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# INTERSECTIONALITY MATTERS IN FOOD AND DRUG LAW

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*Feminist scholars critique food and drug law as a site of gender bias and regulatory neglect. The historical exclusion of women from clinical trials by the FDA prioritized male bodies as the object of clinical research and therapies. Likewise, the FDA's prior restriction on access to contraceptive birth control illustrates how patriarchal and paternalistic attitudes within the Agency can harm women's reproductive health. However, there is little analysis of how race and gender intersect in this domain.*

*This Article uses the regulation of skin-lightening cosmetics products to illustrate why and how intersectionality matters in food and drug law. While the inadequate regulation of cosmetics has a disparate impact on women's health, it is women of color who predominantly use skin-lightening products, similar to some hair care products that are disproportionately marketed to women of color. Additionally, skin-lightening products are often toxic because they contain*

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*mercury and other harmful substances. The skin-lightening industry has also historically (and contemporarily) targeted women of color with racist and colorist advertising messages that idealize light skin as the pinnacle of beauty.*

*The inadequate regulation of cosmetics illustrates why intersectional analysis is essential in food and drug law. An intersectional lens uncovers the various underlying forces that produce a disparate health impact for women of color: systemic racism in health, racially targeted marketing, and hegemonic beauty norms shaped by race and skin color constructs. The increased toxicity of these products also overexposes women of color to more serious health risks from cosmetics. While cosmetics reform has ushered in new regulations that improve the Agency's authority to regulate cosmetics, the health risks posed to women of color from toxic personal care products in general deserves urgent attention in food and drug discourses. Intersectional analysis uncovers the contours of this urgency and offers an important response to the de-prioritization of women of color within food and drug law discourses.*

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## INTRODUCTION

The Food and Drug Administration's ("FDA" or "Agency") policies regarding women's health demonstrate how gender bias has influenced food and drug law.[1] The Agency's lax regulation

1. *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, 149–50 (2017); 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, 1165–66 (1999); *see also* Thomas Koenig & Michael Rustad, *His and Her Tort Reform: Gender Injustice in Disguise*, 70 WASH. L. REV. 1, 51 (1995) ("FDA inaction directly damaged the health of large numbers of women on more than one occasion."). *See generally* Marie Boyd, *Preemption & Gender & Racial (In)equity: Why State Tort Law Is Needed in the Cosmetics Context*, 102 B.U. L. REV. 167 (2022) (discussing the intersecting failures of cosmetic regulation, healthcare, and tort law and its disproportionate impact on Black Women); Marie Boyd, *Gender, Race & the Inadequate Regulation of Cosmetics*, 30 YALE J.L. & FEMINISM 275, 301 (2018) (arguing that cosmetics law and regulation have been deprioritized as a result of their longstanding and close association with femininity and that this may disproportionately affect women who are members of other excluded groups); Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627 (2022) (discussing a series of agency failures to protect women's health, especially

of feminized products, including reproductive medical devices, has exposed women to adverse health outcomes.[2] Accordingly, some feminist scholarship critiques the FDA for its susceptibility to gender bias and the politicization of its administrative processes despite others viewing it as objective or neutral. This body of scholarship illuminates food and drug law's disparate impact on women's health.[3]

The regulation of cosmetics is case in chief. The devaluation of cosmetics in regulatory law is likely due to its feminization and association with women.[4] For decades now, cosmetics has been the least regulated product category within the Agency's jurisdiction.[5] Unlike drugs, for example, there are no pre-approval requirements to determine cosmetics' safety before market distribution.[6] And, until December 2022, cosmetics law and regulation had not been updated in over eighty years.[7] This has left women vulnerable to untested and poorly regulated products, confirming feminist claims that food and drug law neglects women's health.

While there is extensive feminist analysis in this research area, there is little intersectional analysis that accounts for the effects of both race and gender. Coined by legal scholar and professor Kimberlé Crenshaw, intersectionality emerged as a theoretical intervention to account for Black women's[8] erasure

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reproductive and sexual health, over the course of decades due to gender bias); Christina Cole, *Women and the FDA: Remedying the Past and Preserving the Future*, 7 HOUS. J. HEALTH L. & POL'Y 127 (2007) (involving an historical analysis of FDA regulations and the problems they caused for women).

2. *See generally* Boyd (2018), *supra* note 1. This Article primarily uses the term "women" as a socially constructed term when discussing feminized products because women are still the largest consumers of these products and cosmetics is still considered an important aspect of gender socialization and performance for women. The Article does not intend to exclude people with other gender identities, but their specific relationship to cosmetics is beyond the scope of this Article.

3. Trompeter, *supra* note 1, at 1165–68.

4. *See generally* Boyd (2018), *supra* note 1.

5. *Id*. at 301.

6. Boyd (2022), *supra* note 1, at 170–71.

7. Congress updated the regulatory scheme for cosmetics in the Consolidated Appropriations Act of 2023, H.R. 2617, 117th Cong. §§ 3501–3508 (2022) (enacted) (Modernization of Cosmetics Regulation Act of 2022 ("MoCRA")). *See infra* Part III.A for a discussion of the inadequacies of cosmetics law and regulation.

8. This Article sometimes uses the terms "Black women" and "African American women" interchangeably, though there are important distinctions: the former refers to all Black women (domestically and globally), while the latter refers to women whose ancestral lineage is tied to the enslavement of Africans in the United States. At times this Article distinguishes between the two in order to disentangle the unique historical experiences of African Americans in relation to

within anti-racist and feminist discourses because of a tendency to treat race and gender as mutually exclusive categories.[9] It also offers a liberatory response to the plight of the multiply subordinated.[10] Intersectionality offers a generative lens for examining raced *and* gendered dynamics in food and drug law.

This Article employs the regulation of skin-lightening cosmetics products to illustrate how and why intersectionality matters in food and drug law. Women of color are the predominant consumers of skin lightening cosmetics.[11] This phenomenon stems from hegemonic beauty standards that idealize proximity to Whiteness, systemic racism and colorism, and market forces.[12] While people of all genders increasingly use these products, it is still predominantly a feminized practice.[13]

Federal and local public health agencies are aware of the prevalence of skin-lightening products in the United States and the public health risks they pose.[14] These products often contain highly toxic ingredients like mercury.[15] Because of the lax regulation of cosmetics, they are widely available in immigrant communities and communities of color in beauty supply stores and online.[16] On its consumer update page, for example, the

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processes of racialization in the U.S. For the most part, however, it employs the broad term "Black women," including when discussing issues related to contemporary colorism, beauty norms, racial marketing, and health disparities.

9. Kimberlé Crenshaw, *Demarginalizing the Intersection of Race and Sex: A Black Feminist Critique of Antidiscrimination Doctrine, Feminist Theory and Antiracist Politics*, 1989 U. CHI. LEGAL F. 139, 139 (1989); Kimberlé Crenshaw, *Mapping the Margins: Intersectionality, Identity Politics, and Violence against Women of Color*, 43 STAN. L. REV. 1241, 1242–44 (1991).

10. Crenshaw (1989), *supra* note 9, at 139.

11. *See generally* Imani Perry, *Buying White Beauty*, 12 CARDOZO J.L. & GENDER 579 (2006); Evelynn Nakano Glenn, *Yearning for Lightness: Transnational Circuits in the Marketing and Consumption of Skin Lighteners*, 22 GENDER & SOC'Y 281 (2008); Margaret L. Hunter, *Buying Racial Capital: Skin-Bleaching and Cosmetic Surgery in a Globalized World*, 4 J. PAN AFR. STUD. 142 (2011).

12. *See generally* Glenn, *supra* note 11.

13. Hunter (2011), *supra* note 11, at 143.

14. *See infra* Part III.

15. *Mercury Poisoning Linked to Skin Products*, FDA, https://www.fda.gov/consumers/consumer-updates/mercury-poisoning-linked-skin-products [https://perma.cc/V3FY-JV4G].

16. Ronald Hall, *Women of Color Spend More than $8 Billion on Bleaching Creams Worldwide Every Year*, CONVERSATION (Feb. 19, 2021, 8:19AM), http://theconversation.com/women-of-color-spend-more-than-8-billion-on-bleaching-creams-worldwide-every-year-153178 [https://perma.cc/YJ5G-8G7X]; Lariah Edwards et al., *Beauty Inside Out: Examining Beauty Product Use Among Diverse Women and Femme-Identifying Individuals in Northern Manhattan and South Bronx Through an Environmental Justice Framework*, ENV'T JUST. 1, 11 (2022),

FDA explains that these products are prevalent "in shops catering to the Latino, Asian, African, or Middle Eastern communities."[17] In light of this, the Agency has issued various consumer warnings advising of their risks.[18] From a public health perspective, the case for more stringent regulation of these products is compelling.[19]

Regulating these products also makes sense from a health equity perspective. It is well established that systemic racism poses a greater health risk for Black women.[20] Additionally, because of the cosmetics industry's marketing practices that target communities of color, women of color are at an increased risk of exposure to poorly regulated products. The cosmetics industry has traditionally used advertising that capitalizes on exclusionary beauty norms by associating lighter skin with positive attributes, including attractiveness, youthfulness, health and well-being, and greater social mobility.[21] In this context, manufacturers do not only mirror existing aesthetic norms—they construct them and reproduce a standard of beauty centered around Whiteness.[22]

For these reasons, the inadequate regulation of cosmetics has a disparate impact on women of color. Intersectionality offers a theoretical lens for grappling with this issue including emerging health disparities due to toxic exposure to cosmetics. This Article demonstrates how and why intersectionality matters in food and drug law. Moreover, to truly protect the public health, the Agency must account for the distinct experiences of women of color, especially Black women.

This Article proceeds in four parts: Part I discusses existing feminist discourses that reveal how gender bias informs FDA

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https://www.liebertpub.com/doi/pdf/10.1089/env.2022.0053 [https://perma.cc/5FT2-EW5T].

17. *Mercury Poisoning Linked to Skin Products*, *supra* note 15.

18. *Id.*

19. *Cosmetic Products*, FDA, https://www.fda.gov/cosmetics/cosmetic-products-ingredients/cosmetic-products [https://perma.cc/MR5E-6U2M].

20. Kelly Glass, *From the Cradle to the Grave: How Systemic Racism Affects Black Women's Health*, TODAY, https://www.today.com/specials/how-systemic-racism-affects-black-women-s-health/ [https://perma.cc/2BSH-FABS] (arguing how the harmful stereotype that Black women are more resilient and inherently stronger than other women has led to Black women being unprotected by America's healthcare system).

21. *See infra* Section II.C for a discussion of the industry's marketing strategies.

22. *See infra* Section II.C for a discussion on cosmetics manufacturers' assumed beauty standards.

policies and procedures.[23] Part I then analyzes intersectionality's theoretical contribution and ends by exploring why intersectionality is needed in food and drug law.

Part II examines the motivations for and social forces influencing skin lightening. Chiefly, it explores colorism, racism, hegemonic beauty standards, and the cosmetics industry's advertising strategies. Part III discusses the inadequacies of cosmetics law and regulation and the public health challenges in this area. It reviews the history of cosmetics deregulation before providing a brief overview of the Modernization of Cosmetics Regulation Act's ("MoCRA") key provisions. It then concludes by examining the public health impact of skin-lightening products due to the prevalence of mercury and other harmful substances within these products.

Part IV revisits the argument that intersectionality matters. It examines Black women's health outcomes to illustrate why intersectionality matters for women of color generally due to the effects of systemic gendered racism in healthcare.[24] Racial targeting also increases exposure to poorly regulated products that exacerbate health disparities. The Part then offers a critique of cosmetics reform. MoCRA—effective December 2023—increases the Agency's authority to regulate cosmetics more meaningfully.[25] Yet, there are several weaknesses of the new law, including the lack of pre-market safety tests comparable to drugs and the requirement that manufacturers only report "serious" adverse events, which flags only the most extreme injuries associated with cosmetics use.

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23. This Part of the Article admittedly lacks a Critical Race Theory (CRT) analysis because this analysis is largely absent from the administrative law literature. *See generally* Cristina Isabel Ceballos et al., *Disparate Limbo: How Administrative Law Erased Antidiscrimination*, 131 YALE L.J. 370 (2021); Bijal Shah, *Toward a Critical Theory of Administrative Law*, YALE J. ON REGUL.: NOTICE & COMMENT BLOG (July 30, 2020), https://www.yalejreg.com/nc/toward-a-critical-theory-of-administrative-law-by-bijal-shah/, [https://perma.cc/CZ58-5H3V]; Elaine Golin, *Solving the Problem of Gender and Racial Bias in Administrative Adjudication*, 95 COLUM. L. REV. 1532 (1995).

24. Kevin O'Reilly, *AMA: Racism Is a Threat to Public Health*, AM. MED. ASS'N (Nov. 16, 2020), https://www.ama-assn.org/delivering-care/health-equity/ama-racism-threat-public-health [https://perma.cc/7LCQ-5PB3] (acknowledging racism is a public health threat and detailing steps that the American Medical Association plans to take to address it).

25. Consolidated Appropriations Act of 2023, H.R. 2617, 117th Cong. §§ 3501–3508 (2022) (enacted) (codified as amended in scattered sections of 21 U.S.C.).

Additionally, there is no provision for user fees,[26] which is ordinarily an important avenue for the Agency's regulatory enforcement. While it is too soon to discern the full impact of cosmetics reform, MoCRA will likely remain under-enforced if not ineffective. This Part also examines litigation under the Administrative Procedure Act (APA) as a potential avenue for addressing the Agency's lack of action regarding cosmetics products. This Article concludes by reflecting on a broad conceptualization of public health that accounts for the social context in which products are marketed, regulated, and distributed.

Because it primarily emphasizes the United States' social and historical context, the Article admittedly lacks a transnational perspective.[27] However, it is essential to note that the U.S. skin-lightening market is not siloed and is affected by transnational conditions.[28] Moreover, while processes of racialization—including colorism—may manifest differently globally, colorism and skin lightening are pervasive globally.[29] This Article's analysis may therefore be substantively extrapolated elsewhere due to the global prevalence of skin lightening.[30]

While there is little data on this issue, the FDA's discussion of the communities primarily featuring these products indicates that it is likely an issue in immigrant communities, including Black women immigrants. In the United States, these demographics are more likely to use skin-lightening products because of shifting cultural norms in America that reject skin lightening among African Americans.[31] However, it is important

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26. *Id.* § 3508.

27. *See generally* Evelyn Nakano Glenn, *Yearning for Lightness: Transnational Circuits in the Marketing and Consumption of Skin Lighteners*, 22 GENDER & SOC'Y 281 (2008).

28. *Id.* at 294 (noting that, although some of these products were manufactured outside of the United States, they are found throughout the United States in immigrant communities).

29. *See generally* Angela R. Dixon & Edward E. Telles, *Skin Color and Colorism: Global Research, Concepts, and Measurement*, 43 ANN. REV. SOCIO. 405 (2017).

30. Glenn, *supra* note 27 at 294.

31. It is worth noting that, from a recent history standpoint, *Ebony* ads marketing skin-lightening products to the African American community existed as late as the 1980s. *See infra* Part II.C. *See also* Hall, *supra* note 16 ("In the aftermath of the civil rights movement, dark-complected immigrants from developing countries flocked to the U.S., carrying with them an ideal of light-skinned beauty – and they bleached their skin to attain it."); *see also* Ronald Hall, AN HISTORICAL

to note that the impact of systemic colorism and hegemonic beauty standards transcends geographic boundaries for Black women. This impact remains palpable across the diaspora.

Lastly, while this Article primarily emphasizes personal care products used by Black women, its critique is relevant to food and drug law generally. Agencies are increasingly grappling with the impact of systemic racism in public health, particularly on the heels of the COVID-19 pandemic.[32] The pandemic exposed the racial fault lines that have long rendered people of color vulnerable in public health.[33] As a result, agencies can no longer claim to do the work of public health while ignoring large swaths of the population. This is especially true for Black women, who are most vulnerable in the healthcare system.

## I. CRITIQUES OF FOOD AND DRUG LAW AND THE NEED FOR INTERSECTIONALITY

While food and drug law has been traditionally understood as an objective domain, feminist critiques reveal the ways in which women's bodies and their health have been deprioritized by the Agency. The following literature exposes how gender bias, informed by patriarchal and paternalistic considerations, has subjected women's health to harm. Additionally, feminized products have been subjected to considerable neglect. This Part examines case studies that illustrate key feminist critiques of the FDA. It then turns to examining why and how intersectionality offers a generative theoretical lens for addressing the disparate impact of food and drug law on Black women's health.

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ANALYSIS OF SKIN COLOR DISCRIMINATION IN AMERICA (2010) (explaining that it is primarily immigrant Black women and Black women in the Global South who use skin-lightening products); *see* Edwards et al., *supra* note 16 (indicating that Asian women are more likely to use skin-lightening products in Upper Manhattan and the lower Bronx).

32. Indeed, the Agency acknowledged that health equity is "a policy priority and an important component of fulfilling FDA's mission to protect and promote public health." Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26454 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1162) [hereinafter Tobacco Product Standard].

33. *Id.* In a recent executive order, the federal government likewise noted the importance of addressing underlying racial disparities in health. Exec. Order No. 13995, Ensuring an Equitable Pandemic Response and Recovery, 86 Fed. Reg. 7193 (Jan. 21, 2021).

### *A. Feminist Critique*

Feminist legal theory sheds light on the law's imposition of patriarchal oppression in women's lives. In the food and drug law context, the historical exclusion of women from clinical trials and the approval process for Plan B illustrate how patriarchal considerations have informed the FDA's policies and negatively harmed women's health. After reviewing these cases, this Section raises important considerations regarding the neglect of women of color within feminist discourses and offers a case study of product regulation—the Dalkon Shield intrauterine device (IUD)—to illustrate why intersectionality matters in the food and drug law context.

#### 1. Gender Bias in Food and Drug Law

That law is fundamentally informed by gender is a foundational principle in feminist scholarship.[34] The "woman question" asks how law reinforces patriarchal oppression in women's lives, and feminist legal theorists have applied it across various legal contexts.[35] Feminist legal theory rejects assumptions that law can be objective, even when it is seemingly neutral. Instead, it identifies how law plays a key role in neglecting women's experiences and silencing them.[36] Like other fields of critical inquiry, this literature examines law's disparate impact on women's lives.

Food and drug law offers a generative space for interrogating the woman question. The FDA is tasked with protecting the public health by ensuring the safety of products within its jurisdiction.[37] There are certain scientific and

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34. *See generally* Katharine T. Bartlett, *Feminist Legal Methods*, 103 HARV. L. REV. 829, 869 (1990).

35. *Id.*; *see also* Breanne Sergent, *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); Martha Chamallas, *Vicarious Liability in Torts: The Sex Exception*, 48 VAL. U. L. REV. 133 (2013); Martha Chamallas & Jennifer Wriggins, *The Measure of Injury: Race, Gender, and Tort Law* (2010) (describing how, in the 1970s, feminists successfully fought for repeal of cautionary instructions that warned juries to be wary of rape charges and prompted complaint requirements that prohibited prosecutions if the victims did not report the offense almost immediately after being victimized).

36. Bartlett, *supra* note 34.

37. *What We Do*, FDA, https://www.fda.gov/about-fda/what-we-do [https://perma.cc/4WYC-MSNR].

administrative safeguards that guarantee consumer health and safety. For instance, there is generally a consensus that the FDA's drug approval process is the "international gold standard"[38] in part because it relies on a "high level of scientific expertise."[39] Additionally, in carrying out its duties, the Agency is ordinarily expected to be immune from bias because science guides its decision-making.[40]

However, critical scholarship in this area reveals how gender bias has influenced the Agency's decision-making and policies,[41] in part due to sociopolitical influences.[42] Notably, its lax regulation of feminized products has disproportionately harmed women.[43] Furthermore, its paternalistic policies have arbitrarily restricted women's reproductive choices. [44] Case in point is the Agency's discriminatory policy regarding the medical abortion drug mifepristone.[45] Law professor Greer Donley demonstrates how the Agency's Risk Evaluation and Mitigation Strategy ("REMS") policy imposed more stringent restrictions on mifepristone than are imposed on other drugs. As a result, the policy segregated abortion healthcare and restricted women's healthcare access and reproductive rights. As this Part further explains, this is not an anomaly. It symbolizes a common thread permeating the Agency's approach to women's healthcare generally.

### 2. FDA Exclusion of Women from Clinical Drug Trials

To obtain drug approval by the Agency, manufacturers must conduct clinical trials supporting the drug's safety and efficacy and file a New Drug Application ("NDA") that includes the drug's safety data.[46] The Agency, however, initially adopted a

38. Sanders, *supra* note 1, at 149.
39. *Id.*
40. *See generally* Trompeter, *supra* note 1, at 1165–66.
41. Donley, *supra* note 1, at 667; Sanders, *supra* note 1, at 149–50; Cole, *supra* note 1.
42. Sanders, *supra* note 1, at 170 (arguing that interest groups have utilized sociopolitical influences to seize on existing biases within the FDA and distort its scientific processes regarding products affecting women's health).
43. Boyd (2018), *supra* note 1.
44. *See generally* Donley, *supra* note 1, at 643.
45. *Id.*
46. 21 U.S.C. § 355(d); 21 C.F.R. § 330.

policy that explicitly excluded women[47] of childbearing capabilities from clinical drug trials.[48] This policy reflected the patriarchal and paternalistic influences that harmed women's health: it was primarily motivated by concerns over the health of fetuses, not women.[49] Additionally, the policy perpetuated the problematic scientific norm of centering male bodies and their treatment in clinical research.

The official exclusionary policy began in 1977 but originated in part in the thalidomide scandal of the 1950s.[50] That case involved birth defects and organ malformation in children of pregnant people who were prescribed the drug for morning sickness.[51] The manufacturer, a German company, apparently ignored animal studies that indicated there were teratogenic effects (i.e., potential harm to a fetus or embryo). As a result, the drug caused over ten thousand birth defects between 1959 and 1962.[52] While tort liability is often cited as a reason for women's exclusion from clinical trials, some scholars argue that teratogenic concerns—not women's health—ultimately guided the Agency's policy.[53]

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47. This reference to women's exclusion from clinical trials relies on sex-based differences, not gender, which is a social construct.

48. Trompeter, *supra* note 1, at 1168.

49. Anna C. Mastroianni, *HIV, Women, and Access to Clinical Trials: Tort Liability and Lessons from DES*, 5 DUKE J. GENDER L. & POL'Y 167, 168 (1998).

50. Cole, *supra* note 1, at 131 n.22 (explaining that the genesis of the policy was the thalidomide incident and the estrogen diethylstilbestrol ("DES") drug); Donley, *supra* note 1, at 676 n.351 ("FDA was also likely motivated to ban women of childbearing age from research after the thalidomide scandal, where a drug that was initially thought of as safe ended up causing over 10,000 birth defects."); *see also* Vicki Lawrence MacDougall, *Medical Gender Bias and Managed Care*, 27 OKLA. CITY U. L. REV. 781, 818 (2002) ("The FDA policy in 1977 limited participation of fertile women in drug testing. Pregnable women, unless they suffered from a life-threatening disease, were only allowed to participate after phase I and II drug studies were complete. Prescription drug manufacturers though were not required to include women in phase III studies and thus women were commonly excluded.").

51. MacDougall, *supra* note 50, at 816–17 n.153 ("Over a thousand limb reduction defects and organ malformations in children were caused by maternal ingestion of Thalidomide. The manufactures [*sic*] ignored animal studies which indicated teratogenic effects.").

52. Trompeter, *supra* note 1, at 1168 n.159.

53. Mastroianni, *supra* note 49, at 168 ("Although many factors may have contributed to the underrepresentation of women in clinical studies, the potential exposure of drug trial sponsors to tort liability frequently is cited as one of the primary reasons for excluding women from trials. The true source of legal anxiety in the recruitment of female research subjects arises, however, not from a concern for women's safety, but from the fear of potential injuries to their offspring."); Trompeter, *supra* note 1, at 1168.

The policy predictably resulted in a lack of testing on women,[54] as clinical trials systematically used male subjects as the norm.[55] By centering the male body as the object of medical research and treatment, the policy mirrored the scientific community's problematic assumption that men's bodies can effectively serve as the norm for experimentation.[56] This assumption stemmed in part from the construction of women's bodies in relation to "unknown variables" such as the menstrual cycle, pregnancy, and menopause.[57] Scientists found these variables apparently unwieldy or simply lacked the desire to fully account for them in experiments.

For these reasons, many drugs designed for general use in the population, and even exclusively for women's use, were never tested on women. Further, doctors treated women with therapeutics that had not been tested on a single woman.[58] This was particularly harmful in cases where women experienced higher incidences of a disease than men.[59]

In 1993, the Agency revised its exclusionary policy to instead include women in trials, acknowledging that it had engaged in gender discrimination.[60] It noted that the early exclusion may have also "perpetuated . . . a view of the male as the primary focus of medicine and drug development, with women considered secondarily."[61] This revised policy, however, did not require companies to include women as a condition for

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54. Trompeter, *supra* note 1, at 1168.

55. *Id.*

56. Karen H. Rothenberg, *Gender Matters: Implications for Clinical Research and Women's Health Care*, 32 HOUS. L. REV. 1201, 1206 (1996).

