

YOU DON'T KNOW WHAT'S IN YOUR SHAMPOO, AND NEITHER DOES THE FDA: A CALL FOR CHANGE

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ABSTRACT

American consumers seldom contemplate whether the ingredients in their shampoo or other personal care products are poisoning them. Most erroneously believe some government entity, such as the Food and Drug Administration (FDA), regulates the ingredients these products may contain, and thus assume they are safe. The alarming reality is that the FDA lacks the authority to regulate ingredients or issue an independent recall. To date, all modern congressional attempts to effectively regulate our exposure to toxic chemical ingredients have failed. And existing legislation, passed in 1938, does little to address modern manufacturing trends. While implementing new regulations may be unpopular in the United States' current political climate, toxic exposure to these ingredients knows no political affiliation. And if the function of government is not at its very core to protect public welfare – then what is? Pending legislation, which has received bipartisan support, would grant the FDA authority to regulate permissible ingredients, conduct limited pre-market surveillance of ingredients, and issue an independent recall.

This analysis, however, goes beyond the need for new regulations. In addition to implementing pending legislation, Congress should look to the European Union (EU) laws and adopt additional safeguards. Similar to the EU, it is essential that the FDA be granted authority to reevaluate and update permissible ingredients on a rolling basis. For the first time since 1938, Congress must take action to protect American consumers from the hazardous chemical exposure that occurs

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during a seemingly safe part of their daily routines.

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INTRODUCTION

Amidst the advertisements from beauty industry retailers lies something far less desirable than the vast array of perfectly packaged cosmetics.¹ Faced with thousands of different brands and products to choose from, the average consumer is guided only by a store employee willing to suggest a product. Missing from the dialogue, however, is information about the products' ingredients and whether they may be harmful—information

1. This Note uses the term "cosmetics" interchangeably with "personal care products." Both terms can be used to describe products, such as shampoo, that manufacturers can sell to consumers with virtually no regulations on the ingredients they may contain.

that is largely difficult for the average consumer to find while perusing the store. A consumer's best effort to find the information for herself through a Google search may not reveal that a chemical contained in a product in the United States may be barred from use in that same product in Germany.²

In 2014, eleven-year-old Eliana Lawrence lost most of her hair after using the widely advertised hair-conditioning product, WEN by Chaz Dean, touted to make hair softer, fuller, and stronger.³ Lawrence, left wondering whether her hair would ever grow back, was not alone.⁴ Plaintiffs in both California and New York filed class action suits, which have since been consolidated, against Guthy-Renker, LLC and Wen By Chaz Dean, Inc.⁵ Lead plaintiff in the California case, Amy Friedman, suffered serious hair loss within two weeks of using WEN Cleansing Conditioner, ultimately losing "one quarter to one third of the hair on her head."⁶ On August 22, 2017, both Wen by Chaz Dean, Inc. and Guthy-Renker received final approval for a \$26.25 million settlement.⁷ Consumers who experienced adverse effects are entitled to receive up to \$20,000.⁸ Despite reaching settlement, representatives from Guthy-Renker claim that WEN is safe, and that the settlement was merely a "business decision" taken to "put this behind us so that we can focus on delivering quality products."⁹

The Food and Drug Administration's (FDA or Administration) involvement with the WEN litigation was alarmingly

2. See *infra* Sections I.B.1.-2.

3. Jericka Duncan, *FDA Issues Safety Alert for Popular Hair Care Product Over Hair Loss Complaints*, CBS NEWS (Aug. 18, 2016, 7:24 PM), <http://www.cbsnews.com/news/fda-issues-safety-alert-for-popular-hair-care-product-over-hair-loss-complaints/>.

4. *Id.*

5. *Friedman v. Guthy-Renker LLC*, No. 2:14-cv-06009-ODW(AGR), 2016 WL 2758240, at *1 (C.D. Cal. May 12, 2016).

6. Class Action Complaint ¶ 27, *Friedman v. Guthy-Renker LLC*, No. 2:14-cv-06009-ODW(AGR), 2016 WL 2758240 (C.D. Cal. May 12, 2016), 2014 WL 3944013.

7. *Frequently Asked Questions*, WEN HAIR CARE CLASS ACTION OFFICIAL SETTLEMENT WEBSITE, <https://www.wenclasssettlement.com/FrequentlyAskedQuestions#q8> (last visited Nov. 16, 2017).

8. *Class Action Lawsuit Over Wen Hair Products Gets Preliminary Settlement Approval*, CBS L.A. (Oct. 31, 2016, 11:18 PM), <http://losangeles.cbslocal.com/2016/10/31/class-action-lawsuit-over-wen-hair-products-gets-preliminary-settlement-approval/>.

9. *Id.*

limited: the Administration issued a mere safety warning upon learning WEN received over 21,000 complaints about hair loss, rashes, and balding.¹⁰ In a request for comment, an FDA spokesperson told CBS News “the company . . . did not address safety concerns related to hair loss. We do not know if the company has other safety data, and we do not have the legal authority to require a cosmetics firm to provide product safety information.”¹¹ Perhaps more troubling, WEN products remain on store shelves today. This is the result of the FDA’s lack of authority to issue an independent recall on personal care products, no matter how clearly the circumstances necessitate one.¹²

While controversial, many scientific studies have concluded that chemicals contained in cosmetics cause health problems, such as birth defects, endocrine disruption, reproductive development abnormalities, and cancer.¹³ Despite these studies, the United States remains one of few modern countries that fails to regulate the chemicals contained in cosmetic products prior to distribution for sale.¹⁴ Today, pending legislation – the Personal Care Products Safety Act – would serve as a starting point for the regulation of personal care products in the United States.¹⁵ Many portions of the current bill, however, could be improved either prior to implementation or before a similar bill is pro-

10. *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> (last updated May 9, 2017).

11. Duncan, *supra* note 3.

12. *See infra* Section I.B.3. (discussing how pending legislation would grant the FDA the authority to issue an independent recall).

13. Compare TIM LITTLE ET AL., INV’R ENVTL. HEALTH NETWORK, BENEATH THE SKIN: HIDDEN LIABILITIES, MARKET RISK AND DRIVERS OF CHANGE IN THE COSMETICS AND PERSONAL CARE PRODUCTS INDUSTRY 13 (2007), <http://www.iehn.org/filesalt/IEHNCosmeticsReportFin.pdf> (listing the health implications of nanoparticles once they enter human cells), and Walter J. Crinnion, *Toxic Effects of the Easily Avoidable Phthalates and Parabens*, 15 ALT. REV. MED. 190 (2010), <http://www.altmedrev.com/publications/15/3/190.pdf> (asserting that phthalates should be avoided whenever possible due to their correlation with potentially serious health effects), with *Phthalates- Consumers: Health and Safety*, AM. CHEMISTRY COUNCIL, <http://phthalates.americanchemistry.com/Health-and-Safety/> (last visited Oct. 2, 2017) (suggesting individuals need not avoid phthalates because studies have not shown a direct effect of phthalates on human health).

