

NOTE

RETHINKING FDA'S REGULATION OF COSMETICS

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The Food, Drug, and Cosmetic Act's treatment of cosmetics has been largely unchanged since it was first passed in 1938. Now, with the growth of a billion-dollar "natural" cosmetics market, as well as interest from legislators in revitalizing the FDCA, the safety of conventional cosmetics is once again in the public consciousness. Academic interest has come back and many papers call for more stringent cosmetic regulation,¹ but largely under the existing legal framework. This article accomplishes three things. First, it gives a modern overview of how the FDA actually regulates potentially harmful chemicals in cosmetic products, which is done through a largely voluntary and industry-run system. Second, the article explores the difference between the current individualized ingredient review and the cumulative exposure problem. Finally, the article proposes a new framework for regulating cosmetic ingredients that takes into consideration an individual's cumulative exposure from total cosmetic use, as well as long-term, rather than immediate, effects.

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¹ See, e.g., Rajiv Shah & Kelly E. Taylor, *Concealing Danger: How the Regulation of Cosmetics in the United States Puts Consumers at Risk*, 23 *FORDHAM ENVTL. L. REV.* 203 (2011).

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I. INTRODUCTION

As consumers have grown more conscious about healthy living overall, many have turned this attention to their beauty routines as well. The natural and/or organic beauty market has been growing rapidly and is estimated to reach \$25.11 billion by 2025.² Consumers are increasingly concerned about preservatives and other ingredients in traditional cosmetics that are linked to cancer and reproductive toxicity.³

Concern about natural and organic ingredients has prompted multiple consumer safety organizations to push for tighter regulations of chemicals in cosmetics. Senators Dianne Feinstein (D-Cal.) and Susan Collins (R-Me.) introduced the Personal Care Safety Act (“PCPA”) in 2017 to strengthen the FDA’s regulatory powers over the cosmetics industry.⁴

Independent organizations and non-profit groups have also stepped in to fill the need for more information about cosmetic ingredients. The Environmental Working Group, for example, maintains a database of cosmetic products on the market and their ingredients. They state “Americans’ frequent exposures to cosmetics and personal care products raise questions about the potential health risks from the myriad of un-assessed ingredients in them. These ingredients migrate into the bodies of nearly every American.”⁵

This interest in chemical exposure raises a new challenge for regulators: how to evaluate long-term exposure from a repeated use of multiple cosmetics, rather than immediate harm from individual products. This Article will explore this problem, looking first at the current state of cosmetic regulation in the United States, followed by a description of the cumulative exposure

² *Organic Personal Care Market Size Worth \$25.11 Billion By 2025*, GRAND VIEW RES. (Mar. 2018), <http://www.grandviewresearch.com/press-release/global-organic-personal-care-market> [https://perma.cc/AW4S-8YYF].

³ See Carolyn Butler, *Soaps, Makeup and Other Items Contain Deadly Ingredients, Say Consumer Advocates*, WASH. POST (Jan. 30, 2012), https://www.washingtonpost.com/national/health-science/soaps-makeup-and-other-items-contain-deadly-ingredients-say-consumer-advocates/2012/01/24/gIQAeJ56cQ_story.html?utm_term=.ae3ae3c0c567 [https://perma.cc/ZE2K-G3JG].

⁴ Kate Samuelson, *Senators Propose Bill to ‘Ensure the Safety of Cosmetics,’* TIME (May 12, 2017), <http://time.com/4777231/fda-bill-cosmetics-feinstein-collins/> [https://perma.cc/49DB-SYB5].

⁵ *Why This Matters – Cosmetics and Your Health*, ENVTL WORKING GRP., <https://www.ewg.org/skindeep/2011/04/12/why-this-matters/#.WvWWg9Pwb-Y> [https://perma.cc/5VHF-34RQ] (last visited Oct. 12, 2018) [hereinafter *Why This Matters*].

problem. Finally, the Article will address some possible options for legislative reform.

People are generally aware of the Food and Drug Administration's ("FDA") framework for regulating food and drugs. But cosmetics regulation receives much less attention. The FDA has authority to regulate cosmetics under the Food, Drug, and Cosmetic Act ("FDCA")⁶ and the Fair Packaging and Labeling Act ("FPLA").⁷ However, cosmetics are subject to significantly less stringent requirements than their food and drug counterparts.

This lack of regulation creates two problems. First, because the FDA is limited in its ability to regulate cosmetics, the agency is less able to positively assure consumers that their cosmetics are safe. A lack of clear guidelines over "clean" or "natural" beauty leaves consumers at risk for falling for faulty claims. This Article will explore this problem by looking at the ingredients of concern to clean-beauty advocates and examining how the FDA currently regulates them.

Second, current FDA regulations do not take into account that exposure to toxins—from both beauty products and the surrounding environment—is not uniform along race, class, and gender lines. Women use more products than men,⁸ and products marketed towards women of color contain more hazardous materials than those marketed towards white women.⁹ Additionally, data shows the level of certain harmful toxins that are found in both cosmetic and non-cosmetic products vary by race.¹⁰

The Article will detail these issues and evaluate other models for cosmetic regulation. This Article argues that a stronger regulatory regime would better address harmful ingredients in cosmetics in the context of overall usage and give consumers more confidence in the safety of cosmetics overall.

II. A HISTORY OF FDA COSMETIC REGULATION

Cosmetics were not always under the FDA's control. The 1906 Pure Food and Drug Act prohibited the sale of foods or drugs that were misbranded or adulterated but did not include the pre-market approval mecha-

⁶ 21 U.S.C. § 301–399h (2012).

⁷ 15 U.S.C. § 1451–61 (2012).

⁸ See Amy Westervelt, *Not So Pretty: Women Apply an Average of 168 Chemicals Every Day*, THE GUARDIAN (Apr. 30, 2015), <https://www.theguardian.com/lifeandstyle/2015/apr/30/fda-cosmetics-health-nih-epa-environmental-working-group> [<https://perma.cc/5KD3-4W6L>]; see also *Exposure Adds Up -Survey Results*, ENVTL. WORKING GRP., <https://www.ewg.org/skindeep/2004/06/15/exposures-add-up-survey-results/#.W7EVhxNKjq0> [<https://perma.cc/D5K5-R93Q>] (last visited Sept. 26, 2018);

⁹ 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> [<https://perma.cc/55S7-BGY6>].

¹⁰ *Phthalates*, SAFECOSMETICS.ORG, <http://www.safecosmetics.org/get-the-facts/chemicals-of-concern/phthalates/> [<https://perma.cc/374T-DSDU>] (last visited May 9, 2018).

nism for drugs that exists today.¹¹ Although regulators attempted to enforce the act aggressively, the courts quickly limited their powers by requiring the government to prove the company intended to defraud consumers.¹² By the 1930s, the public was increasingly outraged about the sale of dangerous (and sometimes entirely useless) drugs, and, along with the FDA itself, pushed Congress to update the old law. Some of the most egregious products on the market—which the old law kept out of FDA’s reach—included a radium-based tonic, worthless “cures” for tuberculosis, and an eyelash dye that caused permanent blindness.¹³ The FDA compiled a list of such products to demonstrate why new regulations were needed. But the law was not passed until after a true “therapeutic disaster” occurred. In 1937, one company marketed a new “wonder drug” to treat strep infections (usually in children), which included a chemical compound similar to antifreeze.¹⁴ Over 100 people died from the medicine, and the public outcry ultimately pushed the new FDCA through Congress.¹⁵

The FDCA defines a cosmetic by its intended use. A cosmetic is an “article[] intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body. . . for cleansing, beautifying, promoting attractiveness, or altering the appearance.”¹⁶ This definition covers moisturizers, perfumes, lipsticks, nail polish, most makeup, and shampoos.¹⁷

However, some products that we traditionally think of as cosmetics can actually be regulated as drugs. The FDCA can define a drug by its intended use, among other characteristics.¹⁸ For example, a regular shampoo would be classified as a cosmetic, but an anti-dandruff shampoo would be a drug,

¹¹ *About Us, Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm> [<https://perma.cc/C4VS-H7BV>] (last updated Oct. 5, 2017).

¹² *Id.*

¹³ *About Us, Part II: 1938, Food, Drug, Cosmetic Act*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm> [<https://perma.cc/B9F2-XNSN>] (last updated Oct. 5, 2017).

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ 21 U.S.C. § 321(i) (2012).

¹⁷ Curiously, the definition of cosmetic does not include “soap.” Soap is instead regulated by the Consumer Products Safety Commission. To be a “true” soap, the product must be made from fatty acids and an alkali (typically lye). Much of the soap on the market (e.g., liquid hand soap, body wash) are not “true soaps” and are regulated as either a drug or a cosmetic. For example, if the “soap” is intended to moisturize or provide fragrance, it would be treated as a cosmetic. And if the “soap” were intended to treat acne or kill germs, it would be regulated as a drug. However, any of the above products can use the word “soap” on the label, regardless of whether the product is a “soap” according to the regulatory definition. See *Cosmetics, Soap: FAQs*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm115449.htm> [<https://perma.cc/XTE4-SGYG>] (last updated Nov. 15, 2017).

¹⁸ Drugs include “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.” 21 U.S.C. § 321(g)(1).

because it is intended to treat dandruff.¹⁹ Other cosmetic/drug combinations include fluoride toothpaste, antiperspirants, acne washes, and moisturizers or makeup that double as sunscreen.²⁰ Products like these must meet the requirements for both cosmetics and drugs.²¹ The exact same product can even become a drug, rather than a cosmetic, based on marketing and intended use alone. For instance, “a fragrance marketed for promoting attractiveness” would be a cosmetic. But the same exact fragrance marketed with certain “aromatherapy” claims, such as “assertions that the scent will help the consumer sleep or quit smoking,” would qualify as a drug because of its intended use.²² These cosmetic/drug combinations must list the active ingredients before the other ingredients.

In the 1970s and 80s, the FDA increased attention on these so-called “cosmeceutical” products that straddled the line between cosmetics and drugs.²³ Anti-wrinkle claims drew the most attention, both because of the potential skin irritants within them (AHAs, BHAs, and retinoids)²⁴ and because of manufacturers’ over-hyped claims.²⁵ Regulation of “cosmeceuticals” has been a topic of scholarly interest for the last twenty-plus years.²⁶ Products like these are considered cosmetics in the European Union (“EU”) but “have been classified by the US FDA as Over-the-Counter (“OTC”) drugs,

¹⁹ *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm> [<https://perma.cc/3CVG-UGFJ>] (last updated Aug. 2, 2018) [hereinafter *Cosmetic or Drug*].