57. Trompeter, *supra* note 1, at 1167 n.158.

58. Cole, *supra* note 1, at 132 ("In short, women were being treated with medications that had never even been tested on one woman subject . . . .").

59. The policy potentially affected dosing recommendations for women (i.e., weight-adjusted dosing), which the Agency acknowledged. Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 58 Fed. Reg. 39406, 39408 (July 22, 1993) [hereinafter Guideline] ("There is reason to believe that earlier participation of women in studies would increase the likelihood that gender-specific data might be used to make appropriate adjustments in larger clinical studies (e.g., different doses in women or weight adjusted (milligram per kilogram) dosing instead of fixed doses)."); *see* Cole, *supra* note 1, at 141 (noting that major cardiovascular events among younger women not affected by low-dose aspirin despite the fact that this population is more likely to die from a heart attack than men).

60. Guideline, *supra* note 59, at 39408.

61. *Id.*

drug approval.[62] Trials could still exclude women based on their absence from earlier trials.

Over the next decade, the Agency further revised its policies to remedy this issue.[63] Despite these developments, the treatment of sex disparities in clinical trials is still a source of concern due to lack of enforcement. For example, in 2001, the Government Accountability Office ("GAO") issued a report indicating a failure on the part of some manufacturers (about one-third) to comply with the 1998 regulation requiring disaggregation of data by sex.[64] Additionally, the Agency lacked a system to effectively track sex-based differences in trials. [65] Moreover, while the guidelines authorize the Agency to refuse NDAs without this data, the Agency has not exercised this authority.[66] These developments have not resulted in serious gains.[67]

The Agency has recently acknowledged this as an ongoing problem.[68] The troubling assumption that male bodies can serve as the norm for drug trials persists, as some "researchers still use exclusively male animals and cell lines in their research."[69] The Agency's policy (and sexism more broadly within the

62. Trompeter, *supra* note 1, at 1170–71.

63. Cole, *supra* note 1, at 135. In 1998, it amended its regulations governing NDAs to require that sponsors provide drug safety and efficacy data by gender, age, and race. This amendment came after Congress passed the FDA Modernization Act in 1997, which requested that the National Institutes of Health (NIH), the FDA, and the drug manufacturing industry create guidance on the inclusion of women and minorities in clinical trials. This amendment also gave the Agency the power to refuse applications without this data. Again, in 2000, the Agency's Final Rule on Investigational New Drugs ("INDs") empowered it with the right to refuse any application that excluded women from drug trials for a life-threatening disease and where women were excluded only due to concerns over reproductive risks of developmental toxicity.

64. Cole, *supra* note 1, at 135–36.

65. Donley, *supra* note 1, at 676 (citing U.S. GOV'T ACCOUNTABILITY OFF., GAO-93-17, WOMEN'S HEALTH: FDA NEEDS TO ENSURE MORE STUDY OF GENDER DIFFERENCES IN PRESCRIPTION DRUG TESTING 2–3 (1992), https://www.gao.gov/assets/220/216966.pdf [https://perma.cc/YCE3-KT8C]).

66. Cole, *supra* note 1, at 136 (citing U.S. GOV'T ACCOUNTABILITY OFF., GAO-01-754, WOMEN'S HEALTH: WOMEN SUFFICIENTLY REPRESENTED IN NEW DRUG TESTING, BUT FDA OVERSIGHT NEEDS IMPROVEMENT 20 (2001), http://www.gao.gov/new.items/d01754.pdf [https://perma.cc/44FY-M3VM]).

67. Donley, *supra* note 1, at 677–78.

68. *Id.* at 677. The Consolidated Appropriations Act of 2023, H.R. 2617, 117th Cong. (2022) (enacted), sections 3501–3607 addressed this recently. It now mandates "diversity action plans" for manufacturers to account for the inclusion of race, sex, and other categories in clinical trials. Donley, *supra* note 1, at 677.

69. Donley, *supra* note 1, at 678.

scientific research community) exposed women to riskier and ineffective therapies such that a majority of drugs withdrawn from the market between 1997 and 2001 were more harmful to women than men.[70] There are far-reaching consequences of the Agency's failure to include women fully in the clinical experimentation process.[71]

### 3. FDA's Early Restrictions on Access to Plan B

The Plan B approval process also exposes how paternalism and patriarchal concerns influence the Agency's policies, subject women to greater health risks, and restrict women's reproductive healthcare access.[72] In 2001, several organizations, including the Center for Reproductive Rights, filed a Citizen Petition asking the Agency to switch Plan B from prescription status to over-the-counter ("OTC") status.[73] The FDA failed to

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70. Cole, *supra* note 1, at 137 (citing U.S. GOV'T ACCOUNTABILITY OFF., GAO-01-286R, DRUG SAFETY: MOST DRUGS WITHDRAWN IN RECENT YEARS HAD GREATER HEALTH RISKS FOR WOMEN 3 (2001), http://www.gao.gov/new.items/d01286r.pdf [https://perma.cc/2VA9-WVYR]) ("[O]f the ten prescription drugs removed from the market from 1997-2000, nine of the drugs posed a greater degree of harm to women compared to men.").

71. Sanders, *supra* note 1, at 150. The neglect of women's health has also manifested in the failure to adequately fund research on diseases that primarily affect women by scientific bodies like the NIH. Arthur A. Mirin, *NIH Can No Longer Turn Its Back on Chronic Fatigue Syndrome*, 66 WORK 365 (2020) (illustrating that the NIH has traditionally underfunded diseases such as Myalgic Encephalomyelitis /Chronic Fatigue Syndrome ("ME/CFS") while over-funding diseases that primarily affect men); *see also* Colleen Campbell, *How Long COVID Is Forcing a Reckoning with the Neglect of Post-Infectious Chronic Illnesses*, PETRIE-FLOM CTR.: BILL OF HEALTH BLOG (July 29, 2021), https://blog.petrieflom.law.harvard.edu/2021/07/29 /long-covid-chronic-illness [https://perma.cc/6JQM-YDNS] (arguing that the lack of preparedness by the public health community for the mass disabling event of Long COVID stems in part from pre-existing failures to prioritize women's bodies within regulatory, scientific, and public health frameworks).

72. Tummino v. Torti, 603 F. Supp. 2d 519, 523 (E.D.N.Y. 2009) (agreeing with plaintiff's claims that the FDA's actions regarding Plan B were "arbitrary and capricious because they were not the result of reasoned and good faith agency decision-making").

73. 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, 408 (2008) (citing Citizen's Petition (Feb. 14, 2001)http:////_). Likewise, in April 2003, Women's Capital Corporation applied to the FDA also requesting that Plan B be used as an OTC drug. U.S. GOV'T ACCOUNTABILITY OFF., GAO-06-109, FOOD AND DRUG ADMINISTRATION: DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL 1 (2005), http://www.gao.gov /new.items/d06109.pdf [https://perma.cc/K5PB-6MBV] [hereinafter GAO REPORT].

respond for nearly five years and, when it did reply in 2006, denied the petition to grant it OTC status.[74] While the Agency eventually approved the drug in 2006 as a non-prescription drug, it instituted unique barriers that effectively rendered the drug "behind-the-counter."[75]

When the FDA approved Plan B, it restricted access to only women over eighteen years old in pharmacies and health clinics. It also required pharmacists to shelve it behind the pharmacy counter.[76] This meant that pharmacists with moral /or religious objections to contraception could refuse to dispense the drug.[77] These restrictions prevented women from fully accessing reproductive health services and exercising their reproductive rights.

The GAO found several features of the review process unusual. For example, after the FDA's joint advisory committee voted to approve the initial "switch" application request in May 2004, the director of the FDA instead chose to deny the application against this recommendation.[78] Additionally, "high-level management" was more involved in the Plan B approval process than for other applications.[79] The GAO concluded that the Agency departed from its regular administrative procedures.[80]

Feminist organizations later filed a lawsuit against the Agency arguing it had acted arbitrarily and capriciously under the APA.[81] In *Tummino v. Torti*, the district court agreed, finding the Agency acted in bad faith and arbitrarily and capriciously in its decision-making. The court observed that the process was affected by "political considerations, delays, and implausible justifications."[82] For instance, as justification for its action, the Agency discussed the goal of deterring "promiscuous"

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74. *Tummino,* 603 F. Supp. 2d at 526; *see also* Allen, *supra* note 73, at 408 (citing Aid for Women v. Foulston, 427 F. Supp. 2d 1093 (D. Kan. 2006)).

75. Allen, *supra* note 73, at 401–02.

76. *Id.*

77. *Id.*

78. *Id.*; *see also Tummino,* 603 F. Supp. 2d at 537. The officials normally "responsible for signing an action letter disagreeing with the decision" also refused to sign the "not-approvable letter for Plan B." GAO REPORT, *supra* note 73, at 3, 13.

79. *Tummino*, 603 F. Supp. 2d. at 537.

80. *See generally* GAO REPORT.

81. *Id.* at 545.

82. *Id.* at 523.

behavior, something it had not previously done in reviewing switch applications.[83]

In 2013, the court remanded the case back to the Agency, which agreed to approve Plan B for OTC use for all ages.[84] However, the Secretary of the Department of Health and Human Services intervened and overruled the FDA Commissioner's decision[85] reportedly due to the "cognitive and behavioral" differences between adolescent girls and younger girls of reproductive age.[86] Again, the manufacturers sued, and the district court agreed that the Agency acted arbitrarily and capriciously in denying the supplemental new drug application ("sNDA").[87] On appeal, the court recognized the unusual political involvement in the approval process.[88] It ordered the Agency to approve Plan B for OTC access for women and girls of all ages.[89] This decision was not appealed.

These cases reveal how the Agency's procedures may be influenced by gender bias.[90] They demonstrate important

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83. *Id.*; *see also* Allen, *supra* note 73, at 437. The Agency's own expert panel found that Plan B was safe for women and girls of all age. *Tummino,* 603 F. Supp. 2d. at 545–46. Nevertheless, the Agency departed from its review recommendations. *Id.*

84. Tummino v. Hamburg, 936 F. Supp. 2d 162, 166–67 (E.D.N.Y. 2013).

85. *Id.* at 167. The Secretary specifically argued that "the data submitted for this product do not establish that prescription dispensing requirements should be eliminated for all ages." *Id.* The Obama Administration also agreed with this determination. *Id.* at 167–68.

86. *Id.*

87. *Id.* at 197. A supplement is an application that allows a company to make changes in a product that already has an approved NDA. A supplemental new drug application ("sNDA") allows a company to change a label, market a new dosage or strength of a drug, or change the way it manufactures a drug. *See Drugs@FDA Glossary of Terms*, FDA, https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms [https://perma.cc/996H-5PSB] (Nov. 14, 2017) (defining "supplement").

88. *Tummino,* 936 F. Supp. 2d at 170 (discussing the FDA's unusual treatment of emergency contraception and discussing how the political interference came straight from the Secretary of Health and Human Services, a member of the President's Cabinet).

89. *Id.* at 169. The Agency observed specifically that less-safe drugs (like acetaminophen) were available to pediatric consumers, while Plan B (levonorgestrel), which only caused nausea and a delay in menses as its major side effects, was banned. *Id.* at 171–74. The court further noted that "the issue in this case involves the interpretation of a general statutory and regulatory scheme relating to the approval of drugs for over-the-counter sale. The standards are the same for aspirin and for contraceptives." *Id.* at 169.

90. Allen, *supra* note 73, at 410–11; *see also* Sanders, *supra* note 1, at 149–50; Heather Ruth Wishik, *To Question Everything: The Inquiries of Feminist*

themes in feminist scholarship regarding law's disparate impact on women's lives. While there is a wealth of analysis on gender in food and drug law literature, not much scholarship has offered an intersectional analysis of both race (or even skin color) and gender. Intersectionality offers a theoretical prism for this analysis that is ordinarily obscured in dominant feminist scholarship.

### *B. Intersectionality's Theoretical Intervention*

#### 1. Addressing the Erasure of Black Women

Kimberlé Crenshaw, a founder of critical race theory (CRT), coined the term intersectionality to address the inadequacies of anti-racist and feminist theories.[91] These theories, she demonstrated, obscured Black women's intersectional subordination because they considered race and gender as mutually exclusive categories. Intersectionality built upon the works of CRT scholarship, which posits centrally that law naturalizes racial hierarchies and reinforces racial subordination.[92] Even where the law articulates seemingly neutral principles, it may institutionalize racial inequality through its disparate impact on the lives of people of color.[93] These tenets are equally applicable to the administrative arena.[94]

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*Jurisprudence*, 1 BERKELEY WOMEN'S L.J. 64, 72–76 (1985). *See generally* Donley, *supra* note 1.

91. *See* Crenshaw (1989), *supra* note 9, at 140.

92. *See generally* DERRICK BELL, FACES AT THE BOTTOM OF THE WELL: THE PERMANENCE OF RACISM (reprt. ed. 1993); IAN HANEY LÓPEZ, WHITE BY LAW: THE LEGAL CONSTRUCTION OF RACE 14 (1996) (examining the legal construction of racial categories). For a discussion of race and biomedicine, see Osagie K. Obasogie, *The Return of Biological Race? Regulating Innovations in Race and Genetics Through Administrative Agency Race Impact Assessments*, 22 S. CAL. INTERDISC. L.J. 1 (2012); Khiara Bridges, *The Dangerous Law of Biological Race*, 82 FORDHAM L. REV. 21, 21 (2013) (arguing that the Supreme Court never rejected race science, even as it constrained what race meant for the law); DOROTHY ROBERTS, FATAL INVENTION: HOW SCIENCE, POLITICS, AND BIG BUSINESS RE-CREATE RACE IN THE TWENTY-FIRST CENTURY 26 (2012).

93. *See, e.g.*, John A. Powell, *The Colorblind Multiracial Dilemma: Racial Categories Reconsidered*, 31 U. SAN FRANCISCO L. REV. 789, 790 (1997) (noting that racial categories are used to attack the validity of race-conscious programs like affirmative action, maintaining racial hierarchy).

94. Despite this area being ripe for critical analysis, a CRT perspective is largely absent from administrative law literature because of the erasure of antidiscrimination principles from agency law. *See* Ceballos et al., *supra* note 23,

Intersectionality added a Black feminist perspective to this framework by incorporating the simultaneity of the "woman question" and "race problem."[95] As a critique, intersectionality exposed a blind spot in feminist legal theory, namely the traditional centering of White women's experiences. Feminist legal theory essentialized the woman experience as a fundamentally White one, writes legal scholar Angela P. Harris.[96] By assuming Whiteness as the norm,[97] feminist legal theory failed to adequately contend with how race, class, or other forms of oppression shape the experiences of women of color.[98] Otherwise put, feminist legal theory reproduced the same silencing of Black women that the law engenders for women generally.

For example, dominant approaches to domestic violence proved myopic for women of color because of the neglect of the host of barriers they face, argued Crenshaw.[99] In addition to systemic gender violence, women of color face obstacles to escaping abuse imposed by poverty, unemployment, lack of childcare support, and lack of adequate housing, among others.[100] These barriers often prevent women of color—especially those already materially disadvantaged—from seeking and accessing legal resources to address gender violence. Without accounting for these additional barriers, it is not possible to reach the most vulnerable survivors, even with well-intentioned policies addressing violence against women.[101]

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at 370 (noting this is administrative law's blind spot, namely the erasure of race from agency law); Shah, *supra* note 23 ("[O]utdated beliefs about what constitutes objective legal analysis and intellectual rigor continue to mold research and writing in administrative law."); Golin, *supra* note 23, at 1533 (examining how race, gender, and cultural bias influence ALJ decisions).

95. PATRICIA HILL COLLINS, BLACK FEMINIST THOUGHT: KNOWLEDGE, CONSCIOUSNESS, AND THE POLITICS OF EMPOWERMENT 228 (10th anniversary rev. ed. 2000).

96. Angela P. Harris, *Race and Essentialism in Feminist Legal Theory,* 42 STAN. L. REV. 581, 585 (1990) (noting that this silencing occurs in feminist legal theory, even from well-meaning anti-racist scholars); *see also* Devon W. Carbado & Cheryl I. Harris, *Intersectionality at 30: Mapping the Margins of Anti-Essentialism, Intersectionality, and Dominance Theory*, 132 HARV. L. REV. 2193, 2200 (2019).

97. *See* Carbado & Harris, *supra* note 96, at 2201.

98. Harris, *supra* note 96, at 585 ("Just as law itself, in trying to speak for all persons, ends up silencing those without power, feminist legal theory is in danger of silencing those who have traditionally been kept from speaking, or who have been ignored when they spoke, including black women.").

99. Crenshaw (1991), *supra* note 9, at 1243–44.

100. *Id.* at 1245–46.

101. *Id.* at 1246–50.

In a similar vein, an intersectional analysis revealed the limits of anti-racist politics and its failure to grapple with hetero-patriarchal oppression for women of color. Crenshaw identified, for example, the tendency for anti-racist critiques of rape law to emphasize that these laws merely condemn the rape of White women by Black men.[102] By exclusively focusing on the consequences for Black men, this discourse essentially devalued Black women's experiences of rape.[103] Additionally, these issues are often framed as pitting Black women against the larger quest for racial justice and potentially diluting broader causes for the Black community.[104] Calls to address violence against Black women were therefore often met with resistance within the Black community.[105]

The lack of an intersectional framework also proved harmful for Black women as plaintiffs in antidiscrimination case law because of courts' tendencies to center plaintiffs who were most privileged within discriminated subgroups.[106] In gender discrimination claims, courts refuse to certify Black women plaintiffs as class representatives for women litigants.[107] Similarly, courts do not allow Black women plaintiffs to represent Black men even in the presence of racial and gender disparities.[108] Black women plaintiffs therefore must choose

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102. *Id.* at 1271–73. This concern is grounded in the history of White lynching of Black men accused of raping White women.

103. *Id.*

104. The history of mass incarceration and pervasive police violence against Black men illustrate that carceral responses to domestic violence potentially expose Black men to overpolicing and surveillance by the state.

105. Crenshaw (1991), *supra* note 9, at 1257 n.51. (noting that resistance often stemmed from an aversion to confirming negative stereotypes against African Americans).

106. Crenshaw (1989), *supra* note 9, at 141–42; DeGraffenreid v. Gen. Motors Assembly Div., St. Louis, 413 F. Supp. 142, 143 (E.D. Mo. 1976) (finding that antidiscrimination law was not intended to remedy both race and gender discrimination and Congress did not anticipate providing a "super-remedy" for Black women).

107. Crenshaw (1989), *supra* note 9, at 144; Moore v. Hughes Helicopters, Inc., 708 F.2d 475, 480 (9th Cir. 1983) ("Moore [plaintiff] had never claimed before the EEOC that she was discriminated against as a female, but only as a [B]lack female . . . . [T]his raised serious doubts as to Moore's ability to adequately represent White female employees.").

108. Crenshaw (1989), *supra* note 9 at 146–47. One court observed that the sex disparity created such a conflict between Black men and women that the latter could not represent Black men. *Id.* at 147 (citing Payne v. Travenol Lab'ys, Inc., 416 F. Supp. 248 (N.D. Miss. 1976)). Plaintiffs brought claims on behalf of all Black employees, but the district court refused to allow them to certify on behalf of Black men. *Id.* It allowed cert only on behalf of Black women. *Id.* Despite finding that

between pursuing intersectional claims or rejecting their gender-based claims in order to include Black men.[109]

Intersectionality provides a "bottom-up" praxis to address the complex intersection of multiple forces of oppression for Black women and marginalized groups generally.[110] In the food and drug law context, it offers a meaningful intervention in the feminist literature.[111] The case of the Dalkon Shield IUD below illustrates that, when regulatory systems fail, the burden falls disproportionately on poor women of color because of distinct health risks due to systemic racism and classism.

### 2. Dalkon Shield Intrauterine Device

The Dalkon Shield IUD was in circulation from 1970 to 1974 and approximately 2.5 million women purchased it.[112] About two hundred thousand women sued the manufacturer for injuries associated with using the device.[113] While the Agency's inaction and delay in this case exposed its neglect of women's health,[114] there were also intersectional forces at play.

The device manufacturer, A.H. Robins, failed to test its safety and long-term effects.[115] As a result, the device's design defect was not discovered until after it entered the market.[116] Notably, its coiled, braided wire rings were conducive to

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there was discrimination, Black men could not participate in the remedy "for fear that their conflicting interests would not be adequately addressed." *Id.* The Fifth Circuit agreed. *Id.* (citing Payne v. Travenol Lab'ys, Inc., 673 F.2d 798 (5th Cir. 1982)).

109. *Id.* at 148.

110. *Id.* at 151.

111. *See generally* Boyd (2018), *supra* note 1, at 289. See *infra* Part IV for a discussion of the harmful effects of skin-lightening products.

112. Robin Marantz Henig, *The Dalkon Shield Disaster*, WASH. POST (Nov. 17, 1985), https://www.washingtonpost.com/archive/entertainment/books/1985/11/17/the-dalkon-shield-disaster/6c58f354-fa50-46e5-877a-10d96e1de610 [https://perma.cc/7VTH-BNX4]; *see also* Gina Kolata, *The Sad Legacy of the Dalkon Shield*, N.Y. TIMES (Dec. 6, 1987), https://www.nytimes.com/1987/12/06/magazine/the-sad-legacy-of-the-dalkon-shield.html [https://perma.cc/B6XA-BGPV].

113. Kolata, *supra* note 112.

114. Koenig & Rustad, *supra* note 1, at 51.

115. Rebecca Weisman, *Reforms in Medical Device Regulation: An Examination of the Silicone Gel Breast Implant Debacle*, 23 GOLDEN GATE U. L. REV. 973, 984 (1993).

116. *Id.* at 987.

bacterial growth and infection.[117] The company also intentionally suppressed information regarding adverse reports from the medical community.[118] A.H. Robins's "legal and moral coverup" caused women to suffer from a host of injuries, including infection, pelvic inflammatory disease, sterility, miscarriage, and death.[119] The device caused at least twenty-one deaths and thirteen thousand cases of sterility or infertility.[120]

The Agency's lack of timely response further exacerbated the catastrophe of the Dalkon Shield.[121] When the Agency was notified of the devastating effects of the product, it failed to request safety data in a timely manner despite being authorized to do so.[122] Even after gaining jurisdiction over the device, the Agency stalled in responding to the crisis despite obtaining information regarding injuries associated with the device.[123] The Agency arguably became concerned only when it was apparent that the Dalkon Shield could cause involuntary abortions.[124] The device was officially recalled in 1984.[125]

African American women felt the harmful effects most acutely because of underlying health disparities and systemic racism. African American women were especially vulnerable because of higher rates of underlying reproductive conditions that the device exacerbated.[126] The IUD worked by constantly irritating the uterine lining,[127] which exacerbated health issues such as uterine fibroids, endometriosis, and cancer.[128] Because African American women experience higher incidence of these

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117. HARRIET A. WASHINGTON, MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT 201 (1st ed. 2006).

118. Weisman, *supra* note 115, at 987.

119. Henig, *supra* note 112; *see also* Weisman, *supra* note 115, at 985; Koenig & Rustad, *supra* note 1, at 39, 53.

120. Henig, *supra* note 112.

121. Weisman, *supra* note 115, at 984–87.

122. *Id.* at 986 (explaining that a Dr. C. Donald Christian reported his adverse findings to the FDA, which "kept telling him to go away").

123. *Id.*; Koenig & Rustad, *supra* note 1, at 51.

124. Weisman, *supra* note 115, at 986.

125. Henig, *supra* note 112 ("As of mid-1985, at least 21 women are dead, at least 13,000 are sterile or infertile, and probably hundreds more are the mothers of damaged children—all as the direct result of the unconscionable actions of . . . 'a few men with little on their minds but megabucks.'").

126. WASHINGTON, *supra* note 117, at 201.

127. *Id.*

128. *Id.*

conditions, "the IUD proved disastrous for African Americans," wrote bioethicist and scholar Harriet Washington.[129]

Systemic racism in biomedical research further exposed African American women to greater pre- and post-approval risks associated with novel reproductive technologies, including IUDs, Norplant, and Depo-Provera.[130] Scientists initially tested them on poor women of color in the developing world.[131] Once approved domestically, they were first widely distributed by inner-city clinics in poor communities to patients on Medicaid who were predominantly Black and Latinx women.[132] Essentially, researchers "overwhelmingly apportion[ed]" the risks associated with these technologies to women of color domestically and globally.[133]

Privileged White women were largely spared the immediate risks associated with post-approval use because these products only gained popularity among middle- and upper-class White women patients *after* they were in widespread use among communities of color.[134] Unsurprisingly, poor women of color predominantly suffered from the adverse effects of these novel reproductive technologies.

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129. *Id.* The device also caused loss of fertility among its users. For instance, reproductive justice scholar and advocate Loretta Ross became sterilized at the age of twenty-three as a result of the Dalkon Shield. Interview by Joyce Follet with Loretta Ross, in Northampton, Mass. (Nov. 3–5 2004), https://www.smith.edu/libraries/libs/ssc/vof/transcripts/Ross.pdf [https://perma.cc/878B-ZZJF].

