Hofstra Law Review

Volume 51 | Issue 1 Article 7

9-1-2022

First You Buy the Moisturizer, Then You Pay the Price: An Overview of the United States' Lack of Cosmetic Market Regulations and How it Harms the Consumers

Megan Scime
Maurice A. Deane School of Law at Hofstra University

NOTE

FIRST YOU BUY THE MOISTURIZER, THEN YOU PAY THE PRICE: AN OVERVIEW OF THE UNITED STATES' LACK OF COSMETIC MARKET REGULATION AND HOW IT HARMS THE CONSUMER

"The most beautiful makeup of a woman is passion. But cosmetics are easier to buy."

Yves Saint Laurent[1]

I. INTRODUCTION

Each morning you likely wake up, shower, wash your face, complete your skincare routine, and put on some quick makeup before running out the door to start the day.[2] There are a million other things to worry about besides the same routine that you have done every morning since you were a teenager—but what if that routine is secretly putting your health at risk?[3] If you identify as a woman, you have likely used twelve products in that routine, and if you identify as a man, you have used about six.[4] One day, you may decide to pick a new shampoo off the

1. SocksLane Compression, *The 5 Golden Rules of Makeup for Women Over 40*, MEDIUM (July 29, 2018), https://medium.com/@slcompression/yves-saint-laurent-once-said-the-most-beautiful-makeup-of-a-woman-is-passion-73752c5c976d [https://perma.cc/FR2J-Q8C8]. Yves Saint-Laurent once said, "The most beautiful makeup of a woman is passion. But cosmetics are easier to buy." *Id.* "His practical, albeit humorous, approach to beauty and maquillage is something everyone can learn from." *Id.*

2. The Story of Stuff Project, *The Story of Cosmetics*, YOUTUBE (July 21, 2010), https://www.youtube.com/watch?v=pfq000AF1i8 [https://perma.cc/L6QA-RRAK] (examining the average morning routine and the number of products used by both men and women). On average, women use about twelve products per day, while men use about six products per day. *Id.*

3. *See generally Common Beauty Project Injuries*, FARAH & FARAH, https://farahandfarah.com/studies/common-beauty-product-injuries [https://perma.cc/7YG7-XQ5S] (last visited Nov. 18, 2022) (explaining the most common injuries caused by personal care products).

4. The Story of Stuff Project, *supra* note 2. Throughout this Note, the author will be using the terms "man" and "woman" because of the gendered marketing of cosmetics. *Infra* Parts I–V; Helen Carefoot, *Why Beauty Brands Are Removing Gender from Their Marketing*, WASH. POST

store shelf because your favorite social media influencer recommends it;

(Mar. 30, 2020), https://www.washingtonpost.com/lifestyle/wellness/hello-coverboy-cosmetics-and-skin-care-brands-turn-to-gender-neutral-packaging/2020/03/02/2c30f49e-54d4-11ea-9e47-59804be1dcfb_story.html [https://perma.cc/4ZUA-SS3E]. Gendered marketing is the idea that marketing for cosmetics has been primarily geared towards gender norms that assume there are only two genders. Freddie Braun, *Skin Deep: Is the Future Of Skincare Gender Neutral?*, VOGUE (May 4, 2020), https://www.vogue.in/beauty/content/skin-deep-is-the-future-of-skincare-gender-neutral [https://perma.cc/78SC-TXJ4]. Despite this gendered marketing, this Note acknowledges the gender binary and the existence of more than two genders. *See id.*; *infra* Parts I–V. Many cosmetic brands are becoming more ingredient focused, rather than gender focused, in order to make their products inclusive for all. Braun, *supra*; The Story of Stuff Project, *supra* note 2 (examining the average morning routine and products used by both men and women). Another issue to contemplate when considering this Note is that on average, women use about six more products per day than men, making cosmetics heavily gendered products, and their regulation follows suit. The Story of Stuff Project, *supra* note 2. Some see the lack of legislative prioritization for cosmetics law as a consequence of women's exclusion from political participation and representation. Justice Tecson, *Total Makeover: Federal Cosmetics Regulation and Its Need for Legislative Overhaul to Ensure Consumer Protection*, 51 GOLDEN GATE U. L. REV. 127, 129 (2021). For example, under current FDA regulations, ingredients deemed unsafe for topical use in a drug are considered safe in a cosmetic, despite the chemicals being absorbed in the same way. Emily Jones, *Stripped from Sunscreen, but Fine for Foundation: How the Regulatory Dichotomy of Topically Applied Skin Products Endangers Women*, 35 WISC. J.L. GENDER & SOC'Y 143, 151 (2020). Another example is that ingredients that are considered known dangers in sunscreens are allowed without regulation in foundation—a cosmetic used daily, primarily by women. *Id.* These ingredients include chemicals such as Aminobenzoic acid up to fifteen-percent, Avobenzone up to three-percent, Cinoxate up to three-percent, Dioxybenzone up to three-percent, Homosalate up to fifteen-percent, Menthyl anthranilate up to five-percent, Octocrylene up to ten-percent, Octyl methoxycinnamate up to seven-and-a-half-percent, Octyl salicylate up to five-percent, Oxybenzone up to six-percent, Padimate O up to eight-percent, Phenyl benzimidazole sulfonic acid up to four-percent, Sulisobenzone up to ten-percent, Titanium dioxide up to twenty-five-percent, Trolamine salicylate up to twelve-percent, Zinc oxide up to twenty-five-percent, Ensulizole up to four-percent, Homosalate up to fifteen-percent, Meradimate up to five-percent, Octinoxate up to seven-and-a-half-percent, and Octisalate up to five-percent. Giulio Pirotta, *An Overview of Sunscreen Regulations in the World*, RESEARCHGATE (July 2015), https://www.researchgate.net/profile/Giulio-Pirotta-2/publication/283515177_An_overview_of_sunscreen_regulations_in_the_world/links/563cdb7508aec6f17dd7e0d6/An-overview-of-sunscreen-regulations-in-the-world.pdf [https://perma.cc/KD9Q-QXYQ]. The average woman is exposed to more than 200 chemicals a day through her daily products. Lauren Zanolli, *Pretty Hurts: Are Chemicals in Beauty Products Making Us Ill?*, GUARDIAN (May 23, 2019), https://www.theguardian.com/us-news/2019/may/23/are-chemicals-in-beauty-products-making-us-ill [https://perma.cc/76TT-SQPG]. Women use products more frequently in a week than men, and therefore suffer higher cumulative exposure at the hands of this unregulated cosmetic industry. Jones, *supra* at 156. Many scholars believe cosmetics are severely under-researched because of their current social status as a gendered product. Marie Boyd, *Gender, Race & the Inadequate Regulation of Cosmetics*, 30 YALE J.L. & FEMINISM 275, 284 (2018). For example, when the Campaign for Safe Cosmetics conducted a study testing the lead in lipsticks, a product primarily marketed towards women, it found that sixty-one percent of lipsticks contained lead. Lauren Jacobs, *Beauty Shouldn't Cause Pain: A Makeover Proposal for the FDA's Cosmetics Regulation*, 39 J. NAT'L ASS'N L. JUD. 82, 90-91 (2019). The FDA investigated this data twenty-four months later, only after mounting pressure from consumers and a letter addressing the situation from three U.S. Senators. Jacobs, *supra*, at 91. When the FDA finally did investigate, it found four times the amount of lead in lipstick than the Campaign for Safe Cosmetics' study discovered. Jacobs, *supra*.

you wash your hair, and it feels the same as any other day.[5] The next day, you wake up and look in the mirror to see if your hair is as shiny as the influencer had promised, only to find that the shampoo has caused severe burns to your scalp.[6] As it turns out, this injury is even severe enough to call out of work because you need to visit the emergency room or a doctor's office.[7] In 2016, more than 2,300 people visited a doctor due to reactions from a new cosmetic they had tried, most commonly for burns.[8] However, even if your reaction is not severe enough to warrant a doctor's visit, you can still experience issues such as hair loss or skin irritation.[9] It is probable that all of these symptoms can be traced back to your decision in the cosmetic aisle.[10]

Cosmetic regulation has remained largely unchanged since the passage of the Federal Food, Drug, and Cosmetic Act in 1938, an Act that continues to allow hazardous cosmetics to land in the hands of consumers.[11] In the United States, the Federal Food, Drug, and Cosmetic Act does not require registration of companies or products whose claimed "intended use" is that of a cosmetic.[12] This means that the

5. *Common Beauty Project Injuries Exploring Cosmetic Injuries Reported to the FDA from 2004 to 2018*, *supra* note 3.

6. *Id.*

7. *Id.* ("Not only are consumers reporting experiencing negative reactions to cosmetic products, but they are also experiencing severe outcomes in some cases. In 2016, there was a huge spike in the number of reported visits to health care providers because of cosmetic product side effects. More than 2,300 people reported going to their provider that year, compared to only 57 in 2010. Each year after that steadily increased, except for 2017 when there was a dip to 954.").

8. *Id.* Many of these doctor and hospital visits were linked to products that were later recalled. *Id.* The most common issues reported at these visits were reactions including burning and choking. *Id.*

9. *See generally id.* (explaining the most common injuries caused by personal care products). The most common injury from a hair product was hair loss, the second most common injury from makeup products was burning, and the fourth most common reported injury from facial products was severe itching. *CFSAN Adverse Event Reporting System (CAERS)*, FOOD & DRUG ADMIN. (Aug. 15, 2022), https://www.fda.gov/food/compliance-enforcement-food/cfsan-adverse-event-reporting-system-caers [https://perma.cc/PXM7-SZ2S].

10. *See generally Common Beauty Project Injuries Exploring Cosmetic Injuries Reported to the FDA from 2004 to 2018*, *supra* note 3 (explaining injuries caused by common personal care products).

11. Scott Faber, *80 Years Later, Cosmetic Chemicals Still Unregulated*, ENV'T WORKING GRP. (June 25, 2018), https://www.ewg.org/news-insights/news/80-years-later-cosmetics-chemicals-still-unregulated [https://perma.cc/6CV5-27PN].

12. *Is It a Cosmetic, a Drug, or Both (Or Is It Soap?)*, FOOD & DRUG ADMIN. (Feb. 25, 2022), https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap#Definecosmetic [https://perma.cc/4RLC-F2EC] (explaining that the intended use of a product is dictated by the manufacturer and the FDA provides only informal suggestions on how to decide the intended use, but lacks any formal guidelines on the requirements); *see also* United States v. Article Consisting of 216 Cartoned Bottles, More or Less, Sudden Change, 409 F.2d 734, 736-39 (2d Cir. 1969). This case held that a cosmetic cannot have a treatment claim but continue to allege a "cosmetic" intended use to the FDA. *Id.* Here, a company who claimed their moisturizer was a

government has no way of tracking what cosmetics enter the market.[13] Cosmetics are considered articles that are used for cleansing, beautifying, promoting attractiveness, or altering the user's appearance.[14] The U.S. Food and Drug Administration ("FDA") provides examples of cosmetics including skin moisturizers, perfumes, lipsticks, nail polish, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, deodorants, and any substance intended for use as a component of a cosmetic product.[15] The manufacturers of these products personally decide what the "intended use" of a product is, and there is no oversight before the product goes to market.[16] Companies are abusing this broad definition to create makeup and skincare titled as "cosmetics" that actually have the intended use of a drug, meaning they are designed to treat something.[17] This abuse has led to products on the market that would typically go through rigorous pre-market testing, to now be placed on the shelves with no information given to the consumer regarding the possible harm they may cause them.[18] Both drug-like products that are marketed as cosmetics, and traditional products that meet the FDA's definition of cosmetics, are unregulated and may cause consumers' health to be harmed.[19]

The shortfall of federal oversight for cosmetics under the Federal Food, Drug, and Cosmetic Act puts consumers' health and safety at risk.[20] This Note will argue that the Federal Food, Drug, and Cosmetic

---

"facelift in a bottle" but alleged its intended use as cosmetic, was convicted of misbranding in violation of the Federal Food, Drug, and Cosmetic Act. *Id.*

13. *Voluntary Cosmetic Registration Program*, FOOD & DRUG ADMIN. (Mar. 29, 2022), https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program#about [https://perma.cc/P7BC-QV3P].

14. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 § 201(i) (2018); *Is It a Cosmetic, a Drug, or Both (Or Is It Soap?)*, *supra* note 12.

15. *Is It a Cosmetic, a Drug, or Both (Or Is It Soap?)*, *supra* note 12.

16. *Id.*; *see also* Tommy Tobin, *A Cosmetic, A Drug, or Both?*, CONSUMER PROT. REV. (Aug. 1, 2019), https://www.consumerprotectionreview.com/2019/08/a-cosmetic-a-drug-or-both [https://perma.cc/5PFU-8XE5] (suggesting that the intended use of the product is relevant to the FDA classification as a cosmetic or a drug, and therefore manufacturers should be weary of the claims they are advertising before deciding the intended use).

17. *Is It a Cosmetic, a Drug, or Both (Or Is It Soap?)*, *supra* note 12.

18. *Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics*, FOOD & DRUG ADMIN. (Apr. 1, 2022), https://www.fda.gov/cosmetics/warning-letters-related-cosmetics/warning-letters-address-drug-claims-made-products-marketed-cosmetics [https://perma.cc/4JZ6-C2KB]. The FDA will issue a warning letter to companies who appear to have abused the manufacturer's right to claim the "intended use" of a product. *Id.* These companies sold cosmetic products with drug-like claims, with no pre-market testing done. *Id.* Drug-like claims may include that a product can "treat" an issue, such as acne or hair loss. *Id.*

19. *The Ugly Side of Cosmetics*, GREEN AM. MAG., https://www.greenamerica.org/green-living/ugly-side-cosmetics [https://perma.cc/4JZ6-C2KB] (last visited Nov. 18, 2022).