14. *See infra* Section I.B.1. (discussing the Personal Care Products Safety Act).

15. *See infra* Section I.B.3.

posed and passed in the future.¹⁶ In order to adequately protect consumers, it is essential for the United States to uniformly regulate the cosmetics industry at the federal level.¹⁷

This Note argues that to best protect consumers, Congress should grant the FDA authority to require manufacturers to register products and the ingredients they contain with the FDA prior to sale, as well as the independent authority to recall products. In the meantime, consumer education is the best way to protect consumers. Many countries, including all members of the European Union, have taken these measures.¹⁸ Additionally, the FDA already has authority to regulate other types of consumer goods, such as drugs, food (organic/GMO), and tobacco products.¹⁹ Because personal care products may be equally dangerous, new regulations are necessary to adequately protect consumers.

Part I of this Note surveys the dangers associated with the current lack of regulations in the United States, and presents a comparison to personal care product regulations in the European Union. Part II asserts that some EU regulatory requirements should be included in pending legislation, the Personal Care and Products Safety Act, or amended to include additional regulations in the future. These additional measures are necessary to adequately protect American consumers from the unregulated ingredients to which they are currently exposed.²⁰ Because congressional action is never a certainty, Part II concludes by proposing education as the best method for protecting Americans until formal regulations are implemented.

16. See *infra* Section II.C.

17. But see 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, 254-55 (2012) (arguing "there is great opportunity to pursue improved regulation of cosmetics at the state and local levels").

18. See *infra* Part II.

19. See generally U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/default.htm> (last updated Oct. 2, 2017) (demonstrating the FDA's authority to regulate consumer goods).

20. See *infra* Part II.

I. BACKGROUND

A. *The Danger of Personal Care Product Ingredients*

Each day, the average American consumer uses ten personal care products that, together, may contain up to 126 distinct ingredients.²¹ Of the 75,000 chemicals registered for consumer use in the United States, one in seven are related to the personal care industry.²² It is crucial to realize these chemicals can be absorbed through the skin.²³ And because consumers typically use the products on a daily basis, they subject themselves to “additive contributions” – a bioaccumulation of chemicals in the body.²⁴ Unlike allergic reactions, bioaccumulation may remain dormant, masking derivative health problems until many years later.²⁵ Additionally, the chemicals contained within the products may exacerbate existing health problems.²⁶ Together, exposure to many harmful ingredients may cause more severe adverse health effects than exposure to one ingredient alone.²⁷ In sum, unbeknownst to the consumer, these products cause a variety of health problems that, in many instances, are untraceable.²⁸

B. *Regulating Personal Care Products*

This section surveys the United States standards and regulations governing the ingredients that may be used in personal care and cosmetic products. A discussion of the regulations applicable throughout the EU follows, noting how the EU

21. LITTLE ET AL., *supra* note 13, at 2.

22. *Id.*

23. *Id.*

24. Mary L. Lyndon, *The Toxicity of Low-Dose Chemical Exposures: A Status Report and a Proposal*, 52 JURIMETRICS J. 457, 460 n.13, 472 (2012) (reviewing CARL F. CRANOR, LEGALLY POISONED: HOW THE LAW PUTS US AT RISK FROM TOXICANTS (2011)); *see also* Patrick Regoniel, *What is the Difference Between Bioaccumulation and Biomagnification?*, KNOJI, <https://environment.knoji.com/what-is-the-difference-between-bioaccumulation-and-biomagnification/> (last visited Nov. 14, 2017).

25. *See* Lyndon, *supra* note 24, at 468.

26. *Id.* at 472 n.73.

27. *Id.* at 472.

28. *See* LITTLE ET AL., *supra* note 13, at 2–4.

implements safety measures extending far beyond what the United States' current regulatory legislation, the Federal Food Drug and Cosmetic Act of 1938 (FFDCA),²⁹ covers.

1. United States

a. Current authority of the FDA

Current legislation regulating personal care products, written in 1938, does not bar specific ingredients from personal care products.³⁰ Rather, the FFDCA³¹ prohibits the adulteration or misbranding of cosmetics in interstate commerce,³² along with the introduction or delivery,³³ receipt,³⁴ and manufacture³⁵ of the same.³⁶ A cosmetic is adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual"³⁷

29. See *infra* Section I.B.2.

30. According to the FDA:

Some examples are skin moisturizers, perfumes, lipsticks, fingernail polishes, makeup, shampoos, permanent waves, hair colors, toothpastes, and deodorants. These products and their ingredients are not subject to FDA premarket approval, except color additives (other than coal tar hair dyes). Cosmetic companies have a legal responsibility for the safety of their products and ingredients.

Cosmetics Safety Q & A: Personal Care Products, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ResourcesForYou/Consumers/ucm136560> (last updated Dec. 9, 2015).

31. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399g (2016).

32. *Id.* § 331(b).

33. *Id.* § 331(a).

34. *Id.* § 331(c).

35. *Id.* § 331(g).

36. *Id.* § 321(i) (defining a cosmetic as: "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap").

37. *Id.* § 361(a); see also *id.* § 361(b) (defining a cosmetic as adulterated "[i]f it consists in whole or in part of any filthy, putrid, or decomposed substance."); *id.* § 361(c) (defining a cosmetic as adulterated "[i]f it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health"); *id.* § 361(d) (defining a cosmetic as adulterated "[i]f its container is composed in whole

Today, the Office of Cosmetics and Colors, a subdivision of the FDA, implements the adulterated substance provision of the FFDCFA; the Office is responsible for ensuring cosmetics are safe for their intended use, and that they are not adulterated or misbranded.³⁸ In addition to monitoring compliance with regulations, the Office oversees research programs, and conducts industry outreach, educates consumers, and administers post-market surveillance to address potential health risks associated with the chemical or biological contaminants.³⁹

Current law grants the FDA the authority to enforce the FFDCFA in three ways when it has “reliable scientific information showing that the product is harmful when consumers use it according to directions on the label or in the customary way.”⁴⁰ First, the FDA may seek an injunction against the manufacturer of the adulterated cosmetic in a federal district court.⁴¹ The FDA may also pursue libel for condemnation proceedings against a manufacturer for alleged misbranding.⁴² Finally, products deemed adulterated may be seized, destroyed, and potentially disposed of “after entry of the [final] decree.”⁴³ Furthermore, as noted by the Supreme Court, beyond the enumerated penalties in the FFDCFA, manufacturers are subject to reputational harm upon the “announcement that their cosmetics have been seized as ‘adulterated.’”⁴⁴

However, while the FDA may *aid* manufacturers in *warning* consumers of a recall, the Administration may not *issue a recall* of harmful products—this ability belongs entirely to the manu-

or in part, of any poisonous or deleterious substance which may render its contents injurious to health”).

38. *How the FDA Evaluates Regulated Products: Cosmetics*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm262353.htm> (last updated Mar. 15, 2017).