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ Bryan A. Liang & Kurt M. Hartman, *It's Only Skin Deep: FDA Regulation of Skin Care Cosmetics Claims*, 8 CORNELL J.L. PUB. POL'Y 249, 261 (1999).

²⁴ Alpha Hydroxy Acids (AHAs) and Beta Hydroxy Acids (BHAs) are both chemical exfoliants and common ingredients in skincare products. See *Beta Hydroxy Acids*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/productsingredients/ingredients/ucm107943.htm> [<https://perma.cc/A3Y2-4G99>] (last visited Nov. 13, 2018). The most common BHA used is salicylic acid, a common treatment for acne. *Id.* “Products containing AHAs are marketed for a variety of purposes, such as smoothing fine lines and surface wrinkles, improving skin texture and tone, unblocking and cleansing pores, and improving skin condition in general.” *Alpha Hydroxy Acids*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm107940.htm> [<https://perma.cc/GD38-PLK7>] (last visited Nov. 13, 2018). Glycolic acid and lactic acid are common AHAs. *Id.* Retinoids, of which retinol is a common variety, are vitamin-A derivatives used in skincare products for anti-aging and anti-acne benefits. See Corrie Pikul, *The One Thing Dermatologists Agree On (Other Than Sunscreen)*, HUFFINGTON POST (Sept. 29, 2014), https://www.huffingtonpost.com/2014/09/29/benefits-of-retinoids-retinol_n_5845764.html [<https://perma.cc/BFS8-W292>].

²⁵ Liang & Hartman, *supra* note 23, at 265.

²⁶ See, e.g., Laura A. Heymann, *The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids*, 52 FOOD & DRUG L.J. 357 (1997); see also Amity Hartman, *FDA's Minimal Regulation of Cosmetics and the Daring Claims of Cosmetic Companies That Cause Consumers Economic Harm*, 36 W. ST. U. L. REV. 53 (2008) (discussing issues with the FDA's cosmetics regulation); Roseann B. Terminin & Leah Tressler, *American Beauty: An Analytical View of the Past and Current Effectiveness of Cosmetic Safety Regulations and Future Direction*, 63 FOOD & DRUG L.J. 257 (2008) (discussing the history of the FDA's cosmetics regulation and proposing reforms).

including sunscreen products, anticavity toothpastes, antiperspirants, anti-dandruff preparations, skin protectants and hair restorers.”²⁷

Regulation of cosmetics bears some similarity to food and drugs but also differs in important ways. Unlike drugs, cosmetic products and ingredients do not need pre-market approval, except for certain color additives.²⁸ Cosmetic manufacturers are also not required to register or file their product formulations with the FDA, and no registration number is required to import cosmetics into the United States. However, products intended for retail sale must list their ingredients, much like food products.²⁹ Like food, the ingredient label on cosmetics must “bear a declaration of the name of each ingredient in descending order of predominance, except that fragrance or flavor may be listed as fragrance or flavor.”³⁰ Ingredients must also go by a specified name or, if a name is not specified, the ingredient should be labeled as the name adopted by the Cosmetic, Toiletry and Fragrance Association, Inc. (“CTFA”).³¹ Labeling is not required for products intended solely for professional use.³² Furthermore, the FDA does not have the authority to issue product recalls, although it can request that companies recall a product.³³

In addition to the FPLA—which requires cosmetic labels to not be “misleading” in the label, packaging, or fill of the bottle—cosmetics cannot be “adulterated.” Adulterated products are those that are poisonous, putrid, unsanitary or contaminated, or otherwise injurious to health.³⁴ The FDA has only banned a few ingredients outright in the formulation of cosmetics; using these in any cosmetic automatically makes a product “adulterated”:

- Bithionol (21 C.F.R. § 700.11)
- Mercury compounds (§ 700.13)
- Vinyl chloride (§ 700.14) (formerly used in aerosols)
- Halogenated salicylanilides (§ 700.15)
- Zirconium (when used in aerosols) (§ 700.16)
- Chloroform (§ 700.18)

²⁷ See Gerhard J. Noyheck et al., *Safety Assessment of Personal Care Products/Cosmetics and Their Ingredients*, 243 TOXICOLOGY & APPLIED PHARMACOLOGY 239, 241 (2010).

²⁸ *Cosmetic or Drug*, *supra* note 19.

²⁹ 21 C.F.R. § 701.3(c)(1) (2011). However, fragrances and other trade secrets are permitted to be excluded from the label, and companies can just list “fragrance.” *Id.*

³⁰ *Id.*

³¹ *Id.* 701.3(c)(1)(i).

³² The use of chemicals in professional settings is nevertheless worrisome, as beauty technicians are often exposed to the products more frequently and at higher levels than their customers. See Sarah M. Nir, *Perfect Nails, Poisoned Workers*, N.Y. TIMES (May 11, 2015), <https://www.nytimes.com/2015/05/11/nyregion/nail-salon-workers-in-nyc-face-hazardous-chemicals.html> [<https://perma.cc/ZE7V-48PF>].

³³ *Cosmetics*, AM. CANCER SOC’Y (May 28, 2014), <https://www.cancer.org/cancer/cancer-causes/cosmetics.html> [<https://perma.cc/P5CV-SJV5>].

³⁴ *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, But Are FDA-Regulated*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm> [<https://perma.cc/FB7J-NA46>] (last updated July 24, 2018) [hereinafter *FDA Authority*].

- Methylene chloride (§ 700.19)
- Chlorofluorocarbon propellants (§ 700.23)
- Prohibited cattle materials (§ 700.27)

Some of the items listed above actually reference a few related substances. For example, the section banning “halogenated salicylanilides” actually lists four related chemical compounds, all of which are banned.³⁵ But the list is still strikingly short and perhaps under-inclusive. Formaldehyde, a known carcinogen, is not banned from use in cosmetics in the United States. Some studies suggest one in five cosmetics in the U.S. market either contain or release formaldehyde.³⁶ This relatively short list has raised alarm for those who are concerned about harmful chemicals in cosmetics, especially in relation to stricter regulation abroad.³⁷

A. Current Tools for Evaluating Cosmetic Safety

Because the FDA does not pre-approve cosmetic ingredients, the agency has other tools for ensuring that cosmetics in the market are safe to use. Most notably, the law requires cosmetic companies to sell safe products and to label them correctly.³⁸ If the FDA determines a cosmetic is not safe, it can take regulatory action against a manufacturer, regardless of whether the product contains one of the ingredients listed above.³⁹ Usually, the first action the agency takes is issuing a warning letter to the manufacturer, which details the violation and states that if the company does not remedy the situation, it could be subject to enforcement actions.⁴⁰ The FDA also issues “untitled letters” for potential violations not significant enough for a warning letter.⁴¹ These letters suggest that a company should remedy some defect but do not state that the company would be subject to enforcement if they do not.⁴²

³⁵ See 21 C.F.R. § 700.15 (2011); see also COSMETIC INGREDIENT REV., COSMETIC INGREDIENTS/MATERIAL PROHIBITED/RESTRICTED BY FDA (Nov. 2011), <https://www.cir-safety.org/sites/default/files/prohibitedrestrictedbyFDA%2011-30-2011.pdf> [<https://perma.cc/J3P7-Q7ST>].

³⁶ *Exposing The Cosmetics Cover-Up: Is Cancer-Causing Formaldehyde In Your Cosmetics?*, ENVTL. WORKING GRP., http://www.ewg.org/research/exposing-cosmetics-cover/formaldehyde-releasers#.We61_RNSwXo [<https://perma.cc/49QR-L9BY>] (last visited Nov. 4, 2018); see also *infra* Section IV.5.

³⁷ See *infra* Section V.A.

³⁸ See 21 C.F.R. § 700; *id.* § 701.

³⁹ See *Prohibited & Restricted Ingredients*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm> [<https://perma.cc/F4HF-NXVX>] (last updated Nov. 3, 2017).

⁴⁰ See, e.g., Lime Crime 7/29/15, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm456525.htm> [<https://perma.cc/6FH7-WSTX>] (last updated Dec. 2, 2015).

⁴¹ See, e.g., *Warning Letters Cite Cosmetics as Adulterated Due to Microbial Contamination*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ComplianceEnforcement/WarningLetters/ucm085147.htm> [<https://perma.cc/LZ57-9V78>] (last updated Mar. 13, 2018).

⁴² See *id.*

The vast majority of the warning letters on the FDA's website concern cosmetic companies making improper drug claims on their products.⁴³ Such letters highlight how, as discussed above, certain marketing claims can change the status of a product from a cosmetic to a drug.⁴⁴ For example, some of these cited companies made claims for "removing wrinkles instantly" by "stimulating regeneration⁴⁵ of cell tissues"⁴⁶ or using essential oils "to help control eczema or psoriasis and heal the scalp."⁴⁷ These types of warning letters are common for products designed to treat acne, reduce cellulite, remove wrinkles, and restore hair growth.⁴⁸

If a company makes drug-like claims, the product is considered a new drug and must go through the proper drug-approval process. The FDA suggests that the company review its advertising claims in order to bring the product into compliance—but these types of violations have nothing to do with the underlying safety of the product.⁴⁹ If a warning letter does not bring the company into compliance, the FDA can also request that the Department of Justice bring an action, and the FDA can also request a restraining order in court against the shipment of the product.⁵⁰ However, the FDA does not have the authority to recall products, although it can ask that a company recall a product voluntarily.⁵¹ If a company decides to recall a product, the FDA is involved in monitoring the recall, and the FDA may issue public notice about the recall.⁵²

The FDA has various mechanisms for monitoring the safety of products. The agency has the authority to conduct inspections of cosmetic manufacturers without prior notice.⁵³ The FDA does not have binding regulations on cosmetic manufacturing but does have a list of Good Manufacturing

⁴³ See *Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ComplianceEnforcement/WarningLetters/ucm081086.htm> [<https://perma.cc/CV8A-MPEA>] (last updated Feb. 13, 2018) [hereinafter *Warning Letters for Products Marketed as Cosmetics*].

⁴⁴ See *Hollywood Skincare International Inc. 4/14/16*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm504411.htm> [<https://perma.cc/73ZM-BLYJ>] (last updated June 8, 2016) [hereinafter *Hollywood Skincare*].

⁴⁵ *Healing Scents 7/29/16*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm518517.htm> [<https://perma.cc/VE3W-S8JP>] (last updated Sept. 1, 2016) [hereinafter *Healing Scents*].

⁴⁶ *Hollywood Skincare*, *supra* note 44.

⁴⁷ *Healing Scents*, *supra* note 45.