130. WASHINGTON, *supra* note 117, at 201–02. These are long-acting reversible contraceptives ("LARC") that offer longer-term birth control up to several years (i.e., Norplant) and are administered in different ways. Khalida Itriyeva, *Use of Long-Acting Reversible Contraception (LARC) and the Depo-Provera Shot in Adolescents*, 48 CURRENT PROBS. IN PEDIATRIC & ADOLESCENT HEALTH CARE 321 (2018). Norplant is administered through silicone capsules that are inserted in a woman's arm and release small amounts of progestin over five years. *Norplant: A New Contraceptive with the Potential for Abuse*, ACLU (Jan. 31, 1994), http://www.aclu.org/documents/norplant-new-contraceptive-potential-abuse [https://perma.cc/QM5B-NMEM]. Depo-Provera is administered through injection every three months. *Birth Control Shot*, PLANNED PARENTHOOD, https://www.plannedparenthood.org/learn/birth-control/birth-control-shot [https://perma.cc/C92A-SPXU].

131. WASHINGTON, *supra* note 117, at 201–02 ("The Pill, Norplant, and the Depo-Provera shot were first tested in Mexico, Africa, Brazil, Puerto Rico, and India."); *see also Norplant: A New Contraceptive with the Potential for Abuse*, *supra* note 130; DOROTHY E. ROBERTS, KILLING THE BLACK BODY: RACE, REPRODUCTION, AND THE MEANING OF LIBERTY 124 (1st ed. 1997) (noting that, prior to Norplant's approval, there were similar concerns regarding its long-term safety such as risk of breast and cervical cancer—concerns that were never fully addressed).

132. WASHINGTON, *supra* note 117, at 202.

133. *Id.* at 201–02.

134. *Id.* at 202.

African American women—especially those in poor communities—were also vulnerable due to state reproductive policies. Professor Dorothy Roberts has written extensively about the systematic control and coercion of native African American women's reproduction since the antebellum era.[135] During the twentieth century, the coercion of poor women's reproduction continued in the eugenics era and later in the campaign of compulsory sterilization of African American women on public assistance. The state also deployed reproductive medical devices in its population-control policies toward African American women in the twentieth century.[136] For these reasons, African American women were especially vulnerable to the risks associated with devices like the Dalkon Shield and failures in regulatory law to protect women's health.[137]

### *C. Why Intersectionality is Needed in Food and Drug Law*

An intersectional framework remedies the erasure of women of color within dominant public health discourses on gender and race.[138] This erasure is significant because there are unique challenges that Black women in particular face in healthcare due to the interlocking systems of racism and sexism. This may, at times, manifest as differential access to healthcare and risk-mitigation resources, as well as health disparities in underlying reproductive conditions. However, there has been little research examining how processes of racialization intersect with gender within this domain.

As a general matter, there is a paucity of critical race analysis in the administrative law context: a paucity produced by the general erasure of antidiscrimination principles from agency law.[139] In food and drug law, the FDA's regulation of race-based drugs has notably given rise to generative discourses

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135. *See generally* ROBERTS, *supra* note 131.

136. *Id.* at 184–85.

137. *Id.* at 122–25.

138. *See generally* Crenshaw (1989), *supra* note 9; Crenshaw (1991), *supra* note 9; Osagie K. Obasogie, *Anything But a Hypocrite: Interactional Musings on Race, Colorblindness, and the Redemption of Strom Thurmond*, 18 YALE J.L. & FEMINISM 451 (2006).

139. A CRT perspective is generally absent from administrative law literature despite this area being ripe for critical analysis. Ceballos et al., *supra* note 23, at 370 (noting this is administrative law's blind spot, namely the erasure of race from its purview); Shah, *supra* note 23; Golin, *supra* note 23, at 1533.

regarding the reproduction of biological race by administrative bodies.[140] Several scholars have critiqued the Agency's approval of the drug BiDil exclusively for treating heart disease among African Americans, for example.[141] This scholarship argues that the approval of the drug in fact reenforced biological racial categories that inevitably institutionalize racial hierarchies and subordination.[142] This scholarship calls for greater scrutiny of the regulation of race-based therapeutics (i.e., those designed for specific ethno-racial groups) in light of their problematic consequences.[143]

In cosmetics regulation, Professor Marie Boyd has examined how race and gender intersect in the context of the lax regulation of cosmetics.[144] She examines "cosmetics as a gendered product and industry" and identifies how "product use and exposure may be shaped by the intersection of gender, race, and class."[145] In particular, she explores why women, and "particularly women who are members of other excluded groups, may be disproportionately impacted by the failures of cosmetics law and regulation."[146]

Boyd recently analyzed the potential for tort law and regulatory reforms to address gaps in regulatory law. For example, *Ingham v. Johnson & Johnson* involved Johnson & Johnson's talcum baby powder product.[147] Plaintiffs alleged that the product caused their ovarian cancer because of its asbestos content.[148] Boyd argues against the preemption of state tort law in cosmetics reform so that those most harmed by cosmetics, including underrepresented women, may have recourse in tort

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140. *See, e.g.*, Obasogie (2012), *supra* note 92; Kimani Paul-Emile, *The Regulation of Race in Science*, 80 GEO. WASH. L. REV. 1115, 1125–30 (2013); Catherine Lee & John D. Skrentny, *Race Categorization and the Regulation of Business and Science*, 44 LAW & SOC'Y REV. 617, 617 (2012) (noting "the importance of examining legal regulations for exploring how the meaning of race or ethnicity are [*sic*] contested and constructed in law."); *see also* Bridges, *supra* note 92 at 41.

141. *See generally* Obasogie (2012), *supra* note 92; Paul-Emile, *supra* note 140.

142. *See generally* Obasogie (2012), *supra* note 92.

143. *Id.*

144. Boyd (2022), *supra* note 1.

145. Body (2018), *supra* note 1, at 280.

146. *Id.*

147. *Id.* at 174; Ingham v. Johnson & Johnson, 608 S.W.3d 663 (Mo. Ct. App. 2020); *see also* Press Release, Johnson & Johnson, Johnson & Johnson Takes Steps to Equitably Resolve All Current and Future Talc Claims (Oct. 14, 2021), https://www.jnj.com/johnson-johnson-takes-steps-to-equitably-resolve-all-current-and-future-talc-claims [https://perma.cc/X5UM-HXYX].

148. *See Ingham*, 608 S.W.3d at 678.

law.[149] In particular, she argues that "[t]he gender and race-related disparities in tort law and the healthcare system may intersect and reinforce each other" and disproportionately harm women of color.[150] Furthermore, she notes that, if a defective or unreasonably dangerous cosmetic injures a Black woman and she seeks medical care, she does so in a system in which Black patients are more likely to receive a lower quality of care and healthcare providers underestimate the severity of Black Americans' injuries.[151]

More broadly, *Ingham* reveals the harmful consequences of regulatory neglect and its disparate impact. As early as 1972, the Agency was aware of "the potential safety hazard that the presence of asbestos in talc containing cosmetic product poses to the consumer."[152] By 1976, however, the FDA effectively gave up regulating asbestos in talc, in part due to Johnson & Johnson encouraging the industry trade group, then the Cosmetic, Toiletry, and Fragrance Association ("CTFA"), to preempt government regulation with self-regulation and approve an industry-wide voluntary standard for cosmetic talc.[153] The Agency's abdication of its responsibility in setting asbestos standards caused thousands of women to suffer from the product's adverse effects.

An overlooked aspect of the *Ingham* litigation, however, is the extent of racial targeting by the company.[154] The company resorted to targeting African American women *after* its safety issues became publicized and its sales among White women plummeted.[155] The company deployed marketing tactics similar to those used by the skin-lightening industry, namely racist

149. *See* Boyd (2022), *supra* note 1, at 175–77.

150. *Id.* at 211.

151. *Id.* Boyd adds that, if a Black woman then seeks redress for her injury through the tort system, she may receive a smaller award and lower pain and suffering damages because of her race and gender. *Id.*

152. *Ingham*, 608 S.W.3d at 716.

153. Casey Cep, *Johnson & Johnson and a New War on Consumer Protection*, NEW YORKER (Sept. 12, 2022), https://www.newyorker.com/magazine/2022/09/19/johnson-johnson-and-a-new-war-on-consumer-protection [https://perma.cc/6BNT-USA8].

154. *See* Joe Hernandez, *Johnson & Johnson Targeted Black Women With Products Linked to Cancer, Lawsuit Says*, NPR (July 29, 2021, 3:28 PM), https://www.npr.org/2021/07/29/1022355144/johnson-johnson-targeted-black-women-powder-products-cancer-lawsuit [https://perma.cc/3MQ5-2BYV].

155. *Id.*

stereotypes about Black women's bodies that include fatphobic stigmatization of Black women.[156]

A lawsuit filed by the National Council of Negro Women uncovered the extent of the company's tactics to reach this demographic.[157] It hired a firm to hand out one hundred thousand gift bags containing baby powder products at Black churches in Chicago, launched a 2010 radio-advertising campaign in the South targeting "Curvy Southern Women 18-49 Skewing African American,"[158] and considered signing Patti LaBelle or Aretha Franklin as spokespersons.[159] Internal data from the company details its strategy to market towards "high propensity consumers" such as African American women.[160] Not surprisingly, by 2006, about 60 percent of Black women were using baby powder compared to 30 percent of the general population.[161] In other words, the company's racial-targeting strategy was quite effective.

Race-targeted marketing has emerged in another agency context as well. Legal scholar and professor Andrea Freeman examined the problematic alliance between the Department of Agriculture (USDA) and the baby formula industry.[162] According to Freeman, racial disparities in breastfeeding rates arise directly from the USDA's policies and the formula industry's race-specific marketing toward African American women.[163] Throughout the twentieth century, for example, the USDA subsidized the formula industry and served as a major stakeholder in the industry as the single largest purchaser of

156. Chris Kirkham & Lisa Girion, *Special Report: As Baby Powder Concerns Mounted, J&J Focused Marketing on Minority, Overweight Women*, REUTERS (Apr. 9, 2019) https://www.reuters.com/article/us-johnson-johnson-marketing-specialrepo/special-report-as-baby-powder-concerns-mounted-jj-focused-marketing-on-minority-overweight-women-idUSKCN1RL1JZ [https://perma.cc/3J3B-QYB2].

157. *See* Catherine Thorbecke & Micah Washington, *Ben Crump Files Lawsuit Against Johnson & Johnson on Behalf of Black Women*, ABC NEWS (Jul. 27, 2023, 5:06 PM), https://abcnews.go.com/Business/ben-crump-files-lawsuit-johnson-johnson-behalf-black/story?id=79088901 [https://perma.cc/3QFC-BM7M] (noting that Ben Crump filed the lawsuit on behalf of the National Council of Negro Women).

158. Kirkham & Girion, *supra* note 156.

159. Hernandez, *supra* note 154.

160. *Id.* The information was derived from 2006 internal data.

161. *Id.*

162. ANDREA FREEMAN, SKIMMED: BREASTFEEDING, RACE, AND INJUSTICE 4 (2019) (describing the relationship between the formula industry and the USDA, which is the largest single purchaser of formula).

163. *Id.* at 6.

formula.[164] It did so by funneling baby formula for free to poor women on public assistance through the Women Infants and Children ("WIC") program.[165] This increased the likelihood that women in the program would not breastfeed, Freeman explains, a fact that is borne out by the statistics.[166]

This symbiosis between agency and industry actors capitalized on poor women of color's vulnerability as recipients of state aid and ultimately reproduced negative stereotypes about Black women's maternity.[167] Today, Black women are disproportionately represented in government programs that distribute free formula. They also have lower breastfeeding rates.[168] The maternal and fetal health consequences are apparent from this reality since formula is less nutritious than breast milk.[169] The World Health Organization (WHO) discourages formula use unless breastfeeding is not feasible.[170] This problematic relationship between the agency and the industry, as well as the racial marketing of the industry, has undoubtedly exacerbated fetal and maternal health disparities for Black women.

This bourgeoning body of scholarship illustrates why an intersectional lens is needed within the food and drug law literature. Notably, an intersectional lens offers a generative space for examining the complex forces at play, including agency and industry actors and historical and contemporary racism, sexism, and colorism. Skin-lightening product regulation contributes to this growing body of scholarship.

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164. *Id.* at 4–5.

165. *Id.* at 5. Freeman explains that the USDA receives generous rebates on formula, paying only 80 percent of the price of formula. *Id.* at 4. It then funnels these rebates into the WIC program budget, which in turn distributes free formula to women in its program. *Id.* Freeman also describes the ways in which the USDA uses its WIC and school lunch nutritional programs to redistribute food that consumers do not want by giving it to women and children in need of government assistance. *Id.* at 5.

166. *See id.* at 6.

167. *Id.* at 6–7. Freeman explains that there are several factors that contribute to low breastfeeding rates among Black women, including, among others, race-targeted marketing, unequal distribution of resources for new mothers, and racism and sexism. *Id.* at 6. Notably, Black women face stereotypes that portray them as bad mothers, while White mothers are positively stereotyped as "kind, generous, and self-sacrificing" and thus more likely to breastfeed. *Id.* at 7.

168. *Id.* at 6.

169. Daniel Munblit et al., *Health and Nutrition Claims for Infant Formula Are Poorly Substantiated and Potentially Harmful*, BMJ (2020).

170. *Breastfeeding*, WHO, https://www.who.int/health-topics/breastfeeding [https://perma.cc/CCP9-DMKM].

## II. MOTIVATIONS FOR SKIN LIGHTENING

Skin lightening is now a pervasive global phenomenon that is produced by complex and varied structural causes.[171] While the practice is often individualized, there are key institutional, historical, and social forces that give rise to skin lightening: forces that are often obscured in dominant discourses on the subject. Notably, in the West, these forces include systemic racism and colorism, hegemonic beauty norms, transnational capitalism, and racial marketing. This Part turns to these forces in order to add complexity and context to a discourse that often lacks nuance. While the forces implicated in this practice are multifarious and vary by geography,[172] this Article focuses primarily on the U.S. regulatory, social, and historical contexts for ease of analysis.[173]

### *A. Systemic Colorism*

The issue of colorism has largely been underexamined in discourses on racism. Nevertheless, skin-color discrimination is as pervasive as racism and remains a potent social, economic, and political force in communities of color. Because colorism, separate from racism, also produces tangible socioeconomic benefits (and disadvantages), this Section examines colorism as a distinct social and historical force that deserves special attention. In so doing, it is possible to properly contextualize the complex influence of skin color in the lives of people of color. It

171. The following sources provide data on the global scope of the practice or the statistics for specific geographical contexts: WHO, PREVENTING DISEASE THROUGH HEALTHY ENVIRONMENTS: MERCURY IN SKIN-LIGHTENING PRODUCTS (WHO ed. 2019) https://www.who.int/publications/i/item/WHO-CED-PHE-EPE-19.13 [https://perma.cc/7KFU-DADS] [hereinafter WHO Report]; *see also Global Skin Lighteners Market to Reach $10 Billion by 2015, According to New Report by Global Industry Analysts*, PRWEB, https://www.prweb.com/releases/skin_lighteners/fairness_creams_lotions/prweb2489104.htm [https://perma.cc/PH69-ZTR] (Jun. 22, 2009) [hereinafter Global Industry Analysts]; N.C Dlova et al., *Skin-Lightening Practices: An Epidemiological Study of South African Women of African and Indian Ancestries*, 173 BRIT. J. DERMATOLOGY, 2015 at 2, 7; Saja H. Hamed et al., *Skin-Lightening Practice Among Women Living in Jordan: Prevalence, Determinants, and User's Awareness*, 49 INT. J. DERMATOLOGY 414, 415 (2010).

172. Glenn, *supra* note 11, at 298.

173. For example, South Asia's history of casteism and its association with skin color was exacerbated by Western colonialism and globalization. *See* Itisha Nagar, *The Unfair Selection: A Study on Skin-Color Bias in Arranged Indian Marriages*, SAGE OPEN 1, 2 (2018).

also becomes possible to understand how colorism operates as a primary motivation for skin lightening and other practices.

### 1. Defining Colorism

Systemic colorism has long shaped U.S. race relations.[174] Though inextricably linked with racism, colorism is distinct.[175] This distinction is crucial. Despite its political and social origins, U.S. law has institutionalized and constructed race as a genetic concept.[176] Race is accordingly traditionally conceptualized in genetic terms as an immutable feature of the body that manifests through specific identity markers; these include phenotype, physiognomy (i.e., facial features), hair texture, skin color, and ancestry.[177]

Racism refers to the social, political, and economic processes that create and reinforce the hierarchical position of the dominant ethno-racial group in the United States (i.e., White Americans) vis-à-vis subordinated groups (i.e., non-White Americans).[178] It typically encompasses discrimination against persons based on their racial status or identity, which may or may not relate to skin-color features.

Colorism, by contrast, manifests most visibly as an idealization of phenotypic proximity to Whiteness and the social valuation of those features.[179] Because of colorism, which largely stems from colonialism, darker skin is often devalued due to its association with Africans or Indigenous Peoples.[180] Colorism refers to discrimination against individuals based on their physiognomy, particularly skin color and African features.[181] It is the systemic social preference for lighter skin

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174. Kimberly Jade Norwood & Violeta Solonova Foreman, *The Ubiquitousness of Colorism*, *in* COLOR MATTERS: SKIN TONE BIAS AND THE MYTH OF A POST-RACIAL AMERICA 9, 15–19 (Kimberly Jade Norwood ed., 2014).

175. *See generally* Trina Jones, *Shades of Brown: The Law of Skin Color*, 49 DUKE L.J. 1487 (2000). Angela P. Harris, *From Color Line to Color Chart: Racism and Colorism in the New Century,* 10 BERKELEY J. AFR.-AM. L. & POL'Y 52, 54 (2008)

176. *See* Obasogie (2012), *supra* note 92, at 14–15 (describing various laws during the eugenics era that were predicated on biological race).

177. *See* Jones, *supra* note 175, at 1494.

178. *Id.* at 1494–95.

179. *See* Kimberly Jade Norwood, *Introduction*, *in* COLOR MATTERS: SKIN TONE BIAS AND THE MYTH OF A POST-RACIAL AMERICA, *supra* note 174.

180. *See* Margaret Hunter, *"If You're Light You're Alright:" Light Skin Color as Social Capital for Women of Color*, 16 GENDER & SOC'Y 175, 176 (2002).

181. Norwood & Foreman, *supra* note 174, at 9 (attributing the coining of "colorism" to Alice Walker, who defined it as the prejudicial treatment of same-race

color and the resulting social stratification due to skin-color distinctions.[182]

Though distinct, colorism cannot be understood apart from racism. Both systems of domination emanate from specific socio-cultural, institutional, and historical processes, including the institutions of slavery and colonialism. Like racism, colorism is a vestige of antebellum-era norms and practices institutionalized to reinforce the racial hierarchy. Consequently, both systems institutionalize White superiority and the correlation of positive social value with proximity to Whiteness.[183]

Both also use physical features to assign categories that are accorded social and symbolic meaning.[184] As legal scholar and professor Trina Jones writes, colorism, like racism, is not merely a system of classification, but a system that attaches meaning to racial and skin color categories to maintain inequality.[185] Consequently, lighter skin is symbolically associated with positive attributes such as intelligence, higher socioeconomic status, moral superiority, and attractiveness.[186] Colorism materially affects the lives of people of color *because* it is predicated on the actual meanings, values, and associations given to skin color.

Both racism and colorism may manifest interpersonally or institutionally.[187] However, while racism traditionally manifests *between* ethno-racial groups, colorism may be a source

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people based solely on their color); *see also* Jones, *supra* note 175, at 1489; Verna M. Keith, *A Colorstruck World: Skin Tone, Achievement, and Self-Esteem Among African American Women*, *in* SHADES OF DIFFERENCE: WHY SKIN COLOR MATTERS 25 (Evelyn Nakano Glenn ed., 2009); Ellis Monk, *Skin Tone Stratification Among Black Americans, 2001-2003*, 92 SOC. FORCES 1313, 1316 (2014).

182. *See generally* Ellis Monk, *The Cost of Color: Skin Color, Discrimination, and Health Among African Americans*, 121 AM. J. SOC. 396 (2015).

183. *See* YABA BLAY, ONE DROP: SHIFTING THE LENS ON RACE 10 (2021) (noting that European and White nationalism associated European features with moral and physical superiority).

184. *See id.*

185. Jones, *supra* note 175, at 1527.

186. *Id.* at 1499–1500.

187. For a typology of the different forms of racism, see Ian F. Haney López, *Institutional Racism: Judicial Conduct and a New Theory of Racial Discrimination*, 109 YALE L.J. 1717, 1811 (2000) ("Purposeful racism is directed racial status—enforcement motivated by an intent to discriminate harmfully. Institutional racism is directed or undirected racial status-enforcement influenced in an unrecognized manner by racial institutions.").

of both *inter*- and *intra*racial oppression.[188] Therefore, both White and Black Americans may discriminate against darker-skinned Black Americans based on skin color.[189] This intraracial distinction and its material consequences are often obscured in dominant discourses on racial inequality. Yet it is essential to understand how skin-color politics serve as a distinct avenue for upholding the racial and skin-color hierarchies.

### 2. Antebellum Politics and Its Aftermath

Colorism is rooted in the political economy of slavery and the racial politics of the antebellum era. A critical concern of colonial society was the rise in interracial relationships between Whites and free Blacks.[190] In response, states enacted antimiscegenation laws to prevent indentured servants from uniting with Blacks because their unity posed a threat to slavery.[191] These laws, however, were inadequate to prevent consensual relationships between Blacks and poor Whites, writes legal scholar and professor Trina Jones.[192] They were similarly ineffective at protecting Black women from rape by slave owners.[193] Invariably, states needed to address the legal (and social) status of the growing population of mixed-race peoples, which resulted in a skin-color hierarchy that reinforced the racial hierarchy.[194]

The responses to the legal status of the growing mixed-race population varied geographically. State legislatures in the Upper South took a harsher stance than the Lower South, as Virginia's 1662 statute illustrates.[195] Departing from the traditional English rule of patrilineal citizenship, the statute

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188. *See* Leland Ware, *"Color Struck:" Intragroup and Cross-Racial Color Discrimination*, 13 CONN. PUB. INT. L.J. 75, 77–78 (2013) (documenting W.E.B. DuBois's observations of intra-racial colorism in Philadelphia); Perry, *supra* note 11, at 582 (describing how light skin became the standard of beauty in several continents); Hunter (2002), *supra* note 180, at 177 (arguing that lighter skin becomes a form of "social capital" within racialized hierarchies).

189. *See* W.E.B. DU BOIS, THE PHILADELPHIA NEGRO: A SOCIAL STUDY 316 (1899).

190. Jones, *supra* note 175, at 1503 (noting that colonial legislatures in the Upper South took the harshest stance against miscegenation and mixed-race individuals).

191. *Id.* at 1502.

192. *Id.*

193. *Id.*

194. *Id.*

195. *Id.* at 1503.

provided that mixed-race or mulatto children inherited their mother's status.[196] Later, in 1785, Virginia adopted a law that defined a "Negro" as a person with a Black parent or grandparent; this was eventually expanded to include persons with less than one-fourth Black blood.[197]

This schema eventually gave rise to the one-drop rule for mulattos.[198] Under this rule, any person with "a drop of Black blood"—that is, traceable African ancestry—was classified as Black. By lumping mulattos in the same racial category as unmixed Blacks, the one-drop rule entrenched Whites' superior status in the racial hierarchy.[199]

States in the Lower South, like Louisiana, were more lenient regarding miscegenation and developed a system that elevated the status of mulattos above enslaved Africans.[200] The state categorized mulatto or Creole people of various admixtures.[201] For example, a quadroon was legally categorized as being one-quarter/ Negro and three-quarters/ White; an octoroon was one-eighth/ Negro and seven-eighths/ White.[202] This system produced a large intermediate mulatto population that distinguished itself from the African population and received preferential treatment from Whites.[203]

Case in chief: lighter-skinned Creoles were legally presumed to be free and, in some cases, barred from mingling with enslaved darker-skinned Africans.[204] The buffer class between enslaved Africans and Whites allowed the White planter class to retain its social, economic, and political power

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196. *See "Negro Womens Children to Serve According to the Condition of the Mother"* (1662), VA. HUMANITIES: ENCYCLOPEDIA VA. (Dec. 7, 2020), https://encyclopediavirginia.org/entries/negro-womens-children-to-serve-according-to-the-condition-of-the-mother-1662 [https://perma.cc/KHY2-TWFC] (transcribing a 1662 Virginia law documented in Hening's Statutes at Large, Volume 2, Page 170). *See* also Camille A. Nelson, *American Husbandry: Legal Norms Impacting the Production of (Re)Productivity*, 19 YALE J.L. & FEMINISM 1, 18–19 (2007); Colleen Campbell, *Medical Violence, Obstetric Racism, and the Limits of Informed Consent for Black Women*, 26 MICH. J. RACE & L. 47 (2021) [hereinafter Campbell, *Medical Violence*].

197. Jones, *supra* note 175, at 1505.

198. *Id.* at n.69 (noting that the rule is also known as the "one Black ancestor rule," the "traceable amount rule," or the rule of hypo-descent).

