

June 2021

Total Makeover: Federal Cosmetics Regulation and Its Need for Legislative Overhaul to Ensure Consumer Protection

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Recommended Citation

Justice Tecson, *Total Makeover: Federal Cosmetics Regulation and Its Need for Legislative Overhaul to Ensure Consumer Protection*, 51 Golden Gate U. L. Rev. 127 (2021).

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COMMENT

TOTAL MAKEOVER: FEDERAL
COSMETICS REGULATION AND ITS
NEED FOR LEGISLATIVE
OVERHAUL TO ENSURE
CONSUMER PROTECTION

JUSTICE TECSON*

“History has repeatedly shown that when there is insufficient regulatory oversight, a few unscrupulous people or companies will exploit the vulnerable public for profit.”¹

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¹ Robert M. Califf, et al., *Cosmetics, Regulations, and the Public Health: Understanding the Safety of Medical and Other Products*, 177 JAMA INTERNAL MED. 1080, 1080 (2017).

INTRODUCTION

A woman in Florida purchased hair conditioner after viewing advertisements that promoted the product's "safe, innovative and gentle qualities."² Within two weeks of using the product, she lost significant and abnormal amounts of hair.³ Despite discontinuing usage of the product, she continued experiencing hair loss, ultimately losing one-quarter to one-third of the hair on her head.⁴ Such is the story of Amy Friedman, one of more than 200 consumers⁵ harmed by WEN Cleansing Conditioner haircare products.⁶

Haircare products like WEN Cleansing Conditioner are categorized as cosmetics.⁷ Cosmetics are defined as articles and ingredients "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance."⁸ The Food & Drug Administration ("FDA" or "Agency") regulates cosmetics marketed in the United States primarily through the Federal Food Drug & Cosmetic Act ("FFDCA" or "Act") of 1938.⁹

Over the last century, the sale and manufacturing of cosmetic products has evolved into a multibillion-dollar industry.¹⁰ In May of 2012, the worldwide cosmetic, beauty supply, and perfume retail industry had more than \$250 billion in annual retail sales.¹¹ In 2017, the global cosmetics market was valued at approximately \$532 billion.¹² Research

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

³ *Id.*

⁴ *Id.*

⁵ Jane E. Brody, *For Cosmetics, Let the Buyer Beware*, N.Y. TIMES (Aug. 7, 2017), <https://www.nytimes.com/2017/08/07/well/for-cosmetics-let-the-buyer-beware.html>; see also *Class Action Lawsuits Over Wen Hair Products Gets Preliminary Settlement Approval*, CBS LOS ANGELES (Oct. 31, 2016), <https://losangeles.cbslocal.com/2016/10/31/class-action-lawsuit-over-wen-hair-products-gets-preliminary-settlement-approval/> (providing details of the WEN lawsuit and preliminary settlement proceedings).

⁶ *Friedman Complaint*, *supra* note 2, at 8-14.

⁷ See 21 U.S.C. § 321(i).

⁸ *Id.*

⁹ See 21 U.S.C. §§ 321-399 (providing the FDA with regulatory authority over food, drugs, medical devices and cosmetics); see also *FDA Authority Over Cosmetics: How Cosmetics are not FDA-Approved, but are FDA-Regulated*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated> (last updated Aug. 24, 2020).

¹⁰ JAMES T. O'REILLY & KATHERINE A. VAN TASSEL, FOOD & DRUG ADMIN. § 17:1, at 1 (4th ed. 2020).

¹¹ AMALIA K. CORBY-EDWARDS, CONG. RESEARCH SERV., R42594, FDA REGULATION OF COSMETICS AND PERSONAL CARE PRODUCTS 1 (2012).

¹² *Global Cosmetics Products Market expected to reach USD 805.61 billion by 2023 –Industry Size & Share Analysis*, MARKETERS MEDIA (Mar. 13, 2018), <https://marketersmedia.com/global->

shows that the global cosmetics products market is expected to reach approximately \$805 billion by 2023.¹³

Although revenue within the cosmetics industry has dramatically increased in recent years, the same cannot be said of its regulation.¹⁴ Among all the FDA product categories, cosmetics products are among the least regulated.¹⁵ Under current federal regulations, which have not changed since 1938, the FDA has no authority to require registration and product information from cosmetic companies, mandate pre-market testing or approval of products, or order mandatory recalls of proven or potentially hazardous products.¹⁶ Additionally, the current scheme does not require cosmetic companies to report adverse events related to their cosmetic products to the FDA.¹⁷

In recent years, several legislative attempts to solve the lack of FDA cosmetic regulation proved unsuccessful.¹⁸ For instance, the Safe Cosmetics and Personal Care Products Act of 2019 (“SCPCPA”) proposed to amend the FFDCA to require cosmetic companies to register their facilities¹⁹ and provide information regarding their cosmetics’ ingredients to the FDA.²⁰ The SCPCPA would provide the FDA with the authority to recall cosmetics that posed threats to consumer safety,²¹ ban most use of animal testing in cosmetics,²² and fund research into safer alternatives to hazardous ingredients that negatively affect women and girls of color.²³ However, like cosmetics bills that came before it, the SCPCPA was never passed.²⁴

cosmetics-products-market-expected-to-reach-usd-805-61-billion-by-2023-industry-size-share-analysis/313185.

¹³ *Id.*

¹⁴ O’REILLY & VAN TASSEL, *supra* note 10, § 17:1, at 1 (providing a historical overview of cosmetics regulation in the United States).

¹⁵ Some scholars believe that this is because there has not yet been an established need for extensive federal cosmetics regulation in the United States. On the other hand, because cosmetics are a gendered industry primarily targeted to women, some see the lack of legislative prioritization of cosmetics law as a consequence of women’s exclusion from political participation and representation. *See* O’REILLY & VAN TASSEL, *supra* note 10, § 17:1, at 1; *see also* Marie Boyd, *Gender, Race & the Inadequate Regulation of Cosmetics*, 30 *YALE J. L. & FEMINISM* 275, 307-10 (2019).

¹⁶ *FDA Authority Over Cosmetics: How Cosmetics are not FDA-Approved, but are FDA-Regulated*, *supra* note 9.

¹⁷ *Id.*

¹⁸ *See* Safe Cosmetics and Personal Care Products Act of 2019, H.R. 4296, 116th Cong. (2019).

¹⁹ *Id.* § 612.

²⁰ *Id.* § 615.

²¹ *Id.* § 622.