⁴⁸ *Warning Letters for Products Marketed as Cosmetics*, *supra* note 43.

⁴⁹ See, e.g., *Healing Scents*, *supra* note 45; *Hollywood Skincare*, *supra* note 44.

⁵⁰ *Id.*

⁵¹ *FDA Recall Policy for Cosmetics*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ComplianceEnforcement/RecallsAlerts/ucm173559.htm> [<http://perma.cc/3GLV-E2BR>] (last updated Feb. 15, 2018).

⁵² *Id.*

⁵³ *Inspection of Cosmetics*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ComplianceEnforcement/ucm136455.htm> [<http://perma.cc/X84A-YTFB>] (last updated Nov. 3, 2017).

Practice Guidelines, which it encourages companies to follow.⁵⁴ The FDA also collects “Adverse Event Reports” filed by consumers or health care professionals who experience a problem using cosmetics.⁵⁵ However, manufacturers are not required to report complaints that they receive directly to the FDA.⁵⁶

The FDA also maintains a Voluntary Cosmetics Reporting Program (“VCRP”) for manufacturers and distributors to register their facilities and report products. Owners and operators of cosmetic manufacturing or packing facilities can register their facilities. In addition, any manufacturer or distributor can file a Cosmetic Product Ingredient Statement (“CPIS”) for each product the company distributes in the United States.⁵⁷ This program allows the FDA to keep a list of manufacturers and product ingredients, which can be helpful for inspections or in the event of a recall.⁵⁸ However, companies are not required to register. As a result, the FDA estimates this program covers only a fraction of the market.⁵⁹

So, how does the FDA evaluate the safety of cosmetic ingredients? Because manufacturers must ensure their products are safe, companies often test their products internally to ensure consumers will not have adverse reactions.⁶⁰ However, this type of testing is probably not sufficient for long-term health hazards like cancer.⁶¹ The FDA suggests companies use available peer-reviewed data as well in evaluating the safety of their cosmetics.⁶²

The FDA also relies on, and suggests that companies consult, the Cosmetic Ingredient Review (“CIR”) panel on ingredient safety.⁶³ The CIR is part of an industry trade association funded by the Personal Care Products Council that was established in 1976.⁶⁴ The panel meets quarterly to assess the safety of ingredients in cosmetics based on manufacturer’s information

⁵⁴ See *Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm2005190.htm> [<http://perma.cc/K37N-YG8A>] (last updated Nov. 3, 2017).

⁵⁵ *Using Adverse Event Reports to Monitor Cosmetic Safety*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ComplianceEnforcement/AdverseEventReporting/ucm531634.htm> [<http://perma.cc/96QF-9DUX>] (last updated Nov. 3, 2017) [hereinafter *Adverse Event Reports*].

⁵⁶ *Id.*

⁵⁷ *Voluntary Cosmetic Registration Program*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/RegistrationProgram/default.htm#about> [<http://perma.cc/R3VY-7TS8>] (last updated Dec. 4, 2017).

⁵⁸ See *Adverse Event Reports*, *supra* note 55.

⁵⁹ *Id.*

⁶⁰ *See Product Testing*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ScienceResearch/ProductTesting/default.htm> [<http://perma.cc/CPX9-XVFP>] (last updated Feb. 27, 2018).

⁶¹ See *id.*

⁶² *Id.*

⁶³ See *id.*; *About the Cosmetic Ingredient Review*, COSMETIC INGREDIENT REV., <https://www.cir-safety.org/about> [<http://perma.cc/3GPX-TWC4>] (last visited Nov. 4, 2018).

⁶⁴ *About the Cosmetic Ingredient Review*, *supra* note 63.

and peer-reviewed data.⁶⁵ The FDA takes these findings into consideration, but it neither votes on the panel nor is bound by the results. CIR publishes its findings in the *International Journal of Toxicology* and on the CIR website.

The CIR prepares an annual list of substances for review, based upon the FDA's voluntary reporting database.⁶⁶ The panel then decides whether the ingredient is safe, not safe, or whether it needs more information to be reviewed.⁶⁷ The panel also keeps a list of ingredients that are "safe for use in cosmetics, with qualifications"—usually meaning the ingredient is safe in a particular formulation or at a specific level.⁶⁸ The panel also has published reports on background information about aerosols in products⁶⁹ and potential endocrine-disrupting ingredients.⁷⁰

However, some scholars argue the CIR process is incomplete. As of 2005, the CIR had only evaluated an estimated 11 percent of ingredients used in cosmetics, leaving 89 percent completely untested.⁷¹ Furthermore, as some scholars note, "when the CIR does review ingredients, it generally focuses on the ingredients' potential to cause short-term dermatological reactions such as rashes and eye irritation, not their potential to cause long term health problems such as cancer or reproductive harm."⁷² As of April 2018, the CIR had only listed eleven ingredients as unsafe, three of which are considered safe in certain levels but unsafe at higher ones.⁷³

⁶⁵ Letter from Dayle Cristinzio, Acting Assoc. Comm'r for Legislation, U.S. Food & Drug Admin., to Senator Dianne Feinstein (Oct. 5, 2016), https://www.feinstein.senate.gov/public/_cache/files/2/6/2619f3d2-f537-405c-b6e0-759aacb7d09c/C2C841EA1ADC6C76FC295473995A1A24.response-feinstein-cosmetics.pdf [<https://perma.cc/9ZUC-MPX7>].

⁶⁶ COSMETIC INGREDIENT REV., COSMETIC INGREDIENT REVIEW PROCEDURES, § 30 (Oct. 2010), <https://www.cir-safety.org/sites/default/files/CIR%20Procedures%20-%20June%202018.pdf> [<https://perma.cc/5KFC-9T5Q>].

⁶⁷ *Id.* at § 42.

⁶⁸ COSMETIC INGREDIENT REV., SAFE WITH QUALIFICATIONS: QUICK REFERENCE TABLE (Apr. 2018), <https://www.cir-safety.org/sites/default/files/SQ-122017posted042018.pdf> [<https://perma.cc/3UJC-6ZE2>].

⁶⁹ See COSMETIC INGREDIENT REV., CIR PRECEDENTS: AEROSOLS (Sept. 2012), https://www.cir-safety.org/sites/default/files/aeroso092012rep_0.pdf [<https://perma.cc/7M2R-KPCR>].

⁷⁰ See COSMETIC INGREDIENT REV., CIR PRECEDENTS: ENDOCRINE ACTIVITY (Sept. 2017), <https://www.cir-safety.org/sites/default/files/CIR%20Precedents%20-%20Endocrine%20Activity.pdf> [<https://perma.cc/X58N-2QLE>]; Shah & Taylor, *supra* note 1, at 226.

⁷¹ Shah & Taylor, *supra* note 1, at 204 (citing *FDA Warns Cosmetic Industry to Follow Law on Untested Ingredients*, ENVTL. WORKING GRP. (Sept. 27, 2007), <https://www.ewg.org/news/testimony-official-correspondence/fda-warns-cosmetics-industry-follow-law-untested-ingredients> [<https://perma.cc/Y3CT-ZSWJ>]). The Environmental Working Group is a non-profit organization specializing in educating consumers in matters involving public health and the environment. *About Us*, ENVTL. WORKING GRP., <https://www.ewg.org/about-us> [<https://perma.cc/K6QW-B8DW>] (last visited Dec. 11, 2011).

⁷² Shah & Taylor, *supra* note 1, at 204 (citing STACY MALKAN, NOT JUST A PRETTY FACE - THE UGLY SIDE OF THE BEAUTY INDUSTRY, 11–12 (2007)).

⁷³ COSMETIC INGREDIENT REV., UNSAFE: QUICK REFERENCE TABLE (Apr. 2018), <https://www.cir-safety.org/sites/default/files/U-122017posted042018.pdf> [<https://perma.cc/2R26-XGUU>]. Note that this does not include the fourteen ingredients that the FDA bans, on which the CIR does not conduct review. See COSMETIC INGREDIENT REV., *supra* note 35.

III. THE NEW MARKET FOR "NATURAL COSMETICS"

Perhaps unsurprisingly, the market has reacted faster to the concern about harmful chemicals than regulators have. The market for "clean" beauty has been growing rapidly.⁷⁴ All-natural beauty companies often point to the lack of regulation in the United States and the more stringent restrictions in the EU as evidence that "clean" beauty is important—and worth the premium price.⁷⁵ Clean cosmetic advocates often focus on avoiding chemicals that are considered harmful in the long run because they cause cancer, birth defects, or other reproductive toxicity.⁷⁶

But "clean" beauty has no legal definition. "Natural" beauty products can range from those simply excluding certain harmful chemicals (i.e., phthalates or petrochemicals) to lipstick made entirely of food-grade materials. But there is virtually no regulation in the U.S. for what can be sold or marketed as a "natural" beauty product. In addition, the FDA does not regulate the term "organic" as applied to cosmetics, but a cosmetic can display the U.S. Department of Agriculture ("USDA") organic label if ninety-five percent of it is made from organic agricultural products.⁷⁷ However, if the product is not made up of mostly agricultural ingredients, there is simply no equivalent labeling scheme.

This has understandably caused both confusion and safety hazards. The FDA routinely cautions that organic or natural products, even if properly labeled as such, are not necessarily safe. A perusal of FDA's recent recalls and alerts provides some notable examples. The FDA investigated a product called Wen's Cleansing Conditioner—a product that now holds the title for most consumer complaints ever filed about any hair cleanser.⁷⁸ The Wen's website boasts the product as "an alternative to ordinary shampoos that contain harsh sulfates."⁷⁹ Nevertheless, customers have complained that the

⁷⁴ Rina Raphael, *What's Driving The Billion-Dollar Natural Beauty Movement?*, FAST COMPANY (May 26, 2017), <https://www.fastcompany.com/3068710/whats-driving-the-billion-dollar-natural-beauty-movement> [http://perma.cc/M75C-E44D].

⁷⁵ See, e.g., *Why Beautycounter Bans More Ingredients Than The U.S.*, BEAUTYCOUNTER.COM (Jan. 13, 2017), <https://www.beautycounter.com/know-everything/why-beautycounter-bans-more-ingredients-than-the-u-s> [http://perma.cc/UMN3-NAQ9].

⁷⁶ See *infra* Section IV.

⁷⁷ U.S. DEP'T OF AGRIC., NATIONAL ORGANIC PROGRAM, FACT SHEET: COSMETICS, BODY CARE PRODUCTS, AND PERSONAL CARE PRODUCTS (Apr. 2008), <https://www.ams.usda.gov/sites/default/files/media/OrganicCosmeticsFactSheet.pdf> [https://perma.cc/SM2E-UYW6]; "Organic" Cosmetics, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Cosmetics/Labeling/Claims/ucm203078.htm#If_a_cosmetic [http://perma.cc/XAP9-TSBF] (last updated Sept. 4, 2018).