39. *CFSAN - What We Do*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/WhatWeDo/default.htm> (last updated Aug. 18, 2016).

40. *Parabens in Cosmetics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm128042.htm> (last updated Oct. 5, 2016).

41. 21 U.S.C. § 332; *see also id.* § 332(b) (detailing a defendant-manufacturer’s right to demand trial by jury).

42. *Id.* § 334(a).

43. *Id.* § 334(d)(1).

44. *Gardner v. Toilet Goods Ass’n*, 387 U.S. 167, 172 (1967).

facturer.⁴⁵ And while manufacturers found in violation of the FFDCa may face consequences, the FDA still cannot review product ingredients in cosmetics before they are sold to consumers.⁴⁶ However, an exception exists, permitting pre-market FDA approval for limited products for cosmetics that make drug-like claims.⁴⁷ Unlike cosmetics, these products are subject to FDA pre-market approval because manufacturers claim a therapeutic use for the product or consumers use the products to treat a condition, such as dandruff.⁴⁸ Referred to by the cosmetics industry as “cosmeceuticals,” these products are screened by the FDA to ensure the truthfulness behind the manufacturer’s claims.⁴⁹ For example, the FDA regulates dandruff shampoo because it is marketed with the promise of reducing dandruff on the scalp.⁵⁰

Because many manufacturers make drug-like claims regarding how their products will work without the necessary FDA approval, the FDA frequently sends warning letters allowing a manufacturer either to change how the product is advertised or risk further action.⁵¹ An example of further action occurred in 2007, when the FDA responded to a manufacturer’s unfounded drug-like claims related to an eyelash applicator.⁵² The FDA seized approximately \$2 million worth of product from Jan Marini Skin Research, Inc. (JMSR) based on the belief that the product could harm users’ eyesight, along with other

45. See Roseann B. Termini & 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, 271–72 (2008) (emphasis added) (explaining that the FDA does not have the power to recall a product).

46. *Id.* at 263.

47. *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm> (last visited Nov. 14, 2017).

48. *Id.*

49. *Id.*

50. *Id.*

51. *Id.*

52. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., THE ENFORCEMENT STORY: \$2 MILLION OF HARMFUL “COSMETIC” EYE PRODUCT SEIZED 4- 8 (2008), <https://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129814.pdf>.

adverse ocular effects.⁵³ Consumers should not, however, overvalue the “cosmeceutical” exception—products deemed “hypoallergenic,” for example, are not regulated.⁵⁴ Indeed, the FDA acknowledges “no Federal standards or definitions [exist] that govern the use of the term ‘hypoallergenic.’ The term means whatever a particular company wants it to mean.”⁵⁵ While the FDA has limited enforcement power, the Administration has adopted creative approaches to more adequately protect consumers, namely the Voluntary Cosmetic Regulation Program.⁵⁶

b. The Voluntary Cosmetic Registration Program

The Voluntary Cosmetic Registration Program (VCRP) is an FDA post-market reporting program allowing cosmetics manufacturers to voluntarily register their manufacturing or packing establishments, the ingredients contained in an individual product, or both.⁵⁷ According to the FDA, participating in the program assists the agency “in carrying out its responsibility to regulate cosmetics.”⁵⁸ Notably, the FDA considers receiving “voluntary submissions” through the VCRP as “*the best information available* about cosmetic products and ingredients, their frequency of use, and businesses engaged in their manufacture and distribution.”⁵⁹ Put differently, the FDA’s best information regarding the exact ingredients contained in personal care products, some of which consumers apply directly to their

53. *Id.*

54. “Hypoallergenic” Cosmetics, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/Labeling/Claims/ucm2005203.htm> (last updated Nov. 3, 2017).

55. *Id.*

56. Voluntary Cosmetic Registration Program, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/cosmetics/registrationprogram/ucm2005171.htm> (last updated Dec. 4, 2017) [hereinafter VCRP].

57. *Id.*

58. *Id.* But cf. Termini & Tressler, *supra* note 45, at 271 (casting doubt that “corporations would voluntarily recall a product and risk bad publicity if they were not requested to do so by the FDA”).

59. VCRP, *supra* note 56 (emphasis added) (first citing Voluntary Cosmetic Registration Program, 73 Fed. Reg. 76,360 (Dec. 16, 2008); then citing Voluntary Registration of Cosmetic Product Establishments, 69 Fed. Reg. 9339 (Feb. 27, 2004)).

skin, is based on voluntary submissions from manufacturers.⁶⁰ The VCRP provides two benefits to manufacturers: (1) their participation assists the Cosmetic Ingredient Review panel's safety review process; and (2) they may use the FDA database to backup product information on the secure, off-site server.⁶¹

The Cosmetic Ingredient Review (CIR) is a panel of independent experts tasked with evaluating cosmetic ingredient safety in the VCRP database.⁶² The CIR, according to the FDA, is an "independent, industry-funded panel of scientific experts" that determines whether the ingredients are safe.⁶³ At the meetings, the CIR discusses which ingredients the panel believes should be reviewed, then completes a Scientific Literature Review to determine which specific ingredients are hazardous to human health.⁶⁴ To date, the CIR has found merely twelve ingredients "unsafe."⁶⁵ As the FDA notes, however, these numbers do not reflect the total amount of manufacturers or personal care products in the United States since the VCRP is voluntary.⁶⁶

2. *The European Union*

Unlike the United States, the EU has adopted legislation allowing member states to require manufacturers to meet pre market safety standards.⁶⁷ The EU regulates personal care prod-

60. *Id.*

61. VCRP, *supra* note 56.

62. *Id.*

63. *Id.*; see also COSM. INGREDIENT REV., <http://www.cir-safety.org> (last visited Nov. 13, 2017) (stating the panel's goal of assessing the safety of cosmetic ingredients "in an open, unbiased, and expert manner" and publishing peer-reviewed results of the same).

64. COSM. INGREDIENT REV., COSMETIC INGREDIENT REVIEW PROCEDURES 11-15 (Oct. 2010), <http://www.cir-safety.org/sites/default/files/pdf1.pdf> [hereinafter COSMETIC INGREDIENT REVIEW PROCEDURES]. FDA representatives attend CIR meetings but they cannot vote. VCRP, *supra* note 56.

65. CIR Findings- Unsafe, COSM. INGREDIENT REV., <http://www.cir-safety.org/sites/default/files/unsafe-042017posted062017.pdf> (last visited Nov. 14, 2017) (listing ingredients deemed unsafe).

66. *Registration Reports*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Cosmetics/RegistrationProgram/RegistrationReports/default.htm> (last updated Dec. 4, 2017).

