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Gender, Race & the Inadequate Regulation of Cosmetics

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Gender, Race & the Inadequate Regulation of Cosmetics

Marie Boyd[†]

ABSTRACT: Scholars and other commentators have identified failures in the regulation of cosmetics—which depends heavily on voluntary industry self-regulation—and called for more stringent regulation of these products. Yet these calls have largely neglected an important dimension of the problem: the current laissez-faire approach to the regulation of cosmetics disproportionately places women, and particularly women who are members of other excluded groups, at risk. This Article examines federal cosmetics law and regulation through a feminist lens. It argues that cosmetics law and regulation have lagged behind that of the other major product categories regulated by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act of 1938 because cosmetics are a gendered product and industry. In addition, conflicting views of the meaning of cosmetics among self-identified feminists, and differences in women’s relationships to cosmetics, mean that reform efforts must confront opposition and tension both within and outside of feminism. Ultimately, this Article questions the legitimacy of the current approach to cosmetics law and regulation. It concludes with several recommendations about how to address some of the failures of cosmetics law and regulation.

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INTRODUCTION

*The excessive use of lipstick has greatly increased the world's troubles. Lipstick is not healthful for women. It is not safe for men.*¹

The approximately fifty billion-dollar American cosmetics and beauty product industry is a gendered industry,² “created and maintained by women.”³ Whether this industry “is a harmful, objectifying creation or a source of strength and independence for women” has been described as “one of the most contentious debates in American feminisms.”⁴ Regardless of whether cosmetics are viewed as oppressive, liberating, or something else, many women use or are otherwise exposed to cosmetics.⁵ For example, 86 percent of women “use some

1. CHARLES WESLEY DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD 156 (1938) (reproducing 78 Cong. Rec. 8955-67 (May 16, 1934)) (statement of Senator Matthew Mansfield Neely during debate on legislation to extend federal food and drug law to cosmetics, which ultimately culminated in the passage of the Federal Food, Drug, and Cosmetic Act (FDCA) of 1938).

2. See ANYA COHEN, IBISWORLD INDUSTRY REPORT 32562: COSMETIC & BEAUTY PRODUCTS MANUFACTURING IN THE US 4 (Mar. 2018). The “cosmetic and beauty product industry” definition is not entirely coterminous with the FDCA’s definition of “cosmetics.” Compare *id.* at 2, with FDCA § 201(i), 21 U.S.C. § 321(i) (2012); see also *infra* Section I.A (discussing the FDCA’s definition of cosmetics).

3. Amber R. Clifford, *Feminism*, in THE AMERICAN BEAUTY INDUSTRY ENCYCLOPEDIA 111 (Julie Willett ed., 2010) (stating that “the key to the growth of the American beauty industry has been the involvement of women as consumers, creators, and icons”). Of course, men also use cosmetics and men’s personal care products are a growing industry. See RITA FREEDMAN, BEAUTY BOUND 225 (1986) (stating that men “are buying more cosmetics every year”); GWEN KAY, DYING TO BE BEAUTIFUL: THE FIGHT FOR SAFE COSMETICS (2005); KATHY PEISS, HOPE IN A JAR: THE MAKING OF AMERICA’S BEAUTY CULTURE (1998); Andria Cheng, *The Surprising Trend in Beauty? Skincare Sales Growing the Fastest Among Men’s Grooming Products*, FORBES (June 15, 2018, 6:00 AM), <https://www.forbes.com/sites/andriacheng/2018/06/15/the-gift-your-dad-really-wants-this-fathers-day-anti-aging-cream/#71241e5133ba> [<https://perma.cc/3DVZ-58XU>]; MINTEL, MEN’S PERSONAL CARE U.S. (Nov. 2017) [hereinafter MEN’S PERSONAL CARE].

4. Clifford, *supra* note 3, at 111; see, e.g., FREEDMAN, *supra* note 3, at 53, 231 (“Cosmetic strategies do help to normalize women, but they insidiously confirm female deviance even while counterbalancing it.”); *id.* at 231 (“If women don’t want to be regarded as decorative dolls, can they still delight in self-display? Is the ultimate goal to be accepted for oneself—uncoiffed, unadorned, and therefore, in the eyes of many, unkempt? . . . When are cosmetic transformations a negative act of self-rejection, and when are they a positive act of self-enhancement? . . . Many feminists have difficulty finding personal answers to such questions, for they, too, experience the conflict between conviction and convention, between the utopian ideal of natural beauty that includes all, and the actual ideal of cultured beauty that excludes so many.”); NAOMI WOLF, THE BEAUTY MYTH: HOW IMAGES OF BEAUTY ARE USED AGAINST WOMEN 113 (1992) (discussing the cosmetics industry and stating that “[w]asting women’s money is the calculable damage; but the damage this fraud does women through its legacy of the dread of aging is incalculable”); BELL HOOKS, BLACK LOOKS: RACE AND REPRESENTATION (1992).

5. This exposure may not be voluntary. For example, employers may have dress codes that require female employees to wear makeup. See *Jespersen v. Harrah’s Operating Co.*, 444 F.3d 1104 (9th Cir. 2006). Many women are exposed to cosmetics in their workplaces. For example, according to industry estimates, 96% of the workforce in nail salons and other personal care services in the United States is women. CENTERS FOR DISEASE CONTROL & PREVENTION, NAT’L INST. FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH), NAIL TECHNICIANS’ HEALTH AND WORKPLACE EXPOSURE CONTROL (internal citation omitted), <https://www.cdc.gov/niosh/topics/manicure/default.html> [<https://perma.cc/F7AH-H94U>] [hereinafter NIOSH, NAIL TECHNICIANS’ HEALTH]. There is also debate over whether or not cosmetics use can

type of make-up” and women comprise 92.6 percent of hairdressers, hairstylists, and cosmetologists—jobs that often involve exposure to cosmetics.⁶

The Food and Drug Administration (FDA) regulates “cosmetics” under the Federal Food, Drug, and Cosmetic Act (FDCA). Since enacting the FDCA in 1938, Congress has significantly changed and strengthened the Act’s provisions for the other major product categories that were present in the original 1938 Act (i.e., food, drugs, and medical devices). However, the cosmetics provisions—which span less than two pages of the approximately 500-page amended FDCA—have remained largely unchanged for the past eighty years.⁷

Accordingly, there is a substantial divide between the law and regulation for cosmetics and that for the other major product categories.⁸ Cosmetics are the least regulated of the major product categories within FDA’s jurisdiction.⁹ The Director of FDA’s Office of Cosmetics and Colors has stated, for example, that FDA does not “know the number of manufacturers [of tattoo inks (a type of cosmetic)], who they are, where they are, and what they make.”¹⁰ The Director has also indicated that FDA is “just seeing the tip of the iceberg” in terms of the reporting of adverse events related to cosmetics in the voluntary reporting system.¹¹

The cosmetics industry has argued that “[c]osmetics are the safest products that FDA regulates.”¹² Yet this does not mean that cosmetics are safe, given the

ever be truly voluntary given societal pressures. *See, e.g.*, FREEDMAN, *supra* note 3, at 48 (discussing beauty routines and the “strong human need to conform to social norms”); PEISS, *supra* note 3, at 4.

6. MINTEL, COLOR COSMETICS-US-JULY 2017 [hereinafter COLOR COSMETICS]; BUREAU OF LABOR STATISTICS, EMPLOYED PERSONS BY DETAILED OCCUPATION, SEX, RACE, AND HISPANIC OR LATINO ETHNICITY tbl.11 (Jan. 19, 2018), <https://www.bls.gov/cps/cpsaat11.htm> [<https://perma.cc/Y5PW-TP7R>] [hereinafter BLS, DETAILED OCCUPATION] (“Hairdressers, hairstylists, and cosmetologists”).

7. *See* FDCA, 21 U.S.C. ch. 9 (2012); *compare* FDCA, 21 U.S.C. §§ 361-364 (1938 supp. IV) *with* FDCA, 21 U.S.C. §§ 361-364 (2012); *see also* 21 U.S.C.A. §§ 361-364 (West 2018).

8. *See infra* Section II.C.2.e. (discussing how cosmetics law and regulation lag behind that of other product categories.)

9. Jordan Paradise & Ethan Fitzpatrick, *Synthetic Biology: Does Re-Writing Nature Require Re-Writing Regulation?*, 117 PENN ST. L. REV. 53, 70 (2012); *see also* U.S. GEN. ACCOUNTING OFFICE (GAO), GAO/HRD-90-58, COSMETICS REGULATION: INFORMATION ON VOLUNTARY ACTIONS AGREED TO BY FDA AND THE INDUSTRY (Mar. 1990), <https://www.gao.gov/assets/220/212263.pdf> [<https://perma.cc/JH3V-CF3X>] [hereinafter GAO/HRD-90-58]; U.S. GEN. ACCOUNTING OFFICE (GAO), STATEMENT OF GREGORY J. AHART, DIRECTOR, HUMAN RESOURCES DIV., BEFORE THE SUBCOMM. ON OVERSIGHT & INVESTIGATIONS, HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE ON THE FOOD AND DRUG ADMINISTRATION’S REGULATION OF COSMETICS (Feb. 3, 1978), <https://www.gao.gov/assets/100/98639.pdf> [<https://perma.cc/QEF8-XKSP>]; U.S. GEN. ACCOUNTING OFFICE (GAO), HRD-78-139, LACK OF AUTHORITY HAMPERS ATTEMPTS TO INCREASE COSMETIC SAFETY (Aug. 8, 1978), <https://www.gao.gov/assets/130/123795.pdf> [<https://perma.cc/7VD6-MV6Y>] [hereinafter GAO, HRD-78-139].

10. FDA, *Using Adverse Event Reports to Monitor Cosmetic Safety: A Conversation with Linda Katz* (Nov. 3, 2017), <https://www.fda.gov/cosmetics/complianceenforcement/adverseeventreporting/ucm531634.htm> [<https://perma.cc/U7AH-H8TA>] [hereinafter FDA, *Adverse Event Reports*].

11. FDA, *Adverse Event Reports*, *supra* note 10.

12. *See, e.g.*, *Testimony Peter Barton Hutt, Senior Counsel, Covington & Burling, LLP, Before the Health Subcomm. of Comm. on Energy & Commerce U.S. House of Representatives* (Mar. 27, 2012), <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/Health/20120327/HHRG-112-IF14-WState-HuttP-20120327.pdf> [<https://perma.cc/MU6J-STYJ>]; *Testimony of Halyna Breslawec, Ph.D., Chief Scientist & Exec. Vice President for Sci., Pers. Care Prod.*

large number of people that foodborne illnesses, medications, and tobacco products kill and injure each year.¹³ Indeed, there is much uncertainty about the safety of cosmetics, and some may not be safe.¹⁴ Yet the current approach to cosmetics law and regulation, rather than helping to assess these claims, hinders meaningful evaluation of the safety of the industry.

This Article examines federal cosmetics law and regulation from a feminist perspective.¹⁵ Specifically, it asks the “woman question” about cosmetics law and regulation in order to “identify the gender implications” of this regulatory system, “which might otherwise appear to be neutral or objective.”¹⁶ The association between cosmetics and femininity is so strong that some readers may question whether there is even a need to ask the “woman question” about cosmetics law and regulation. But as this Article argues, the relationship between the under-regulation of cosmetics and their association with women is both strong and complex. Cosmetics law and regulation have been deprioritized for many reasons, including as a result of differences in women’s usage of cosmetics, the longstanding and close association of cosmetics with femininity and women, and the debate among self-described feminists regarding cosmetics. Explicitly considering how cosmetics law and regulation fail to account for the needs and experiences of women and members of other excluded groups is necessary if these omissions are to be remedied.

Council, Before the Health Subcomm. of Comm. on Energy & Commerce U.S. House of Representatives (Mar. 27, 2012), <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/Health/20120327/HHRG-112-IF14-WState-BreslawecH-20120327.pdf> [<https://perma.a.cc/PDS4-Q7YD>].

13. There are an estimated “106 000 deaths/year from nonerror, adverse effects of medications” in the United States. Barbara Starfield, Commentary, *Is US Health Really the Best in the World?*, 284 JAMA 483, 484 (July 26, 2000). In addition, the Centers for Disease Control and Prevention estimates that “[a]bout 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases.” FDA, FOOD SAFETY MODERNIZATION ACT (FSMA), INSPECTION & COMPLIANCE, <https://www.fda.gov/food/guidanceregulation/fsma/ucm257978.htm> [<https://perma.cc/3EFM-LMAW>]. About “16 million Americans are living with a disease caused by smoking” and “cigarette smoking is responsible for more than 480,000 deaths per year in the United States.” Centers for Disease Control & Prevention, *Fast Facts: Diseases and Death*, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm [<https://perma.cc/A2AA-4JVC>].

14. See also *infra* Section II.B (discussing potential risks and harms of cosmetics).

15. This Article focuses on gender and FDA’s regulation of cosmetics with respect to human health and safety under the FDCA; it does not consider the role that other federal laws (e.g., the Toxic Substances Control Act, the Federal Trade Commission Act, Occupational Safety & Health Act) and agencies (e.g., EPA, FTC, and OSHA) play in the regulation of cosmetics. See, e.g., FED. TRADE COMM’N (FTC), <https://www.ftc.gov/> [<https://perma.cc/588Y-M9AN>]; U.S. ENVTL. PROT. AGENCY (EPA), <https://www.epa.gov/> [<https://perma.cc/32WU-2U3N>]; U.S. DEP’T OF LABOR OCCUPATIONAL SAFETY & HEALTH ADMIN. (OSHA), <https://www.osha.gov/> [<https://perma.cc/SLJ7-37NY>]; Occupational Safety & Health Act, Pub. L. No. 91-956, 84 Stat. 1590 (codified as amended at 29 U.S.C. §§ 651-78 (2012)); Federal Trade Commission Act, 15 U.S.C. §§ 41-58 (2018 supp. V); Lanham Act, 15 U.S.C. § 1125(a) (2012); Toxic Substances Control Act, 15 U.S.C. § 2604 (2018 supp. V). This Article also does not examine state cosmetics laws and tort law. See, e.g., California Safe Cosmetics Act, http://www.leginfo.ca.gov/pub/05-06/bill/sen/sb_0451-0500/sb_484_bill_20051007_chaptered.pdf [<https://perma.cc/B75T-9C3X>]; 148 AM. JUR. 3D *Proof of Facts* § 207 (originally published in 2015).

16. See Katharine T. Bartlett, *Feminist Legal Methods*, 103 HARV. L. REV. 829, 837 (1990).

This Article proceeds as follows: Part I defines several key terms and introduces the “woman question” as a feminist legal method. Part II examines cosmetics as a gendered product and industry, and highlights several ways that product use and exposure may be shaped by the intersection of gender, race, and class. It then discusses the safety of cosmetics and explains why women, and particularly women who are members of other excluded groups, may be disproportionately impacted by the failures of cosmetics law and regulation. Part II then provides an overview of cosmetics law and regulation, with a focus on how they have lagged behind that of the other major product categories in the FDCA. Against this backdrop, Part III argues that cosmetics law and regulation have been deprioritized as a result of their longstanding and close association with femininity and women, as well as women’s exclusion from political participation and representation. It also argues that cosmetics law and regulation have been deprioritized as a result of the debate among self-described feminists over the meaning of cosmetics, as well as differences in women’s relationships to and perspectives on cosmetics. Part IV considers the implications of this analysis for reform. Ultimately, this Article uses a feminist lens to question the legitimacy of the current approach to cosmetics law and regulation and strives to make readers do the same.¹⁷

I. TERMINOLOGY & METHODOLOGY

Before turning to a discussion of the gendered and racialized impact of the contemporary regulation of cosmetics in Part II, the current Part discusses several important terms and provides a discussion of the method employed in later sections. In particular, this Article uses an expanded version of “the woman question,” which analyzes “gender . . . within the contexts of multiple identities” to ask how cosmetics law and regulation “leave out or disadvantage women and members of other excluded groups.”¹⁸

A. Defining “Cosmetics”

This Article focuses on “cosmetics” as defined under the FDCA. The FDCA defines “cosmetics” to mean “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

17. See Allison M. Blackman, *Manufactured Home Displacement and Its Disparate Impact on Low-Income Females: A Violation of the Fair Housing Act in Boise, Idaho?*, 4 THE CRIT: CRITICAL STUD. J. 67, 68-69 (2011) (“Thus, the underlying goal of this article is to challenge and provoke—to raise awareness about involuntary manufactured home displacement, and ultimately to make readers question the legitimacy of ‘fair housing’ laws in their status quo operation.”).

18. Bartlett, *supra* note 16, at 831, 848.

appearance.”¹⁹ The definition includes components of such articles but excludes soap, which FDA has defined narrowly.²⁰ For example, cosmetics include hair products (e.g., hair dyes, permanent waves, relaxers, cleansing shampoos, and conditioners), makeup (e.g., eye products, lipstick, novelty makeup, permanent makeup, and tattoo ink), nail products (e.g., fingernail polishes and artificial nails), perfumes, deodorants, and skin moisturizers.²¹

Because the subject of this Article is cosmetics law and regulation, this Article focuses on products that FDA regulates as cosmetics, not as cosmetics and another product category (i.e., products with dual classification).²² It is important to note, however, that “cosmetics” may also meet the definition of one of the FDCA’s other product categories. For example, a “cosmetic” may also be a “drug,”²³ which includes articles intended for therapeutic use and “articles . . . intended to affect the structure or any function of the body of man.”²⁴ The intended use of a product is central to determining whether it is a cosmetic or a drug or both.²⁵ The classification of a product determines the scope of FDA’s authority over it and the requirements that the manufacturer must meet. If a product is a drug or a drug and a cosmetic, it is subject to the requirements for

19. FDCA § 201(i), 21 U.S.C. § 321(i) (2012).

20. *Id.* The FDA has interpreted the term “soap” to mean articles where “[t]he bulk of the nonvolatile matter . . . consists of an alkali salt of fatty acid and the detergent properties . . . are due to the alkali-fatty acid compounds” and articles that are “labeled, sold, and represented only as soap.” 21 C.F.R. § 701.20 (2018).

21. FDA, FDA AUTHORITY OVER COSMETICS: HOW COSMETICS ARE NOT FDA-APPROVED, BUT ARE FDA-REGULATED, <https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm> [<https://perma.cc/G8NJ-9S5A>] [hereinafter FDA AUTHORITY OVER COSMETICS].

22. Cosmetics may include ingredients that are regulated as “color additives,” however, these are distinct regulatory categories with distinct regulatory requirements. *See* FDCA § 201(t), 21 U.S.C. § 321(t) (2012) (“color additive”); FDCA § 301(i), 21 U.S.C. § 321(i) (2012) (“cosmetic”); FDCA § 721, 21 U.S.C. § 379e (2012) (Listing and Certification of Color Additives for Foods, Drugs, Devices, and Cosmetics). Unlike “cosmetics,” “color additives” have to be listed (i.e., approved) for a particular use before being so used. *Id.* Perhaps most importantly for the purposes of the current analysis, “color additives” are not limited to use in cosmetics. *Id.* FDA may approve a color additive for use in or on food, drugs, and devices—product categories that unlike cosmetics do not have a long gendered-history. *See infra* Section II.A.

23. *See* 21 U.S.C. § 359 (stating that the drugs and devices subchapter of FDCA “shall not apply to any cosmetic unless such cosmetic is also a drug or device”); *see also* FDA, IS IT A COSMETIC, A DRUG, OR BOTH? (OR IS IT SOAP?), <https://www.fda.gov/cosmetics/guidanceregulation/lawsregulations/ucm074201.htm> [<https://perma.cc/U3X4-2N3A>].