⁷⁸ *Statement on FDA Investigation of Wen by Chaz Dean Cleansing Conditioners*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm511626.htm> [http://perma.cc/ZHM2-UG94] (last updated Nov. 15, 2017) [hereinafter *Wen by Chaz Dean*].

⁷⁹ *Frequently Asked Questions*, WEN.COM, <http://www.wen.com/faq.html?lang=default> [http://perma.cc/2P9E-7ZQ6] (last visited Oct. 14, 2018).

Wen product has caused hair loss, breakage, balding, and itching.⁸⁰ The FDA has received many complaints directly, and is investigating another 21,000 negative reports made to the company.⁸¹

What if the “natural” cosmetic isn’t harmful, but is nevertheless not quite as “clean” as consumers think it is? A recent survey done by the Federal Trade Commission and USDA found that consumers believe cosmetics with organic claims conform to higher standards than is actually the case.⁸² As discussed above, consumers have little recourse with the FDA as long as the product and its ingredients are generally considered safe. Instead, consumers have turned to deceptive advertising class actions against companies.⁸³ For example, one class action alleged that Jason and Avalon Organics products (both sold at Whole Foods) were marketed as either “Natural & Organic” or “Organic,” despite being made up of largely non-organic ingredients.⁸⁴ Multiple lawsuits have been filed against Jessica Alba’s The Honest Company, which sells a wide variety of home goods, cleaning supplies, diapers, and cosmetics. One such lawsuit alleges the company’s shampoos and body washes are falsely labeled “natural and plant based”; another alleges the company’s baby foods and soaps are incorrectly labeled “organic.”⁸⁵ A previous lawsuit alleged The Honest Company’s sunscreen both contained synthetic ingredients *and* was ineffective.⁸⁶ Finally, a drugstore shampoo brand called Organix faces a lawsuit over deceptive labeling. Despite the name of the company and claims that their shampoos “contain or-

⁸⁰ *Wen by Chaz Dean*, *supra* note 78.

⁸¹ *Id.*

⁸² BUREAU OF ECON. & BUREAU OF CONSUMER PROT., FED. TRADE COMM’N, CONSUMER PERCEPTION OF “RECYCLED CONTENT” AND “ORGANIC” CLAIMS (2016), https://www.ftc.gov/system/files/documents/public_events/975753/consumer_perception_of_recycled_content_and_organic_2016-08-10_-published_on_ftc-gov.pdf [<https://perma.cc/W36D-NAQB>]; see *Consumer Perceptions of “Organic” Claims Roundtable* (Oct. 20, 2016), FED. TRADE COMM’N, <https://www.ftc.gov/news-events/events-calendar/2016/10/consumer-perceptions-organic-claims-ftc-usda-roundtable> [<http://perma.cc/NKE5-Z7QZ>].

⁸³ See, e.g., Complaint at 1–2, *Brown v. Hain Celestial Grp.*, 913 F. Supp. 2d 881 (N.D. Cal. Dec. 22, 2012) (No. C 11-03082 LB), <https://www.truthinadvertising.org/wp-content/uploads/2014/02/Brown-v.-The-Hain-Celestial-Group-amended-complaint-pdf> [<https://perma.cc/52NH-DTY2>]; Complaint at 1–3, *Golloher v. Todd Christopher Int’l Inc.*, No. C 12-06002 RS, 2014 U.S. Dist. LEXIS 91942 (N.D. Cal. July 7, 2014), <https://www.truthinadvertising.org/wp-content/uploads/2013/10/Golloher-v.-Todd-Christopher-International-amended-complaint-pdf> [<https://perma.cc/SAG3-YJ36>]; Corrado Rizzi, *Lawsuit Claims Certain ‘All-Natural’ Credo Beauty Products Contain Synthetic Ingredients*, CLASSACTION.ORG, <https://www.classaction.org/news/lawsuit-claims-certain-all-natural-credo-beauty-products-contain-synthetic-ingredients> [<https://perma.cc/82GH-LPUV>] (last updated Sept. 13, 2017).

⁸⁴ Complaint at 3, *Golloher*, 2014 U.S. Dist. LEXIS 91942, *supra* note 83.

⁸⁵ Adele Chapin, *All the Lawsuits Filed Against Jessica Alba’s The Honest Company*, RACKED (Apr. 24, 2016), <https://www.racked.com/2016/4/27/11518654/jessica-alba-honest-company-lawsuits> [<http://perma.cc/9CCF-YDHL>].

⁸⁶ See John Kell, *Jessica Alba’s Honest Co. Accused of ‘Deceptive’ Labeling*, FORTUNE (Feb. 17, 2016), <http://fortune.com/2016/02/17/jessica-alba-honest-lawsuit/> [<https://perma.cc/F4WZ-EURS>].

ganic ingredients,” virtually none of the ingredients in the product are organic.⁸⁷

Plaintiffs in these lawsuits typically do not allege that they were hurt by the non-natural ingredients. Rather they paid more for the product, believing it was organic or plant-based, than they otherwise would. But there are many consumers who believe that many of the chemicals in conventional cosmetics are *unsafe*.⁸⁸ Studies show that many common ingredients in conventional cosmetics (phthalates, sulfates, parabens, etc.) are linked to cancer, interfere with reproductive organs, hasten the growth of skin lesions, or contribute to antibiotic resistance.⁸⁹ Customers are likely purchasing products with all-natural or organic branding to avoid some of these chemicals, even though the FDA does not consider them so dangerous to ban outright. One study showed that fifty-five percent of pregnant women considered cosmetic use a risk during pregnancy.⁹⁰

Not only is there a consumer interest for “clean cosmetics,” but new consumer groups have focused on removing chemicals that are found in many cosmetics and personal care products that can be harmful.⁹¹ Historically, the FDA has focused regulatory action on harmful active ingredients. These consumer groups seek to shift the regulatory focus away from the safety and efficacy of the active ingredient to the rest of the product formulation, and from individually harmful cosmetics to overall exposure.

IV. INGREDIENTS OF CONCERN

Many of the ingredients consumers are currently concerned about are used in a variety of products. These chemicals are often added as preservatives to extend the shelf-life of the product or to change the consistency of the product (into a lather, for example), or to preserve the scent of a product, rather than as the active ingredient. Parabens and phthalates are two commonly-cited chemicals present in a wide variety of products—from lotions and creams to plastic food packaging—and act as preservatives (parabens) and make plastics pliable (phthalates).⁹² This section will detail some of the

⁸⁷ Complaint at 3, *Golloher*, 2014 U.S. Dist. LEXIS 91942, *supra* note 83.

⁸⁸ See *Why This Matters*, *supra* note 5.

⁸⁹ See *Myths on Cosmetic Safety*, ENVTL. WORKING GRP., <https://www.ewg.org/skindeep/myths-on-cosmetics-safety/#.Wgpp1xNSwXo> [<https://perma.cc/BG7M-XK8G>] (last visited May 9, 2018); *Top Tips for Safer Products*, ENVTL. WORKING GRP., <https://www.ewg.org/skindeep/top-tips-for-safer-products/#.WgpoMBNSwXo> [<https://perma.cc/84GA-DFKN>] (last visited May 9, 2018).

⁹⁰ See Cecile Marie et al., *Changes in Cosmetics Use During Pregnancy and Risk Perception by Women*, 13 INT. J. ENVIRON. RES. PUB. HEALTH 383 (2016), <http://www.mdpi.com/1660-4601/13/4/383/htm> [<https://perma.cc/P74Z-WPGE>].

⁹¹ See *About Us*, ENVTL. WORKING GRP., <https://www.ewg.org/about-us> [<https://perma.cc/K6QW-B8DW>] (last visited Dec. 11, 2011); *About Us*, SAFECOSMETICS.ORG, <http://www.safecosmetics.org/about-us/> [<https://perma.cc/2R7K-TNAE>] (last visited May 9, 2018).

⁹² See Susan Matthews, *Please Don't Panic Over the Chemicals in Your Mac and Cheese*, SLATE (July 14, 2017), http://www.slate.com/articles/health_and_science/medical_examiner/

most common chemicals listed as concerning by consumer advocates and where they are commonly found to illustrate the problem. The list is not exhaustive.⁹³

A. BHA and BHT

BHA (butylated hydroxyanisole) and BHT (butylated hydroxytoluene) are synthetic antioxidants that are used to extend the shelf-life of products. They are usually found in lipsticks, moisturizers, and other creams.⁹⁴ They are also widely used in food products as preservatives.⁹⁵ BHA and BHT can cause skin irritations and allergic reactions. In addition, the International Agency for Research on Cancer classifies BHA as a possible human carcinogen.⁹⁶ Some evidence also suggests that BHA and BHT can mimic estrogen, causing reproductive harm. BHA is currently banned in Europe, and in California, products containing BHA must contain a label stating that the ingredient may cause cancer.⁹⁷

Note that BHA (butylated hydroxyanisole) is not the same as the ingredients called BHAs that are commonly used in exfoliants and anti-aging products.⁹⁸ Also known as salicylic acid, the FDA considers these products safe to use, even though they do cause increased sensitivity to sunlight and, therefore, increased risk for sunburn.⁹⁹ However, studies on the long-term effects are still being evaluated, and in the meantime the FDA recommends people use sun protection as well.¹⁰⁰

B. Coal Tar Dye

Coal tar dyes are found in many products, but are most prevalent in hair dye and shampoos. Coal tar dyes are produced as a byproduct of coal manufacturing. Although coal tar is a known carcinogen, studies are mixed as to whether, when used as a hair dye, it has any harmful effects. In Canada,

2017/07/don_t_panic_over_the_chemicals_in_your_mac_and_cheese.html [https://perma.cc/D2MQ-M8V4]; *Phthalates*, *supra* note 10.

⁹³ See, e.g., *Chemicals of Concern*, SAFE COSMETICS.ORG, <http://www.safecosmetics.org/get-the-facts/chem-of-concern/> [https://perma.cc/SX7W-ZQKP] (last visited May 9, 2018) (listing over 25 categories of harmful ingredients).

⁹⁴ See *The Never List*, BEAUTY COUNTER.ORG, <https://www.beautycounter.com/the-never-list/> [https://perma.cc/VC6S-KUNE] (last visited May 9, 2018).