²² H.R. 4296, 116th Cong. § 624; *see also* *National Cosmetic Safety Reform*, BREAST CANCER PREVENTION PARTNERS, <https://www.bcpp.org/resource/federal-cosmetic-safety-reform/> (last visited Mar. 11, 2020).

²³ H.R. 4296, 116th Cong. § 463C; *see also* *National Cosmetic Safety Reform*, *supra* note 22.

²⁴ *See* H.R. 4296, 116th Cong. § 612.

The cosmetic industry's lack of federal oversight has given rise to concerns regarding consumer safety.²⁵ Amy Friedman's story is one example of how the current lack of FDA cosmetic regulation causes actual harm to consumers.²⁶ The current regulatory scheme allows cosmetic companies to operate with little to no government review, leaving consumers vulnerable to potential bad actors.²⁷ This Comment discusses the problematic effects of the current regulatory framework on the health and safety of consumers, and explores the SCPCPA and its proposed amendments to the FDA's regulatory authority over cosmetics. This Comment argues that the SCPCPA is a necessary legislative solution to the current lack of federal cosmetics regulation. Consequently, this Comment argues that the SCPCPA should be re-introduced and passed in order to protect the health and safety of consumers.

Part I begins with a discussion of the FFDCA and the FDA's limited authority to regulate cosmetics. Part II provides an overview of the proposed SCPCPA bill and its provisions. This section explores how the bill purported to amend the FFDCA by broadening the FDA's regulatory power over the cosmetics industry. Part III details two instances wherein the lack of federal oversight over cosmetics threatened consumer safety: the WEN incident and a second one involving Johnson & Johnson talcum powder found to be contaminated with asbestos. Lastly, Part IV argues that Congress should enact the SCPCPA because it would provide the FDA with the necessary authority to effectively regulate cosmetics and protect consumers. This section begins by examining the provisions of the SCPCPA in the context of the WEN and Johnson's incidents, and argues that these incidents could have been prevented or minimized if the FDA had the authority the SCPCPA aimed to provide. To illustrate the feasibility of the SCPCPA provisions, this section then looks to the success of similar provisions in California's existing cosmetics legislature including the state's recently enacted Toxic-Free Cosmetics Act. Lastly, this section addresses legislators' concerns as to federal preemption and the SCPCPA's effect on small businesses.

²⁵ See Brody, *supra* note 5; Tiffany Hsu & Roni Caryn Rabin, *Johnson & Johnson Recalls Baby Powder Over Asbestos Worry*, N.Y. TIMES, <https://www.nytimes.com/2019/10/18/business/johnson-johnson-baby-powder-recall.html> (last updated Nov. 19, 2019).

²⁶ See Friedman *Complaint*, *supra* note 2.

²⁷ See 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>.

I. FEDERAL COSMETICS REGULATION AND THE FDA

A. THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

The federal regulation of cosmetic products began in 1938 when Congress passed the Federal Food, Drug, and Cosmetic Act (“FFDCA”).²⁸ Prior to its enactment, cosmetics were regulated by a collection of state laws that were in place to regulate food and drugs.²⁹ The FFDCA granted the FDA the authority to regulate cosmetic products and their ingredients.³⁰ The FFDCA provisions that regulate the cosmetics industry, with the exception of those pertaining to color additives, have not changed since the Act was first passed nearly a century ago.³¹

The FFDCA prohibits the adulteration and misbranding of cosmetic products in interstate commerce.³² The Act also prohibits the introduction, delivery for introduction, and receipt of such adulterated or misbranded cosmetic products into interstate commerce.³³ Legislators included these provisions in the FFDCA in reaction to several incidents in which cosmetics allegedly caused serious problems to consumer health.³⁴

B. FDA REGULATORY AUTHORITY AND ITS LIMITATIONS OVER COSMETICS

Under the FFDCA, if the FDA finds an adulterated or misbranded cosmetic product in interstate commerce, the Agency has the power to seize the product, seek an injunction preventing production and distribution of the product, and, in some instances, pursue criminal penalties.³⁵ A cosmetic company may also be sued for product liability for products

²⁸ O'REILLY & VAN TASSEL, *supra* note 10, § 17:1, at 1.

²⁹ CORBY-EDWARDS, *supra* note 11, at 5.

³⁰ *Id.*

³¹ Some types of cosmetics are also federally regulated under the Fair Packaging and Labeling Act (FPLA) and related regulations. CORBY-EDWARDS, *supra* note 11, at 5.

³² 21 U.S.C. § 331(b); *see also* 21 U.S.C. § 361 (stating that a cosmetic is deemed adulterated if it contains a poisonous substance, a substance that may otherwise injure the user under the product's prescribed usage, or any filthy, putrid, or decomposed substance); *see also* 21 U.S.C. § 362 (explaining that a cosmetic is considered misbranded if its labeling is false or misleading, if its packaging does not contain the proper labeling information or meet the listed labeling requirements, or if the container holding the product was made, formed, or filled in a misleading manner).

³³ 21 U.S.C. § 331(a), (c).

³⁴ CORBY-EDWARDS, *supra* note 11, at 5.

³⁵ *Id.* (quoting 21 U.S.C. §§ 331-334).

that are adulterated, misbranded, or are otherwise in violation of the FFDCA.³⁶

The FDA also has the power to conduct inspections of cosmetic establishments, to ensure that the products manufactured and sold at the facility are safe, and to evaluate the products for potential adulteration or misbranding violations.³⁷ The FDA may decide to inspect a facility based on its own surveillance initiatives, the facility's compliance history, or complaints made by a consumer.³⁸

During these inspections, the FDA may collect samples from cosmetics establishments for examination and analysis.³⁹ The FFDCA does not require the FDA to notify the establishments prior to conducting inspections, only that the inspections be conducted "at reasonable times and within reasonable limits and in a reasonable manner."⁴⁰ The FDA does not have a required schedule for conducting inspections in cosmetic facilities.⁴¹ The Agency acknowledges its limited inspectional authority over cosmetics establishments as well as its lack of authority to obtain cosmetic testing records.⁴²

The FDA also lacks the authority to collect cosmetics information⁴³ from companies.⁴⁴ The FFDCA neither requires cosmetic facility registration nor cosmetics manufacturers to report the ingredients they use in their products.⁴⁵ Furthermore, the FFDCA does not require cosmetic establishments to report cosmetic-related injuries to the FDA.⁴⁶ In contrast, other FDA-regulated products such as food, drugs, medical devices, and

³⁶ *Id.* at 9-10 (citing Nicole Abramowitz, *The Dangers of Chasing Youth: Regulating the Use of Nanoparticles in Anti-Aging Products*, U ILL. TECH & POLICY 199, 208-09 (Spring 2008)).