24. FDCA § 201(g)(1), 21 U.S.C. § 321(g)(1) (2012).

25. *See* FDCA § 201(g), (i), 21 U.S.C. § 321(g), (i) (2012); *see also* Laura A. Heymann, *The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids*, 52 *FOOD & DRUG L.J.* 357, 358 (1997) (stating that the answer to the question of whether a product is a cosmetic or a drug under most interpretations of the FDCA is “rooted not in the chemical composition or physiological effect of AHAs but rather in how the manufacturer has positioned the product and the promises made as to its effects”). *But see* PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW: CASES AND MATERIALS* 118 (4th ed. 2014) (“FDA has manifested an inclination to categorize articles containing pharmacologically active ingredients as drugs even when their manufacturers make only cosmetic claims.”). The cosmetics industry uses the term *cosmeceutical* to “refer to cosmetic products that have medicinal or drug-like benefits,” but neither FDCA nor FDA recognize this term. FDA, *COSMECEUTICAL*, <https://www.fda.gov/cosmetics/labeling/claims/ucm127064.htm> [<https://perma.cc/RHV7-X36X>].

drugs, which are much more stringent than those for cosmetics.²⁶ For example, FDA must approve a “new drug” before it can be lawfully sold,²⁷ whereas no approval is needed for a cosmetic.²⁸

Because cosmetics law and regulation lag so far behind the law and regulation of the other major product categories, there is a lot riding on a product’s classification and it is a significant source of tension: indeed, one commentator wrote that this tension “has been the primary feature of the evolution of cosmetic law in the last fifty years.”²⁹

Finally, because some of the literature and sources cited in this Article use terms such as personal care products, beauty products, beauty supplies, and toilet preparations, it is important to note that while these terms may include “cosmetics,” they are not coterminous with the legal definition of cosmetics. For example, these terms may include products that fall within another product category under the FDCA (e.g., drugs, devices, or dietary supplements) or outside of its reach entirely (e.g., consumer products).³⁰

B. *The “Woman Question” as a Feminist Legal Method*

This Section begins by defining feminism. It then discusses the “woman question” as a feminist legal method—including the method’s strengths and limitations—and how this Article employs the method to examine federal cosmetics law and regulation.³¹

26. See *infra* Section II.C.2.e.

27. FDCA §§ 201, 505(a), 21 U.S.C. §§ 321, 355(a) (2012); see also Jacqueline A. Greff, *Regulation of Cosmetics That Are Also Drugs*, 51 FOOD & DRUG L.J. 243 (1996); Heymann, *supra* note 25, 364. The new drug development and application process is time-consuming and expensive: it can take over a decade and hundreds of millions of dollars. See Gail A. Van Norman, *Drugs, Devices and the FDA: Part 1: An Overview of Approval Processes for Drugs*, 1 JACC: BASIC TO TRANSLATIONAL SCI. 170 (Apr. 2016), <https://www.sciencedirect.com/science/article/pii/S2452302X1600036X> [<https://perma.cc/PCT8-X9WT>]; Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (May 2016), <https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291> [<https://perma.cc/VN6E-Z3J6>] (estimating the research and development costs (including post-approval research and development) for a new drug to be about \$2.87 billion dollars); Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, JAMA INTERNAL MED. 1569 (2017) <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2653012> [<https://perma.cc/6PH3-5KLH>] (estimating research and development costs to be about \$648 million).

28. See FDCA, 21 U.S.C. ch. 9 (2012).

29. Greff, *supra* note 27, at 243.

30. See FDA, *Cosmetics Safety Q&A: Personal Care Products*, <https://www.fda.gov/Cosmetics/ResourcesForYou/Consumers/ucm136560.htm> [<https://perma.cc/JBU2-RUGQ>]; FDA, *Cosmetics & Pregnancy*, <https://www.fda.gov/cosmetics/resourcesforyou/consumers/ucm388727.htm> [<https://perma.cc/Y65D-KAQR>] (last updated Mar. 6, 2018) (“Not all ‘personal care products’ . . . are cosmetics.”).

31. See Bartlett, *supra* note 16.

1. *Defining Feminism*

The term “feminism” is “troublesome”: it is “confusing and difficult” and even the notion of “‘defining’ feminism is controversial.”³² It has been defined both narrowly and broadly, and is not static.³³ Despite the many definitions of feminism, feminism does have boundaries.³⁴ It “takes gender as a central category of analysis.”³⁵ One definition of feminism is “the movement for social, political, and economic equality of men and women.”³⁶ Feminism according to this definition consists of a movement with goals for change, “[a]nd implicit in these goals is *access* to sufficient information to enable women to make responsible choices.”³⁷ Although having the benefits of being concise, this definition is not unproblematic, as like other short definitions it “reduce[s] the subtle complexity of a messy field of knowledge to [a] neat slogan[.]”³⁸

In her article, *Feminist Critical Theories*, Deborah L. Rhode identifies several common features of the critical feminist theories that she examines.³⁹ Specifically, she states that (1) “they seek to promote equality between women and men;” (2) they “make gender a focus of analysis” and “aim . . . to reconstitute legal practices that have excluded, devalued, or undermined women’s concerns;” and (3) they “aspire to describe the world in ways that correspond to women’s experience and that identify the fundamental social transformations necessary for full equality between the sexes.”⁴⁰ While the approach of feminist theory differs from other critical approaches, like critical legal studies and critical race scholarship, it also overlaps and often draws upon these approaches.⁴¹ The general goal of these theories, “to challenge existing distributions of power,” is one which this Article shares.⁴²

32. CHRIS BEASLEY, *WHAT IS FEMINISM? AN INTRODUCTION TO FEMINIST THEORY* ix, xi (1999).

33. *Id.* at xiv, xiii, 25-48.

34. *Id.* at xv.

35. Deborah L. Rhode, *Feminist Critical Theories*, 42 *STAN. L. REV.* 617, 617-18 (1990); *see also* Mary Anne C. Case, *Disaggregating Gender from Sex and Sexual Orientation: The Effeminate Man in the Law and Feminist Jurisprudence*, 105 *YALE L.J.* 1, 6 (1995) (discussing “how gender and sex came to be conflated in the language of the law” and arguing that “it is important to distinguish between them”); Megan Bell, Comment, *Transsexuals and the Law*, 98 *NW. U. L. REV.* 1709, 1716 (2004) (discussing distinctions between gender and sex).

36. JENNIFER BAUMGARDNER & AMY RICHARDS, *MANIFESTA: YOUNG WOMEN, FEMINISM, AND THE FUTURE* 56 (2000).

37. *Id.*

38. *See* BEASLEY, *supra* note 32, at 26 (noting that despite the benefits of short definitions of feminism, such definitions “are of limited value if you want to grasp the character of the term, feminism, more fully and appreciate its heterogenous forms”).

39. Rhode, *Feminist Critical Theories*, *supra* note 35.

40. *Id.* at 619.

41. *Id.* at 618-19.

42. *Id.*

2. Asking the “Woman Question”

In *Feminist Legal Methods*, Katharine T. Bartlett describes the “woman question” as a set of questions “designed to identify the gender implications of rules and practices which might otherwise appear to be neutral or objective.”⁴³ She phrases these questions as: “[H]ave women been left out of consideration? If so, in what way; how might that omission be corrected? What difference would it make to do so?”⁴⁴ This inquiry “helps to demonstrate how social structures embody norms that implicitly render women different and thereby subordinate.”⁴⁵

The “woman question” has been used to “examin[e] how the law fails to take into account the experiences and values that seem more typical of women than of men . . . or how existing legal standards and concepts might disadvantage women.”⁴⁶ There is a long history of feminist scholarship asking the “woman question” about diverse areas of the law.⁴⁷ For example, it has been asked in some form about voting limitations, legal inequities associated with marriage, and birth control.⁴⁸ It has also been asked about the Restatement (Third)’s standard for medical product defect claims,⁴⁹ pharmacist refusal clauses,⁵⁰ health care reform,⁵¹ and how the legal system has responded to HIV infection.⁵²

This Article adds to the existing literature by asking the “woman question” about federal cosmetics law and regulation. Cosmetics are a highly gendered product and industry. This Article uses the “woman question” to argue that by allowing cosmetics law and regulation to lag behind that of the other traditional

43. Bartlett, *supra* note 16, at 837.

44. *Id.* While different scholars have framed the questions somewhat differently, there is substantial overlap in how they have done so. *See, e.g.,* Heather Ruth Wishik, *To Question Everything: The Inquiries of Feminist Jurisprudence*, 1 BERKELEY WOMEN’S L.J. 64, 72-76 (1985) (discussing seven questions, the first four of which “help . . . to identify how law and existence is gendered by patriarchy” and the last three of which “involve the challenge of inventing, of imagining a world for which [there are] no givens”); *see also* Lydia A. Clougherty, *Feminist Legal Methods and the First Amendment Defense to Sexual Harassment Liability*, 75 NEB. L. REV. 1, 8 (1996) (discussing the essential features of the “woman question” and providing examples of questions that have been asked).

45. Bartlett, *supra* note 16, at 843.

46. *Id.* at 837.

47. *See id.* at 838; *see also* Clougherty, *supra* note 44, at 3 n.7 (listing law review articles that apply the “woman question” to different areas of the law).

48. Bartlett, *supra* note 16, at 838.

49. Dolly M. Trompeter, *Sex, Drugs, and the Restatement (Third) of Torts, Section 6(c): Why Comment E Is the Answer to the Woman Question*, 48 AM. U. L. REV. 1139, 1145 (1999).

50. Claire A. Smearman, *Drawing the Line: The Legal, Ethical and Public Policy Implications of Refusal Clauses for Pharmacists*, 48 ARIZ. L. REV. 469, 501 (2006).

51. *See* John A. Robertson, *Asking the “Woman Question” About Health Care Reform*, 3 TEX. J. WOMEN & L. 1 (1994).

52. Breanne Sergent, Comment, *To Include or to Exclude? The Policy Question Plaguing Women’s Role in Clinical Trials*, 34 J. LEGAL MED. 235 (2013); Mary Anne Bobinski, *Women and HIV: A Gender-Based Analysis of a Disease and Its Legal Regulation*, 3 TEX. J. WOMEN & L. 7, 56 (1994). And although not explicitly identified as such, it has been asked about FDA’s drug approval process and women’s representation in clinical trials. Christina Cole, Comment & Note, *Women and the FDA: Remediating the Past and Preserving the Future*, 7 HOUS. J. HEALTH L. & POL’Y 127 (2006).

product categories that FDA regulates under the FDCA and by failing to adequately regulate cosmetics, Congress and FDA have left women—and their needs and experiences—out of consideration, thereby jeopardizing their health. However, at the same time that this Article asks the “woman question,” it also recognizes that this method is not without its limitations and has been the subject of critique.⁵³

First, using “women” as a category is problematic.⁵⁴ It is too general in that it obscures the fact that women and their experiences are not monolithic and undifferentiated, and thus risks essentialism.⁵⁵ Focusing on women as a category of analysis, without recognizing that women’s experiences are shaped by other factors such as race, ethnicity, sexual orientation, and class, which intersect and interact with gender and shape women’s experiences, excludes women who are burdened on more than one dimension.⁵⁶ For example, Kimberlé Crenshaw has argued with respect to black women that “[b]ecause the intersectional experience is greater than the sum of racism and sexism, any analysis that does not take intersectionality into account cannot sufficiently address the particular manner in which Black women are subordinated.”⁵⁷ Of particular relevance to the current analysis, Angela P. Harris has argued that “[t]he relation of black women to the ideal of white beauty is not a more intense form of white women’s frustration: It is something other, a complex mingling of racial and gender hatred”⁵⁸ These other factors do not simply magnify the effects of gender, but intersect and interact with gender to mold women’s experiences. The result of essentialism, Harris has argued, “is not only that some voices are silenced in order to privilege others . . . but that the voices that are silenced turn out to be the same voices silenced by the mainstream legal voice . . . among them, the voices of black women.”⁵⁹ Indeed, one longstanding critique of mainstream feminism and feminist legal thought is that they privilege already “race- and class-privileged

53. See Bartlett, *supra* note 16, at 837-49. As Bartlett notes, some may question whether the “woman question” is really just “a mask for something else, such as legal substance, or politics.” *Id.* at 843-44. Just because the method shapes substance, however, does not mean that it is substance. *Id.* Indeed, this is not a distinguishing feature of the “woman question” as a legal method as “all legal methods shape substance.” *Id.* at 844-45.

54. See, e.g., Martha Minow, *Introduction: Finding Our Paradoxes, Affirming Our Beyond*, 24 HARV. C.R.-C.L. L. REV. 1, 2 (1989).

55. See, e.g., Bartlett, *supra* note 16, at 872-73; Angela P. Harris, *Race and Essentialism in Feminist Legal Theory*, 42 STAN. L. REV. 581, 615 (1990) (arguing “that gender essentialism is dangerous to feminist legal theory because in the attempt to extract an essential female self and voice from the diversity of women’s experience, the experiences of women perceived as ‘different’ are ignored or treated as variations on the (white) norm”).

56. Kimberlé Crenshaw, *Demarginalizing the Intersection of Race and Sex: A Black Feminist Critique of Antidiscrimination Doctrine*, 1989 U. CHICAGO L. FORUM 139; see also Bartlett, *supra* note 16, at 847.

57. Crenshaw, *supra* note 56, at 140.

58. Harris, *supra* note 55, at 597-98.

59. *Id.* at 585.

women.”⁶⁰ There is also a risk that the use of “woman” as a category may “reinstat[e] . . . the isolation and stigmatization of women.”⁶¹

In the context of the current analysis, the use of “women” as a category is problematic because factors other than gender likely impacted the development of cosmetics law. For example, many of the prominent advocates of reform were white middle- and upper-class women who brought their respective values to their reform work.⁶² The use of “women” is also problematic because different women use and are exposed to cosmetics in different and particular ways, and the risks that this exposure poses are shaped by a variety of factors; therefore, the inadequate regulation impacts them in different and particular ways.⁶³ Race, ethnicity, sexual orientation, age, socio-economic status, and other factors impact women’s experiences with and exposure to cosmetics and how the limitations of current cosmetics law and regulation impact them.⁶⁴ For example, the risks to an African American woman who uses chemical relaxers and deep conditioners;⁶⁵ a Vietnamese immigrant woman who works in a nail salon;⁶⁶ and a white woman who uses dark hair dyes may differ.⁶⁷ Yet all of these women may be exposed to risks from cosmetics.

Because “factors other than gender victimize women,” it is necessary to ask about other excluded groups.⁶⁸ Bartlett suggests recasting the “woman question”

60. Crenshaw, *supra* note 56, at 140; *see, e.g.*, bell hooks, *Black Women: Shaping Feminist Theory*, in *WORDS OF FIRE: AN ANTHOLOGY OF AFRICAN-AMERICAN FEMINIST THOUGHT* 270 (Beverly Guy-Sheftal ed., 1995); PATRICIA HILL COLINS, *BLACK FEMINIST THOUGHT: KNOWLEDGE, CONSCIOUSNESS, AND THE POLITICS OF EMPOWERMENT* (2d ed. 2000); ANGELA Y. DAVIS, *WOMEN, RACE & CLASS* (1981); Harris, *supra* note 55; Audre Lorde, *Age, Race, Class, and Sex: Women Redefining Difference*, in *FEMINIST THEORY: A READER* 289, 290 (Wendy K. Kolmar & Frances Bartkowski eds., 2013); *see also* Sojourner Truth, *Ain’t I a Woman?*, *FORDHAM UNIVERSITY, MODERN HISTORY SOURCEBOOK* (Dec. 1851), <https://sourcebooks.fordham.edu/mod/sojtruth-woman.asp> [<https://perma.cc/236G-RH9X>].

61. *See* Bartlett, *supra* note 16, at 835.

62. KAY, *supra* note 3, at 15, 17, 31; *see also id.* at 31-33 (discussing “morality of visible makeup”); PEISS, *supra* note 3, at 7, 41 (discussing “morality of visible makeup” and racial attitudes towards cosmetics).

63. *See infra* Section II.B.1 & 2; *see, e.g.*, Ami R. Zota & Bhavna Shamasunder, *Viewpoint, The Environmental Injustice of Beauty: Framing Chemical Exposures from Beauty Products as a Health Disparities Concern*, *AM. J. OBSTETRICS & GYNECOLOGY* 418, 418-20 (Oct. 2017) (discussing “[p]reexisting vulnerabilities” to and “cumulative impacts” of chemical exposures and the “[s]ocial and economic dimensions of product use”); *COMM. ON HEALTH CARE FOR UNDERSERVED WOMEN*, *AM. COLL. OBSTETRICIANS & GYNECOLOGISTS, EXPOSURE TO TOXIC ENVIRONMENTAL AGENTS* (2013), <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/ExposuretoToxic.pdf> [<https://perma.cc/SVZ5-Y355>] [hereinafter *EXPOSURE TO TOXIC AGENTS*] (discussing how a number of factors can impact exposure to toxic environmental chemicals and health disparities).

64. *See* Rhode, *Feminist Critical Theories*, *supra* note 35, at 622; Harris, *supra* note 55, at 587.

65. Adana AM Llanos et al., *Hair Product Use and Breast Cancer Risk Among African American and White Women*, 38 *CARCINOGENESIS* 883 (Sept. 2017).

66. Cora Roelofs et al., *Results from a Community-based Occupational Health Survey of Vietnamese-American Nail Salon Workers*, 10 *J. IMMIGRANT & MINORITY HEALTH* 353 (Aug. 2008), <https://www2a.cdc.gov/nioshtic-2/BuildQyr.asp?s1=200343886&View=e&> [<https://perma.cc/GH68-NB9T>]; NIOSH, *NAIL TECHNICIANS’ HEALTH*, *supra* note 5.

67. Llanos et al., *supra* note 65.

68. Bartlett, *supra* note 16, at 847.

as the “Question of the Excluded,” asking how “women and members of other excluded groups” have been left out or disadvantaged.⁶⁹ Thus, in considering the “woman question” in the context of cosmetics law, this Article considers how “factors other than gender victimize women” and asks about other excluded groups since “analysis of gender must occur not apart from but within the contexts of multiple identities.”⁷⁰ In addition, this Article tries to specify the women to which it refers.⁷¹ Yet even the more specific categories which this Article uses may be too general in that they risk other forms of essentialism.⁷² As Harris has remarked in critiquing gender essentialism by focusing on black women, “her aim is not to establish a new essentialism . . . based on the essential experience of black women.”⁷³ Similarly, the aim of this Article is not to replace gender essentialism with other forms of essentialism.

Using “women” as a category for analysis, however, is also too specific. Men also use and are exposed to cosmetics.⁷⁴ The dangers and risks to human health that cosmetics may pose cannot be controlled by only focusing on women.⁷⁵ The reforms that this Article proposes in the final Part are likely to have broader benefits in terms of understanding and assessing the risks of cosmetics.

Asking about how cosmetics law and regulation impact “women” creates the illusion of a binary world—woman or man, female or male, feminine or masculine—which fails to account for the complexities of sex and gender.⁷⁶

69. *Id.* at 831, 847-48.

70. *Id.* at 847.

71. *See id.* at 848 (stating that “any analysis using the general category of woman is itself exclusionary” and discussing E. SPELMAN, *INESSENTIAL WOMAN: PROBLEMS OF EXCLUSION IN FEMINIST THOUGHT* (1988), which, according to Bartlett, “suggests that in speaking of ‘women,’ the speaker should name explicitly which women she means”).

72. *See* Harris, *supra* note 55, at 585; Bartlett, *supra* note 16, at 848 (“Any category, no matter how narrowly defined, makes assumptions about the remaining characteristics of the group that fail to take account of members of the group who do not have those characteristics.”); *see also* Harris, *supra* note 55, (“My suggestion is only that we make our categories explicitly tentative, relational, and unstable. . .”).

73. *See* Harris, *supra* note 55, at 585.

74. Env'tl. Working Group (EWG), *Exposures Add Up—Survey Results*, https://www.ewg.org/skin-deep/2004/06/15/exposures-add-up-survey-results/#.W1iAC_GwXo [<https://perma.cc/VGC4-BZBX>] [hereinafter EWG, *Exposures Add Up*]; *see also* Meredith Melnick, *Men's Grooming Products: Are They Really Any Different From Women's?*, HUFFINGTON POST (Feb. 9, 2012), https://www.huffingtonpost.com/2012/02/09/mens-grooming-products-different-womens_n_1264137.html [<https://perma.cc/Q5BL-R7ES>].

75. *See* Minow, *supra* note 54, at 2.

76. *See, e.g.,* Sara R. Benson, *Hacking the Gender Binary Myth: Recognizing Fundamental Rights for the Intersexed*, 12 CARDOZO J.L. & GENDER 31 (2005) (discussing the rights of intersexed people and “[t]he gender binary model [which] posits that only two sexes exist and that every person must fit easily into the category of male or female” and arguing for a right to gender identity, which would recognize “a variable spectrum of gender induced identities”); Katie Reineck, Note, *Running from the Gender Police: Reconceptualizing Gender to Ensure Protection for Non-Binary People*, 24 MICH. J. GENDER & L. 265, 266 (2017) (noting that “non-binary people—who do not identify within the accepted gender binary as men or women. . . may present in a way typically associated with women, by wearing makeup, keeping their hair long, or wearing clothing sold in the women’s section; in a way typically associated with men, by keeping their hair short, growing facial hair, or wearing clothing sold in the men’s section; or may present androgynously by mixing elements of the two”).