⁹⁵ DAVID SUZUKI FOUND., THE “DIRTY DOZEN” INGREDIENTS INVESTIGATED IN THE DAVID SUZUKI FOUNDATION SURVEY OF CHEMICALS IN COSMETICS 2 (2010), <https://david Suzuki.org/wp-content/uploads/2010/10/dirty-dozen-BACKGROUNDER.pdf> [https://perma.cc/VN8V-HA7D].

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Beta Hydroxy Acids*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm107943.htm> [https://perma.cc/5GV9-7JQH] (last updated Nov. 15, 2017).

⁹⁹ *Id.*

¹⁰⁰ *Id.*

some coal tar dyes are prohibited in products that are used in the eye (like eyeshadow and mascara) but are allowed in hair dyes.¹⁰¹ The United States has a separate rule for coal tar used in hair dyes, and such products require a warning label.¹⁰²

C. *Dioxane*

Although not usually listed as an ingredient, dioxane is found in many liquid products that create suds (like shampoo, hand soap, etc.). Dioxane is created as a byproduct of manufacturing when ethylene oxide is added to other chemicals to make them less harsh.¹⁰³ Research suggests dioxane is carcinogenic, especially to breast tissue, and is listed as a carcinogen by the EPA.¹⁰⁴ However, the FDA does not require this to be listed as an ingredient on cosmetics, because it is technically a manufacturing byproduct. Despite this, surveys suggest that dioxane is quite prevalent: “Environmental Working Group’s analysis suggests that 97 percent of hair relaxers, 57 percent of baby soaps[,] and 22 percent of all products in [the] Skin Deep” database contain dioxane.¹⁰⁵ Dioxane is listed as “Reasonably Anticipated To Be [A] Human Carcinogen” by the National Toxicology Program.¹⁰⁶

D. *Ethanolamines (DEA, MEA, TEA and Related Chemicals)*

DEA is used in cosmetics to make them creamy or sudsy. DEA can be harmful on its own, but it is more concerning when it reacts with nitrites also found in cosmetic products. When combined, the DEA can react and create nitrosamines, a known human carcinogen.¹⁰⁷ “The European Union Cosmetics Directive restricts the concentration and use of cocamide and lauramide DEA in cosmetics, and limits the maximum nitrosamine concentration in products containing these ingredients.”¹⁰⁸

¹⁰¹ DAVID SUZUKI FOUND., *supra* note 95, at 3.

¹⁰² *Prohibited & Restricted Ingredients*, *supra* note 39.

¹⁰³ *1,4-Dioxane*, SAFECOSMETICS.ORG, <http://www.safecosmetics.org/get-the-facts/chemicals-of-concern/14-dioxane/> [<https://perma.cc/8E38-ZSGF>] (last visited May 9, 2017); *see also* DAVID SUZUKI FOUND., *supra* note 95, at 10.

¹⁰⁴ *1,4-Dioxane*, *supra* note 103.

¹⁰⁵ *Id.*

¹⁰⁶ DEP’T OF HEALTH & HUMAN SERVS., NAT’L TOXICOLOGY PROGRAM, SUBSTANCES LISTED IN THE FOURTEENTH REPORT ON CARCINOGENS 3 (2016), https://ntp.niehs.nih.gov/ntp/roc/content/listed_substances_508.pdf [<https://perma.cc/4VAV-UFEN>].

¹⁰⁷ DAVID SUZUKI FOUND., *supra* note 95, at 4.

¹⁰⁸ *Id.*; *see also* *Ethanolamine Compounds (MEA, DEA, TEA and Others)*, SAFECOSMETICS.ORG, <http://www.safecosmetics.org/get-the-facts/chemicals-of-concern/ethanolamine-compounds/> [<https://perma.cc/3QHN-KBEG>] (last visited May 9, 2018).

E. Formaldehyde-releasing Preservatives

Formaldehyde is another known human carcinogen. Many cosmetics use formaldehyde-releasing preservatives, which give off a small amount of formaldehyde over time to preserve the product (known as “off-gassing”).¹⁰⁹ This is found in many cosmetics but most commonly in nail polishes. Off-gassing of formaldehyde from products can be a concern, since the consumer can inhale it.¹¹⁰ Plus, these ingredients may be used commonly elsewhere in the home, such as wood resins and plastics, so the consumer might be inhaling formaldehyde from multiple sources.¹¹¹ It is worth noting that preservatives, which inhibit the growth of harmful molds, fungus, or bacteria, can be very important for the health of consumers.

F. Parabens

Parabens are widely used as preservatives in cosmetics. Studies suggest that somewhere between 75 and 90 percent of cosmetics include parabens, albeit at low levels.¹¹² Parabens can penetrate the skin, interfere with hormone regulation, affect the male reproductive system, and have been linked to breast cancer.¹¹³ “It has been estimated that women are exposed to fifty mg per day of parabens from cosmetics.”¹¹⁴ Other urine studies have found concentrations of parabens to be higher in teenage girls than in boys.¹¹⁵

Paraben concentrations are regulated in Europe.¹¹⁶ “While the Cosmetic Ingredient Review recommends concentration limits for single (up to 0.4 percent) and total paraben concentrations (up to 0.8 percent) in a single product, these recommendations do not account for exposure to parabens from several products by a single individual.”¹¹⁷ Parabens have been linked to breast cancer in women. In addition, daily topical application of parabens (specifically methylparaben) might also lead to skin damage and potentially skin cancer.¹¹⁸

¹⁰⁹ Such chemicals include: DMDM hydantoin, diazolidinyl urea, imidazolidinyl urea, methenamine, quaternium-15 and sodium hydroxymethylglycinate. DAVID SUZUKI FOUND., *supra* note 95, at 6.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.* at 7; *see also Parabens*, SAFE COSMETICS.ORG, <http://www.safecosmetics.org/get-the-facts/chemicals-of-concern/parabens/> [https://perma.cc/6W4K-HQRU] (last visited May 9, 2018).

¹¹³ DAVID SUZUKI FOUND., *supra* note 95, at 7.

¹¹⁴ *Id.* (citing Philippa D. Darbre & Philip W. Harvey, *Paraben Esters: Review of Recent Studies of Endocrine Toxicity, Absorption, Esterase and Human Exposure, and Discussion of Potential Human Health Risks*, 28 J. APPLIED TOXICOLOGY 561 (2008)).

¹¹⁵ *Parabens*, SAFE COSMETICS.ORG, http://www.safecosmetics.org/get-the-facts/chemicals-of-concern/parabens/#_edn3 [https://perma.cc/6W4K-HQRU] (last visited May 9, 2018).

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

However, like formaldehyde, preservatives can help prevent the growth of mold and fungus in cosmetic products. Because consumer preferences are shifting away from parabens, the FDA currently prioritizes enforcement against cosmetics that claim to use “natural preservatives” or “no preservatives” over traditional cosmetics because of the concern about the growth of bacteria.¹¹⁹

G. Phthalates

Phthalates are used in a host of consumer goods, not just cosmetics.¹²⁰ Typically used in manufacturing to make plastics pliable, they can show up in packaged foods and shower curtains. Because of this, most people in the United States show some level of phthalates in their system.¹²¹ Like parabens, exposure is not uniform, and “[w]hile levels of DEP have declined over time, disparities in exposure persist. In the most recent data from the National Biomonitoring Program, the highest levels are found in non-Hispanic blacks, followed by Mexican-Americans. Non-Hispanic whites have the lowest levels.”¹²² In cosmetics, some phthalates are used in nail polishes, others are commonly found as ingredients in perfumes.¹²³ However, because they are commonly present in manufacturing processes and plastics, they may incidentally show up in other cosmetics.

Phthalates are thought to be endocrine disruptors. Some studies show that large doses can interfere with fertility or cause birth defects.¹²⁴ As a result, the EU classifies them as potentially harmful and bans them from all cosmetics.¹²⁵ The FDA does not currently have evidence suggesting that phthalates are harmful in cosmetics.¹²⁶

H. Triclosan

Triclosan is an antibacterial chemical usually found in hand soaps and hand sanitizers. Beyond cosmetics, it “can be found in a wide range of household products, including garage bags, toys, linens, mattresses, toilet fixtures, clothing, furniture fabric, paints, laundry detergent.”¹²⁷ Triclosan can be absorbed through the skin, and “U.S. Centers for Disease Control and

¹¹⁹ U.S. FOOD & DRUG ADMIN., COMPLIANCE PROGRAM GUIDANCE MANUAL, pt.1 (2016), <https://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/GuidanceDocuments/UCM208412.pdf> [<https://perma.cc/Q333-ACDF>].

¹²⁰ Matthews, *supra* note 92.

¹²¹ DAVID SUZUKI FOUND., *supra* note 95, at 7.

¹²² Phthalates, *supra* note 10.

¹²³ DAVID SUZUKI FOUND., *supra* note 95, at 5.

¹²⁴ *Id.*

¹²⁵ Phthalates, *supra* note 10.

¹²⁶ Phthalates, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm128250.htm> [<https://perma.cc/ZT3H-W6NY>] (last updated Feb. 22, 2018).

¹²⁷ DAVID SUZUKI FOUND., *supra* note 95, at 14.

Prevention scientists detected triclosan in the urine of nearly seventy-five percent of those tested (2,517 people ages six years and older).¹²⁸ Studies suggest the chemical is an endocrine disruptor for humans and can also irritate the skin.¹²⁹ Triclosan is very toxic for aquatic organisms and persists in the environment without breaking down for a long time.¹³⁰

The FDA recently issued regulations finding that triclosan and triclocarban, along with twenty-three other chemicals, were no longer generally recognized as safe and effective when used in over-the-counter hand washes. In fact, no data existed showing their use was more effective than plain soap and water.¹³¹

I. Talc

Talc is a naturally occurring mineral used most commonly in baby powder, although it does appear in other cosmetic powder products, such as blush or eyeshadow.¹³² The IARC notes that there is limited evidence available and that talc *might* be carcinogenic to humans.¹³³ However, recent anecdotal evidence suggests that routine application of baby powder to the genitals may increase risk of ovarian cancer in women.¹³⁴ For example, Johnson & Johnson currently faces upwards of 6000 lawsuits claiming that lifelong use of baby powder caused ovarian cancer in some women. Some of the lawsuits claim the talc powder contained trace amounts of asbestos, even though asbestos has been banned since the 1970s.¹³⁵ Other lawsuits argue the talc itself was the problem.