199. *Id.*

200. *Id.* at 1506–07.

201. BLAY, *supra* note 183, at 12–13.

202. *Id.*

203. Jones, *supra* note 175, at 1506 (describing "quadroon balls," where wealthy White men courted mulatto women).

204. BLAY, *supra* note 183, at 12.

over the African population.[205] It also prevented the formation of cross-racial and economic solidarity with darker-skinned Africans, a fact that served the interest of the propertied elite.

In the wake of the Civil War, states in the Lower South eventually shifted toward the one-drop rule,[206] which has since generally governed race relations in the United States. Processes of racialization, including skin-color politics, have shifted over time and varied geographically. Nevertheless, proximity to Whiteness has generally served as a form of symbolic capital for lighter-skinned people of color, regardless of geography and the historical moment.

Certain practices in the antebellum era concretized the entrenched colorism that we have inherited today. For example, enslaved mulattos commanded a higher price because their light skin increased their economic value.[207] Skin color also influenced one's likelihood of gaining manumission, as some mulattos ultimately acquired their freedom and many were already free by the end of the Civil War, writes legal scholar and professor Kimberly Jade Norwood.[208] Some mixed-race Blacks even inherited enslaved people of their own through their White fathers, she explains.[209]

Lighter-skinned enslaved people also generally had greater "employment" options available to them.[210] While darker-skinned enslaved people were relegated to the fields for backbreaking labor in the sun, mulattos were sometimes able to acquire trade skills and hired out to work.[211] Mulattos could also serve in the slave masters' homes, some of whom were their White fathers. This meant greater access to social and cultural capital for mulattos, as they were sometimes taught to read and write and accessed greater educational opportunities.[212] They were also more familiar with White cultural, language, and speech practices.[213]

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205. *See* Jones, *supra* note 175, at 1508.
206. *Id.* at 1510.
207. *Id.*
208. Kimberly Jade Norwood, *Colorism and Blackthink*: *A Modern Augmentation Of Double Consciousness*, *in* COLOR MATTERS: SKIN TONE BIAS AND THE MYTH OF A POST-RACIAL AMERICA, *supra* note 174, at 160.
209. *Id.* at 159.
210. *Id.*
211. *Id.*
212. Jones, *supra* note 175, at 1527.
213. Norwood, *supra* note 208, at 159.

The material benefits of light skin in the antebellum era cannot be overstated.[214] After slavery, many of these practices continued within the Black community, as the progenitor of American sociology, W.E.B. Du Bois, forecasted presciently when he said the problem of the "color line" would plague the twentieth century.[215] While White Americans gave preferential treatment to lighter-skinned Black Americans, elite and middle-class light-skinned Black Americans maintained their privileged status through exclusionary practices that exacerbated socioeconomic disparities and tensions within the Black community.[216]

The skin-color politics of the antebellum era and its immediate aftermath persist today as skin color remains a powerful axis of social stratification.[217] Like race, skin color shapes the spectrum of human experiences for people of color because proximity to Whiteness is still a form of symbolic capital.[218] Social science literature illustrates that skin color affects socioeconomic status, education, occupation, housing, incarceration outcomes, and sentencing in carceral proceedings, among others.[219] As a result, some scholars have argued for the recognition of skin color as a basis for discrimination in civil rights and employment discrimination claims.[220]

Colorism also stratifies health outcomes in ways that are traditionally obscured by dominant health-equity discourses.

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214. *Id.* at 160 (citing RONALD E. HALL, AN HISTORICAL ANALYSIS OF SKIN COLOR DISCRIMINATION IN AMERICA: VICTIMISM AMONG VICTIM GROUP POPULATIONS 125 (2010)).

215. W.E.B. DU BOIS, THE SOULS OF BLACK FOLK 8 (Henry Louis, Jr. Gates ed., Oxford Univ. Press 2007) (1903) (describing this as the problem of "the relation of the darker to the lighter races").

216. Norwood, *supra* note 208, at 160 (describing certain practices such as the "brown paper bag test," for instance, where one's skin had to be lighter than a brown paper bag in order to gain admission into certain networks).

217. Monk (2015), *supra* note 182, at 433. *See generally* William Pizzi et al., *Discrimination in Sentencing on the Basis of Afrocentric Features*, 10 MICH. J. RACE & L. 327 (2005); Verna M. Keith & Cedric Herring, *Skin Tone and Stratification in the Black Community*, 97 AM. J. SOC. 760 (1991).

218. Norwood, *supra* note 208, at 159. *See generally* Monk (2015), *supra* note 182 (discussing the social stratification of Black people along the color continuum).

219. Michael Tonry, *The Social, Psychological, and Political Causes of Racial Disparities in the American Criminal Justice System*, 39 CRIME & JUST. 273 (2010) (noting that carceral outcomes and severity of punishment are affected by colorism and Afro-American features).

220. *See* Harris, *supra* note 175, at 58 (noting that increasing colorism-related legal claims will lead to more nuanced and realistic conceptions of race discrimination from judges and scholars).

Sociologist Ellis Monk found that "[t]he magnitude of differences in key health outcomes along a color continuum within the African-American population (i.e., from the lightest to the darkest skinned) are virtually indistinguishable from or even exceed the disparities between blacks and whites as a whole."[221] That is, the intraracial variation due to colorism either mirrors that produced by racism or, in some cases, is *greater* than interracial disparities. However, the effects of colorism on health outcomes have largely escaped inquiry in dominant public health discourses centered around systemic racism.

Lastly, skin color shapes one's access to power and privilege, influencing one's social status, reputation, and social networks. It is no surprise that Black Americans—and other ethno-racial groups as well—who are traditionally publicly upheld as symbols of racial progress tend to be lighter-skinned. They include former President Barack Obama, former Secretary of State Colin Powell, singer Beyoncé, actor Will Smith, and actress Kerry Washington. Moreover, as discussed below, the effects of skin color intersect with gendered processes to shape perceptions of beauty, which also materially affect women of color. Further, despite being significant in the everyday lives of people of color, analyses of skin color unfortunately remain sparse in contemporary discourses on racial inequality.

### *B. Hegemonic Beauty Norms*

Skin lightening must also be contextualized as a product of systemic beauty norms and patriarchy. Women's negotiation with beauty standards is a complex matter that is the subject of much analysis in feminist literature.[222] For women of color, this negotiation is often layered with racial and skin-color politics, rendering beauty an alienating space for them because they are expected to cultivate their bodies to satisfy both gendered and Eurocentric aesthetic ideals.

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221. Monk (2015), *supra* note 182, at 433.

222. Deborah Zalesne, *Lessons from Equal Opportunity Harasser Doctrine: Challenging Sex-Specific Appearance and Dress Code*s, 14 DUKE J. GENDER L. & POL'Y 535, 554 (2007) (noting that because some workplaces enforce grooming policies that mandate the use of makeup, cosmetics use should not be regarded as trivial); *see also* LYNN S. CHANCER, RECONCILABLE DIFFERENCES: CONFRONTING BEAUTY, PORNOGRAPHY, AND THE FUTURE OF FEMINISM 83 (1998).

Beauty is a site of contestation.[223] For some women, beauty norms symbolize subordination and oppression because beauty is often filtered through the heteropatriarchal gaze.[224] While beauty standards have varied over time, beauty today is typically viewed through the myopic prism of mass advertising and commercialization.[225] Usually, the typology of the ideal female body is White (or light), feminine, slim, and genteel.[226] For this reason, some scholars frame beauty as a space for the enactment of exclusionary and unrealistic ideals that devalue, objectify, and often sexualize women.[227]

Others argue that beauty need not be, nor has it always been, a space for the monopoly of the masculine gaze. This contrasting vision of beauty depicts it—for some women at least—as a potential space for creative self-expression and actualization. Rather than enacting bodily alienation and objectification, beauty may cultivate identity performance, expression of individuality, and possibly empowerment.[228]

To that point, cosmetics use, a well-established aspect of beauty, originally emerged as an act of agency and even defiance against the moral dictates of Victorian society, writes historian Kathy Peiss.[229] In fact, beauty norms and salon culture in the nineteenth century were dominated by women and women-of-color entrepreneurs.[230] With the emergence of the male-dominated cosmetics industry, these spaces and practices

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223. *See generally* Deborah L. Rhode, *Appearance as a Feminist Issue*, 69 SMU L. REV. 697, 706 (2016).

224. *Id.* (describing participants in a study on wearing makeup in the workplace and expressing the belief that those women who do not wear makeup do not appear heterosexual).

225. *See generally* KATHY PEISS, HOPE IN A JAR: THE MAKING OF AMERICA'S BEAUTY CULTURE (Univ. of Pa. Press 2011) (1998).

226. *See generally* SABRINA STRINGS, FEARING THE BLACK BODY: THE RACIAL ORIGINS OF FAT PHOBIA 6 (2019).

227. *See generally* NAOMI WOLF, THE BEAUTY MYTH: HOW IMAGES OF BEAUTY ARE USED AGAINST WOMEN (Perennial 2002) (1991).

228. Rhode, *supra* note 223, at 697 ("The question for the women's movement is whether it is possible to find some common ground, and to develop a concept of beauty that is a source of pleasure rather than shame, and that enhances, rather than dictates self-worth.").

229. PEISS, *supra* note 225, at 135. *See generally* Angela King, *The Prisoner of Gender: Foucault and the Disciplining of the Female Body*, 5 J. INT'L WOMEN'S STUD. 29 (2004).

230. PEISS, *supra* note 225, at 61–62 (explaining that early entrepreneurs like Madam C.J. Walker were key actors in shaping beauty norms for women of color).

eventually became distorted by mass advertising and commercialization.[231]

Whether beauty is a source of pleasure, creativity, and empowerment; alienation and oppression; or all of the above is beyond the scope of this Article. What is key here is that the burdens imposed by beauty norms have never been equally distributed because of racial constructs of the body. Discourses on race have always co-constituted ideological constructs of the body, including feminine aesthetics. Indeed, race and skin-color politics have always shaped ideologies of the body, including the stereotypes regarding Black women as aesthetically undesirable.

Sociologist Sabrina Strings illustrates some of the historical reasons for this.[232] She argues that racial science, including the scientific construction of African bodies as physiologically distinct and inferior, developed in lockstep with discourses in aesthetics. That is, racial science depicted people of African descent as not only inferior, but aesthetically less appealing. This was particularly salient in feminine aesthetics. As Strings illustrates, the historical rise in anti-fatness produced a particular vision of the body that was specifically anti-Black-woman.[233] Elite White Americans used fatphobia to assert their monopoly on bodily capital and distinct social status above the poor and people of color. Though it was also used to control White women's bodies, fatness became a measure of bodily capital informed by the stigmatization of Black women's bodies.[234]

Hair-grooming standards also incorporate racist aesthetics and are used to alienate and regulate Black women's bodies.[235] In professional spaces, for example, these norms often

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231. *Id.* at 4–5, 97–98.

232. *See, e.g.*, STRINGS, *supra* note 226, at 6.

233. *Id.*

234. *Id.*; *see also* PIERRE BOURDIEU, DISTINCTION: A SOCIAL CRITIQUE OF THE JUDGEMENT OF TASTE 197, 207 (Richard Nice trans., Routledge 8th prtg. 1984) (describing the body as a product of one's social status that often corresponds to one's position in the social hierarchy).

235. For a discussion of policies explicitly banning natural hair styles like dreadlocks, see Patricia A. Banks, *Hair Rules: Race, Gender, and Stigmatization in Schools*, 25 U. PA. J.L. & SOC. CHANGE 1 (2021); *see also* Patricia A Banks, *No Dreadlocks Allowed: Race, Hairstyles, and Exclusion in Schools*, 25 MULTICULTURAL PERSPECTIVES 30 (2023). Several states have enacted the CROWN Act to address ongoing hair discrimination. *See* JOY COLLECTIVE, THE C.R.O.W.N. RESEARCH STUDY: CREATING A RESPECTFUL AND OPEN WORKPLACE FOR NATURAL HAIR (2019) (finding that Black women are more discriminated against because of their hair).

unreasonably require that Black women wear "their hair straight and hanging down."[236] This is impractical because, while there are alternative means of straightening their hair, this aesthetic likely entails the use of chemical products to do so. Importantly, these unreasonable professional standards devalue Black women's natural hair and often subject them to identity discrimination in the workplace.[237]

Colorism also influences beauty norms to the extent that it permeates our everyday vernacular.[238] It is not unusual for a dark-skinned woman to be told that she is beautiful, but with the qualifier, *for a dark-skinned* woman; or that one is dark-skinned *but* beautiful, nonetheless. Sometimes the comments are less innocuous and quite explicit. Whether thinly veiled "compliments" made consciously or unwittingly by people of color or more explicitly problematic statements, these comments communicate that being both beautiful *and* dark-skinned is a culturally exceptional if not oxymoronic phenomenon. Actress Lupita Nyong'o, for example, was told that she was "too dark to be on television."[239]

Not surprisingly, these beauty norms produce tangible consequences for women in the marriage and dating markets. As a result, lighter-skinned women fare much better in marital outcomes because skin color (along with hair texture) increases

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236. Angela Onwuachi-Willig, *Another Hair Piece: Exploring New Strands of Analysis Under Title VII*, 98 GEO. L.J. 1079, 1082–83 (2010); *see also* Camille Gear Rich, *Performing Racial and Ethnic Identity: Discrimination by Proxy and the Future of Title VII,* 79 NYU L. REV. 1134 (2004).

237. D. Wendy Greene, *Splitting Hairs: The Eleventh Circuit's Take on Workplace Bans Against Black Women's Natural Hair in* EEOC v. Catastrophe Management Solutions, 71 U. MIA. L. REV. 987 (2017) (explaining this invariably prevents them from gaining equity and dignity in the workplace).

238. PATRICIA HILL COLLINS, BLACK FEMINIST THOUGHT: KNOWLEDGE, CONSCIOUSNESS, AND THE POLITICS OF EMPOWERMENT 91 (2000) (reflecting on the specific alienation of dark-skinned women through the use of "controlling images"). She offered the infamous children's rhyme heuristically to convey the specific marginalization of dark-skinned people: "Now, if you're white you're all right, / If you're brown, stick around, / But if you're Black, Git back! Git back! Git back!" *Id.* at 89. Hill Collins explains the meaning of the rhyme: "Prevailing standards of beauty claim that no matter how intelligent, educated, or 'beautiful' a Black woman may be, those Black women whose features and skin color are most African must 'git back.'" *Id.*

239. Jacob Pollack, *Hollywood's Colorism Problem: Where Has Lupita Nyong'o Been?*, 34TH ST. (Feb. 21, 2022, 1:00 PM), https://www.34st.com/article/2022/02/lupita-nyongo-oscar-hollywood-colorism-black-actress-zendaya-viola-davis-racism [https://perma.cc/W8GY-AAEC].

their desirability index in these markets.[240] Lighter-skinned women are not only more likely to marry, they also often "marry up"—that is, have spouses from higher socioeconomic ("SES") backgrounds.[241] Indeed, colorism and racism often systematically converge with gendered beauty standards to shape our intimate lives, even if people are not cognizant of this. This convergence also produces tangible SES benefits and disadvantages for some women.

Ideally, beauty should be a fluid and malleable concept that accommodates and embraces a diversity of bodies and features, regardless of ethno-racial category, skin color, /or hair texture. Yet, beauty norms have never been race- or color-neutral. Unfortunately, beauty today encodes extremely limited typologies that disproportionately burden dark-skinned Black women whose bodies do not conform to the norm. These standards fuel the bourgeoning beauty industry which produces toxic products like skin-lightening technologies and chemical hair relaxers marketed primarily to Black women and dark-skinned women of color.

### *C. Industry Marketing Practices*

The cosmetics industry has long deployed marketing strategies that target women of color and capitalize on the prevailing exclusionary aesthetic norms. Therefore, multinational firms do not merely mirror or reproduce existing norms. Rather, they are producers of these discriminatory norms themselves and ought to be considered as important causal actors in phenomena like skin-lightening practices. While public health discourses often scrutinize individual women who engage

240. Margaret Hunter, *Colorstruck: Skin Color Stratification in the Lives of African American Women*, 68 SOCIO. INQUIRY 517, 522 (1999); *see id.* at 520 (describing the focus on long, naturally straight hair and light skin in Black beauty pageants and the social life at historically Black universities); Hunter (2002), *supra* note 180, at 178 (citing MAXINE LEEDS, *Young African-American Women and the Language of Beauty*, *in* IDEALS OF FEMININE BEAUTY: PHILOSOPHICAL, SOCIAL, AND CULTURAL DIMENSIONS (1994)) (describing "a pronounced awareness of Black men's preference for light-skinned women" and a concomitant "desire on the part of the girls [Black women] to have longer and straighter hair.").

241. *See* Hunter (2002), *supra* note 180 at 186 (finding data to support that light-skinned African American women marry higher-status men); Dream McClinton, *Why Dark-Skinned Black Girls Like Me Aren't Getting Married*, GUARDIAN (Apr. 8, 2019), http://www.theguardian.com/lifeandstyle/2019/apr/08/dark-skinned-black-girls-don't-get-married [https://perma.cc/83YP-9EWF].

in the practice, the industry's problematic marketing practices also deserve scrutiny.

For contemporary context, today the global market for skin lightening comprises approximately $8.6 billion,[242] with the United States' share standing at approximately $2.3 billion.[243] It is still unfortunate that, with such a large market base in the United States, so little empirical inquiry and analyses have been devoted to skin-lightening practices in the United States. Moreover, the industry's sheer size warrants examining how it has historically (and contemporarily) reproduced racist and colorist norms through its quest for capital. This quest creates a perverse incentive to both manufacture and sustain a global "yearning for lightness," which in turn drives skin-lightening practices.[244]

While there is a large international market for these products, they have a long history in the United States. Marketing for skin lightening began as early as the nineteenth century in the United States.[245] In the early twentieth century, they were marketed as "freckle waxes" or "skin bleaches" to White women and women of color, dark- or light-skinned.[246] Their use spanned the spectrum of effects, including freckle removal for overall lighter skin. During the 1920s and 1930s, as White consumers opted for tanning lotions that allowed them to "embody new forms of White privilege," skin lighteners became primarily associated with people of color.[247]

Eventually, later in the twentieth century, several brands of skin-lightening products dominated magazines targeting the Black community. Nadinola Bleaching Cream, for example, became a popular skin-lightening brand that appeared regularly

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242. Hall, *supra* note 16 (observing that the global market is expected to expand to $12.3 billion by 2027); *see also* Global Industry Analysts, *supra* note 171 (reporting that Asia-Pacific is now the fastest-growing market for the skin-lightening industry).

243. Hall, *supra* note 16.

244. Glenn, *supra* note 11 (coining the term "yearning for lightness" to describe the practice of skin lightening).

245. *See* PEISS, *supra* note 225 at 25.

246. Lynn M. Thomas, *The Skin Lightening Industry's History of Colorism and the Impact of Black Lives Matter*, YAHOO! FINANCE (Nov. 29, 2020), https://finance.yahoo.com/news/skin-lightening-industry-history-colorism-183423487.html [https://perma.cc/RQB4-3MV5]. These products were known to contain mercury even then.

247. *Id.*

in *Ebony* magazine in the 1950s and early 1960s.[248] Among other messages, the marketing strategies for these products conveyed that dark-skinned Black women were undesirable aesthetically and romantically.[249] Nadinola's DeLuxe Bleaching Cream accordingly promised to make dark-skinned Black women more beautiful and desirable to romantic counterparts.[250]

Other products promised social mobility by using images that associated light skin with economic privilege.[251] They portrayed upwardly mobile, lighter-skinned Black women with straight hair and pearl earrings or necklaces.[252] They offered to make one's skin soften, glow, and become brighter. In some ways, these messages conveyed the problematic reality—that is, lighter skin does in fact often lead to more socioeconomic mobility. But of course, the actual problem to be fixed was not the skin color of darker-skinned women; rather, it was systemic colorism and the economic discrimination that darker-skinned people of color faced.

Many of these products eventually lost popularity in the United States because of the Black Power movement in the latter part of the twentieth century. Yet some firms sought to co-opt the rhetoric of the Black Power movement, like J. Strickland & Co., which rebranded Nadinola skin-bleaching cream as a "skin brightener" in the 1960s.[253] The firm ran a campaign titled "Black is Beautiful" with the following language:

> Black is beautiful. Naturally beautiful. But there's one requirement: naturally beautiful skin. That's where Nadinola comes in. Nadinola brings out the natural beauty of your complexion, gives you a smooth, glowing skin tone that's even all over. No blotches. No uneven dark areas. No

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248. SIMONE PUFF, *Writing (About) the Black Female Body*, *in* BLACK WOMEN AND POPULAR CULTURE: THE CONVERSATION CONTINUES 230 (describing the rise of skin-bleaching creams in the early and mid-twentieth century).

249. *Ad for Nadinola DeLuxe Bleaching Cream*, EBONY, Mar. 1963, at 10.

250. *Id.* In one advertisement, the product paired an image of a light-skinned Black woman receiving a bouquet of flowers with the promise that "wonderful things happen when your complexion is clear, bright, Nadinola-light." *Ad for Nadinola Skin Lightening Cream*, EBONY, Nov. 1959, at 24. Some products admonished readers to "Give romance a chance! Don't let a dull, dark complexion deprive you of popularity." *Id.*; *see also Ad for Nadinola DeLuxe Bleaching Cream*, EBONY, Feb. 1960, at 21.

251. *See, e.g.*, *Ad for Artra Skin Tone Cream*, EBONY, March 1964, at 142.

252. *Id.*

253. *Ad for Nadinola Products,* EBONY, Oct. 1968, at 215.

> blemishes. Just a beautiful you. Black is beautiful. What makes it even more beautiful? Nadinola. Naturally.[254]

This cynical maneuver to identify skin lightening as a technology for revealing one's "naturally beautiful skin" communicated paradoxically that some form of Blackness was indeed palatable. However, this naturally beautiful Blackness needed to be of the right hue. With these pronouncements, the firm could argue that it was not technically anti-Black on its face—though any messaging that stigmatizes *any* form of Blackness is inherently anti-Black—it was merely in favor of the *right type of Blackness*. Rather than an act of racial erasure then, products merely *restored* one's inner Black beauty, provided it is of the right complexion.

Thanks to the Black Power movement in the United States, manufacturers have largely abandoned these explicitly racist and colorist marketing strategies. These marketing tactics are patently untenable in the United States—but they are still prevalent globally. But because the explicit messages are no longer acceptable in the United States, firms now depict their products as moisturizers or creams that remove blackheads and restore an *even* skin tone. Instead of bleaching the body, for instance, these products merely offer skin *toning* or treatment for blemishes.[255] Moreover, while the explicit *language* on these products has changed, the advertisements continue to feature *images* of light-skinned Black women or other women of color. This confirms their intent as lightening agents and also reinforces the stigma attached to dark skin.[256]

### *D. Skin Lightening as Self-Hate*

Despite the myriad social forces that inform skin lightening, public health discourses nevertheless often deflect attention away from powerful institutional actors such as the cosmetics industry.[257] Instead, the dominant narratives typically

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254. *Id.*

255. *Ad for Vantex Skin Bleaching Creme*, EBONY, Apr. 1989, at 66.

256. *Ad for Original and Deluxe Nadinola*, EBONY, Feb. 1970, at 17.

257. *See* Ronald Hall, *The Bleaching Syndrome: African Americans' Response to Cultural Domination Vis-a-Vis Skin Color*, 26 J. BLACK STUD. 172 (1995) (arguing that the "bleaching syndrome" is an assimilationist response to cultural and racial domination, the internalization of dominant anti-Black cultural ideals, and a pathological disdain for Blackness or dark skin); Hall, *supra* note 16; *see also*

individualize skin-lightening and reproduce problematic stereotypes that invariably pathologize women.[258] Consider, for instance, the self-hate thesis and its depiction of women who engage in skin lightening as lacking self-esteem /or hating their Blackness. In its most patronizing manifestation, it paints women as simply unaware that Black is beautiful.[259] Because this narrative has broad appeal and effect in public health discourses, it is worth critically examining.

Public health interventions informed primarily by the self-hate thesis are likely ineffective for many reasons.[260] Aside from the fact that they individualize the phenomenon and shift attention away from some of the root structural forces at play, they paternalistically seek to educate women that being dark-skinned is beautiful or try to reinforce what true beauty means.[261] These approaches presume that it is possible to overcome the deluge of cultural messages—historically and contemporarily—that have encoded and systematized colorism by merely telling women that "Black (or dark skin) is beautiful." That is, they rather naively assume that simply telling women to embrace or love their dark skin ought to be sufficient to overcome the deeply ingrained legacy of gendered colorism that has long denigrated dark-skinned women.

To be clear, public health awareness messaging is necessary, especially those messages that inform people about the health risks of skin-lightening ingredients. However, efforts that effectively oversimplify feminized phenomena like skin lightening—because they rely almost exclusively on self-hate—merely negate women's complexity and capacity to fully apprehend and negotiate with societal beauty norms. For instance, they fail to contemplate that, rather than mere

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Hamed et al., *supra* note 171, at 419 (articulating the need to educate Arab women about perceptions of beauty: "Arab women [need] to start to change their beauty perception and to value their natural blemish-free even-toned skin").

