Makeup Call: How Cosmetic Product Use Affects Women Absent Federal Regulation

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INTRODUCTION

The lack of federal cosmetics regulation by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) has a disparate impact on women. The scarcity of federal cosmetics regulation and its biased effect on women are further accentuated when viewed in comparison to the extent of the FD&C Act’s food and drug regulations, as well as in light of cosmetics research and reports conducted over the past eighty years. Statistics show that women use more cosmetic products than men overall.1

The lack of federal cosmetics regulation thus results in the FD&C Act being gender-biased by not offering the users of cosmetic products (i.e., women) the same protections provided to both men and women in the regulation of the FD&C Act's other two jurisdictional industries—food and drugs.²

Part I of this Note analyzes the FD&C Act provisions regulating cosmetics and contrasts them with the far more extensive regulations over food and drugs. It also explores the legislative history of the FD&C Act in an attempt to answer the question of why there is comparatively so little federal cosmetics regulation. Part II takes an in-depth look at cosmetics—what they are, how they affect women as their core users more so than men, and the limited legal remedies that exist. Part III then argues the lack of cosmetics regulation under the FD&C Act results in a disparate impact on women as cosmetic products’ main users, which must be remedied with new federal cosmetics legislation. Finally, Part IV asserts the claim that the gender bias stemming from this lack of cosmetics regulation under the FD&C Act is not cured by the cosmetic industry’s self-regulation, and instead requires additional provisions to be amended to the cosmetics subchapter of the FD&C Act. This final part explores three pieces of legislation that are currently in front of Congress and the industry’s response to their provisions.

I. CONTRASTING COSMETICS REGULATION IN THE FD&C ACT TO THAT OF FOOD AND DRUGS TO ESTABLISH A LACK OF COSMETICS REGULATION

A. Federal Food, Drug, and Cosmetic Act Regulation of Cosmetics Versus its Regulation of Food and Drugs

The scope of cosmetics regulation under the FD&C Act is far less expansive than regulations of both food and drugs, which captures more nuances in those industries than the cosmetics subchapter.³ Cosmetics regulation spans a mere three sections of the entire Act: (1) what constitutes an adulterated cosmetic, (2) what constitutes a misbranded cosmetic, and (3) a note on regulations making exemptions to any aforementioned cosmetic labeling requirement.⁴ These

sections are not extensive: the longest section, the misbranding provision, contains only six subsections, which are each only—at most—several lines long. Perhaps most notably absent are provisions outlining any FDA approval or notification processes for cosmetic products and their ingredients, other than requiring pre-market approval for color additives contained in cosmetics.

Analyzing the provisions regulating food and drugs under the FD&C Act further emphasizes the major deficiency in federal cosmetics regulation. The FD&C Act’s subchapter on food contains twenty-seven sections in addition to three sections analogous to those regulating cosmetics. The food adulteration and misbranding provisions are also more comprehensive with many more definitions and nuances. The presence of over two dozen additional sections provides more guidance and awareness of the law and further demonstrates the depth of regulation that the FDA via the FD&C Act has over food versus cosmetics.

The FD&C Act food subchapter features provisions governing such specificities as bottled water and infant formula. Although there are obvious human health and safety concerns that lead to regulating the food industry in this in-depth manner, cosmetics do not garner the same relative protections.

Drugs under the FD&C Act are regulated even more exhaustively than food. The drug subchapter is divided into nine parts with a total of over one hundred governing provisions. These again include the same three analogous cosmetics provisions, which here have a multitude of nuanced subsections. As with food, the health and safety rationale behind these provisions is clear, but sharpens the contrast with regard to the comparative lack of cosmetics regulation.

5. See id. § 362.
10. Id. §§ 342–43.
11. §§ 361–63; see also §§ 341–501-1.
12. §§ 349, 350a.
15. See §§ 351–60fff-7; see also §§ 341–501-1.
17. See §§ 351–53.
18. See Cavers, supra note 13, at 3.
Throughout the rest of the FD&C Act, beyond the cosmetics subchapter, the FDA has been given the legal authority to inspect cosmetic facilities as well as imported cosmetics. This authorization is given in tandem with the right of the FDA to also inspect food, drug, device, and tobacco product facilities. Despite this after-the-fact mechanism for regulation, however, the FD&C Act requires no pre-market approval for cosmetics or cosmetic ingredients (with the exception of color additives), and leaves the safety determination to the manufacturer. As the FDA explains, "companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products. Neither the law nor FDA regulations require specific tests to demonstrate [that] safety . . . . The law also does not require cosmetic companies to share their safety information with FDA." The FDA can, and does, issue non-binding guidance documents that advise cosmetics manufacturers on a number of topics from general good manufacturing practices to more specific topics, such as the recommended maximum level of lead in lipstick. Notwithstanding these suggestions, guidance documents do not confer rights on or limit manufacturers, nor do they give legal authority to the FDA. Manufacturers are still free to use alternative approaches as long as they do not violate the applicable law, in other words, the FD&C Act. The cosmetics industry, thus, is the party responsible for ensuring product safety, and no specific rules exist to establish the safety of cosmetic products or ingredients.

This self-regulatory scheme provides the cosmetics industry with only a vague idea of determining a product or ingredient to be safe:

[The] FDA has stated that "the safety of a product can be adequately substantiated through (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic, and (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information."
While the FDA also conducts its own cosmetics safety research, action is only taken against an allegedly unsafe product after that product has been introduced on the market and may have affected consumers.28

B. Federal Food, Drug, and Cosmetic Act Legislative History

Delving into the legislative history of the FD&C Act reveals little information on the thinking behind creating such comprehensive regulation for food and drugs, and comparatively so little for cosmetics.29 Congress passed the FD&C Act in 1938 and for the first time created consumer protection over medical devices and cosmetics.30

Upon its consideration by the seventy-fourth Congress in 1935, President Roosevelt said of the then-bill:

[i]t is time to make practical improvements. A measure is needed which will extend the controls formerly applicable only to labels to advertising also; which will extend protection to the trade in cosmetics; which will provide for a cooperative method of setting standards and for a system of inspection and enforcement to reassure consumers grown hesitant and doubtful; and which will provide for a necessary flexibility in administration as products and conditions change.31