³⁷ *Id.* at 6.

³⁸ *Id.* (quoting FDA, *Inspection of Cosmetics: An Overview*, <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm136455.htm>).

³⁹ *Id.* (quoting 21 U.S.C. § 374(d); FDA, *Inspection of Cosmetics: An Overview*, <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm136455.htm>; FFDCA § 704(c)).

⁴⁰ 21 U.S.C. § 374; CORBY-EDWARDS, *supra* note 11, at 6 (quoting 21 U.S.C. § 374(a); FFDCA § 704(a)).

⁴¹ CORBY-EDWARDS, *supra* note 11, at 6.

⁴² O'REILLY & VAN TASSEL, *supra* note 10, § 17:10, at 1.

⁴³ "Cosmetics information" includes, but is not limited to, cosmetic facility registration, cosmetic product ingredient statements, and information regarding the discontinuation or amendment of product formulations. See *Voluntary Cosmetic Registration Program*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program> (last updated Aug. 24, 2020).

⁴⁴ See 21 U.S.C. § 374; O'REILLY & VAN TASSEL, *supra* note 10, § 17:10, at 1.

⁴⁵ CORBY-EDWARDS, *supra* note 11, at 6 (citing 21 C.F.R. Parts 710, 720; FDA, *Bad Reaction to Cosmetics? Tell FDA*, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm241820.htm>).

⁴⁶ *Id.* (quoting FDA Authority Over Cosmetics, <http://www.fda.gov/Cosmetics/Guidance/ComplianceRegulatoryInformation/ucm074162.htm>; Donald R. Johnson, *Not in my Makeup: The Need for Enhanced Premarket Regulatory Authority Over Cosmetics In light of Increased Usage of Engineered Nanoparticles*, 26 J. CONTEMP. HEALTH L. & POLICY 82, 114 (2009)).

tobacco have several registration requirements.⁴⁷ Drug manufacturers, unlike cosmetics manufacturers, are required to report to the FDA adverse reactions to the drugs they produce.⁴⁸

Since the FDA cannot mandate the registration of cosmetic information, whether or not a company notifies the FDA of its existence or the formulation of its products is entirely the company's choice.⁴⁹ The Agency created a Voluntary Cosmetic Registration Program ("VCRP") to be used by "manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the United States."⁵⁰ The VCRP applies to establishments regardless of whether or not their products enter interstate commerce.⁵¹ The FDA encourages cosmetic manufacturers and packaging companies to register their establishments and product ingredients through the VCRP within 30 days of beginning operation.⁵²

Furthermore, since the FDA cannot require companies to report unfavorable reactions to their cosmetic products, the Agency finds out about adverse events in the cosmetic industry only when consumers, manufacturers, or healthcare professionals voluntarily report them.⁵³ Adverse events include any problems a consumer experienced when using a cosmetic product.⁵⁴ A consumer, healthcare professional, attorney, or member of the cosmetic industry may report an adverse event related to cosmetics by calling an FDA Consumer Complaint Coordinator, or by completing a "Voluntary MedWatch form" on the FDA's website.⁵⁵

The FDA's regulatory authority over the cosmetics industry is significantly less comprehensive than its authority over other FDA-regulated products such as food, biologics, and medical devices.⁵⁶ For instance, although the FDA can pursue enforcement actions against products or entities that do not comply with the law, the law does not require

⁴⁷ CORBY-EDWARDS, *supra* note 11, at 6 (quoting 21 U.S.C. § 350d (food); 21 U.S.C. § 360 (drugs and devices); 21 U.S.C. § 387e (tobacco)).

⁴⁸ *Id.*

⁴⁹ See *FDA Authority Over Cosmetics: How Cosmetics are not FDA-Approved, but are FDA-Regulated*, *supra* note 9.

⁵⁰ *Voluntary Cosmetic Registration Program*, *supra* note 43.

⁵¹ 21 C.F.R. § 710.1 (2019).

⁵² 21 C.F.R. §§ 710.2, 720.4 (2019); see also CORBY-EDWARDS, *supra* note 11, at 22.

⁵³ *Using Adverse Event Reports to Monitor Cosmetic Safety*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/how-report-cosmetic-related-complaint/using-adverse-event-reports-monitor-cosmetic-safety> (last updated Nov. 3, 2017).

⁵⁴ *Id.*

⁵⁵ *How to Report a Cosmetic Related Complaint*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/how-report-cosmetic-related-complaint> (last updated Aug. 24, 2020).

⁵⁶ See *FDA Authority Over Cosmetics: How Cosmetics are not FDA-Approved, but are FDA-Regulated*, *supra* note 9; see also CORBY-EDWARDS, *supra* note 11, at 6.

FDA approval for cosmetic products or ingredients before they go on the market, with the exception of color additives.⁵⁷ Also, the FDA does not have the statutory authority to require pre-market notification, safety testing, or pre-market review of these cosmetic products and ingredients.⁵⁸ As such, the burden falls on cosmetic establishments to ensure products are safe before being marketed to the public.⁵⁹ Cosmetics manufacturers and companies who market cosmetics in the United States have a legal duty to substantiate the safety of their products.⁶⁰ However, neither the law nor any FDA regulations require specific testing methods to demonstrate safety.⁶¹ The FDA promulgated that the safety of a product may be substantiated through “(a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic, and (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information.”⁶²

Since the FFDCRA failed to specify how cosmetic products and their ingredients should be tested, the Personal Care Products Council (“PCPC”), the cosmetic industry’s trade association, created a Cosmetic Ingredient Review (“CIR”) program to help provide some guidance on the matter.⁶³ The program reviews the safety of cosmetic product ingredients with the use of existing data, published and unpublished, of each individual cosmetic ingredient.⁶⁴ Under this program, an expert panel analyzes the safety of cosmetic ingredients from an annual priority list.⁶⁵ The list is generated based on ingredients currently used in cosmetics commercially available in the United States, and considers information from the VCRP as well as “toxicological considerations.”⁶⁶ The panelists then analyze the data and determine whether an ingredient is safe for use in cosmetic products.⁶⁷ However, although the CIR findings on cosmetic ingredients are published, the cosmetic industry is under no legal obligation to act in accordance with these findings.⁶⁸

⁵⁷ *FDA Authority Over Cosmetics: How Cosmetics are not FDA-Approved, but are FDA-Regulated*, *supra* note 9.