Although sex and gender have often been conflated in the law,⁷⁷ many have argued that these should be distinguished, as sex is not gender, but “merely one component” of it.⁷⁸ Especially relevant to the current analysis is the fact that transgender and non-binary individuals use cosmetics and thus are impacted by the state of cosmetics law and regulation.⁷⁹

Despite the limitations of the “woman question,” it is a useful frame of analysis and “it still makes sense to talk about ‘women.’”⁸⁰ First, imperfect as these categories are, analyzing cosmetics law and regulation using categories—including “women”—helps to illuminate the shortcomings of the current regulatory approach.⁸¹ Second, the current analysis is constrained by the limitations of the existing data, information, and scholarship that it examines. Many of these sources use “women” as a category and reflect a binary understanding of gender. Nuanced gender information is often unavailable and sources addressing cosmetics, their use, and the people that influenced early reform efforts largely do so within a binary framework.⁸² There is a need for explicit examination of how cosmetics law and regulation have impacted and continue to impact transgender and gender non-conforming individuals. As the cosmetics industry is beginning to explicitly recognize, many transgender and gender non-conforming individuals use cosmetics.⁸³

77. See Rhode, *Feminist Critical Theories*, *supra* note 35, at 617-18; see also Case, *supra* note 35, at 6; Bell, *supra* note 35, at 1716 (discussing distinctions between gender and sex).

78. See Adam R. Chang & Stephanie M. Wildman, *Gender In/sight: Examining Culture and Constructions of Gender*, 18 GEO. J. GENDER & L. 43, 54 (2017) (noting that “[a]n increasing number of educators and scholars presently explain gender as being a combination of sex, gender identity, and gender expression”); see generally JUDITH BUTLER, *GENDER TROUBLE: FEMINISM & THE SUBVERSION OF IDENTITY* (1990).

79. See, e.g., Rachel Lubitz, *Is “Gender-Neutral” Just A Beauty Buzzword—Or Something Greater?*, REFINERY29.COM (Aug. 22, 2018 2:00 PM), <https://www.refinery29.com/en-us/gender-neutral-makeup-beauty-brands> [<https://perma.cc/LK2K-2GAA>] (stating that people with different gender expression have used makeup but that new brands are “signaling . . . that everyone, including cis women, cis men, and transgender, gender non-conforming, non-binary, and gender-fluid individuals, can be their customers and use their products”); *Classes for Confidence*, SEPHORA STANDS, https://www.sephorastands.com/classes_for_confidence/ [<https://perma.cc/HY3N-ELWP>] (indicating that beauty retailer Sephora offers beauty classes in its participating stores entitled “Bold Beauty for the Transgender Community”).

80. Christine A. Littleton, *Does It Still Make Sense to Talk About “Women”?*, 1 UCLA WOMEN’S L.J. 15, 16 (1991). This Article uses the term “women” largely to refer to people who others (e.g., legislators, regulators, medical professionals, and scholars) have regarded as women, similar to how Christine A. Littleton “use[s] the term ‘women’ to refer to people who are regarded by those in power . . . as women.” *Id.* at 16.

81. Harris, *supra* note 55, at 582 (“To think is to forget differences, generalize, make abstractions.”).

82. See, e.g., *infra* Section II.A (discussing cosmetics usage and pressures on women to use cosmetics); *infra* Section III.A.1 & 2 (arguing that cosmetics law and regulation have been deprioritized as a result of women’s exclusion from political participation and representation and because of their longstanding and close association with femininity and women).

83. See, e.g., Ivana Rihter, *How 4 Next-Gen Makeup Lines are Serving the Transgender Community*, VOGUE.COM (July 30, 2018, 4:57 PM), <https://www.vogue.com/article/transgender-community-beauty-tutorials-makeup-skin-brands-sephora-fluide> [<https://perma.cc/J857-EV76>] (noting that “even though it may seem like makeup has long been at the center of the queer community, often considered a tool for self-expression, identification, and reinvention, most transgender people ‘don’t feel included in the beauty world’” and discussing “gender nonbinary brands and charities that are supporting members of the

This information deficit relates to another feature of the “woman question” that should be acknowledged from the outset. As a legal method the “woman question” “neither guarantees a particular result nor even the right result.”⁸⁴ Accordingly, it “does not require decision in favor of a woman,” but rather seeks to expose “interests and concerns that otherwise may be, and historically have been, overlooked.”⁸⁵ Accordingly the reforms that this Article suggests in the final Part are aimed at providing additional information in order to better assess the risks that the current regulatory approach poses. This Article proceeds mindful of the limitations of its chosen method.

II. THE GENDERED & RACIALIZED IMPACT OF THE CONTEMPORARY APPROACH TO THE REGULATION OF COSMETICS

This Part begins by discussing the gendered nature of cosmetics in the United States. Although men use cosmetics, cosmetics are strongly associated with women and femininity, and, on average, women use more cosmetics. Cosmetics use is also shaped by factors other than gender, including race, ethnicity, socioeconomic status, and age. This Part also discusses the risks to women’s health that cosmetics may pose and how such risks may be shaped by factors other than gender. It argues that because cosmetics are a highly gendered product and industry, failures in cosmetics law and regulation may disproportionately jeopardize the health of women, particularly women who are members of other excluded groups. This Part then provides an overview of the cosmetics provisions of the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), which largely remain unchanged. Finally, it examines current cosmetics law and regulation and how they lag behind the law and regulation for other major product categories regulated under the FDCA.

A. *Gender, Race, Class & Cosmetics*

Cosmetics are a highly gendered product and industry. On average, women use more cosmetics than men.⁸⁶ For example, one survey found that “[t]he

LGBTQ+ community”); Vanessa Chesnut, *Not Your Mama’s Makeup: New Cosmetics Target Consumers Across Gender Spectrum*, NBC NEWS (May 11, 2018 4:08 PM), <https://www.nbcnews.com/feature/nbc-out/not-your-mama-s-makeup-new-cosmetics-target-consumers-across-n873386> [<https://perma.cc/6WX A-9E33>] (stating that “a growing number of transgender, gender-nonconforming and male identified people . . . are seeking out gender-inclusive makeup products, and companies—both old and new—are responding to their demand”).

84. Bartlett, *supra* note 16, at 849.

85. *Id.* at 846.

86. There is, however, a “growing permissibility” of cosmetics and hair dye for straight men. ROBIN TOLMACH LAKOFF & RAQUEL L. SCHERR, *FACE VALUE: POLITICS OF BEAUTY* 224 (1989); see also Jacob Gallagher, *More Men Are Wearing Makeup Than You Think—Here’s Why*, WALL ST. J. (Apr. 13, 2018), <https://www.wsj.com/articles/more-men-are-wearing-makeup-than-you-thinkheres-why-1523626771>

average woman uses 12 products containing 168 unique ingredients every day,” whereas the average man “use[s] 6 products daily with 85 unique ingredients.”⁸⁷ Another poll found that 54 percent of male respondents indicated that they use no “skin care and styling products (such as moisturizers, hair styling products, and makeup) . . . to get ready in the morning on a typical day” whereas only 16 percent of female respondents indicated they use no products.⁸⁸ A larger portion of women than men indicated that they use three or more products (45 percent vs. 11 percent).⁸⁹ And as noted earlier, most women (86 percent) use makeup—a type of cosmetic.⁹⁰

Cosmetics use may not be voluntary for women. For example, employers may have gendered employee dress codes that require female—but not male—employees to wear makeup.⁹¹ And even when employers do not require women to use cosmetics, women may face other pressures to do so.⁹² For example, cosmetics use can impact how people perceive themselves and are perceived by others and may have significant effects on both interpersonal relationships and economic opportunities.⁹³

Women also may be exposed to cosmetics through their employment. Women are significantly more likely than men to hold certain jobs that often involve exposure to cosmetics as beauty work is often done for women by

[<https://perma.cc/TAN8-UNVX>]; PEISS, *supra* note 3, at 265. The men’s grooming and personal care products industry in the United States has grown in recent years. *See, e.g.*, MEN’S PERSONAL CARE, *supra* note 3.

87. EWG, *Exposures Add Up*, *supra* note 74.

88. *Survey*, YOUGov (Sept. 10–11, 2013), http://cdn.yougov.com/cumulus_uploads/document/ypg8eyjbsv/tabs_skincare_0910112013.pdf [<https://perma.cc/UR2N-ZRFA>] (surveying subjects regarding their morning and evening routines, as well as the cosmetics products used in the process).

89. *Id.* The number of products used varied by other factors including age, race, and education. *Id.*

90. COLOR COSMETICS, *supra* note 6; FDCA § 201(i), 21 U.S.C. § 321(i).

91. *See* *Jespersen v. Harrah’s Operating Co.*, 392 F.3d 1076 (9th Cir. 2004). *Jespersen v. Harrah’s Operating Co.* was a case that involving a female bartender who was fired for refusing to wear makeup in violation of her employer’s appearance standards. *Id.* Her case was not successful. *Id.* The Ninth Circuit Court of Appeals affirmed the grant of summary judgment to the employer; it held that the employee failed to establish a prima facie case of gender discrimination under Title VII of the Civil Rights Act of 1964. *Id.* Employer dress codes may have class implications.

92. Beauty serves as a “proxy for status and ability.” Nancy L. Etcoff et al., *Cosmetics as a Feature of the Extended Human Phenotype: Modulation of the Perception of Biologically Important Facial Signals*, 6 PLOS ONE e25656 (Oct. 2011), <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0025656#pone.0025656-Etcoff2> [<https://perma.cc/6HK5-8YMS>]. However, beauty is malleable. Lauren Silverio, *Makeup’s Effects on Self-Perception* (Old Dominion Univ., STEM Educ. & Prof’l Stud., OTS Master’s Level Projects & Papers 49, 2010), https://digitalcommons.odu.edu/cgi/viewcontent.cgi?article=1048&context=ots_masters_projects [<https://perma.cc/4JPT-HKEJ>]. For example, one study found that study participants “[w]hen inferring trustworthiness, likeability, or competence from an image” of a woman, were “influenced significantly” not only by inherited features “but by the effects of . . . makeup.” Etcoff, *supra*.

93. Kirsten Dellinger & Christine L. Williams, *Makeup at Work: Negotiating Appearance Rules in the Workplace*, GENDER & SOC’Y 151, 153 (1997); Deborah L. Rhode, *The Injustice of Appearance*, 61 STAN. L. REV. 1033, 1037-38 (2009). Cosmetics may also be a source of pleasure. *See, e.g.*, PEISS, *supra* note 3, at 269.

women.⁹⁴ For example, in 2017, 92.6 percent of hairdressers, hairstylists, and cosmetologists were women.⁹⁵ In addition, 90.5 percent of the people employed in beauty salons were women, as were 73.9 percent of those in nail salons and other personal care services.⁹⁶

Factors other than gender also impact cosmetics use and exposure. Cosmetics usage and exposure differ among women of different racial and ethnic groups.⁹⁷ For example, African Americans' spending on personal care products as a portion of the total market, according to one estimate, exceeds their portion of the U.S. population, which "suggest[s] that they buy and use more such products."⁹⁸ Another study similarly found that African American women spend 80% more than the general market on cosmetics, and two times that of other ethnic groups on hair products.⁹⁹

Indeed, there also may be racial differences in the types of cosmetics women use.¹⁰⁰ For example, many African American girls have chemical relaxers applied to their hair for the first time during childhood and "African American . . . women are more likely [than white women] to use a greater number and variety of hair products, and to have their hair chemically or professionally treated."¹⁰¹ In addition, "Black women are more likely . . . to use vaginal douches as well as other fragranced feminine cleansing products such as sprays and wipes."¹⁰²

94. PEISS, *supra* note 3; KAY, *supra* note 3. While the economic opportunities in the cosmetics industry provides should not be minimized, it is important to recognize that these opportunities may be accompanied by workplace exposure to the cosmetics and associated risks. See *infra* Section II.B.

95. BLS, DETAILED OCCUPATION, *supra* note 6. Of those 76.7% were white, 16.3% Hispanic/Latina, 13.5% black, and 5.6% Asian. *Id.*

96. BUREAU OF LABOR STATISTICS, EMPLOYED PERSONS BY DETAILED INDUSTRY, SEX, RACE, AND HISPANIC OR LATINO ETHNICITY tbl.18 <https://www.bls.gov/cps/cpsaat18.htm> [<https://perma.cc/D5XD-TBBB>] [hereinafter BLS, DETAILED INDUSTRY].

97. Zota & Shamasunder, *supra* note 63, at 418–20 (noting that "[w]orkers in the beauty industry, who are predominately women of color and immigrant women, can . . . face occupational health hazards from chemicals in professional cosmetic products").

98. PAUL PESTANO ET AL., ENVIRONMENTAL WORKING GROUP, BIG MARKET FOR BLACK COSMETICS, BUT LESS-HAZARDOUS CHOICES LIMITED (2016), <http://www.firstresearch.com/Industry-Research/Personal-Care-Products-Manufacturing.html> [<https://perma.cc/4HHC-TR2T>].

99. See Stephanie D. Smith, *Essence Panel Explores Beauty Purchasing*, WWD (May 19, 2009), <https://wwd.com/beauty-industry-news/color-cosmetics/essence-panel-explores-beauty-purchasing-2139829/> [<https://perma.cc/7Z58-AQYG>]; Rajiv Shah & Kelly E. Taylor, Note, *Concealing Danger: How the Regulation of Cosmetics in the United States Puts Consumers at Risk*, 23 FORDHAM ENVTL. L. REV. 203, 212 (2012); see also Tamarra James-Todd et al., *Racial/Ethnic Differences in Hormonally-Active Hair Product Use: A Plausible Risk Factor for Health Disparities*, 14 J. IMMIGRANT & MINORITY HEALTH 506 (2012) (finding that African American and African-Caribbean women from the New York metropolitan area were more likely to be exposed to hormonally-active chemicals in hair products compared to white women); Zota & Shamasunder, *supra* note 63.

100. Dark-skinned women of various races may disproportionately use skin lightening creams, which have several potential adverse outcomes. See Zota & Shamasunder, *supra* note 63, at 419 (table); see also Imani Perry, *Buying White Beauty*, 12 CARDOZO J.L. & GENDER 579, 590-91 (2006) (discussing skin-bleaching creams and stating that "[t]he whitening of the world's wealthy is a much safer affair than that of its poorer, and blacker, populations").

101. Zota & Shamasunder, *supra* note 63, at 419.

102. *Id.* at 420.

There also may be significant racial differences in employment in certain jobs that involve the use of cosmetics. For example, while 76.7 percent of hairdressers, hairstylists, and cosmetologists are white and 5.6 percent are Asian,¹⁰³ only 44.8 percent of people employed in “nail salons and other personal care services” are white and 46.3 percent are Asian.¹⁰⁴

Furthermore, there may be class differences between beauty workers and customers. For example, in *The Managed Hand: Race, Gender, and the Body in Beauty Service Work*, Miliann Kang “explore[s] commonalities and differences” among Asian immigrant women in the nail salon industry in the United States.¹⁰⁵ She discusses how nail salons bring “women who usually would not find themselves in the same social circles” into close physical contact and how these interactions “demonstrate how women inhabit bodies differently as well as how women’s bodies are differentially valued and employed.”¹⁰⁶ Kang explores how gender, race, and class interact in nail salons through “three different forms of body labor at Asian-owned nail salons: ‘pampering body labor’ in nail art salons serving mostly white upper-[]and middle-class women; ‘expressive body labor’ in nail art salons serving mostly black working-and lower-middle-class women; and ‘routinized body labor’ at discount nail salons serving racially and socioeconomically mixed customers.”¹⁰⁷

B. *Cosmetics Safety*

The cosmetics industry and FDA have stated that “[c]osmetics are the safest products that FDA regulates.”¹⁰⁸ But even if cosmetics are the safest products that the agency regulates, cosmetics are not necessarily safe, as the harms caused by other products that FDA regulates are well-documented.¹⁰⁹

103. BLS, DETAILED OCCUPATION, *supra* note 6.

104. BLS, DETAILED INDUSTRY, *supra* note 96.

105. MILIANN KANG, *THE MANAGED HAND: RACE, GENDER, AND THE BODY IN BEAUTY SERVICE WORK* 11-12 (2010) (ebook). Kang’s work focuses on Korean women working in the nail salon industry in New York City. *Id.* at 12.

106. *Id.* at 11-12.

107. *Id.* at 16.

108. See, e.g., *Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 112th Cong. (2012) (statement of Peter Barton Hutt, Senior Counsel, Covington & Burling, LLP), <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/Health/20120327/HHRG-112-IF14-WState-HuttP-20120327.pdf> [<https://perma.cc/MU6J-STYJ>]; *Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 112th Cong. (2012), (Statement of Halyna Breslawec, Chief Scientist & Exec. Vice President for Sci., Pers. Care Prod. Council), <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/Health/20120327/HHRG-112-IF14-WState-BreslawecH-20120327.pdf> [<https://perma.cc/PDS4-Q7YD>]; Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 461 (2008).

109. See FDCA § 301, 21 U.S.C. § 331 (2012) (prohibiting certain acts with respect to “any food, drug, device, tobacco product, or cosmetic”); U.S. FOOD & DRUG ADMINISTRATION, FOOD, <https://www.fda.gov/Food/default.htm> [<https://perma.cc/N3RM-TMCM>] (food); U.S. FOOD AND DRUG ADMINISTRATION, DRUGS, <https://www.fda.gov/Drugs/default.htm> [<https://perma.cc/57BA-VK7R>]

While a comprehensive review of the literature on cosmetics safety is beyond the scope of this Article,¹¹⁰ there is reason to be concerned about the potential hazards that cosmetics may pose. Other legal scholars and commentators have discussed the potential risks of a host of cosmetics products, ingredients, and contaminants, including phthalates, permanent hair relaxers,¹¹¹ spray tan solutions,¹¹² tattoos and micropigmentation inks,¹¹³ henna (and henna containing PPD and lead),¹¹⁴ nail salon products,¹¹⁵ nanoparticles,¹¹⁶ and chemicals that have the potential to disrupt the human endocrine system.¹¹⁷ The potential hazards that the literature discusses vary, and include severe scalp burns, early puberty in girls, premature delivery, adverse effects on male reproductive development, and cancer.¹¹⁸

Women may be disproportionately impacted due to differences in exposure. As noted earlier, on average, women use more cosmetics than men and are exposed to more chemicals than men through this use.¹¹⁹ Women may also be exposed to cosmetics through their work, as “beauty work” is often done by women.¹²⁰ Women also may be uniquely vulnerable to potential health harms from chemical exposure. For example, women’s bodies may “store chemicals cumulatively more effectively than men’s bodies, placing women at greater

(drugs); U.S. FOOD AND DRUG ADMINISTRATION, TOBACCO PRODUCTS, <https://www.fda.gov/TobaccoProducts/default.htm> [<https://perma.cc/4DMF-3NUV>] (tobacco products); *supra* note 13 (discussing harms of drugs, foodborne diseases, and cigarettes).

110. The focus of this Article is on physical risks, but cosmetics may pose economic harms as well. See 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, 250 (1999) (“However, the FDA’s focus on physical safety, and its attempted designation of skin care cosmetics as drugs, has ignored the significant responsibility of the agency to protect the public against highly questionable efficacy claims by certain cosmetics manufacturers.”); 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, 54 (2008) (“The current regulatory scheme does not always give consumers adequate economic protection.”).

111. Shah & Taylor, *supra* note 99, at 210–14.

112. Jessica M. Dugdale, *A Plea for Consumer Protection: The Potential Human Health Hazards of the Spray Tanning Epidemic*, 11 IND. HEALTH L. REV. 347, 359–60 (2014).

113. Jessica C. Dixon, *The Perils of Body Art: FDA Regulation of Tattoo and Micropigmentation Pigments*, 58 ADMIN. L. REV. 667, 682 (2006).

114. Carrie Griffin Basas, *Henna Tattooing: Cultural Tradition Meets Regulation*, 62 FOOD & DRUG L.J. 779, 791 (2007).

115. Sarah A. Walsh, *Beyond the Polish: An Examination of Hazardous Conditions in Nail Salons and Potential Solutions for the Industry in New York City*, 21 J.L. & POL’Y 243, 256–60 (2012).

116. Gregory Mandel, *Nanotechnology Governance*, 59 ALA. L. REV. 1323, 1340–44 (2008); Donald R. Johnson, *Not in My Makeup: The Need for Enhanced Premarket Regulatory Authority over Cosmetics in Light of Increased Usage of Engineered Nanoparticles*, 26 J. CONTEMP. HEALTH L. & POL’Y 82, 94–102 (2009); Robin Fretwell Wilson, *Nanotechnology: The Challenge of Regulating Known Unknowns*, 34 J.L. MED. & ETHICS 704, 705–06, 708–09 (2006).

117. Valerie J. Watnick, *The Missing Link: U.S. Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment*, 31 PACE ENVTL. L. REV. 595, 607–11 (2014); Anastasia De Paz, *The Cosmetic Regime Needs A Makeover: Advocating to Empower the FDA Through the Safe Cosmetics Act of 2011*, 31 TEMP. J. SCI. TECH. & ENVTL. L. 337, 340–42 (2012).