Roosevelt specifically called for the protection of the cosmetics industry in his special statement to Congress, yet only a few provisions were ultimately included.32

The major issues surrounding the bill made no mention of the discrepancies in the depth and breadth of regulation between cosmetics and food and drugs.33 These issues dealt primarily with the FDA’s power to make multiple product seizures; which agency should have jurisdiction over food, drug, and cosmetic advertising; and judicial review of regulations made by the Secretary of Agriculture.34 Over the next few years the bill was debated, and in 1937, the definition of

29. See generally Cavers, supra note 13, at 2–5.
31. Cavers, supra note 13, at 12–13 (emphasis added) (citation omitted).
34. Id.
"cosmetic" was added.\textsuperscript{35} The bill eventually passed in both the House of Representatives and the Senate, and President Roosevelt signed it into law in June of 1938.\textsuperscript{36} Since its passage, the Act has largely remained the same with regard to cosmetics; a fourth section originally in the cosmetics subchapter, which directed the Secretary to promulgate regulations for the listing of coal tar coloring in cosmetics, was repealed in 1960.\textsuperscript{37}

The legislative history of the FD&C Act offers little insight into the reasoning for the relatively short list of cosmetics regulations.\textsuperscript{38} Perhaps there were simply fewer cosmetic products in the 1930s, or cosmetic products were not that commonplace. Regardless of the cosmetics statistics of the years leading up to the passage of the Act, in the past eighty years, the cosmetics industry has grown significantly as new ingredients and products have been developed and have become more widely used.\textsuperscript{39} The presence of such relatively extensive regulations on food and drugs in the FD&C Act still begs the question of why the same level of protection is not afforded to cosmetics, given their own health and safety implications.\textsuperscript{40}

II. COSMETICS AND THEIR CORE USERS: WOMEN

A. Defining "Cosmetic" and Analyzing Use

The United States cosmetics industry boasts an annual revenue of over sixty billion dollars.\textsuperscript{41} The United States was considered the most valuable beauty and personal care market globally in 2016, leading North America to make up almost a quarter of the cosmetic market worldwide.\textsuperscript{42} The United States cosmetics industry employs over 63,000 people, and the industry’s gross product is about $14 billion.\textsuperscript{43} Before breaking down the statistics further to determine the industry’s main consumer, it is imperative to understand the definition of "cosmetic" under the FD&C Act:

\begin{itemize}
\item \textsuperscript{35} Id. at 16–18.
\item \textsuperscript{36} Id. at 21–22.
\item \textsuperscript{37} 21 U.S.C.A. § 364 (repealed 1960). This topic is now covered in a separate general authority provision encompassing cosmetics as well as food, drugs, and devices. See 21 U.S.C.A. § 379e (West 2012).
\item \textsuperscript{38} See 21 U.S.C.A. §§ 361–63; see generally Cavers, supra note 13.
\item \textsuperscript{40} See §§ 361–60ff-7, 361–63; see also §§ 341–501-1.
\item \textsuperscript{42} Id.
\item \textsuperscript{43} Id.
\end{itemize}
The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.44

Products that fall into this definition include, among many others, such items as skin moisturizers, perfumes, lipsticks, and hair colors, as well as individual components of a cosmetic product.45 Some products that would otherwise be included in this definition are defined elsewhere in the FD&C Act as a drug, device, or dietary supplement,46 or outside of the FDA’s jurisdiction altogether, as it is the case with soap.47

Returning to the statistics, analyzing specific product categories sheds more light on who is actually consuming cosmetics.48 Haircare products represent the largest part—twenty-four percent—of the United States beauty industry.49 Foundation sales reach over $980 million.50 The leading cosmetic brand is Neutrogena, and their top product is their makeup remover.51 Revlon’s “Beyond Natural” false eyelashes alone account for $3.4 million in sales.52 Each of these statistics seems to represent popular products among not just consumers, but women specifically.53

Thirty-five percent of women use one to two cosmetic products daily, with seventeen percent using three to four.54 Fifty-four percent of men, on the other hand, will not use a single cosmetic product on a given day.55 Women also reportedly spend more just because they are women, often as a result of sexual prejudice in the market.56 A study observing women across the United States found companies charging “an unjustified markup for products marketed towards females . . . . [and] on average women pay $151 billion in extra fees and markups that men don’t have to pay.”57

44. 21 U.S.C.A. § 321(i) (West 2016).
45. FDA Authority over Cosmetics, supra note 7.
46. Id.
47. Soap: FAQs, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Cosmetics/Products Ingredients/Products/ucm115449.htm [https://perma.cc/E5L8-GBL8].
49. Id.
50. Id.
51. Id.
52. Id.
53. Id.
54. Adams, supra note 1.
55. Id.
56. Id.
57. Id.
Specific statistics and research tend to support the data's conclusion that women consume cosmetic products more than men overall. A study conducted by the Centers for Disease Control and Prevention (CDC) in 2000 found that a wide variety of cosmetic products contained phthalates, which were largely not labeled in the products' ingredient lists. The CDC researchers discovered widespread exposure throughout the population—with adult women showing higher levels of phthalate metabolites from the use of personal care products. Moreover, research has shown a significant relationship between phthalate levels in a pregnant woman's body and subsequent adverse effects on male reproductive development.

Further, African-American women spend eighty percent more per capita on cosmetic products than any other ethnic group, mainly on haircare products such as relaxers. It appears evident that women, who tend to have longer hair than men, would be more likely to use such products for styling or simply easier maintenance.

Even products that are more gender-neutral on their face show a discrepancy in use between women and men. A CDC study from 2013 showed that sunscreen, used to mitigate ultraviolet radiation exposure and help prevent skin cancer, is used by women double the amount when compared to men's usage. Over twenty-nine percent of women said that they regularly use sunscreen on their face and exposed skin, whereas only fourteen percent of men reported the same. More women admitted to using sunscreen regularly only on their face (about forty-three percent) versus on other exposed skin (thirty-four percent). In men, these numbers were approximately eighteen and twenty percent, respectively.