⁵⁸ CORBY-EDWARDS, *supra* note 11, at 7.

⁵⁹ *Id.* at 11.

⁶⁰ *FDA Authority Over Cosmetics: How Cosmetics are not FDA-Approved, but are FDA-Regulated*, *supra* note 9.

⁶¹ *Id.*

⁶² *FDA Authority Over Cosmetics: How Cosmetics are not FDA-Approved, but are FDA-Regulated*, *supra* note 9 (citing 40 Fed. Reg. 8763, 8916 (Mar. 3, 1975)).

⁶³ CORBY-EDWARDS, *supra* note 11, at 13.

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.* at 14.

Additionally, under the current regulatory framework, the law does not require cosmetics manufacturers to use Good Manufacturing Practices (“GMPs”) unless their cosmetic products are also drugs as defined by statute.⁶⁹ This is significant because, according to the FDA, adherence to GMPs minimizes the risk of having products that violate the FFDCA.⁷⁰ And although the FDA created a Draft Guidance Document establishing what it deems to be GMPs for cosmetics, the document lays out non-binding recommendations rather than legally enforceable responsibilities.⁷¹ The opposite is true for the drug industry: the FDA strictly monitors industry compliance with the current GMP regulations that apply to drugs, as these regulations are legally enforceable and codified in the Code of Federal Regulations.⁷²

Unlike food and medical devices, the FDA does not have the authority to order a mandatory recall of cosmetic products found to be in violation of the FFDCA.⁷³ Rather, the FDA may request that a company recall certain cosmetic products.⁷⁴ Recalls of cosmetic products are voluntary actions on the part of the manufacturers and distributors.⁷⁵ Once a company voluntarily recalls a cosmetic product, the FDA retains the authority to monitor the progress of a recall,⁷⁶ evaluate the health hazard presented by the product,⁷⁷ and ensure the public is notified when necessary.⁷⁸

⁶⁹ *Id.* at 7.

⁷⁰ See *Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist for Cosmetics*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/cosmetics-guidance-documents/good-manufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics> (last updated Aug. 24, 2020).

⁷¹ *Draft Guidance for Industry: Cosmetic Good Manufacturing Practices*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices> (last updated Nov. 14, 2018).

⁷² *Current Good Manufacturing Practice (CGMP) Regulations*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations> (last updated Sep. 21, 2020).

⁷³ *FDA Authority Over Cosmetics: How Cosmetics are not FDA-Approved, but are FDA-Regulated*, *supra* note 9; CORBY-EDWARDS, *supra* note 11, at 10.

⁷⁴ CORBY-EDWARDS, *supra* note 11, at 10.

⁷⁵ See *FDA Authority Over Cosmetics: How Cosmetics are not FDA-Approved, but are FDA-Regulated*, *supra* note 9.

⁷⁶ 21 C.F.R. § 7.53 (2019); *FDA Recall Policy for Cosmetics*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-recall-policy-cosmetics> (last updated Aug. 24, 2020).

⁷⁷ 21 C.F.R. § 7.41 (2019); *FDA Recall Policy for Cosmetics*, *supra* note 76.

⁷⁸ 21 C.F.R. §§ 7.42(b)(2), 7.50 (2019); *FDA Recall Policy for Cosmetics*, *supra* note 76.

II. THE PROPOSED SAFE COSMETICS AND PERSONAL CARE PRODUCTS ACT OF 2019

The Safe Cosmetics and Personal Care Products Act of 2019 (“SCPCPA”) bill, introduced by Rep. Jan Schakowsky, purported to reform the regulation of cosmetics by amending the FFDCFA to broaden the FDA’s regulatory powers over cosmetics.⁷⁹ The Safe Cosmetics and Personal Care Products Act of 2019 was the reintroduced version of the 2018 and 2013 bills with the same name that had died in previous Congresses.⁸⁰

If Congress had enacted the SCPCPA, the FDA would have finally been granted some of the authority it needs to effectively regulate the cosmetics industry. First, the SCPCPA would have required cosmetic establishments to register with the FDA.⁸¹ The FDA would then make the list of registered establishments available to the public through publication on its website.⁸² The SCPCPA would have also required cosmetic establishments to submit all safety information on their products and product ingredients to the FDA.⁸³ Based on the information submitted, the FDA would then review and evaluate the safety of the cosmetic product.⁸⁴ In evaluating cosmetic safety under the SCPCPA, the Agency would be allowed to consider certain authoritative sources, such as the Environmental Protection Agency, the International Agency for Research on Cancer, the National Institutes of Health, the California Environmental Protection Agency, and any other government entity determined by the FDA.⁸⁵ Under the SCPCPA, cosmetic companies would also be required to report all serious adverse events to the FDA within fifteen days after the companies receive knowledge of them.⁸⁶

In addition to reporting and registration requirements, and akin to FDA’s authority over food products, the SCPCPA would have provided the FDA with the authority to issue mandatory recalls of products determined to be hazardous.⁸⁷ Similarly, the bill would have directed the FDA to establish a safety standard for cosmetics and issue regulations on

⁷⁹ *National Cosmetic Safety Reform*, *supra* note 22.

⁸⁰ See *H.R. 4296 (116th): Safe Cosmetics and Personal Care Products Act of 2019*, GOVTRACK, <https://www.govtrack.us/congress/bills/116/hr4296> (last visited Jan. 12, 2021).

⁸¹ Safe Cosmetics and Personal Care Products Act of 2019, H.R. 4296, 116th Cong. § 612 (2019).

⁸² *Id.* § 612(d)(1)(B).

⁸³ *Id.* § 615(a).

⁸⁴ *Id.* § 615(c).

⁸⁵ *Id.* § 615(c).

⁸⁶ *Id.* § 622.

⁸⁷ *Id.* § 620(d).