67. See Council Regulation 1907/2006 on REACH, 2006 O.J. (L 136) (EC) [hereinafter REACH Regulation]; see also Council Regulation 1223/2009 on Cosmetic Products, 2009 O.J. (L 342) [hereinafter Cosmetic Regulation], <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02009R1223-20150416&from=EN>.

ucts under two different legislative acts.⁶⁸ First, the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), implemented in 2006, governs the regulation of both newly created and existing chemicals used throughout the EU.⁶⁹ Additionally, the Cosmetic Regulation, strengthened in 2009, outlines which ingredients are barred for use in cosmetics.⁷⁰ Together, EU regulations effectively “plac[e] the burden on chemical companies to prove the safety of their products, and in the interim, ban[] ingredients that may be harmful.”⁷¹

The first legislative measure, REACH, was a consolidation of other legislation adopted because a “large number of substances ha[d] been manufactured and placed on the market in Europe for many years, sometimes in very high amounts, and yet there [wa]s insufficient information on the hazards that they pose to human health and the environment.”⁷² The European Chemicals Agency, created by the REACH legislation, regulates chemicals by managing manufacturers’ registrations.⁷³ Registrations must contain “information on the properties of the[] chemical substances,” their hazards, and their risks.⁷⁴ REACH is based on a “one substance, one registration” principle: all manufacturers and importers of the same substance must file their registrations jointly.⁷⁵

Requiring data sharing between manufacturers reduces registration costs and prevents unnecessary animal testing; according to the Agency, “[n]ew studies on vertebrate animals cannot be repeated.”⁷⁶ Data sharing is also required for chemicals falling into the “high concern” category, including those contain-

68. *Id.*

69. REACH Regulation, *supra* note 67, art. 7.

70. Cosmetic Regulation, *supra* note 67, annex 2.

71. Shah & Taylor, *supra* note 17, at 240.

72. REACH, EUR. COMMISSION, http://ec.europa.eu/environment/chemicals/reach/reach_en.htm (last updated Aug. 24, 2016).

73. *Id.*

74. *Id.*

75. *Registration*, EUR. CHEMICALS AGENCY, <https://echa.europa.eu/regulations/reach/registration> (last visited Nov. 14, 2017).

76. *Data Sharing*, EUR. CHEMICALS AGENCY, <https://echa.europa.eu/regulations/reach/registration/data-sharing> (last visited Nov. 14, 2017).

ing carcinogens, those harmful to human reproductive health, and those with bioaccumulative or toxic properties.⁷⁷ Even if a manufacturer's submission meets the Agency's standards initially, registration may be revoked if the Agency later recognizes a safer alternative.⁷⁸

Depending on the member state, violations of REACH regulations may result in either criminal or administrative proceedings.⁷⁹ To ensure compliance, the member states' authorities can restrict the use of a chemical if required registration criteria is not met.⁸⁰ Also, if a chemical presents an "unacceptable risk" to consumers or the environment, member states or the EU Commission can propose restrictions.⁸¹ Although recalls are typically temporary, they may be renewed and lead to "permanent legislation" banning the product.⁸² As previously discussed, the FDA lacks similar authority to issue independent recalls.⁸³

Striving for continuous improvement, the EU Commission reviews REACH legislation every five years to determine whether legislative goals have been achieved.⁸⁴ The Commission also reviews European Chemicals Agency (ECHA) reports on REACH implementation and operation, and input from each member state indicating REACH's local efficacy.⁸⁵ Together, the Commission views these reports and legislation as evidence of

77. REACH Regulation, *supra* note 67, arts. 33, 57.

78. REACH, *supra* note 72.

79. See generally MILIEU, REPORT ON PENALTIES APPLICABLE FOR INFRINGEMENT OF THE PROVISIONS OF THE REACH REGULATION IN THE MEMBER STATES (2010) [hereinafter REPORT ON PENALTIES], http://ec.europa.eu/environment/chemicals/reach/pdf/report_reach_penalties.pdf (describing different ways member states have enforced REACH regulations).

80. *Understanding REACH*, EUR. CHEMICALS AGENCY, <https://echa.europa.eu/regulations/reach/understanding-reach> (last visited Nov. 14, 2017).

81. *Restriction Procedure*, EUR. CHEMICALS AGENCY, <https://echa.europa.eu/regulations/reach/restrictions/restriction-procedure> (last visited Nov. 14, 2017).

82. *Specific Products, Standards and Risks*, EUR. COMMISSION, http://ec.europa.eu/consumers/consumers_safety/product_safety_legislation/standards/index_en.htm (last visited Nov. 14, 2017).

83. See *infra* Section I.B.3. (discussing how pending legislation would grant the FDA the authority to issue an independent recall).

84. *The Reach REFIT Evaluation (REACH Review 2017)*, EUR. COMMISSION, http://ec.europa.eu/environment/chemicals/reach/review_2017_en.htm (last visited Nov. 14, 2017).

85. EUR. COMM'N, EVALUATION AND FITNESS CHECK (FC) ROADMAP 3 (2017), http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_005_reach_refit_en.pdf [hereinafter ROADMAP].

the effectiveness of REACH and considers potential changes accordingly.⁸⁶ For example, by June 2019, the Commission will review REACH Article 33 to determine whether it should propose an amendment adding more dangerous substances to the “high concern” category.⁸⁷

Additionally, the second piece of legislation governing personal care products in the EU is the Cosmetic Regulation.⁸⁸ The Cosmetic Regulation lays out registration, safety, and mandatory reporting requirements for when a product causes “serious undesirable effects.”⁸⁹ Before a product is registered, “the manufacturer must ensure that cosmetic products undergo an expert scientific safety assessment,” which is outlined by the EU Commission.⁹⁰ If the product meets Commission standards, it may then be sold in any member state.⁹¹

Supplementing strong pre-market surveillance and consumer education in the EU, the Cosmetic Regulation details how a product may be removed from the market should a consumer experience “serious undesirable effects.”⁹² Each member state is responsible for market surveillance of the products within its respective state.⁹³ When market surveillance authorities from a member state discover an adverse effect caused by a cosmetic product, they must notify the national authorities in that state, and create a report on the remedial steps taken by “the responsible person or distributor.”⁹⁴ A “responsible person” is appointed as a readily identifiable individual who is responsible for the initial registration of a cosmetic product and participates in the subsequent notification process that ensues if the regis-

86. *Id.* at 1.

87. REACH Regulation, *supra* note 67, art. 138.

88. *Legislation*, EUR. COMMISSION, https://ec.europa.eu/growth/sectors/cosmetics/legislation_en (last visited Nov. 14, 2017).

89. *Id.*

90. *Scientific and Technical Assessment*, EUR. COMMISSION, https://ec.europa.eu/growth/sectors/cosmetics/assessment_en (last visited Nov. 14, 2017).

91. *Id.*

92. *Market Surveillance*, EUR. COMMISSION, https://ec.europa.eu/growth/sectors/cosmetics/market-surveillance_en (last visited Nov. 14, 2017).