258. *See generally* Hall, *supra* note 16.

259. *Id.* ("As I see it, public education and activism on this issue [skin lightening] must prevail to protect the health and self-esteem of women of color.").

260. David McFadden, *Skin Bleaching a Growing Problem in Jamaican the Slums*, BET (Apr. 11, 2011, 9:28 AM), https://www.bet.com/article/wli9a1/skin-bleaching-a-growing-problem-in-jamaica-slums [https://perma.cc/ZDB5-7PES].

261. Nancy Rosenbaum, *'You Have Dark Skin And You Are Beautiful': The Long Fight Against Skin Bleaching*, NPR (Feb. 25, 2018, 8:14 AM), https://www.npr.org/2018/02/25/588632658/you-have-dark-skin-and-you-are-beautiful-the-long-fight-against-skin-bleaching [https://perma.cc/N3CH-RFH8] ("The biggest takeaway from this presentation is that every shade is beautiful.").

unwitting victims of internalized self-hate who lack self-esteem and appreciation of what true beauty means, women of color—including those who lighten their skin—generally understand precisely what "true" beauty means from a societal standpoint. Indeed, darker-skinned Black women especially negotiate daily with what it means to be gazed upon through the prism of exclusionary racist, sexist, and colorist lenses. Moreover, because they are usually reminded that they are *not* beautiful, so-called outsider women—marginalized because of their race, skin color, and gender—perceive rather acutely the socio-cultural messages that define beauty normatively.

Importantly, as far as navigating complex exclusionary norms, skin-lightening users arguably respond to these cultural cues rather rationally.[262] That is, the self-hate thesis precludes the possibility that *some people* may engage in the practice because of the rational benefits of skin lightening in employment or even marriage markets, for example.[263] For some women, skin lightening may be an act for rational ends to acquire bodily capital—or even for survival. As colorism expert Yaba Blay explains, some people view skin lightening as an act of deploying the body as a bartering tool in exchange for social and economic benefits, as well as more personal ones.[264] Considering the various socioeconomic and interpersonal benefits of having a lighter skin color, this is a legitimate explanation.[265]

Admittedly, these competing explanations are not mutually exclusive. Indeed, some individuals may well engage in skin lightening because of internalized stigma about Blackness and dark skin. That is certainly possible given the structural forces of racial and skin-color domination, although not much empirical analysis has been devoted to this. It is sufficient to note here that these explanations can co-exist: *some people* may also view the practice in commoditized and rational terms,

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262. Hunter (2011), *supra* note 11, at 151.

263. Yaba Amgborale Blay, *Skin Bleaching and Global White Supremacy: By Way of Introduction*, 4 J. PAN AFR. STUD. 4, 22 (2011) (finding that some women viewed skin lightening as a means for attaining social or economic capital in addition to wanting to appear beautiful or attract potential mates); *see also* Hamed et al., *supra* note 171, at 419 (finding that people who used skin lighteners fully perceived the "benefits associated with having a lighter skin tone including perceptions of beauty, personal and professional success (i.e. job opportunity and marriage)").

264. Blay, *supra* note 263.

265. Hunter (2011), *supra* note 11, at 151.

namely a vehicle for accessing bodily capital.[266] At the same time, the practice of skin lightening may symbolize internalized racist and sexist beauty norms. Overreliance on any one theoretical lens in this context precludes a firm grasp of this complexity.

That is, exclusive reliance on the self-hate narrative overshadows other explanations, as well as women's ability to exercise agency within structures of domination. Importantly, it leads to the pathologization and stigmatization of women of color especially. As the next Part explores the potential health risks associated with the practice, it is also particularly helpful to have a contextual analysis of the various complex motivations for skin lightening.

## III. REGULATORY AND PUBLIC HEALTH CHALLENGES

Skin-lightening products have received scrutiny in recent years by state public health departments across the United States. The FDA in particular has raised concerns with the health risks associated with them because of their toxic ingredients, including mercury. This Part reviews the regulatory framework for cosmetics, including the historically lax regulation of cosmetics, before providing a brief overview of the recent cosmetics reform law. It then follows with a specific analysis of the public health impact of skin-lightening products.

### *A. Cosmetics Regulation*

The cosmetics industry has been largely unregulated, or rather, self-regulated in the United States for over eighty years—that is, until recently. As a result, the regulation of

266. Perhaps this rationalized explanation may hold more explanatory power with men increasingly engaging in the practice globally. *See Gabon, Jamaica and Sri Lanka unite to fight hazardous skin lightening products*, UNEP (Feb. 14, 2023), https://www.unep.org/news-and-stories/press-release/gabon-jamaica-and-sri-lanka-unite-fight-hazardous-skin-lightening [https://perma.cc/FXG8-6HSK]; Gideon Lasco, *Tall, pale and handsome: why more Asian men are using skin-whitening products*, THE CONVERSATION (Nov. 24, 2016, 2:22 AM), https://theconversation.com/tall-pale-and-handsome-why-more-asian-men-are-using-skin-whitening-products-67580 [https://perma.cc/2FSQ-TMQL] ("A 2015 study found that the prevalence of skin-whitening product use among male university students in 26 low and middle-income countries was 16.7%. The figure was higher in many Asian countries: 17.4% in India, 25.4% in the Philippines, and 69.5% in Thailand.").

cosmetics products in the United States has lagged considerably behind states like the European Union, which has far surpassed the United States in cosmetics standards. The passage of the Modernization of Cosmetics Regulation Act ("MoCRA"), however, promises to substantially alter the Agency's authority to regulate cosmetics. This section briefly examines the history of cosmetics deregulation in the United States and provides an overview of MoCRA's main provisions.

### 1. The Historical Neglect of Cosmetics

Cosmetics has been the least regulated product within the FDA's jurisdiction for over eighty years.[267] Some scholars argue that its trivialization in regulatory law stems from its characterization as a superficial beautifying agent and its feminization, since women are the primary consumers.[268] Today, cosmetics regulation continues to lag considerably behind other product categories and places women's health at risk: an illustration of food and drug law's devaluation of women's health.[269]

Preliminarily, the neglect of women's health is visible in the history of the Food, Drug, and Cosmetic Act ("FDCA" or "Act"). Its precursor, the Pure Food and Drug Act ("PFDA") of 1906,[270] did not originally include cosmetics.[271] Cosmetics was later incorporated into the FDCA in 1938 because of the Progressive

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267. *See, e.g.*, Boyd (2018), *supra* note 1, at 278 ("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. Accordingly, there is a substantial divide between the law and regulation for cosmetics and that for the other major product categories. Cosmetics are the least regulated of the major product categories within the [FDA] jurisdiction."). The only other product category that is comparatively poorly regulated is food.

268. *Id.* at 318–19.

269. *Id.* at 301; Jacqueline A. Greff, *Regulation of Cosmetics That Are Also Drugs*, 51 FOOD & DRUG L.J. 243, 243 (1996); Jordan K. Paradise & Ethan Fitzpatrick, *Synthetic Biology: Does Re-Writing Nature Require Re-Writing Regulation?*, 117 PA. ST. L. REV. 53 (2012). Cosmetics is the only major FDA-regulated product group that does not have a designated center within the FDA. These products are instead regulated by the Agency's Center for Food Safety and Applied Nutrition ("CFSAN"). *What We Do at CFSAN*, FDA (Sept. 16, 2019) https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/WhatWeDo/default.htm [https://perma.cc/5KQC-X2HB].

270. Pure Food and Drug Act of 1906, c. 3915, §§ 1–5, 7–14, 15, 34 Stat. 768 (replaced by the Federal Food, Drug, and Cosmetic Act of 1938).

271. Boyd (2018), *supra* note 1, at 313. This original exclusion stemmed from women's relative lack of political power within the legislative process. *Id.*

movement and women's activism.[272] Yet, the cosmetics portion of the Act remained substantially the same over the past eighty years while other portions have evolved and expanded.[273] MoCRA addresses some of the longstanding weaknesses of cosmetics law and regulation.[274] Before examining some of these changes, it is worth examining the regulatory scheme of cosmetics prior to MoCRA.

### 2. Cosmetics Regulation Before and After MoCRA

The FDCA defines cosmetics as products intended to be rubbed or poured on the body for the purpose of beautifying or altering one's appearance.[275] Drugs, by contrast, are intended to affect the physiologic structure or function of the body. The safeguards built into the drug approval process illustrate how comparatively inadequate cosmetics regulation has generally been.

Compared to drugs, there are no pre-approval regulatory standards for cosmetics that would ensure their safety *before* entry into commerce.[276] The drug approval process requires clinical trials to determine whether a drug is generally recognized as safe and effective ("GRASE"). Before entering the market, the drug manufacturer must submit a New Drug Application ("NDA") with data supporting the drug's safety and efficacy,[277] and the Agency must enlist independent expert advisory committees to perform risk-benefit assessments.[278] There have been no similar requirements for cosmetics,[279] and,

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272. *Id.* at 295–96.

273. *Id.* at 297. For example, originally, the provisions of the FDCA accounted for about ten pages in length. *Id.* at 278. Since 1938, Congress has strengthened the Act's provisions for the other major product categories, but the cosmetics provisions—which span less than two pages of the approximately five-hundred-page amended FDCA—remained largely unchanged until December 2022. *Id.*; *see also* 21 U.S.C. §§ 361–363.

274. Consolidated Appropriations Act of 2023, H.R. 2617, 117th Cong. §§ 3501–3508 (2022) (enacted) (Modernization of Cosmetics Regulation Act of 2022 ("MoCRA")); *see infra* Part IV.

275. 21 U.S.C. § 321(i). *But see* Greff, *supra* note 269, at 252–57 (discussing when the FDA will classify cosmetics as drugs in order to apply more stringent drug regulations to the product).

276. Greff, *supra* note 269, at 243.

277. 21 U.S.C. § 355(d).

278. Sanders, *supra* note 1, at 156–57.

279. Greff, *supra* note 269, at 243.

as discussed below, MoCRA does not provide for pre-market testing.

Prior to MoCRA, cosmetics manufacturers did not need to register with the FDA or register their ingredient statements. Registration was voluntary. As a result, there was no accurate account of the cosmetics manufacturers or ingredients in the market.[280] For this reason, the ingredients in the market have likely exceeded, or are distinct from, those registered with the Agency.

One of the most profound weaknesses of the Act prior to MoCRA was the Agency's inability to recall or suspend harmful cosmetics, even if they were life-threatening.[281] Recall efforts by manufacturers were entirely voluntary. As a result, products that have been recalled or restricted in places like Canada, Brazil, Australia, and the European Union have remained available in the United States.[282] Case in point is formaldehyde, a keratin hair-straightening chemical more commonly known as the Brazilian blowout.[283]

Prior to MoCRA, manufacturers also did not have to report "serious adverse events" such as those that result in death, a life-threatening event, significant disfigurement, disability, congenital anomaly, or hospitalization, among others.[284] Additionally, manufacturers did not need to provide their safety records for examination.[285] These actions were entirely voluntary. These limitations have had profound consequences for the Agency's ability to regulate cosmetics meaningfully.

There are two enforcement mechanisms for cosmetics, which are worth discussing: the misbranded and adulterated provisions.[286] A product is misbranded if its labeling is false, misleading, or fails to list ingredients and manufacturer information.[287] An adulterated product is poisonous or fails to conform to manufacturing standards.[288] In the latter case,

280. Boyd (2018), *supra* note 1, at 301.
281. *Id.*
282. *See* Katie Becker, *10 American Beauty Ingredients That Are Banned in Other Countries*, COSMOPOLITAN (Nov. 8, 2016), https://www.cosmopolitan.com/style-beauty/beauty/g7597249/banned-cosmetic-ingredients/ [https://perma.cc/A65G-ML8D].
283. *Id.*
284. 21 U.S.C. § 604(5).
285. Boyd (2018), *supra* note 1, at 301.
286. These provisions are contained in 21 U.S.C. § 601.
287. 21 U.S.C. § 362.
288. 21 U.S.C. § 361.

without the ability to impose registration of ingredients or inspection requirements on manufacturers, the Agency could not ascertain which products were adulterated and thus posed serious risks to consumers. And even if the Agency could make these ascertainments, it could not recall the products. Not surprisingly, products frequently contain ingredients such as lead, mercury, and formaldehyde.[289]

These enforcement mechanisms have been largely ineffective in part because of these structural weaknesses of the Act. MoCRA addresses some of these structural limitations and promises to improve cosmetics regulation in the United States. MoCRA was passed on December 29, 2022, as part of the Omnibus Reform package.[290] The law took effect in December 2023. MoCRA generally improves the Agency's authority in cosmetics regulation.

There are several key provisions that are worth highlighting. First, it addresses the Agency's recall authority and serious adverse events. It authorizes the Agency to conduct mandatory recalls of cosmetics that are adulterated or misbranded and are likely to cause "serious adverse health consequences or death."[291] This recall authority is significant because the Agency no longer needs to wait for a manufacturer's voluntary compliance in this regard.

It also requires the reporting of serious adverse events and authorizes the Agency to request a list of ingredients if the Agency believes that a cosmetics product was associated with a serious adverse event.[292] Secondly, there are registration and ingredient listing requirements that manufacturers must comply with. Manufacturers must register their facilities with

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289. *See* Sheila Kaplan, *Cosmetics May Face New Safety Regulation — And, Surprisingly, the Industry Is on Board*, STAT (Sept. 27, 2016), https://www.yahoo.com/news/cosmetics-set-safety-regulation-surprisingly-153819367.html [https://perma.cc/VWW6-YF44]; Lori Copan et al., *Mercury Toxicity and Contamination of Households from the Use of Skin Creams Adulterated with Mercurous Chloride (Calomel)*, 12 INT'L J. ENV'T RES. & PUB. HEALTH 10943, 10943–54 (2015); Yu Bin Ho et al., *Mercury Contamination in Facial Skin Lightening Creams and Its Health Risks to User*, 88 REG. TOXICOLOGY & PHARMACOLOGY 72, 72–76 (2017).

290. On December 23, 2022, Congress passed the Food and Drug Omnibus Reform Act of 2022 as part of the Consolidated Appropriations Act of 2023. *See* Consolidated Appropriations Act of 2023, H.R. 2617, 117th Cong. §§ 3501–3508 (2022) (enacted) (MoCRA).

291. *Id.* § 3502 (MoCRA § 611).

292. *Id.* (MoCRA § 605).

the Agency and renew their registration every two years.[293] The Agency may suspend a facility's registration if it determines that a cosmetics product created at the facility may cause serious health problems or death.[294] Manufacturers are also required to list their products and product ingredients lists with the Agency.[295] The Agency may now identify more of the ingredients in the market and address potentially harmful ingredients.

Lastly, the law imposes other obligations on the Agency, including establishing regulations regarding good manufacturing practices ("GMP").[296] Regarding regulations for GMP, the Agency must publish a final rule within three years of the statute's enactment.[297] And, in what can only be described as long overdue, the Agency is now mandated to develop standards for testing asbestos within one year of the law's enactment.[298] These changes are auspicious for cosmetics regulation in the United States. MoCRA will certainly enable the Agency to better enforce cosmetics regulations and protect public health. While welcome, however, there are nevertheless substantial critiques to MoCRA that Part IV discusses.

### *B. The Failure of Industry Self-Policing*

Self-policing has largely failed despite the industry often touting its self-regulating efficacy in response to efforts to improve cosmetics regulation. The Personal Care Products Council ("PCPC") is the cosmetics industry's trade association responsible for funding the Cosmetics Ingredient Review ("CIR")

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293. *Id.* (MoCRA § 607(a)).

294. *Id.* (MoCRA § 607(f)).

295. *Id.* (MoCRA § 607(c)).

296. *Id.* (MoCRA § 606); Ryan Nelson, *PCPC 'Cautiously Optimistic' About Cosmetics Reform Bill Moving Through Senate*, HBW INSIGHT (June 16, 2022), https://hbw.pharmaintelligence.informa.com/RS152639/PCPC-Cautiously-Optimistic-About-Cosmetics-Reform-Bill-Moving-Through-Senate [https://perma.cc/PN8Q-NY9K]. Additional recent federal legislations include the: No PFAS in Cosmetics Act, H.R. 3990, 117th Cong. (2021); No PFAS in Cosmetics Act, S. 2047, 117th Cong. (2021); and, Natural Cosmetics Act, H.R. 5872, 117th Cong. (2021). On the state level, there is also newly enacted and anticipated legislation targeting cosmetics. *Food & Consumer Packaged Goods Litigation*, PERKINS COIE (Feb. 2022), https://www.perkinscoie.com/images/content/2/5/250755/2022-Food-CPG-Litigation-YIR-Report.pdf [https://perma.cc/X4AA-A9PH].

297. Consolidated Appropriations Act of 2023, H.R. 2617, 117th Cong. § 3502 (2022) (enacted) (MoCRA § 607).

298. *Id.* § 3505.

panel, the body tasked with reviewing cosmetics' safety.[299] While the PCPC has largely maintained that the CIR is independent from it and the industry, environmental advocates argue this independence is largely fiction.[300] Furthermore, the industry's aggressive campaign to resist more stringent regulatory standards and its historical political influence over the Agency partly explain why cosmetics regulation has lagged considerably in the United States.[301]

The industry often points to the work of the CIR relating to product safety to defend the adequacy of self-policing.[302] Yet, there are glaring inadequacies of the CIR. Chief among them is that the panel only examines voluntary manufacturer-provided data and makes nonbinding conclusions regarding product safety.[303] Additionally, when the CIR does engage in safety assessment, it only evaluates a small percentage of ingredients.[304] For example, over a thirty-three-year period, the

299. *About PCPC*, PERS. CARE PRODS. COUNCIL, https://www.personalcarecouncil.org/about-us [https://perma.cc/58Y6-EC2P]. This association was formerly named the Cosmetic Toiletry and Fragrance Association ("CTFA").

300. Priyanka Narayan, *The Cosmetics Industry Has Avoided Strict Regulation for over a Century. Now Rising Health Concerns Has FDA Inquiring*, CNBC (Aug. 2, 2018), https://www.cnbc.com/2018/08/01/fda-begins-first-inquiry-of-lightly-regulated-cosmetics-industry.htmlhttps:////// [https://perma.cc/MF23-PVWFhttps://].

301. Casey Cep, *Johnson & Johnson and a New War on Consumer Protection*, NEW YORKER (Sept. 12, 2022), https://www.newyorker.com/magazine/2022/09/19/johnson-johnson-and-a-new-war-on-consumer-protection [https://perma.cc/6BNT-USA8] ("[A]nother reason cosmetics are barely regulated is that the industry has successfully fought for more than eighty years to keep Congress from updating the rules that cosmetic companies must abide by."); Kaplan, *supra* note 289; Tess Bird et al., *A Review of the Talc Industry's Influence on Federal Regulation and Scientific Standards for Asbestos in Talc*, 31 NEW SOL. 152, 163 (2021) ("[T]he CTFA, J&J, and other industry representatives exerted considerable influence in three key areas in the 1970s: (1) regulatory proceedings at the FDA; (2) testing methods and the manipulation of test results (including undisclosed results); and (3) press coverage and the medical literature. After 1976, when the industry succeeded in preventing government regulation of cosmetic talc products, their influence continued.").

302. *FDA Warns Cosmetic Industry to Follow Law on Untested Ingredients*, ENV'T WORKING GRP. (Sept. 27, 2007), https://www.ewg.org/news-insights/statement/fda-warns-cosmetics-industry-follow-law-untested-ingredients [https://perma.cc/NF3J-XEVE] [hereinafter EWG 2007].

303. Anh-Thi Le, *French-Tipped Formaldehyde: Why FDA's Statutory Framework Enables Toxic Chemical Exposures in Manicure Products; How Rulemaking or Congressional Action Can Curb Its Detrimental Effect on Occupational Health*, 75 ADMIN. L. REV. 393, 403–06 (2023).

304. *Id.*; Rajiv Shah & Kelly E. Taylor, *Concealing Danger: How the Regulation of Cosmetics in the United States Puts Consumers at Risk*, 23 FORDHAM ENV'T L.

CIR evaluated only about 11 percent of the 10,500 cosmetics ingredients catalogued by the FDA, according to a statement by the Environmental Working Group ("EWG").[305]

Perhaps it is not that self-policing has failed, but in fact, it is working as it should. That is, it is tantamount to asking the proverbial fox to guard the hen house. In any case, and at best, the CIR is a "fake police force" with no actual authority over manufacturers who flout regulatory standards.[306] That cosmetics safety standards in the United States have been so poor should not be too surprising from this reality.

The historical lack of oversight of cosmetics is further exacerbated by the presence of an aggressive trade association which has effectively influenced the Agency's regulatory standards. Regarding the PCPC's aggressive posture, in negotiating with the PCPC over proposals to submit before Congress, the Agency noted that the latter's goal was to *reduce* the FDA's ability to regulate cosmetics.[307] In the Agency's own words, the PCPC's proposal during negotiations "would actually reduce FDA's current ability to take action against dangerous cosmetics and could put Americans at greater risk from cosmetic-related illness and injury than they are today."[308]

This is not surprising considering the PCPC has generally fought against more stringent cosmetics regulations.[309] Where

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REV. 203, 204 (2012) (explaining that, in its review, the CIR usually focuses on the potential of cosmetics to cause short-term dermatological reactions like eye irritation and rashes instead of long-term health problems, such as cancer or reproductive harm).

305. EWG 2007, *supra* note 302; Le, *supra* note 303, at 403–06 ("Since its inception in 1976, the CIR panel has only analyzed eleven to thirteen percent of all cosmetic ingredients and has only found eleven unsafe chemicals out of the 10,000 used in cosmetics. Additionally, some believe the industry-funded findings pose a conflict of interest and question the impartiality of the CIR panel. This ambivalence toward current ingredient safety determinations demonstrates a need for FDA to obtain its own independent ingredient review authority.").

306. Narayan, *supra* note 300 (quoting the Environmental Watch Group's dismissal of the CIR as "a 'fake police force,' with no authority over bad actors in the industry").

307. Rebecca Kessler, *More Than Cosmetic Changes: Taking Stock of Personal Care Product Safety*, 123 ENV'T HEALTH PERSPS. A120, A126 (2015).

308. *Id.* Internal quotes omitted.

309. Kaplan, *supra* note 289. Case in point is its opposition to more stringent cosmetics regulations proposed by California. *Testimony of Dr. Jay Ansell Before California Assembly Committee on Environmental Safety and Toxic Materials*, PERS. CARE PRODS. COUNCIL (Apr. 9, 2019), https://www.personalcarecouncil.org/testimony/testimony-for-dr-jay-ansell-personal-care-products-council-assembly-committee-on-environmental-safety-and-toxic-materials [https://perma.cc/BEL2-2E9H]. In response to California's Assembly Bill 495, which proposed an outright

the PCPC has seemingly supported federal legislation in recent years, these laws were compromises that were not adequate to address the real challenges in cosmetics regulation.[310]

Regarding the industry's political influence over the Agency, this was glaring in the case of *Ingham*. Indeed, this influence likely accounts for the absence of adequate standards for measuring asbestos in cosmetics containing talc, until recently that is. The *Ingham* court detailed the PCPC's (and Johnson & Johnson's) actions to ensure that asbestos standards were ineffective, despite the presence of alternative effective standards.[311]

The court, for example, compared the pre-concentration method to the J-41 method, which was unreliable in detecting asbestos.[312] With the J-41 method, only if a certain mineral was present would the sample be further tested under light microscopy to determine whether asbestos was present.[313] Johnson & Johnson, however, aggressively lobbied the PCPC—then the Cosmetics, Toiletry, and Fragrance Association ("CTFA")—to recommend that the FDA adopt the J-41 method.[314]

The company's internal records confirm its tireless efforts in the 1970s to influence the Agency's standards through the CTFA:

> We believe it is critical for the C.T.F.A. to now recommend [the J-41 method] to the F.D.A. before the art advances to more sophisticated techniques with higher levels of sensitization. We deliberately have not included a

ban on many ingredients, the PCPC's position was that federal law already provided sufficient enforcement authority. *Id.* The PCPC noted that federal law already "sets severe penalties for product manufacturers that do not meet these strict requirements," a tenuous claim considering the historical lack of adequate regulations and enforcement of existing cosmetics law. *Id.*

310. *See infra* Section IV.B (discussing the limitations of cosmetic reform).

311. Ingham v. Johnson & Johnson, 608 S.W.3d 663, 716 (Mo. Ct. App. 2020).

312. *Id.* at 717 ("The J-41 method uses an x-ray diffraction instrument to detect asbestos in a talc sample. Only if the x-ray diffraction instrument detects an amphibole mineral is the talc sample is [*sic*] further analyzed under polarized light microscopy to determine whether asbestos is present.").