59. Id.
60. Id.
61. Id.
62. Id. at 212.
64. See Study: Most Americans Don't Use Sunscreen, AM. ACAD. DERMATOLOGY (May 19, 2015), http://www.aad.org/media/newsreleases/study-most-americans-don-t-use-sunscreen [https://perma.cc/P8RY-4XQT] [hereinafter Study: Most Americans].
65. Id. Although sunscreen is actually defined as a drug under the FD&C Act, this still offers proof that cosmetics (and products like sunscreen that would otherwise fit the definition of "cosmetic" in the absence of their own specific provisions elsewhere in the FD&C Act) are used by more women than men. See 21 U.S.C.A. § 360fff (West 2014).
66. Study: Most Americans, supra note 64.
67. Id.
68. Id.
"Women may be more likely to use sunscreen on the face because of the anti-aging benefits, or because of the many cosmetic products on the market that contain sunscreen." In further support of this notion, the study also discovered that men (at almost forty-four percent) were more likely than women (at twenty-seven percent) to never use sunscreen on their face, and at similar percentages with regard to other exposed skin. Despite women's and men's respective reasons for sunscreen use or non-use, this study shows that even products marketed to the general population (as opposed to just women), for something gender-nonspecific like skin cancer prevention, are still more likely to be used by women.

Looking back to the FD&C Act, food and drug consumption and usage certainly seem more equally spread amongst the genders: both women and men consume food and use drug products and medical devices. It is true that some drugs are specifically produced for use by only one gender (e.g., birth control); however, the outstanding difference between these gender-specific drugs and cosmetic products is that such drugs are regulated under the FD&C Act, while cosmetics are not.

B. Cosmetics Affect Women More Than They Affect Men

Cosmetics usage has the potential to affect women (adversely, as well as beneficially) on a larger scale than men. Health concerns may arise primarily because cosmetic products often wind up ingested or absorbed into the body. Perhaps the most obvious example of this is lipstick, trace amounts of which undoubtedly get inadvertently ingested when the wearer eats, drinks, or licks her lips—the average woman is said to "eat" one to three tubes of lipstick per year, equating to a shocking four to nine pounds in her lifetime. Tracing the history of lipstick helps to shed some light on its overall lack of regulation, as well as its potential impact.

At the beginning of the twentieth century, lipstick in America began to not only symbolize femininity, but also female emancipation, as suffragettes endorsed the product. American women would

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69. Id. (citation omitted).
70. Id.
71. Id.
74. Id.
75. Id. at 165.
76. Id. at 176.
publicly apply their lipstick, often in a noticeable red hue, with the intent of appalling men and reclaiming the product as one of female rebellion.\textsuperscript{77} Lipsticks first appeared in their modern tubes in 1915, making them more readily available, but neither federal nor state safety laws examined issues with lipstick preservation or their continued use.\textsuperscript{78} Despite the absence of cosmetics regulation under the Pure Food and Drugs Act of 1906 (the predecessor to the FD&C Act), some states considered limiting lipstick’s use, though not for the reasons one would hope\textsuperscript{79}:

New York’s Board of Health considered banning lipstick out of concern that it might poison the men who kissed women wearing it. A bill introduced in the Kansas legislature’s 1915 session would have made it a misdemeanor for any woman under age 44 to wear cosmetics if “for the purpose of creating a false impression.”\textsuperscript{80}

These sexist proposals did little to address the safety implications of women’s use of lipstick, but were instead concerned only with how such use would affect men.\textsuperscript{81}

The passage of the FD&C Act in 1938 opened the door for cosmetics regulation in its grant of jurisdiction to the FDA.\textsuperscript{82} The Act’s limitations on poisonous or deleterious substances, as well as on false or misleading claims, allowed progress to be made in the aftermath of its enactment, and prompted some state regulation as well.\textsuperscript{83} Further regulations involving labeling and color additives were legislated over the next several decades.\textsuperscript{84} The FDA attempted to regulate lipstick itself as a color additive, which would require FDA pre-approval before sale, but the Second Circuit Court of Appeals struck this down as exceeding the FDA’s statutory authority.\textsuperscript{85}

Self-regulation has ruled since the late twentieth century, with the FDA believing cosmetics to be of the lowest concern in terms of being hazardous.\textsuperscript{86} Concerns about shortcomings of industry self-regulation were not addressed by the FDA, it was only addressed in some state legislatures.\textsuperscript{87} During the 1990s, the FDA grappled with
(a) conflicting views of allowing the cosmetics industry to self-regulate based on cosmetics’ low risk, and (b) ending self-regulation based on industry reporting problems—the cosmetics industry had only been reporting problems at the rate of one in every fifty reports. Today, the FDA can still only regulate pre-market with regard to adulterated or misbranded cosmetics and can test and analyze products post-market to address safety concerns.

In December 2016, the FDA issued non-binding draft guidance on the recommended maximum level of lead in cosmetic lip products and externally applied cosmetics. This guidance stemmed from the 2007 Campaign for Safe Cosmetics’ (CSC) finding of lead in a small selection of lipsticks on the market. In response, the FDA examined lead levels not only in lipsticks, but in other externally applied cosmetics such as mascara, eyeshadows, lotions, and powders. The results showed that more than ninety-nine percent of the cosmetics surveyed had less than ten parts per million (ppm) lead. The FDA concluded that because it seemed that the vast majority of manufacturers could keep lead levels in their products at ten ppm or below, this number should be the threshold amount. They further determined that up to ten ppm lead in cosmetic products does not pose a health risk to the (specified as female) user:

Exposure to lead from lipstick is mainly by swallowing, such as after a consumer licks her lips, so we used the same approach for cosmetic lip products that we use to estimate exposure to lead from food. We determined that exposure to 10 ppm lead from incidental ingestion of cosmetic lip products is very small and cannot be measured in routine blood testing.

