetics.[251] As noted above, women's role in the cosmetic business diminished as the market grew, around the time of the FDCA's enactment, despite being the primary consumer of cosmetics.[252] This largely holds true today.[253] Women are underrepresented in the "leadership of the companies placing cosmetics on the market and in the bodies regulating the industry."[254] For instance, six of the top global beauty companies sold in the United States have male Chief Executive Officers.[255] Even though the FDA's female-to-male ratio is nearly equal today,[256] the House Committee for Energy and Commerce Health Subcommittee (the body responsible for reviewing and updating legislation such as the FDCA[257]) has far fewer women than men.[258] The subcommittee is comprised of twenty-one males but merely thirteen females.[259]

Furthermore, the adverse events that presumably prompted the FDCA's enactment, such as the fatality resulting from the application of Lash Lure, do not mirror the current dangers facing consumers.[260] Instead, many of the adverse effects of using products containing harmful substances are far less immediate, taking many

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[251] *See* Jones, *supra* note 225, at 161–62.

[252] *See Cosmetics and Personal Care Products in the Medicine and Science Collections: Make-up*, *supra* note 39.

[253] *See* Jones, *supra* note 225, at 161–62.

[254] *Id.* at 161.

[255] *See generally* Jamie Matusow, *Meet the 6 New CEOs of our Top 20 Global Beauty Brands*, BEAUTY PACKAGING (Nov. 1, 2021), https://www.beautypackaging.com/contents/view_online-exclusives/2021-11-01/meet-the-5-new-ceos-of-our-top-20-global-beauty-brands/.

[256] *See generally FDA Leadership Profiles*, FDA, https://www.fda.gov/about-fda/fda-organization/fda-leadership-profiles (Dec. 3, 2021).

[257] *See* Jones, *supra* note 225, at 162.

[258] *See Health,* HOUSE COMM. ON ENERGY & COM., https://energycommerce.house.gov/subcommittees/health-117th-congress (last visited Jan. 3, 2022).

[259] *Id.*

[260] *See* Jones, *supra* note 225, at 162–63.

years after exposure for symptom onset.[261] Additionally, because these chemicals typically cause long-term health effects, as opposed to short-term ones, it is challenging for researchers to accurately study the effects of such products.[262] Such difficulties are only exacerbated by the fact that the ingredients found in products vary considerably over time, making it difficult to ascertain the true health effects of the product's use.[263] In turn, it becomes harder for researchers to demonstrate a clear link between a substance or a product and an adverse effect.[264] Prominently, one of the most significant hurdles to furthering cosmetic regulation with respect to adverse events is the fact that the FDA lacks the authority to require cosmetic companies to report adverse events.[265] As a result, the adverse effects of cosmetic products are underestimated.[266] Accordingly, the underreporting of adverse events and the less-immediate adverse health effects likely explain Congress's lack of motivation to reform the regulation of cosmetics.

III. THE FUTURE OF COSMETIC REGULATION

A. *Recent Proposed Legislation: The Safer Beauty Bill Package of 2021*

On October 8, 2021, Illinois Congresswoman Jan Schakowsky represented a group of Democratic lawmakers before the House of Representatives and introduced the Safer Beauty Bill Package of 2021 ("SBBP").[267] The SBBP contains four bills: The Toxic-Free Beauty Act of 2021, The Cosmetic Fragrance and Flavor Right to

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[261] *See Cosmetics and Cancer Risk*, AM. CANCER SOC'Y, https://www.cancer.org/healthy/cancer-causes/chemicals/cosmetics.html (last visited Nov. 9, 2022) ("For most substances that cause cancer, it takes many years after exposure to the substance for cancer to occur.").

[262] *Id.*

[263] *Id.*

[264] *See id.*

[265] *See* Linda Katz, *Using Adverse Event Reports to Monitor Cosmetic Safety*, FDA, https://www.fda.gov/cosmetics/how-report-cosmetic-related-complaint/using-adverse-event-reports-monitor-cosmetic-safety (Nov. 3, 2017).

[266] Hale Z. Toklu et al., *Cosmetovigilance: A Review of the Current Literature*, 8 J. FAM. MED. & PRIMARY CARE 1540, 1541 (2019).

[267] Cunningham & Reese, *supra* note 28, at 1.