20. *See infra* Part III.

Act be amended to: (1) require mandatory registration with the FDA for all cosmetic companies and manufacturers; (2) require adverse event reporting to the FDA for all serious consumer complaints or injuries; (3) mandate ingredient review in partnership with the Cosmetic Ingredient Review Board on an annual basis; and (4) no longer allow self-regulatory bodies, such as the Personal Care Products Council, to monitor the cosmetic market, but rather give jurisdiction directly to the FDA.[21] This will allow the FDA to have more authority over the cosmetic industry, without seriously disrupting the original drafters' intent regarding the regulation of cosmetics under the Federal Food, Drug, and Cosmetic Act.[22] This oversight of cosmetic manufacturers and distributors would aid the FDA in protecting consumers from dangerous and unregulated cosmetic products.[23]

In Part II, this Note will explain the history of cosmetic regulation in the United States and its shortcomings.[24] Part II will examine the drafters' intent when they constructed the Federal Food, Drug, and Cosmetic Act,[25] the significant differences between drug and cosmetic regulation as it currently stands,[26] past and current proposed legislation regarding the cosmetics market,[27] and finally, the direct harms that consumers experience due to the lack of government regulation and the punishment that comes with it.[28] Subsequently, in Part III, this Note will explain how the lack of cosmetic regulation under the Federal Food,

---

21. *See infra* Part IV.

22. *Compare Foods, Drugs, and Cosmetics: Hearing Before the Comm. on Com.*, 73rd Cong. 3-4 (1934) (statement of Florence E. Wall, Consultant in Cosmetic Chemistry) (illustrating that the drafters were in opposition to severe regulation being created under the Federal Food, Drug, and Cosmetic Act despite it being proposed by chemists) *with* Lydia Ramsey Pflanzer, *A $60 Billion Industry Is Shockingly Unregulated*, BUS. INSIDER (Oct. 11, 2015, 9:37 AM), https://www.businessinsider.com/cosmetic-industry-is-shockingly-unregulated-2015-10 [https://perma.cc/M2XG-YMHH] (explaining that cosmetics have successfully stayed unregulated despite the massive boom the industry has experienced since the Federal Food, Drug, and Cosmetic Act was passed).

23. Priyanka Narayan, *The Cosmetics Industry Has Avoided Strict Regulation for Over a Century. Now Rising Health Concerns Has FDA Inquiring*, CNBC (Aug. 2, 2018, 10:08 AM), https://www.cnbc.com/2018/08/01/fda-begins-first-inquiry-of-lightly-regulated-cosmetics-industry.html [https://perma.cc/CJ64-26FQ]; *see also* Annie Clark, *Collins, Feinstein Introduce Bill to Strengthen Oversight of Personal Care Products*, SUSAN COLLINS U.S. SENATOR FOR ME. (Mar. 13, 2019), https://www.collins.senate.gov/newsroom/collins-feinstein-introduce-bill-strengthen-oversight-personal-care-products [https://perma.cc/DDB2-9BY7] (explaining that Senator Feinstein wants the Personal Care Products Act passed by Congress to better protect American consumers).

24. *See infra* Part II.

25. *See infra* Part II.A.

26. *See infra* Part II.B.

27. *See infra* Part II.C.

28. *See infra* Part II.D.

Drug, and Cosmetic Act harms consumers.[29] Next, in Part IV, this Note will propose four amendments to the Federal Food, Drug, and Cosmetic Act to better protect consumer health.[30] Finally, in Part V, this Note will conclude and explain how the amendment will lead to safer cosmetics for American consumers.[31]

II. THE HISTORY OF COSMETIC REGULATION IN THE UNITED STATES

Part II of this Note discusses the background of cosmetic regulation in the United States.[32] To begin, Subpart A will cover the enactment of the Federal Food, Drug, and Cosmetic Act, including the drafters' original intent regarding cosmetics.[33] Next, Subpart B will discuss the differences between cosmetics and drugs in the eyes of the FDA, including: the definitions of cosmetic and drug, the "intended use" requirement, and the differences between the regulation of the two.[34] Subsequently, Subpart C will explore past and current proposed legislation on cosmetics in the United States.[35] Following this, Subpart D will consider the self-regulation of the cosmetics industry.[36] Finally, Subpart E will discuss the ways in which the shortfalls of cosmetic regulations have directly caused consumer harm.[37]

A. Federal Food, Drug, and Cosmetic Act: The Drafters' Intent

Prior to the passage of the Federal Food, Drug, and Cosmetic Act, the controlling law on this topic was the 1906 Food and Drugs Act.[38] The law prohibited misbranded or adulterated food and drugs from entering interstate commerce.[39] It did not take long to realize that the Food and Drugs Act was not only inadequately protecting consumers, but also left gaps that allowed hazardous products to remain on the

29. *See infra* Part III.
30. *See infra* Part IV.
31. *See infra* Part V.
32. *See infra* Part II.
33. *See infra* Part II.A.
34. *See infra* Part II.B.
35. *See infra* Part II.C.
36. *See infra* Part II.D.
37. *See infra* Part II.E.
38. *How Did the Federal Food, Drug, and Cosmetic Act Come About?*, FOOD & DRUG ADMIN. (Mar. 28, 2018), https://www.fda.gov/about-fda/fda-basics/how-did-federal-food-drug-and-cosmetic-act-come-about [https://perma.cc/VL7H-G9YK] ("The first comprehensive federal consumer protection law was the 1906 Food and Drugs Act, which prohibited misbranded and adulterated food and drugs in interstate commerce. Arguably the pinnacle of Progressive Era legislation, the act nevertheless had shortcomings—gaps in commodities it covered plus many products it left untouched—and many hazardous consumer items remained on the market legally.").
39. *Id.*

market.[40] This was first made evident in the 1930s when the United States witnessed a general outrage concerning egregious consumer products poisoning, maiming, and killing people.[41] However, the last straw for American citizens came in 1937 when an untested pharmaceutical killed over 100 patients, including children, as soon as it went on the market.[42] As a result, one year later, Congress passed the Federal Food, Drug, and Cosmetic Act.[43]

When the Federal Food, Drug, and Cosmetic Act was first introduced by Senator Royal S. Copeland of New York, it was as if he had started the next revolution.[44] The first committee meeting on the bill had to be moved to the largest committee room that Congress had, and even then it was not big enough to hold every member who wanted to be heard in opposition to the bill.[45] Initially, many lawmakers thought the bill would seriously affect employment in chemical and drug industries, and argued that it would put thousands of men and women out of work.[46] However, Senator Copeland and other leaders worked tirelessly to frame the bill as creating an obligation to the public, a strategy that ultimately helped garner significant support for the bill's passing.[47] In addition to working with corporations and leaders in the field regarding changes in food and drug regulation, this proposal also incorporated cosmetics into

40. *Id.*

41. Grace Hopkins, *Life Before Consumer Protection and the Food, Drug, and Cosmetic Act*, MASTERCONTROL (Mar. 3, 2022), https://www.mastercontrol.com/gxp-lifeline/history_food_drug_cosmetic_act_0210 [https://perma.cc/9FCQ-LE7B].

42. Carol Ballentine, *Sulfanilamide Disaster*, FOOD & DRUG ADMIN. (June 1981), https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf [https://perma.cc/4GRJ-GF8C]. The medicine that killed over 100 patients was Elixir Sulfanilamide, a drug used to treat streptococcal infections safely for many years prior in tablet and powder form. *Id.* A salesman reported a demand for the drug in liquid form, a request that would turn the drug into a disturbingly dangerous toxin. *Id.* The new formulation had not been tested for toxicity because, at the time, the Food and Drug Act did not require any safety studies to be completed for new drugs. *Id.* At the time, selling toxic drugs was not considered illegal in the United States. *Id.* Victims were ill for between seven to twenty-one days and had symptoms such as kidney failure, stoppage of urine, severe abdominal pain, nausea, convulsions, and intense and unrelenting pain. *Id.* The most painful realization is that a few simple experimental tests or basic literature research would have indicated that the ingredient creating the liquid form, diethylene glyoxal, was toxic. *Id.* The firm that produced the product did not feel the same, explaining in their statement that they did nothing illegal and followed all the protocol—the government saw that was true, and decided that was exactly the problem. *Id.* One year later, the Federal Food, Drug, and Cosmetic Act was passed. *Id.*; *see also* Hopkins, *supra* note 41.

43. *See* Hopkins, *supra* note 41.

44. Ole Salthe, *A Brief Review of the Legislative History of the Federal Food, Drug, and Cosmetic Act*, 3 FOOD, DRUG, & COSM. L.Q. 148, 149 (1948).

45. *Id.*

46. *Id.*

47. *Id.* at 150.

the statutory law.[48] Most of the legislative history surrounding the bill dealt with the changes to the existing food and drug law.[49] It was clear from conversations throughout the stages of legislation that cosmetics were not the priority in this law and would not be as regulated as food or drugs.[50] By the time this legislation was passed, there was almost no regulation in the law surrounding cosmetics, and it has stayed nearly frozen this way since 1938.[51]

B. The Differences in Regulation for Drugs and Cosmetics

Under the Federal Food, Drug, and Cosmetic Act, cosmetics are defined by their intended use as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced to, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance."[52] Under the same Act, a drug is defined, in part, by their intended use as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[53] Drugs and cosmetics are both governed by the Federal Food, Drug, and Cosmetic Act, but differ significantly through their regulation.[54] The regulation process for both drugs and cosmetics begins with determining the "intended use" of the product through considerations including product claims,[55] marketing,[56] and purpose.[57]

Whether or not a product is classified as a drug or a cosmetic under the Federal Food, Drug, and Cosmetic Act depends solely on the "intended use" of the product given by the manufacturer.[58] This is such

48. CHARLES WESLEY DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGIS. REC. 26 (1938).

49. *Id.* at 25.

50. *Foods, Drugs, and Cosmetics: Hearing Before the Comm. on Com.*, *supra* note 22, at 320-21.

51. Boyd, *supra* note 4, at 278.

52. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 § 201(i) (2018).

53. *Id.* § 201(g)(1).

54. *Is It a Cosmetic, a Drug, or Both (Or Is It Soap?)*, *supra* note 12.

55. *Id.* ("Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials. Certain claims may cause a product to be considered a drug, even if the product is marketed as if it were a cosmetic. Such claims establish the product as a drug because the intended use is to treat or prevent disease or otherwise affect the structure or functions of the human body. Some examples are claims that products will restore hair growth, reduce cellulite, treat varicose veins, increase or decrease the production of melanin (pigment) in the skin, or regenerate cells.").

56. *Id.* Firms can be considered to have violated the law by marketing a cosmetic with drug claims, such as that it can treat issues like hair loss. *Id.*

57. *Id.*

58. *Id.*

an important manufacturer decision because it will later determine whether or not the product goes through government regulation.[59] However, despite this importance, there are very few guidelines or rules on determining the intended use of a product.[60] The FDA says intended use can be established in a number of ways and suggests basing the decision on product labeling, advertising claims, consumer perception, and known therapeutic ingredients.[61] However, because there are no specific requirements, this process allows for a lot of abuse by cosmetic companies whose products are offering drug-like claims but state the intended use as a cosmetic to avoid regulation.[62] The FDA is no stranger to this issue, and even includes a warning on their website about such misrepresentation, stating:

> Whether a product is a cosmetic or a drug under the law is determined by a product's intended use. Different laws and regulations apply to each type of product. Firms sometimes violate the law by marketing a cosmetic with a drug claim or by marketing a drug as if it were a cosmetic, without adhering to the requirements for drugs.[63]

So, why does it matter whether or not that moisturizer on the Sephora shelf promising to be a "facelift in a bottle" is considered a drug or a cosmetic?[64] It matters because the "intended use" the manufacturer selects when creating a product will drastically change the amount of pre-market and post-market regulation a company must go through before they can sell their product.[65] Drugs are heavily regulated by the FDA, meaning that data on the drugs' effects have been reviewed by the Center for Drug Evaluation and Research.[66] From that review, drugs are

59. Morgan G. Egeberg, *Beauty Is Pain: An Analytical View of the American Beauty Industry and the Effects of Regulation on Consumers*, 23 QUINNIPIAC HEALTH L.J. 303, 309-10 (2020).

60. *Id.*

61. *Is It a Cosmetic, a Drug, or Both (Or Is It Soap?)*, *supra* note 12.

62. *Id.* Drug-like marketing claims include statements such as the product's ability to treat or cure an ailment. *Id.*

63. *Id.* (illustrating that the FDA is aware of the issue of drug-like products being misbranded as cosmetics).

64. United States v. Article Consisting of 216 Cartoned Bottles, More or Less, Sudden Change, 409 F.2d 734, 739 (holding that a lotion that claimed to be a "facelift" without surgery is a drug based on the label claims and, therefore, could not be sold without going through the necessary pre-market steps for drugs).

65. *Compare Cosmetics & U.S. Law*, FOOD & DRUG ADMIN. (Feb. 25, 2022), https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program#about [https://perma.cc/USU2-WFAH] (explaining the limited regulation of cosmetics) *with* Emily Miller, *FDA Approval Process*, DRUGWATCH, https://www.drugwatch.com/fda/approval-process [https://perma.cc/SJH2-ZTNJ] (Sept. 1, 2021) (explaining the extensive pre- and post-market regulation of drugs).