Exposure to lead from other cosmetics is by absorption through the skin, but the amount absorbed is very small. This means that exposure to lead from a product such as eyeshadow or body lotion is

88. Id. at 211.
89. *FDA Authority over Cosmetics*, supra note 7.
92. Id.
93. Id.
94. Id.
95. Id. (emphasis added).
96. Id.
even lower than exposure to lead from a lipstick or other lip cosmetics; moreover, it cannot be measured in routine blood testing.\(^{97}\)

Unaddressed by the FDA, however, is whether women using a combination of many externally applied cosmetics with a trace amount of lead increases chances of a health risk.\(^{98}\) It is also imperative to recall that FDA guidance documents do not establish legal remedies and merely reflect the FDA’s current stance on a topic.\(^{99}\)

Despite health and safety concerns brought to the FDA’s attention by individuals and organizations such as CSC, because these examinations in response are conducted post-market, it is inevitable that some products fall through the cracks and continue to be sold and used.\(^{100}\) In 2004, Jessica Simpson debuted her “Dessert Beauty” collection, which included lip glosses, lotions, and fragrances, all marketed as edible.\(^{101}\) Pink and glittery Dessert Beauty advertisements declared “It’s a fragrance. It’s a flavor.” and “Be fabulously flavored.”\(^{102}\) Although it is the Federal Trade Commission (FTC), not the FDA, that has jurisdiction over both food and cosmetics advertising,\(^{103}\) no lawsuit was filed alleging adulteration or misbranding as either a food or cosmetic product, nor was a health and safety concern brought to the FDA.\(^{104}\) The line was discontinued years later following intellectual property lawsuits alleging patent and copyright infringements, but one must wonder how safe it really was for female customers to “eat” these products.\(^{105}\)

Beyond the safety fears of ingesting lipstick, a myriad of cosmetics health and safety concerns exist with the increased potential to affect women as cosmetics’ core consumers. For instance, Keratin hair-straightening treatments can contain formaldehyde, a known carcinogen and eye, nose, throat, skin, and lung irritant.\(^{106}\) These

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98. See id.
100. *FDA Authority over Cosmetics*, supra note 7.
104. Telfer, supra note 101.
105. Id.
treatments have been found to contain formaldehyde even when labeled formaldehyde-free, but it is not illegal under the FD&C Act to manufacture and sell formaldehyde-containing cosmetics. Industry self-regulation can also be misleading, as products are deemed safe only in accordance with short-term side effect studies that do not include data regarding continued product use over a long or specific developmental period of time (e.g., puberty).

Continued cosmetics usage logically results in continued ingestion and/or absorption of their ingredients:

Cosmetics that are applied to the skin will be absorbed. What is absorbed will be stored in fatty tissue. Studies show that women's bodies store chemicals cumulatively more effectively than men's bodies, placing women at greater risk. While exposures to an individual chemical in a single personal care product may not cause harm, the average American woman uses 12 personal care products per day exposing her to approximately 126 unique chemicals.

Other chemicals regularly used in cosmetic products, such as progesterone and estrogenic chemicals, are also dangerous to women, posing harm during puberty and pregnancy and increasing the risk for breast cancer. Biological differences in combination with simply using more cosmetic products more frequently over long periods of time, place women at a heightened health and safety risk with very little federal legal recourse.

C. Adversely Affected Women Currently Have Limited Options in Seeking Legal Recourse Without Federal Cosmetics Regulation

Since the FDA can only take legal action over products alleged to be adulterated or misbranded, it cannot issue a mandatory product recall or seizure upon receipt of adverse reports. Furthermore, when consumers make adverse product reports to the manufacturer, the manufacturer is not legally required to send these or other reports of adverse events to the FDA. This roadblock results in

107. Id.
108. Id. at 340–41.
109. Id. at 341.
110. Id.
111. Id.
112. FDA Information for Consumers About WEN by Chaz Dean Cleansing Conditioners, U.S. FOOD & DRUG ADMIN. (Nov. 3, 2017), http://www.fda.gov/Cosmetics/Products Ingredients/Products/ucm511631.htm [https://perma.cc/VD8X-B5NT] [hereinafter FDA Information for Consumers].
113. Id.
class action personal injury lawsuits against the manufacturer, but
without accompanying FDA-sanctioned consequences. In the case of Friedman v. Guthy-Renker, LLC, plaintiffs brought a class action suit against WEN by Chaz Dean, Inc., the brand, and Guthy-Renker, the manufacturer, alleging hair loss and scalp irritation resulting from the use of WEN haircare products. All but one claim (for breach of warranty) were brought under California law, absent the ability to seek an injunction from the FDA to stop the production or sale of this product. Defendants continued to stand behind the safety of their products, as WEN “has not been proven to cause hair loss to consumers, nor has it been legally determined that any advertising of the [products] was false or misleading.” Despite the defendants’ assertions and to avoid the costs of litigation, the case resulted in a settlement, which was granted preliminary approval by the United States District Court for the Central District of California in 2016. An order granting final approval and a final settlement judgment were granted in August 2017, with several subsequent appeals filed a month later.

Even if these affected women ultimately receive a settlement payment, their suffering was likely much more distressing than if the victims were men. “Hair loss in women can be absolutely devastating for the sufferer’s self image and emotional well being. Unfortunately, society has forced women to suffer in silence. It is considered far more acceptable for men to go through the same hair loss process.” Societal norms have created an environment in which female hair loss results in psychological damage, that can be so emotionally taxing in a way that may eventually affect physical health.

Whether physical, mental, or both—health issues arising from the use of cosmetic products can and do affect women in a more significant way than they affect men. Women, as the primary consumers of cosmetic products, ultimately use these products at a greater rate.

116. Id. at *4.
117. FDA Information for Consumers, supra note 112.
118. WEN HAIR CARE, supra note 114.
122. Id.
123. Id.
than men. A greater percentage of women than men report regularly using even gender-neutral products like sunscreen. On the other end of the product spectrum, lipstick, a socially female-specific cosmetic, gets inadvertently ingested but has no federal ingredient requirements or limitations. Other products pose health concerns to women simply due to biological differences, such as women's predisposition of higher chemical retention in fatty tissue. Still, more products may cause adverse effects that are more emotionally devastating to women than they would be to men, which, in turn, can also affect their physical health. Overall, cosmetics affect women, and so does the lack of federal cosmetics regulation under the FD&C Act.

III. THE LACK OF FD&C ACT REGULATION OVER COSMETICS HAS A DISPARATE IMPACT ON WOMEN

The ways in which cosmetics affect women specifically cause the FD&C Act to have a disparate impact on women as a class. “Disparate impact” is defined as “[a]pparently neutral behavior that has a discriminatory effect.” A disparate impact claim has no requisite intent and may be established even if the law is facially nondiscriminatory. The FD&C Act is clearly neutral on its face; there are no provisions which apply or grant protections to only males or only females. But due to the overall lack of cosmetics regulation under the Act, and for the concerns set forth in Part II of this Note, the Act effectually has a disparate impact on women.