Know Act of 2021, The Cosmetic Supply Chain Transparency Act of 2021, and The Cosmetic Safety for Communities of Color and Salon Workers Act.[268] Californian Senator and sponsor of the SBBP, Dianne Feinstein, stated that "[the] bipartisan bill will finally bring the FDA into the [twenty-first] century by giving it authority to ensure personal care products are safe."[269] Another proponent, Senator Susan Collins of Maine, stated that "[b]y strengthening FDA oversight of the ingredients in personal care products for the first time in more than [eighty] years, our legislation would help protect the health of consumers, support small businesses, and provide regulatory certainty for manufacturers."[270]

The Toxic-Free Beauty Act of 2021 proposes the addition of several substances to the FDA's current list of banned ingredients in cosmetics.[271] The list of prohibited ingredients proposed includes PFAS substances which have been identified in over half of cosmetics in the United States and are linked to severe adverse health effects.[272] The other ingredients sought to be banned by the bill include those prohibited by the European Union, California, and Maryland.[273]

The Cosmetic Fragrance and Flavor Ingredient Right to Know Act of 2021 closes the current loophole that allows cosmetic manufacturers to circumvent labeling requirements and not disclose "fragrance" or "flavor" ingredients.[274] Specifically, the bill requires manufacturers to disclose on its packaging the fragrance or flavor ingredients if they are included among the lists identified in the bill

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[268] *Id.* at 1–3; *see also* H.R. 5537, 117th Cong. (2021); H.R. 5538, 117th Cong. (2021); H.R. 5539, 117th Cong. (2021); H.R. 5540, 117th Cong. (2021).

[269] Press Release, United States Senator for California: Dianne Feinstein, Feinstein, Collins Introduce Bill to Modernize Safety Standards for Personal Care Products (June 17, 2021), https://www.feinstein.senate.gov/public/index.cfm/2021/6/feinstein-collins-introduce-bill-to-modernize-safety-standards-for-personal-care-products.

[270] *Id.*

[271] H.R. 5537, 117th Cong. (2021).

[272] Whitehead et al., *supra* note 175, at 538.

[273] *Safer Beauty Bill Package to be Introduced in Congress*, HAPPI (July 29, 2021), https://www.happi.com/contents/view_breaking-news/2021-07-29/safer-beauty-bill-package-to-be-introduced-in-congress/.

[274] *See* H.R. 5538, 117th Cong. (2021); *Cosmetics Labeling Guide*, *supra* note 229.

and any of the fragrances identified as "allergens" under the European Union.[275] Additionally, it mandates that substances required to be listed on the product's packaging also be listed on its website along with any other added fragrance or flavor ingredients.[276]

If passed, the Cosmetic Supply Chain Transparency Act of 2021 would require various entities along the supply chain of a cosmetic product, such as ingredient suppliers and formulating labs, to provide "brand owners with the ingredient disclosure, toxicity and safety data, and the certificate analyses needed to make safer beauty and personal care products."[277] The bill specifically provides that upon request by a brand owner of a cosmetic product, a supplier must provide the owner information; this information includes health and environmental hazards, a full and complete list of ingredients, and any other information used to determine the safety of the ingredients within ninety days.[278] The bill would also impose civil penalties for failure to comply with the provisions outlined therein.[279]

Lastly, the Cosmetic Safety for Communities of Color and Salon Workers Act seeks to remedy the current disproportionate burden of toxic chemicals affecting communities of color and salon workers.[280] Its provisions include awarding grants for research of "chemicals that are linked to adverse health effects and most commonly found in cosmetics marketed to women and girls of color," "the use of cosmetics containing such chemicals by women and girls of color across their lifespans," and "the specific adverse health effects experienced by women and girls of color from exposure to unsafe chemicals present in cosmetics used by them;" this information

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[275] H.R. 5538, 117th Cong. (2021); Cunningham & Reese, *supra* note 28, at 2–3.

[276] H.R. 5538, 117th Cong. (2021); Cunningham & Reese, *supra* note 28, at 2–3.

[277] *Safer Beauty Bill Package to be Introduced in Congress*, *supra* note 273; *see also* H.R. 5539, 117th Cong. (2021).

[278] H.R. 5539, 117th Cong. (2021).