GMPs for the industry.⁸⁸ The SCPCPA bill also aimed to institute an immediate ban on over one dozen of the most hazardous chemicals in cosmetics⁸⁹ and required full disclosure of fragrance product ingredients.⁹⁰ The bill would have also banned most use of animal testing in the development of cosmetics.⁹¹

The SCPCPA also included provisions specifically designed for the protection of “highly exposed and vulnerable populations.”⁹² These vulnerable populations include infants, children, pregnant women, the elderly, salon workers, and communities of color.⁹³ The SCPCPA is the only federal bill to date to address the severe exposure to hazardous chemicals experienced by salon workers and communities of color.⁹⁴ The bill would have provided for the funding of research into safer alternatives to the hazardous ingredients that negatively affect these communities.⁹⁵

III. THE FDA’S LACK OF REGULATORY AUTHORITY OVER COSMETICS POSES A RISK TO CONSUMER SAFETY

The cosmetics industry’s heavy reliance on the self-regulation of its establishments poses significant risks to consumer health and safety.⁹⁶ Due to the FDA’s lack of statutory authority to regulate cosmetics, the Agency is essentially powerless to protect consumers from unsafe products. Several instances illustrate this point.

In 2016, the FDA had received 1,386 adverse-event reports that were obtained from consumers of WEN by Chaz Dean Cleansing Conditioner products (“WEN”), which marked the highest number of reports ever received by the FDA for any haircare product.⁹⁷ However, after fur-

⁸⁸ *Id.* § 614.

⁸⁹ H.R. 4296, 116th Cong. § 616(b)(2); *see also National Cosmetic Safety Reform*, *supra* note 22.

⁹⁰ H.R. 4296, 116th Cong. § 613(g).

⁹¹ *Id.* § 624.

⁹² *See National Cosmetic Safety Reform*, *supra* note 22.

⁹³ H.R. 4296, 116th Cong. § 611(13); *see also National Cosmetic Safety Reform*, *supra* note 22.

⁹⁴ *New Federal Bill Will Be the First in the Nation to Ensure That Beauty and Personal Care Products Are Safe for All*, BREAST CANCER PREVENTION PARTNERS (Sept. 12, 2019), <https://www.bcpc.org/resource/new-federal-bill-will-be-the-first-in-the-nation-to-ensure-that-beauty-and-personal-care-products-are-safe-for-all/>.

⁹⁵ H.R. 4296, 116th Cong. § 463C; *National Cosmetic Safety Reform*, *supra* note 22.

⁹⁶ *See Narayan*, *supra* note 27.

⁹⁷ The FDA published a safety alert announcing that it would conduct investigations based on the consumer reports of hair breakage, balding, rashes, and itching as a result of using WEN. *Statement on FDA Investigation of WEN by Chaz Dean Cleansing Conditioners*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/cosmetic-products/statement-fda-investigation-wen-chaz-dean-cleansing-conditioners> (last updated Nov. 15, 2017).

ther investigation the Agency discovered that Chaz Dean, Inc. and Guthy-Renker, LLC, manufacturers of WEN, received more than 21,000 complaints of hair loss and scalp damage from consumers who had used the Cleansing Conditioner products.⁹⁸ The manufacturers did not disclose information to the FDA as to what could have caused the reactions.⁹⁹

In 2016, Chaz Dean, Inc. and Guthy-Renker, LLC settled a class action lawsuit against it filed by more than 200 consumers for \$26.3 million.¹⁰⁰ When the settlement was announced, WEN released a statement saying that its products were safe and the decision to settle was merely a business decision meant to avoid the time-consuming and costly process of litigation.¹⁰¹ As such, despite tens of thousands of complaints, an ongoing FDA investigation, and a \$26.3 million settlement of consumer claims, WEN is still allowed to sell its products and continues to do so today.¹⁰²

There has also been concern of asbestos contamination in cosmetic products containing talc.¹⁰³ In 2018, the FDA initiated an ongoing survey of cosmetic products for asbestos contamination.¹⁰⁴ As part of this survey, the FDA tested approximately 50 cosmetic products for the presence of asbestos, among which were two samples of Johnson's baby pow-

⁹⁸ Brody, *supra* note 5.

⁹⁹ *FDA Information for Consumers About WEN by Chaz Dean Cleansing Conditioners*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/cosmetic-products/fda-information-consumers-about-wen-chaz-dean-cleansing-conditioners> (last updated Nov. 3, 2017).

¹⁰⁰ Brody, *supra* note 5; *Class Action Lawsuits Over Wen Hair Products Gets Preliminary Settlement Approval*, CBS LOS ANGELES (Oct. 31, 2016, 11:18 PM), <https://losangeles.cbslocal.com/2016/10/31/class-action-lawsuit-over-wen-hair-products-gets-preliminary-settlement-approval/>.

¹⁰¹ *Class Action Lawsuits Over Wen Hair Products Gets Preliminary Settlement Approval*, *supra* note 100.

¹⁰² Julie Edgar, *WEN Case Spurs Call for Beauty Product Regs*, WEBMD HEALTH NEWS (Feb. 7, 2018), <https://www.webmd.com/beauty/news/20180207/wen-case-spurs-call-for-beauty-product-regs>; Brody, *supra* note 5.

¹⁰³ Talc is a naturally occurring mineral that is used in cosmetic and personal care products to absorb moisture, improve the feel of a product, and to prevent "caking" in makeup. Some literature suggests a connection between the usage of talc powders and the development of ovarian cancer. However, the research on the matter has been non-conclusive and the FDA is still conducting further research in this area. Asbestos, on the other hand, is a known carcinogen. Since both minerals may be found in close proximity to each other, there is the potential for contamination of talc with asbestos. As such, it is important that manufacturers select talc mining sites carefully and take steps to purify the talc ore sufficiently. *Talc*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/cosmetic-ingredients/talc> (last updated Aug. 18, 2020); *see also* *Baby powder manufacturer voluntarily recalls products for asbestos*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/news-events/press-announcements/baby-powder-manufacturer-voluntarily-recalls-products-asbestos> (last updated Oct. 18, 2019).

¹⁰⁴ *Baby powder manufacturer voluntarily recalls products for asbestos*, *supra* note 103.

der.¹⁰⁵ The results revealed that a sample from one lot of baby powder contained chrysotile fibers, a type of asbestos.¹⁰⁶

In October of 2019, Johnson & Johnson Consumer Inc. (“J&J”) voluntarily recalled the lot of baby powder that tested positive for asbestos, which totaled around 33,000 bottles.¹⁰⁷ Thirteen days before the FDA released its findings, J&J CEO Alex Gorsky testified that the products were safe.¹⁰⁸ Despite the FDA findings, J&J stood by the safety of its products and executed the recall only “out of an abundance of caution.”¹⁰⁹ At the time of the announcement, there were approximately 15,000 ongoing lawsuits against J&J by plaintiffs who claimed that the company’s talc powders had caused their cancer.¹¹⁰ However, this incident is the first in which J&J recalled its baby powder for asbestos contamination, and the first time the FDA announced a finding of asbestos in the J&J product.¹¹¹