¹²⁸ *Id.*

¹²⁹ See K. B. PAUL ET AL., TRICLOSAN AND ENDOCRINE DISRUPTION: EVIDENCE FOR ALTERATIONS IN THYROID HORMONE HOMEOSTASIS, U.S. ENVTL. PROT. AGENCY (2007), https://cfpub.epa.gov/si/si_public_record_Report.cfm?dirEntryID=175343 [<https://perma.cc/48QP-NBNS>]; see also Nicole Greenfield, *The Dirt on Antibacterial Soaps*, NRDC (Mar. 15, 2016), <https://www.nrdc.org/stories/dirt-antibacterial-soaps> [<https://perma.cc/7RPQ-4LA3>]; YIXING FENG ET AL., ENDOCRINE DISRUPTING EFFECTS OF TRICLOSAN ON THE PLACENTA IN PREGNANT RATS, NAT'L CTR. FOR BIOTECHNOLOGY INFO., U.S. NAT'L LIBRARY OF MED., NAT'L INSTS. OF HEALTH (2006) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4858197/> [<https://perma.cc/W3YV-RLTV>].

¹³⁰ *Id.*

¹³¹ See *Topical Antiseptic Products: Hand Sanitizers and Antibacterial Soaps*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm444681.htm> [<https://perma.cc/WAX7-K22C>] (last updated Dec. 19, 2017).

¹³² *Talcum Powder and Cancer*, AM. CANCER SOC'Y, <https://www.cancer.org/cancer/cancer-causes/talcum-powder-and-cancer.html> [<https://perma.cc/VSF8-DYN5>] (last updated Nov. 13, 2017).

¹³³ INT'L AGENCY FOR RESEARCH ON CANCER, 93 IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS: CARBON BLACK, TITANIUM DIOXIDE, AND TALC (2010), <https://monographs.iarc.fr/ENG/Monographs/vol93/mono93.pdf> [<https://perma.cc/CCL9-N368>].

¹³⁴ Julie Steenhuysen, *Evidence on Talc Cancer Risk Differs for Jurors, Researchers*, SCI. AM. (Feb. 24, 2016), <https://www.scientificamerican.com/article/evidence-on-talc-cancer-risk-differs-for-jurors-researchers/> [<https://perma.cc/J9Q6-FUHP>].

¹³⁵ Jen Christensen, *Does Talcum Powder Cause Cancer? A Legal and Scientific Battle Rages*, CNN (Apr. 11, 2018), <https://www.cnn.com/2018/04/11/health/talc-ovarian-cancer->

Current data is not available on whether talc could be to blame.¹³⁶ And of course, cancer development can be a combination of many risk factors, including genetics and other lifestyle differences, and so the talc powder could be just a contributing factor.¹³⁷ However, multiple studies conducted since the 1990s have found no association between talc use and ovarian cancer.¹³⁸ The FDA is currently reviewing whether talc powder, applied to the genital area, causes greater cancer risk.¹³⁹

Although the above list may sound alarming, it is not currently known whether repeated, long-term exposure to these chemicals from multiple sources is harmful. Some scientific articles suggest that the current method of testing ingredients (high dose studies on simulated skin or animals and creating a dose-response curve) is insufficient to show the true risk from lower levels of exposure.¹⁴⁰ Others suggest that, because the chemical compounds from different products likely act differently or are metabolized differently, it is very unlikely that using multiple products would create cumulative harm.¹⁴¹ Furthermore, many scientists think it is unlikely that long-term use of cosmetics can have a harmful effect because the dosages are so small and usually applied topically (rather than ingested or injected, as with food or drugs).¹⁴² However, little evidence is available concerning how

cases/index.html [https://perma.cc/4HQE-UMR5]. The FDA did do a recent survey of cosmetic products containing talc to see if any contained asbestos and found that they did not. However, only four of the nine contacted companies sent samples, so the FDA does not think that these results necessarily prove that all talc-containing cosmetics are asbestos-free. See *Talc*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm293184.htm [https://perma.cc/W2H8-WF9V] (last updated Mar. 12, 2018).

¹³⁶ See AM. CANCER SOC'Y, *supra* note 132; Dorota M. Gertig et al., *Prospective Study of Talc Use and Ovarian Cancer*, 92 J. NAT'L CANCER INST. 249 (2000), https://academic.oup.com/jnci/article/92/3/249/2965050 [https://perma.cc/4UUC-L7F3]; Laurie McGinley, *Does Talcum Powder Cause Ovarian Cancer? Experts Are Divided*, WASH. POST (Aug. 23, 2018), www.washingtonpost.com/news/to-your-health/wp/2017/08/23/does-talcum-powder-cause-ovarian-cancer-experts-are-divided/?utm_term=.0c24df681eec [https://perma.cc/U5N8-ACNF].

¹³⁷ See Christensen, *supra* note 135.

¹³⁸ See *Talc - in Depth*, COSMETIC, TOILETRY & PERFUMERY ASS'N, http://www.thefactsabout.co.uk/talc---in-depth/content/245 [https://perma.cc/S5T3-P62C] (last visited May 9, 2018).

¹³⁹ *Talc*, *supra* note 135.

¹⁴⁰ See Julia R. Barrett, *Chemical Exposures: The Ugly Side of Beauty Products* 113 ENVTL. HEALTH PERSPECTIVES A24 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1253722/ [https://perma.cc/6496-LT5K] ("Therein lies the controversy—environmental groups view the CDC data as evidence of widespread exposure, whereas industry groups view it as evidence of low-level exposure that falls well below amounts shown to cause problems in animal studies."); L.N. Vandenberg et al., *Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses*, 33 ENDOCRINE REV. 378 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3365860/ [https://perma.cc/9V6S-AH8J] (arguing that "... effects of low doses cannot be predicted by the effects observed at high doses. Thus, fundamental changes in chemical testing and safety determination are needed to protect human health.").

¹⁴¹ See Gerhard J. Nohyenk et al., *Endocrine Disruptors: Fact or Urban Legend?*, 223 TOXICOLOGY LETTERS 295, 296 (2013).

¹⁴² *Cosmetics*, AM. CANCER SOC'Y, https://www.cancer.org/cancer/cancer-causes/cosmetics.html [https://perma.cc/M9QF-LUUL] (last updated May 28, 2014).

the body actually absorbs cosmetics under conditions of regular use.¹⁴³ Additionally, population-based studies have other limitations. It is hard to tell which exposure in a person's regular activities (between home, work, ambient air pollution, etc.) caused a cancer, and studies must track people for years. The American Cancer Society explains that, because it is difficult to do long-term studies, there is virtually no information available about the long-term health effects of cosmetic use.¹⁴⁴

Furthermore, the effect from these ingredients, if there is one, is not distributed equally. Women use twice as many personal care products as men (twelve products versus six products, respectively), exposing them to more chemical compounds (168 vs. eighty-five, respectively).¹⁴⁵ Many of the organic/natural products (those that are *actually* organic, not just those which claim to be) are more expensive, and may not be within the budget of a low-income family. Low-income families might also be exposed to more toxins overall, if they are unable to remove lead from their homes, update outdated furniture (coated in harmful flame-retardant chemicals), or purchase organic foods.¹⁴⁶ Lead exposure is particularly acute in African-American neighborhoods. And although the FDA has evaluated common cosmetic products like eyeliner and lipstick and has found relatively low levels of lead,¹⁴⁷ the FDA does not have the regulatory tools to consider lead content in the context of these broader economic and racial disparities.

Lead is one illustration of how the larger problem of the burden of chemical exposure from conventional personal care products may fall disproportionately on non-white, non-affluent people.¹⁴⁸ A recent study of beauty products conducted by the Environmental Working Group (a consumer advocacy organization) found that, overall beauty products marketed towards African-American women were more hazardous than products marketed to

¹⁴³ See *id.*

¹⁴⁴ *Id.*; see also John A. Bukowski, *Review of the Epidemiological Evidence Relating Toluene to Reproductive Outcomes*, 33 REG. TOXICOLOGY & PHARMACOLOGY 147 (2001) (discussing limitations of drawing conclusions from occupational studies).

¹⁴⁵ *Exposures Add Up – Survey Results*, ENVTL. WORKING GRP., <https://www.ewg.org/skindeep/2004/06/15/exposures-add-up-survey-results/#.W7EVhxNKjq0> [<https://perma.cc/D5K5-R93Q>] (last visited Oct. 14, 2018).

¹⁴⁶ Terrence McCoy, *Freddie Gray's Life a Study on the Effects of Lead Paint on Poor Blacks*, WASH. POST (Apr. 29, 2015), https://www.washingtonpost.com/local/freddie-grays-life-a-study-in-the-sad-effects-of-lead-paint-on-poor-blacks/2015/04/29/0be898e6-eea8-11e4-8abc-d6aa3bad79dd_story.html?utm_term=.d70c72385c22 [<https://perma.cc/BJ85-DRKJ>].

¹⁴⁷ *Lead in Cosmetics*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/productsingredients/potentialcontaminants/ucm388820.htm> [<https://perma.cc/BJ85-DRKJ>] (last visited Oct. 14, 2018).

¹⁴⁸ See Cheryl Wischhover, *Your Beauty Products Are Not Killing You*, RACKED (May 5, 2016, 10:52 AM), <https://www.racked.com/2016/5/5/11591300/natural-skincare-clean-beauty-toxins> [<https://perma.cc/5KEF-LSQ3>].

the general public.¹⁴⁹ And African-American women also spend significantly more money on beauty products than women of other races.¹⁵⁰

The current framework thus poses two problems: First, the FDA is not well-equipped to evaluate or regulate harms from low-level, continuous exposure to the types of chemicals listed above. The concerns presented by consumer groups suggest we should at least consider changing how product safety is evaluated to test ingredients as they are used in context of a person's total potential exposure, rather than individually.

Second, because the FDA is limited in how it evaluates cosmetic ingredients, the agency is not fully capable of assuring that their cosmetics are safe when they are *in fact* safe. A lack of clear guidelines over "clean" or "natural" beauty leaves consumers at risk for falling for faulty claims, as described above. Overall, a stronger regulatory system would allow the agency to both investigate actual hazards and give consumers more confidence that their other products are safe to use.

V. POTENTIAL FIXES

Right now, the FDA can only take action if a cosmetic is adulterated or misbranded. For some of the reasons discussed above, it is entirely possible that none of the chemicals of concern will be shown to cause long-term harms when used in cosmetics. However, the current structure of the FDCA does not enable the FDA to evaluate these potential harms, due to the limited information the FDA has on cosmetic ingredients and the current focus on reacting to complaints from consumers in the marketplace.¹⁵¹

Congress should pass new legislation giving the FDA broader authority to regulate harmful ingredients in cosmetics. Recently proposed reforms, such as the Personal Care Products Safety Act, would improve reporting by making registration mandatory and would put the FDA in a better position to review safety of all the cosmetics in the market. More substantive changes—such as allowing the FDA to set limits on ingredients below the safety threshold based on the precautionary principle¹⁵²—would be necessary to really deal with the cumulative effect of consumer exposure. This Section details a few current regulatory options that have been considered and discusses other potential avenues for reform.