313. *Id.*

314. *Id.*

> concentration technique as we felt it would not be in worldwide company interests to do this.[315]

As a result of the CTFA adopting this standard, and the Agency's acquiescence to industry, studies of cosmetics samples failed to detect asbestos in products for several years.[316]

The fallout from *Ingham* illustrates both how and why self-policing has categorically failed in the United States, if public health and safety are the metrics by which success is measured here. In this context, it becomes clear why U.S. cosmetics standards have taken almost a century to evolve.[317]

But deploying political resources to influence laws and regulations is arguably expected of companies and industry actors. This is not unique to the cosmetics industry. Though, what *Ingham* reveals are the dire consequences of a *self-policing industry*, which has been far more influential in dictating regulatory standards than it should have been. Of course, this failure must also be imputed to the Agency, which abdicated its regulatory obligation in the context of asbestos standards.

### *C. Public Health Challenges*

#### 1. Health Risks Associated with Mercury-Containing Products

There is little U.S.-based research on skin-lightening products and their health risks.[318] These products are used to prevent melanin synthesis and are usually topically applied creams over a large area of the body, which further increases dermal exposure and associated health risks. The risks associated with skin-lightening products are due to their active ingredients, particularly mercury, hydroquinone,[319] and

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315. *Id.*

316. *Id.* ("Over several years, Defendants consistently found the Products contained no asbestos using the J4-1 [*sic*] method. However, another method for testing cosmetic talc for asbestos existed and Defendants knew it: the 'pre-concentration method.' . . . This technique prevents asbestos from 'hiding' behind talc particles and enhances imaging equipment's ability to detect asbestos.").

317. *See generally* Greff, *supra* note 269, at 248; Boyd (2018), *supra* note 1, at 299.

318. Much of the body of research in this context has been from international studies.

319. While this discussion primarily emphasizes mercury, there are significant public health concerns associated with hydroquinone, which is only marginally

corticosteroids.[320] The safety concerns related to skin-lightening products are amplified because of these ingredients.[321] It is worth briefly exploring some of the public health risks associated with the most toxic ingredient, mercury.

Mercury has been banned in cosmetics with limited exceptions.[322] It is permitted only if no other effective and safe

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safer than mercury. *See* Perry, *supra* note 11, at 593. Hydroquinone is hepatotoxic and carcinogenic. Mètogbé Honoré Gbetoh & Marc Amyot, *Mercury, Hydroquinone and Clobetasol Propionate in Skin-Lightening Products in West Africa and Canada*, 150 ENV'T RES. 403, 403 (2016). The Agency has also cited fertility and toxicokinetic studies regarding hydroquinone. Skin Bleaching Drug Products for Over-the-Counter Human Use, 71 Fed. Reg. 51146, 51147–51 (proposed Aug. 29, 2006) (to be codified at 21 C.F.R. pt. 310) [hereinafter 2006 NPR]. The Agency cited two studies (from 1989 and 1992) by its National Toxicology Program ("NTP") finding that hydroquinone was carcinogenic in rats and mice. *Id.* at 51147 (citing FRANK W. KARI, NAT'L TOXICOLOGY PROGRAM TECHNICAL REPORT ON THE TOXICOLOGY AND CARCINOGENESIS STUDIES OF HYDROQUINONE IN F344/N RATS AND B6C3F1 MICE (GAVAGE STUDIES) (1989); Frank W. Kari et al., *Toxicity and Carcinogenicity of Hydroquinone in F344/N Rats and B6C3F1 Mice*, 30 FOOD CHEMISTRY TOXICOLOGY 737 (1992)). The Agency's own Center for Drug Evaluation and Research ("CDER") Carcinogenicity Assessment Committee concurred with the National Toxicology Program assessments. 2006 NPR at 51147. *See also* FDA, NOMINATION PROFILE: HYDROQUINONE [CAS 123-31-9]: SUPPORTING INFORMATION FOR TOXICOLOGICAL EVALUATION BY THE NATIONAL TOXICOLOGY PROGRAM 35 (2009) [hereinafter Hydroquinone Nomination Profile].

320. Corticosteroids, which are topical steroids that include clobetasol propionate, also comprise a large share of skin-lightening products. Yetunde M. Olumide et al., *Complications of Chronic Use of Skin Lightening Cosmetics*, 47 INT'L J. DERMATOLOGY 344, 349 (2008). Although it is not exactly clear the mechanism through which topical steroids operate to lighten the skin, it is believed that they inhibit endogenous steroid production and precursor hormones that are necessary for melanocyte stimulation. *Id.*

321. M. H. Maneli et al., *Combinations of Potent Topical Steroids, Mercury and Hydroquinone Are Common in Internationally Manufactured Skin-Lightening Products: A Spectroscopic Study*, 41 CLINICAL & EXPERIMENTAL DERMATOLOGY 196, 197 (2016). Many skin-lightening active compounds work by inhibiting tyrosinase, the enzyme involved in melanogenesis (or skin pigment production). The side effects may be exacerbated due to a number of other factors, including use over a large part of the body. *See* Gbetoh & Amyot, *supra* note 319, at 403 (noting that various factors—i.e., transit time, exposure to heat, and stronger concentrations of a substance—exacerbate the risks by the time of purchase by the consumer); Olumide et al., *supra* note 320, at 345 (speculating that length of use may impact the severity of side-effects experienced); Barr et al., *Levels of Mercury in Urine Correlated with the Use of Skin Lightening Creams*, 59 AM. J. CLINICAL PATHOLOGY 36, 37–38 (1973) (finding that research subjects that used skin-lightening creams more frequently and for a longer period after the initial study had higher concentrations of mercury in their urine in a follow-up study).

322. *See, e.g.*, Maneli et al., *supra* note 321, at 196 (finding that twenty-two of the twenty-nine skin-lightening products examined contained levels of mercury and hydroquinone illegal in South Africa and the United States); Gbetoh & Amyot, *supra* note 319, at 407 (finding that 68–84 percent of the ninety-eight skin-lightening creams analyzed exceeded FDA regulatory guidelines for at least one

preservative is available. The FDCA allows mercury only if the product contains less than 1 part per million (ppm),[323] and its use is permitted in eye-area products provided it does not exceed 65 ppm (or 0.0065 percent).[324] Current regulations generally regard mercury-containing cosmetics products, with this limited exception, as misbranded[325] /or adulterated.[326] As such, products exceeding regulatory standards are potentially susceptible to regulatory action.[327] Despite these provisions, empirical studies confirm that skin-lightening products often exceed the FDA's standards.[328] The health risks associated with mercury are also well documented.[329] Mercury exposure can affect virtually all organs of the body,[330] including the kidneys, which are its major site of deposition and concentration.[331] With

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ingredient); Antonio Cristaudo et al., *Use of Potentially Harmful Skin-Lightening Products Among Immigrant Women in Rome, Italy: A Pilot Study*, 226 DERMATOLOGY 200, 201 (2013) ("The lightening agents contained in these products consist mainly of mercury (Hg), hydroquinone (1,4-dihydroxybenene) and topical corticosteroids (TCs), at different concentrations . . . .").

323. 21 C.F.R. § 700.13(d)(2)(i) (2020).

324. 21 C.F.R. § 700.13(d)(2)(ii) (2020).

325. 21 C.F.R. § 700.13(d)(1) (2020). ("[A]ny product containing mercury as a skin-bleaching agent and offered for sale as skin-bleaching, beauty, or facial preparation is misbranded . . . and may be a new drug without approval in violation of section 505 of the Federal Food, Drug, and Cosmetic Act. Any such preparation shipped within the jurisdiction of the Act after January 5, 1973 *will be the subject of regulatory action*.") (emphasis added).

326. 21 C.F.R. § 700.13(d)(2)(ii) (2020).

327. 21 C.F.R. § 700.13(d)(1) (2020).

328. Cristaudo et al., *supra* note 322, at 204. In a 2013 study evaluating fourteen skin-lightening products, researchers found that one product contained a concentration of 2–4 percent. *Id.*; *see also* Carsten R. Hamann et al., *Spectrometric Analysis of Mercury Content in 549 Skin-Lightening Products: Is Mercury Toxicity a Hidden Global Health Hazard?*, 70 J. AM. ACAD. DERMATOLOGY 281, 283 (2014) (noting that, of 549 products tested, 6 percent of products purchased contained mercury above 1000 ppm, while 3.3 percent of products purchased in the United States contained mercury in excess of 1000 ppm).

329. *See* Thomas Chan, *Inorganic Mercury Poisoning Associated with Skin-Lightening Cosmetic Products*, 49 CLINICAL TOXICOLOGY 886, 887–90 (2011) (summarizing that inorganic mercury is distributed to all tissues after absorption, causing particular damage to the kidneys). Skin-lightening creams often contain numerous sources of inorganic mercury, like mercurous chloride, ammoniated mercury, or mercurous oxides. *Id.* at 886. For an explanation of how the skin absorbs inorganic mercury after exposure to skin-lightening creams, see Robert B. Palmer et al., *Transdermal Kinetics of a Mercurous Chloride Beauty Cream: An In Vitro Human Skin Analysis*, 38 J. TOXICOLOGY: CLINICAL TOXICOLOGY 701, 701–07 (2000). After absorption, mercury is distributed widely before elimination occurs. Chan, *supra* note 329, at 887. The half-life is approximately one to two months. *Id.* at 888.

330. *See generally* Chan, *supra* note 329.

331. *Id.*

repeated applications, the cumulative effect of even prolonged low-dose exposure may lead to nephrotic syndrome, marked by a collection of symptoms of kidney damage often identifiable from too much protein in the urine.[332] The syndrome is usually caused by damage to blood vessels in the kidneys that filter waste and excess water from the blood.[333]

Mercury can also affect the central nervous system because it can accumulate in the central nervous system and cause neurotoxicity.[334] This is despite the fact that penetration of the blood-brain barrier by mercury is generally poor.[335] The epidemiological literature points to a slew of potential risks associated with mercury use.[336]

As noted above, while this discussion primarily emphasizes mercury, there are public health concerns associated with skin-lightening drug products containing hydroquinone, which the FDA has traditionally regulated as OTC drug products.[337] Because of the Coronavirus Aid, Relief, and Economic Security

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332. *Id.* at 888. Proteinuria and nephrotic syndrome are often symptoms of minimal change disease, which prolonged use of skin-lightening creams can cause. Hon-Lok Tang et al., *Minimal Change Disease Caused by Exposure to Mercury-Containing Skin-Lightening Cream: A Report of 4 Cases*, 79 CLINICAL NEPHROLOGY 326, 326–29 (2013).

333. *See, e.g.*, David B.G. Oliveira et al., *Membranous Neuropathy Caused by Mercury-Containing Skin Lightening Cream*, 63 POSTGRADUATE MED. J. 303, 304 (1987).

334. Chan, *supra* note 329, at 888. For a discussion of the different types of mercury, see WHO, MERCURY IN SKIN LIGHTENING PRODUCTS 2 (2019) ("Mercury in cosmetics exists in two forms: inorganic and organic. Inorganic mercury is used in skin lightening creams and soaps. Organic mercury compounds (e.g., thiomersal, which contains ethyl mercury, and phenyl mercuric salts) are used as cosmetic preservatives in eye makeup, including mascara, and in eye makeup cleansing products. These forms of mercury differ in their degree of toxicity, and have varying effects on the nervous, digestive and immune systems, as well as the lungs, kidneys, skin and eyes.").

335. *Id.*

336. Mercury exposure from skin-lightening products also has possible reproductive effects, with one study indicating that mercury accumulated in the ovaries of mice following the oral administration of skin-lightening creams. *See* Iman Al-Saleh, Neptune Shinwari & Mona Al-Amodi, *Accumulation of Mercury in Ovaries of Mice After the Application of Skin-Lightening Creams*, 131 BIOLOGICAL TRACE ELEMENT RES. 43, 43–54 (2009); Iman Al-Saleh, *Potential Health Consequences of Applying Mercury-Containing Skin-Lightening Creams During Pregnancy and Lactation Periods*, 219 INT'L J. HYGIENE & ENV'T HEALTH 468, 468–74 (2016).

337. The Agency first issued a notice of proposed rulemaking in 1978 limiting the allowable concentration of hydroquinone to 2 percent. Skin Bleaching Drug Products for Over-the-Counter Human Use: Establishment of a Monograph, 43 Fed. Reg. 51,546 (proposed Nov. 3, 1978) (to be codified at 21 C.F.R. pt. 358).

("CARES") Act, these skin-lightening products are now automatically considered new drugs within section 201(p) of the Act, and they require an approved NDA.[338] Without an approved NDA, they are unapproved new drugs that are unlawfully misbranded under section 502 of the Act.[339] In 2022, the Agency also issued warning letters to twelve companies for selling over-the-counter skin-lightening products with hydroquinone.[340] It is not clear how effective these recent letters have been or whether the Agency has begun any formal enforcement against non-compliant manufacturers. Nevertheless, this is indeed a promising shift in the law for these classes of skin-lightening products that are also regulated as drugs.[341]

The reclassification of hydroquinone skin-lightening drug products does not address the longstanding systemic public health problems related to the accessibility of hydroquinone as an OTC drug, despite the known health risks associated with hydroquinone.[342] Nor does this address the systemic deregulation of mercury-containing cosmetics or cosmetics generally.

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338. Theresa M. Michele, *An Exciting New Chapter in OTC Drug History: OTC Monograph Reform in the CARES Act*, FDA: FDA VOICES (Aug. 6, 2020), https://www.fda.gov/news-events/fda-voices/exciting-new-chapter-otc-drug-history-otc-monograph-reform-cares-act [https://perma.cc/U3TB-59AB]. The CARES Act modernized the way some OTC drugs are regulated and allowed the Agency to circumvent the "slow, burdensome" notice-and-comment rulemaking process that had dictated the review of OTC drugs. *Id.* The Agency may now regulate OTC drugs by administrative order instead of rulemaking. *FDA Regulation of Over-the-Counter (OTC) Drugs: Overview and Issues for Congress*, https://sgp.fas.org/crs/misc/R46985.pdf [https://perma.cc/CJE3-3296]; 2006 NPR, *supra* note 319, at 51152].

339. *See FDA Works to Protect Consumers from Potentially Harmful OTC Skin Lightening Products*, FDA (May 10, 2022), https://www.fda.gov/drugs/drug-safety-and-availability/fda-works-protect-consumers-potentially-harmful-otc-skin-lightening-products [https://perma.cc/S4E2-E4VT] [hereinafter *FDA Works to Protect*].

340. *Id. See, e.g.*, Letter from Carolyn E. Becker, Dir., Office of Unapproved Drugs & Labeling Compliance, Ctr. For Drug Evaluation & Rsch., to David Lennarz, AMBI Enterprises LLC (Apr. 13, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ambi-enterprises-llc-628367-04132022. Warning letters are informal enforcement actions for obtaining voluntary compliance by manufacturers prior to a formal enforcement action. Jordan Paradise & Elise Fester, *FDA Publicity and Enforcement in the Covid-19 Era*, 60 WASHBURN L.J. 77, 85 (2020).

341. The Agency has also noted that "[m]any of FDA's safety concerns regarding the use of hydroquinone in OTC skin lightening drug products also apply to the use of hydroquinone in cosmetic products." See *FDA Works to Protect*, *supra* note 339.

342. For a discussion of the health effects of hydroquinone including the Agency's own findings, see *supra* note 319.

As noted above, this Article emphasizes mercury-containing products because of the severity of health risks associated with them. The fact that mercury-containing products are widely available exposes the longstanding weaknesses of cosmetics regulations and enforcement. This also suggests that any assumption that cosmetics products are generally safe is unfounded. Indeed, cosmetics products can be considered *presumptively unsafe* for women of color especially.

### 2. Public Health Responses to Skin-Lightening Products

While there is little data collection on skin-lightening products in the United States, there is sufficient documentation of their existence and the risks they pose. Despite this, public health bodies have not met the challenge of responding to this issue in recent years. Instead, they have merely issued consumer warnings, which invariably place the burden on the consumer to avoid or mitigate risks.

Federal and local agencies are aware of the risks related to these products, including mercury exposure. Various reports indicate that these products are widely available, especially in communities of color and immigrant communities.[343] Case in point: The Agency recently issued public health awareness messaging regarding mercury-containing products.[344] In a consumer update on its website, the FDA's Office of the Commissioner noted the discovery of products connected to mercury poisoning or elevated mercury levels.[345] The Agency recommended that the public read product packages and avoid products that either list mercury as an ingredient or do not contain a list of ingredients.[346] "[A]s you wade through the

343. *Mercury Poisoning Linked to Skin Products*, *supra* note 15 (explaining that these products are manufactured abroad but sold illegally to "Latino, Asian, African, or Middle Eastern communities"); *see also* Charles A. McKay, *Public Health Department Response to Mercury Poisoning: The Importance of Biomarkers and Risks and Benefits Analysis for Chelation Therapy*, 9 J. MED. TOXICOLOGY 308, 309 (2013) ("Recently, some states have seen cases of inorganic mercury exposure attributed to the use of skin-lightening creams, which may contain over 3% mercury by weight.").

344. *Mercury Poisoning Linked to Skin Products*, *supra* note 15.

345. *Id.*

346. *Id.* The article further advises consumers "[i]f the ingredients aren't listed and there is no product label, don't assume it's fine," and "[i]f the words 'mercurous

beauty aisles," it noted, "you should avoid skin creams, beauty and antiseptic soaps, and lotions that contain mercury."[347]

The Centers for Disease Control (CDC) has also reported a case of elevated blood mercury levels due to exposure to unlabeled skin-lightening creams.[348] In a 2012 case, the CDC found that both the absorption of mercury through the skin and the inhalation of mercury vapor were likely modes of exposure, and both users *and nonusers* living in the same households were exposed.[349] State and local departments monitoring the case advised users and the public to stop using the creams, issuing clinical health alerts notifying physicians about the risks of mercury toxicity from skin-lightening cosmetics.[350]

The New York State Department of Health also released a study indicating high mercury exposure levels among Afro-Caribbean residents primarily due to skin-lightening products.[351] This is not surprising given the prevalence of skin-lightening products in certain communities throughout New York City. [352] The issue is not confined to any geographic locality, as it has also emerged in the Midwest, in a study by the Minnesota Department of Health.[353] Several samples of the

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chloride,' 'calomel,' 'mercuric,' 'mercurio,' or 'mercury' are listed on the label, mercury' [*sic*] is in it—and you should stop using the product immediately." *Id.*

347. *Id.*

348. Lori Copan et al., *Mercury Exposure Among Household Users and Nonusers of Skin-Lightening Creams Produced in Mexico—California and Virginia, 2010*, 61 MORBIDITY & MORTALITY WKLY. REP. 33, 33–35 (2012).

349. *Id.*

350. *Id.* at 33.

351. Wendy McKelvey et al., *Population-Based Inorganic Mercury Biomonitoring and the Identification of Skin Care Products as a Source of Exposure in New York City*, 119 ENV'T HEALTH PERSPS. 203, 205–08 (2011).

352. Danielle E. Engler, *Mercury "Bleaching" Creams*, 52 J. AM. ACAD. DERMATOLOGY 1113, 1113 (2005). A 2005 study from an informal survey found that every pharmacy and beauty-aid store within a five-block stretch of Columbia University Medical Center in New York City sold at least one brand of skin-lightening cream with no mercury concentration listed or listed an illegal concentration. *Id.* A more recent 2023 study by Edwards and colleagues also noted that local beauty supply stores were more likely to sell skin-lightening products in the Harlem/Northern Manhattan area. Edwards et al. *supra* note 16. This study found a higher rate of skin lightening among Asian women but higher rates of hair relaxers among Black women.

353. In 2013, the Minnesota Department of Health analyzed samples of skin-lightening creams taken from store shelves in immigrant communities and communities of color in the Twin Cities. McKay, *supra* note 343, at 309; *Mercury Exposure from Skin Lightening Products: Fact Sheet for Health Care Providers*, MINN. DEP'T OF HEALTH 1, 1 (Jan. 2020), https://www.health.state.mn.us/communities/environment/skin/docs/provfs.pdf [https://perma.cc/P7M4-BMBB]. Several samples contained high levels of mercury far in excess of the FDA's limit.

study of skin-lightening products contained high levels of mercury far in excess of the FDA's limit.[354] The state's Department of Health encouraged doctors to ask patients about a history of skin lightening, noting that mercury or other regulated chemicals may be the active ingredient in these products.

Public health entities have, with little success, attempted to address this issue. These attempts have not been successful in part because of the lack of robust cosmetics regulation historically. Prior to MoCRA, the structural deficiencies of cosmetic law and regulation rendered the Agency virtually powerless in the face of this challenge. Without the ability to recall products, its response has generally been to issue press releases or request that a company recall a product. [355] While useful, this individualized approach has merely placed the burden on consumers to mitigate risks, an unreasonable expectation given the information asymmetry between manufacturers and consumers.

For instance, consumers generally do not have access to information about the *specific* health risks of cosmetics ingredients.[356] Product labels are often inaccurate and fail to correspond to the measured or active ingredient concentrations in products.[357] Warning labels—whenever present—usually

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*Id.* Specifically, the Minnesota Department of Health analyzed twenty-seven samples and found that eleven of them contained prohibited mercury levels ranging from 300 parts per million (ppm) up to 3.3 percent mercury. *Id.* The state's Department of Health encouraged doctors to ask patients about a history of skin lightening, noting that mercury or other regulated chemicals may be the active ingredient in these products.

354. *Mercury Exposure from Skin Lightening Products: Fact Sheet for Health Care Providers*, *supra* note 353.

355. 21 U.S.C. §§ 301–399a; Rajiv Shah & Kelly E. Taylor, *Concealing Danger: How the Regulation of Cosmetics in the United States Puts Consumers at Risk*, 23 FORDHAM ENV'T L. REV. 203, 203 (2012); Roseann B. Termini & Leah Tressler, *American Beauty: An Analytical View of the Past and Current Effectiveness of Cosmetic Safety Regulations and Future Direction*, 63 FOOD & DRUG L.J. 257, 271–72 (2008) ("While FDA may monitor and check effectiveness of the recalls, as well as issue press releases concerning recalls, only the manufacturer may decide to voluntarily recall a product.").

356. Gbetoh & Amyot, *supra* note 319, at 409.

357. JANE HOULIHAN ET AL., NOT TOO PRETTY: PHTHALATES, BEAUTY PRODUCTS AND THE FDA 4–6 (2002) (noting the absence of product labeling indicating the presence of phthalates in part because "phthalates are claimed as fragrances or as a part of trade secret formulas and are exempt from federal labeling requirements"); *see also* Gbetoh & Amyot, *supra* note 319, at 409 (concluding from a study of skin-lightening products found in sub-Saharan West Africa and in small ethnic shops in

caution users to avoid contact with the eyes or discontinue use if irritation occurs. They do not generally state the specific risks of a product, such as effects on the reproductive system or that the product may be poisonous.[358]

These circumstances impair consumers' ability to make informed choices.[359] Manufacturers understandably shirk their responsibility to warn consumers about deleterious ingredients and/ health risks.[360] Yet, consumers must also have access to this information for there to be true, meaningful informed consent. They should not bear the burden of this access, however. A structural approach, by contrast, responds to these concerns by addressing the root cause of the problem, including lax regulatory standards that allow adulterated products to pervade the market in the first place. It also entails measures that place the burden on the manufacturer to mitigate risks, such as mandatory (as opposed to voluntary) good manufacturing practices ("GMPs") that include testing for chemicals. This proactive approach intervenes at the manufacturer level and not the consumer level, when it is too late. Fortunately, MoCRA addresses some of these structural deficiencies, including a provision for GMPs.

The Agency has also attempted to address this issue through discrete interventions at the border such as issuing import alerts for its field staff to refuse admission of mercury-containing products. This addresses some of the products that arrive in formal circuits of distribution. This approach is likely ineffective for products that are already in the United States, and it is not clear how comprehensive the Agency's field sites have been in addressing this issue. Implementation at the border would necessarily require systematic testing of products to determine their mercury content.

Moreover, many of these products invariably flow through informal and formal avenues of distribution and land in the beauty supply stores in local communities.[361] The Agency must therefore account for these products within communities once

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Canada that most products do not inform consumers correctly of the exact concentrations of active ingredients or the serious risks associated with products).

358. Perry, *supra* note 11, at 599–600.

359. *Id.* at 601 (explaining that any presumed consent to injury is "a weak consent at best").

360. HOULIHAN ET AL., *supra* note 357.

361. *See* Glenn, *supra* note 11, at 294–97 (discussing international circuits of distribution of skin-lightening products).

they cross the border. It is not clear whether these products will be a priority post-MoCRA. As discussed in Part IV, the underfunding of cosmetics is an ever-present challenge for the Agency. Given its anemic resources, an intersectional approach requires that the Agency prioritize the most vulnerable groups, namely economically marginalized women of color who are more likely to consume the most adulterated products on the lowest end of the market. It is worth noting here that, as a policy matter, this Article does not advocate for a ban on the act of skin lightening or even skin-lightening products across the board. Instead, it supports a more comprehensive response to these products. Admittedly, calls for greater regulatory attention to feminized products is essentially a paternalistic stance, which this Article rejects.

But there is a meaningful distinction between, on the one hand, broadly banning skin lightening *itself* or even skin-lightening products across the board and, on the other, calling for greater regulatory enforcement regarding specific *toxic* ingredients, like mercury. This distinction is worth elaborating on. First, regarding toxic ingredient enforcement, it is essential that, especially post-MoCRA, the Agency begins to stringently enforce existing regulations regarding mercury; that is long overdue. Secondly, toxic ingredient enforcement addresses specific public health concerns, whereas banning skin lightening is preoccupied with regulating specific beauty regimes, a rather paternalistic and patriarchal endeavor (this is discussed in greater detail in the last Part of this Article).