93. *Id.*

94. *Id.*

tered product causes “serious undesirable effects,” which ensures accountability.⁹⁵

3. *Pending reform in the United States*

Reintroduced to the Senate in May 2017 by Senator Diane Feinstein (D-CA), the Personal Care Products Safety Act (PCPSA) is a bipartisan bill that, if passed, would improve consumer safety by protecting consumers from ingredients proven to be harmful to human health.⁹⁶ The PCPSA would amend the Federal Food, Drug, and Cosmetic Act, granting the FDA the necessary authority to issue an independent recall, among other changes.⁹⁷ The PCPSA is composed of two parts. First, “Title I—Cosmetic Safety” includes the registration and review of cosmetics, reporting adverse effects, inspection and mandatory authority to recall products, exceptions for small businesses, animal testing alternatives, enforcement, and consumer information.⁹⁸ Second, “Title II—Fees Related to Cosmetic Safety” explains fees, which would be imposed on manufacturers, necessitated to fund the new provisions set forward in Title I.⁹⁹

At the heart of the PCPSA is a specific amendment to the FFDCFA,¹⁰⁰ which further defines the meaning of “adulterated” and requires new protocol to be followed before products can be sold to consumers.¹⁰¹ The proposed amendment,¹⁰² as follows, states that a cosmetic product is “adulterated,” and thus banned:

(f) If the methods used in, or the facilities or controls used for, its manufacture, processing,

95. *Legislation, supra* note 88.

96. *Washington: Feinstein Testifies in Support of Personal Care Products Safety Act*, PLUS MEDIA SOLUTION (Sept. 22, 2016), <https://www.feinstein.senate.gov/public/index.cfm/press-releases?id=6237DD59-167A-4B5C-861C-4A95F117739F> [hereinafter *Feinstein Testifies*]; see also Personal Care Products Safety Act, S. 1113., 115th Cong. (2017).

97. S. 1113 § 105.

98. See *id.* §§ 101–05.

99. *Id.* § 201.

100. 21 U.S.C. § 361 (2016).

101. S. 1113 § 113(b).

102. *Id.*

packing, or holding do not conform to current good manufacturing practice, as prescribed by the Food and Drug Administration in accordance with section 610.

(g) If it contains, after the date prescribed under section 608(e), an ingredient that the Food and Drug Administration has determined under section 608(d)(4) to be not safe, or not safe under the conditions of use recommended or suggested in the label or a non-functional constituent that the Food and Drug Administration has determined under section 608(d)(4) to be not safe or not safe in the amount present in the cosmetic.

(h) If it is a cosmetic product for which any requirement of section 609 (relating to safety substantiation) is not met.¹⁰³

In effect, this means that the FDA will review five ingredients per year to determine whether they are harmful. For the first year, Congress will require the ingredients tested by the FDA to include "diazolidinyl urea, lead acetate, methylene glycol/methanediol, formaldehyde, propyl paraben, and quaternium-15."¹⁰⁴ Thereafter, the FDA may consider advisory committee recommendations and public comment from consumers to determine which ingredients should be tested.¹⁰⁵ After finding an ingredient adulterated, the FDA will be able to issue a mandatory recall.¹⁰⁶ Ultimately, ingredients deemed adulterated will be listed on the FDA website.¹⁰⁷

Further, the passage of the PCPSA will bring several changes for manufacturers in the cosmetic industry. First, manufacturers will be required to submit a cosmetic ingredient

103. *Id.*

104. *Id.* § 608(a)(3)(A).

105. *Id.* § 608(a)(3)(B).

106. *Id.* § 613(b)(1) (explaining mandatory recall authority when "the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic within the time and in the manner prescribed by the [FDA]").

107. *Id.* § 608(b).

statement (CIS) to the FDA, listing all ingredients used in each of their products.¹⁰⁸ For products that are already on the market, this means manufacturers will have until the end of the calendar year in which the PCPSA is implemented to comply.¹⁰⁹ For new products, this will mean submitting a CIS sixty days before the product is marketed and sold to consumers.¹¹⁰ Each submission will require detailed information, such as the facility where the product is made, the full brand name of the product as it appears on the label, the applicable cosmetic category of the product, a list of the ingredients contained in the product including fragrances and flavors, the title and contact information of the individual submitting the statement, and proper labeling as required by section 614 of the PCPSA.¹¹¹ The CIS must also include “attestation that such person has substantiated the safety of the product and its ingredients in accordance with the requirements of section 609.”¹¹²

After receiving submissions, the FDA will then review the CIS in order to determine whether, based on the ingredients it contains, the product has “a reasonable probability of causing serious adverse health consequences or death to humans.”¹¹³ If found harmful, the product would be suspended, and the manufacturer would be required to correct the issue before the suspension is lifted.¹¹⁴ Additionally, if the FDA determines that the product in question may have contaminated other products at the facility, the Administration would have the power to suspend the facility until the violation has been addressed, corrected, and a final determination is made that the suspension is no longer necessary.¹¹⁵

The introduction of the 2017 PCPSA was not the first time senators have taken the initiative in amending the Federal Food,

108. *Id.* § 606(a), (b).

109. *Id.* § 606(b)(1).

110. *Id.* § 606(b)(2)(A).

111. *Id.* § 606(c)(2).

112. *Id.* § 606(e)(1).

113. *Id.* § 607(b).

114. *Id.* § 607(c).

115. *Id.* § 607(a).

Drug, and Cosmetic Act.¹¹⁶ On September 22, 2016, the Committee held congressional hearings regarding the same bill. While introducing the bill at the hearing, Senator Feinstein testified to the importance of updating the law surrounding cosmetic regulations, which are nearly eighty years old.¹¹⁷ In addition to bipartisan support in the Senate,¹¹⁸ the PCPSA has also gained support from a wide range of companies and consumer health organizations, including: “L’Oréal, which makes Garnier, Maybelline, Lancome, Redken, Kiehl’s, Essie, and the Body Shop products; Unilever, with brands such as Dove, Suave, and Vaseline; [and] California Baby, a popular natural children’s brand; March of Dimes; Society for Women’s Health Research; American Cancer Society.”¹¹⁹ As Feinstein explained, “[t]hese are just some of the 17 companies, representing over 160 brands, and 24 organizations that have come together to form exactly the type of broad coalition needed to get a bill done.”¹²⁰

II. THE CALL FOR CHANGE IN THE UNITED STATES

While recent studies have shown the dangers of many ingredients contained in personal care products,¹²¹ proving non-visible injuries remains difficult for the average consumer. In many instances, courts have dismissed plaintiffs’ claims where plaintiffs have alleged manufacturers misrepresented products as safe.¹²² Similarly, courts have repeatedly dismissed claims where the plaintiff is unable to point to current injury, refusing

116. See Personal Care Products Safety Act, S. 1014, 114th Cong. (2015).

117. *Feinstein Testifies*, *supra* note 96.

118. See S. 1113 - *Personal Care Products Safety Act*, CONGRESS.GOV, <https://www.congress.gov/bill/115th-congress/senate-bill/1113/cosponsors> (last visited Nov. 14, 2017) [hereinafter CONGRESS.GOV] (providing a complete list of senators who cosponsored the PCPSA).

119. *Feinstein Testifies*, *supra* note 96.