66. *Center for Drug Evaluation and Research | CDER*, FOOD & DRUG ADMIN. (June 21, 2022), https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder

determined to provide benefits that outweigh their known potential risks for the intended population.[67] Drugs seeking FDA approval go through a rigorous, five-step approval process before going to market.[68] This includes: (1) the discovery and concept stage; (2) preclinical research; (3) clinical research to validate claims and uses; (4) FDA review; and (5) post-market safety monitoring.[69]

Throughout this process, the Center for Drug Evaluation and Research considers the drug within a structured framework.[70] The process begins by looking at the analysis of the target condition of the drug and the alternative available treatments.[71] This portion of the process is centered around evaluating what the drug is meant to treat and the current drug landscape for that ailment, which helps provide context when considering the drug's benefits and risks.[72] The assessment of the benefits and risks from clinical data is also considered.[73] The FDA expects a drug maker to submit results from two well-designed clinical trials, unless the disease is rare and only one trial is sustainable.[74] Finally, because all drugs inherently have risks, the strategies for managing risks will be considered.[75] Risk management strategies include an FDA approved label describing the benefits and risks, and how risks can be detected or managed.[76] If more effort is needed to manage risks, the manufacturer will be asked to implement a "Risk Evaluation and Mitigation Strategy."[77] The standard review process takes about ten

---

[https://perma.cc/SP7C-K94B] ("The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines. For example, fluoride toothpaste, antiperspirants, dandruff shampoos and sunscreens are all considered drugs.").

67. *Development & Approval Process | Drugs*, FOOD & DRUG ADMIN. (Aug. 8, 2022), https://www.fda.gov/drugs/development-approval-process-drugs [https://perma.cc/L6SC-W4P3].

68. *Id.*

69. Miller, *supra* note 65.

70. *Development & Approval Process | Drugs*, *supra* note 67.

71. *Id.*

72. *Id.*

73. Miller, *supra* note 65.

74. *Development & Approval Process | Drugs*, *supra* note 67.

75. *Id.*

76. Miller, *supra* note 65; *see also Development & Approval Process | Drugs*, *supra* note 67.

77. *Risk Evaluation and Mitigation Strategies | REMS*, FOOD & DRUG ADMIN. (Dec. 17, 2021), https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems [https://perma.cc/VRP8-G985]. A Risk Evaluation and Mitigation Strategy is a drug safety program that the FDA may require for certain medications that are determined to have serious safety concerns. *Id.* This program helps the FDA ensure the benefits of the medication outweigh its risks. *Id.* All medications have labeling that informs about risks, but only a few medications require

months once the clinical trials and required data points are completed.[78] If the manufacturer applies for priority review, and it is granted, the approval process can be completed in six months.[79]

The drug approval process requires time, money, and scientific experts, all to ensure the protection of the health and safety of American consumers.[80] Contrary to this, the cosmetic regulatory process requires no pre-market approval.[81] Most cosmetic companies will consider the FDA requirements when creating their labeling claims.[82] However, the regulatory efforts stop there.[83] There is no regulatory oversight for cosmetics before they hit the market.[84] Therefore, manufacturers who have set the intended use of a product as a cosmetic will attempt to slip through the cracks and use drug-like advertising[85] as a selling point,

---

a Risk Evaluation and Mitigation Strategy. *Id.*; *see also Development & Approval Process | Drugs*, *supra* note 67.

78. Miller, *supra* note 65; *see also Development & Approval Process | Drugs*, *supra* note 67.

79. *Development & Approval Process | Drugs*, *supra* note 67. Priority review is granted by the FDA in order to direct attention and resources to that drug before others. *Id.* This typically occurs if the priority review were to be approved, it would allow for significant improvements in safety and effectiveness of the treatment, diagnosis, or prevention of the serious condition compared to the standard applications. *Id.* Significant improvement can be measured by evidence of increased effectiveness in treatment, elimination of a treatment-limiting drug reaction, documented enhancement of patient compliance, or evidence of safety and effectiveness in a new subpopulation. *Id.*

80. *See generally* Miller, *supra* note 65 (explaining the drug approval process).

81. *Is It a Cosmetic, a Drug, or Both (Or Is It Soap?)*, *supra* note 12.

82. *Id.* Cosmetic labeling must be truthful and not misleading. *Cosmetics Labeling*, FOOD & DRUG ADMIN. (Feb. 25, 2022), https://www.fda.gov/cosmetics/cosmetics-labeling [https://perma.cc/ZS3Z-YGAX]. "Products intended to affect the structure or function of the body, or for a therapeutic purpose, such as treating or preventing disease, are subject to regulation as drugs." *Id.*

83. *Is It a Cosmetic, a Drug, or Both (Or Is It Soap?)*, *supra* note 12.

84. Pflanzer, *supra* note 22 ("The makeup brand Lime Crime came under fire from the FDA in July for having color additives, the single ingredient the FDA does require approval for in cosmetics, in some of its products . . . . In recent years, one of the most controversial chemicals in the cosmetic industry have been chemicals called phthalates. They're found in nail polish—that's what gives them that stretchy, plastic-y feeling—and perfumes. According to the National Institute of Environmental Health Sciences, phthalates are a known environmental contaminant that could have an impact on human health, though they don't yet have enough conclusive evidence to say exactly how.").

85. *Are Some Cosmetics Promising Too Much?*, FOOD & DRUG ADMIN. (Mar. 23, 2015), https://www.fda.gov/consumers/consumer-updates/are-some-cosmetics-promising-too-much [https://perma.cc/NA6F-AHD6]. American consumers spend a lot of money on cosmetics that claim to make their skin and hair better, but sometimes the claims of these products go too far. *Id.* The FDA warns companies that certain claims could make their product a drug, not a cosmetic. *Id.* Some examples of these claims are acne treatment, dandruff treatment, and hair restoration. *Id.* The FDA will then send a warning letter to the company explaining that they must remove their drug claim from the label or go through the FDA's drug approval process. *Id.* These products must be evaluated by the FDA as drugs in order to make claims that their product can change the hair or skin or can treat diseases like acne, rosacea, eczema or psoriasis. *Id.* There is no one size fits all answer to

when in reality, there have been no signs of validity to their claims.[86] All the while, their product is a drug under the guise of a cosmetic to avoid regulation.[87] Therefore, as a result of no formal regulation, non-governmental entities have been created, such as the Cosmetic Ingredient Review Board and the Personal Care Products Council.[88]

At present there is a program that allows cosmetic companies to register with the FDA on a voluntary basis.[89] This system, known as the Voluntary Cosmetic Registration Program, allows companies to register cosmetic manufacturing or packaging establishments, file cosmetic product ingredient statements, and amend or discontinue product formulas.[90] This system applies to only cosmetics sold to consumers, and not to those cosmetics that will be used for professional use or non-sale, such as in hotels or free gifts with purchase.[91]

Currently, there is no government body or agency tasked with evaluating ingredients for safety in cosmetics.[92] However, some independent industry leaders have decided to take matters into their own hands.[93] The Cosmetic Ingredient Review Board ("Review Board") is the largest, industry-funded, independent review board, composed of scientific experts.[94] The Review Board was established in 1976 by the Personal Care Product Council, however they are a separate body from the Council.[95] The panel uses information from the Voluntary Cosmetic

---

marketing, but generally, if your product is both a cosmetic and a drug, it must meet the FDA standards for both products. *Id.*

86. Deborah L. Livornese & Kalie E. Richardson, *A Rose by Any Other Name: Drug Claims Make Your Cosmetic a Drug*, ARNALL GOLDEN GREGORY LLP (Aug. 17, 2017), https://www.agg.com/news-insights/publications/a-rose-by-any-other-name-drug-claims-make-your-cosmetic-a-drug-08-17-2017 [https://perma.cc/97Q3-R4PH].

87. *Id.*

88. *Voluntary Cosmetic Registration Program*, *supra* note 13.

89. *Id.* ("The VCRP assists FDA in carrying out its responsibility to regulate cosmetics marketed in the United States. Because product filings and establishment registrations are not mandatory, voluntary submissions provide FDA with the best estimate of information available about cosmetic products and ingredients, their frequency of use, and businesses engaged in their manufacture and distribution.").

90. *Id.*

91. *Id.* (explaining the limitations of products included in this system, including that no products that may be given to a consumer free of charge will be included).

92. *Voluntary Cosmetic Registration Program*, *supra* note 13 (explaining that the nonprofit Cosmetic Ingredient Review does the ingredient review, not the FDA).

93. *About the Cosmetic Ingredient Review*, COSM. INGREDIENT REV., https://www.cir-safety.org/about [https://perma.cc/27M4-CJ4S] (last visited Nov. 18, 2022).

94. *Id.*

95. *Id.* ("General policy and direction are given by a 7-member Steering Committee chaired by the President and CEO of the Council, with a dermatologist representing the American Academy of Dermatology, a toxicologist representing the Society of Toxicology, a consumer representative representing the Consumer Federation of America, an industry scientist (the current chair of the

Registration Program to assist the expert panel in deciding what ingredients they should review and in what order.[96] The panel then may put the ingredients into one of four basic categories:

> [1] Safe ingredients - Ingredients safe in the practices of use (product categories) and concentrations of use for each product category as documented in the safety assessment. [2] Unsafe ingredients - These are ingredients with specific adverse effects that make them unsuitable for use in cosmetics. [3] Safe ingredients, with qualifications - The Panel may reach the conclusion that an ingredient can be used safely, but only under certain conditions. Qualifications frequently relate to maximum concentration, but may also address rinse-off versus leave-on uses and other restrictions. [4] Ingredients for which the data [is] insufficient - If the Panel reaches an "insufficient data" conclusion, it does not state whether the ingredient is safe or unsafe. The Panel is, however, describing a situation in which the available data [does] not support safety. The specific data that would allow the Panel to complete its assessment always [is] identified.[97]

The Review Board may re-evaluate every fifteen years, as new information may have become available.[98] Currently, the Review Board is still funded by the Personal Care Products Council.[99] However, the Council claims to have no control over the decisions the Review Board makes.[100] Although these bodies are currently involved in the cosmetic market in limited ways, they are born from the industry, and do not come from any government regulation.[101]

Although the Federal Food, Drug, and Cosmetic Act prohibits misbranded[102] or adulterated[103] cosmetics, many common product labels remain untruthful due to the absence of FDA disclosure requirements or

---

Council's CIR Committee), Chair of the Expert Panel for Cosmetic Ingredient Safety, and the Council's Executive Vice President for Science.").

96. *Voluntary Cosmetic Registration Program*, *supra* note 13.

97. *How Does CIR Work?*, COSM. INGREDIENT REV., https://www.cir-safety.org/how-does-cir-work [https://perma.cc/7AA8-BRNF] (last visited Nov. 18, 2022).

98. *Id.*

99. *About the Cosmetic Ingredient Review*, *supra* note 93.

100. *Id.*

101. *Id.*

102. Misbranded Cosmetics, 21 U.S.C. § 362 (1938) ("A cosmetic shall be deemed to be misbranded . . . if its labeling is false or misleading in any particular.").

103. *Adulterated Cosmetic Law and Legal Definition*, U.S. LEGAL, https://definitions.uslegal.com/a/adulterated-cosmetic [https://perma.cc/HS9C-P6D5] (last visited Nov. 18, 2022) ("Adulterated cosmetic[s] refers to those cosmetics that contain any poisonous or harmful substance which may render [them] injurious to users. Adulterated cosmetic[s] contain ingredients which may cause skin irritation on certain individuals. Adulterated cosmetics are prohibited to be transported in interstate commerce, as provided under the Food, Drug and Cosmetic Act.").

mandatory pre-market approvals.[104] Phrases like "dermatologist tested,"[105] "allergy tested,"[106] "non-irritating,"[107] "gentle,"[108] "herbal,"[109] and "botanical"[110] all lack any sort of standard, and, therefore, any manufacturer can put these words on their product, and no one (including the FDA) can question it.[111] However, this also applies to

104. *Premarket Approval (PMA)*, FOOD & DRUG ADMIN. (May 16, 2019), https://www.washingtonpost.com/lifestyle/wellness/hello-coverboy-cosmetics-and-skin-care-brands-turn-to-gender-neutral-packaging/2020/03/02/2c30f49e-54d4-11ea-9e47-59804be1dcfb_story.html [https://perma.cc/SR9A-LGB5] ("Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of Class III devices. Therefore, these devices require a premarket approval application under section 515 of the FD&C Act in order to obtain marketing approval.").

105. *What Does Dermatologist Tested Mean? What Do They Test?*, BRIGHTON DERMATOLOGY (July 26, 2019), https://www.brightondermatology.com.au/what-dermatologist-tested-mean [https://perma.cc/5FGH-BMME] ("At its most basic, [dermatologist tested] means that the product was tested by or in consultation with a dermatologist for tolerance and signs of obvious or severe skin reactions. Dermatologically tested may mean that a doctor of dermatology may or may not have been in charge of the tolerance tests that were carried out on voluntary test persons while using the product. The generally accepted meaning for 'dermatologically tested' relates to the following claims: [(1)] That the product has been tested on human skin; [(2)] That the formula has been found to be mostly safe when applied to the skin; [(3)] That the finished product was well tolerated by persons who tested it on their skin, and in most cases, it did not cause skin reactions.").

106. *Allergy Tested Defined*, AM. ACAD. OF ALLERGY, ASTHMA & IMMUNOLOGY, https://www.aaaai.org/Tools-for-the-Public/Allergy,-Asthma-Immunology-Glossary/Allergy-Testing-Defined [https://perma.cc/YC5C-YY53] (last visited Nov. 18, 2022) ("Allergy testing, also known as skin, prick or blood testing, is a method for determining to what substances a person is allergic. Skin allergy testing is the most common, reliable and relatively painless form of allergy testing. A very small amount of certain allergens is put into your skin by making a small indentation or 'prick' on the surface of your skin. A skin allergy test determines specific allergens based on skin reactions. You don't have to wait long to find out what is triggering your allergies. Reactions occur within about 15 minutes. If you have allergies, just a little swelling will occur where the allergen which you are allergic to was introduced. For instance, if you are allergic to ragweed pollen but not to cats, only the ragweed allergen will cause a little swelling or itching. The spot where the cat allergen was applied will remain normal.").