Equal protection is not a novel issue for the FDA. In the clinical trial context, FDA guidelines from 1977 “recommended the exclusion of women of childbearing potential from early phase drug trials.” Over a decade later, the FDA modified this guidance with

125. Study: Most Americans, supra note 64.
126. See Limiting Lead in Lipstick, supra note 91.
128. See, e.g., Women’s Hair Loss, supra note 121.
130. Id.
132. See discussion supra Part II.
134. Id. at 147.
the 1993 Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs.\textsuperscript{135} This recommended that the subjects in a clinical study reflect the actual population that will receive the drug once it is on the market.\textsuperscript{136} Although this new guideline advocated, but did not require, that women participate in the early stages of drug trials, it created an expectation of identifying whether a gender difference exists in response to a drug, and, if so, the basis of that gender difference.\textsuperscript{137} The inclusion of women in clinical studies would help to indicate post-market effects on women that were never before evaluated pre-market, such as response to a drug based on the varying hormone levels of the menstrual cycle.\textsuperscript{138} Additionally, female inclusion would open the door to recognizing the need for further testing on specific subsets of the population to determine the drug’s safety and efficacy.\textsuperscript{139}

The Supreme Court has not decided an equal protection challenge to a demographic restriction in clinical trials, but “legal experts maintain that research policies that result in the exclusion of women as a class, whether on their face (with explicit exclusionary language) or in effect (because they result in disproportionate participation of men and women), may be found to contradict the equal protection clause.”\textsuperscript{140} The Supreme Court’s holding that the equal protection clause of the Constitution restricts the government’s (and its agencies’) right to treat similarly situated people differently supports this theory.\textsuperscript{141}

Critically, a law being unconstitutional and a law having a disparate impact are not the same.\textsuperscript{142} The Supreme Court in \textit{Feeney} held that a neutral law may have a disproportionate, adverse effect on a minority but requires a discriminatory intent to be unconstitutional.\textsuperscript{143} The Court further held that “[c]lassifications based upon gender, not unlike those based upon race, have traditionally been the touchstone for pervasive and often subtle discrimination.”\textsuperscript{144} This Note does not purport to argue that the FD&C Act and its lack of cosmetics regulation are unconstitutional because its drafters intended to adversely discriminate against women; the FD&C Act

\begin{itemize}
\item \textsuperscript{135}Id. at 139.
\item Id. at 139–40.
\item Id. at 140.
\item Id.
\item Id.
\item Id. at 139.
\item Id. at 146 (emphasis omitted).
\item See id.
\item Id.
\item Id. at 273.
\end{itemize}
instead has a disparate impact on women in its application that must be remedied.

IV. THE COSMETICS INDUSTRY'S CURRENT SELF-REGULATION REGIME DOES NOT CURE THIS DISPARATE IMPACT; THUS, ADDITIONAL FEDERAL REGULATION IS NEEDED

One could argue that the cosmetics industry’s current self-regulatory scheme does not require federal intervention because the FDA’s current authority is sufficient and has worked since the FD&C Act’s enactment. 145 Although the industry is ultimately responsible for product safety, the FDA can advise by issuing guidance documents and monitor once a product has been flagged as unsafe. 146 In regards to cosmetic testing, the FDA has consistently advised the industry to use whatever testing necessary to ensure product safety. 147 The FDA also monitors the conduction of product recalls, and may even request a recall if a company refuses to remove dangerous products from the market. 148 However, unlike in the past, much of the industry seems to agree that this is not enough. 149 A study conducted from 2004 to 2016 found that consumers and healthcare providers reported an average of 400 cosmetics-attributed adverse events per year. 150 Consumer complaints more than doubled from 2015 to 2016 due to the WEN haircare product events. 151 Most notably, the number of cosmetics-related adverse events reported to the FDA was considerably lower than those reported for drugs and medical devices. 152 Cosmetics manufacturers are not required to disclose to the FDA any complaints they receive, which likely explains this discrepancy. 153 “[U]nder existing law, the [FDA] could take action against [a] company only if it could prove a product had been mislabeled or contaminated. If the product turns out to be dangerous but legal, the government has no recourse.” 154

146. FDA Authority over Cosmetics, supra note 7.
147. Id.
148. Id.
149. See, e.g., Pepper Hamilton LLP, supra note 145.
150. Id.
151. Id.
152. Id.
153. Id.
This lack of oversight in effect puts the burden on the consumer to investigate which ingredients may be harmful to her.\textsuperscript{155} "It is a situation in which the old adage 'let the buyer beware' truly applies."\textsuperscript{156} Furthermore, many effects of certain ingredients on human—namely, women's—health were not known in 1938; thus, the law as it stands does not reflect the past eighty years' breadth of knowledge.\textsuperscript{157} Three notable pieces of legislation—the Personal Care Products Safety Act, the Safe Cosmetics Modernization Act, and the FDA Cosmetic Safety and Modernization Act of 2017—have been introduced over the past several years in both the House and the Senate aiming to tackle the disparate impact on the female consumer, albeit to varying degrees.\textsuperscript{158}

A. Personal Care Products Safety Act

Introduced by Senators Dianne Feinstein and Susan Collins in 2015 and reintroduced in May 2017, the Personal Care Products Safety Act (PCPSA) would broaden FDA authority over cosmetics in a number of ways.\textsuperscript{159} The bill requires the FDA to evaluate a minimum of five ingredients per year to determine their safety and appropriate use, going so far as to dictate the first five ingredients to be analyzed: four preservatives and one color additive.\textsuperscript{160} PCPSA outlines the standard of review for this requirement as “determining whether there is 'adequate evidence to support a reasonable certainty among competent scientists that the ingredient is not harmful.'”\textsuperscript{161}