118. See, e.g., Shah & Taylor, *supra* note 99, at 211–18.

119. See *supra* Section II.A.

120. PEISS, *supra* note 3; KAY, *supra* note 3; *supra* note 69 and accompanying text; *supra* Section II.A.

risk.”¹²¹ Women of reproductive age and their offspring may be at particular risk from these exposures, as “preconception and prenatal exposure to toxic environmental agents can have a profound and lasting effect on reproductive health across the life course.”¹²²

Women who are members of other excluded groups may be at even greater risk. These women may use or otherwise be exposed to more cosmetics, including particular types of cosmetics, as cosmetics usage and work are not only gendered, but also differ by race.¹²³

The cosmetics that women who are members of other excluded groups are exposed to also may be more hazardous. For example, Imani Perry suggests that “the availability of technological resources is higher for those who are already privileged” and that this may reinforce existing hierarchies: “[i]f one can afford to . . . purchase the gentler products, the odds are that the person is already closer to the [beauty] ideal.”¹²⁴ One analysis found that “[a] smaller share of hair and beauty products marketed to Black women scored low in potentially harmful ingredients than products aimed at the general public.”¹²⁵ Cosmetics have been associated with health hazards in women of color.¹²⁶ For example, one study found an association between using hair dye more than twice a year, use of dark hair dye shades, and salon application of hair dyes and the risk of estrogen-positive breast cancer in African American women.¹²⁷

Some women may have greater exposure to toxic environmental chemicals due to a variety of factors. A report by the Committee on Health Care for Underserved Women of the American College of Obstetricians and Gynecologists notes that “harmful environmental exposure is inequitably and unequally distributed, which leaves some populations, including underserved

121. De Paz, *supra* note 117, at 341.

122. *Id.*; Shah & Taylor, *supra* note 99, at 209. One analysis found that women ages eighteen to thirty-four—women of reproductive age—are more likely to be “the heaviest buyers of cosmetics.” *Millennial Women Key to Growth in Cosmetics Industry*, TABS ANALYTICS BLOG (Jan. 20, 2016), <https://www.tabsanalytics.com/blog/millennial-women-key-to-growth-in-cosmetics-industry> [<https://perma.cc/Y2NX-S7WP>]; see also AM. COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS COMM. ON GYNECOLOGIC PRAC., COMMITTEE OPINION, NUMBER 589, FEMALE AGE-RELATED FERTILITY DECLINE (Mar. 2014 reaffirmed 2018), <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Female-Age-Related-Fertility-Decline> [<https://perma.cc/M4HU-YF75>] (discussing age and fertility).

123. See Perry, *supra* note 100, at 588; see also Zota & Shamasunder, *supra* note 63.

124. Perry, *supra* note 100, at 595.

125. PESTANO ET AL., *supra* note 98.

126. See, e.g., Lauren A. Wise et al., *Hair Relaxer Use and Risk of Uterine Leiomyomata in African-American Women*, 175 AM. J. EPIDEMIOLOGY 432, 435 (2012) (finding “increased risks of uterine leiomyomata in association with ever use of hair relaxers, duration of use, frequency of use, and total number of burns experienced during use”); Jasmine A. McDonald et al., *Hair Product Use, Age at Menarche and Mammographic Breast Density in Multiethnic Urban Women*, 17 ENVIRON. HEALTH 1, 8 (2018) (concluding that “childhood hair product use is associated with earlier age at menarche, an established risk factor for breast cancer”).

127. Llanos et al., *supra* note 65, at 888. The study also found an association between certain hair products and breast cancer in white women. *Id.* The study noted that there are differences in product use among African American and white women. *Id.*

women, more vulnerable to adverse reproductive health effects than other populations.”¹²⁸ The exposure sources listed for some of the chemicals linked to negative reproductive or developmental health effects in the report include cosmetics and personal care products.¹²⁹ “[B]eauty product use may be one way that structural discrimination becomes biologically embedded,” as racial discrimination can influence product use and “[t]argeted racial/ethnic marketing can influence product use and related health inequities.”¹³⁰

Some workplaces may expose the women who work in them to high levels of potentially toxic chemicals from cosmetics.¹³¹ For example, one study of Vietnamese women working in nail salons in California noted that “[n]ail technicians handle solvents, glues, polishes, and other agents on a daily basis exposing them to numerous chemicals, many of which are known or suspected to cause cancer, allergies, and respiratory, neurologic, and reproductive harm.”¹³² The study measured levels of total volatile organic compounds that exceed the Environmental Protection Agency’s recommended levels and were “in the range . . . at which discomfort is expected and complaints of health symptoms, including headaches and irritations of the eyes, nose, and throat, are common.”¹³³

Because of differences in usage, exposure, and biology, women may be subject to greater risk from exposure to toxic chemicals in cosmetics than men are. As a result, any regulatory failure to control these risks may disproportionately impact women. Furthermore, because of differences in usage and exposure, women who are members of other excluded groups may be at particular risk. This Article now turns to the shortcomings of cosmetics law and regulation.

C. *Cosmetics Law & Regulation*

Despite significant changes in the law with respect to the other major product categories under FDA’s jurisdiction, the FDCA’s cosmetics provisions have remained largely unchanged since the Act was passed in 1938. This Section begins with an overview of the 1938 Act. It then discusses the current laws and regulations with an emphasis on the changes since the FDCA was enacted. It also discusses the cosmetics industry’s self-regulatory measures and how FDA

128. EXPOSURE TO TOXIC AGENTS, *supra* note 63, at 1.

129. *Id.* at 3-4 tbl.2.

130. Zota & Shamasunder, *supra* note 63, at 419.

131. Women who receive services in these locations may also be exposed to potentially toxic chemicals although likely for shorter time periods than workers. Cosmetics intended for professional use only are less regulated than those intended for consumer use, which may also lead to differences in exposure. See *supra* Section II.2.d-e.

132. Thu Quach et al., *Characterizing Workplace Exposures in Vietnamese Women Working in California Nail Salons*, 101 AM. J. PUB. HEALTH S271, S271 (2011).

133. *Id.* at S274.

regulates cosmetics in this environment. This Section ends by highlighting several significant differences between how cosmetics and other products are regulated. It argues that the divide between cosmetics law and regulation and the law and regulation of the other major product categories defined in the FDCA has grown since the 1938 Act was first enacted. These changes have deprioritized the regulation of cosmetics, the product category most closely associated with women. The limitations of cosmetics law and regulation hinder the ability to meaningfully assess the safety of cosmetics.

1. *The Federal Food, Drug & Cosmetic Act of 1938*

The 1938 FDCA created the first federal law for the regulation of cosmetics.¹³⁴ As discussed in Section I.A, cosmetics are “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,” including articles intended to be a component of those articles, but not soap.¹³⁵

The FDCA prohibited certain acts related to the misbranding and adulteration of cosmetics as well as the causing of those acts provided that certain interstate commerce connections were met.¹³⁶ The FDCA provided that a cosmetic is adulterated if it “contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the [its] labeling . . . or under such conditions of use as are customary or usual,” but it excepted coal-tar hair dyes that comply with certain labeling requirements.¹³⁷ The FDCA also provided that a cosmetic that “consists in whole or in part of any filthy, putrid, or decomposed substance” or that “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,” is adulterated.¹³⁸ A cosmetic’s container could also render the cosmetic adulterated if the “container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.”¹³⁹ The FDCA also provided that a cosmetic other than a hair dye containing a coal-tar color that had not been properly batch certified is adulterated.¹⁴⁰

134. See Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. 75-717, 52 Stat. 1040 (June 25, 1938).

135. *Id.* § 201(i). The definition of cosmetics in the original Act has remained unchanged. Compare *id.*, with FDCA § 201(i), 21 U.S.C. § 321(i) (2012).

136. FDCA § 301 (1938).

137. *Id.* § 601(a).

138. *Id.* § 601(b)-(c).

139. *Id.* § 601(d).

140. *Id.* § 601(e).

The FDCA also provided that a cosmetic with labeling that “is false or misleading in any particular” is misbranded.¹⁴¹ A packaged cosmetic is also misbranded if it does not bear a label with “the name and place of business of the manufacturer, packer, or distributor,” and “an accurate statement of the quantity” of contents.¹⁴² Other misbranding provisions addressed the prominence of required information and misleading containers.¹⁴³

2. *Current Law & Regulation*

a. The Federal Food, Drug & Cosmetic Act of 1938 as Amended

Since 1938, the FDCA’s cosmetics provisions have changed little. The FDCA has grown from about 10 pages to nearly 500,¹⁴⁴ yet the cosmetics provisions remain less than two pages.¹⁴⁵ As in the original act, the current cosmetics provisions focus on prohibiting the certain acts related to the adulteration and misbranding of cosmetics,¹⁴⁶ and like the original act, they except coal-tar hair dyes from the adulteration provision for cosmetics containing any poisonous or deleterious substance.¹⁴⁷

141. *Id.* § 602(a).

142. *Id.* § 602(b).

143. *Id.* § 601(c)-(d).

144. Compare 21 U.S.C. §§ 301-392 (1938 supp. IV), with 21 U.S.C. ch. 9 (2012).

145. See generally FDCA, 21 U.S.C. ch. 9 (2012).

146. The FDCA provides that a cosmetic that “contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the [product’s] labeling . . . or under such conditions of use as are customary or usual” or that contains an “unsafe” color additive as defined in FDCA § 721 (21 U.S.C. § 379e(a)) is adulterated, although it excepts coal-tar hair dyes. FDCA §§ 301, 601, 21 U.S.C. §§ 331, 361 (2012). A cosmetic’s container can also render the cosmetic adulterated if the “container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.” *Id.* Finally, the FDCA also provides that a cosmetic that “consists in whole or in part of any filthy, putrid, or decomposed substance” or that “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,” is adulterated. *Id.* In addition, the FDCA provides that a cosmetic the labeling of which “is false or misleading in any particular” is misbranded. FDCA § 602(a), 21 U.S.C. § 362(a); see also 21 C.F.R. § 1.21 (2018) (failure to reveal material facts); 21 C.F.R. pt. 701 (2018) (Cosmetic Labeling). A cosmetic in packaged form the label of which does not contain “the name and place of business of the manufacturer, packer, or distributor,” “an accurate statement of the quantity” of contents, or the required ingredient declarations is also misbranded. FDCA § 602(b), 21 U.S.C. § 362(b); 15 U.S.C. § 1456 (2012); 21 C.F.R. § 701.3 (2018). Other misbranding provisions address the prominence of required information, misleading containers, color additives that don’t conform to packaging and labeling requirements, and violations of regulations issued pursuant to the provisions of the Poison Prevention Packaging Act of 1980 regarding special packaging standards for household substances to protect children from serious injury or illness and noncomplying packages (21 U.S.C. §§ 1472-1473). FDCA § 601(c)-(f), 21 U.S.C. § 362(c)-(f) (2012). There are also requirements for cosmetics under other laws. For example, under the Federal Trade Commission Act, false, misleading, or deceptive advertising claims for cosmetics are prohibited. Federal Trade Commission Act, 15 U.S.C. § 41-58; see also Jason Rea, “Actual Results May Vary”: Toward Fiercer National Regulation of Digitally Manipulated Cosmetics Advertisements, 19 WM. & MARY J. WOMEN & L. 161, 163 (2012).

147. FDCA § 601(a), 21 U.S.C. § 361(a) (2012).

The adulteration and misbranding provisions have been amended to reflect the changes in how color additives are regulated: the adulteration provisions now refer to unsafe color additives instead of uncertified coal-tar colors in the provision providing that a cosmetic—other than a hair dye—that contains an unsafe color additive is adulterated.¹⁴⁸ The misbranding provisions also have been amended to add a provision providing that a cosmetic that is a color additive is misbranded if its packaging and labeling do not conform with the regulations for that color additive.¹⁴⁹ The misbranding provisions have also been amended to provide that a cosmetic is misbranded “[i]f its packaging or labeling is in violation of an applicable regulation issued pursuant to [the Poison Prevention Packaging Act (PPPA) (15 U.S.C. 1473-73)].”¹⁵⁰ Also, intentionally added plastic microbeads in wash-off cosmetics have been banned¹⁵¹ due to environmental concerns about microbead pollution.¹⁵²

b. FDA Regulations

Until 1972, FDA lacked a formal regulatory program for cosmetics, instead taking “regulatory action on a case-by-case basis.”¹⁵³ In the years since, FDA has promulgated regulations specifically for cosmetics under the authority granted to it by Congress under the FDCA, the PPPA, and the Fair Packaging & Labeling Act.¹⁵⁴ Many of FDA’s cosmetics regulations set forth labeling requirements.¹⁵⁵ For example, cosmetics that are marketed to consumers are required to have a list of ingredients,¹⁵⁶ although there are exceptions for fragrances and flavors, which may be listed as such.¹⁵⁷

FDA has also restricted or prohibited the use of eleven ingredients or types of ingredients in cosmetics due to safety concerns.¹⁵⁸ It requires warnings on

148. FDCA § 601(e), 21 U.S.C. § 361(e) (2012).

149. FDCA § 602(e), 21 U.S.C. § 362(e) (2012). Colors that “are marketed and intended for use only in or on hair dyes” are excepted. *Id.*

150. FDCA § 602(f), 21 U.S.C. § 362(f) (2012).

151. FDCA § 301(ddd), 21 U.S.C. § 331(ddd) (2017 supp. V).

152. *See, e.g., Sarah Kettenmann, Nationwide Ban on Plastic Microbeads in Cosmetics*, NAT. RESOURCES & ENV’T, Summer 2016, at 58.

153. GAO, HRD-78-139, *supra* note 9, at iii.

154. *See* 21 C.F.R. pts. 700-740 (2018).

155. 21 C.F.R. § 701 (2018). There are also regulations related to the approval of color additives for specific uses in cosmetics.

156. FDCA § 601, 21 U.S.C. § 361; 15 U.S.C. § 1456 (2012); 21 C.F.R. § 701.3; *see also* FDA AUTHORITY OVER COSMETICS, *supra* note 21 (noting that “[t]his requirement does not apply to cosmetics distributed solely for professional use, institutional use (such as in schools or the workplace), or as free samples or hotel amenities”). Cosmetics that do not have the required ingredient list are deemed misbranded. *See* FDCA § 601, 21 U.S.C. § 361; 21 C.F.R. § 701.3 (2018).

157. FDCA § 602(a), 21 U.S.C. § 362(a); 21 C.F.R. § 701.3(a).

158. *See* 21 C.F.R. pt. 700 (2018); 21 C.F.R. § 250.250 (2018) (Hexachlorophene, as a component of drug and cosmetic products); *see also Examining the Current State of Cosmetics: Hearing Before the Subcomm. on Health, Comm. on Energy & Commerce, and H.R.*, 112 Cong. (2012) (statement of Michael M. Landa, Director of Center for Food Safety & Applied Nutrition, Food & Drug Administration), <https://>

certain cosmetics—feminine deodorant sprays, foaming detergent bath products, coal tar hair dyes posing a risk of cancer, and sun tanning preparations—as well as cosmetics in self-pressurized containers and cosmetics containing an ingredient that has not been “adequately substantiated for safety.”¹⁵⁹ In addition, FDA has promulgated regulations that require tamper-resistant packaging for certain cosmetics that are accessible to the public while held for retail sale.¹⁶⁰

c. FDA Staff & Resources

Cosmetics are the only major product category that does not have its own center within FDA; instead, cosmetics are regulated by FDA’s Center for Food Safety and Applied Nutrition (CFSAN).¹⁶¹ Within the CFSAN, FDA’s Office of Cosmetics and Colors is responsible for both the oversight of cosmetics regulation¹⁶² as well as the color additive certification program.¹⁶³ In a 2008 report prepared by Peter Barton Hutt for the Science Review Subcommittee of the FDA Science Board, he noted that FDA was unable to separate the funding and personnel numbers for cosmetics from the numbers for CFSAN, a difficulty that he indicated others had encountered as well.¹⁶⁴ Nevertheless, Hutt determined that between 1977 and 2007, funding and staff levels for cosmetics regulation decreased to a total of fourteen staff at CFSAN—which he described as “clearly insufficient”—and \$3.5 million—which he described as “minimal.”¹⁶⁵

archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/Health/20120327/HHRG-112-IF14-WState-LandaM-20120327.pdf [https://perma.cc/382A-ZWEL] [hereinafter Landa Statement]. These ingredients are bithionol, mercury compounds, vinyl chloride, certain halogenated salicylanilides, zirconium, chloroform, methylene chloride, chlorofluorocarbon propellants, certain cattle materials, sunscreens, and hexachlorophene. 21 C.F.R. pt. 700; 21 C.F.R. § 250.250 (Hexachlorophene, as a component of drug and cosmetic products). In contrast, the European Union, which has taken a more stringent approach cosmetics, has “banned the sale of cosmetics or personal care products that contain any ingredients on a list of more than one-thousand chemicals known or suspected of causing cancer, genetic mutations, or birth defects.” Deborah E. Mason, *Kiss and Make-Up: A Need for Consolidation of FDA and Cosmetic Industry Regulation Programs*, 18 HEALTH MATRIX 181, 192 (2008).

159. 21 C.F.R. pt. 740 (2018).

160. 21 C.F.R. § 700.25 (2018).

161. FDA, *About FDA, CFSAN—What We Do*, <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/WhatWeDo/default.htm> [https://perma.cc/JJ67-FNLC] [hereinafter FDA, CFSAN]; Greff, *supra* note 27, at 248.

162. FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS, SMG 1231.141, FOOD AND DRUG ADMINISTRATION, OFFICE OF FOODS AND VETERINARY MEDICINE, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, OFFICE OF COSMETICS AND COLORS, DIVISION OF COLOR CERTIFICATION AND TECHNOLOGY (Oct. 1, 2012), <https://www.fda.gov/Downloads/Aboutfda/Reportsmanualsforms/Staffmanualguides/Ucm328610.Pdf> [https://perma.cc/8QMY-WFQK].

163. *Id.*

164. Hutt, *supra* note 108, at 433.

165. *Id.* at 460-61. FDA’s operating plan for fiscal year 2018, indicates a total of 11.7 million dollars in budget authority funding for cosmetics activities (8.106 million for the center, 3.414 for the field, and 0.18 for the National Center for Toxicological Research). FDA, *Food and Drug Administration, Operating Plan for FY 2018*, <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Rep>

d. Industry Measures

FDA relies heavily on voluntary industry measures for cosmetics.¹⁶⁶ FDA has created a voluntary registration program for cosmetics establishments.¹⁶⁷ It also has created a voluntary filing program for cosmetics ingredient composition statements.¹⁶⁸ These voluntary programs exclude cosmetics that are for professional use only and those that are not for sale.¹⁶⁹ The cosmetics industry supported these voluntary programs as a way “to demonstrate the industry’s willingness to supply information to FDA and to discourage Congressional legislation.”¹⁷⁰

The cosmetics industry has undertaken other voluntary measures. For example, the Cosmetic Ingredient Review (CIR) reviews the safety of cosmetics ingredients. The Personal Care Products Council (PCPC), “the leading national trade association representing the global cosmetic and personal care products industry,” created and funds the review.¹⁷¹ As of March 2017, CIR had done safety assessments of 4,740 ingredients—“4,611 [were] determined to be safe as used or safe with qualifications, 12 [were] determined to be unsafe, and 117 [were] ingredients for which the information is insufficient to determine

orts/BudgetReports/UCM610299.pdf [https://perma.cc/K7KV-LWY3]; see also FDA, *FY 2018 Operating Plan Narrative*, <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM610298.pdf> [https://perma.cc/67BT-VTHT].

166. For an analysis of how this compares with the regulation of other products, see Section II.C.2.e below.

167. 21 C.F.R. §§ 710 & 720 (2018).

168. *Id.* §§ 710 & 720. FDA has also issued guidance regarding cosmetics. See, e.g., FDA, DRAFT GUIDANCE FOR INDUSTRY: COSMETIC GOOD MANUFACTURING PRACTICES (June 2013), <https://www.fda.gov/cosmetics/guidanceregulation/guidancedocuments/ucm353046.htm> [https://perma.cc/T5D5-CUR4] [hereinafter FDA, COSMETIC GOOD MANUFACTURING PRACTICES]; FDA, GUIDANCE FOR INDUSTRY: SAFETY OF NANOMATERIALS IN COSMETIC PRODUCTS (June 2014), <https://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/GuidanceDocuments/UCM300932.pdf> [https://perma.cc/R5WM-2MVS]; FDA, GUIDANCE FOR INDUSTRY, LEAD IN COSMETIC LIP PRODUCTS AND EXTERNALLY APPLIED COSMETICS: RECOMMENDED MAXIMUM LEVEL DRAFT GUIDANCE (Dec. 2016), <https://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/GuidanceDocuments/UCM517268.pdf> [https://perma.cc/EZ2V-X4JH] [hereinafter FDA: LEAD IN COSMETIC LIP PRODUCTS].