107. *Nonirritating*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/nonirritating [https://perma.cc/83NF-E84T] (last visited Nov. 18, 2022). Merriam Webster's Dictionary defines non-irritating as "not causing irritation; not irritating." *Id.*

108. *Gentle*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/gentle [https://perma.cc/D5LT-GYH7] (last visited Nov. 18, 2022). Merriam-Webster's Dictionary defines gentle as "free from harshness, sternness, or violence." *Id.*

109. *Herbal*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/herbal [https://perma.cc/2T8M-HHFR] (last visited Nov. 18, 2022). Merriam-Webster's Dictionary defines herbal as "of, relating to, utilizing, or made of herbs." *Id.*

110. *Botanical*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/botanical [https://perma.cc/NA84-PQQ8] (last visited Nov. 18, 2022). Merriam-Webster's Dictionary defines botanical as "of or relating to plants or botany; derived from plants." *Id.*

111. *Cosmetics Labeling Claims*, FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/labeling/claims/default.htm [https://perma.cc/D9DL-DBGJ] (last

terms that consumers likely think have legal standards.[112] This includes a new token phrase in the beauty industry, "cruelty free"[113] or "not tested on animals."[114] There is no legal definition for these terms, and therefore these claims cannot be considered misbranding by the FDA.[115] Many consumers assume that when common claims like "organic" are on a cosmetic label, someone is regulating that claim, but that is not true.[116] The FDA, who controls cosmetic regulation, does not define "organic" in the Federal Food, Drug, and Cosmetic Act.[117] Some terms, such as "organic" are defined by the U.S. Department of Agriculture, however, these definitions are meant to apply to food, not cosmetics.[118] Therefore, when consumers see these claims on products, they should know that there is no legal definition, and because of that, the product cannot be considered misbranded.[119]

Even terms that lure consumers to select a product from the hundreds of options on the shelf, like "hypo-allergenic" or "natural," can mean "anything or nothing at all" because dermatologists say they have no medical meaning.[120] To the surprise of many consumers, "certified organic" cosmetics can contain as little as ten percent organic

---

visited Nov. 18, 2022). While the FDA regulates cosmetics labeling, the Federal Trade Commission regulates advertising claims. *Id.*; *see also* Jacobs, *supra* note 4, at 102.

112. *"Organic" Cosmetics*, FOOD & DRUG ADMIN. (Feb. 25, 2022), https://www.fda.gov/cosmetics/cosmetics-labeling-claims/organic-cosmetics [https://perma.cc/H35R-V9JK]. Some terms, such as "organic" are defined by the U.S. Department of Agriculture, however, these definitions are meant to apply to food, not cosmetics. *Id.*

113. *"Cruelty Free"/"Not Tested on Animals"*, FOOD & DRUG ADMIN. (Feb. 25, 2022), https://www.fda.gov/cosmetics/cosmetics-labeling-claims/cruelty-freenot-tested-animals [https://perma.cc/FWN2-EPSP] ("Consumers sometimes ask about use of claims such as 'Cruelty-Free' or 'Not Tested on Animals' on cosmetic labeling. Some cosmetic companies promote their products with claims of this kind in their labeling or advertising. The unrestricted use of these phrases by cosmetic companies is possible because there are no legal definitions for these terms. Some companies may apply such claims solely to their finished cosmetic products. However, these companies may rely on raw material suppliers or contract laboratories to perform any animal testing necessary to substantiate product or ingredient safety. Other cosmetic companies may rely on combinations of scientific literature, non-animal testing, raw material safety testing, or controlled human-use testing to substantiate their product safety. Many raw materials, used in cosmetics, were tested on animals years ago when they were first introduced. A cosmetic manufacturer might only use those raw materials and base their 'cruelty-free' claims on the fact that the materials or products are not 'currently' tested on animals.").

114. *Id.* The term "not tested on animals" is used interchangeably with "cruelty-free." *Id.*

115. Jacobs, *supra* note 4, at 102.

116. *"Organic" Cosmetics*, *supra* note 112.

117. *Id.*

118. *Id.*

119. *Id.*

120. Jacobs, *supra* note 4, at 102 (explaining the FDA has not created any medical meaning for commonly used terms in cosmetic marketing).

ingredients by weight or volume.[121] So, despite consumers purchasing products labeled as natural or organic, the cosmetics in their hands are not necessarily safer than any other on the shelf.[122]

C. Past and Current Proposed Legislation

The claim that cosmetics have been allowed to slip through the cracks of the FDA is not a new one.[123] Lawmakers, companies, advocacy groups, and even the FDA itself, have known for years that the United States has allowed their cosmetic regulation laws to remain stagnant.[124] All while other countries, and even state governments, have continued to advance legislation to protect consumer health.[125] Congress has repeatedly tried to pass legislation for stricter regulation of cosmetics, but each time they have failed.[126] It is important to look at past proposed regulations to evaluate the aspects that were effective and ineffective in regulating cosmetics.[127]

Despite the lack of federal regulation, some states have taken cosmetic regulation upon themselves, including California, Minnesota, and Washington.[128] California is a leader in the field, beginning with the passage of the Safe Cosmetics Act in 2005.[129] This Act requires manufacturers to disclose to the State of California any product with ingredients known to cause cancer or birth defects.[130] From 2009, when

---

121. *Id.*

122. *Id.*

123. *Cosmetic Safety Act of 1974: Hearing on H.R. 1235 Before the Subcomm. on Health, Comm. on Lab. and Pub. Welfare*, 93rd Cong. 215 (1974) (statement of Ralph Nader, Esq; Accompanied by Sidney Wolfe, M.D., and Nancy Chasen, Health Research Group) (suggesting that current cosmetic legislation is inadequate (that is, the Food, Drug, and Cosmetic Act) and proposing the Cosmetic Safety Act of 1973 to aid in better protecting consumers).

124. Narayan, *supra* note 23.

125. *Internal Market, Industry, Entrepreneurship, and SMEs*, EUROPEAN COMM'N, https://ec.europa.eu/growth/sectors/cosmetics/legislation_en [https://perma.cc/KGM2-Z8RL] (last visited Nov. 18, 2022); *see also* WASH. REV. CODE § 70A.430.010 et seq.; CAL. HEALTH & SAFETY CODE § 111791 (West 2006).

126. *Discussion Draft of the Food and Drug Administration Globalization Act Legislation: Device and Cosmetic Safety Provisions: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Com.*, 110th Cong. 159-60 (2008) (statement of Jane Houlihan, Vice President for Research of the Environmental Working Group).

127. Joe Williams, *Industry Split on Cosmetic Reform Bills, 2016 Could Be Year of Action*, 22 INSIDEHEALTHPOLICY.COM FDA WEEK 4, 1, 13 (Jan. 29, 2016).

128. *State Laws*, CAMPAIGN FOR SAFE COSMETICS: A PROJECT OF BREAST CANCER PREVENTION PARTNERS, https://www.safecosmetics.org/get-the-facts/regulations/state-laws [https://perma.cc/MLB5-QDNQ] (last visited Nov. 18, 2022) (summarizing information on state laws that have passed or been proposed in recent years regarding cosmetic safety).

129. HEALTH & SAFETY § 111791.

130. *Id.* The California legislature has compiled a list in Proposition 65 of ingredients that qualify as carcinogens for the purpose of this statute. *State Laws*, *supra* note 128.

the Act was implemented, to 2020, 583 companies reported the sale of 86,376 beauty and personal care products in California containing ninety-four unique carcinogens and reproductive toxins.[131] Although the Safe Cosmetics Act was touted as a law that would largely protect consumers, that is not the law's reality.[132] The Safe Cosmetics Act has simply become another reporting statute, only giving notice to the State of California.[133] This Act still does not give the consumer more information regarding their own personal health and safety.[134] This allows the California cosmetic industry and state government to continue to keep consumers in the dark, while deciding what steps, if any, to take with the data presented to them.[135] California also passed the Professional Cosmetics Labeling Requirements Act to require companies that sell professional salon products to include ingredients on their labeling.[136] Although this is an important step toward better health for salon workers, it still does not stop unsafe chemicals and ingredients from entering their workplace.[137] Instead, it simply informs employees that they are present within their environment.[138] This Act is extremely limited in scope, and covers no other workplaces and no non-salon products.[139]

Minnesota has banned the use of formaldehyde, a cancer-causing chemical, in any children's personal care products such as shampoos,

131. *State Laws*, *supra* note 128.

132. H. Kim Sim, *California Safe Cosmetics Act of 2005: A Sleeper That May Awake in 2014*, CONKLE, KREMER & ENGEL (Oct. 26, 2014), https://www.conklelaw.com/california-safe-cosmetics-act-of-2005-a-sleeper-that-may-awake-in-2014 [https://perma.cc/CR94-MEPP].

133. *Id.*

134. *Id.*

135. *Id.*

136. *State Laws*, *supra* note 128 (contending that with the passage of this law, salon workers and their clients will have the information they need to avoid the risk of exposure to toxic chemicals like toluene, formaldehyde, and phthalates); *see also* HEALTH & SAFETY § 111791. An additional issue in this area remains: the fact that women and people of color are a large part of the labor force in the beauty industry. Jones, *supra* note 4, at 156. Because of this fact, we again see the lack of regulation in cosmetics as an issue that effects primarily women. *Id.* Ninety-four percent of hairstylists registered in the United States are women. *Id.* Nail technicians as a group often have significant cumulative exposure to chemicals from cosmetics. *Id.* In California, fifty-nine percent of all nail technicians are Vietnamese, making this an issue that disproportionally affects minority women. *Id.* Additional chemical exposure from professional cosmetic products is an important issue in cosmetic legislation, and one that also goes largely unnoticed. *Id.* Employees in the beauty industry are experiencing significant cumulative exposure in their lifetimes, causing women and people of color to have higher concentrations of chemicals occurring in their bodies while the legislature turns a blind eye to the issue. *Id.*

137. *State Laws*, *supra* note 128.

138. *Id.*

139. *Id.*

lotions, and bubble baths.[140] The law applies to all products intended to be used by children under eight years old.[141] The State of Washington adopted the Children's Safe Product Act, which requires manufacturers of children's items, including personal care items, to report to the state government if their product contains a chemical of high concern to children.[142] However, this legislation is extremely limited in scope, and the state has passed no legislation regarding general cosmetics or personal care products not intended for children.[143]

Although some states have passed limited legislation regarding cosmetics, the federal government has not been quite as successful.[144] As mentioned previously, federal cosmetic legislation has remained nearly stagnant since the Federal Food, Drug, and Cosmetic Act was passed.[145] However, two pieces of legislation are currently being considered in the House of Representatives.[146] One current regulation under consideration is the Cosmetics Safety Enhancement Act of 2019.[147] This Act would require cosmetic companies to substantiate the safety of their products, notify the FDA of adverse health effects, and give the FDA the power to conduct their own safety reviews in addition to mandating increased transparency in product labeling.[148] Another proposed piece of legislation regarding cosmetics is the Personal Care Products Safety

140. MINN. STAT. § 325F.177 (2013); *see also State Laws*, *supra* note 128 (describing major state laws in cosmetics).

141. *State Laws*, *supra* note 128 (describing major state laws in cosmetics, including Minnesota).

142. WASH. REV. CODE § 70A.430.010 et seq. After the passage, Washington made it clear that this law applied to Proposition 65 carcinogens. *State Laws*, *supra* note 128. Chemicals on this list include (but are not limited to): Formaldehyde, Aniline, N-Nitroso dimethylamine, Benzene, Vinyl chloride, Acetaldehyde, Methylene chloride, Carbon disulfide, Methyl paraben, Ethylene glycol, 4-Chloroaniline, Benzophenone-2 (Bp-2), and Chlorinated paraffins. WASH. REV. CODE § 70A.430.010 et seq. However, the list does not end there; for the other seventy-three banned chemicals, please see WASH. REV. CODE § 70A.430.010 et seq.

143. WASH. REV. CODE § 70A.430.010 et seq.

144. Narayan, *supra* note 23.

145. *Id.* ("The only government oversight of cosmetics companies comes under the Federal Food, Drug and Cosmetic Act, passed in 1938. The act is focused mainly on regulating adulterated or misbranded products, or products that are falsely packaged. However, labeling products as natural or organic does not qualify as misbranding. The 1938 act also does not require the FDA to recall potentially dangerous items or monitor the ingredients used in products.").

146. *Federal Laws*, CAMPAIGN FOR SAFE COSMETICS: A PROJECT OF BREAST CANCER PREVENTION PARTNERS, https://www.safecosmetics.org/get-the-facts/regulations/federal-laws [https://perma.cc/8LJX-N3QL] (last visited Nov. 18, 2022).

147. *Kuster Amendment to Help Keep PFAS Out of Cosmetics Included in Legislation to Ensure Safety of Cosmetics*, ANN MCLANE KUSTER CONGRESSWOMAN FOR N.H. 2ND DIST. (Mar. 13, 2021), https://kuster.house.gov/news/documentsingle.aspx?DocumentID=2204 [https://perma.cc/G66E-QZA7].