In both of these cosmetic-related incidents, the public perceived a dire lack of cosmetics regulation by the federal government.¹¹² Consumers noted the lack of pre-market approval and testing, as well as the FDA’s inability to order a mandatory recall of potentially injurious products.¹¹³ These concerns may have played a part in cosmetics legislation gaining brief Congressional attention.¹¹⁴

IV. THE SCPCPA IS A NECESSARY AND FEASIBLE SOLUTION THAT CONGRESS SHOULD ENACT TO PROTECT CONSUMERS

The SCPCPA’s proposal to broaden the FDA’s regulatory authority over cosmetics is necessary to protect consumer safety. The harmful effects and safety risks resulting from the WEN and Johnson’s incidents¹¹⁵

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Johnson & Johnson Consumer Inc. to Voluntarily Recall a Single Lot of Johnson’s Baby Powder in the United States*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/johnson-johnson-consumer-inc-voluntarily-recall-single-lot-johnsons-baby-powder-united-states> (last updated Oct. 18, 2019); *see also Johnson & Johnson confirms no asbestos in Johnson’s Baby Powder*, CNBC (Dec. 3, 2019, 7:18 PM), <https://www.cnbc.com/2019/12/03/johnson-johnson-confirms-no-asbestos-in-johnsons-baby-powder.html>.

¹⁰⁸ Chad Terhune, Lisa Girion, & Mike Spector, *J&J CEO testified Baby Powder was safe 13 days before FDA bombshell*, REUTERS (Oct. 22, 2019, 1:03 PM), <https://www.reuters.com/article/us-johnson-johnson-talc-ceo-insight/johnson-johnson-ceo-testified-baby-powder-was-safe-13-days-before-fda-bombshell-idUSKBN1X12GF>.

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *See Brody, supra note 5; Hsu & Rabin, supra note 25.*

¹¹³ *Hsu & Rabin, supra note 25.*

¹¹⁴ *Narayan, supra note 27.*

¹¹⁵ *See Brody, supra note 5; Hsu & Rabin, supra note 25.*

could have been prevented—or at the very least, minimized—if the FDA had the statutory power that the SCPCPA aimed to provide.

First, apart from being required to register with the FDA, the cosmetics establishments would have had to submit safety information to the Agency.¹¹⁶ This information would have been made readily available to the public through the FDA website.¹¹⁷ From these provisions alone, the public could have received advanced notice regarding the safety of a particular product.¹¹⁸ Additionally, the mandatory adverse-event reporting proposed by the SCPCPA bill could have more swiftly alerted the FDA to the potentially hazardous products.¹¹⁹ For example, in the WEN incident, if the FDA had the authority to require cosmetic establishments to report adverse events, the Agency would have known about the adverse effects of the cosmetic sooner.¹²⁰ Under the SCPCPA, companies would have been required to inform the FDA of any adverse events relating to its products within fifteen days of the company's knowledge.¹²¹ As such, the Agency would have learned of consumer complaints regarding the WEN products before that number reached 21,000.¹²²

Similarly, in the Johnson's incident, if the SCPCPA had been implemented, the FDA would have had information on the company's talc sources and testing methods to better substantiate the likelihood of asbestos contamination in the products.¹²³ The FDA, through reviewing and evaluating the safety information submitted by the respective companies,¹²⁴ could have been able to identify safety concerns and notify the public earlier, thus minimizing any consumer exposure to potentially injurious products. Additionally, had the FDA possessed the authority to order mandatory product recalls¹²⁵ in both of the instances described, the Agency could have acted in order to lessen consumer exposure to the potentially hazardous cosmetics. This power would have been particu-

¹¹⁶ Safe Cosmetics and Personal Care Products Act of 2019, H.R. 4296, 116th Cong. §§ 612, 615 (2019).

¹¹⁷ *Id.* §§ 613, 615.

¹¹⁸ *Id.* §§ 613, 615.

¹¹⁹ *See id.* § 622.

¹²⁰ *See Statement on FDA Investigation of WEN by Chaz Dean Cleansing Conditioners*, *supra* note 97.

¹²¹ H.R. 4296, 116th Cong. § 622.

¹²² *See Statement on FDA Investigation of WEN by Chaz Dean Cleansing Conditioners*, *supra* note 97; *Using Adverse Event Reports to Monitor Cosmetic Safety*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/how-report-cosmetic-related-complaint/using-adverse-event-reports-monitor-cosmetic-safety> (last updated Nov. 3, 2017).

¹²³ *See* H.R. 4296, 116th Cong. § 615.

¹²⁴ *See id.* § 615.

¹²⁵ *See id.* § 620.

larly beneficial in the instance of WEN, whose harmful haircare products are still on the market today.¹²⁶

The SCPCPA's proposal to provide the FDA with more comprehensive regulatory authority over cosmetics is also reasonable. In fact, some of the regulatory powers proposed by the SCPCPA are already within the Agency's authority over other FDA-regulated products.¹²⁷ For instance, the SCPCPA would have provided the FDA with the authority to order mandatory recalls of harmful cosmetic products—something that the FDA already has the power to do with respect to food products.¹²⁸ The FDA can and does use its statutory power to force companies to recall unsafe food products, effectively taking those products off the market.¹²⁹ Mandatory recall authority is necessary for consumer protection, particularly in instances where a company refuses to recall products voluntarily.¹³⁰ By having the power to order recalls of food products, the FDA shields consumers from the harm that could result from companies continuing to sell unsafe food products to the public. Providing the FDA with mandatory recall authority over cosmetics would similarly protect consumers from harm caused by having hazardous cosmetic products on the market.

The SCPCPA's mandatory registration, ingredient disclosure, and adverse-event reporting provisions would provide the FDA with the power to collect vital information on cosmetics, allowing for swifter regulation and added protection for consumers. With this power, the FDA would be able to find out earlier whether a product is hazardous or in violation of the FFDCFA. The Agency would no longer be limited to whatever information, if any, a company is willing to provide as to a product's ingredients and safety. Neither would the Agency have to rely solely on voluntary adverse event reports from consumers and other parties in order to know if a product has caused harm. And since information on a product's ingredients and safety would be made available to the public under the SCPCPA, consumers would have notice of potentially harmful cosmetic products.¹³¹

¹²⁶ Edgar, *supra* note 102.

¹²⁷ See CORBY-EDWARDS, *supra* note 11, at 10.