[279] *Id.*

[280] *Safer Beauty Bill Package to be Introduced in Congress*, *supra* note 273; *see also* Zota & Shamasunder, *supra* note 185, at 2–3; H.R. 5540, 117th Cong. (2021).

would then be disseminated to prevent unsafe chemical exposures.[281] Additionally, the bill requires all ingredients to be listed on product labeling and brand websites and further provides for increased availability of Safety Data Sheets for products.[282] It also includes various administrative measures aimed at creating future regulations, such as mandating collaboration between different government agencies.[283]

B. *Looking Forward: Likely Outcomes & Alternative Solutions*

The SBBP has amassed a large number of supporters.[284] From non-governmental organizations to businesses, over 140 different entities support the bill package.[285] Nonetheless, given the history of failed efforts to change cosmetic regulations, one might be hesitant to believe that the SBBP will be passed. There are, however, several reasons why Congress may take an unprecedented shift and decide to pass this bill package. First, the support for the SBBP goes beyond organizations that have routinely supported all legislative efforts that protect consumers from the harmful effects of cosmetics[286] to include some of the largest cosmetic brands: Johnson & Johnson, Proctor & Gamble, Unilever, L'Oréal USA, and Revlon.[287] Second, the legislative trends of enacting similar regulations at the state-level, such as in California and Maryland, may motivate Congress to enact similar legislation at the federal-level.[288] Third, because the SBBP is divided into four individual bills, it increases the

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281 H.R. 5540, 117th Cong. (2021).

282 Cunningham & Reese, *supra* note 28, at 3–4.

283 *See id.*

284 *Safer Beauty Bill Package: Endorsing Organizations, Businesses, and Government Agencies*, BREAST CANCER PREVENTION PARTNERS, https://www.bcpp.org/resource/safer-beauty-bill-package-2021/ (last visited Mar. 27, 2023).

285 *Id.*

286 *See Feinstein, Collins Introduce Bill to Modernize Safety Standards for Personal Care Products*, *supra* note 269.

287 *Id.*

288 Cunningham & Reese, *supra* note 28, at 4; *see also* Miranda Green, *New State Law Banning Toxic Chemicals in Cosmetics Will Transform Industry*, CAL. HEALTHLINE (Nov. 19, 2020), https://californiahealthline.org/news/new-california-law-banning-toxic-chemicals-in-cosmetics-will-transform-industry/; *Maryland Consumer Protection Bill Becomes Law*, PERS. CARE PRODS. COUNCIL (June

odds that at least part of the SBBP will pass.[289] Even if only part of the package is passed, it would still be a significant step in the right direction for cosmetic regulation. Finally, "[e]ven if some or all of the bills do not pass, they reflect heightened consumer awareness of chemicals and a demand for more transparency from companies . . . [a]nd as consumer concern grows, so too will additional regulatory and litigation risk."[290]

Other recent events may also spur consumer attention towards the FDA's role in ensuring the safety of their products—namely, the COVID-19 pandemic. When the COVID-19 vaccines were first released, the FDA only granted the vaccines emergency authorization,[291] leaving many individuals hesitant to receive the vaccine until they were fully approved.[292] Headlines consistently focused on the safety of the COVID-19 vaccines, namely the role the FDA plays in this safety determination.[293] Accordingly, consumers may have likely become more cognizant of the FDA's role and may begin to recognize the shortcomings of the FDA's authority over other products, such as cosmetics. In turn, this may prompt consumer concern and make it more likely that the SBBP will be passed.

Although these reasons make the passing of the SBBP more promising than previous efforts, Congress may nonetheless regard the bills as too radical a shift in regulation and refuse to pass the SBBP. Is there an alternative that could meet consumer needs by strengthening and modernizing cosmetic regulations without upsetting the system that has been in place for over eighty years? One

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1, 2021), https://www.personalcarecouncil.org/news-release/maryland-consumer-protection-bill-becomes-law/.

289 Cunningham & Reese, *supra* note 28, at 4.

290 *Id.*

291 Shawn Radcliffe, *When Will the FDA Give Full Approval for COVID-19 Vaccines?*, HEATHLINE (July 6, 2021), https://www.healthline.com/health-news/when-will-the-fda-give-full-approval-for-covid-19-vaccines.

292 Wendi Redman, *Fact Finders: Is it Safer to Wait for Full FDA Approval for Covid-19 Vaccine?*, KOLD NEWS (June 2, 2021, 8:34 PM), https://www.kold.com/2021/06/03/fact-finders-is-it-safer-to-wait-for-full-fda-approval-for-covid-19-vaccine/.