148. Jones, *supra* note 4, at 167-69.

Act.[149] This Act alleges to be a comprehensive consideration of cosmetic regulation reform, including: mandatory registration of cosmetic facilities; cosmetic ingredient statements; serious adverse event reporting; creation of good manufacturing practices ("GMPs"); and ingredient review.[150] Although these are important starting points, the Act still allows many of the issues in the cosmetic sector to remain unsolved, including the self-regulation within the industry.[151] Cosmetic regulation has gone untouched since 1938.[152] In order to protect American consumers, the next legislation to be passed must be a comprehensive overhaul of the FDA's power over cosmetics.[153]

In addition to the proposed legislation, it is important to remember the constituent base behind this issue.[154] The constituent base is made up of many people who have been affected by unregulated cosmetics, and often have first-hand experiences that many lawmakers do not have available to them.[155] Many advocacy groups are lobbying for reform of the cosmetic market, such as the Campaign for Safe Cosmetics, a project of the Breast Cancer Prevention Partners.[156] These advocacy groups work to spread information about current state laws, the laws of other countries, and how to make cosmetics safer for all.[157]

149. Clark, *supra* note 23.

150. *Id.*

151. *Id.*

152. Boyd, *supra* note 4, at 278.

153. Jacobs, *supra* note 4, at 120.

154. *State Laws*, *supra* note 128.

155. *About Us*, CAMPAIGN FOR SAFE COSMETICS: A PROJECT OF BREAST CANCER PREVENTION PARTNERS, https://www.safecosmetics.org/about-us [https://perma.cc/K3C5-TZFL] (last visited Nov. 18, 2022) (introducing a group started in order to educate on the adverse effects of unregulated cosmetics).

156. *See generally id.* ("The Campaign for Safe Cosmetics coalition, a project of Breast Cancer Prevention Partners (formerly the Breast Cancer Fund), works to protect the health of consumers, workers and the environment through public education and engagement, corporate accountability and sustainability campaigns and legislative advocacy designed to eliminate dangerous chemicals linked to adverse health impacts from cosmetics and personal care products. The Campaign has educated millions of people about the problem of toxic chemicals in cosmetics, which has led to an increased demand for safer products in the marketplace. Now hundreds of cosmetic companies fully disclose ingredients and avoid the use of cancer-causing chemicals, reproductive toxicants and other unsafe chemicals, demonstrating these practices are not only possible, but profitable. Retailers, too, are becoming part of the solution by requiring the national brands they sell to eliminate chemicals of concern and practice a higher level of ingredient transparency.").

157. *About: Accomplishments*, BREAST CANCER PREVENTION PARTNERS, https://www.bcpp.org/about-us/accomplishments [https://perma.cc/UU98-3YGX] (last visited Nov. 18, 2022).

D. Self-Regulation of the Cosmetics Industry Fails to Protect Consumers

The American cosmetics industry brings in approximately seventy billion dollars a year.[158] The FDA's Office of Cosmetics and Colors has an annual budget of a mere eight million dollars and only twenty-seven staff members, despite the size of the industry they are expected to oversee.[159] The law governing the FDA's Office of Cosmetics and Colors runs only two pages long and has not been updated since the Federal Food, Drug, and Cosmetic Act was first enacted in 1938.[160] These modest tools leave federal officials nearly powerless to regulate the makeup, toothpaste, lotion, deodorant, and other products that are often applied to the most intimate parts of the human body.[161] As a result, the industry has become self-regulated.[162]

The federal government has been able to disregard cosmetic regulation for years under the guise that the industry is "self-regulated."[163] Since its emergence, the cosmetics sector has followed a policy of self-policing its products. [164] The Personal Care Products Council is an advocacy group in which funds its own self-regulatory body for the cosmetics industry.[165] The one exception to self-regulation is color additives, because some synthetic colors are

158. Tony Cenicola, *Do You Know What's in Your Cosmetics*, N.Y. TIMES (Feb. 9, 2019), https://www.nytimes.com/2019/02/09/opinion/cosmetics-safety-makeup.html [https://perma.cc/F2JF-DHZ6].

159. *Id.*

160. *Compare* Boyd, *supra* note 4, at 278 *with* 21 U.S.C. § 301 et seq.

161. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 § 201(i) (2018).

162. *About PCPC*, PERS. CARE PRODS. COUNCIL (Sept. 2021), https://www.personalcarecouncil.org/about-us [https://perma.cc/8HH2-PKQ9].

163. The Story of Stuff Project, *supra* note 2.

164. Narayan, *supra* note 23 ("Self-policing its products has been the standard for the cosmetics sector. The Personal Care Products Council, a cosmetic industry advocacy group that represents 600 companies engaged in the manufacture, distribution and supply of cosmetics products, has existed for more than 100 years and funds its own self-regulatory body. The one exception to self-regulation is color additives, because some synthetic colors are made of coal tar and contain lead."); *see also* Pflanzer, *supra* note 22 ("Lochhead told Business Insider the reason the FDA is so concerned with color additives relative to other chemicals is part of the agency's history: In the 1950s, some of the color additives in food and other materials caused some serious health complications, namely FD&C Orange No. 1, which made many children sick after it was used in Halloween candy.").

165. *About PCPC*, *supra* note 162. Founded in 1894, the Personal Care Products Council ("PCPC") is the leading national trade association, representing cosmetics and personal care product companies. *Id.* The council serves as the voice on scientific, legal, regulatory, legislative, and international issues for the $499.6 billion global industry. *Id.* PCPC's 600 member companies represent more than ninety-percent of the U.S. beauty industry and are some of the most beloved brands in beauty and personal care today. *Id.* They manufacture, distribute, and supply the vast majority of personal care products marketed in the United States, and are global leaders committed to product safety, quality, and innovation. *Id.*

made of coal tar and contain lead.[166] However, with no formal enforcement power, the Personal Care Products Council is handcuffed and unable to ensure the market is remaining safe for consumers.[167]

In addition to being powerless to effectuate meaningful change, the Personal Care Products Council has also made some questionable political decisions, such as donating nearly two million dollars to lobbying efforts, even though they were designed to regulate the industry.[168] The lobbying efforts became even more alarming when the Personal Care Products Council created a panel to investigate chemicals, and started reaching conclusions that no other group had.[169] Some of the panel's conclusions have been at odds with those of impartial government entities, such as the National Toxicology Program.[170] Of the more than 5,000 chemicals that the panel has evaluated since its inception in 1976, only eleven have been found unsafe for use.[171] The panel made those determinations not by testing chemicals or cosmetics directly, but by reviewing available data, "which for many ingredients is [insubstantial] at best."[172] As of present, self-regulation methods fail to protect consumers.[173] By allowing a "self-regulated" industry, led by the Personal Care Products Council that holds no governing power, cosmetics are successfully hidden from any significant regulation at all.[174]

166. CASEY MEE LEE DAUM, SELF-REGULATION IN THE COSMETIC INDUSTRY: A NECESSARY REALITY OR A COSMETIC ILLUSION? 3, 26 (2006) https://dash.harvard.edu/bitstream/handle/1/8965615/Daum06.html?sequence=2 [https://perma.cc/6P78-PSZM].

167. The Story of Stuff Project, *supra* note 2; *see also* Cenicola, *supra* note 158.

168. Cenicola, *supra* note 158.

169. *Compare* Cenicola, *supra* note 158 ("The only panel tasked with determining the safety of individual cosmetic ingredients, the Cosmetic Ingredient Review, is funded and staffed by the Personal Care Products Council, a trade group that spends roughly $2 million a year on the panel—or about as much as it spends lobbying Congress.") *with About PCPC*, *supra* note 162. The Personal Care Products Council website does not detail the funding of the Personal Care Products Council. *About PCPC*, *supra* note 162.

170. David Willis, *Pallone: FDA Should Probe for Asbestos in Makeup Sold in Claire's, Justice*, CONGRESSMAN FRANK PALLONE JR. (Feb. 21, 2018), https://pallone.house.gov/media/in-the-news/pallone-fda-should-probe-asbestos-makeup-sold-claires-justice [https://perma.cc/ZM9C-BXJ5]; *see also* Cenicola, *supra* note 158 ("Industry trade groups have spent years quashing efforts to close these gaps in regulatory oversight. As court records show and several news outlets have reported, the Personal Care Products Council (then called the Cosmetic, Toiletry, and Fragrance Association) waged a decades-long war with regulators and consumer safety advocates over asbestos-laced talcum powder. As far back as the 1960s, the organization insisted that such powder was safe, even as its own members' scientists warned that it might not be.").

171. Cenicola, *supra* note 158.

172. *Id.*

173. Egeberg, *supra* note 59, at 324.

174. Boyd, *supra* note 4, at 300-01.

E. Concealing the Effects of Your Cover-Up

Under normal circumstances, one might not think to report to a company if a product caused them watery eyes, hair loss, or skin irritation.[175] However, when it is happening to hundreds of users across the country, the FDA should be made aware.[176] With the lack of regulation and minimal state laws failing to adequately protect consumers, the health of consumers continues to be a low-level priority in cosmetics.[177] Despite marketing teams pushing empty words such as "natural beauty," "organic cosmetics," and "safer ingredients"—consumers continue to remain at risk.[178]

Possibly one of the most alarming shortcomings of cosmetic regulation revolves around the multiple lawsuits filed against Johnson & Johnson, claiming that their talc baby powder led to ovarian cancer.[179] Talc was a commonly used personal care product for women throughout the twentieth century and was often used on the most intimate areas of a woman—including her vagina, underarms, and breasts.[180] Talc products historically contained asbestos, but it was later eradicated from talcum powder after widespread outrage.[181] Johnson & Johnson continued selling its talcum powder, now claiming the powder was "asbestos free," however, years later, even women who used this newly formulated "asbestos free" talcum powder are having serious long-term health effects.[182] In a class action lawsuit filed in 2014, twenty-two women alleged that Johnson & Johnson's baby powder caused long term health issues.[183] All twenty-two women had used the talc-based baby powder for feminine hygiene over a period of several years, and all eventually

175. *Common Beauty Project Injuries*, *supra* note 3.

176. *Id.*

177. *See infra* Part III.D.

178. Jacobs, *supra* note 4, at 102.

179. Lisa Girion, *Johnson & Johnson Knew for Decades That Asbestos Lurked in Its Baby Powder: A Reuters Investigation*, REUTERS INVESTIGATES (Dec. 14, 2018), https://www.reuters.com/investigates/special-report/johnsonandjohnson-cancer [https://perma.cc/2F4F-A8S2].

180. Dacy Knight, *Is Talc in Makeup Bad for You? A Cosmetic Chemist Gives It to Us Straight*, BYRDIE (Nov. 24, 2021), https://www.byrdie.com/is-talc-in-makeup-bad [https://perma.cc/CL6W-5YY6]. Talc, in its natural state, contains asbestos. *Id.* Talc is used in many beauty products, most notably face powders. *Id.*; *see also* Jacobs, *supra* note 4, at 90.

181. Jacobs, *supra* note 4, at 90-91.

182. *Id.* at 91 ("When talking about whether or not talcum powder is linked to cancer, it is important to distinguish between talc that contains asbestos and talc that is asbestos-free . . . . Talc that has asbestos is generally accepted as being able to cause cancer if it is inhaled. This type of talc is not used in modern consumer products. The evidence about asbestos-free talc, which is still widely used, is less clear.").

183. *Id.* at 90-91.

developed ovarian cancer.[184] The jury in that case awarded 4.6 billion dollars in damages to the twenty-two women.[185] Lawsuits began all over the country, with 325 million dollars being awarded in California to plaintiffs, and twenty-five million dollars being awarded to plaintiffs in New Jersey—just to name a few.[186]

Another frightening lawsuit for consumer health was filed against the makers of WEN haircare.[187] In Florida, a woman purchased hair conditioner after seeing advertisements about the product's "safe, innovative, and gentle qualities."[188] Within two weeks of using the product, she began to notice significant and abnormal hair loss.[189] She immediately stopped using the product but continued to experience hair loss, ultimately losing twenty-five to thirty-three percent of the hair on her head.[190] Amy Friedman was one of more than two hundred consumers who experienced serious adverse reactions to WEN Cleansing Conditioner haircare products.[191] These comments were not hidden from the public or the FDA, as one was notably on WEN's Facebook page, stating, "[s]tarted using in August . . . . Hair looks great but have lost sixty percent of my hair."[192] Complaints continued to build for over a year before Amy Friedman filed the class action lawsuit.[193]

---

184. *Id.*

185. *Id.*

186. *Id.*

187. *WEN Hair Loss & Scalp Irritation Settlement Class Action Over Damaged Hair to End for $26 Million*, CONSIDER THE CONSUMER (Sept. 8, 2021), https://considertheconsumer.com/class-action-settlements/wen-hair-loss-scalp-irritation-settlement-class-action-over-damaged-hair-to-end-for-26-million [https://perma.cc/X5VU-WPLT]. Those eligible for the class action lawsuit include anyone who bought eligible WEN haircare products from November 1, 2007, to September 19, 2016. *Id.* Eligible claims fall into two categories: the first being tier one, where consumers who bought and used any eligible products can claim twenty-five dollars for personal injury. *Id.* The second, more serious tier, includes buyers who can make a claim of up to $20,000 in the event that they have documented adverse reactions to using any of the eligible WEN haircare products. *Id.*

188. Complaint at 8, Friedman v. Guthy-Renker LLC, No. 2:14-cv-06009, 2014 WL 3944013 (C.D. Cal. July 31, 2014).

189. *Id.*; *see also* Tecson, *supra* note 4, at 128.

190. *WEN Hair Loss & Scalp Irritation Settlement Class Action Over Damaged Hair to End for $26 Million*, *supra* note 187; *see also* Complaint at 8, *Friedman*, No. 2:14-cv-06009, 2014 WL 3944013.