120. *Id.*

121. See generally Lyndon, *supra* note 24, at 487-88 (discussing chemical exposures and a range of negative health outcomes).

122. See, e.g., *Herrington v. Johnson & Johnson Consumer Cos.*, No. C. 09-1597 CW, 2010 U.S. Dist. LEXIS 90505, at *29 (N.D. Cal. Sept. 1, 2010) (dismissing plaintiffs’ claim under California’s Unfair Competition Law where “the alleged non-disclosures [were] not actionable” because plaintiffs failed to “aver[] facts that show that the levels of these substances caused them or their children harm, under the objective test for materiality . . .”).

to accept scientific studies showing a plaintiff will suffer a future injury.¹²³ Thus, it is clear that consumers have limited recourse after being exposed to ingredients that are associated with serious health problems. And with no FDA pre-market regulations as to the ingredients personal care products may contain, there is no real alternative solution.

There are several changes this Note will discuss which, if implemented, would dramatically improve consumer safety. In addition to the proposed changes set forward in pending legislation – the Personal Care Products Safety Act – other measures taken in the EU would serve as beneficial additions to these proposed changes. Because most American consumers believe they are safely using personal care products, there is a present need for consumer education until more stringent regulations are successfully implemented. This Note will analyze these possibilities in detail to show that together, adopting these changes would best protect American consumers from the harms they are so frequently exposed to.

A. *Pre-Market Surveillance*

In the United States today, there is no pre-market registration requirement of personal care products allowing the FDA to review ingredients.¹²⁴ Instead, the current safety protocol is limited to a voluntary program; as discussed, the Cosmetic Ingredient Review (CIR) panel only reviews the safety of cosmetics if the manufacturer first participates in the voluntary registration program, the VCRP.¹²⁵ To date, the CIR panel has

123. *See, e.g., id.* at *13 (dismissing plaintiffs' claims for lack of standing, where plaintiffs did not "allege that 1,4-dioxane and formaldehyde are in fact carcinogenic for humans."); *Crouch v. Johnson & Johnson Consumer Cos.*, No. 09-CV-2905 (DMC), 2010 U.S. Dist. LEXIS 37517, at *11-12 (D.N.J. Apr. 15, 2010) (dismissing a defective product claim where a chemical was not banned by FDA, but permitting claims related to banned ingredients to proceed); *Koronthaly v. L'Oreal USA, Inc.*, No. 07-CV-5588 (DMC), 2008 U.S. Dist. LEXIS 86419, at *11-12 (D.N.J. Oct. 23, 2008) (denying a motion to reconsider dismissal of plaintiff's complaint alleging consumer fraud because the injury was "a purely subjective allegation of harm" and FDA does not regulate lead contained in lipstick).

124. *See supra* Section I.B.3. (discussing how pending legislation would grant the FDA the authority to conduct, albeit limited, pre-market review of ingredients).

125. COSMETIC INGREDIENT REVIEW PROCEDURES, *supra* note 64, at 11.

found only twelve ingredients dangerous.¹²⁶ If registration were required, however, it is highly likely that the CIR panel would find far more ingredients unsuitable for consumption based on the sheer volume of products on the market.¹²⁷ Additionally, if Congress required registration, as proposed in the PCPSA, the FDA would be able to protect consumers swiftly by recalling all products manufactured at a particular facility and made up of similar, harmful formulations.¹²⁸ Accordingly, the enactment of new regulations to ensure consumer safety without any substantial increase in government spending will likely boast even greater bipartisan support in the future.

Presently, the FDA cannot ensure ingredients are safe before manufacturers place personal care products on the market because it lacks the authority to compel manufacturers to turn over information related to internal safety testing.¹²⁹ Quite differently, in the EU, each manufacturer is responsible for proving the safety of its products through pre-approved analytical methods.¹³⁰ By increasing pre-market surveillance, requiring manufacturers to produce safety data, it becomes less likely that a recall would be necessary in the future.

Pending legislation, the Personal Care Products Safety Act, is a step in the right direction in further protecting consumers; however, if implemented, it still would not protect American consumers in a timely fashion, given the serious, negative health effects the ingredients cause.¹³¹ If implemented, the Act would require manufacturers to complete a Cosmetic Ingredient Statement (CIS) by submitting all ingredients contained in new and existing cosmetics, such as fragrances and perfumes.¹³² Manufacturers would be required to submit the CIS for new

126. See generally *CIR Findings- Unsafe*, *supra* note 65 (charting the six ingredients).

127. See Personal Care Products Safety Act, S. 1113, 115th Cong. § 604(2) (2017) (defining “cosmetic product” broadly); see also *id.* § 605(a)(1) (requiring all manufacturers of cosmetic products to register their facilities with the FDA); Shah & Taylor, *supra* note 17, at 210-13 (noting a variety of products containing potentially toxic ingredients).

128. See S. 1113 § 607(a).

129. See generally Duncan, *supra* note 3 (describing the scope of the FDA’s authority).

130. *Scientific and Technical Assessment*, *supra* note 90.

131. See *supra* Section I.B.1.

132. S. 1113 § 606(a), (b).

products sixty days before shelving the products in stores.¹³³ Products already on the market, however, would be granted a longer grace period; manufacturers would have until the end of the calendar year to comply with the FDA's new requirements and safety standard.¹³⁴ While pre-market surveillance represents a significant and positive change in the United States, allowing for such a long grace period for compliance contravenes the Act itself, which inherently recognizes the danger posed by these products and the need for new legislation in the first place. Furthermore, while the yearlong grace period may help manufacturers comply with new regulations without significant financial ramifications, these costs are negligible compared to the safety risks the products create.¹³⁵ Congress should instead immediately prioritize consumer safety, even if that means an FDA recall of all non-compliant products.

While the PCPSA would task the FDA with reviewing the safety of ingredients, the EU takes a more cost-efficient approach by requiring manufacturers to test their own products' safety. If the U.S. adopted this approach, the FDA could better conserve its resources and complete safety reviews in a more timely fashion.¹³⁶ Enhanced premarket surveillance would also be more effective than the current review panel in the United States, the CIR, which is currently tasked with reviewing voluntary submissions.¹³⁷

B. *The Recall Process*

The Federal Food, Drug, and Cosmetic Act,¹³⁸ which has been the law in the United States since 1938, does not grant the FDA

133. *Id.* § 606(b)(2)(A).

134. *Id.* § 606(b)(1).

135. See Philip Perry, *You'll Never Guess How Many Chemicals Are Inside Your Body Right Now*, BIG THINK (Aug. 30, 2017), <http://bigthink.com/philip-perry/youll-never-guess-how-many-chemicals-are-inside-your-body-right-now> (noting support from cosmetic industry participants for the PCPSA despite the financial burden imposed by regulations).

136. S. 1113 § 608(a)(3)(A) (prescribing five cosmetic ingredients to be reviewed in 2018).

137. *VCRP*, *supra* note 56 (noting that "product filings and establishment registrations are not mandatory" but the VCRP database is shared with the CIR).