293 *See generally* Lisa Maragakis & Gabor D. Kelen, *Full FDA Approval of a Covid-19 Vaccine: What You Should Know*, JOHNS HOPKINS MED. (Aug. 23, 2021), https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/full-fda-approval-of-a-covid-19-vaccine-what-you-should-know.

solution to achieve both goals would be to simply amend the definitions of "drug" and "cosmetic" under the FDCA, by removing the phrase "intended to" in both definitions.[294]

Presently, whether a product is classified—and thereby regulated—as either a drug or cosmetic hinges on its intended use.[295] This classification system has been criticized and regarded as unpredictable and manipulable because "the status of a product may change according to the whims of the manufacturer, depending on the advertising claims the manufacturer has promulgated, the label, promotional material, and 'any other relevant source.'"[296] Indeed, the Second Circuit in *Sudden Change* stated, "[r]egardless of the actual physical effect of a product, it will be deemed a drug for purposes of the [FDCA] where the labeling and promotional claims show intended uses that bring it within the drug definition."[297] While this assertion unequivocally demonstrates the troubling disregard for the actual physical effect of a product, this can likely be attributed to the court's focus on consumer *economic interests*.[298] With this protection in mind, it is no surprise that the court cited to multiple cases where products were deemed a drug because its labeling and promotional claims had the potential to jeopardize consumer economic interests.[299] For instance, the court cited to a case where cigarettes were classified as a drug because its promotional

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294 *See* 21 U.S.C. § 321.

295 *See* 21 U.S.C. § 321(g)(1); 21 U.S.C. § 321(i); *see also* Heymann, *supra* note 15, at 366.

296 *See* Heymann, *supra* note 15, at 365–66 ("[W]hether a product actually has an effect on a structure or function of the body would be irrelevant: If the manufacturer claims it does, it is considered a drug; if it does not, it is considered a cosmetic. A dangerous chemical for which only cosmetic claims were made might avoid premarket regulation, whereas a claim that a product consisting wholly of water would "plump up skin cells" would cause the product to be regulated as a drug.").

297 United States v. An Article of a Drug Consisting of 216 Individually Cartoned Bottles, More or Less, of an Article Labeled in part: Sudden Change, 409 F.2d 734, 739 (2d Cir. 1969).

298 *Id.* at 740 ("A primary purpose of the [FDCA] is the protection of the ultimate consumer's economic interests.").

299 *Id.* at 739; *see, e.g.*, United States v. 354 Bulk Cartons Trim Reducing Cigarettes, 178 F. Supp. 847, 851 (D.N.J. 1959); United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes, 113 F. Supp. 336, 337–38 (D.N.J. 1953).

claims included stating that it prevented respiratory disease.[300] Nonetheless, the court later noted the Act's purpose of ensuring public health.[301]

In merely focusing on the intended use of a product—as opposed to its actual effects—the purpose of the FDCA is undermined. The primary purpose of the FDCA "is to 'safeguard' and 'protect' consumers from 'dangerous products' affecting public health and safety."[302] If the FDA aims to protect the health of consumers, the distinction between cosmetics and drugs should focus on how a product and its ingredients actually affect the health of users. Consider the $26 million class action lawsuit against the brand *WEN by Chaz Dean* for one of its conditioners; this followed reports from users across forty different states alleging extreme hair loss, hair breakage, visible balding, scalp irritation, and rashes.[303] In this case, the conditioner was classified as a cosmetic.[304] Given that the product contained no claims suggesting that the product would alter user's body, it followed that the conditioner was not deemed a drug under the current regulatory system. Yet, users experienced adverse reactions to the product,[305] which suggests that the product did ultimately affect user's bodies. Accordingly, the conditioner would have fallen squarely within the definition of a drug if the "intended to" phrase was excluded; had it been classified as such, the stringent testing requirements for drugs may have prevented users from experiencing these adverse effects. Furthermore, this modification of the definition is entirely within the purview of the Act's purpose of ensuring the health of consumers.

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300 *Sudden Change*, 409 F.2d 734, 739 (2d Cir. 1969) (citing United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes, 113 F. Supp. 336, 337–38 (D.N.J. 1953)).