¹⁴⁹ Pestano, *supra* note 8. EWG collects data on individual ingredients in cosmetics, and gives them a hazardous rating based on the potential concern and the reliability of the scientific evidence. It then rates personal care products from low to high hazard based on the score of the individual ingredients. See *About Environmental Working Group's Skin Deep*, ENVTL. WORKING GRP., <https://www.ewg.org/skindeep/site/about.php#3> [<https://perma.cc/7989-5NZ5>] (last visited Oct. 14, 2018). Some think the rating system is largely overblown, since the concentrations of most ingredients is so low, and little data exists on whether, as used, the formulation actually poses a danger to humans. See Wischhover, *supra* note 148.

¹⁵⁰ Shah & Taylor, *supra* note 1, at 212.

¹⁵¹ See Letter from Dayle Cristinzio, *supra* note 65.

¹⁵² See Shah & Taylor, *supra* note 1, at 240.

A. *European Model*

Many advocates point to the European system as being more stringent than the U.S. system because the EU has banned over 1300 ingredients from use in cosmetics.¹⁵³ However, many of these ingredients are not currently used in cosmetics, either in the EU or the United States. If a cosmetic in the EU does not contain any of those ingredients, or one of the restricted ingredients above an approved concentration, it is considered safe if the manufacturer has the appropriate safety data.¹⁵⁴

The EU does not technically require products to be pre-approved, but it does mandate that manufacturers conduct a much more stringent safety assessment than does the United States.¹⁵⁵ A person with a university degree in pharmacology or another similar discipline must conduct the safety assessment.¹⁵⁶ The safety assessment must consider:

[T]he general toxicological profile of each ingredient used; the chemical structure of each ingredient; the level of exposure of each ingredient; the specific exposure characteristics of the areas on which the cosmetic product will be applied; and the specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.¹⁵⁷

In addition, the EU requires all products to be registered in the Cosmetic Products Notification Portal—an EU-wide database—before they can be marketed in the EU.

Because the EU safety assessment focuses more on systemic harms from use of the product rather than individual ingredients, it might be better suited to dealing with the problem of repeated, long-term use. But as of right now, it is not clear whether long-term effects, such as cancer, are being studied more in the EU than in the United States. Furthermore, it is hard to say for sure whether the EU is better off than the United States because of these regulations. The United States ranked seventh in the world in cancer

¹⁵³ Press Release, Office of California Senator Diane Feinstein, Feinstein Testifies in Support of Personal Care Products Safety Act (Sept. 22, 2016), <https://www.feinstein.senate.gov/public/index.cfm/press-releases?id=6237DD59-167A-4B5C-861C-4A95F117739F> [<https://perma.cc/9XSG-RT46>]. The chemicals are listed in Annex II of the EC regulation on cosmetics. See Regulation 1223/2009 O.J. (L 342/59) 83 (EC), <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:EN:PDF> [<https://perma.cc/WLM3-TVBT>]. Other cosmetics that can be used but only in restricted fashion are listed in Annex III.

¹⁵⁴ *Ingredients*, COSMETIC, TOILETRY & PERFUMERY ASS'N, <http://www.ctpa.org.uk/content.aspx?pageid=430> [<https://perma.cc/5BFU-RJ6T>] (last visited Oct. 10, 2018).

¹⁵⁵ *See Confidence in Cosmetics*, COSMETIC, TOILETRY & PERFUMERY ASS'N, <http://www.thefactsabout.co.uk/confidence-in-cosmetics/content/128#safety> [<https://perma.cc/8E96-MY2B>] (last visited Oct. 10, 2018); see also 2009 O.J. (L 342/46), 67.

¹⁵⁶ 2009 O.J. (L 342/46), 67.

¹⁵⁷ *Id.* at 76; *accord Assessing Safety*, COSMETIC, TOILETRY & PERFUMERY ASS'N, <http://www.ctpa.org.uk/content.aspx?pageid=426> [<https://perma.cc/4NX2-3WN9>] (last visited May 9, 2018).

incidents in 2011,¹⁵⁸ faring better than some European countries, including Denmark and France, but much worse than many others.¹⁵⁹ Separating harms from cosmetic use and other factors, such as genetics and lifestyle choices (i.e., smoking), make it virtually impossible to say for certain that the EU cosmetic regulations keep consumers safer.

B. Personal Care Products Act

In 2017, Senators Dianne Feinstein and Susan Collins introduced the PCPA, a law designed to update FDA regulation of cosmetics and protect consumers.¹⁶⁰ The bill would have required the FDA to review the safety of at least five cosmetic ingredients each year. The bill also would have allowed the FDA to issue mandatory recalls of cosmetics with hazardous substances. As mentioned earlier, right now such recalls are voluntary.¹⁶¹

The law would make some noteworthy changes to the FDA's authority. First, the law would require mandatory registration for cosmetic manufacturers and mandatory submission of cosmetic ingredients.¹⁶² Second, by requiring the FDA to review the safety of at least five different chemicals or chemical categories each year, the law creates a positive mandate to review chemicals that is currently lacking.¹⁶³ Three of the chemicals required for review in the first year are propyl paraben, formaldehyde, and lead acetate.¹⁶⁴ Finally, the law would require companies to submit adverse health reports to the FDA when they occur.¹⁶⁵ Each of these changes would improve the FDA's ability to respond to consumer reports of adverse reactions and independently evaluate ingredients for their safety.

¹⁵⁸ *Cancer Rates: See How Countries Compare Worldwide*, GUARDIAN: DATA BLOG (Jan. 24, 2011) <https://www.theguardian.com/news/datablog/2011/jan/24/worldwide-cancer-rates-uk-rate-drops> [<https://perma.cc/NBS7-4KB2>].

¹⁵⁹ Not only is it difficult to draw conclusions from these data due to the host of lifestyle, cultural, and health-care related causes of cancer, but also there is reason to think the numbers are influenced mostly by rates of lung cancer, which is still the most prevalent form of cancer in the U.S. (and curiously, lung cancer is more deadly in the United States than in Europe despite lower rates of smoking in the United States). See John Horgan, *Cancer Spending Higher in U.S. Than in Europe-and So Is Cancer Mortality*, SCI. AM.: CROSS-CHECK (June 8, 2015), <https://blogs.scientificamerican.com/cross-check/cancer-spending-higher-in-u-s-than-in-europe-and-so-is-cancer-mortality/> [<https://perma.cc/KF2B-5MFZ>]. For more detailed statistics, see generally *Cancer Fact Sheets*, WORLD HEALTH ORG., INT'L AGENCY FOR RESEARCH ON CANCER, http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx [<https://perma.cc/KE8Q-ZB9D>].

¹⁶⁰ Press Release, Office of California Senator Dianne Feinstein, Senators Introduce Bill to Strengthen Personal Care Product Oversight (Apr. 20, 2015), <https://www.feinstein.senate.gov/public/index.cfm/press-releases?ID=89FF88B8-5FB1-4617-B96A-C46547CA14EF> [<https://perma.cc/5LZE-UVL7>].

¹⁶¹ See Personal Care Products Safety Act, S. 1113, 115th Cong. sec. 105 (2017) ("Personal Care Products Safety Act").

¹⁶² *Id.* at sec. 605–06.

¹⁶³ *Id.* at sec. 608.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.* at sec. 611.

The law also changes the scope of safety concerns that the FDA can investigate.¹⁶⁶ Section 608 proscribes that, when the FDA does the annual review of the ingredients, it should consider:

The probable cumulative and aggregate effect in humans of relevant exposure to the ingredient or non-functional constituent or to any chemically or pharmacologically related substances from use in cosmetics or other products with similar routes of exposure under recommended or suggested conditions of use or their customary use, to the extent adequate data is available for analysis. In appropriate cases, the [FDA] may consider available information on the total exposure to an ingredient or non-functional constituent from all sources.”¹⁶⁷

This is a significant change from the FDA’s current focus on merely “adulterated” ingredients to considering aggregate effects. The scope of what the FDA can deem unsafe under the definition of “adulterated” has not been fully tested, but the prior legislative history of the FDCA suggests a legislative amendment might be needed in order to give the FDA such authority. The first version of the FDCA, when introduced in 1933, stated that “a cosmetic would be deemed adulterated if it was or could be “injurious” to the user under the usual or prescribed conditions of use, or if it contained any ‘poisonous or deleterious ingredient.’”¹⁶⁸ However, after opposition, this version of the bill was amended to remove the “injurious” provision, thus focusing “FDA regulation on the composition of the cosmetic as the source of injury.”¹⁶⁹ Because of this language, the FDA can currently only regulate cosmetics as adulterated if the ingredient in the product is harmful in isolation.¹⁷⁰ Amending the act to allow the FDA to consider cumulative effects from all sources would broaden the FDA’s ability to protect consumers.

This legislation would give the FDA many more tools to evaluate the safety of cosmetic ingredients. However, the law does have gaps. Because of the paucity of studies on cosmetics as applied and the difficulties in conducting such studies, there may not be enough data for the FDA to state reliably that a product is safe or unsafe within the review process. As described above, studies on cancer development take ten to twenty years, and so the FDA may not be in a position, after reviewing the evidence, to say whether a product is or is not safe.

¹⁶⁶ *Id.* at sec. 608.

¹⁶⁷ *Id.*

¹⁶⁸ See Heymann, *supra* note 26, at 362.

¹⁶⁹ *Id.*

¹⁷⁰ See *supra* Section II.

C. California Ingredient Registration System

In 2005, the California legislature passed the California Safe Cosmetics Act, which set up a state reporting system for cosmetics that use ingredients of concern.¹⁷¹ Under that Act, the California Department of Health Services creates a list of cosmetic ingredients that are considered potential toxins by any of the following:

- (1) A substance listed as known or reasonably anticipated to be a human carcinogen in a National Toxicology Report on carcinogens.
- (2) A substance given an overall carcinogenicity evaluation of Group 1, Group 2A, or Group 2B by the International Agency for Research on Cancer.
- (3) A substance identified as a Group A, Group B1, or Group B2 carcinogen, or as a known or likely carcinogen by the United States Environmental Protection Agency.
- (4) A substance identified as having some or clear evidence of adverse developmental, male reproductive, or female reproductive toxicity effects in a report by an expert panel of the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction.¹⁷²

The department then requires any cosmetics company that sells cosmetics in the state to submit a list of its products that contain any of the listed ingredients. The department has also created a website listing both all of the ingredients of concern, as well as cosmetics that have been reported to the department.¹⁷³ When a consumer goes to the database, they can search for a product, and when they click on it, the page shows the ingredients reported.¹⁷⁴ The page states that the ingredients were reported pursuant to the California Safe Cosmetics Program, but that the products are not necessarily harmful. Many of the resources on the website are geared towards salon workers as much as they are to consumers. The program is designed to inform consumers and cosmetic industry workers about the products.¹⁷⁵ However, the California system does not require any companies to change their formulations or display additional warnings about the product.