PCPSA also grants the FDA the authority to establish conditions for safe use of an ingredient, order recalls of cosmetics posing safety risks, and conduct cosmetics safety activities funded by cosmetics companies’ required fees.\textsuperscript{162} Cosmetics facilities would have to register with the FDA, and companies would also be required to submit annual reports of all adverse events.\textsuperscript{163} An express preemption provision in the bill would prohibit states from imposing regulations different from or in addition to the FDA’s.\textsuperscript{164}

\begin{itemize}
\item[\textsuperscript{155}] Should the FDA Crackdown on the Cosmetics Industry?, CTL. FOR. PLAST. SURGERY (Sept. 15, 2016), http://www.cpsdocs.com/blog/fda-crackdown-cosmetics-industry [https://perma.co/K3KL-SCK5].
\item[\textsuperscript{156}] Id.
\item[\textsuperscript{157}] See id.
\item[\textsuperscript{158}] See Lipton & Abrams, supra note 154; see also Pepper Hamilton LLP, supra note 145.
\item[\textsuperscript{159}] See Pepper Hamilton LLP, supra note 145.
\item[\textsuperscript{160}] Id.
\item[\textsuperscript{161}] Id. (citation omitted).
\item[\textsuperscript{162}] Id.
\item[\textsuperscript{163}] Id.
\item[\textsuperscript{164}] Id.
\end{itemize}
Response to PCPSA has been positive from many of the big names in the industry.\textsuperscript{165} Johnson & Johnson created a webpage entitled “Consumer Confidence Is More Than a Formula” to outline its support for PCPSA.\textsuperscript{166} The webpage names the key features of PCPSA to highlight the goal of “bringing peace of mind to consumers.”\textsuperscript{167} A Johnson & Johnson lobbyist touted PCPSA as “supported by a vast and diverse group of people and groups who all want the same thing—cosmetic regulations that best serve the public health and give consumers confidence in the products and ingredients they choose for their families.”\textsuperscript{168} Proctor & Gamble reiterated its support for PCPSA even after the introduction of a second cosmetics reform bill in the Senate in October 2017.\textsuperscript{169} Other major environmental, consumer, and health groups, including the American Cancer Society, have also supported the bill.\textsuperscript{170}

Others, including the Independent Cosmetic Manufacturers and Distributors (ICMAD) and cosmetics company Mary Kay, have criticized PCPSA as “overreaching” and failing to provide a clear uniform safety standard.\textsuperscript{171} The beauty care trade association, to which WEN haircare’s distributor belongs, has also lobbied against PCPSA.\textsuperscript{172} “The fight has pitted smaller independent players against the giants of the beauty products industry, which back the proposed regulations, seeing them as an avenue toward regaining public trust, and have the size and muscle to comply with them.”\textsuperscript{173} In response to this backlash, the most recent version of PCPSA added a provision exempting small businesses (those averaging less than $500,000 in gross sales over 3 years as well as home-based businesses averaging less than $1 million) from its requirements.\textsuperscript{174}

\textbf{B. Safe Cosmetics Modernization Act}

In response to smaller companies’ backlash against PCPSA, Representative Pete Sessions introduced competing legislation in

\begin{itemize}
\item \textsuperscript{165} See Lipton & Abrams, supra note 154.
\item \textsuperscript{166} Consumer Confidence is More Than a Formula, JOHNSON & JOHNSON, http://www.cosmeticreform.com/index.html [https://perma.cc/ZN9I-ZQZU].
\item \textsuperscript{167} Id.
\item \textsuperscript{168} Lipton & Abrams, supra note 154 (citation omitted).
\item \textsuperscript{170} See Lipton & Abrams, supra note 154.
\item \textsuperscript{171} Id.
\item \textsuperscript{172} Id.
\item \textsuperscript{173} Id.
\item \textsuperscript{174} See Pepper Hamilton LLP, supra note 145.
\end{itemize}
the House in late 2015, and again in early 2017.\textsuperscript{175} The Cosmetic Modernization Amendments, also referred to as the Safe Cosmetics Modernization Act (SCMA),\textsuperscript{176} establishes similar requirements to PCPSA.\textsuperscript{177} The key difference for PCPSA critics lies in SCMA’s grant of authority for the FDA to establish exemptions to the bill’s requirements “for . . . efficient and cost-effective implementation.”\textsuperscript{178}

ICMAD opposes PCPSA, claiming that it would place too large a burden on small businesses, would not provide reasonable national uniformity, and would stifle industry innovation.\textsuperscript{179} ICMAD instead “strongly supports” SCMA, which asserts that it would modernize current FDA cosmetics regulation while supporting small businesses and innovation.\textsuperscript{180} While PCPSA would allow the FDA to collect approximately twenty million dollars in annual fees from cosmetics companies to help cover the cost of the mandatory safety testing on at least five ingredients per year, SCMA does not grant the authority to order recalls or collect industry fees for safety evaluation.\textsuperscript{181}

SCMA purports to cure the issue of national uniformity by remaining consistent with the Safe and Accurate Food Labeling Act and the Microbead-Free Waters Act of 2015.\textsuperscript{182} “Unlike the Personal Care Products Safety Act, [SCMA] creates transparency in all health and safety decisions related to cosmetics and increases consumer protections. It does all this without overburdening small businesses or stifling the innovation that is the lifeblood of our industry.”\textsuperscript{183}

C. FDA Cosmetic Safety and Modernization Act of 2017

In October 2017, Senator Orrin Hatch introduced another piece of federal cosmetics oversight legislation, which, like SCMA, addresses existing concerns with PCPSA.\textsuperscript{184} This bill, known as the FDA

\textsuperscript{175} See Cosmetic Modernization Amendments of 2017, H.R. 575, 115th Cong. (2017); see also ICMAD’s Statement on Support of Legislation to Modernize the FDA’s Oversight Over Cosmetics, INDEF. COSM. MANUFACTURERS AND DISTRIBUTORS (Aug. 15, 2016), http://icmad.org/advocacy/legislative-advocacy-program [https://perma.cc/Y9ZL-RZBL] [hereinafter ICMAD’s Statement].

\textsuperscript{176} ICMAD’s Statement, supra note 175.


\textsuperscript{178} H.R. 575, 115th Cong. § 1(b) (2017).

\textsuperscript{179} ICMAD’s Statement, supra note 175.

\textsuperscript{180} Id.

\textsuperscript{181} See Lipton & Abrams, supra note 154.

\textsuperscript{182} ICMAD’s Statement, supra note 175.