¹²⁸ See *id.*

¹²⁹ See, e.g., Maggie Fox, *FDA forces mandatory recall of kratom, says it's a first*, NBC NEWS, <https://www.nbcnews.com/health/health-news/fda-forces-mandatory-recall-kratom-says-it-s-first-n862481> (last updated Apr. 4, 2018) (recounting an instance where the FDA forced a company to recall its potentially contaminated kratom products after the company had refused to recall the products voluntarily).

¹³⁰ See, e.g., *id.*

¹³¹ See Safe Cosmetics and Personal Care Products Act of 2019, H.R. 4296, 116th Cong. §§ 612, 613, 615 (2019).

The success of mandatory ingredient disclosure and reporting provisions is best seen in California's cosmetics legislation. In 2005, California enacted the California Safe Cosmetics Act, codified in California Health & Safety Code, section 111791.¹³² This California Act was the country's first state cosmetics regulatory act.¹³³ In passing the statute, the legislature noted the lack of federal regulation and weaknesses in FDA regulatory authority over cosmetics.¹³⁴ As a way of strengthening cosmetic regulation, the California Safe Cosmetics Act requires cosmetics establishments to report the use of potentially harmful products or ingredients to California's Department of Health Services ("DHS").¹³⁵ Manufacturers selling cosmetic products in California must notify the DHS of any product containing "any ingredient that is a chemical identified as causing cancer or reproductive toxicity."¹³⁶ The DHS then notifies the public of this information.¹³⁷ Additionally, under the California Safe Cosmetics Act, the DHS has the authority to require manufacturers to submit health effects data, and to investigate whether products could be toxic under a consumer's ordinary usage.¹³⁸ Manufacturers in California that do not comply with the DHS could face legal action.¹³⁹

From 2007 to 2013, California has identified five additional hazardous chemicals that manufacturers are required to disclose, under the act's mandatory reporting requirements.¹⁴⁰ Within this time, in addition to making the reporting system available online, the state notified approximately 7,000 manufacturers that they were out of compliance with the act's provisions.¹⁴¹ Furthermore, and perhaps most notably, under the act the California Attorney General was able to obtain an injunction against the manufacturer of "Brazilian Blowout," a Brazilian hair relaxing treatment that was found to emit formaldehyde gas, a known carcinogen.¹⁴²

¹³² See Meryl C. Maneker & Vickie E. Turner, *Cosmetics and Beauty Product Litigation*, 59 THE PRACTICAL LAW. 29, 31 (2013), http://www.wilsonturnerkosmo.com/tasks/sites/wtk/assets/Image/TPL1302_Maneker.pdf.

¹³³ Cynthia Washam, *Legislation: California Enacts Safe Cosmetics Act*, 114(7) ENVTL. HEALTH PERSPECTIVES (2006), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1513294/>.

¹³⁴ See Maneker & Turner, *supra* note 132, at 31.

¹³⁵ Washam, *supra* note 133.

¹³⁶ Cal. Health & Safety Code § 111792(a) (2020); see also Maneker & Turner, *supra* note 132, at 32.

¹³⁷ Washam, *supra* note 133.

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ Maneker & Turner, *supra* note 132, at 32.

¹⁴¹ *Id.*

¹⁴² Maneker & Turner, *supra* note 132, at 32; see also *Formaldehyde and Cancer Risk*, NAT'L CANCER INST., [https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/formaldehyde/formaldehyde-fact-sheet#:~:text=the%20International%20Agency%20for%20Research,Report%20on%20Carcinogens%20\(3\)](https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/formaldehyde/formaldehyde-fact-sheet#:~:text=the%20International%20Agency%20for%20Research,Report%20on%20Carcinogens%20(3).). (last updated June 10, 2011).

The achievements of the California Safe Cosmetics Act indicate that mandatory reporting and ingredient disclosure provisions are essential to strengthening cosmetics regulations. Furthermore, the success of such provisions on a state level help show the kind of impact similar provisions may have on a federal level. In enacting the California Safe Cosmetics Act and requiring companies to report key cosmetic information to the DHS, California essentially expedited the regulatory process for cosmetics by eliminating any prior hurdles the state agency faced due to a lack of access to information. Through the act, the state is able to effectively protect its consumers by identifying hazardous chemicals in cosmetic products and promptly notifying the public. The act also enables the state to hold companies accountable for the safety of their products. The SCPCPA's proposal to provide the FDA with the power to collect cosmetics information from companies would similarly expedite the federal cosmetics regulatory process, afford additional protection for consumers, and hold companies accountable for the safety of products they sell on the market.

Additionally, the SCPCPA's proposal to ban certain known toxic chemicals from cosmetics and personal care products is an attainable solution that is a necessary step in ensuring the safety of consumers. Again, California's state legislature best illustrates this point. As of September 2020, California became the first state to ban twenty-four toxic chemicals in cosmetics and personal care products.¹⁴³ The Toxic-Free Cosmetics Act, codified in California Health & Safety Code, section 108980, is the nation's first state-level ban of certain toxic ingredients for use in cosmetic products and personal care products.¹⁴⁴ Among these banned ingredients are formaldehyde and the most toxic types of phthalates and parabens,¹⁴⁵ some of which the SCPCPA proposed to ban as well.¹⁴⁶ The passing of such state legislation is a testament to the shortcomings of current federal legislation, and an indication that banning toxic chemicals from cosmetics and personal care products is necessary and feasible. A parallel federal level proposition is a reasonable solution.

Through its provisions, the SCPCPA would have protected not only regular consumers but vulnerable populations as well.¹⁴⁷ The SCPCPA

¹⁴³ Monica Amarelo, *California First State to Ban 24 Toxic Chemicals in Personal Care Products and Cosmetics*, ENVTL. WORKING GROUP (Sept. 30, 2020), <https://www.ewg.org/release/california-first-state-ban-24-toxic-chemicals-personal-care-products-and-cosmetics>.

¹⁴⁴ *Id.*

¹⁴⁵ See CAL. HEALTH & SAFETY CODE § 108980 (2021).

¹⁴⁶ See Safe Cosmetics and Personal Care Products Act of 2019, H.R. 4296, 116th Cong. § 616 (2019).