Lastly, banning skin lightening targets the *consequence, not the root cause*, of colorism and commercialized beauty standards. State interventions can be potentially futile if they do not address the root causes of a phenomenon, including systemic forces like the toxic skin-lightening industry and its marketing practices.

Specific state responses must be appropriately tailored—that is, not overbroad. An overall ban may potentially be overbroad because, for example, they target products that arguably do not pose any public health risks. As discussed in Part IV, there is a bourgeoning organic skin-lightening market that arguably lacks any public health urgency and tailors to wealthier consumers.[362] A broad ban on skin-lightening /or all

362. This argument relies on the assumption that the products are indeed healthy and do not carry similar risks. The lack of safety substantiation in this

categories of skin-lightening products would be overly broad—that is, if the goal is to protect the public health. The intervention should therefore be tailored appropriately.

It is also entirely possible that a broad ban may have an unintended effect: the *growth* of extralegal and informal markets that potentially channel even *more* adulterated products. Indeed, the expansion of extralegal networks is an entirely foreseeable consequence of any type of prohibition or ban. This in turn will exacerbate public health risks. It may also potentially stigmatize women who lighten their skin—women who are already stigmatized.

## IV. INTERSECTIONALITY MATTERS

This Article concludes by exploring how intersectionality matters in this context, notably because of how racism adversely affects health for Black women especially. This Part also raises important critiques of cosmetics reform and identifies ways to address the disparate health impact of food and drug law on Black women's lives. It concludes by arguing for a broad construction of public health that accounts for the social context in which goods are regulated, marketed, and distributed.

### *A. Systemic Racism and Black Women's Health*

In the wake of national conversations about systemic racism, several public health entities have observed that systemic racism is a public health crisis.[363] For Black women, racism intersects with sexism to produce adverse health outcomes.[364] Among other things, it exposes Black women to higher rates of underlying health conditions, medical neglect,

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area, however, begs the question of whether products that are marketed as organic are indeed healthy and carry no public health risks. That inquiry is beyond the scope of this analysis, though it is a fair critique of this argument. This qualification also applies to the discussion regarding organic products in Section IV.E, *infra*.

363. AM. PUB. HEALTH ASS'N, ANALYSIS: DECLARATIONS OF RACISM AS A PUBLIC HEALTH CRISIS 1 (Oct. 2021), https://www.apha.org//media/Files/PDF/topics/racism/Racism_Declarations_Analysis.ashx [https://perma.cc/9GKH-B22G] (These "resolutions create[d] the opportunity for strategic action to eliminate racist policies and practices and adopt those that advance racial equity.").

364. *See generally* Zinzi D. Bailey et al., *Structural Racism and Health Inequities in the USA: Evidence and Interventions*, 389 LANCET 1453, 1456–58 (2017) (discussing adverse health consequences of structural racism).

and inadequate healthcare resources.[365] While all women of color experience the health effects of both racism and sexism, the intersectional pathways for Black women are distinct. For this reason, this discussion primarily emphasizes Black women's health.

Case in point: Maternal health disparities expose the curious ways that racism exacerbates health outcomes for Black women.[366] Black women experience dramatically higher rates of maternal mortality.[367] Within class-stratified samples, educated Black women (i.e., those possessing a college degree or higher) fare comparatively worse than their similarly educated White counterparts.[368] However, these disparities are not merely observed between educated Black women and educated White women. Educated Black women fare comparatively worse than *non-educated* White women.[369] For instance, the maternal mortality rate for Black women with a college education or higher is approximately 1.6 times greater than that of White women with *less than a high school diploma*.[370]

These statistics reveal how class mobility, ordinarily a health-promoting factor,[371] fails to protect upwardly mobile Black women. Professor Khiara Bridges notes poignantly that "race has everything to do with why Black women are more

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365. Linda Villarosa, *Why America's Black Mothers and Babies Are in a Life-or-Death Crisis*, N.Y. TIMES MAG. (Apr. 11, 2018), https://www.nytimes.com/2018/04/11/magazine/black-mothers-babies-death-maternal-mortality.html [https://perma.cc/XS83-2S9B].

366. *See generally* Khiara M Bridges, *Racial Disparities in Maternal Mortality*, 95 N.Y.U. L. REV. 5 (2020).

367. Campbell, *Medical Violence*, *supra* note 196, at 71.

368. *See* Emily E. Petersen et al., *Racial/Ethnic Disparities in Pregnancy-Related Deaths — United States, 2007–2016*, 68 MORBIDITY & MORTALITY WKLY. REP. 762, 763 (2019) ("Among women with a college education or higher, the PRMR for black women was 5.2 times that of their White counterparts. The black:white disparity ratio in the PRMR for the states in the lowest, middle, and highest tertiles was 3.0, 3.3, and 2.8, respectively.").

369. *Id.* For a general discussion of how class mobility affects Black women's health, see Arline Geronimus et al., *"Weathering" and Age Patterns of Allostatic Load Scores Among Blacks and Whites in the United States*, 96 AM. J. PUB. HEALTH 826, 830 (2006) (noting that "nonpoor Blacks have a greater probability of high scores than do poor Whites" in reference to allostatic load scores, which measure the impact of stress on the body).

370. Petersen et al., *supra* note 368.

371. *See generally* Jo C. Phelan & Bruce G. Link, *Is Racism a Fundamental Cause of Inequalities in Health?*, 41 ANN. REV. SOCIO. 311–30 (2015) (explaining how socioeconomic status is correlated to health). *See also* Bruce G. Link & Jo Phelan, *Social Conditions as Fundamental Causes of Disease*, J. HEALTH & SOC. BEHAV. 80 (1995).

likely to die" during pregnancy, and not because of the effects traditionally associated with class marginalization.[372] Public health discourses should account for how racism—beyond its class associations— independently shapes Black women's health outcomes.

Regulatory neglect of cosmetics occurs within this context, where systemic racism renders Black women especially vulnerable to adverse health outcomes. It also occurs within a context of racial targeting by market actors who contribute to this vulnerability. The data on the serious reproductive health effects associated with hair-care products should be alarming considering this wider context.

Consider the emerging data on endocrine-disrupting chemicals ("EDCs") in products primarily consumed by Black women. Often present in common consumer products like hair oil and hair relaxers, EDCs are associated with greater rates of diseases such as earlier menarche, cancer, weight gain, asthma, and fertility issues.[373] A 2018 study confirmed that there are higher levels of EDCs among products marketed to Black women compared to those marketed to White women or the general population.[374] The study measured the presence of EDCs among products purchased by Black women and compared them to the average amount found in products for the general population.[375] The authors noted that the greater prevalence of EDCs in

372. KHIARA M. BRIDGES, REPRODUCING RACE: AN ETHNOGRAPHY OF PREGNANCY AS A SITE OF RACIALIZATION 109 (2011).

373. *See generally* Thaddeus T. Schug et al., *Endocrine Disrupting Chemicals and Disease Susceptibility*, 127 J. STEROID BIOCHEMISTRY & MOLECULAR BIOLOGY 204 (2011). *See* Tamarra M. James-Todd et al., *Racial and Ethnic Variations in Phthalate Metabolite Concentration Changes Across Full-Term Pregnancy*, 27 J. EXPOSURE SCI. & ENV'T EPIDEMIOLOGY 160, 160–66 (2017); Louise A. Brinton et al., *Skin Lighteners and Hair Relaxers as Risk Factors for Breast Cancer: Results from the Ghana Breast Health Study*, 39 CARCINOGENESIS 571, 571–79 (2018) (acknowledging that, while there may not be a substantial relationship between skin lightening and ovarian cancer, the study findings were "less assuring" for hair relaxers).

374. Jessica S. Helm et al., *Measurement of Endocrine Disrupting and Asthma-Associated Chemicals in Hair Products Used by Black Women*, 165 ENV'T RES. 448, 454–55 (2018); *see also* Ami R. Zota & Bhavna Shamasunder, *The Environmental Injustice of Beauty: Framing Chemical Exposures from Beauty Products as a Health Disparities Concern*, 217 AM. J. OBSTETRICS & GYNECOLOGY 418 (2017).

375. Helm et al., *supra* note 374, at 449. The authors noted that there was some difference in the types of products used by Black women (i.e., hair relaxers), compared to the other products in the general population (i.e., shampoos and hair conditioners). *Id.* at 449. This is a limitation of the study.

products used by Black women[376] is connected to the higher levels found in "biomonitoring samples from Black women compared to White women."[377] In other words, the health risks associated with these products for Black women are demonstrable and should not be underestimated.

A 2019 study found higher rates of breast cancer linked to the use of hair dyes.[378] However, this risk was greater for Black women than for White women and increased with frequency of use. For example, for Black women, the use of permanent dyes every five to eight weeks or more correlated with a *60 percent increase in risk of breast cancer*.[379] For White women, by contrast, the risk increased by 7 percent.[380] While all women are at risk from cosmetics harm, Black women fare worse because of the interlocking systems of race, gender, and class.

Broader conversations on health disparities must address how toxic cosmetics are environmental risk factors produced by the intersection of regulatory neglect, racist marketing practices, and hegemonic beauty norms informed by colorism and racism.[381] Furthermore, because of the unique ways that racism adversely affects Black women's health, cosmetics law

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376. These are human-made chemicals ordinarily used as preservatives in cosmetics.

377. Helm et al., *supra* note 374, at 448.

378. Carolyn E. Eberle et al., *Hair Dye and Chemical Straightener Use and Breast Cancer Risk in a Large US Population of Black and White Women*, 147 INT'L J. CANCER 383, 389–90 (2020).

379. *Id.* at 387–89; *see also* Patti Neighmond, *Hair Dyes and Straighteners Linked to Higher Cancer Risk, Especially for Black Women*, NPR (Dec. 4, 2019), https://www.npr.org/sections/health-shots/2019/12/04/784838430/hair-dye-and-straightener-use-linked-to-higher-cancer-risk-especially-for-black- [https://perma.cc/WX8W-R5UR] ("[P]ermanent hair dye use was associated with about a 7% higher risk of developing breast cancer among White women, 'whereas in black women that risk was about 45 percent.'"). Likewise, a 2022 NIH study found that hair relaxers are associated with a greater risk of uterine cancer. Che-Jung Chang et al., *Use of Straighteners and Other Hair Products and Incident Uterine Cancer*, 114 J. NAT'L CANCER INST. 1636, 1640–41 (2022); *see also* Becky Sullivan, *Hair Straightening Chemicals May Increase Women's Risk of Uterine Cancer, Study Finds*, NPR (Oct. 19, 2022), https://www.npr.org/2022/10/19/1129764003/hair-straightening-chemicals-may-increase-womens-risk-of-uterine-cancer-study-fi [https://perma.cc/42MP-3B9E]. While there were no observed race-related disparities, the authors suggested that this issue should be particularly concerning for Black women because of their higher rates of use of hair-straightening chemicals. *Id.* at 1642. The study identified additional factors, including earlier age of use among Black women and the presence of harsher chemical formulations that may contribute to health disparities. *Id.* at 1640–41.

380. Eberle et al., *supra* note 378, at 383.

381. *See* Helm et al., *supra* note 374, at 455–56.

and regulation must specifically address how the impact of regulatory neglect is compounded by these underlying dynamics.

### *B. Cosmetics Reform: MoCRA's Limitations and Context*

MoCRA is regarded as "the most significant" augmentation of the FDA's authority since the FDCA was implemented.[382] Undoubtedly, MoCRA enhanced the Agency's ability to meaningfully regulate cosmetics in an unprecedented way. But this is likely because cosmetics were previously so profoundly unregulated in the United States. Moreover, where the floor has been so low, modest gains can seem quite monumental.

The law falls short in several respects. Notably, it lacks any provisions for pre-market review; it requires the reporting of only the most extreme cases of cosmetic harm; and Congress did not mandate a provision for user fees, which impairs the Agency's enforcement authority. MoCRA's potential impact may be limited for these reasons, especially relating to addressing the health of women of color. These considerations are worth exploring in greater detail.

First, one of the law's key weaknesses is that there is still no requirement of pre-market review of cosmetics like there are for drugs. While MoCRA requires that companies must now substantiate the safety of their products, the Agency has clarified that "[n]either the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients."[383] In other words, the exact definition of safety under the law is ambiguous. Moreover, a responsible person (i.e., manufacturer),[384] must only maintain records to support

382. *Modernization of Cosmetics Regulation Act of 2022*, FDA https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022 [https://perma.cc/CL57-FS8T] (June 30, 2023).

383. *Id.*; *see also* MoCRA § 608(a), 21 U.S.C. § 364d(a) (containing the specific safety substantiation provision). The Act also clarifies: "The term 'safe' means that the cosmetic product, including any ingredient thereof, is not injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual. The Secretary shall not consider a cosmetic ingredient or cosmetic product injurious to users solely because it can cause minor and transient reactions or minor and transient skin irritations in some users. In determining for purposes of this section whether a cosmetic product is safe, the Secretary may consider, as appropriate and available, the cumulative or other relevant exposure to the cosmetic product, including any ingredient thereof." *Id.* § 608(c)(2), 21 U.S.C. § 364d(c)(2).

384. MoCRA § 604(4), 21 U.S.C. § 364(4) (defining a responsible person as the manufacturer, packer, or distributor).

product safety. This is concerning since MoCRA failed to ban a slew of chemicals known to be highly toxic.

In fact, MoCRA has apparently weakened existing regulations regarding safety demonstration. For example, neither MoCRA nor existing regulations provide specific safety standards for manufacturers to use to demonstrate safety. Furthermore, under MoCRA, manufacturers only need to demonstrate safety under "customary or usual usages," as opposed to "reasonably expected related uses."[385] But current FDA regulations require consideration of the latter.[386] MoCRA appears to take a step backward insofar as it codifies a "weaker safety" standard.[387]

Second, the reporting requirements under MoCRA might not be adequate in light of how cosmetic harm manifests. For example, the law mandates the reporting of only "serious adverse events."[388] As noted previously, serious adverse events are the most severe incidents that cause death, disability, hospitalization, or are otherwise life-threatening.[389] By contrast, an adverse event is generally any health event associated with a cosmetics product. However, a manufacturer only needs to *maintain records* of "adverse events" for possible inspection.[390]

Mandating the reporting of *only* the most extreme health events ignores the nature of cosmetics harm in the ordinary

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385. Le, *supra* note 303, at 405–06 ("FDA could improve pre-market product safety but has failed to define testing or evidence requirements for safety substantiations. . . . Cosmetic manufacturers are not required to provide specific research to demonstrate ingredient safety or share their safety information with FDA before distributing their products in commerce.").

386. *Id.*

387. *Id.* ("MOCRA appears to supersede FDA regulations with reduced standards for cosmetic safety substantiations that manufacturers must provide prior to marketing. Ultimately, by failing to offer uniform testing and evidence standards for manufacturer safety substantiations, FDA effectively enables manufacturers to downplay the risks associated with certain chemical ingredients before marketing their cosmetics.") (internal quotes omitted); *see also* Eva Temkin et al., *Act II: The Senate Unveils Its Draft*, KING & SPAULDING (June 1, 2022), https://www.kslaw.com/attachments/000/009/704/original/Act_II_-_The_Senate_Unveils_Its_Draft.pdf [https://perma.cc/85DD-F2MU] [hereinafter Senate Unveils Its Draft] (noting that MoCRA requirements "are not as sweeping as anticipated" given "buzz" over the previously introduced Personal Care Products Safety Act, which included provisions requiring the FDA to review the safety of cosmetics ingredients annually).

388. MoCRA § 605(a), 21 U.S.C. § 364a(a).

389. *Id.* § 604(5), 21 U.S.C. § 364(5).

390. *Id.* § 605(e), 21 U.S.C. § 364a(e). These records should be available for inspection if needed and maintained for a specific time period.

course—that is, it is usually cumulative and chronic, as opposed to severe and acute. Even low-dose cumulative exposure to EDCs in cosmetics can cause certain hormonally sensitive conditions or affect the endocrine system.[391] This is because EDCs can have negative health effects at "extremely low levels" of exposure.[392] It is not surprising that these health effects may take years to materialize on the body. A reporting mechanism that prioritizes serious adverse events may not capture the full extent of how cosmetics harm the body, which may be invisible in the short term.[393]

Lastly, Congress did not allocate user fees for the new law, which was a significant concession to the industry.[394] User fees have been a key aspect of supplementing the Agency's funding in order to enable it to carry out its duties.[395] Federal law authorizes the Agency to collect fees and negotiate the amount with drug manufacturers every five years, for example.[396] In return, the Agency agrees to meet certain performance metrics,

391. Laura N. Vandenberg et. al., *Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses*, 33 ENDOCRINE REVS. 378 (2012); *see also Endocrine Disruptors*, NAT'L INST. OF ENV'T HEALTH SCIS., [hereinafter NIEHS report] ("Even low doses of endocrine-disrupting chemicals may be unsafe. The body's normal endocrine functioning involves very small changes in hormone levels, yet we know even these small changes can cause significant developmental and biological effects. This observation leads scientists to think that endocrine-disrupting chemical exposures, even at low amounts, can alter the body's sensitive systems and lead to health problems.").

392. *Low Dose Effects and Timing of Exposures*, BREAST CANCER PREVENTION PARTNERS, https://www.bcpp.org/resource/low-dose-effects-and-timing-of-exposures [https://perma.cc/8BLW-8H8T]; *see also Low-Dose Exposures*, CAMPAIGN FOR SAFE COSMETICS, https://www.safecosmetics.org/resources/health-science/low-dose-exposures [https://perma.cc/FH8H-UESU].

393. There are, of course, occasional serious adverse events that ought to be reported. For example, in a 2022 CNN special on skin-lightening products, a Somali woman in Minnesota experienced peripheral vision loss from skin-lightening products. Meera Senthilingam, *Mother Loses Peripheral Vision from Apparent Exposure to Mercury in Beauty Creams*, CNN HEALTH, https://www.cnn.com/2022/11/29/health/skin-whitening-beauty-creams-mercury-vision-loss-mother-families-as-equals-intl-cmd/index.html [https://perma.cc/E5G3-7TLG]. According to the special, this vision loss was irreversible. This was a discrete case of a severe adverse event that stemmed from long-term use of skin-lightening products. But these cases are arguably rare. And, when the reporting system eventually flags them, it may be too late.

394. Consolidated Appropriations Act of 2023, H.R. 2617, 117th Cong. § 3508 (2022) (enacted).

395. *FDA: User Fees Explained*, FDA, https://www.fda.gov/industry/fda-user-fee-programs/fda-user-fees-explained [https://perma.cc/3BQN-7AWQ].

396. *Id.*

like processing drug applications within a predictable time frame.[397] User fees are therefore essential for supplementing the Agency's funds.

Cosmetics regulation lacks this additional resource for enforcement, which has undoubtedly impaired cosmetics enforcement. This begs the important question of whether MoCRA can be effective without the resources available for enforcement.[398] This continued underfunding of cosmetics will likely perpetuate its neglect and devaluation in food and drug law.

There are additional critiques of MoCRA that further illuminate its weaknesses.[399] Some accordingly describe MoCRA as a compromise that was palatable to the cosmetics industry; in other words, it might not have passed in the absence of this compromise.[400] There is some legitimacy to that position when MoCRA is further contextualized.

MoCRA was one of several recently proposed reform bills in Congress. It was not the strongest proposal, and for years it was anticipated that a competitor bill, the Personal Care Products

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397. *Id.*

398. For a list of recent seizures, see *Seizures and Injunctions—Health Fraud,* FDA (May 17, 2023), https://www.fda.gov/consumers/health-fraud-scams/seizures-and-injunctions-health-fraud [https://perma.cc/Z5JS-5X4S]. It is worth noting that the FDA's cosmetics office has typically been "grossly underfunded." EWG 2007, *supra* note 302 ("Grossly underfunded and encumbered by a cosmetic safety law that renders the Agency nearly impotent, FDA's cosmetic office has no standing cosmetic review safety committee, cannot require testing of products or ingredients, cannot require companies to report injuries or even deaths from the use of their products, and cannot force companies to recall harmful products.").

399. Kaplan, *supra* note 289. MoCRA contains an express preemption provision applied to states regarding registration, GMPs, recalls, records, adverse event reporting, and safety substantiation, where there are already federal regulations in place. MoCRA § 614, 21 U.S.C. § 364j. There is also an exception for state tort laws or state referendums like California's Proposition 65. *Id.* While states may prohibit the use of an ingredient or limit it in cosmetics, preemption will likely make it more difficult for states seeking to enact and enforce more stringent standards than what federal law mandates. New York, for instance, recently banned mercury in cosmetics. Brooke Kato, *NY Bans Cosmetics with Deadly Mercury Amid Health Concerns*, N.Y. POST (Jan. 26, 2023, 4:41 PM), https://nypost.com/2023/01/26/ny-bans-cosmetics-with-deadly-mercury-amid-health-concerns [https://perma.cc/EMQ8-MUPP].

400. Tom Branna, *Personal Care Products Council Provides More Insights on MoCRA*, HAPPI (Mar. 24, 2023), https://www.happi.com/contents/view_online-exclusives/2023-03-24/personal-care-product-council-provides-more-insights-on-mocra [https://perma.cc/8QRQ-Q88P] (describing MoCRA as a compromise between the industry and the Agency).

Safety Act ("PCPSA" or "SB 2100"),[401] would pass. This bill is substantially the same as MoCRA with minor exceptions. SB 2100 is only slightly more stringent.

While SB 2100 contains similar enforcement provisions to MoCRA, it also mandates that the FDA review at least five cosmetics ingredients annually.[402] MoCRA lacks this requirement. SB 2100 also would have required that the FDA promulgate a rule banning the addition of per- and polyfluoroalkyl substances (PFAS), which are also EDCs.[403] This, too, was not enacted within MoCRA. The removal of these provisions appears to be a key concession to the cosmetics industry.

To be clear, these requirements that are codified in SB 2100 are quite modest considering there are approximately 57,000 chemicals in cosmetics.[404] Reviewing five ingredients annually would have only a negligible effect in this context. But since the United States bans only eleven ingredients,[405] SB 2100 might appear to be quite radical.[406] Let us also compare this to the

401. Personal Care Products Safety Act, S. 2100, 117th Cong. (2021) [hereinafter S. 2100].

402. *Id.* § 607(3); Le, *supra* note 303, at 416 ("[T]he Act [MoCRA] did not go as far as imposing any pre-market review for cosmetics. And unlike in a prior reform effort, cosmetic ingredient review provisions are "notably absent"—Congress declined to grant FDA the authority to analyze specific cosmetic ingredients for safety under MOCRA.").

403. S. 2100, 117th Cong. § 116 (2021). PFAS are human-made chemicals that accumulate in the body and environment and have been linked to health issues including cancer. *See Per- and Polyfluoroalkyl Substances (PFAS)*, FDA, https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas [https://perma.cc/EQM8-G2D5] (May 31, 2023).

404. Jennifer B. White, *Pretty Toxic*, YOUTUBE (Apr. 28, 2019) https://www.youtube.com/watch?v=8-iZe25BcVw [https://perma.cc/BJ6G-DA3X].

405. 21 C.F.R §§ 700.11–700.35 (2023); *Prohibited & Restricted Ingredients in Cosmetics*, FDA, https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics [https://perma.cc/8V8C-W2RE].

406. The law similarly requires the disclosure of toxic chemical ingredients in personal-care products. Cosmetic Fragrance and Flavor Ingredient Right to Know Act of 2021, H.R. 5538, 117th Cong. (2021). It also requires suppliers to disclose full ingredient lists and safety data to cosmetic companies. Cosmetic Supply Chain Transparency Act of 2021, H.R. 5539, 117th Cong. (2021). Bills, such as the Safer Beauty Bill Package of 2021, might also appear to be even more radical given the minimal standards in the United States. *See* Toxic-Free Beauty Act, H.R. 5537, 117th Cong. (2021). This bill bans eleven of the most toxic chemicals, such as those linked to breast cancer and endocrine disruption. These chemicals are all currently banned in the European Union. *Id.* This includes hair-straightening chemicals like formaldehyde, paraformaldehyde, and methylene glycol; and parabens, which are commonly found in sunscreens and lotions, such as isobutylparaben and isopropylparaben. *See also Safer Beauty Bill Package*, BREAST CANCER

European Union,[407] which already bans over 1,300 chemicals and restricts another 256. Even if SB 2100 was adopted, it would be virtually impossible for the United States to match the European Union at this rate.[408]

When viewed in this broader context, it is now easy to see that MoCRA's gains are, in fact, quite modest—both when compared to other proposals that were rejected and other regulatory schemes internationally. While it is lauded as an important step forward for the United States, this context should not be lost. Nor should the safety implications of this context be obscured. MoCRA is a step forward, but it is hardly sufficient. Unfortunately, in some ways, MoCRA might also be aptly considered as *regressive* regarding safety standards.