\textsuperscript{184} Hawana, supra note 169.
Cosmetic Safety and Modernization Act (referred to as the “Hatch bill”), introduces measures for the FDA to regulate cosmetic ingredients, monitor adverse reactions, and establish good manufacturing practices. Specifically, the Hatch bill gives the FDA authority to accredit third-party organizations to determine chemical safety, and preempts state action on cosmetic chemical ingredients once the FDA identifies such an ingredient for review.

An essential difference between the Hatch bill and PCPSA is the source of funding for the FDA’s new work. While PCPSA allows the FDA to collect fees from the cosmetics industry, the Hatch bill relies on congressional appropriations and allows for accredited third parties to assess safety. It is unclear whether congressional appropriations would fund such third parties or if they must bear the cost themselves; however, the third parties must not be financially affiliated with any cosmetics manufacturer or supplier. The Hatch bill thus takes the burden off the industry itself to incur regulatory costs, but would in turn be an additional cost to the government controlled by Congress.

The two Senate bills also differ with regard to their burdens of proof for cosmetic product safety. Whereas PCPSA requires the FDA to review the safety of five chemicals per year and places the burden on the manufacturer to establish that chemicals in their products show reasonable certainty of no harm, the Hatch bill takes a different approach. The Hatch bill authorizes chemical safety reviews by accredited third parties, but without any timeline or further specifics. The ultimate burden lies with the FDA to show that a chemical is “not injurious” under usual use.

The Hatch bill enjoyed immediate support from the Personal Care Products Council, as well as from ICMAD. Critiques from organizations such as the Environmental Working Group (EWG)

185. Id.
186. Id.
187. Id.
188. Id.
189. Id.
190. Hawana, supra note 169.
191. Id.
192. Id.
193. Id.
194. Id.
196. Hawana, supra note 169.
maintained support for PCP, expressing concern that the Hatch bill would be less protective of consumers and would fail to provide funding to the FDA to support this new regulatory role.\textsuperscript{197}

EWG asserts that the Hatch bill “is full of loopholes that would make a broken law even worse.”\textsuperscript{198} In contrast to PCP, the Hatch bill does not require (1) companies to share ingredient information with the FDA; (2) safety substantiation records; (3) review of a specific number of chemicals with any deadline; nor (4) disclosure of salon product ingredients in an effort to protect salon workers who are exposed to these products daily.\textsuperscript{199} The Hatch bill requires reporting of only “serious” adverse effects and does not consider temporary hair loss to be “serious.”\textsuperscript{200} Also of note, the Hatch bill would prevent states from enacting their own cosmetics regulations once the FDA identifies a chemical for review, which would allow an administration to preempt state action “by simply creating a list of chemicals.”\textsuperscript{201}

EWG concludes that the Hatch bill is not bipartisan, is unsupported by the industry in terms of cosmetics manufacturers and health groups and does not meet the principles laid out by the Personal Care Products Association, the industry trade association.\textsuperscript{202} Relying on Congress to appropriate funding does not guarantee any amount for the Hatch bill to support itself.\textsuperscript{203} In contrast, PCP relies on industry funding, while still exempting smaller cosmetics companies, which would provide greater assurance that the FDA would have the resources to comply.\textsuperscript{204}

D. The Personal Care Products Safety Act Has the Greatest Potential to Address the Current Disparate Impact on Women and Should Thus Become the New FDA Cosmetics Regulatory Regime

Though each piece of proposed legislation arguably contains pros and cons, it is clear that some form of federal cosmetics regulation must be enacted. The Personal Care Products Council in its support for the Hatch bill stated:

\textsuperscript{197} Id.
\textsuperscript{199} Id.
\textsuperscript{200} Id.
\textsuperscript{201} Id.
\textsuperscript{202} Id.
\textsuperscript{203} Id.
\textsuperscript{204} See Benesh & Faber, supra note 198.
We support modernizing cosmetics regulation to ensure FDA has the appropriate resources and administrative authority to continue to oversee our products. We also believe strongly that well-crafted, science-based reforms will enhance our industry’s ability to innovate and further strengthen consumer confidence in the products they trust and enjoy every day.\(^{205}\)

They further emphasized that they “urge Congress to move swiftly to pass cosmetics legislation this year.”\(^{206}\) EWG, a staunch opponent of the Hatch bill and proponent of PCPSA, noted that the current regime is “badly broken” and should be modernized after eighty years of failure.\(^{207}\) Regardless of which bill they support, the overall consensus among those in the cosmetics industry favors an update to the FD&C Act in the name of consumer protection.\(^{208}\)

Overall, however, PCPSA appears to be the best equipped to tackle the disparate impact women face with regard to cosmetics regulation, or its current lack thereof.\(^{209}\) For the foregoing reasons enumerated by EWG, PCPSA has a strong advantage over the Hatch bill in ultimately providing consumer assurance and protection.\(^{210}\)

Returning to the WEN haircare events to illustrate an example, the Hatch bill only requires the reporting of “serious” adverse effects, which do not include temporary hair loss.\(^{211}\) The women affected by the WEN hair products would still have no legal recourse under the Hatch bill separate from suing the manufacturer directly—the Hatch bill creates no additional protection.\(^{212}\)

Similarly, the House SCMA bill “would require beauty care companies to notify the F.D.A. of ‘serious cosmetic adverse events,’ but it would not grant the agency the power to order a recall.”\(^{213}\) It would also “broadly and retroactively” preempt any state laws with higher standards, thus eliminating any additional state-specific protection.\(^{214}\)

In contrast, PCPSA requires cosmetic manufacturers to report to the FDA any serious adverse effects within fifteen days of being made aware, as well as to provide annual reports of all adverse effects.\(^{215}\)

\(^{205}\) Statement by Lezlee Westine, supra note 195.
\(^{206}\) Id.
\(^{207}\) Benesh & Faber, supra note 198.
\(^{208}\) See Lipton & Abrams, supra note 154; Statement by Lezlee Westine, supra note 195; see, e.g., Benesh & Faber, supra note 198.
\(^{209}\) See Benesh & Faber, supra note 198.
\(^{210}\) Id.
\(^{211}\) Id.
\(^{212}\) See id.
\(^{213}\) Lipton & Abrams, supra note 154 (citation omitted).
\(^{214}\) Id.
\(^{215}\) See Benesh & Faber, supra note 198.
Even if PCPSA, like the Hatch bill, did not define cosmetic-product-use-induced hair loss as “serious,” the FDA would still be notified of such events within a year. The affected women would therefore have additional remedies in the form of an FDA-authorized recall and government action against Guthy-Renker for failing to substantiate the safety of the WEN products.