138. 21 U.S.C. § 301 (2016).

the independent authority to issue a recall of personal care products, even if they are found to pose an immediate danger to consumers.¹³⁹ Instead, the FDA may only aid a manufacturer's recall announcement by issuing press releases through the media.¹⁴⁰ The PCPSA, however, would amend the definition of "adulterated" to encapsulate the new safety standards.¹⁴¹ More specifically, manufacturers would be responsible for reporting a "serious adverse event," resulting in "death; a life-threatening experience; inpatient hospitalization; a persistent or significant disability or incapacity; congenital anomaly or birth defect; or significant disfigurement, including serious and persistent rashes or infections."¹⁴²

Broadening FDA authority to issue independent recalls is necessary to protect consumers from unsafe products. In support of granting the FDA the ability to recall products independently, legislators should look to the EU as a model for change.¹⁴³ Consumers throughout the EU are protected by law, which allows the European Commission to issue an independent recall of substances with "unmanageable risks."¹⁴⁴ The United States, by relying on manufacturers to recall products, assumes that these manufacturers have consumers' best interests in mind when making business decisions. While it is true, as discussed by the Supreme Court,¹⁴⁵ that manufacturers' reputations become tarnished if their products are deemed unsafe, this is only true if a plaintiff's claim succeeds. Future reputational harm simply does not protect consumers from present, intangible health effects caused by repeated exposure to chemical ingredients.

Although manufacturers may notify the FDA if a product

139. Termini & Tressler, *supra* note 45 (explaining that it is up to the manufacturer, and not the FDA, to recall a product).

140. *Id.*

141. S. 1113 § 113(b) (proposing to amend the Food, Drug and Cosmetic Act's definition of prohibited cosmetics).

142. *Id.* § 611(a), (b)(2).

143. *See supra* Section I.B.2.

144. *Understanding REACH, supra* note 80.

145. *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167, 172 (1967).

causes a serious allergic reaction, it is extremely unlikely a manufacturer would report a potential for dormant adverse health effects.¹⁴⁶ While some manufacturers report widespread allergic reactions, there is no obligation to release details about complaints they perceive as minor, or complaints made about potential future adverse effects.¹⁴⁷ Even where safety reports are completed by the manufacturer, that manufacturer is not required to provide safety report information to the FDA.¹⁴⁸ For example, in response to WEN litigation, the FDA released a statement that added, “We do not know if the company has other safety data, and we do not have the legal authority to require a cosmetics firm to provide product safety information.”¹⁴⁹ Notably, if the FDA had the authority to mandate which ingredients could be used in personal care products, it would be irrelevant that a manufacturer was not required to turn over a safety report later. Until the FDA is granted the authority to gather the safety data information, consumers remain largely unprotected.

C. Additional Changes to Implement Following the European Union

While pending legislation in the United States today serves as a positive starting point for transforming cosmetics regulation, Congress should supplement the changes to make them more effective in the future. By considering measures the EU has implemented, Congress could strengthen legislation by protecting consumers and preventing wasteful spending — all at once. The proposed changes would also reduce the financial burden on manufacturers, albeit a less important consideration. Moreover, while reviewing potential regulatory provisions and determining which to adopt, Congress should remain cognizant of

146. See, e.g., Shah & Taylor, *supra* note 17, at 204; see also LITTLE ET AL., *supra* note 13, at 3 (explaining that due to a lack of pre-market review of cosmetics, “health threats or actual harms may only be found after widespread penetration into the market and exposure to potentially millions of customers.”).

147. Shah & Taylor, *supra* note 17, at 218.

148. *Id.*

149. Duncan, *supra* note 3.

purpose: to protect unsuspecting consumers.

One measure the EU has implemented that reduces government spending requires companies to register jointly for the chemical ingredient they plan to use in their products.¹⁵⁰ While not mentioned in the United States' pending legislation, this joint registration provision should be considered in the future.¹⁵¹ Although the EU system of cosmetics regulation works differently—in a two-step process that regulates both ingredients (REACH Legislation)¹⁵² then the safety of each product (Cosmetic Regulation)¹⁵³—shared-data testing amongst manufacturers would be equally effective if implemented in the United States. By requiring companies to apply jointly based on ingredients, the FDA would save time and costs in reviewing submissions. This would be an essential step toward reform because, as previously explained, there is no pre-market regulation of cosmetic ingredients in the United States today.¹⁵⁴

Yet another step the EU takes in regulating personal care products is a continuous review of prior decisions in which the EU found an ingredient safe.¹⁵⁵ After an ingredient is deemed safe, the manufacturer may then sell the product in any member state; however, if the EU later finds that a safer alternative exists, the prior “safe” designation and approval can be revoked.¹⁵⁶ In a world where technology is ever-advancing in a way that allows for the detection of even latent harm to the human body, this is a common-sense provision that the United States Congress should seriously consider. Based on the FDA's current structure, the Cosmetic Ingredient Review panel, currently tasked with reviewing voluntary submissions from manufacturers, could be assigned the new task of completing a

150. See *Data Sharing*, *supra* note 76.

151. See generally *Personal Care Products Safety Act*, S. 1113, 115th Cong. (2017) (requiring each manufacturer to register only its facilities with the FDA).

152. See *REACH*, *supra* note 72.

153. See *Cosmetic Regulation*, *supra* note 67.

154. See *Termini & Tressler*, *supra* note 45, at 261.

155. See *REACH Regulation*, *supra* note 67, art. 61.

156. *Id.* arts. 69–75.

periodic review of ingredients approved as safe in the past.¹⁵⁷ Alternatively, Congress could create a new division of the FDA solely tasked with ingredients review. Given the potential dangers posed by the ingredients in these products,¹⁵⁸ the importance of the resources dedicated to their detection cannot be overstated.

D. FDA Authority and Precedent

President Trump has vowed to decrease government regulations, and has already done so in a variety of ways.¹⁵⁹ Additionally, the U.S. Department of Health and Human Services' budget for fiscal year 2018 includes an \$854 million cut for the FDA.¹⁶⁰ Although faced with these potential difficulties, passing the PCPSA is not out of the question, as the Act has received bipartisan support.¹⁶¹ Regardless of whether the PCPSA legislation passes, increased FDA regulation on these products is an issue that will almost certainly arise again in the future.¹⁶²

When considering whether the FDA should have the authority to regulate personal care products, a useful comparison can be drawn to drugs, another type of consumer good the FDA already has the authority to regulate.¹⁶³ In regulating drugs prior to market sales, the FDA acknowledges the commonly accepted rationale that when a drug enters the human body, dangerous effects can result if the product is unsafe. The FDA

157. See *supra* Section I.B.1.b. (outlining the duties of the Cosmetic Ingredient Review panel).

158. See generally Lyndon, *supra* note 24 (describing the toxicity of even slight exposure to common chemicals).

159. Lauren Rosenblatt, *Trump Boasts About Dumping Many Obama-era Regulations. Here's a Look at Some*, L.A. TIMES (June 28, 2017), <http://www.latimes.com/politics/la-na-pol-congressional-review-regulations-20170628-htmstory.html>.