301 *Id.* at 740 (citing United States v. Dotterweich, 320 U.S. 277, 280 (1943)).

302 KATHRYN B. ARMSTRONG & JENNIFER A. STAMAN, CONG. RSCH. SERV. R43609, ENFORCEMENT OF THE FOOD, DRUG, AND COSMETIC ACT: SELECT LEGAL ISSUES 2 (2018) (citing United States v. Sullivan, 332 U.S. 689, 696 (1948)).

303 Monika Markovinovic, *$26 Million Hair Loss Lawsuit Against Wen Hair Care Products is Moving Forward*, HUFFPOST (Nov. 2, 2016, 11:10 AM), https://www.huffpost.com/archive/ca/entry/26-million-hair-loss-lawsuit-against-wen-hair-care-products-is_n_12769254.

304 *See* Hassan Z. Sheikh & Agata Bodie, CONG. RSCH. SERV. R42594, *FDA Regulation of Cosmetics and Personal Care Products*, 29 n.250 (2022).

305 *See* Markovinovic, *supra* note 303.

By removing the "intended to" phrase, a vast number of products currently classified as cosmetics would be classified as drugs and subject to more stringent requirements to ensure safety.[306] For instance, this would include the large number of cosmetics sold in the United States containing toxic chemicals associated with cancer, weakened immunity, and low birth rate.[307] This is because such adverse reactions plainly affect the body and public health. Essentially, by slightly modifying the current definitions, ingredients found in products linked to adverse health effects (that have long-been largely unregulated due to their classification as a cosmetic) would now be subject to strict regulatory safeguards to ensure consumer safety. This proposed modification appears to be in line with the Supreme Court's assertion in *United States v. Dotterweich*.[308] In that case, the Court stated:

> [t]he purposes of [the FDCA] touch[es] phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.[309]

On balance, passage of the SBBP is the optimal solution for ensuring the safety of cosmetics. Unlike the proposed definition modification described above, the provisions set forth in the four bills are specifically tailored to address the safety of cosmetics.[310] For example, the Cosmetic Safety for Communities of Color and Professional Salon Workers Act of 2021 incentivizes research on health concerns impacting professional salon workers to address the disproportionate adverse health effects of salon workers—an issue uniquely specific to cosmetics.[311] In contrast, the proposed definition modification does not offer regulations designed specifically

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306 *See supra* note 61 and accompanying text.

307 Daly, *supra* note 7.

308 320 U.S. 277, 280 (1943).

309 *Id.*

310 *See generally* H.R. 5537, 117th Cong. (2021); H.R. 5538, 117th Cong. (2021); H.R. 5539, 117th Cong. (2021); H.R. 5540, 117th Cong. (2021).

311 H.R. 5540, 117th Cong. (2021).

with cosmetics in mind. It simply subjects cosmetics that affect the health of users to the stringent drug requirements. Nevertheless, it serves as a valuable alternative approach if Congress finds the SBBP too radical a change. Modifying the definitions within the FDCA—or any legislative reform of cosmetic regulations for that matter—would be a critical step in the right direction of ensuring public safety.

CONCLUSION

As the cosmetic industry evolves, the regulations in place to protect consumers consistently fail to follow suit.[312] The significant changes in the cosmetic industry exacerbate the shortcomings of the FDCA.[313] The current regulatory system provides the FDA with minimal authority and thereby severely limits its ability to protect the health of consumers effectively and adequately.[314] Studies detailing the wide-spread prevalence of dangerous substances in cosmetic products are well known, yet Congress repeatedly fails to implement stricter regulations to enhance consumer safety.[315] This is particularly striking given that the very purpose of the FDCA is to protect the health and safety of consumers.[316]

Ideally, Congress will begin to appreciate the potential dangers to public health and pass the SBBP. Any modernization of the current regulation, however, would be pivotal in safeguarding the health of cosmetic consumers. Increased public awareness about the FDA's authority and state-level cosmetic regulation reform increases the likelihood of Congress *finally* modifying the current regulation of cosmetics.[317] Until such legislative reform occurs, *if ever*, the health and safety of consumers remains at the hands of cosmetic companies and primarily with consumers themselves.

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312 *See supra* Section II.B.
313 *See supra* Part II.
314 *See supra* Section I.B.
315 *See supra* Sections II.A–B.
316 *See supra* Section III.B.
317 *See supra* Section III.B.