169. FDA, *Voluntary Cosmetic Registration Program*, <https://www.fda.gov/cosmetics/registration-program/default.htm> [https://perma.cc/N9VK-256L].

170. Personal Care Prods. Council, *About Us: A Centennial History of the Personal Care Products Council*, <https://www.personalcarecouncil.org/about-us/history?page=2> [https://perma.cc/9QWK-TCYW].

171. *Id.*; Personal Care Prods. Council, <https://www.personalcarecouncil.org> [https://perma.cc/2K9G-RNWZ]; Personal Care Products Council, *CTFA Changes Name to the Personal Care Products Council, Launches Consumer Information Web Site on Product Safety* (Nov. 29, 2007), <https://www.personalcarecouncil.org/newsroom/ctfa-changes-name-personal-care-products-council-launches-consumer-information-web-site-product-safe> [https://perma.cc/S5WC-U7NV]; Casey Mee Lee Daum, *Self-Regulation in the Cosmetic Industry: A Necessary Reality or a Cosmetic Illusion?* (May 2006) (unpublished paper written to satisfy third-year writing requirement, Harvard Law School), <https://dash.harvard.edu/bitstream/handle/1/8965615/Daum06.html?sequence=2> [https://perma.cc/PV8H-VPCL].

safety.”¹⁷² The CIR is limited in that “it generally focuses on the ingredients’ potential to cause short-term dermatological reactions . . . not their potential to cause long-term health problems.”¹⁷³ Also, because the CIR is a voluntary industry measure, companies are not required to follow it.¹⁷⁴ It often finds insufficient data to “substantiate safety”¹⁷⁵ and a significant amount of information is not available to FDA and the public due to trade secret and fragrance exceptions to public review.¹⁷⁶

e. How Cosmetics Law & Regulation Lag Behind that of Other Product Categories

While the FDCA has been amended to give FDA greater authority over the other major product categories under its jurisdiction and strengthen its regulation of those product categories, as discussed above, the cosmetics provisions have remained largely unchanged. Accordingly, cosmetics are the least regulated of the major product categories within the Food and Drug Administration’s (FDA) jurisdiction.¹⁷⁷ This Section highlights some of the ways cosmetics law and regulation are less stringent than the law and regulation for other product categories.

As discussed in Section II.B, even if cosmetics are the safest product category, they are not necessarily safe. The shortcomings of current cosmetics law and regulation are particularly problematic because they hinder the ability to

172. Ivan J. Boyer et al., *The Cosmetic Ingredient Review Program—Expert Safety Assessments of Cosmetic Ingredients in an Open Forum*, 36 INT’L J. TOXICOLOGY (SUPPLEMENT 2) 5S, abstract (2017). For a discussion of the number of cosmetics ingredients, see *infra* notes 186–195 and accompanying text. The Research Institute for Fragrance Material, another self-regulatory program, reviews fragrance safety. Caroline M. Reeb, *Fragrant or Foul? Regulation of the Global Perfume Industry and the Implications for American Sovereignty*, 34 HASTINGS INT’L & COMP. L. REV. 223, 237 (2011) (discussing critiques of the expert panel which reviews fragrance safety data). *But see* Thomas J. Donegan, Jr., *Fifty Years of Cosmetic Safety: A Government and Industry Partnership*, 50 FOOD & DRUG L.J. 151, 156 (1995) (arguing that “[t]he CIR and RIFM programs combined are very effective in protecting public safety and in anticipating problems before government action is necessary”).

173. Shah & Taylor, *supra* note 99, at 204; Env’tl. Working Group (EWG), *FDA Fails to Protect Consumers* (2005), https://www.ewg.org/skindeep/2005/10/05/fda-fails-to-protect-consumers/#.W2sDii_GzGJ [<https://perma.cc/XWK2-YL4L>] [hereinafter EWG, *FDA Fails to Protect*]; *see also* ALEXANDER SCRANTON, WOMEN’S VOICES FOR THE EARTH, COSMETIC INGREDIENT REVIEW: FAILING THE PUBLIC. FAILING MANUFACTURERS. AN INVESTIGATIVE BRIEF BY WOMEN’S VOICES FOR THE EARTH (Apr. 2018), https://www.womensvoices.org/wpcontent/uploads/2018/04/CIR_final_report.pdf [<https://perma.cc/T76D-P6H5>] (arguing that “the CIR has significantly underestimated or dismissed potential health and environmental hazards of cosmetic ingredients”).

174. *See* Boyer et al., *supra* note 172, at 5S; Sarah E. Schaffer, *Reading Our Lips: The History of Lipstick Regulation in Western Seats of Power*, 62 FOOD & DRUG L.J. 165, 200 (2007).

175. Hartman, *supra* note 110, at 64; EWG, *FDA Fails to Protect*, *supra* note 173.

176. Shah & Taylor, *supra* note 99, at 226.

177. Paradise & Fitzpatrick, *supra* note 9, at 70; *see also* GAO/HRD-90-58, *supra* note 9; STATEMENT OF GREGORY J. AHART, *supra* note 9; GAO, HRD-78-139, *supra* note 9; *see also supra* note 161 and accompanying text (noting that cosmetics are the only major product category that does not have its own center devoted to their regulation).

accurately assess the safety of cosmetics, which in turn hinders the development of an appropriate regulatory system for cosmetics, leaving consumers at risk.

While drug, device, and tobacco product establishments and food facilities must register with FDA,¹⁷⁸ FDA has no mandatory registration requirement for cosmetics.¹⁷⁹ Instead, FDA's registration program for consumer cosmetics products is voluntary.¹⁸⁰ As a result, FDA may not "know the number of manufacturers, who they are, where they are, and what they make."¹⁸¹ Since the Voluntary Cosmetics Registration Program was established in 1972, there have been 3,260 active cosmetics establishment registrations,¹⁸² but because registration is voluntary and only covers products marketed to consumers, this does not represent "the total number of companies manufacturing or marketing cosmetics in this country."¹⁸³

Import and industry data suggest that the number of cosmetics establishments eligible for registration may be much higher than the number who have registered. Based on import records, FDA estimates that there are 29,000 foreign companies that manufacture cosmetics for or export cosmetics to the United States,¹⁸⁴ and IBISWorld estimates that there are 4,055 cosmetics and beauty product manufacturers in the United States.¹⁸⁵

Furthermore, unlike drug registrants, which are required to list with FDA drugs for commercial distribution and provide the name of each ingredient,¹⁸⁶ cosmetics manufacturers are not required to report the ingredients in their cosmetics products to FDA. FDA "estimate[s] that only one-third of cosmetics

178. See FDCA § 510(g), 21 U.S.C. § 360; FDCA § 415, 21 U.S.C. § 350d; FDCA § 905, 21 U.S.C. § 387e; 21 C.F.R. pt. 807 (2018); 21 C.F.R. pt. 1, subch. H (2018); 21 C.F.R. pt. 207 (2018).

179. See FDA, *Voluntary Cosmetic Registration Program*, *supra* note 169; Landa Statement, *supra* note 158, at 4–5, 9; COHEN, *supra* note 2, at 35.

180. FDA, *Voluntary Cosmetic Registration Program*, *supra* note 169; see also Landa Statement, *supra* note 158, 4–5; COHEN, *supra* note 2, at 35.

181. FDA, *Adverse Event Reports*, *supra* note 10.

182. FDA, *Registration Reports*, <https://www.fda.gov/Cosmetics/RegistrationProgram/RegistrationReports/default.htm> [<https://perma.cc/CR62-8CXH>]; see also Landa Statement, *supra* note 158 (stating that in 2012 the Voluntary Cosmetics Registration Program "ha[d] almost 1,600 domestic and foreign registered cosmetics establishments").

183. FDA, *Registration Reports*, *supra* note 182; FDA, *Voluntary Cosmetic Registration Program*, *supra* note 169 ("About VCRP").

184. Letter from Anna K. Abram, Deputy Commissioner for Policy, Planning, Legislation & Analysis, U.S. Food & Drug Admin., to the Honorable Frank Pallone, Jr., Ranking Member, Committee on Energy & Commerce, House of Representatives 2 (June 30, 2017), <https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/FDA%20Response%20to%20Rep.%20Pallone%20on%20Cosmetic%20Imports.pdf> [<https://perma.cc/GK4Z-XKFR>].

185. COHEN, *supra* note 2, at 4; see also *supra* Section I.A (discussing definition of cosmetics).

186. FDCA § 510, 21 U.S.C. § 360 (2018 supp. V); Who must list drugs and what drugs must they list?, 21 C.F.R. § 207.41 (2018); What listing information must a registrant submit for a drug it manufactures?, 21 C.F.R. § 207.49 (2018); see also FDCA § 904(a)(1), 21 U.S.C. § 387d (2012); FDA, *Submit Ingredient Listing for Tobacco Products*, <https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm602792.htm#9> [<https://perma.cc/RK3G-FV62>]. While food manufacturers generally do not need to notify or otherwise inform FDA of all of the ingredients that they use in food, this has been the subject of significant critique. See, e.g., Martha Dragich, *GRAS-Fed Americans: Sick of Lax Regulation of Food Additives*, 49 IND. L. REV. 305, 311 (2016).

manufacturers voluntarily file ingredient statements for their products” through the Voluntary Cosmetic Registration Program,¹⁸⁷ which, as noted above, only includes consumer cosmetics.¹⁸⁸ And unlike drugs and foods, which are generally required to have ingredient labeling regardless of whether the product is intended for consumer or professional use,¹⁸⁹ only cosmetics intended for retail sale are required to have ingredient labeling under the Fair Packaging and Labeling Act (FLPA) and FDA’s regulations.¹⁹⁰ Cosmetics intended for professional use only are not required to have ingredient labeling.¹⁹¹ Accordingly, both the identity and number of ingredients used in cosmetics is unknown. And consumers and workers may be unaware that the cosmetic intended for professional use only contains a potentially harmful ingredient.¹⁹²

The number of ingredients used in cosmetics is likely higher than the number of ingredients voluntarily reported by the cosmetics industry.¹⁹³ The number of ingredients that the industry has submitted to the Voluntary Cosmetic Registration Program and the number of ingredients in the International Cosmetic Ingredient Dictionary, however, may give some indication of the number of ingredients used in cosmetics. The industry has submitted about “6,000 ingredients used in 81 product categories” to the Voluntary Cosmetic Registration Program.¹⁹⁴ The International Cosmetic Ingredient Dictionary and Handbook “lists over 21,000 individual ingredients that were once used, are currently used, or are merely a supplier’s hope for future use,” and one review of the CIR process estimates that about “30% may be excluded from . . . review” and about “32% are currently in use.”¹⁹⁵ FDA estimated at one point that there were “[a]bout 12,500 different cosmetic ingredients and a similar number of fragrance ingredients . . . being used by the cosmetic industry.”¹⁹⁶

Concerns about cosmetics manufacturers failing to voluntarily register their establishments and products and file ingredient statements are not new. In a 1978 report, the United States General Accounting Office (GAO) recommended that

187. Landa Statement, *supra* note 158.

188. *See supra* note 180 and accompanying text.

189. FDCA § 403(i), (q), 21 U.S.C. § 343(i), (q) (2012); FDCA § 502(e), 21 U.S.C. § 352(e) (2012).

190. *See* FDCA, Fair Packaging and Labeling Act (FLPA), Pub. L. No. 89-755, 80 Stat. 1296 (1966) (codified at 15 U.S.C. §§ 1451–1461 (1970)); 21 C.F.R. § 701.3 (2018).

191. *See* AMALIA K. CORBY-EDWARDS, ANALYST IN PUB. HEALTH & EPIDEMIOLOGY, CONG. RESEARCH SERVICE, R42594, FDA REGULATION OF COSMETICS AND PERSONAL CARE PRODUCTS (July 9, 2012), http://asbcouncil.org/sites/default/files/library/docs/crs_report_fda_regulation_of_cosmetics_and_personal_care_products.pdf [<https://perma.cc/9SY8-XJBR>].

192. *See, e.g.*, Sharon E. Jacob et al., Commentary, *p-Phenylenediamine in Black Henna Tattoos: A Practice in Need of Policy in Children*, ARCHIVES OF PEDIATRICS & ADOLESCENT MED. 790, 791 (2008).

193. *See* Boyer et al., *supra* note 172.

194. *Id.* at 7S.

195. *Id.* at 7S, 10S.

196. FDA, COMPLIANCE PROGRAM GUIDANCE MANUAL, PROGRAM 7329.001 ch. 29 (Sept. 30, 2008), <https://web.archive.org/web/20090528173701/http://www.cfsan.fda.gov/~acrobat/cp29001.pdf> [<https://perma.cc/PSL7-UDHU>].

Congress give FDA the authority to require cosmetics establishment and product registration and the filing of ingredient statements.¹⁹⁷

The infrequency of cosmetics establishment inspections is also cause for concern. While the frequency of inspection for food, drug, device, and tobacco product establishments is specified by law, there are no comparable requirements for cosmetics establishments.¹⁹⁸ For example, the FDCA provides that domestic food facilities must be inspected, depending on their risk classification, once every three or five years.¹⁹⁹ The FDCA has also directed FDA to inspect drug and device establishments according to a risk-based schedule established by regulation.²⁰⁰

Given the lack of statutory mandate for cosmetics establishment inspection and the FDA's limited resources, it is not surprising that cosmetics establishments are inspected infrequently. In 2016, FDA inspected a total of 136 cosmetics establishments—133 domestic and 3 foreign.²⁰¹ The lack of required establishment registration may also complicate inspection efforts, as FDA may be unaware of some cosmetics establishments.²⁰² The low inspection rate for cosmetics establishments is not new. In 1978, FDA's Cosmetics Director noted that “[a]t FDA's fiscal 1979 levels, a cosmetic plant would be inspected without special circumstances every 20 to 25 years.”²⁰³

Furthermore, the scope of FDA's inspection authority for cosmetics is limited compared to drugs, certain devices, tobacco products, and foods. For example, if FDA has a reasonable belief that a food is adulterated and presents a threat of serious adverse health consequences or death, it may access records related to the food.²⁰⁴ FDA may also inspect records bearing on whether “prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products” are adulterated.²⁰⁵

197. See GAO, HRD-78-139, *supra* note 9, at 133.

198. See FDCA § 510(h), 21 U.S.C. § 360(h); FDCA § 421, 21 U.S.C. § 350j; FDCA § 905(g), 21 U.S.C. § 387e(g).

199. FDCA § 421, 21 U.S.C. § 350j.

200. FDCA § 510, 21 U.S.C. § 360(h).

201. FDA, OFFICE OF REGULATORY AFFAIRS—FIELD ACTIVITIES, FY 2018 FOODS (2018), <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM566331.pdf> [<https://perma.cc/YHC6-7U9A>].

202. See GAO, HRD-78-139, *supra* note 9; see also GAO, HRD-78-139, *supra* note 9, at v (stating that in the mid-1970s FDA “identified about 1,000 additional manufacturers, which it had never inspected because they had been unknown to the agency”).

203. 2 JAMES T. O'REILLY & KATHARINE A. VAN TASSELL, FOOD AND DRUG ADMINISTRATION § 17:9 (2018) (citing Address by Eiermann, FDA Cosmetics Director, to Society of Cosmetics Chemists (Sept. 27, 1978)).

204. FDCA § 704, 21 U.S.C. § 374; FDCA § 414, 21 U.S.C. § 350c(a)(1); see also FDA, GUIDANCE FOR INDUSTRY, FDA RECORDS ACCESS AUTHORITY UNDER SECTIONS 414 AND 704 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (Apr. 2014), <https://www.fda.gov/Food/GuidanceRegulation/ucm292745.htm> [<https://perma.cc/NW4J-B94Y>].

205. FDCA § 704, 21 U.S.C. § 374.

In contrast, FDA's inspection authority for cosmetics is generally restricted to certain establishments and vehicles and does not extend to records.²⁰⁶ Accordingly, manufacturers "have refused Food and Drug Administration inspectors access to manufacturing records."²⁰⁷ This may prevent FDA from, for example, effectively enforcing its requirement "that labeling of cosmetics that have not been adequately tested for safety including a warning to that effect," as the law doesn't require that manufacturers "make their test results available to the agency."²⁰⁸ This may also limit FDA's ability to investigate safety issues potentially associated with cosmetics.²⁰⁹

While FDA has promulgated quality systems regulations, known as Current Good Manufacturing Practice regulations, for foods,²¹⁰ drugs,²¹¹ and devices,²¹² it has only issued non-binding draft guidance and guidelines for cosmetics.²¹³ This may hinder FDA's ability to adequately regulate cosmetics as Good Manufacturing Practice regulations would provide "criteria to determine whether adequate methods, facilities, and controls are used in all phases of manufacturing and distribution of cosmetics."²¹⁴

The lack of mandatory reporting of adverse events to FDA is another area where cosmetics lag behind. While dietary supplement, drug, and device manufacturers must report certain adverse events²¹⁵ and food manufacturers must report reportable foods,²¹⁶ there are no comparable mandatory requirements for cosmetics.²¹⁷ FDA relies on voluntary measures for cosmetics.²¹⁸ Without

206. *Id.*

207. GAO, HRD-78-139, *supra* note 9, at iii.

208. *Id.*

209. FDA, *FDA Information for Consumers About WEN by Chaz Dean Cleansing Conditioners*, <https://www.fda.gov/cosmetics/productsingredients/products/ucm511631.htm> [<https://perma.cc/JW68-F7RF>] [hereinafter FDA, *Information About WEN*].

210. 21 C.F.R. pts. 110, 111 (2018).

211. 21 C.F.R. pts. 210, 211, 225, 226 (2018).

212. 21 C.F.R. pt. 820 (2018).

213. FDA, COSMETIC GOOD MANUFACTURING PRACTICES, *supra* note 168; Landa Statement, *supra* note 158; *see also* Greff, *supra* note 27, at 246. The FDCA requires FDA to promulgate regulations regarding tobacco product manufacturing practice regulations. *See* FDCA § 906, 21 U.S.C. § 387f(e); *see also* FDA, Tobacco Product Manufacturing Practice; Request for Comments, 82 Fed. Reg. 55,613 (Nov. 22, 2017).

214. GAO, HRD-78-139, *supra* note 9, at v.

215. FDCA § 201(ff), 21 U.S.C. § 321(ff); FDCA § 761, 21 U.S.C. § 379aa-1 (dietary supplements); FDCA § 760, 21 U.S.C. § 379aa (nonprescription drugs); FDCA § 761(a)(1), 21 U.S.C. § 379aa-1(a)(1); 21 C.F.R. § 314.80 (drugs) (2018); 21 C.F.R. § 803 (medical devices) (2018); *see also* FDA, *Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities*, <https://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/reportingadverseevents/default.htm> [<https://perma.cc/AHE5-2P39>].

216. FDCA § 417, 21 U.S.C. § 350f.

217. *See* FDA, *Adverse Event Reports*, *supra* note 10.

218. Daum, *supra* note 171. CFSAN has an adverse event report system where consumers, manufacturers, and health care professionals can voluntarily report adverse events associated with regulated products including cosmetics. *See* FDA, *Adverse Event Reports*, *supra* note 10; Michael Kwa et al., Research Letter, *Adverse Events Reported to the US Food and Drug Administration for Cosmetics and Personal Care Products*, Research Letter, 177 JAMA INTERNAL MED. 1202 (Aug. 2017).

mandatory reporting for cosmetics, as the Director of FDA's Office of Cosmetics and Colors recently stated in an interview, "often . . . [FDA is] just seeing the tip of the iceberg in [the adverse event reporting system]."²¹⁹ For example, as of November 15, 2016, FDA had received 1,386 consumer "reports of reactions reported to be associated with" certain cosmetics cleansing conditioners.²²⁰ "When . . . FDA inspected the manufacturing and distribution facilities for these products, [it] learned that consumers had reported reactions in more than 21,000 complaints submitted to . . . the companies that market and manufacture the products."²²¹ Under the current law, the companies are not required to report these complaints.²²² At one point, FDA had regulations for a voluntary program for the filing of cosmetics product experiences by cosmetics manufacturers, but these regulations were revoked.²²³

Finally, cosmetics do not require FDA approval prior to sale.²²⁴ In every other major product category included in the 1938 FDCA, at least some products now must be approved before they can be lawfully sold.²²⁵ Under the FDCA, the policing of the adulteration and misbranding of "cosmetics" as a category takes place after a violation occurs.²²⁶ And in a judicial action to enforce the Act, the burden is on the government to prove that the product is adulterated or misbranded,²²⁷ rather than on the manufacturer to show that it is safe.²²⁸

219. FDA, *Adverse Event Reports*, *supra* note 10.

220. FDA, *Information About WEN*, *supra* note 209.

221. *Id.*

222. *Id.*

223. See 21 C.F.R. § 730 (1997) (Voluntary Filing of Cosmetic Product Experiences); FDA, Food and Cosmetic Labeling; Revocation of Certain Regulations, 62 Fed. Reg. 43,071, 43,073 (revoking 21 C.F.R. pt. 730); FDA, *Adverse Event Reports*, *supra* note 10. In the notice proposing to revoke the Voluntary Cosmetic Reporting Program regulations, FDA noted that the program suffered from "serious limitations": industry participation was "very limited and selective, the reports lack[ed] sufficient details to be useful, and annual reports are sent in long after the occurrence of an adverse reaction." FDA, Food and Cosmetic Labeling; Revocation of Certain Regulations; Opportunity for Comment, 61 Fed. Reg. 29,708, 29,710 (June 12, 1996) (proposed rule). FDA also noted its "budgetary constraints." *Id.*

224. See FDA, *Voluntary Cosmetic Registration Program*, *supra* note 169.

225. See FDCA § 409, 21 U.S.C. § 348 (food additives); FDCA § 505, 21 U.S.C. § 355 (new drugs); FDCA §§ 513, 515, 21 U.S.C. §§ 360c(a), 360e (class III devices). As noted earlier, "color additives" have to be approved for a particular use before being so used. See *supra* note 22.