### *C. Centering Women of Color in Reform*

In recent years, a bill was introduced in the U.S. House of Representatives specifically addressing women of color and some of the issues highlighted in this Article.[409] The Cosmetic Safety for Communities of Color and Professional Salon Workers Act of 2021 imposes a set of requirements and standards for cosmetics that are marketed to women and girls of color or used by professional nail, hair, and beauty salon workers.[410] It represents an intersectional approach to cosmetics that considers the impact of race and class in food and drug law.

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PREVENTION PARTNERS, https://www.bcpp.org/resource/safer-beauty-bill-package-2021 [https://perma.cc/PQ6S-QDQC]. The bill was introduced by Rep. Jan Schakowsky. Press Release, Rep. Jan Schakowsky, Schakowsky Announces The Safer Beauty Bill Package to Protect Consumers from Harmful Products in Cosmetics and Personal Care Products (July 29, 2021), https://schakowsky.house.gov/media/press-releases/schakowsky-announces-safer-beauty-bill-package-protect-consumers-harmful [https://perma.cc/BBB5-A8M4].

407. Kate McDonough, *Nine Ingredients in Baby Products You Should Know About*, HOWGOOD (July 8, 2019), https://howgood.com/2019-6-19-nine-ingredients-in-baby-products-you-should-know-about [https://perma.cc/6JE4-F8UH].

408. Katie Becker, *10 American Beauty Ingredients That Are Banned in Other Countries*, COSMOPOLITAN (Nov. 8, 2016), https://www.cosmopolitan.com/style-beauty/beauty/g7597249/banned-cosmetic-ingredients [https://perma.cc/47NB-PEJP].

409. Cosmetic Safety for Communities of Color and Professional Salon Workers Act, H.R. 5540, 117th Cong. (2021) [hereinafter Cosmetic Safety for Communities of Color Act].

410. *Id.* §§ 6–7.

The bill requires research on health disparities related to cosmetics marketed to women and girls of color.[411] It will subsidize research on "the specific adverse health effects experienced by women and girls of color resulting from exposure to unsafe chemicals present in cosmetics used by them."[412] It also mandates research on health concerns impacting the aforementioned salon employees. [413]

This bill proposes the formation of a permanent advisory committee that includes individuals from organizations representing women of color and salon workers in the ingredient review process.[414] Membership in the advisory committee would also include the Deputy Assistant Secretary for Minority Health (or its designee).[415] This requirement addresses longstanding issues of access, equity, and power differentials within administrative law processes. Incorporating the perspectives of individuals from communities of color will enhance agencies' accountability and expand democratic access to agencies.[416] These identity-conscious measures enhance diversity, reduce power disparities, and increase overall representation within the Agency's processes. Such changes are welcome considering that well-resourced groups are ordinarily dominant in these processes.

This bill represents a significant shift in addressing food and drug law's disparate impact, and it incorporates underrepresented groups within regulatory proceedings. The bill also addresses another important avenue of disparate exposure for women of color—the professional use of cosmetics. It centers the health of women of color and identifies the various ways toxic exposure to cosmetics affects them—through occupational and personal use. In sum, while it is not clear how

411. *Id.* §§ 3–4.

412. *Id.* § 3.

413. *Id.* §§ 4–5. The FDA would be required to conduct, or award grants for, research regarding the chemicals linked to adverse health effects and commonly found in these cosmetics. The bill also supports safer alternatives to toxics cosmetics. The Agency would award grants to support research focused on designing safer cosmetic chemicals, without inherent toxicity. This aspirational provision includes supporting research on "replacing chemicals in cosmetic products marketed to women and girls of color" with "chemicals that are not associated with adverse health events."

414. *Id.* § 9.

415. *Id.*

416. *See* Brian D. Feinstein, *Identity-Conscious Administrative Law: Lessons from Financial Regulators*, 90 GEO. WASH. L. REV. 1 (2022).

likely this type of legislation is to be passed, this intersectional legislation is necessary to supplement the body of proposals in cosmetics.

### *D. Unreasonable Delay Claim Under Section 706(1) of the Administrative Procedure Act*

While courts are generally deferential to agencies, an "agency's discretion is not unbounded."[417] Under section 706(1), the APA authorizes a court to direct the Agency to act where it has unreasonably delayed or withheld action on a matter.[418] Given the Agency's history of neglect in addressing women's health, the APA offers the possibility of seeking recourse from the courts where the Agency has unreasonably delayed. In recent years, advocacy organizations have attempted to use the APA to compel the Agency to act to redress cosmetics harm.

Briefly, a claim under Section 706(1) requires that a plaintiff allege a failure to take a "discrete agency action that [the Agency] is required to take."[419] Ordinarily, this obligation emerges by statute or when "an agency decides to take a particular action" regarding a regulatory matter.[420] In assessing whether there is undue delay or inaction, courts often consider the length of time since the agency came under a duty to act, the reasonableness of the delay, and the impact of the delay, such as

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417. Cutler v. Hayes, 818 F.2d 879, 896 (D.C. Cir. 1987).

418. 5 U.S.C. § 706(1); *see* Telecomms. Rsch. & Action Ctr. v. FCC, 750 F.2d 70, 76–77 (D.C. Cir. 1984) ("[C]ourts designated by statute to review agency actions may play an important role in compelling agency action that has been improperly withheld or unreasonably delayed."). Likewise, an agency must conclude a matter presented to it "within a reasonable time" pursuant to section 555(b) of the APA. 5 U.S.C. § 555(b).

419. Am. Anti-Vivisection Soc'y v. USDA, 351 F. Supp. 3d 16, 24 (D.D.C. 2018), *rev'd and remanded,* 946 F.3d 615 (D.C. Cir. 2020) (dismissing Section 706(1) claim because Agency was not legally required to undertake discrete action in question).

420. Pub. Citizen Health Rsch. Grp. v. Comm'r, FDA, 724 F. Supp. 1013, 1020–21 (D.D.C. 1989) ("Unnecessarily, women are unknowingly subjecting themselves to Toxic Shock Syndrome simply because defendants proceed to drag their feet in promulgating a regulation standardizing tampon absorbency labels. This delay has existed for more than enough years. Even though defendants are in the process of drafting a final regulation, this Court finds that a more than seven-year delay in issuing a regulation impacting on women's health is certainly an unreasonable delay."); *see also In re* A Cmty. Voice, 878 F.3d 779, 787 (9th Cir. 2017) (finding the EPA acted unreasonably in its eight-year delay regarding implementing a rule banning lead after granting a petition).

economic consequences or loss of life.[421] Delays that may be "reasonable in the context of economic regulation are 'less tolerable when human lives are at stake.'"[422]

Organizations have, with varying success, recently attempted to use this provision to compel agency action regarding the cosmetics ingredient formaldehyde, which has been on the Agency's radar for some time now. The case *Environmental Working Group v. United States Food & Drug Administration* illustrates the challenges of organizational advocacy in this context. While the lawsuit was not ultimately successful, it exposes how internal conflict within the Agency—as well as courts' hesitancy to grant standing to advocacy groups—present significant barriers to addressing cosmetics harm.

The background of the case resonates with other areas of lax product regulation affecting women's health. The case is a classic illustration of delay and inaction regarding women's health. In 2016, the Environmental Working Group ("EWG") and Women's Voices for the Earth ("WVE")[423] sued the Agency to address the lack of regulation of formaldehyde.[424] The lawsuit alleged that the Agency failed to respond to a 2011 Citizen Petition requesting that it issue a rulemaking banning the chemical.[425]

Formaldehyde, a key chemical in the Brazilian blowout, caused a slew of health issues among users and salon workers over a decade ago.[426] According to the CDC, short-term exposure to it can cause headaches and shortness of breath; the Occupational Safety and Health Administration (OSHA) also

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421. *Cutler*, 818 F.2d at 897–98; *see also* Pub. Citizen Health Rsch. Grp. v. Comm'r, FDA, 740 F.2d 21, 35 (D.C. Cir. 1984).

422. *Pub. Citizen Health Rsch. Grp.*, 724 F. Supp. at 1019 (D.D.C. 1989) (quoting Pub. Citizen Health Rsch. Grp. v. Auchter, 702 F.2d 1150, 1157 (D.C. Cir. 1983)).

423. This organization advocates for salon workers.

424. Env't Working Grp. v. FDA, 301 F. Supp. 3d 165, 167 (D.D.C. 2018); *see also* Melanie Benesh, *'Let's Just Ban the Damn Ingredient': Inside FDA Scientists' Failed Attempt to Ban Formaldehyde in Hair Treatments*, ENV'T WORKING GRP. (Oct. 21, 2020), https://www.ewg.org/news-insights/news/lets-just-ban-damn-ingredient-inside-fda-scientists-failed-attempt-ban [https://perma.cc/8SJL-CKK2] [hereinafter EWG 2020]; Complaint, Env't Working Grp. v. FDA, 301 F. Supp. 3d 165, 173 (D.D.C. 2018) (No. 16-cv-02435) [hereinafter EWG Compl.].

425. EWG Compl., *supra* note 424.

426. Roni Caryn Rabin, *The F.D.A. Wanted to Ban Some Hair Straighteners. It Never Happened*, N.Y. TIMES (Oct. 21, 2020), https://www.nytimes.com/2020/10/21/health/brazilian-blowout-formaldehyde-fda.html [https://perma.cc/BKS4-KLRY].

considers it to be a carcinogen.[427] OSHA provides very strict limitations to formaldehyde exposure in the workplace and even imposes a higher standard than its regulations require.[428]

The FDA was aware of the health effects of formaldehyde for decades. As early as 1984, the Cosmetics Industry Review ("CIR") panel ruled that formaldehyde was not safe in cosmetics "intended to be aerosolized."[429] The CIR also recommended "extremely tight restrictions" of formaldehyde in cosmetics.[430] Yet, the Agency has not banned the chemical to date nor imposed any strict restrictions on formaldehyde.

There were efforts within the FDA to impose stricter regulations. These efforts failed, however, due to internal resistance within the FDA and the lack of apparent will to overcome it. According to documents from a Freedom of Information Act (FOIA) request by EWG, FDA scientists urged the FDA to ban formaldehyde in 2016, after declaring that it was not safe.[431] In fact, Agency scientists engaged in a comprehensive safety assessment of the chemical and the FDA's Center for Food Safety and Applied Nutrition ("CFSAN")—which oversees cosmetics—approved a ban thereafter.[432]

Nevertheless, the FDA failed to ban the chemical in part because its scientists were ignored and stymied by other Agency actors.[433] It had not taken any action in over a decade. Even when the 2016 litigation spurred another internal push within the Agency to ban the chemical, the lawyer responsible for the rulemaking was pulled off the regulation days after the lawsuit

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427. Kaplan, *supra* note 289.

428. EWG Compl., *supra* note 424, at ¶¶ 18–19.

429. EWG 2020, *supra* note 424; *Final Report on the Safety Assessment of Formaldehyde*, 3 J. AM. COLL. TOXICOLOGY 157, 157 (1984).

430. *Id.* at ¶ 20.

431. EWG 2020, *supra* note 424.

432. *Id.* (discussing the contents of email communications between Agency personnel regarding banning formaldehyde).

433. *Id.* An Agency scientist communicated this much. In a December 16, 2016 email, Nakissa Sadrieh, PhD, director of the cosmetics division of the FDA Office of Cosmetics and Colors, noted the following: "Well, to update you, [the Office of Regulations, Policy and Social Science] has changed the attorney on the formaldehyde reg development and I doubt that anything will now happen, at least in my lifetime." *Id.* Sadrieh was one of the main actors pushing for a ban on formaldehyde. Additionally, with the Trump administration's antiregulation agenda, it was unlikely that any further regulation would be issued during the Trump years.

was filed. This effectively prevented any further rulemaking on formaldehyde.[434]

The Agency replied to the Citizen Petition a few months after the 2016 lawsuit.[435] However, the Agency merely agreed to review whether to ban formaldehyde and denied the request to require a warning label. The lawsuit was eventually dismissed in 2018 by the D.C. District Court for lack of standing for injunctive relief.[436] The court found that EWG could not establish organizational standing merely by demonstrating that it had expended lobbying and education advocacy costs within the ordinary course of business.[437] Unless it could demonstrate that there was a "perceptible impairment" of its daily operations beyond those normally expended, there was no standing.[438]

The court also rejected the WVE's argument that it had associational standing because the harm suffered by its members (salon workers) was only from prior use of

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434. *Id.* In what can only be described as a long-overdue gesture after years of delay and neglect, the Agency recently proposed to ban formaldehyde; the ban will take effect in 2024. Jonathan Franklin, *The FDA Is Proposing a Ban on Hair Relaxers with Formaldehyde Due to Cancer Concerns*, NPR (Oct. 21, 2023, 6:05 AM), https://www.npr.org/2023/10/21/1207127777/fda-proposal-ban-hair-relaxers-formaldehyde [https://perma.cc/47ZU-YSR8] ("The proposed rule takes a large step in raising awareness about the potential harm that formaldehyde creates for the many Black women who typically use popular straightening products, including many kinds of chemical relaxers, Brazilian blowouts and keratin treatments."). While this is promising news, formaldehyde is one of many ingredients that need to be banned. Furthermore, MoCRA could have addressed formaldehyde and many other harmful ingredients. In this context, this is still a lacking, piecemeal approach to the numerous harmful chemical ingredients in the market.

435. *Id.*

436. Env't Working Grp. v. FDA, 301 F. Supp. 3d 165, 173 (D.D.C. 2018).

437. *Id.* ("In sum, lobbying expenditures will not suffice, and neither EWG nor WVE plausibly allege that their educational programs have been perceptibly impaired. I therefore conclude that the Plaintiffs have failed to carry their burden to establish organizational standing.").

438. The court noted that an "organization does not suffer an injury in fact where it expend[s] resources to educate its members and others unless doing so subjects the organization to 'operational costs beyond those normally expended." *Id.* at 171 (internal quotes omitted). The agency's conduct must have "perceptibly impaired the organization's ability to provide services" or its daily operations. *Id.* (quoting Turlock Irrigation Dist. v. FERC, 786 F.3d 18, 24 (D.C. Cir. 2015)). *See also* PETA v. USDA, 797 F.3d 1087, 1094 (D.C. Cir. 2015). By contrast, an organization was able to demonstrate standing in *American Anti-Vivisection Society v. United States Department of Agriculture*, 351 F. Supp. 3d 16, 24 (D.D.C. 2018) ("This injury—an inability to gather information, publish reports, and help reduce the neglect and abuse of birds—is traceable to the Department's inaction and could be redressed by an order compelling the Department to issue regulations.").

formaldehyde hair-straightening products, not future harm, which is required for injunctive relief. According to the court, the members could not demonstrate any real and immediate threat that the harm would recur or that they would continue to use the product in the future.[439]

As to the merits of the section 706(1) claim, even if the organizations overcame standing, it is dubious whether they would have actually succeeded. That is, it is unlikely that a court would find unreasonable delay sufficient to compel the Agency to take a specific regulatory action. Considering the factors assessed in the analysis, namely the reasonableness of the delay and the impact of the delay (such as economic consequences or loss of life), a court is less likely to find those factors compelling here. This is in part because of the perceived lack of urgency regarding cosmetics, including the assumptions that they are generally safe or that their risks are easily mitigated or avoided.

This, however, is due to lack of appreciation by courts and regulatory bodies of how cosmetics actually harm the body silently, cumulatively, and chronically.[440] Even at low-dose exposure, the effect can be quite harmful over time. Further, it might take years to observe serious health effects as *Ingham* illustrates. The law and regulatory bodies, however, have not actually caught up with the scientific community's research on this. Instead, cosmetics harm remains trivialized, poorly researched, and misunderstood. For this reason, courts are unlikely to perceive that the Agency's delay was unreasonable.

### *E. Construing Health Broadly*

If the pandemic has revealed anything, it is that health equity falls squarely within the FDA's mandate to protect public health. This Part ends by examining how public health may be broadly construed to encompass not only the physical body but the social body and lives of communities.

While skin-lightening products enable their users to navigate discriminatory norms imposed by colorism—and access

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439. *Env't Working Grp.,* 301 F. Supp. at 173–74 ("a plaintiff who seeks prospective injunctive relief cannot establish standing based on past harm alone . . . [r]ather, 'the plaintiff must "establish a real and immediate threat" that the harm-producing conduct will recur.'" *Id.* (quoting City of Los Angeles v. Lyons, 461 U.S. 95, 105 (1983)).

440. NIEHS report, *supra* note 391.

social status—they also symbolize the marginalization of dark-skinned people of color. Their very presence and prevalence within society indicates their acceptance and tacit legitimization. Yet, in the midst of the recent resurgence in national conversations about systemic racism and public health a "moral" conundrum has surfaced—that is, whether there *should* be a place for such products that explicitly capitalize on the stigmatization of dark skin. This begs the question: can public health be fully realized when the risks and harms posed by these products extend beyond physical harm to the body and enact racial subordination, even if symbolically?

The surge in so-called organic skin-lightening technologies, which presumably do not pose similar health risks, highlights the potential tensions between traditional conceptions of public health and a broader construction. This emerging organic market for vitamin-infused skin lighteners often dominates the higher end of the cosmetics market.[441] It is often the socioeconomically privileged who can afford these products and mitigate the risks associated with more adulterated products. These products arguably do not implicate public health in the same way as the mercury-containing products that dominate the lower-end market.

While they are not a threat to public health in the traditional sense, so-called organic skin-lightening products may nevertheless still impose a form of symbolic social harm to communities, especially with advertising strategies that perpetuate racist and stigmatizing tropes. To the extent that a traditional nexus to public health is tenuous—as it arguably is in the case of organic skin lighteners—the public health nexus may nonetheless be established by interrogating how these technologies affect the social lives of communities, even if psychosocially. This Article does not fully address this important question; it merely acknowledges its existence within this broader discourse.

There are additional tensions that are not fully explored here, including those relating to adopting a broad construction of health. For instance, some may argue for restricting access to

441. *See, e.g.*, *Amaira Natural Lightening Serum with Mulberry and Orchid Extract*, AMAIRA NAT. SKINCARE, https://amairaskincare.com/products/amaira-natural-lightening-serum [https://perma.cc/FH9Q-QS6E] ("Through the use of natural plant extracts, Amaira lightens dark pigments and hyperpigmentation while boosting the healthy radiance of your skin.").

even organic or healthy products for this reason. This position accounts for the broader social ramifications of these products. This Article does not adopt that position for several reasons.

First, skin lightening *potentially*—and this is an important qualification—enables its users to access social privilege and circumvent discriminatory norms. I employ this qualifier because, to the extent that the products visibly damage or scar the skin in the process, it is reasonable to assume that some practitioners may experience the opposite of its intended effect (i.e., social stigmatization). This is because the practice is most effective when it is not discernable that the user is engaging in the practice. Otherwise, these potentially subject users to even more class, gender, and color-based stigma because of the assumptions about those who use skin lighteners as lacking in self-esteem.

Stated otherwise, the practice is most effective if one can "pass." For those who can pass, as discussed in Part II, skin lightening may at times be a practical response to exclusionary racist, colorist, and gendered cultural norms that unfairly burden dark-skinned people of color. A broad ban on skin-lightening products—*including organic options*—arguably limits one avenue for navigating pervasive skin-color discrimination, one that often affects women of color the most because of the significance of aesthetics in women's lives.

Second, there are always concerns that prohibitions in regulatory law that disproportionately affect people of color may expose them to greater surveillance or even criminal sanctions. That is, proposals for greater state intervention may result in the overregulation of communities that are already oversurveilled—yet underserved—by state agencies. Targeting racialized products for special treatment must therefore be evaluated in this context and operationalized in a manner that focuses on offending manufacturers—presumably those who profit the most from these products—*not* already overburdened individual consumers or communities.

It is entirely possible that increased regulatory standards targeting specific toxic chemicals—not skin-lightening products *per se*—will prove ineffective. Perhaps the effect of improved regulatory standards—even under MoCRA—will be more symbolic than actual. Yet, symbolic acts may be significant because they communicate whose lives matter and are

prioritized within the law. Moreover, a failure to respond to this issue merely reproduces the status quo.

These tensions are difficult to resolve here. As such, this Article adopts a vision of public health with these tensions in mind. This mindful approach to public health inquires into the social lives of women and communities of color beyond the traditional contours of public health. In so doing, it adopts a conceptualization of health that accounts for harm to the social and communal bodies of vulnerable groups. However, this approach ought to be tailored as well. For this reason, this Article stops short of recommending a complete ban on products like healthy or organic skin-lightening products, for example, or skin-lightening products as a category. As noted in Part III, these responses are overly broad.

Unfortunately, dominant conversations about skin lightening have been subsumed by a very familiar paternalism associated with feminized phenomena that pathologize women. Admittedly, and relatedly, this discussion lacks a deep conversation about women's agency in the context of hegemonic beauty norms. As a result, some aspects of this Article may be construed as deeply paternalistic, even if unintentional on my part. Yet, as someone who has navigated life with skin-color privilege, and without experiential awareness of anti-dark-skin stigma, I do not believe it is my place to take a normative position on the use of beauty products. This is especially the case when they enable individuals to negotiate with exclusionary aesthetic norms and social barriers erected by these norms. At the same time, I acknowledge that individual choice—including the decision of whether to use skin-lightening products—does not exist within a vacuum, and choice is often socially constructed.

Ultimately, this Article embraces autonomous decision-making for women to do with their bodies as they please. These are cornerstone principles of feminism that I subscribe to. As a result, the scope of this Article is limited to addressing toxic chemicals and their adverse health effects. This Article is otherwise unconcerned with the state's regulation of beauty practices or products that pose no specific public health threat, even if they are symbolically harmful and represent problematic social norms.

## CONCLUSION

Food and drug law discourses primarily grounded in a gendered critique necessarily obscure the broader context of systemic racism, colorism, and market forces that disproportionately affect women of color, especially Black women. Intersectionality provides a theoretical intervention to address these limitations. Indeed, public health bodies cannot truly safeguard public health by failing to account for these intersectional forces.

This Article has centered gendered colorism as an axis of social domination and identified broader issues of regulating Black women's bodies. It offers a rich engagement with and nuanced analysis of issues related to the bodily autonomy and agency of Black women and women of color in the context of state regulation and macroeconomic forces. Quite often these paternalistic discourses lack complexity and strip women of their agency. Moreover, increased awareness regarding issues like the CROWN Act and hair discrimination underscores the urgency of grappling with the unique ways that subcategories of women of color may be routinely policed because of the intersections of race, skin color, hair texture, and/or other Afrocentric features. This awareness in turn sheds light on the public health consequences of these forms of bodily regulation.

As more interdisciplinary conversations begin to address intersectional nuances like gendered colorism, for example, the aims of intersectionality as a bottom-up praxis that addresses the plight of *the most* marginalized may be more fully realized. In other words, while these issues arguably affect women generally, as an intersectional excursion, this Article has unapologetically centered and prioritized the experiences of Black women within regulatory law.

This issue also relates to adjacent themes in tort law and raises the important question of how an intersectional lens might aid analyses within tort law and other scholarship areas.[442] Tort law has historically deprioritized and trivialized women's injuries; it has likewise traditionally devalued the worth of people of color. It is not surprising that so many product liability cases (e.g., those involving DES, Thalidomide, and Dalkon Shield) involve reproductive products that harm women,

442. *See, e.g.*, Boyd (2022) *supra* note 1 (discussing generally the intersectional impact of tort law on Black women).

as Section II.A illustrates. Further scholarship in this area might now benefit from centering the specific experiences of women of color; these discourses might find it generative to account for the intersections of, not only race and gender, but perhaps even skin color within tort law to the extent feasible.[443]

Relatedly, whether tort law can actually mitigate against the deficiencies of the regulatory system is also pressing. Ideally, the deterrent function of tort liability *should* deter companies from producing harmful products.[444] Yet, the litigation in *Ingham* illustrates the dangers of this assumption, as companies may wait for decades to discontinue distributing a product and do so only when litigation becomes prohibitively costly or the product line is no longer profitable.[445]

More insidiously, when the dangers of a product are well known in the general population, a company may seek out more vulnerable markets—vulnerable due to race, gender, and socioeconomic position—among women of color domestically and globally. Johnson & Johnson, for example, continued to market its product globally after it discontinued its product line in the United States. This is all to say that tort law is certainly no substitute for public health regulatory bodies preemptively, actively, and rigorously doing the work necessary to protect women's health and those most vulnerable to harmful marketing practices.

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443. *Id.*

444. Koenig & Rustad, *supra* note 1, at 51 (noting the tort system is ineffective at protecting women, as firms historically have endured extensive litigation and waited to recall products long after substantial injuries have occurred).

445. Tiffany Hsu & Roni Caryn Rabin, *Johnson & Johnson Will Discontinue Talc-Based Baby Powder Globally in 2023*, N.Y. TIMES (Aug. 11, 2022), https://www.nytimes.com/2022/08/11/business/johnson-and-johnson-talc-corn-starch.html [https://perma.cc/AU39-FJU8] ("The company discontinued North American sales of its talc-based baby powder in 2020 after recalling some bottles in 2019, but will stop sales of the product globally in 2023, it said on Thursday. Johnson & Johnson said it was already selling baby powder using cornstarch in countries around the world.").