160. U.S. DEP'T OF HEALTH & HUMAN SERVS., PUTTING AMERICA'S HEALTH FIRST: FY 2018 PRESIDENT'S BUDGET FOR HHS 14 (2017), https://www.hhs.gov/sites/default/files/Consolidated%20BIB_ONLINE_remediated.pdf.

161. See Personal Care Products Safety Act, S. 1113, 115th Cong. (2017) (listing both Democrats and Republicans who are cosponsoring the bill).

162. See Shah & Taylor, *supra* note 17, at 204 ("Cosmetics regulation is particularly ripe for reform due to a renewed focus on hazardous cosmetics in the media.").

163. *Development & Approval Process (Drugs)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess> (last updated Aug. 17, 2017) (outlining the mandatory procedure for introducing new drugs to the market in the United States).

website boasts: “American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world.”¹⁶⁴ Because there is increasing evidence that many personal care products are absorbed through the skin,¹⁶⁵ the FDA should have the authority and resources necessary to meet the same “safest and most advanced . . . in the world” standard when regulating ingredients contained in cosmetics.¹⁶⁶

If taken literally, this would require the FDA’s pre-market approval for all personal care products.¹⁶⁷ While this may seem daunting, it is important to consider that some personal care products, the ones that make medical claims (i.e., “cosmeceuticals”) are already regulated.¹⁶⁸ The products that are not advertised with medical-benefit type claims, however, are no less dangerous than those that are.¹⁶⁹ Hiding in those products, too, are harmful preservatives and additives.¹⁷⁰ Requiring manufacturers to complete FDA mandated studies and submit results to the FDA before these products can be sold to consumers would require less spending than the FDA conducting those same studies. Like the EU, the FDA should prioritize designing acceptable testing methods for manufacturers to use as they complete the necessary testing. By doing so, the FDA would effectively increase consumer safety without a substantial increase in spending.

E. Education: The Best Alternative Until Legislation is Passed

Most consumers are shocked when they realize the ingredients in the shampoo they use each day have not been determined safe by some government entity. This perception is

164. *Id.*

165. See LITTLE ET AL., *supra* note 13, at 12 (“Scientists and consumers have expressed concern that nanoparticles may penetrate past human skin cells in the bloodstream and lymphatic system, and damage many forms of tissue.”).

166. *Development & Approval Process (Drugs)*, *supra* note 163.

167. See *id.*, for an overview of an analogous pre-market approval process.

168. “Cosmeceutical”, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Cosmetics/Labeling/Claims/ucm127064.htm> (last updated July 6, 2017).

169. See *supra* Section I.A.

170. See *supra* Section I.A.

common, which is why consumer education is essential until protective measures are implemented. While high-school students typically spend more than one year studying the three branches of government, far less—if any—emphasis is placed on the executive branch's many administrative agencies. But is it not essential for adolescents to become aware of how the government protects them as consumers? While bureaucracy is quite large and can be an overwhelming area of study, similar steps have been taken in teaching youth about nutrition; the U.S. Government has encouraged it, providing materials to be used in the classroom.¹⁷¹ Much like nutrition, it is essential for consumers to learn how their bodies can be affected by products they apply to their skin, which inevitably enter the body. As discussed, education on this matter is crucial because repeated use of products proven harmful can cause bioaccumulation over time, which has been linked to various adverse health effects.¹⁷²

In addition to classroom education, non-profit organizations serve as another useful resource consumers can learn from. For example, the Environmental Working Group has created a "Skin Deep Database," which is an "online safety guide for cosmetics and personal care products, launched in 2004 to help people find safer products, with fewer ingredients that are hazardous or that haven't been thoroughly tested."¹⁷³ For proactive consumers interested in protecting themselves and in many instances, their families, this database proves far more useful than a Google search.¹⁷⁴ Nonetheless, classroom education remains crucial to the usefulness of a database like this one. Without background knowledge of the dangers many of these products pose, consumers likely will not become concerned about the

171. See *Serving up MyPlate: A Yummy Curriculum*, U.S. DEP'T AGRIC., FOOD & NUTRITION SERV., <https://www.fns.usda.gov/tn/serving-myplate-yummy-curriculum> (last updated May 23, 2017) (providing classroom materials to help elementary school teachers integrate nutrition education into the curriculum).

172. See *supra* Section I.A.

173. FAQ, ENVIL. WORKING GROUP, <http://www.ewg.org/skindeep/faq/> (follow "What is EWG's Skin Deep?" hyperlink) (last visited Nov. 16, 2017).

174. See *id.*

harmful ingredients they contain in the first place.

CONCLUSION

Because it is difficult for consumers to recover from manufacturers absent concrete or imminent injuries,¹⁷⁵ granting the FDA the authority to conduct pre-market surveillance is the most prudent course of action to safeguard consumers from suffering the long-term consequences caused by routine exposure to the ingredients in their personal care products.¹⁷⁶ Pending legislation, if passed, could result in positive changes to ensure consumer protection, including independent authority to issue a recall and limited pre-market surveillance.¹⁷⁷ While the PCPSA would serve as a starting point for increasing the standard in regulating personal care products in the United States, further changes should be implemented to protect consumers in the future. Currently, manufacturers are not required to share safety data with the FDA,¹⁷⁸ nor would they be required to do so under the PCPSA. By contrast, the EU requires manufacturers to submit safety data based on pre approved methodologies.¹⁷⁹ The PCPSA instead proposes that the FDA conduct safety studies for five ingredients per year, beginning in 2018.¹⁸⁰

A better alternative in the future would be to follow the EU model, which would allow for a far broader safety analysis of ingredients. Then, instead of continuing to use the existing CIR panel to review voluntary submissions to the VCRP, the FDA could instead use the CIR panel to conduct limited post-market screening of the ingredients as a check on manufacturer studies. Similarly, Congress should look to the EU's standard of continuous review of products. In an age where technology allows for further developments in determining whether a product is safe, government must use these advancements to protect its

175. See *supra* note 120-23 and accompanying text.

176. Lyndon, *supra* note 24, at 472.

177. See *supra* Section I.B.3.

178. See *supra* Section I.B.1.a.

179. See REACH Regulation, *supra* note 67, arts. 33, 57.

180. Personal Care Products Safety Act, S. 1113, 115th Cong. § 608(a)(3)(A) (2017).

citizens. Thus, Congress should grant the FDA the authority to issue a recall when a product is deemed adulterated as well as when safer alternatives are discovered.

Even if pending legislation, the PCPSA, does not pass, Congress should continue its efforts to pass legislation that will protect consumers from harmful ingredients contained in personal care products. As highlighted throughout this Note, there are significant ways Congress could modify pending legislation to more adequately protect consumers in the future. In the meantime, consumer education is the best way to raise awareness and enable self-protection from the harmful ingredients contained in personal care products.