226. See FDCA §§ 301, 601, 602, 21 U.S.C §§ 331, 361, 362 (2012); see also GAO, HRD-78-139, *supra* note 9 (stating that "a hazardous cosmetic can be marketed until the [FDA] obtains information to prove that the product may be injurious to users"); Letter from Art O. Czabaniuk, Dist. Director, Detroit Dist. Office, U.S. Food & Drug Admin., to Ms. Kathie De Voe, President & Chief Executive Office, Gilchrist & Soames, Inc., Warning Letter 2016-DET-09 (Mar. 16, 2016), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm491990.htm> [<https://perma.cc/4HQc-PRA5>]; Letter from Alonza E. Cruse, Director, Los Angeles Dist., U.S. Food & Drug Admin., to Patricia Alvarez, President, Gemdo Cosmetics Inc., Warning Letter WL-16-15 (Apr. 16, 2015), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm443701.htm> [<https://perma.cc/LQY9-83TM>].

227. FDCA §§ 301, 601, 602, 21 U.S.C §§ 331, 361, 362.

228. See, e.g., GAO, HRD-78-139, *supra* note 9.

III. GENDER, FEMINISM & COSMETICS LAW & REGULATION

This Part argues that cosmetics law and regulation have been deprioritized as a result of their longstanding and close association with femininity and women, and women's exclusion from political participation and representation. The 1906 Pure Food and Drugs Act did not explicitly address cosmetics. While the 1938 Federal Food, Drug and Cosmetic Act did, women were excluded from full participation during the consideration of both Acts, and consideration of the later Act was marred by the biases of some of the male participants. This Part also argues that cosmetics law and regulation have been deprioritized as a result of their longstanding and close association with women and femininity, which have often been devalued. Finally, this Part argues that cosmetics law and regulation have been deprioritized as a result of debate among self-described feminists regarding the meaning of cosmetics and differences in women's relationships to and views of cosmetics more generally.

A. Cosmetics Law & Regulation Have Been Deprioritized as a Result of Women's Exclusion from Political Participation & Representation, as well as their Longstanding & Close Association with Femininity & Women

1. The Pure Food & Drugs Act of 1906

The Pure Food and Drugs Act of 1906 did not regulate cosmetics.²²⁹ Historian Gwen Kay describes the omission of cosmetics from the 1906 act as an economic and political decision.²³⁰ While earlier bills defined "drug" to include "cosmetics,"²³¹ in 1900, cosmetics were dropped from the legislation, apparently in exchange for the support of the National Pure Food and Drug Congress.²³² At that time, the cosmetics industry's scope was limited: the 1899 manufacturing census put the value of "perfumery and cosmetic" industry

229. See Federal Food & Drugs Act, 34 Stat. 768 (June 30, 1906) [hereinafter Pure Food and Drugs Act].

230. KAY, *supra* note 3, at 30.

231. See, e.g., S. 4144, 55th Cong. (1898); H.R. 9154, 55th Cong. (1898).

232. Oscar E. Anderson, Jr., *Pioneer Statute: The Pure Food and Drugs Act of 1906*, 13 J. PUB. L. 189, 195 (1964); CHARLES O. JACKSON, FOOD AND DRUG LEGISLATION IN THE NEW DEAL 4 (1970); KAY, *supra* note 3, at 15. The National Pure Food and Drug Congress was convened to support a food and drug law and was to be comprised of delegates "embrac[ing] as far as possible every interest involved in the production, manufacturer, and sale of food, drugs and liquor products," as well as "Scientists and Health Departments," and "those who have charge of local laws in the various States and Territories." 1898 J. PROC. OF THE NAT'L PURE FOOD & DRUG CONGRESS 4, <https://ia801404.us.archive.org/21/items/journalproceedi00unkngoog/journalproceedi00unkngoog.pdf>. Proposed language from the 1898 proceedings of the National Pure Food and Drug Congress included cosmetics within the definition of drug. *Id.* at 36.

products at about seven million dollars, and in 1904 the value was about eleven million dollars.²³³

Gender—as well as race, ethnicity, and class—likely contributed to the failure of Congress to include cosmetics in the 1906 Pure Food and Drugs Act. Unlike food and drugs—which had problems that generated broad public outrage and which were included in the 1906 Pure Food and Drugs Act²³⁴—cosmetics, while not without their hazards,²³⁵ “were extremely easy to overlook.”²³⁶ The industry was relatively small,²³⁷ and cosmetics were “purchased and consumed by only half the population”: women.²³⁸ In addition, many women made their own cosmetics at home.²³⁹ Even among women who used what today would be considered cosmetics, many may have sought to hide this use as “[a]mong white women . . . popular concern centered on the morality of visible makeup,” which was “associated with prostitutes and actresses.”²⁴⁰ Indeed, the “[w]omen applying dangerous lead-based whitening lotions . . . [who] began to appear in medical case records after the Civil War . . . [went] to great lengths to conceal their cosmetics use.”²⁴¹

The use and advertising of cosmetics also reflected racial and ethnic tensions, including white concerns about maintaining existing racial hierarchies.²⁴² At the time, “the standard of beauty inherently assumed a northern European face.”²⁴³ Skin whiteners—which were marketed to both white and black women—“remained the most popular cosmetic throughout the nineteenth century.”²⁴⁴ Cosmetics “reinforced a noxious racial aesthetic,” in which “[n]otions of Anglo-American beauty . . . were continually asserted in relation

233. U.S. DEP’T OF COMMERCE, BUREAU OF THE CENSUS, BIENNIAL CENSUS OF MANUFACTURES 1921, at 745, 746 tbl.623 (1924) [<https://perma.cc/2HBQ-NCVA>] [hereinafter 1921 MANUFACTURES CENSUS] (“Perfumery and cosmetics include perfumes, toilet waters, toilet preparations, cold cream, face powders, etc.”) (ebook).

234. Pure Food and Drugs Act, *supra* note 229. See, e.g., KAY, *supra* note 3, 17-22; Jeffrey E. Shuren, *The Modern Regulatory Administrative State: A Response to Changing Circumstances*, 38 HARV. J. ON LEGIS. 291, 299 (2001); Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, 2011 WIS. L. REV. 331, 337.

235. See, e.g., PEISS, *supra* note 3, at 41-42.

236. KAY, *supra* note 3, at 30.

237. See *supra* note 68 and accompanying text.

238. KAY, *supra* note 3, at 30.

239. *Id.* at 10-12.

240. *Id.* at 32-33; PEISS, *supra* note 3, at 7.

241. PEISS, *supra* note 3, at 41.

242. *Id.* at 40-43.

243. KAY, *supra* note 3, at 31.

244. PEISS, *supra* note 3, at 40.

to people of color”²⁴⁵ and “[s]kin whiteners and hair straighteners were tokens in a heated debate” about beauty standards among black women.²⁴⁶

While women’s organizations played an important role in the enactment of the 1906 Pure Food and Drugs Act,²⁴⁷ cosmetics do not appear to have been a central focus of many of these groups. This may have been because “[t]he women who belonged to many of these groups, upper-class and white, would most likely not have worn (visible) cosmetics at the beginning of the century”²⁴⁸ because “women who visibly wore cosmetics in the last third of the nineteenth century were [considered] morally suspect and liable to criticism.”²⁴⁹ These groups may have “unconsciously applied middle- and upper-class morals and solutions to the food and drug problem.”²⁵⁰ Indeed, one history of the push for pure food and drug laws, which focuses on the role of women, makes scant mention of cosmetics, noting only in passing that in 1898, a proposed definition of “drug” included cosmetics, and that in 1905 the National Consumers’ Leagues’ Pure Food Committee included in their goals that “agencies should ensure cosmetics were safe and properly labeled.”²⁵¹ But because cosmetics were included within the proposed definition of drugs until 1900, it’s difficult to distinguish early general support for drug legislation from support for cosmetic legislation.²⁵²

Women’s lack of representation in the legislative process during the consideration and passage of the 1906 Pure Food and Drugs Act may have also contributed to the exclusion of cosmetics, as women did not have the right to vote nationwide until approximately 14 years after the Act was signed into law.²⁵³ When the Pure Food and Drugs Act passed in 1906, no woman had ever served in the United States House of Representatives or Senate.²⁵⁴ It would be

245. *Id.* at 31, 34 (stating that “[f]or white Americans, sustaining a visual distinction between white and black masked an uncomfortable truth, that Africans and Europeans were genealogically mixed” and “[i]n advice manuals and formula books, white fears of losing their superior racial identity underwrote old anxieties about cosmetic artifice”).

246. *See, e.g., id.* at 7; NOLIWE M. ROOKS, *HAIR RAISING: BEAUTY, CULTURE, AND AFRICAN AMERICAN WOMEN* 37 (1996).

247. *See, e.g.,* KAY, *supra* note 3; James Harvey Young, *The Government and the Consumer: Evolution of Food and Drugs Laws, The 1938 Food, Drug, and Cosmetic Act*, 13 J. PUB. L. 197, 199 (1964).

248. KAY, *supra* note 3, at 15, 17.

249. *Id.* at 31.

250. *Id.* at 15, 17.

251. LORINE SWAINSTON GOODWIN, *THE PURE FOOD, DRINK, AND DRUG CRUSADERS, 1879-1914*, at 114, 161 (1999).

252. *See* Anderson, *supra* note 232, at 195.

253. U.S. CONST. amend. XIX.

254. JENNIFER E. MANNING & IDA A. BRUDNICK, CONG. RESEARCH SERV., RL30261, *WOMEN IN CONGRESS, 1917-2018: SERVICE DATES AND COMMITTEE ASSIGNMENTS BY MEMBER, AND LISTS BY STATE AND CONGRESS* (2018), <https://fas.org/sgp/crs/misc/RL30261.pdf> [<https://perma.cc/VMN3-KBQJ>]. The lack of diversity was not limited to gender. There were also no African American, Asian American, Native American, or Hispanic American senators. *Ethnic Diversity in the Senate*, UNITED STATES SENATE, <https://www.senate.gov/senators/EthnicDiversityintheSenate.htm> [<https://perma.cc/XZ-K9-AEN8>]. The Asian Americans and Hispanic Americans in the House of Representatives were all non-

over a decade until the first woman served in the House and even longer until a woman served in the Senate.²⁵⁵ As one commentator noted, “the undeniable reality of women’s political impotence in 1906 surely constituted a major factor in the exclusion of cosmetics from the 1906 Act.”²⁵⁶

2. *The Federal Food, Drug & Cosmetic Act of 1938*

While a comprehensive examination of the history of the cosmetics provisions of the 1938 FDCA is beyond the scope of this Article, portions of that history provide examples of how gender shaped consideration of bills to strengthen the law. Between the enactment of the Pure Food and Drugs Act of 1906 and the passage of the 1938 FDCA, it became more socially acceptable for women to use cosmetics, and the cosmetics industry grew substantially. At the same time, a number of women were seriously injured by cosmetics that federal law was powerless to address and there were growing concerns about the safety of cosmetics. The history of cosmetics and the development of cosmetics law during the period preceding the 1906 Pure Food and Drugs Act through the enactment of the 1938 FDCA illustrates the gendered roots of cosmetics law.²⁵⁷ This history is particularly important because this law has changed little in the intervening eighty years. The 1938 Act, with few modifications, remains the basis of cosmetics law and regulation, and women still fall far short of equal representation in the United States Senate and House of Representatives.²⁵⁸

a. Cosmetics Growth & Change, 1906-1938

In the years after the enactment of the 1906 Pure Food and Drugs Act, the cosmetics industry grew rapidly.²⁵⁹ By 1920, the toilet goods industry was “one of the largest . . . in the United States, behind food, clothing, and automobiles.”²⁶⁰ In 1933, the U.S. Census Bureau reported that the value of

voting delegates or resident commissioners from Hawaii and Puerto Rico. HISTORY, ART & ARCHIVES: UNITED STATES HOUSE OF REPRESENTATIVES, <http://history.house.gov/People/Search/> [<https://perma.cc/HCD7-S4UA>] (search by categories and by congress).

255. MANNING & BRUDNICK, *supra* note 254.

256. Daum, *supra* note 171.

257. The Author plans to more fully examine legislative history of the cosmetics provisions of the FDCA and the role of women in future scholarship.

258. Darla Cameron & Kim Soffen, *For Every Woman in Political Office in South Carolina, There Are Six Men*, WASH. POST (Feb. 7, 2018), https://www.washingtonpost.com/graphics/2018/politics/women-running-for-office/?utm_term=.d24fb48a3a96 [<https://perma.cc/3M8H-JS7J>] (stating that 22 out of 100 Senators and 84 out of 432 House members are women).

259. See 1921 MANUFACTURES CENSUS, *supra* note 233, at 745, 746 tbl.623; see also GILBERT VAIL, A HISTORY OF COSMETICS IN AMERICA 137 (1947) (listing statistics from the reports of the United States Census Bureau). In 1929, the value of the industry was approximately \$193 million. It then declined to \$153 million in 1931. VAIL, *supra*, at 137.

260. KAY, *supra* note 3, at 39.

cosmetics industry production was about 97 million dollars.²⁶¹ That same year Senator Royal S. Copeland introduced a bill, S. 1944, to strengthen the 1906 Pure Food and Drugs Act,²⁶² by, among other things, extending the Act to prohibit the adulteration, misbranding, and false advertisement of cosmetics. During a hearing on the bill in December of 1933, the Secretary of Agriculture testified that “[t]he cosmetic industry ha[d] become of first importance,” whereas it had been “in its infancy” when the 1906 Act was written.²⁶³ By 1937—the year before the enactment of the Federal Food, Drug, and Cosmetic Act of 1938—the value of cosmetics industry production was about 132 million dollars.²⁶⁴

The tremendous growth of the industry was accompanied by a shift in the acceptability of cosmetics use. Cosmetics use became more broadly acceptable for women: for example, a 1915 article in *McClure’s* referred to cosmetics as “affording much *legitimate* daily comfort.”²⁶⁵ “[W]omen from across the country, from different social classes and racial-ethnic groups, enthusiastically embraced cosmetics—especially makeup—in the early twentieth century,” although “[a]ge, marital status, economic class, ethnic origins, and residence influenced women’s relationship to the new mass market.”²⁶⁶

Cosmetics, particularly makeup, had a multitude of meanings.²⁶⁷ For example, women used cosmetics “to play the lady or the hussy, to look older or younger, to signify common identities as ‘American’ and ‘respectable,’ or to invoke class and ethnic distinctions.”²⁶⁸ But despite these differences and contradictions, in the 1920s and 1930s, “[m]akeup was a true expression of feminine identity”²⁶⁹ and by the 1930s, “had become an aesthetic expression woven deeply into women’s daily life.”²⁷⁰

At the same time, workplace appearance requirements “became increasingly regimented,” both requiring that women wear cosmetics and regulating women’s cosmetics use.²⁷¹ And the growth of the beauty industry opened up new employment opportunities for women, e.g., as beauticians, product demonstrators, and drugstore clerks.²⁷² Entrepreneurs brought beauty culture and

261. VAIL, *supra* note 259, at 137.

262. See DUNN, *supra* note 1, at 37, 39, 42, 45-46 (S. 1944).

263. DUNN, *supra* note 1, at 1049 (Statement of the Honorable Henry A. Wallace, Secretary of Agriculture).

264. See VAIL, *supra* note 259, at 137 (listing statistics from the reports of the United States Census Bureau).

265. KAY, *supra* note 3, at 39.

266. PEISS, *supra* note 3, at 6, 168.

267. *Id.* at 6, 190.

268. *Id.* at 190.

269. *Id.* at 166. Conversely, “[c]osmetics were not readily reconciled with a heterosexual masculine identity.” *Id.*

270. *Id.* at 200.

271. See *id.* at 193.

272. *Id.* at 5.

cosmetics to customers and “many of the most successful were immigrant, working-class, or black women.”²⁷³

b. The Failures of the 1906 Pure Food and Drugs Act & Consideration of Reform

Concerns about the safety of cosmetics and the limitations of the 1906 Act accompanied the growth of the industry.²⁷⁴ These concerns reflect the gendered state of cosmetics. In the 1930s, there were numerous reports of cosmetics seriously injuring women, which the Pure Food and Drugs Act could not prevent.²⁷⁵

Several books highlighted the dangers of cosmetics and the lack of protections for consumers: for example, in 1933, Arthur Kallet and F.J. Schlink, who founded Consumers Union and Consumers’ Research Inc., published the influential book *100,000,000 Guinea Pigs*.²⁷⁶ The book devotes a chapter to “[d]anger [i]n [c]osmetics,” which begins with a statement about the dangerous “path followed by women of all times and of all countries in search of the beauty promised by magic and mysterious potions.”²⁷⁷ The book noted that “[t]he purchaser of cosmetics has no protection whatever” and discussed women injured by cosmetics and cosmetic procedures.²⁷⁸ In 1934, Mary Catherine Phillips, also of Consumers’ Research, published *Skin Deep: The Truth about Beauty Aids—Safe and Harmful* in response to “numerous women readers” who requested advice on cosmetics brands.²⁷⁹ In *Skin Deep*, Phillips was even more explicit than Kallet and Schlink about who cosmetics consumers were: she stated that “the feminine consumer has little, if any protection against dangerous poisons in the form of cosmetics.”²⁸⁰ Phillips also stated that for some cosmetics “little research has been done of a scientific, disinterested nature that can be used

273. *Id.* at 5, 64-70 (discussing the entrepreneurial successes of Elizabeth Arden, Annie Turnbo Malone, Helena Rubinstein, Madam C.J. Walker); *see also* Perry, *supra* note 100, at 580.

274. These were not the first concerns about or injuries caused by cosmetics. A number of cosmetics in the mid-nineteenth century, for example, contained mercury, lead, and arsenic. *See, e.g.*, PEISS, *supra* note 3, at 21.

275. *See, e.g.*, RUTH DEFOREST LAMB, AMERICAN CHAMBER OF HORRORS: THE TRUTH ABOUT FOOD AND DRUGS viii (1936); Pure Food and Drugs Act, *supra* note 229.

276. ARTHUR KALLET & F.J. SCHLINK, 100,000,000 GUINEA PIGS: DANGERS IN EVERYDAY FOODS, DRUGS, AND COSMETICS (1933).

277. *Id.* at 78.

278. *Id.* at 78, 82–84, 89, 94.

279. MARY CATHERINE PHILLIPS, SKIN DEEP: THE TRUTH ABOUT BEAUTY AIDS—SAFE AND HARMFUL xi (1934). The 1940 Census identified Mary Catherine Phillips as white. *See* USA, BUREAU OF THE CENSUS, SIXTEENTH CENSUS OF THE UNITED STATES, 1940 (Washington, D.C.: National Archives & Records Admin., 1940, T627, 4,643 rolls, *accessed via* Ancestry.com [database on-line]) (listing Mary C. Schlink); *see also* THE HISTORICAL MARKER DATABASE, MARY CATHERINE PHILLIPS, <https://www.hmdb.org/marker.asp?marker=94693> [<https://perma.cc/4ATL-JF75>] (noting that Phillips married Consumer’s Research founder Schlink).