¹⁷¹ CAL. HEALTH & SAFETY CODE § 111791.5 (West 2006), https://leginfo.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=104.&title=&part=5.&chapter=7.&article=3.5 [https://perma.cc/56J5-S9DU].

¹⁷² *Id.*

¹⁷³ *California Safe Cosmetics Program*, CAL. DEP'T PUB. HEALTH, <https://www.cdph.ca.gov/Programs/CCDPPP/DEODC/OHB/CSCP/Pages/CSCP.aspx> [https://perma.cc/TTY5-X763] (last updated Apr. 27, 2018).

¹⁷⁴ *California Safe Cosmetics Program Product Database*, CAL. DEP'T PUB. HEALTH, <https://safecosmetics.cdph.ca.gov/search/default.aspx> [https://perma.cc/2V8D-RXDW] (last visited Nov. 4, 2018).

¹⁷⁵ *Id.*

D. Expanding the FDA's Risk Assessment Authority

Each of the policies described above have important benefits. The PCPA gives the FDA more tools to investigate the safety of cosmetics and ensure compliance. The California system gives more information to consumers so they can make more informed purchases. However, neither of these laws fully deal with the problem that data on long-term exposure, specifically for cancer and reproductive toxicity, can take years to develop. Nor do these proposals deal with overlapping exposures from multiple ingredients. In order to bridge the gap, the FDA should be given additional authority in the following ways.

1. Expanded Ingredient Database and Labeling

The FDA should establish a list—similar to the California list—of ingredients that are potentially harmful to human health. In addition to a mandatory registration like the one under the PCPA, companies should also be required to disclose any cosmetics containing ingredients on the list to the FDA. This would help the FDA understand how many companies are using certain ingredients and in which products, information the agency currently lacks.¹⁷⁶

The FDA should also be given the authority to require additional product labeling for when cosmetics contain such ingredients, if such a label is considered appropriate and necessary.¹⁷⁷ For example, if the company uses an ingredient, the FDA can require companies to use labels such as “may cause cancer,” “potential for reproductive toxicity,” or perhaps “this product contains ingredients that have not been evaluated by the FDA for safety.” Some warning labels like this are already required for certain coal tar hair dyes.¹⁷⁸ However, the warning label would not be required for every ingredient, rather, only those the FDA evaluates as both potentially harmful and harmful given the method and frequency of exposure.

These labels would accomplish multiple goals. First, companies generally prefer not to have warning labels on their packaging, so this system would encourage companies to develop formulas without such ingredients—a trend that some private actors have already successfully achieved in some measure.¹⁷⁹ Second, the labels would indicate to consumers that first, the

¹⁷⁶ See Letter from Dayle Cristinzio, *supra* note 65.

¹⁷⁷ For a more detailed look at the administrative burden under substantial evidence review for determinations such as this one, see Shah & Taylor, *supra* note 1, at 235–39.

¹⁷⁸ *Hair Dyes*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm143066.htm> [<https://perma.cc/2C69-MHM2>] (last updated Nov. 3, 2017).

¹⁷⁹ The Environmental Working Group, the non-profit group behind the Skin Deep Database, has produced an “EWG Verified” seal that private brands can display on their packaging if the product meets EWG’s standards. See *EWG Verified: A New Standard for Your Health*, ENVTL WORKING GRP., <https://www.ewg.org/ewgverified/about-the-mark.php> [<https://>

ingredients may not be safe, and second, it would change the perception that the FDA pre-approves ingredients in cosmetics, a commonly-held misconception.¹⁸⁰

Finally, the labels would bridge the gap between no regulation and a total ban, where scientific evidence suggests there *could be* harm but more information is needed. If the product is eventually considered too dangerous, it will already have been phased out of the market. If further testing shows there is no potential harm, the ingredient could be removed from the list. Because of the difficult nature of testing in this area, it is entirely possible that no study could conclusively determine whether a product definitely causes cancer. In such scenarios, following this method would adopt some measure of extra precaution, but without removing the ingredient entirely from the market.

2. Expanded Risk Assessments

Instead of testing individual products and relying on manufacturer's safety tests, the FDA should be given the authority—similar to the EPA—to do human risk-assessment studies of overall cosmetic use.¹⁸¹ Risk assessments are used in many EPA regulatory decisions and include a consideration of both scientific information about safety and economic, social, and other factors.¹⁸² The EPA does both human health and ecological risk assessments.

Building on the list of potentially dangerous ingredients as outlined above, the FDA should be empowered to conduct human health risk assessments of those ingredients considered potentially harmful, taking into account information about dose amounts, all sources of exposure (including

perma.cc/BS8Y-ZNQS] (last visited Sept. 26, 2018). The campaign is designed to drive companies to avoid certain ingredients in order to become “verified.” Similarly, in the summer of 2018, well-known luxury beauty retailer Sephora debuted a “clean” seal to indicate products that are free of these supposedly harmful ingredients. The Clean Seal means the brand formulates its products without “sulfates (SLS and SLES), parabens, formaldehydes, formaldehyde-releasing agents, phthalates, mineral oil, retinyl palmitate, oxybenzone, coal tar, hydroquinone, triclosan, and triclocarban.” Marci Robin, *Sephora Is Launching a Clean Beauty Category That's Free of Certain Unwanted Ingredients*, ALLURE (May 11, 2018), <https://www.allure.com/story/clean-at-sephora-category-filter-by-ingredient> [<https://perma.cc/U937-CRYN>]. However, these private labels are usually framed as a positive seal, rather than as a negative warning on the non-compliant products.

¹⁸⁰ See Amy E. Newburger, *Cosmetics: Myths and Misconceptions*, 27 CLINICS IN DERMATOLOGY 446, 446 (2009).

¹⁸¹ *Risk Assessment*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/risk/about-risk-assessment> [<https://perma.cc/4UTN-XPFB>] (last visited May 9, 2018).

¹⁸² See U.S. ENVTL. PROT. AGENCY, OFFICE OF THE SCIENCE ADVISOR, STAFF PAPER: RISK ASSESSMENT PRINCIPLES & PRACTICE (Mar. 2004), <https://nctc.fws.gov/resources/course-resources/pesticides/Risk%20Assessment/Risk%20Assessment%20Principles%20and%20Practices.pdf> [<https://perma.cc/CD5Y-NHXQ>]. See also generally U.S. DEP'T HEALTH & HUMAN SERVS., PRESIDENT'S CANCER PANEL, 2008–2009 ANNUAL REPORT, REDUCING ENVIRONMENTAL CANCER RISK (2010), https://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf [<https://perma.cc/83AT-Q7YQ>].

non-cosmetic sources), and timing of exposure under normal use.¹⁸³ This would also include collecting information on what products consumers typically use and how frequently consumers use them. The FDA would also consider issues like potential interactions between ingredients and whether the product is used more by at-risk demographics (such as children, adolescents, or pregnant and breastfeeding women). Similarly, the FDA can take into account differences in exposure across racial and socio-economic groups, to the extent they existed for that chemical.

The purpose of a risk assessment is not to determine an “optimal” level of exposure, but to guide decision makers in their ultimate actions. Thus, in order to make use of risk assessments, the FDA should be given the authority to set limits on chemical concentrations after considering the risk assessment, the economic costs, and the potential benefits but without finding that any use of the ingredient necessarily makes the product “adulterated.” These limits, similar to workplace exposure limits under the Toxic Substances Control Act, do not outlaw the use of a particular substance but rather set a technologically achievable limit based on both safety and potential cost.

Under this proposal, the FDA would also be allowed to limit the concentration of a potentially harmful ingredient below what is shown to be safe based on the evidence that people use multiple products daily containing the same ingredient. For example, if the risk assessment shows that consumers typically use a shampoo, conditioner, and moisturizer daily that all contain the same harmful ingredient, the FDA would be justified in limiting the maximum concentration in those three types of products below what it would otherwise be. Therefore, a consumer who uses all of the products would not be subject to more than the amount considered safe. Of course, the potential number of cosmetics a person could use is limitless, and so at some point, a consumer may be exposed to more than the overall limit. But they would be exposed to less under this regime than the current one.

The FDA could also use the risk assessment information to set company-wide limitations on concentrations of chemicals. With mandatory reporting, the FDA will have more information on which products typically include certain ingredients, and which products are typically used together. If a company markets a “line” of products that are intended to be used together, the FDA could limit the concentration of harmful ingredients on the entire line of products. For example, if a company sells a basecoat, nail polish color, and topcoat, the concentration across all three products of formaldehyde (or formaldehyde-releasing preservatives) would need to be less than the safe level for a product typically used alone. This would target products that consumers are most likely to use together, and thus reduce the overall level of exposure.

¹⁸³ *Human Health Risk Assessment*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/risk/human-health-risk-assessment> [<https://perma.cc/RR3P-RZLQ>] (last visited May 9, 2018).

Finally, the FDA, in conjunction with other government agencies, needs more funding to do long-term studies of potential cancer-causing ingredients when used in cosmetics and applied repeatedly.

These reforms would allow the FDA to independently evaluate the safety of cosmetic ingredients in the manner they are actually used by consumers. Expanded authority is not only necessary to evaluate whether more cosmetic ingredients are harmful, but also to ensure the FDA has the resources to say confidently that some ingredients are safe as currently used.

VI. CONCLUSION

With consumers becoming ever more conscious of health effects from cosmetics, it is possible to see the FDA as not keeping up with industry. This is not necessarily the case—conclusive data does not exist on whether these chemicals are harmful. But as more information comes forth, the FDA will need new tools to manage the risks, especially risks that take years or decades to develop. Expanding the FDA's tools both to compel more disclosure and to investigate harms from long-term repeated use of products would help achieve these aims. Because research on cancer and reproductive risk is often indeterminate, a more balanced approach is needed. Creating a list of potentially risky ingredients is a good start and increasing the FDA's ability to research such ingredients and assess their overall risk would provide consumers with more safe products and more information about what is currently unregulated.