¹⁴⁷ See Erika Wilhelm, *New Federal Bill Will Be the First in the Nation to Ensure That Beauty and Personal Care Products Are Safe for All*, BREAST CANCER PREVENTION PARTNERS (Sept.

was the only federal bill to tackle the disparate effect of the cosmetics industry on people of color and professional salon workers.¹⁴⁸ An analysis by the Environmental Working Group (“EWG”) showed that cosmetics marketed towards Black women were more likely to contain harmful ingredients than those marketed towards the general public.¹⁴⁹ The EWG also found that in 1,177 beauty and personal care products which were aimed towards Black women, about one in twelve was classified as “highly hazardous,” according to the EWG’s scoring system.¹⁵⁰ By supporting research on cosmetics-related health disparities that impact these communities, the SCPCPA purported to lessen their exposure to toxic chemicals.¹⁵¹ The bill also proposed to create a safety standard for cosmetics and to fund research into safer alternatives for toxic ingredients,¹⁵² which would have helped ensure a level of protection for these vulnerable and highly-exposed communities.¹⁵³

Republican lawmakers had expressed concerns regarding the SCPCPA’s proposed changes to FDA regulatory authority.¹⁵⁴ Rep. Michael Burgess noted that the SCPCPA did not adequately address the issue of federal preemption and harmonization between federal and state legislature.¹⁵⁵ According to Rep. Burgess, any law passed on this issue should contain language stating that federal laws preempt any state laws.¹⁵⁶ Yet although the concerns regarding preemption are valid, having a robust preemption clause may discourage states and local governments from enacting laws stronger or more tailored to their residents than the prevailing federal law.¹⁵⁷ Rather than a preemption clause, the

12, 2019), <https://www.bcpp.org/resource/new-federal-bill-will-be-the-first-in-the-nation-to-ensure-that-beauty-and-personal-care-products-are-safe-for-all/>.

¹⁴⁸ *See id.*

¹⁴⁹ Paul Pestano et al., *Big Market for Black Cosmetics, But Less-Hazardous Choices Limited*, ENVTL. WORKING GRP. (Dec. 6, 2016), <https://www.ewg.org/research/big-market-black-cosmetics-less-hazardous-choices-limited#.WgpqtBNSwXo>.

¹⁵⁰ *Id.*

¹⁵¹ *See* H.R. 4296, 116th Cong. § 463C; *see also* Wilhelm, *supra* note 147.

¹⁵² H.R. 4296, 116th Cong. §§ 4, 614.

¹⁵³ *See National Cosmetic Safety Reform*, *supra* note 22.

¹⁵⁴ Isabella Isaacs-Thomas, *Why your cosmetics don’t have to be tested for safety*, PBS NEWS HOUR (Dec. 16, 2019, 5:50 PM), <https://www.pbs.org/newshour/health/why-your-cosmetics-dont-have-to-be-tested-for-safety>.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ The preemption doctrine, derived from the Supremacy Clause of the U.S. Constitution, states that when state law and federal law are in conflict, federal law displaces state law. Where laws are unclear as to whether or not preemption should apply, as is the case with laws lacking preemption clauses, courts tend to follow lawmakers’ intent, and thus favor interpretations avoiding the preemption of state laws. *Preemption*, LEGAL INFO. INST., <https://www.law.cornell.edu/wex/preemption> (last visited Mar. 19, 2021); *see also* Lauren Nardella & Ryan Nelson, *Schakowsky’s Loaded Cosmetics Bill Described as ‘Floor, Not A Ceiling’ for States to Build On*, HBW INSIGHT (Oct. 1,

SCPCPA contained a savings clause allowing states and local governments to establish stricter requirements than those set forth in the bill.¹⁵⁸ Rep. Schakowsky's office, in a section-by-section summary of the SCPCPA, stated: "This bill acts as a floor, not a ceiling."¹⁵⁹

Rep. Burgess also voiced his concern on the bill's effect on small businesses, and noted that the bill would not exempt these businesses from the proposed registration fees and requirements.¹⁶⁰ However, the SCPCPA bill did contain an exemption for businesses with annual cosmetic sales less than \$1,000,000.¹⁶¹ Under the SCPCPA, these businesses, termed "microbusinesses," would be exempt from the bill's registration fees and requirements.

The introduction of the SCPCPA reinforced the notion that the current regulatory framework for cosmetics is outdated and in need of change. Allowing the cosmetics industry to continue to self-regulate with almost no federal oversight leaves the public at the mercy of cosmetic establishments and their inherently greedy business interests.¹⁶² The FDA regulatory authority over cosmetics needs to be strengthened in order to protect consumer safety, and given the current state of federal cosmetics regulation in the country, anything less than the legislative makeover proposed by the SCPCPA may fall short of providing adequate consumer protection.

CONCLUSION

The current regulatory framework for cosmetics is detrimental to consumer safety.¹⁶³ Under the current scheme, the FDA has no statutory authority to require cosmetic companies to submit information on their products, to require pre-market testing or approval of cosmetic products, or to order mandatory recalls of proven or potentially hazardous products.¹⁶⁴ As it stands, the FDA is ill-equipped to prevent consumers from exposure to harmful cosmetics, as demonstrated by the WEN case and the recent instance of asbestos contamination in Johnson & Johnson's products.¹⁶⁵

2019), <https://hbw.pharmaintelligence.informa.com/RS149264/Schakowskys-Loaded-Cosmetics-Bill-Described-As-Floor-Not-A-Ceiling-For-States-To-Build-On>.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ Isaacs-Thomas, *supra* note 154.

¹⁶¹ H.R. 4296, 116th Cong. §§ 611(7), 612(a)(2).

¹⁶² *See, e.g.*, Edgar, *supra* note 102.

¹⁶³ Narayan, *supra* note 27.

¹⁶⁴ *FDA Authority Over Cosmetics: How Cosmetics are not FDA-Approved, but are FDA-Regulated*, *supra* note 9.

¹⁶⁵ *See* Brody, *supra* note 5; Hsu & Rabin, *supra* note 25.

Congress should reintroduce and pass the SCPCPA, which would amend the FFDCA to provide FDA with the necessary regulatory authority over cosmetics in order to effectively protect consumers.¹⁶⁶ Under the SCPCPA, the FDA would have the authority to order mandatory recalls, require adverse-event reporting, and mandate the registration of cosmetics companies and reporting of their product ingredients and safety information.¹⁶⁷ Broadening the FDA's statutory authority through the SCPCPA could also expedite the regulatory processes for cosmetics and allow the Agency to identify potentially harmful products before they are exposed to unknowing consumers.

¹⁶⁶ Safe Cosmetics and Personal Care Products Act of 2019, H.R. 4296, 116th Cong. (2019).

¹⁶⁷ H.R. 4296, 116th Cong. §§ 612, 615, 620, 622.