280. *Id.* at 9.

or relied on by consumers.”²⁸¹ And in 1936, Ruth deForest Lamb, FDA’s first Chief Education Officer, published *American Chamber of Horrors*, which discussed the limits of the 1906 Act and FDA’s lack of authority over cosmetics.²⁸² Like the authors of the other two books discussed above, she provided examples of cosmetics that seriously injured women.²⁸³ The book was based on an FDA-sponsored exhibit that was “so shocking” that a reporter accompanying First Lady Eleanor Roosevelt to see the exhibit, “dubbed [it] the ‘American Chamber of Horrors.’”²⁸⁴

These works also reflect the important role women played in bringing attention to the problems of cosmetics and their regulation.²⁸⁵ In fact, Lamb dedicated her book to the “gallant group of women . . . holding the front-line trenches in the consumers’ war for pure foods, drugs and cosmetics.”²⁸⁶ Women and women’s organizations played a central role in the push for the federal regulation of cosmetics in the first part of the 20th century and the passage of the 1938 Federal Food, Drug, and Cosmetic Act. As Gwen Kay observes in her book, *Dying to Be Beautiful: The Fight for Safe Cosmetics*, “[t]he leading proponents for inclusion of cosmetics in a new law . . . were mostly women’s organizations and consumer groups.”²⁸⁷

In 1933, Senator Copeland introduced S.1944, the “original bill leading to the enactment of the [FDCA].”²⁸⁸ FDA’s Annual Report that same year noted that federal law was “wholly without jurisdiction over cosmetics, except in those

281. *Id.* at xi.

282. LAMB, *supra* note 275, at 15–39; FDA, *Ruth deForest Lamb: FDA’s First Chief Educational Officer*, <https://www.fda.gov/AboutFDA/History/VirtualHistory/HistoryExhibits/ucm341860.htm> [<https://perma.cc/KEA3-PCBU>] [hereinafter FDA, *First Chief Educational Officer*]. The 1930 Census identified “*Ruth Forest Lamb*” as white. USA, BUREAU OF THE CENSUS, FIFTEENTH CENSUS OF THE UNITED STATES, 1930 (Washington, D.C.: National Archives & Records Admin. (1930) T626, 2,667 rolls, accessed via Ancestry.com [database on-line]) [hereinafter FIFTEENTH CENSUS].

283. LAMB, *supra* note 275, at 15–39.

284. PEISS, *supra* note 3, at 197; LAMB, *supra* note 275, at 15–39; Vanessa Burrows et al., *The American Chamber of Horrors*, FDA BLOG (June 29, 2018), <https://web.archive.org/web/20180925190340/https://blogs.fda.gov/fdavoices/index.php/2018/06/the-american-chamber-of-horrors/> (accessing June 29, 2018 Internet Archive). The FDA website notes that Lamb “played a key role in explaining to the public, to Congressmen, and particularly to their wives, the importance of updating the 1906 Pure Food and Drugs Act.” FDA, *First Chief Educational Officer*, *supra* note 282. First Lady Roosevelt “appealed to America’s women to campaign for stronger protections for consumers.” FDA, *100 Years of Protecting and Promoting Women’s Health*, https://www.fda.gov/forconsumers/byaudience/forwomen/ucm118458.htm#1933:Protecting_the_Health_of_Women [<https://perma.cc/29FN-HCDT>] (“1933: Protecting the Health of Women”).

285. See LAMB, *supra* note 275; PHILLIPS, *supra* note 279; KALLET & SCHLINK, *supra* note 276.

286. LAMB, *supra* note 275, at Dedication.

287. KAY, *supra* note 3, at 3; see, e.g., *Foods, Drugs, and Cosmetics: Hearing Before a Subcommittee of the Committee on Interstate and Foreign Commerce on H.R. 6906, H.R. 8805, H.R. 8941 and S. 5, Before the Subcomm. of the Comm. on Interstate and Foreign Commerce, 74th Cong. 1 (1935)* [hereinafter *1935 Hearing*] (stating that the Director of the Bureau of Foods, Drugs, and Hotels of the Kentucky Health Department in her testimony stated that she did not have to tell the committee “that the woman consumer is very definitely interested in cosmetics”).

288. See DUNN, *supra* note 1, at 24, 29–30.

rare instances when the labeling bears medicinal claims.”²⁸⁹ S. 1944 would have extended the Pure Food and Drugs Act of 1906 to prohibit the manufacture, shipment, and sale of adulterated or misbranded cosmetics and the false advertisement of cosmetics.²⁹⁰

In testimony on the proposed legislation, FDA’s chief, W.G. Campbell, referenced “Koremlu Cream” and “Lash Lure,”²⁹¹ two products that caused a series of injuries to women and illustrated the limits of existing law.²⁹² Koremlu was a depilatory that used “thallium acetate, an ingredient commonly found in rat poison, to destroy and remove hair.”²⁹³ The cosmetic, which “was applied mostly to women’s lips,” caused “loss of axial or pubic hair; baldness; temporary or long-term paralysis; and optic nerve damage.”²⁹⁴ FDA cited Koremlu Cream as an example of a product the federal government lacked authority over under the 1906 Act, writing that the product was only removed from the market when “the manufacturer was forced into bankruptcy by accumulation of damage suits.”²⁹⁵

“Lash Lure,” which was used for dyeing eyebrows and eyelashes, “contained paraphenylenediamine (PPD), an aniline dye that repeatedly achieved the rating of ‘most dangerous’ in the list of hair dyes.”²⁹⁶ It resulted in injuries ranging from “temporary nausea, discomfort, or vision problems” to blindness and

289. *Id.* at 26 (reproducing portions of FDA’s 1933 Annual Report).

290. *Id.* at 30, 31, 33; S. 1944, 73rd Cong., § 2(c), 5, 6, 9.

291. DUNN, *supra* note 1, at 1122.

292. KAY, *supra* note 3, at 70. Koremlu is discussed in *100,000,000 Guinea Pigs*, and both Koremlu and Lash Lure are discussed in *Skin Deep* and *American Chamber of Horrors*. See KALLET & SCHLINK, *supra* note 276; PHILLIPS, *supra* note 279; LAMB, *supra* note 275.

293. KAY, *supra* note 3, at 70. See, e.g., *Hillick v. Edwards & Son*, 143 Misc. 277 (N.Y. 1932) (actions of three plaintiffs each alleging that she suffered injuries from the use of Koremlu Cream); *Smith v. Denholm & McKay Co.*, 192 N.E. 631 (Mass. 1934) (action by plaintiff alleging that she suffered peripheral neuritis from thallium poisoning from Koremlu Cream); *Greengard v. Odorono Co.*, 235 A.D. 806 (N.Y. 1932) (action by plaintiff alleging she developed severe skin poisoning from Odorono which was advertised for use in “eliminating perspiration”). But see DUNN, *supra* note 1, at 1041 (statement of American Medical Association representative) (noting “case of child swallowing Odorono,” containing “dangerous lead acetate”). In the United States, the use of thallium in rat poison has been banned “due to its toxicity from accidental exposure.” CDC NIOSH, *Thallium: Systemic Agent*, https://www.cdc.gov/niosh/ersbdb/emergencyresponsecard_29750026.html [<https://perma.cc/R6VB-DY5H>].

294. KAY, *supra* note 3, at 71.

295. DUNN, *supra* note 1, at 26 (reproducing portions of FDA’s 1933 Annual Report). In a 1934 Senate hearing, the FDA chief noted that Koremlu contained a rat poison “for which no antidote has . . . been found” and that it removes the hair not just from the site of application, but from the entirety of the body. DUNN, *supra* note 1, at 1154.

296. KAY, *supra* note 3, at 71.

death.²⁹⁷ Lash Lure was still on the market when the FDA chief first testified about it.²⁹⁸

Koremlu and Lash Lure were not alone in injuring women. The legislative history of the FDCA indicates that “extremely toxic substances” such “as certain coal-tar dyes and metals like lead, arsenic, mercury and thallium” in “a number of preparations . . . caused serious impairment in the health of users.”²⁹⁹

While the debate over the cosmetics provisions of legislation intended to address shortcomings of the 1906 Act mentioned that men used cosmetics “too,”³⁰⁰ much of the focus was on women.³⁰¹ Despite this, women’s direct participation in the legislative proceedings appears to have been relatively limited and debate of the cosmetics provisions of bills reflected the perspectives—and biases—of the male participants.

Senator Hattie W. Caraway, the sole woman Senator at the time, was present for subcommittee hearings on the legislation.³⁰² Women also testified on the legislation before the subcommittee.³⁰³ Both Senator Caraway’s membership on the subcommittee and the testimony of women were of sufficient note that during a December 1933 subcommittee hearing, “Mrs. William Dick Sporborg of Port Chester, [New York]” remarked on them.³⁰⁴ She stated that she was “the first woman . . . permitted to appear” at the hearing and that “all . . . men” had testified before her that day and the day before.³⁰⁵ She also remarked that she

297. *Id.* at 72; *see also* Clyde E. Harner, *Dermato-Ophthalmitis Due to the Eyelash Dye Lash-Lure*, 101 JAMA 1558-59 (1933) (reporting three cases of women injured by Lash Lure); Oliver P. Bourdon, *Severe Eye Symptoms Due to Dyeing the Eyelashes*, 101 JAMA 1559 (1933) (reporting case of woman injured by an eyelash dye, Lariouse); R. C. Jamieson, *Eyelash Dye (Lash-Lure) Dermatitis with Conjunctivitis*, 110 JAMA 1560 (1933) (reporting case of woman injured by Lash-Lure); A. W. McCally et al., *Corneal Ulceration Following Use of Lash-Lure*, 110 JAMA 1560 (1933) (reporting case of woman injured by Lash-Lure); Sigmund S. Greenbaum, *Dermatoconjunctivitis Due to Lash-Lure, An Eyelash and Eyebrow Dye*, 101 JAMA 363 (1933) (reporting case of woman injured by Lash-Lure); S. B. Forbes & W. C. Blake, *Fatality Resulting from the Use of Lash-Lure on the Eyebrow and Eyelashes*, 103 JAMA 1441 (1934) (reporting fatality after using Lash-Lure). American Chamber of Horrors stated that there were at least 17 cases of Lash Lure injuries reported in the Journal of the American Medical Association, but there was no way to know how many women in total were so injured. LAMB, *supra* note 275, at 19.

298. DUNN, *supra* note 1, at 1154-55; *see also* LAMB, *supra* note 275, at 22.

299. DUNN, *supra* note 1, at 115-16; *see also id.* at 160; *id.* at 484; *id.* at 572 (quoting Congressman Virgil Chapman as stating, “Many harmful and dangerous cosmetics have been sold to the public and used by unsuspecting women so as to result in their permanent disfigurement and impairment of their health”); *id.* at 256; *Virgil Munday Chapman*, HISTORY, ART & ARCHIVES, U.S. HOUSE OF REPRESENTATIVES, [http://history.house.gov/People/Listing/C/CHAPMAN,-Virgil-Munday-\(C000317\)/](http://history.house.gov/People/Listing/C/CHAPMAN,-Virgil-Munday-(C000317)/) [<https://perma.cc/J8JP-PW33>]; *see also* DUNN, *supra* note 1, at 256.

300. *See* DUNN, *supra* note 1, at 156.

301. *See, e.g., 1935 Hearing, supra* note 287, at 165 (quoting Congressman Virgil Chapman as stating that “the committee realizes that women use cosmetics externally, internally, and eternally”).

302. DUNN, *supra* note 1, at 150; at 96, 269-70, 597, 969; MANNING & BRUDNICK, *supra* note 254, 96-97. She later served as a conferee for the Senate. DUNN, *supra* note 1, at 597, 969. The 1930 Census identified Senator Caraway as white. FIFTEENTH CENSUS, *supra* note 282.

303. *See, e.g., Hearings Before a Subcommittee of the Committee on Commerce on S. 1944, 73rd Cong. (1933)* [hereinafter *1933 Hearings*]; *1935 Hearing, supra* note 287.

304. *1933 Hearings, supra* note 303, at 339. The 1930 Census identified Mrs. William Sporborg as white. FIFTEENTH CENSUS, *supra* note 282 (listing Constance Sporborg).

305. *Id.* at 339, 340.

was “glad to see a woman on th[e] Senatorial Committee whose decisions and recommendations will effect so many women who are users of drugs, cosmetics, and foods.”³⁰⁶

The Senate debate reflected the male Senators’ attitudes towards women. During Senate debate, male Senators referred to a “beautiful girl” who “lost her eyes” and her vision after use of an eyelash dye.³⁰⁷ The “beautiful girl,” who remains nameless through the debates, appears to have been a social worker who was injured before a dinner to honor her civic activity by an eyelash dye that contained “a poison.”³⁰⁸ The woman was likely Hazel Fay Brown (Musser), whose injuries from Lash-Lure are described in detail (with before and after photographs) in *American Chamber of Horrors*.³⁰⁹

During the debate, the woman is largely reduced to the subject of the male Senator’s viewing.³¹⁰ Senator Copeland appeared to joke about submitting “the photograph of a beautiful young woman” to Senator James Hamilton Lewis, promoting objections about other Senators experiencing “envy” and “the suspension of proper senatorial activities,” as well as laughter.³¹¹ Senator Copeland responded by stating that he would “give [the photograph] to the Senate . . . so that there may be no feeling of discrimination.”³¹² Senator Lewis, in an apparent reference to the photograph, “object[ed] to the exhibits which have caused trouble.”³¹³ And, Senator Matthew M. Neely expressed concern about Senator Copeland “absorbing the entire attention of the Senate in the photographs of the beautiful girl.”³¹⁴

Discussion of the cosmetics provisions of the proposed legislation was punctuated by laughter: Senator Copeland after remarking on the manufacture, sale, and use of cosmetics, prompted laughter when he joked about Senator Lewis having “no doubt . . . been a profound student in the fields involved.”³¹⁵ There was also laughter after Senator Neely stated that lipstick “is not safe for men,” and again after Senator Copeland asked whether Senator Neely would like to “testify on the subject at any great length.”³¹⁶

306. *Id.* at 344.

307. DUNN, *supra* note 1, at 156-57, 279.

308. *Id.* at 156, 279.

309. LAMB, *supra* note 275, at 15-18; KAY, *supra* note 3. The 1930 Census identified Hazel Fay Musser as white. FIFTEENTH CENSUS, *supra* note 282.

310. FDA’s chief, W.G. Campbell appears to have shown a photograph of the injured woman during a 1934 Senate hearing. *See* DUNN, *supra* note 1, at 1154-55.

311. *Id.* at 156; *see also* U.S. SENATE, SENATORS OF THE UNITED STATES, 1789-PRESENT, <https://www.senate.gov/artandhistory/history/resources/pdf/chronlist.pdf> [<https://perma.cc/ZG2M-6KW6>] [hereinafter SENATORS OF THE UNITED STATES] (listing Senators chronologically).

312. *Id.*

313. DUNN, *supra* note 1, at 156.

314. *Id.*; SENATORS OF THE UNITED STATES, *supra* note 312, at 56.

315. DUNN, *supra* note 1, at 156.

316. *Id.*

The debate also reflected the male Senators' judgments about women's use of cosmetics: for example, Senator Neely remarked that he'd be "very much more enthusiastic about the bill if it" "contain[ed] an inhibition against the excessive use of the abominable lipstick."³¹⁷ And Senator Connally remarked that "[i]t seems . . . the more solemn [women] are, the less cosmetics they use."³¹⁸ In contrast, Senator Copeland, who led the push for new legislation, remarked that the woman who was blinded after using the eyelash dye was "preparing herself, as she properly should for an occasion so important to her."³¹⁹ And that he was "glad to say there" that the bill did not prohibit the use of lipstick.³²⁰ Senator Copeland remarked that he viewed "it as the solemn duty of every woman to be as beautiful as she can be" and that he did "not blame any woman for using cosmetics if they tend in the direction of making her more attractive."³²¹ In explaining what he meant by solemn duty, he later stated, "I mean, of course, it is my solemn duty to help them to be as beautiful as they can be."³²²

In the course of the legislative debate, Senator Copeland referenced the "fair woman" becoming fairer as a result of cosmetic use.³²³ Given racialized notions of beauty,³²⁴ this may have had racial undertones. Senator Copeland went on to state that the Senate's "respect for [the fair woman] is such that [they] desire that whatever she uses may be safe to use."³²⁵ Who the law was intended to protect was at times described in limited terms. For example, Senator Copeland remarked, "I want all women, *in whom I have an interest*, to be guarded and protected against the use of things which may be damaging."³²⁶ Copeland also appealed to his fellow male senators, stating that "[e]very Senator having in mind the welfare of *his wife*, his children, his grandchildren, and his great-children if there be such, is interested in having the measure enacted into law because of what it will do—promote their welfare, maintain their health, and extend their lives."³²⁷

3. *Devaluation of Cosmetics & Cosmetics Law & Regulation*

Food is life-sustaining and everyone must eat. Drugs may treat serious illness and can be lifesaving. In contrast to those traditional product categories

317. *Id.*

318. *Id.* at 278.

319. *Id.* at 156.

320. *Id.*

321. *Id.* at 278.

322. *Id.* at 279.

323. *Id.* at 694.

324. See KAY, *supra* note 3; PEISS, *supra* note 3.

325. DUNN, *supra* note 1, at 694.

326. *Id.* at 278 (emphasis added).

327. *Id.* at 185 (emphasis added). *But see id.* at 155 (quoting Senator Copeland as stating that the "bill is intended to safeguard the men and women, the boys and girls, and the babies of this country").

in the FDCA, cosmetics are often viewed as frivolous or trivial.³²⁸ The trivialization of cosmetics may be reinforced by the very meaning of the word “cosmetic,” as one common definition is “superficial.”³²⁹

While cosmetics have different meanings for different women—and these meanings are shaped by factors including race and socio-economic status—cosmetics are closely associated with femininity. In particular, cosmetics are associated with a “deeply-ingrained American cultural definition of femininity denoted as a particular kind of commercialized feminine beauty.”³³⁰ Indeed, cosmetics use has been shown to significantly impact impressions of femininity.³³¹

At the same time that cosmetics are closely associated with femininity, traits and qualities associated with women or femininity have been devalued.³³² For example, Mary Anne C. Case has noted “the continuing devaluation, in life and in law, of qualities deemed feminine.”³³³ And as Deborah Zalesne has observed, in *Jespersen v. Harrah’s Operating Co., Inc.*—a case that unsuccessfully challenged the firing of a female bartender for failing to comply with her employer’s appearance standards, which required female employees to wear makeup—“the court failed . . . to consider the fact that the makeup, hair, and dress requirements are deeply rooted in traditional notions of how men and women should look and are based on stereotypes that deride feminine traits and marginalize individuals who possess such traits.”³³⁴

328. See, e.g., POUCHER’S PERFUMES, COSMETICS AND SOAPS (Hilda Butler ed., 10th ed. 2000); Dellinger & Williams, *supra* note 93, at 153; WOLF, *supra* note 4, at 9.

329. See *Cosmetic*, OXFORD ENGLISH DICTIONARY ONLINE (Oxford University Press) (Aug. 14, 2018).

330. See Steve Craig, *Feminism, Femininity, and the “Beauty” Dilemma: How Advertising Co-opted the Women’s Movement*, THE FEMINIST E-ZINE <http://www.feministezine.com/feminist/fashion/The-Beauty-Dilemma.html> [<https://perma.cc/QWA4-D4AQ>]; see also Kathy Peiss, *Making Up, Making Over: Cosmetics, Consumer Culture, and Women’s Identity*, in THE SEX OF THINGS: GENDER & CONSUMPTION IN HISTORICAL PERSPECTIVE 311, 330 (Victoria de Grazia & Ellen Furlough eds., 1996) (stating that “[i]n the period from 1900 to 1930, making up became one of the tangible ways women in their everyday lives confirmed their identities as women”).

331. See, e.g., Richard Russell, *A Sex Difference in Facial Contrast and Its Exaggeration by Cosmetics*, 28 PERCEPTION 1211, 1217 (2009) (suggesting that “an important function of cosmetics may be to increase the apparent femininity, and hence attractiveness, of the female face by increasing facial contrast”); Jane E. Workman & Kim K.P. Johnson, *The Role of Cosmetics in Impression Formation*, 10 CLOTHING & TEXTILES RES. J. 63 (1991) (stating that “[r]esults support the use of cosmetics as a cue in forming impressions of another’s . . . femininity”); Cathryn L. Cox & William H. Glock, *Resume Evaluations and Cosmetics Use: When More Is Not Better*, 14 SEX ROLES 51, 51, 56 (1986) (noting that “[c]osmetics use has been traditionally used by women to control their physical appearance” and finding “that cosmetics tend to enhance the perceived attractiveness and femininity of women”).

332. See, e.g., Case, *supra*, note 35; Maxine Eichner, *On Postmodern Feminist Legal Theory*, 36 HARV. C.R.-C.L. L. REV. 1, 72 (2001).