191. Complaint at 8, *Friedman*, No. 2:14-cv-06009, 2014 WL 3944013; *see also* Tecson, *supra* note 4, at 128.

192. Amanda Rakes, *Hundreds of Women Join Class Action Lawsuit Claiming WEN Hair Care Product Caused Hair Loss*, FOX 59 (Dec. 15, 2015), https://fox59.com/news/hundreds-of-women-join-class-action-lawsuit-claiming-wen-hair-care-product-caused-hair-loss [https://perma.cc/BD4E-UWMV].

193. *WEN Hair Loss & Scalp Irritation Settlement Class Action Over Damaged Hair to End for $26 Million*, *supra* note 187. The class action lawsuit alleges that WEN advertisements were misleading and that their public relations firm, Guthy-Renker, "reinforce[d] its false statements," leading women to buy products thinking it would lead to positive results and becoming adversely

WEN haircare paid out a twenty-six million dollar settlement to consumers who have used their products.[194] WEN received over twenty-thousand complaints about the effects of their hair products, and never once was it reported to the FDA.[195]

Although these claims largely affect women, they also affect some of the most vulnerable members of society: children.[196] Cosmetics that are sold to children remain just as unregulated, if not more so, than cosmetics marketed towards adults.[197] A prime example of this is the finding that Claire's makeup, geared towards children in their developmental years, contains asbestos.[198] Claire's[199] makeup went unchecked for years without a required ingredient review or pre-market approval.[200] Much like the Johnson & Johnson products, all three

affected. *Id.* Although Ms. Friedman was using the brand's cleansing conditioner, many other WEN products were found by the jury to lead to a very similar adverse result. *Id.* These products include the Anti-Frizz styling crème, bath and body hair oil, defining paste, detangling treatment spray, finishing treatment crème, glossing shine serum, men control texture, men's hair and body oil, nourishing mousse, re-moist intensive hair treatment, re-moist mask, replenishing treatment mist, SIXTHIRTEEN ultra nourishing cleaning treatment, smoothing glossing serum, straightening smoothing gloss, styling crème, texture balm, texturizing spray, treatment mist duo, treatment oil, volumizing root life, and volumizing treatment spray. *Id.*

194. *See generally* Settlement Agreement and Release of Claims, Friedman v. Guthy-Renker LLC, No. 2:14-cv-06009, 2014 WL 3944013 (C.D. Cal. July 31, 2014).

195. *See generally* Friedman v. Guthy-Renker LLC, No. 2:14-cv-06009-ODW(AGRx), 2017 U.S. Dist. LEXIS 220559, at *4-5 (discussing the 21,000 complaints that WEN received prior to the information becoming public knowledge).

196. Madison Park, *Asbestos Found in Claire's Cosmetics, FDA Says*, CNN (Mar. 11, 2019), https://www.cnn.com/2019/03/05/health/claires-asbestos-fda-cosmetics/index.html [https://perma.cc/ZBE7-5TU2].

197. Merrit Kennedy, *FDA Says It Found Asbestos in Makeup at Claire's*, NPR (Mar. 6, 2019), https://www.npr.org/2019/03/06/700830418/fda-says-it-found-asbestos-in-childrens-makeup-at-claire-s [https://perma.cc/5VWF-P7QX]. When news hit of the Claire's products containing asbestos, the FDA included in their statement that "the current law does not require cosmetics to be received and approved by the FDA prior to being sold to American consumers" and noting that all of the responsibility to assure customer safety rests in the hands of the manufacturers. *Id.*

198. *Id.* Asbestos is believed to cause mesothelioma, a type of cancer affecting the lining of the chest and abdomen, and it is also linked to an increased risk of other cancers and some forms of lung disease. *Id.* It is of note that Claire's denies the findings of the FDA studies, saying the studies show significant errors and that the tests have "mischaracterized fibers in the products as asbestos." *Id.* The FDA responded by saying all three labs that tested the sample came back with conclusive results and the company is confident in their findings. *Id.* Other independent testers also dispute Claire's claim that these products are safe. *Id.* The U.S. Public Interest Research Group Education Fund released results that their testing also showed the same three Claire's products contained asbestos. *Id.*

199. *Id.* Claire's sells jewelry and accessories, along with providing ear piercings and other items for children, teens, and tweens. *Id.* Claire's has more than 2,400 locations in North America and Europe. *Id.*

200. *Id.*

products recalled from the Claire's shelf contained talc and asbestos.[201] This was not the first incident, with an additional nine makeup products having been recalled for containing talc and asbestos in 2017.[202] Although no lawsuit came of this, the FDA only began investigating the products after adverse event reporting and customer complaints.[203]

However, these are not isolated incidents.[204] Products can cause severe injury, but unregulated products can also have an impact on the day-to-day life of the consumer, including allergic reactions, skin burns, hair loss, and more.[205] What may seem like one inconvenient incident to a consumer, may be happening to hundreds of people without the consumer ever knowing due to the United States' lack of a proper reporting system.[206] Without proper regulation, these harms continue to be widespread across all types of cosmetics, from body lotions, to nail polish, to powders.[207]

III. THE REGULATION OF COSMETICS

The shortfall of federal oversight for cosmetics under the Federal Food, Drug, and Cosmetic Act puts consumers' health and safety at risk.[208] The current cosmetic regulatory system allows for unchecked self-regulation.[209] The cosmetic industry has successfully concealed their lack of regulation from the public through this faux-police power, causing serious health concerns for the consumer.[210] First, Subpart A will discuss the current self-regulation of the cosmetics market and why it fails to protect consumers.[211] Next, Subpart B will discuss the harm that consumers have faced due to this lack of regulation, while Subpart

201. Sonja Haller, *Claire's Recalls JoJo Siwa's Makeup Kit for Tweens After Finding Asbestos in It*, USA TODAY (June 9, 2019, 6:24 PM), https://www.usatoday.com/story/life/allthemoms/2019/06/09/jojo-siwa-claires-makeup-kit-recalled-after-fda-finds-asbestos/1402366001 [https://perma.cc/HPZ5-XFEF]. The products recalled include makeup from the JoJo Siwa line—a sought-after product for children due to its celebrity endorsement. *Id.*

202. Park, *supra* note 196.

203. *Id.*; *see also* Kennedy, *supra* note 197.

204. *Common Beauty Project Injuries Exploring Cosmetic Injuries Reported to the FDA from 2004 to 2018*, *supra* note 3.

205. *See supra* Part I.

206. *Common Beauty Project Injuries Exploring Cosmetic Injuries Reported to the FDA from 2004 to 2018*, *supra* note 3.

207. *Id.*

208. *See infra* Part III.

209. DAUM, *supra* note 166, at 5.

210. *Id.*; *see also* Narayan, *supra* note 23 ("Faber of the Environmental Watch Group dismissed it as a 'fake police force,' with no authority over bad actors in the industry. 'Self-policing has failed,' he said.").

211. *See infra* Part III.A.

C will discuss the punishment for cosmetic-related crimes.[212] Finally, Subpart D will discuss other countries' models for cosmetic regulation and how they have proven to benefit consumer health.[213]

A. The Personal Care Products Council Has Allowed Congress to Ignore Cosmetic Regulation

The current lack of federal regulation is causing direct harm to the American consumer.[214] Despite its name, the Federal Food, Drug, and Cosmetic Act contains only two pages of regulations regarding cosmetics.[215] The statute only covers the two types of cosmetics that are regulated:

> § 361. Adulterated cosmetics: A cosmetic shall be deemed to be adulterated- (a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual, except that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution-This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness," and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes. (b) If it consists in whole or in part of any filthy, putrid, or decomposed substance. (c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. (d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health. (e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.
>
> § 362. Misbranded cosmetics: A cosmetic shall be deemed to be misbranded- (a) If its labeling is false or misleading in any particular. (b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2)

212. *See infra* Part III.B; *see also infra* Part III.C.
213. *See infra* Part III.D.
214. Pflanzer, *supra* note 22.
215. Boyd, *supra* note 4, at 278.

> of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary. (c) If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. (d) If its container is so made, formed, or filled as to be misleading. (e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 379e of this title. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 361(a) of this title). (f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.[216]

However, those two pages have allowed Congress to claim cosmetics are regulated, without creating any government oversight.[217] In addition, Congress has been able to further ignore the lack of federal involvement due to the self-regulation methods adapted by the market.[218]

The Personal Care Products Council, an example of the self-regulated industry, was created in 1894, calling itself a "trade association"[219] that represents cosmetics and personal care product companies.[220] They allege that they serve as the voice of the industry on scientific, legal, regulatory, legislative, and international issues.[221] Due to this, once the call for action to regulate cosmetics came, Congress was able to point to the self-regulated industry and allege that cosmetic regulation was already being successfully handled.[222] Over the last century, America has realized that this is not the case.[223] Due to the

216. 21 U.S.C. §§ 361–62.

217. *Discussion Draft of the Food and Drug Administration Globalization Act Legislation: Device and Cosmetic Safety Provisions: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Com.*, 110th Cong. 150, 159-60 (2008).

218. *See generally About PCPC*, *supra* note 162 (discussing how they are the self-regulating body for cosmetics in the United States).

219. *Trade Association*, BLACK'S L. DICTIONARY (11th ed. 2019) ("Definition & Citations: Organization where members are involved in the same trade or business.").

220. *About PCPC*, *supra* note 162.

221. *Id.*

222. *Id.*

223. Pflanzer, *supra* note 22.

ability to allege that another private trade association is handling the situation, Congress continued to pass no new legislation after the Federal Food, Drug, and Cosmetic Act.[224] However, the council claiming to be the "voice of the industry on regulations" has shown to be anything but.[225] The Personal Care Products Council is made up of the major corporate players in the industry, touting past members, such as the CEO of Avon, the CEO of Estee Lauder, the Founder of Essence Magazine, the CEO of Revlon, and the CEO of Unilever USA.[226] One of the only major regulations the trade association has spoken out on in the last decade has been their desire to stop counterfeit cosmetics from being sold online, an issue that benefits their corporations as much as, if not more than, the consumer.[227] Instead, the policy should be focusing on the safety of American consumers.[228] Due to this lack of federal law, they are focused not on consumer safety, but instead on the issues that personally benefit the CEOs that make up the council.[229] The Personal Care Products Council claims to be the police power within the cosmetics industry, but they remain totally helpless to actually implement mandates or discipline, leaving American consumers at risk.[230] This lack of federal law to regulate the industry continues to allow this dangerous, faux-police power to claim it regulates cosmetics.[231]

B. Consumers Are Paying the Price for Unregulated Cosmetics

Due to this lack of regulation and insufficient self-policing mechanisms, consumers continue to use unregulated cosmetics daily.[232] There is still no clear understanding of if or how much cosmetics,

224. *Id.*

225. *Legal and Regulatory*, PERS. CARE PRODS. COUNCIL, https://www.personalcarecouncil.org/public-policy/legal-and-regulatory [https://perma.cc/52A6-7DBV] (last visited Nov. 18, 2022).

226. *Cosmetic, Toiletry and Fragrance Association*, NOTABLE NAMES DATABASE, https://www.nndb.com/org/155/000123783 [https://perma.cc/7KRQ-DPA5] (last visited Nov. 18, 2022).

227. Sameer Kumar, *Exploratory Analysis of Global Cosmetic Industry: Major Players, Technology, and Market Trends*, 25 TECHNOVATION 1263, 1269 (2005); *U.S. and EU Cosmetics Regulations*, PERS. CARE PRODS. COUNCIL, https://www.nndb.com/org/155/000123783 [https://perma.cc/8E88-ZZPE] (last visited Nov. 18, 2022).

228. *U.S. and EU Cosmetics Regulations*, *supra* note 227.

229. *Id.*

230. *Is It a Cosmetic, a Drug, or Both (Or Is It Soap?)*, *supra* note 12.

231. Narayan, *supra* note 23. Many refer to the Personal Care Products Council as a "faux-police power" because they claim to be regulating the cosmetic industry, however they have no actual regulatory or disciplinary power. *Id.*

232. The Story of Stuff Project, *supra* note 2.

lotions, and skincare products are absorbed through the skin or mucous membrane.[233] This leads to the issue of consumers waking up in the morning and covering themselves, and their children, in different FDA defined "cosmetics," not knowing how the prolonged exposure is impacting their health.[234]

There is little to no study surrounding the long-term exposure of the chemicals in our everyday cosmetic products.[235] Under current law, there is no government-run ingredient review.[236] Even independent nonprofits, like the Cosmetic Ingredient Review, do not

> evaluate the risks of aggregate or cumulative exposure to an ingredient, from multiple products over many years, or the ways in which different ingredients might interact with one another. Its recommendations are not binding, and its member companies do not have to say whether they follow them.[237]

Cosmetics are frequently considered safe by consumers, often with an assumption that they have been regulated before being put on the shelf.[238] However, that is not the case; researchers have found asbestos in makeup sold at Claire's to young girls,[239] linked chemicals in nail polish to serious long-term health effects in nail salon employees,[240] and traced reproductive health issues and mercury poisoning to common products used by women of color.[241] This lack of regulation causes adverse events and severe consequences of certain chemicals to go unnoticed for many years.[242] The FDA should not need a call to action or

---

233. Jones, *supra* note 4, at 161; *see also* Cenicola, *supra* note 158.

234. The Story of Stuff Project, *supra* note 2 (stating that women in the United States use about twelve personal care products daily, while men use on average six personal care products per day).