PCPSA also addresses the issue of cosmetics that do not produce adverse effects per se but can be unhealthy to use long-term, such as inadvertently ingesting lead-containing lipstick. PCPSA “requires companies to share ingredient information with the FDA so that the agency’s scientists can better evaluate how consumers are exposed to cosmetics chemicals.” It also requires companies to actively substantiate the safety of their cosmetic products and maintain such records, allowing FDA access. These active requirements on companies would not only help to avoid post-market adverse events, but also prevent consumer use of products that only cause health issues over time or under certain circumstances such as pregnancy.

The Hatch bill lacks such ingredient information sharing and safety substantiation requirements. Without these provisions, companies are more likely to continue operating as they do under the self-regulatory system, since the FDA would not require additional safety information to be submitted from them. The Hatch bill attempts to establish good manufacturing practices, but prohibits the FDA “from imposing standards for which there is no current and generally available analytical methodology,” thus limiting its own scope. SCMA, like the Hatch bill, also allows for third party safety substantiation for certain cosmetic ingredients, leaving the door open for the industry to maintain its current routine.

Perhaps the most compelling argument in favor of PCPSA is its source of funding. PCPSA would collect approximately twenty million dollars annually from industry-user fees. This funding would allow the FDA to cover the costs of the bill’s requisite testing.

216. See id.
217. See Benesh & Faber, supra note 198; Pepper Hamilton LLP, supra note 145.
218. See Benesh & Faber, supra note 198.
219. Id.
220. Id.
221. Id.
222. Id.
223. See id.
224. See Hawana, supra note 169.
226. See Benesh & Faber, supra note 198.
227. See Hawana, supra note 169; see also Lipton & Abrams, supra note 154.
of five cosmetics per year, which in turn would help manufacturers in the long run by effectually performing safety substantiations of common cosmetic ingredients for them. The industry funding would also subsidize necessary resources for the FDA’s affirmative power under PCPSA to act in response to adverse events.

PCPSA addresses concerns that many of its opponents have expressed with regard to forcing small businesses to pay fees they cannot afford. It protects smaller cosmetics companies from having to pay these fees when their revenues are below a certain amount. It also allows a simpler registration process for companies with sales below two million dollars, unless they manufacture products deemed to be “high-risk.” Though critics may see this as an industry burden, this high-risk exemption maintains PCPSA’s ultimate goal of effectuating consumer safety in the cosmetics market.

In short, PCPSA, by mandating industry funding, ensures compliance with and performance of its provisions. The absence of mandatory industry fees in both the Hatch bill and SCMA do not allot a clear amount to the FDA to carry out their respective provisions. The Hatch bill’s reliance on congressional appropriation allows legislators to allocate FDA resources on a whim, tolerating potential partisan implications where funding depends on which political party is in power. To remedy the disparate impact that has affected women for at least the past eighty years, the new law should require consistency and neutrality in its resources and application. Of the current proposed legislation, PCPSA is the best prepared to finally eliminate this bias.

CONCLUSION

Cosmetics are barely regulated under the FD&C Act when compared to the Act’s regulations governing food and drugs. Three cosmetic-specific provisions cover adulteration and misbranding, but provide no consumer relief allowing the FDA to regulate cosmetics pre-market via approval or notification mechanisms, similar to those...
in place for certain food and drug products. Nothing in the FD&C Act's legislative history explains this discrepancy, leaving cosmetics regulated today as they were eighty years ago.

As countless statistics demonstrate, women are more likely than men to purchase and use, and thus bear any potential side effects from, cosmetic products. Cosmetics wind up inadvertently ingested and absorbed into the body without mandated pre-market safety testing. Post-market, once an adverse effect has occurred, a consumer can report it to the manufacturer, but there is no guarantee that information will be passed on to the FDA. Even if it is, the FDA does not currently have jurisdiction to initiate a response and can only issue industry guidance that is not legally binding.

The lack of cosmetics regulation in the FD&C Act, therefore, has a disparate impact on women, leaving them to rely on the cosmetic industry's self-regulatory scheme and hope that the products they are using truly are safe. A law with an existing disparate impact minus such intent, does not result in unconstitutionality, but simply a disproportionate effect in its application. Because women use cosmetic products to a much greater degree than men, the FD&C Act has a disparate impact on women that must be addressed.

Despite the cosmetic industry's long history of self-regulation in the absence of federal regulations, this disparate impact continues to exist and requires amendments to the cosmetics subchapter of the FD&C Act to prevent unsafe products from entering the market without approval by, or at least notice to, the FDA. The Personal Care Products Safety Act and the FDA Cosmetic Safety and Modernization Act in the Senate, and the Safe Cosmetics Modernization Act in the House demonstrate Congress's recent efforts and intent to finally impose federal cosmetics regulations. Each bill has garnered its own support and criticisms from different industry players, but there is a noticeable absence of a complete anti-federal regulation stance.

239. See Benesh & Faber, supra note 198.
240. See Adams, supra note 1.
242. See, e.g., Lipton & Abrams, supra note 154.
243. See, e.g., DRAFT GUIDANCE FOR INDUSTRY, supra note 90.
244. See, e.g., Schaffer, supra note 73, at 203–04.
245. See Adams, supra note 1.
246. See Lipton & Abrams, supra note 154.
247. See Benesh & Faber, supra note 198.
248. See Lipton & Abrams, supra note 154.
Women have used cosmetic products long before the FD&C Act’s enactment in 1938. In the eighty years since, despite scientific advancements, research, and adverse reports, the Act’s cosmetics subchapter remains unaltered. The introduction in recent years of cosmetics reform bills in Congress sheds some light on the legislature’s intent to finally modernize a law that has provided little, if any, protection to women since its inception. Hopefully soon, women will wash their hair and put on their lipstick with the assurance that they are not their products’ first test subjects.

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