333. Case, *supra* note 332, at 3.

334. Deborah Zalesne, *Lessons from Equal Opportunity Harasser Doctrine: Challenging Sex-Specific Appearance and Dress Codes*, 14 DUKE J. GENDER L. & POL’Y 535, 554 (2007); see also *Jespersen v. Harrah’s Operating Co., Inc.*, 444 F.3d 1104 (9th Cir. 2006).

FDA is not immune to sociopolitical influences.³³⁵ Thus, the association with women and femininity may have contributed to cosmetics law and regulation being deprioritized. Others have argued that “FDA has been an inadequate protector of women’s health” and that “FDA inaction [has] directly damaged the health of large numbers of women on more than one occasion.”³³⁶ FDA’s guidelines—*Considerations for the Clinical Evaluation of Drugs*—for many years “largely excluded women of childbearing potential from clinical trials,” a position that many viewed as “reflect[ing] gender stereotyping more than concerns about good science.”³³⁷

Gender gaps in clinical research may also impact the study—and regulation—of cosmetics safety.³³⁸ Medicine “generally has paid more attention to the risks and benefits of new drugs with a male model in mind, rather than a female”³³⁹ and “knowledge concerning the effects of various treatments on women and their unique needs remains sparse and underdeveloped.”³⁴⁰ Current knowledge of the effects of cosmetics, a highly gendered product, on women’s health, is similarly underdeveloped. For example, one epidemiologist at the Harvard T.H. Chan School of Public Health stated that “[f]or decades we’ve been studying what’s in the air that you breathe and the water you drink. But you wake up in the morning . . . and you may use a shampoo or a conditioner, and a

335. See Mara Sanders, *Sex, Drugs, and Advisory Committees: An Analysis of Pharmaceutical Industry Manipulation of FDA Vulnerability to Sociopolitical Influences on Matters of Women’s Health*, 48 COLUM. HUM. RTS. L. REV. 149, 150 (2017) (arguing that FDA “displays a number of biases that distort scientific analysis, from normative judgments about women’s sexuality to a patronizing sense that women require heightened protection against the risks posed by otherwise effective drugs”).

336. Thomas Koenig & Michael Rustad, *His and Her Tort Reform: Gender Injustice in Disguise*, 70 WASH. L. REV. 1, 51 (1995); see also Pub. Citizen Health Research Grp. v. Comm’r, Food & Drug Admin., 724 F. Supp. 1013, 1021 (D.D.C. 1989) (holding that “a more than seven year delay in issuing a regulation impacting on women’s health is certainly an unreasonable delay”); Amanda L. Allen, *A Plan C for Plan B: A Feminist Legal Response to the Ways in Which Behind-the-Counter Emergency Contraception Fails Women*, 11 N.Y. CITY L. REV. 401, 411 (2008) (arguing that “[a]t the very least, the ways in which the FDA decision [regarding Plan B, an emergency contraceptive] privileged antiquated views about women’s and girls’ sexuality along with the ideological agenda of a conservative presidential administration over science, medicine, and women’s health offers support for the feminist critique of the law as an inherently patriarchal institution”); Vicki Lawrence MacDougall, *Medical Gender Bias and Managed Care*, 27 OKLA. CITY U. L. REV. 781, 786 (2002) (“rais[ing] the haunting question whether managed care has the built-in propensity to perpetuate—if not sanction and encourage—medical gender bias to the detriment of the health of women enrolled in managed care plans”); Rebecca Weisman, *Reforms in Medical Device Regulation: An Examination of the Silicone Gel Breast Implant Debacle*, 23 GOLDEN GATE U. L. REV. 973, 982 (1993) (discussing silicone gel breast implants, diethylstilbestrol (DES), and the Dalkon Shield and arguing that “failed to act responsibly when dealing with products affecting women’s health and safety”).

337. Karen H. Rothenberg, *Gender Matters: Implications for Clinical Research and Women’s Health Care*, 32 HOUS. L. REV. 1201, 1239 (1996); see also Christina Cole, *Women and the FDA: Remedying the Past and Preserving the Future*, 7 HOUS. J. HEALTH L. & POL’Y 127, 129 (2006).

338. See, e.g., Rothenberg, *supra* note 337, at 1208.

339. Ruth B. Merkatz, *Women in Clinical Trials: An Introduction*, 48 FOOD & DRUG L.J. 161, 162 (1993).

340. Rothenberg, *supra* note 337, at 1203.

toothpaste, and cosmetics, and they all contain many different chemicals. And we pretty much never thought about them.”³⁴¹

B. Reform of Cosmetics Law & Regulation Must Confront Tensions Resulting from the Debate Among Feminists Regarding the Meaning of Cosmetics & Economic Opportunities in the Cosmetics Industry

The debate among self-described feminists regarding the meaning of cosmetics and differences among women with respect to cosmetics may complicate reform efforts. As discussed earlier, the use of, exposure to, and meaning of cosmetics may differ as a result of the intersections between gender, race, and class.³⁴² In addition, the economic and entrepreneurial opportunities that cosmetics may provide may create tensions that may further complicate efforts to reform cosmetics law and regulation.

1. The Debate Among Self-Described Feminists

There is substantial debate among feminists over the meaning of cosmetics and the cosmetics industry. This debate is part of a larger debate about beauty and appearance.³⁴³ In her essay, *Appearance as a Feminist Issue*, Rhode describes an “increasingly fragmented” feminist movement in which “different subcultures have differed sharply on matters of appearance.”³⁴⁴

Some feminists are concerned about the costs of appearance norms, including financial costs, health risks, discrimination, “the devaluation and sexualization of women,” and the exacerbation of economic, racial, and gender inequalities.³⁴⁵ For example, Naomi Wolf argues that images of female beauty” are used “as a political weapon against women’s advancement” and that cosmetics and the cosmetics industry contribute to this “beauty myth,” pressuring women to adhere to unrealistic beauty standards and hence constraining them.³⁴⁶ Other feminists have focused on “[a]pppearance [a]s an

341. Rebecca Kessler, *More than Cosmetic Changes: Taking Stock of Personal Care Product Safety*, 123 ENVIRO. HEALTH. PERSP. A120 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4421754/> [<https://perma.cc/Z2PH-WJQT>].

342. See *supra* Sections II.A & B. They may also differ based on other characteristics including sexual orientation, ethnicity, socio-economic status, and age.

343. See Deborah L. Rhode, *Appearance as a Feminist Issue*, 69 SMU L. REV. 697, 697 (2016) (stating that “as the feminist movement has grown increasingly fragmented, different subcultures have differed sharply on matters of appearance” and that “[w]hen it comes to appearance, what women want is not always the same or always compatible”); see also SUSAN BROWNMILLER, FEMININITY 157-61 (1984) (discussing the feminism and the tensions over makeup).

344. Rhode, *supra* note 343, at 699; see also Craig, *supra* note 330.

345. *Id.* at 699-704.

346. NAOMI WOLF, THE BEAUTY MYTH: HOW IMAGES OF BEAUTY ARE USED AGAINST WOMEN 9-10, 107, 115-18 (1992).

opportunity for self-expression and self-determination,” albeit with limits.³⁴⁷ For example, Jennifer Baumgardner and Amy Richards have argued that “[u]sing makeup isn’t a sign of our sway to the marketplace and the male gaze; it can be sexy, campy, ironic, or simply decorating ourselves without the loaded issues.”³⁴⁸

However, regardless of how one views cosmetics use, the current state of cosmetics law and regulation is concerning because many women use or are exposed to cosmetics. If cosmetics use generally is oppressive, then the current state of cosmetics law and regulation reinforces this because it disproportionately puts women’s health at risk. If cosmetics use is liberating, then the current state of cosmetics law and regulation is troubling because cosmetics use is not liberating if it comes with unknown and, thus, unaccepted risks.

2. *Cosmetics, Entrepreneurship & Economic Opportunity*

Women’s divergent interests may also hinder the development of cosmetics law and regulation. As discussed in Section II.B, cosmetics use and exposure may have negative health effects. But cosmetics are also big business,³⁴⁹ and it is important to recognize the economic opportunities that the cosmetics industry has provided and continues to provide women, including women who are members of other excluded groups. Women’s economic interests and considerations will likely impact any potential reforms.

There is a long history of the cosmetics industry providing economic opportunities for diverse women. For example, Peiss writes that while “beauty culture mainly offered women low-wage work, it became one of a handful of occupations . . . to sustain female entrepreneurship and ownership” and “[w]omen . . . became inventors, manufacturers, and distributors of beauty products.”³⁵⁰

The women entrepreneurs came from different classes (although many were poor), were of different races, and were both immigrants and native-born.³⁵¹ For example, Annie Turnbo Malone and Sarah Breedlove (known as Madam C.J. Walker) were two black women entrepreneurs who built thriving businesses selling hair care products,³⁵² an industry that has “long been one of the few sites of success for black women entrepreneurs.”³⁵³ Florence Nightingale Graham,

347. Rhode, *supra* note 343, at 705–07.

348. Jennifer Baumgardner & Amy Richards, *Feminism and Femininity: Or How We Learned to Stop Worrying and Love the Thong*, in *ALL ABOUT THE GIRL: CULTURE, POWER, AND IDENTITY* 59, 60 (Anita Harris ed., 2004).

349. See *supra* note 2 and accompanying text.

350. PEISS, *supra* note 3, 62–63.

351. *Id.* at 63–64, 96.

352. *Id.* at 67–70.

353. Monica C. Bell, *The Braiding Cases, Cultural Deference, and the Inadequate Protection of Black Women Consumers*, 19 *YALE J.L. & FEMINISM* 125, 128, 133 (2007) (arguing that “state legislators

who grew up in poverty in Canada, established Elizabeth Arden.³⁵⁴ And Helena Rubinstein, who came from “a middling Jewish family” and moved to New York from Europe after World War I started, began a cosmetics company bearing her name.³⁵⁵ All four of these women built “business empires.”³⁵⁶ Although there is some debate over whether Malone or Breedlove was the first black female millionaire in the United States, both women were among the first.³⁵⁷

Beauty work, including that involving the use of cosmetics, is still often done by women, and women comprise the majority of workers in many jobs that involve such work.³⁵⁸ According to the chief scientist of the Personal Care Products Council, “[w]omen and people of color account for nearly 74% of all employment in the personal care products sector and 61.2% of management positions.”³⁵⁹ As a result, many women have an economic interest in cosmetics, which may be impacted by changes in cosmetics law and regulation. For example, in 2012, Deborah May testified at a Congressional hearing about the economic contributions that the handcrafted soap and cosmetic industry makes.³⁶⁰ She stated that the “industry is over 200,000 small businesses hand producing small batches of soaps and cosmetics,” of which 95% “are women-owned” and urged exemptions for small businesses from if FDA were to be given new authority over cosmetics.³⁶¹ Accordingly, any reform efforts may confront opposition from those with divergent interests.

should exempt braiders from cosmetology licensing requirements and authorize state administrators to promulgate substantive regulations that are reasonably related to braiding and natural styling”); *see also* Perry, *supra* note 100, at 581.

354. PEISS, *supra* note 3, 64-66.

355. *Id.* at 66-67.

356. *Id.* at 70.

357. *See, e.g.,* A’Leia Bundles, *Madam C.J. Walker*, ENCYCLOPÆDIA BRITANNICA, <https://www.britannica.com/biography/Madam-C-J-Walker> [<https://perma.cc/TJ38-3QY6>]; Henry Louis Gates, Jr., *Madam Walker, the First Black American Woman to Be a Self-Made Millionaire*, PBS.ORG, <https://www.pbs.org/wnet/african-americans-many-rivers-to-cross/history/100-amazing-facts/madam-walker-the-first-black-american-woman-to-be-a-self-made-millionaire/> [<https://perma.cc/9APK-ZEXV>]; Detetria Irwin, *[Unsung Heroes] Beauty Pioneer Annie Turnbo Malone Opens Doors for Others*, EBONY.COM (Mar. 23, 2006), <https://www.ebony.com/black-history/annie-turnbo-malone-ebonywhm/> [<https://perma.cc/BT8Z-TZFL>].

358. KAY, *supra* note 3; PEISS, *supra* note 3; *see also* BLS, DETAILED OCCUPATION, *supra* note 6 and accompanying text (discussing occupational data); BLS, DETAILED INDUSTRY, *supra* note 96 and accompanying text (same).

359. Exploring Current Practices in Cosmetic Development and Safety Before the S. Comm. on Health, Education, Labor and Pensions, 114th Cong. 3, 3 (2016) (*Statement of Beth Lange Jonas, Chief Scientist, Personal Care Products Counsel*), <https://www.help.senate.gov/imo/media/doc/Jonas3.pdf> [<https://perma.cc/VH7K-8K6P>].

360. Hearing: Examining the Current State of Cosmetics Before the H. Comm. on Energy & Commerce, Subcomm. On Health, 112th Cong. 140, at 2 (2012) (*Statement of Deborah May, President & CEO, Wholesale Supplies Plus, Inc.*), <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/Health/20120327/HHRG-112-IF14-WState-MayD--20120327.pdf> [<https://perma.cc/G2SH-5CZN>].

361. *Id.* at 4. She also stated that she supported several principles related to cosmetic regulation. *Id.* at 4-5.

IV. REFORMING COSMETICS LAW & REGULATION

Finally, this Article considers how asking the woman question and the excluded group question could inform reform efforts.³⁶² It is mindful of the fact that the method that it employs does not lead to a particular end. It does, however, reveal the gendered roots of cosmetics law and regulation, and highlight the need to further investigate how cosmetics and the current state of cosmetics law and regulation impact women, including members of excluded groups. It is not enough to simply claim that cosmetics are the safest product category that FDA regulates, as the current state of cosmetics law and regulation hinders the ability to meaningfully assess the safety of cosmetics. This Article suggests several changes to begin to reform cosmetics law and regulation to better account for women's experiences, safety, and needs.

A number of scholars and other commentators have proposed or supported reforms to cosmetics law and regulations.³⁶³ In addition, the General Accounting Office has studied and issued recommendations on cosmetics law and regulation,³⁶⁴ and members of Congress have introduced bills to strengthen cosmetics law.³⁶⁵ While many of these proposals and bills suggest fairly broad cosmetics reforms, the reforms that this Article argues for are more limited in scope.³⁶⁶ This is not to say that additional reforms are not needed—they very well may be. As an initial matter, however, this Article argues for reforms that facilitate the collection of information to more accurately assess the safety of cosmetics and the risks that they may pose to human health, including that of diverse women. The reforms that this Article suggests would also begin to narrow the gap between the regulation of cosmetics—a highly gendered product—and that of the other major product categories, which lack the same gendered history and associations.

First, Congress and FDA should require that establishments involved in the production and distribution of cosmetics intended for use in the United States register with the FDA, just as food, drug, device, biologics, and tobacco product

362. See Bartlett, *supra* note 16, at 837.

363. See, e.g., De Paz, *supra* note 117; Mason, *supra* note 158; Julie Mueller, *Pulling Our Hair Out and Glossing over the Problem: A Call to Strengthen the FDA's Power to Regulate Cosmetics Through an Amendment to the Federal Food, Drug, and Cosmetic Act*, 79 U. PITT. L. REV. 317 (2017); Shah & Taylor, *supra* note 99; Brittany Stepp, *You Don't Know What's in Your Shampoo, and Neither Does the FDA: A Call for Change*, 10 DREXEL L. REV. 277 (2017); Watnick, *supra* note 117; Johnson, *supra* note 116, at 120.

364. GAO, HRD-78-139, *supra* note 9; see also STATEMENT OF GREGORY J. AHART, *supra* note 9; GAO/HRD-90-58, *supra* note 9.

365. See, e.g., Cosmetic Modernization Amendments of 2017, H.R. 575, 115th Cong. (2017); FDA Cosmetic Safety and Modernization Act, S. 2003, 115th Cong. (2017); Personal Care Products Safety Act, S. 1113, 115th Cong. (2017).

366. There is overlap, however, between the reforms that this Article argues are needed and those proposed by others. See, e.g., Cosmetic Modernization Amendments of 2017, H.R. 575, 115th Cong. (2017); FDA Cosmetic Safety and Modernization Act, S. 2003, 115th Cong. (2017); Watnick, *supra* note 117, at 637–49 (discussing federal legislative proposals); Mueller, *supra* note 363.

establishments do.³⁶⁷ Registration requirements help to facilitate post-market enforcement activities.³⁶⁸ Without mandatory registration, FDA may not even know that a facility is producing cosmetics.

Second, Congress and FDA should require that cosmetics establishments also be required to provide FDA with a listing of ingredients used in cosmetic products intended for use in the United States. As noted above, filing ingredient statements for each cosmetic product is currently voluntary.³⁶⁹ In response to a comment requesting that FDA make the program mandatory, FDA stated that it “has no statutory authority to require mandatory cosmetic product reporting.”³⁷⁰ Together, establishment registration and product listing requirements would provide FDA with information about “the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments,” and help facilitate the distribution of regulatory information and the conduct of inspections.³⁷¹

Third, Congress and FDA should require that cosmetics manufacturers and distributors report certain adverse events to the agency. As noted above, there is no requirement that such events be reported, which hampers FDA’s ability to monitor the safety of cosmetics. The required adverse event reporting should include demographic information, including sex, race, and ethnicity, for the person who experienced the event.

Fourth, Congress should extend FDA’s authority over cosmetics to allow the agency to inspect records under certain circumstances.³⁷² As noted above, under the FDCA, FDA’s general inspection authority with respect to cosmetics is limited to certain establishments and vehicles.³⁷³

Fifth, Congress and FDA should collect and publish data on FDA’s regulatory activities and budget for cosmetics in an easily accessible format. As noted above, such information is not currently readily available, and without this

367. FDCA §§ 415, 510, 901, 905; 21 C.F.R. §§ 207, 607, 807 (2018); FDA, BIOLOGICS ESTABLISHMENT REGISTRATION, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/default.htm> [<https://perma.cc/RJ2N-V2U5>] (2018); FDA, REGISTRATION AND PRODUCT LISTING FOR OWNERS AND OPERATORS OF DOMESTIC TOBACCO PRODUCT ESTABLISHMENTS (Dec. 2017), <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm189539.htm> [<https://perma.cc/8M9T-36YE>].

368. *See, e.g.*, Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, 81 Fed. Reg. 60,170, 60170 (Aug. 31, 2016); *see also* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894 (Oct. 10, 2003); Amendments to Registration of Food Facilities, 81 Fed. Reg. 45,912 (July 14, 2016).

369. *See* Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Cosmetic Registration Program, 73 Fed. Reg. 76,360 (Dec. 16, 2008).

370. 73 Fed. Reg. 76,361.

371. *See* Reducing Regulation and Controlling Regulatory Costs, 69 Fed. Reg. 9,339, 9,339 (Feb. 3, 2017).

372. *See* FDCA § 704, 21 U.S.C. § 374 (2012).

373. FDCA § 704(a), 21 U.S.C. § 374; *see also* FDCA §§ 801-802, 21 U.S.C. §§ 381-382; 21 C.F.R. § 1.101 (2018) (recordkeeping requirements for certain cosmetics exports).

information it is difficult to fully assess the adequacy of FDA's cosmetics regulation.³⁷⁴

Finally, Congress and FDA should encourage more research into the potential hazards that cosmetics may pose to women's health, including to members of other excluded groups, such as racial and ethnic minorities.

The proposals in this Section are not intended to serve as a comprehensive fix, but rather to serve as first steps designed to provide the information needed to more fully assess the current state of cosmetics law and regulation and the safety of cosmetics.

CONCLUSION

Examining cosmetics law and regulation through a feminist lens demonstrates how the shortcomings of current regulatory approach disproportionately jeopardize women's health. Cosmetics are closely associated with cultural constructs of femininity and womanhood, and are a highly gendered product and industry. While women use more cosmetics than men and are the majority of workers in the cosmetics industry,³⁷⁵ cosmetics law and regulation have largely neglected women's diverse experiences and needs. These omissions impact women differently and may vary as a result of many factors, including race and socio-economic status.³⁷⁶ Recognizing the failure of current cosmetics law and regulation for women is a precursor to remedying these injustices.³⁷⁷ The impact of these shortcomings, however, is not limited to women who use cosmetics, either personally or at work. Men and children also use cosmetics, and everyone, regardless of whether they use cosmetics or not, may be exposed to cosmetics. Thus, cosmetics law and regulation should be strengthened in order to more accurately assess the risks that cosmetics may pose to human health.

374. See *supra* Section II.C.2.c.

375. See *supra* Section II.A.

376. See Rothenberg, *supra* note 337, at 1207.

377. See David Stowman, *Getting to Know Ourselves*, BENCH & B. MINN. 5 (Feb. 2005).