235. Cheryl Wischhover, *The "Natural" Beauty Industry Is on the Rise Because We're Scared of Chemicals*, VOX (Sept. 18, 2018), https://www.vox.com/the-goods/2018/9/18/17866150/natural-clean-beauty-products-feinstein-cosmetics-bill-fda [https://perma.cc/QJM7-CV6N?view-mode=client-side&type=image].

236. *About the Cosmetic Ingredient Review*, *supra* note 93.

237. Cenicola, *supra* note 158.

238. Grace Wallack, *Rethinking FDA's Regulation of Cosmetics*, 56 HARV. J. ON LEGIS. 311, 321 (2019). In addition, consumers may assume that cosmetics are safe not because they are regulated, but simply because they are not ingested. *Id.* This is a common mistake, as just as much damage can be done to your health through topicals. *Id.*

239. *See supra* Part II.D.

240. *See supra* Part II.D.

241. Julia Calderone, *Beauty Products May Cause Health Risks in Women of Color, Researchers Warn*, CONSUMER REPS. (Aug. 23, 2017), https://www.consumerreports.org/beauty-personal-care/beauty-products-may-cause-health-risks-in-women-of-color-researchers-warn [https://perma.cc/4HKN-WQ9Q]; *see also supra* Part II.D.

242. *See generally* Friedman v. Guthy-Renker LLC, No. 2:14-cv-06009-ODW(AGRx), 2017 U.S. Dist. LEXIS 220559, at *21 (discussing the $26 million settlement from WEN haircare after it was found that their products had done extreme long-term damage to women's hair).

motivation in order to create new legislation.[243] The FDA was created in order to protect the consumer—and is failing to do so.[244]

C. Crime, but No Punishment

The issue of cosmetic regulation does not just end with the lack of law, but also the differences in punishment.[245] Even for the enforceable violations of misbranding and adulterating cosmetics, such as not being able to put a treatment or drug-like claim on a cosmetic package or label, many companies will partake in this behavior because they know that getting sanctioned is unlikely.[246] When a company gets caught violating the cosmetic regulations, the process can take years before real action is taken.[247] The FDA must receive consumer complaints, send multiple warning letters, and issue a summons or injunction, so for many companies the odds of being reprimanded remains worth the risk.[248]

In addition, all of the more severe punishments available to the FDA under the Federal Food, Drug, and Cosmetic Act do not apply to cosmetics.[249] One punishment for being convicted of a drug-related crime is "debarment."[250] The FDA maintains a list of people who are debarred, meaning they are effectively forbidden from working in the drug industry.[251] This punishment is only available for food and drug import violations under the law, and is not a viable punishment option related to cosmetics, no matter how severe.[252] Civil penalties are also limited to only drug violations.[253] There is no private right of action under the Federal Food, Drug, and Cosmetic Act, meaning that

243. *Is It a Cosmetic, a Drug, or Both (Or Is It Soap?)*, *supra* note 12.

244. *Id.*

245. Jones, *supra* note 4, at 160.

246. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331 (2018) ("The following acts and the causing thereof are prohibited: . . . (b) the adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce."); *see also* Jacobs, *supra* note 4, at 90-91.

247. Jacobs, *supra* note 4, at 104.

248. *Id.*

249. Jones, *supra* note 4, at 161.

250. Juliette Willard, *What Is the FDA Debarment List?*, VERISYS (May 13, 2020), https://verisys.com/what-is-the-fda-debarment-list [https://perma.cc/6MK9-PC5W]. Mandatory debarment occurs when a person is convicted of a felony relating to the development, approval, or regulation of a drug product. *Id.* If convicted, they may no longer provide services in the drug industry; this punishment is usually permanent. *Id.* Temporary debarment is when individuals convicted of federal misdemeanors or state felonies may be debarred for a period of several years. *Id.*

251. *Id.*

252. 21 U.S.C. § 335a (a)–(b) (2012); *see also* Jones, *supra* note 4, at 151.

253. Jones, *supra* note 4, at 151.

individuals themselves cannot bring suit for violation of the Act.[254] This leaves many consumers with the task of finding other applicable law in order to file a suit for the injury sustained from unregulated cosmetics.[255] The only violation that can actually lead to action is if a company is found to have sold adulterated[256] or misbranded[257] cosmetics.[258] Even still, the most the FDA can do is charge the manufacturer or company with libel of information, resulting in the product being seized or condemned.[259] These penalties are the best illustration of the FDA's truly minimal regulatory power over cosmetics under the Federal Food, Drug, and Cosmetic Act.[260] The FDA should not need an incentive to change the lack of regulation or punishment—they were created to protect the health of American consumers and are failing to do so.[261]

D. Increased Federal Oversight Has Proven to Protect Consumers

Harm to consumers from beauty products could be limited if the proper federal regulation were to exist.[262] The European Union ("EU") is a great example of another area of the world that saw this as a legal issue and allowed for more regulation of cosmetics to assure health benefits to the consumer.[263] The EU does not technically require cosmetic products to be pre-approved before going to market.[264] However, it does require a much stricter safety assessment than the United States.[265] The EU requires that every product that goes on consumer shelves be reviewed by someone with a degree in pharmacology or other relevant area of expertise.[266] That pharmacologist must consider the general toxicological profile of each ingredient contained in the cosmetic, the chemical structure of each ingredient, the level of exposure of each

254. Merrell Dow Pharms. Inc. v. Thompson, 478 U.S. 804, 832 (1986) (holding that Congress did not intend a private federal remedy for violations of the statute).

255. Jones, *supra* note 4, at 151.

256. *Adulterated Cosmetic Law and Legal Definition*, *supra* note 103.

257. Misbranded Cosmetics, 21 U.S.C. § 362 (1938).

258. Jones, *supra* note 4, at 161; *see also* 21 U.S.C. § 301 et seq.

259. Jones, *supra* note 4, at 161.

260. *Id.*

261. Ben Panko, *Where Did the FDA Come from, and What Does It Do?*, SMITHSONIAN MAG. (Feb. 8, 2017), https://www.smithsonianmag.com/science-nature/origins-FDA-what-does-it-do-180962054 [https://perma.cc/ZU3G-V35Y].

262. *See infra* Part IV.

263. *Internal Market, Industry, Entrepreneurship, and SMEs*, *supra* note 125.

264. Wallack, *supra* note 238, at 332.

265. *See Confidence in Cosmetics*, COSM., TOILETRY & PERFUMERY ASS'N, http://www.thefactsabout.co.uk/confidence-in-cosmetics/content/128#safety [https://perma.cc/V85N-WPK9] (last visited Nov. 18, 2022).

266. Wallack, *supra* note 238, at 332; *accord Confidence in Cosmetics*, *supra* note 265.

ingredient, the specific exposure characteristics of where the cosmetic is intended to be placed (face, neck, décolletage, legs, etc.), and the specific exposure characteristics of the class of individuals for whom the cosmetic is intended (mature adults, babies, teens, etc.).[267]

In addition to the research required before a product can ever hit the market, the EU also requires that all cosmetics be registered with the Cosmetic Products Notification Portal.[268] This allows all countries in the EU to have access to the database and know what is being sold to their consumers.[269] To further the product-specific regulations the EU has put in place, they have also banned over 1,300 ingredients.[270] This is impressive in comparison to the United States' mere eleven banned ingredients.[271] Although many of these ingredients do not commonly occur in everyday eye cream, foundation, or lotion, the EU is careful to ensure the safety of its citizens through this regulation by focusing on ingredients.[272]

It is hard to pinpoint exactly how much these cosmetic regulations will protect consumers.[273] What is clear from empirical research is that the EU regulations are focused on long-term exposure and long-term consumer health.[274] However, it may be difficult to track whether a woman who uses a particular cosmetic product avoided a cancer diagnosis as a result of the EU cosmetic regulations, or because she was not a smoker.[275] The EU has created a focus in the last decade on consumers being able to feel good about their choices when they walk up to a beauty counter.[276]

---

267. Wallack, *supra* note 238, at 332; *accord Confidence in Cosmetics*, *supra* note 265.

268. *UK Launches Submit Cosmetic Product Notification Portal (SCPN) Portal*, COSMS. BUS. (Jan. 8, 2021), https://cosmeticsbusiness.com/news/article_page/UK_launches_Submit_cosmetic_product_notification_SCPN_portal/173513 [https://perma.cc/YSL6-XVX8].

269. *See generally Cosmetic Product Notification Portal*, EUROPEAN COMM'N, https://ec.europa.eu/growth/sectors/cosmetics/cpnp_en [https://perma.cc/XTE3-DHEH] (last visited Nov. 18, 2022) (explaining the European Union's Cosmetic Product Notification Portal and where the information goes).

270. Wischhover, *supra* note 235.

271. Oliver Milman, *US Cosmetics Are Full of Chemicals Banned in Europe—Why?*, GUARDIAN (May 22, 2019), https://www.theguardian.com/us-news/2019/may/22/chemicals-in-cosmetics-us-restricted-eu [https://perma.cc/5PAG-5C8Q].

272. Wallack, *supra* note 238, at 332.

273. *Id.* at 333 ("Separating harms from cosmetic use and other factors, such as genetics and lifestyle choices (for example, smoking), make it virtually impossible to say for certain that the EU cosmetic regulations keep consumers safer.").

274. *Id.* at 332.

275. *Antiperspirants and Breast Cancer Risk*, AM. CANCER SOC'Y (Oct. 14, 2021), https://www.cancer.org/cancer/cancer-causes/antiperspirants-and-breast-cancer-risk.html [https://perma.cc/PFB8-KQAQ].

276. Wallack, *supra* note 238, at 332.

IV. AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO BETTER AID IN PROTECTING THE HEALTH OF AMERICAN CONSUMERS

Currently, under the Federal Food, Drug, and Cosmetic Act, there are no mechanisms in place for the FDA to oversee cosmetics in the United States.[277] Despite large news stories about the frightening consequences from the lack of cosmetic regulation, consumer harm has been allowed to continue.[278] Cosmetic companies and manufacturers are not accountable to any regulatory body.[279] In order to protect American consumers from continued injury from cosmetics, this Note proposes an amendment to the Federal Food, Drug, and Cosmetic Act.[280] This Act should be amended to change the voluntary registration system to a mandatory registration for cosmetic manufacturers and distributors that wish to sell in the United States.[281] The Federal Food, Drug, and Cosmetic Act should also be amended to include mandatory adverse event reporting, so that both the FDA and consumers are made aware of adverse product reactions.[282] The Federal Food, Drug, and Cosmetic Act should further be amended to include the ability for the FDA to oversee products and conduct a federal, nationwide recall.[283] Finally, the law should be amended to include ingredient review at the national level and prevent any self-regulation bodies to continue.[284]

However, despite these changes, it is imperative that the drafters' intent remains apparent.[285] There have been many times in which legislation and amendments have gone to the floor of Congress and failed.[286] Prior legislation pushed for change too quickly and did not consider the drafters' intent.[287] With these amendments, it is important to keep in mind that the drafters of the Federal Food, Drug, and Cosmetic Act never intended for cosmetics to be regulated at the same level as

277. *Compare* Boyd, *supra* note 4, at 278 *with* 21 U.S.C. § 301 et seq.

278. Pflanzer, *supra* note 22.

279. DAUM, *supra* note 166, at 5.

280. *See supra* Part III.C.

281. *See infra* Part IV.

282. *See infra* Part IV.B.

283. *See infra* Part IV.B.

284. *See infra* Part IV.C.

285. CONGRESSIONAL RESEARCH SERVICE, STATUTORY INTERPRETATION: THEORIES, TOOLS, AND TRENDS 47 (May 27, 2022).

286. *The Future of U.S. Cosmetic Regulations*, REGISTRAR CORP. (Aug. 4, 2021), https://www.registrarcorp.com/the-future-of-u-s-cosmetics-regulations-2 [https://perma.cc/BAW4-9QKW].

287. *Id.* ("This act is not the first of its kind, but similar bills like the FDA Cosmetic Safety and Modernization Act (S.2003) and the recent Safe Cosmetics and Personal Care Products Act of 2018 (H.R.6903) have not made it past Congress committees. They share some commonalties that illustrate the direction U.S. cosmetics regulations may take in the next decade.").

food or drugs.[288] This reflects concerns about the FDA's capacity to handle work.[289] Should the FDA become overwhelmed with the amount of regulations to oversee, this can rapidly lead to other regulations falling to the wayside and posing further risk to consumer health.[290] The FDA is designed to protect consumers and should be able to adapt as new regulatory changes arise.[291] However, no change can be made unless small steps are taken; this Note acknowledges that and hopes to achieve a solution that protects consumers without overwhelming government agencies.[292]

First, Subpart A considers the replacement of the voluntary registration system with one that mandates company registration with the FDA.[293] Next, Subpart B discusses mandatory reporting of serious adverse events and the FDA having oversight of cosmetic recalls.[294] Subsequently, Subpart C discusses ingredient review at the national level.[295] Finally, Subpart D addresses the disbandment of all self-regulatory bodies in the cosmetic industry.[296]

A. The Federal Food, Drug, and Cosmetic Act Should Be Amended to Include a Mandatory Registration System for Manufacturers and Distributors of Cosmetics That Wish to Sell in the United States

The Federal Food, Drug, and Cosmetic Act should be amended to require mandatory registration for all cosmetic manufacturers and distributers.[297] Under the proposed amendment, this voluntary system would be transformed into a mandatory requirement.[298] In doing so, the FDA would have limited oversight of cosmetics, as the drafters intended, while still being able to oversee what cosmetics are being sold to

288. *Foods, Drugs, and Cosmetics: Hearing Before the Comm. on Com.*, *supra* note 22, at 326-27; *see also supra* Part II.A.

289. *Foods, Drugs, and Cosmetics: Hearing Before the Comm. on Com.*, *supra* note 22, at 326-27.

290. *Id.*

291. Panko, *supra* note 261.

292. Angela Onwuachi-Willig, *POV: Ruth Bader Ginsburg Fought Tirelessly for What She Believed Was Right*, BU TODAY (Sept. 20, 2020), https://www.bu.edu/articles/2020/ruth-bader-ginsburg [https://perma.cc/MTM2-KWKU]. Ruth Bader Ginsburg once said that, "[t]he [Supreme] Court moves in small steps rather than in one giant step." *Id.*

293. *See infra* Part IV.A.

294. *See infra* Part IV.B.

295. *See infra* Part IV.C.

296. *See infra* Part IV.D.

297. *The Future of U.S. Cosmetic Regulations*, *supra* note 286.

298. *Id.*; *see also* Clark, *supra* note 23.

consumers.[299] This would allow the FDA to have a better understanding of cosmetic products and ingredients, their frequency of use, and businesses engaged in their manufacturing and distribution.[300]

As of now, the Voluntary Cosmetics Registration Program takes the data collected through the program and allows other nonprofits and trade associations to use the information.[301] With the mandatory system, this will continue.[302] The information gathered through this system would be expansive and cannot possibly be utilized in the most helpful way by allowing only the FDA access to it.[303] The information collected should be published and accessible to American consumers.[304] In addition, the data collected should continue to be given to the Cosmetic Ingredient Review Board.[305] Although under these amendments the FDA is completing ingredient review, continuing to allow non-government agencies access to this information contributes to ingredient review on a mass scale.[306] This would allow our consumers to be informed on the safety of more ingredients per year, and give the FDA more information when considering ingredients to disallow in the United States.[307]

B. The Federal Food, Drug, and Cosmetic Act Should Be Amended to Include Required Serious Adverse Event Reporting and Allow the FDA to Oversee Cosmetic Recalls

The lack of required reporting of serious adverse events is likely the most harmful shortfall of the Federal Food, Drug, and Cosmetic Act due to its direct impact on consumer health.[308] Under current "regulation," a company can receive thousands of reports of an adverse event and would never have to inform the FDA.[309] Under this amendment, serious adverse event reporting would be required for any product that receives over fifty identical or similar complaints.[310]

Serious adverse event reporting would mean that if a cosmetics company sold a shampoo, and then received fifty similar complaints,

299. *Discussion Draft of the Food and Drug Administration Globalization Act Legislation: Device and Cosmetic Safety Provision*, *supra* note 126, at 160.
300. Clark, *supra* note 23.
301. *Voluntary Cosmetic Registration Program*, *supra* note 13.
302. *Id.*
303. *Id.*
304. *Id.*
305. *About the Cosmetic Ingredient Review*, *supra* note 93.
306. *Id.*
307. *Voluntary Cosmetic Registration Program*, *supra* note 13.
308. Settlement Agreement and Release of Claims, Friedman 2014 WL 3944013, at *11.
309. *Id.*
310. Egeberg, *supra* note 59, at 318; *see also* Clark, *supra* note 23.

such as "loss of hair," "hair breakage," or "hair thinning," the product and all events would have to be reported to the FDA for further action.[311] These situations would then be compiled into a database, where consumers can investigate if companies have reported similar issues in the past.[312] From there, the FDA can take further action as it sees fit under its newfound recall power.[313] The action taken will be similar to that of food or drug recalls.[314] As the process currently stands, it can take years to receive complaints, file formal warning letters, and get in touch with a company or issue a recall.[315] This reporting system would help improve consumer safety because the FDA would be alerted to negative product reactions faster, and be able to contact the company or issue a recall sooner.[316]

C. The Federal Food, Drug, and Cosmetic Act Should Be Amended to Include Ingredient Review at the National Level

Ingredient review is one of the tokens of consumer safety in cosmetics, but it is unfortunately severely underfunded and ignored in the United States.[317] Ingredient review allows the FDA and private nonprofits to evaluate ingredients of interest each year, and determine their safety for continued use in cosmetics.[318] Through ingredient review, nonprofits and independent entities have discovered eleven ingredients that are now banned from cosmetics in the United States.[319]

---

311. Alex Formuzis, *Key House Committee Approves Landmark Cosmetics Safety Legislation*, ENV'T WORKING GRP. (Mar. 11, 2020), https://www.ewg.org/news-insights/news-release/key-house-committee-approves-landmark-cosmetics-safety-legislation [https://perma.cc/NQB5-2AB8].

312. *Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics*, *supra* note 18. This Note proposes a similar database to what is currently available for warning letters. *See id.*

313. Emily Miller, *Recalls*, DRUGWATCH (June 6, 2022), https://www.drugwatch.com/fda/recalls [https://perma.cc/DU67-WF62].

314. *Recall Definition & Legal Meaning*, LAW DICTIONARY, https://thelawdictionary.org/recall/ [https://perma.cc/UQ25-MXM5] (last visited Nov. 18, 2022) ("Removal of a contaminated or defective good by its manufacturer, either voluntarily or when forced by a watchdog agency.").

315. Jacobs, *supra* note 4, at 104.

316. *Id.*

317. *Compare* Robert L. Elder Sc.D., *The Cosmetic Ingredient Review—A Safety Evaluation Program*, 11 J. AM. ACAD. DERMATOLOGY 1168, 1169 (1984) *with Internal Market, Industry, Entrepreneurship, and SMEs*, *supra* note 125.

318. *Compare* Robert L. Elder Sc.D., *The Cosmetic Ingredient Review—A Safety Evaluation Program*, 11 J. AM. ACAD. DERMATOLOGY 1168, 1168-69 (1984) *with Internal Market, Industry, Entrepreneurship, and SMEs*, *supra* note 125.

319. *Internal Market, Industry, Entrepreneurship, and SMEs*, *supra* note 125.

However, that number pales in comparison to the number of ingredients considered and banned from cosmetics in other countries.[320]

By allowing the Cosmetic Ingredient Review Board to investigate more ingredients annually and present reports on their findings, the FDA can make better recommendations on what ingredients should be banned in the United States.[321] Currently for cosmetics, the United States has banned only thirty ingredients, while the EU has banned over 1,300.[322] By requiring more ingredient review at the national level, we can better protect consumers from chemicals with long-term side effects after repeat exposure.[323]

D. The Federal Food, Drug, and Cosmetic Act Should Be Amended to Prevent Self-Regulatory Bodies Within the Cosmetics Industry

Cosmetic companies participating in "self-regulation" have aided the industry's ability to harm consumers.[324] Despite the fact that faux-police powers were implemented to "oversee" cosmetics, companies are still able to avoid any real regulation with ease.[325] In allowing companies to "self-regulate," the government is able to effortlessly deflect responsibility while still being able to make the claim that personal care products are being regulated.[326]

---

320. *Compare* Robert L. Elder Sc.D., *The Cosmetic Ingredient Review—A Safety Evaluation Program*, 11 J. AM. ACAD. DERMATOLOGY 1168, 1169 (1984) *with Internal Market, Industry, Entrepreneurship, and SMEs*, *supra* note 125.

321. *Voluntary Cosmetic Registration Program*, *supra* note 13 ("Information from the VCRP database also has been used by the Cosmetic Ingredient Review (CIR), an independent, industry-funded panel of scientific experts, to assist the CIR Expert Panel in establishing their priorities for assessing ingredient safety as part of their ingredient safety review.").

322. Wischhover, *supra* note 235.

323. Egeberg, *supra* note 59, at 324; *see also* Clark, *supra* note 23.

324. *See supra* Part III.A; *see also* DAUM, *supra* note 166, at 17 ("From an administrative standpoint, the prevailing regulatory schema of voluntary industry cooperation with the FDA raises the broad theoretical question of whether or not, from a normative administrative perspective, self-regulation (in lieu of more extensive federal regulation) is a desirable regulatory approach. The current system of voluntary industry self-regulation was born out of pragmatic necessity in the 1970s, when FDA budgetary constraints necessitated industry self-regulation in order to attend to consumer safety. The cosmetic industry now argues that not only does it effectively and efficiently self-regulate, but that it does a better job at ensuring safety than direct federal regulation would be able to accomplish. Despite the professed success of cosmetic industry self-regulation, the administrative standpoint must ask whether or not this is the way that government ought to run, particularly in light of the fact that no other industry in the United States self-regulates in the way that the cosmetic industry does.").

325. DAUM, *supra* note 166, at 5.

326. *Id.*

Under this amendment, all self-regulation mechanisms, such as the Personal Care Products Council, would be disbanded.[327] Removing self-regulation is an important step towards making the American government accountable for cosmetic regulation and consumer health.[328] However, removing the self-regulating bodies is not enough.[329] In addition, the amendments to the Federal Food, Drug, and Cosmetic Act must give the FDA affirmative power to regulate cosmetics in the aforementioned ways.[330] By implementing this change into the FDA bylaws, the FDA would be provided with total control over cosmetic regulation, not just in name but also in power.[331] Once this industry created "oversight" mechanism is removed, the FDA can focus on implementing the other amendments and ensuring compliance from all major cosmetic manufacturers.[332]

V. CONCLUSION

One Saturday Morning, you wake up and decide to go to the mall with your friends to pick up a new shampoo that everyone has been raving about.[333] You go home, take a long hot shower, and use the new

327. Narayan, *supra* note 23 ("Self-policing its products has been the standard for the cosmetics sector. The Personal Care Products Council, a cosmetic industry advocacy group that represents 600 companies engaged in the manufacture, distribution and supply of cosmetics products, has existed for more than 100 years and funds its own self-regulatory body.").

328. DAUM, *supra* note 166, at 19-20 ("Another argument from a pragmatic perspective is one based on incentives – a system of self-regulation can protect consumers because it is in the industry's best interest to create and substantiate a perception of effective self-regulation, thus pragmatically aligning the interests of consumers, the industry, and the FDA. Even those critical of the cosmetic industry's anti-regulation stance acknowledge the industry's natural incentive to maintain safety through self-regulation. For example, one critic writes about the Cosmetic Ingredient Review: 'The CTFA, which administers the voluntary review, argues that no outside watchdog would be more vigilant. After all, who could be better motivated to keep a nice, safe status quo? If makeup did any *real* harm, customers would die, survivors would sue, women would stop buying, and profits would stop.' In addition to the industry's investment in maintaining the safety standards of the industry, individual cosmetic companies themselves have incentives to engage in strict internal self-regulation in order to maintain the company's brand image and reputation among consumers. For example, Jacques Courtin Clarins, the chairman and founder of Clarins, was described as 'a stickler for purity, possessed of an almost neurotic determination to keep his company and its products whiter than white . . . . "He's never afraid to tell us that it is *his* name and *his* reputation on every bottle, every jar."' An incentives-based rationale for self-regulation is ultimately grounded in the power of consumers to 'impact regulation and legislation on multiple levels," and to demonstrate that "their real power is in the marketplace, determining the success or failure of a product.'").

329. Narayan, *supra* note 23.

330. *Id.*

331. *Id.* (explaining the lack of power the FDA has over the cosmetics sector).

332. *Id.*

333. The Story of Stuff Project, *supra* note 2.

shampoo.[334] You go to bed peacefully, no longer having to worry about waking up in the morning to a burning scalp.[335] You know the government has passed legislation to ensure that you as a consumer can find solace in the fact that each choice you make will only affect how shiny your hair is, not your long-term health and safety.[336]

Cosmetics are something that most people in the United States pick up daily, while having no idea the harm that it may cause them.[337] Consumers remain helpless to this fact and must unknowingly rely on Congress to take action and keep them safe.[338] The cosmetic industry is growing rapidly, with new products and brands being announced almost daily.[339] The FDA was designed to serve and protect American consumers, and is currently failing to uphold this responsibility.[340]

Cosmetics are not a product you are exposed to once—they are products you apply on your face, body, or hair multiple times a week, allowing toxins that may be in products to cause severe harm over extended exposure.[341] Due to the severe health risks stemming from continued exposure to some chemicals used in cosmetics, it is critical that the United States act immediately to help protect consumer health.[342]

*Megan Scime**

334. *Id.*
335. *Id.*
336. *Id.*
337. *Id.*
338. *See supra* Part IV.
339. Pflanzer, *supra* note 22.
340. Panko, *supra* note 261.
341. Jones, *supra* note 4, at 161.
342. Narayan, *supra* note 23; *see also* Dennis Thompson, *Increasing Reports of Side Effects from Cosmetics*, CBS NEWS (June 27, 2017, 11:23 AM), https://www.cbsnews.com/news/increasing-number-of-side-effects-from-cosmetics-study [https://perma.cc/N37Y-J7TF].

* J.D. Candidate 2023, Maurice A. Deane School of Law at Hofstra University; B.S. in Marketing and Political Science, Minor in Legal Studies in Business, *magna cum laude*, Seton Hall University, 2019. I want to thank my Notes Editor, Haley Clancy, for her guidance and support. Thank you to Shirantha Stanislaus, for believing in this note from its infancy. Above all, I want to thank Nicole Imperatore, my colleague, confidant, and friend—I would not be an attorney without your friendship and light. I will forever be grateful for going on this journey with you.

None of my success would be possible without my family: Michael Lewis, for treating me as his own. Melinda Scime, for raising me to be the woman I am today. Of course, to Melaina Lewis—for being my sister and best friend. Most importantly, Mimi—for helping raise me and always believing in me even in moments where I struggled to believe in myself.

Finally—thank you to the beauty YouTube community. Tati, Kathleen Lights, Allie Glines, and Lauren Mae Beauty. For showing me that everyone has a place in this industry, for growing up with me, and for teaching me that beauty comes from within (but a little mascara never hurts).